European Medicines Agency

EMEA/MB/138351/2004/en/Final

Work programme for the

European Medicines Agency

2005

Adopted by the Management Board on 16 December 2004

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

Contents

Introduction by the Executive Director

Thomas Lönngren

The year 2005 will be a defining one for the European Medicines Agency: it marks the 10th anniversary of the Agency's creation, and it sees the full entry into force of new legislation that will shape its future development.

The anniversary will be a good opportunity to reflect on what has been achieved so far, assess the needs of the present time, and consider what further contribution we can make to the protection and promotion of public and animal health in Europe.

In 2004, the first part of the new European Union pharmaceutical legislation was introduced, effecting the biggest change in the structure and roles of the Agency since its creation in 1995. Similarly, the entry into force of the remaining provisions on 20 November 2005 will be the focus of our attention this year.

Early cooperation with regulatory authorities in the accession countries prior to the historic enlargement of the European Union in 2004 contributed greatly to their smooth integration into the European medicines network. This first full year of operation as an EU of 25 Member States will, however, increase the activity levels of the network, and will require strong cooperation between its partners.

A number of other important issues that have an impact on the Agency's operations will also require attention: the emergence of innovative new medical technologies and therapies; the increasing globalisation of the pharmaceutical industry and its regulatory environment; the competitiveness of Europe's biotechnology, pharmaceutical and healthcare industries; and the increased expectations of civil society with regard to information, communication and transparency.

The EMEA devoted significant effort in 2004 to drawing up a 'Road Map', in consultation with its stakeholders, setting out the Agency's vision for the years to come and the measures that need to be put in place to respond to the changing environment in which it exists.

This work programme for 2005 incorporates many of the actions detailed in our Road Map implementation plan. Further actions necessary to meet the Agency's long-term objectives will be included in future work programmes, with a view to full implementation of the Road Map by 2010.

To assure the continuing effectiveness of the European medicines system, it is essential that the solid partnership between the EMEA and the national regulatory authorities of the Member States be maintained. That collaboration has already resulted in significant achievements over the past 10 years, and ongoing commitment from all partners will secure our position as one of the foremost regulatory systems in the world.

The key objectives and priorities for 2005 can be summarised as follows:

1. Implementation of the new pharmaceutical legislation and the EMEA long-term plan

Some aspects of the new pharmaceutical legislation came into force in 2004, while fundamental changes to the European regulatory system will have their first effects in 2005.

- ✓ In 2005 the Agency will focus on preparation for the full entry into force of the new legislation in the last part of the year
- ✓ Particular attention will be given to the implementation of provisions reinforcing the safety of medicines, accelerating the availability of medicines to EU patients and creating the right environment to stimulate research. These initiatives include implementation of the concept of risk management plans, expansion of the scope of medicines to be authorised through the centralised procedure, establishment of the accelerated assessment, conditional authorisation and compassionate use procedures, as well as procedures for authorisation of biosimilar and generic products, and support to small and medium-sized enterprises
- ✓ High importance will be attributed to initiatives aimed at increased communication and provision of information to patients, healthcare professionals and the general public

2. Optimisation of the Agency's core business and existing activities

The safety of medicines and improvement of the Agency's core activities will remain priorities in 2005.

- ✓ To provide for safe use of medicinal products, the Agency will reinforce its activities in the area of pharmacovigilance, in particular the EudraVigilance database and the implementation of the EMEA risk management strategy for medicines for human use. The Agency will improve handling of referral procedures to provide faster opinions on questions related to safety of medicines
- ✓ The Agency will remain committed to managing effectively and efficiently its increased tasks and responsibilities, ensuring that patients and users of medicines have access to safe and effective medicinal products within the timelines laid down in the legislation
- ✓ The Agency will work for greater transparency of its operations and activities
- ✓ EMEA will further extend its capacity to provide scientific advice and the quality of that advice
- ✓ It will strive to increase availability of veterinary medicines intended for minor uses and minor species

3. Implementation of the EU telematics strategy for the pharmaceutical sector

The EMEA was given the responsibility to implement the EU telematics strategy and projects agreed by the European Commission, Member States and the Agency, which, once implemented, will increase efficiency of the network, provide better information to users of medicinal products, and contribute to the safe and effective use of medicinal products. The Agency plans to undertake further implementation and expansion of these projects in response to legislative requirements in 2005. As part of this plan:

- ✓ The Agency will carry out additional work to considerably widen the original scope of the EuroPharm database of information on all medicines authorised in the EU. This will allow the general public to access information in the database in all languages and it will include more information
- ✓ The Agency will continue to develop the EudraVigilance database and will add a new component on suspected unexpected serious adverse reactions
- ✓ EMEA will also prepare and design a database of manufacturing authorisations and good manufacturing practice certificates required under the new Directive on human medicines

1 EMEA in the European system

1.1 Management Board

This will be the first full year of activity for the Management Board with its new composition introduced by the revised pharmaceutical legislation. Full composition of the Management Board will be completed in 2005 with the appointment of four members from civil society representing patients', doctors' and veterinarians' organisations.

Objective for 2005:

- To monitor and facilitate the implementation of the new legislation affecting the Agency, increase the transparency of its activities, and provide timely reports and opinions to EU institutions

In addition to its responsibilities in the field of budgetary, planning and reporting matters, the Management Board will carry out these important tasks:

- Continue reflection on the long-term financing of the Agency and the European medicines network
- Adopt rules for the implementation of the new regulation on fees payable to the EMEA
- Consider and endorse provisions aimed at greater openness of the Management Board
- Endorse the EMEA transparency and communication strategies and related policies
- Monitor use of resources by the Agency as well as implementation of EU telematics and other information technology initiatives
- Adopt rules for the implementation of the staff regulations
- Conduct analysis and assessment of the Executive Director's annual activity report for 2004

The Management Board will meet four times in 2005:

Management Board meetings in 2005	
10 March	29 September
26 May	15 December

1.2 Implementation of the new pharmaceutical legislation

Implementation of the new pharmaceutical legislation is among the Agency's key objectives and priorities for 2005. The new legislation introduces changes to the administrative structure of the Agency, extends the scope of the Agency's activities, reinforces its activities in the area of providing scientific advice to companies, and enables the Agency to provide administrative and scientific support to small and medium-sized enterprises.

The scope of medicines for which the centralised procedure is mandatory extends to include new therapeutic categories. In addition, the centralised procedure is open to any other product that constitutes a significant innovation or for which there is a Community interest. The new scope encompasses medicines intended for self-medication, generic products of centrally authorised medicinal products, and biosimilar medicinal products.

A significant impact on the activities of the Agency in 2005 is the introduction of new procedures which reinforce the safety of medicines and facilitate access to new medicines. These include implementation of the concept of risk management plans, as well as accelerated assessment,

conditional authorisation and compassionate use procedures. Some deadlines were shortened in the existing approval process.

The Agency's mandate for openness and provision of information is expanded. The Agency will publish and communicate more information about its processes and activities. The EMEA will provide more information on medicinal products it authorises and supervises. This information will not only be more easily accessible to patients, healthcare professionals and the public, but will also be written in a manner that is understandable to the public.

The legislation provides for a more active role of the Agency in different international forums concerned with regulatory harmonisation. The Agency will cooperate more actively with the WHO and will provide opinions on medicinal products intended exclusively for markets outside the EU.

An extensive consultation exercise with all interested parties in 2004 on the implementation of the new tools provided more details on the specific activities to be undertaken. Part of the new legislation has already come into effect and been implemented. But many of the implementation activities will be carried out and finalised in 2005 when the remaining legislative provisions come into force. The Agency will phase in the whole package of new activities and tasks over the course of 2005 and 2006.

New legislation in the fields of paediatric medicines and tissue engineering is also under development, and the Agency contributes to and monitors its development in anticipation of its future adoption.

The Agency plans to review its organisational structure to be able to carry out its expanded responsibilities in the areas of medical information and provision of support and incentives to small and medium-sized enterprises. To this end, the EMEA will establish two new services in 2005: a sector for medical information and a dedicated structure for the provision of assistance to small and medium-sized enterprises.

1.3 EMEA Road Map to 2010

In addition to legislative challenges, the Agency is also facing rapid development in the field of science and technology, as well as recent changes in the political environment. In order to fully embrace the opportunities presented, the Agency, in addition to implementation of the new legislation, also plans to implement a number of actions originating from the Agency's Road Map to 2010. The actions fall within a number of areas, including:

- Revision of the current procedural framework for the evaluation of medicines, quality assurance and increased level of scientific support by the Agency
- Reinforcement of the Agency's role in the area of supervision and safety of medicines
- Renewal of efforts to ensure availability of the best scientific expertise for evaluation of medicinal products, taking steps to reinforce areas where expertise is insufficient, especially with regard to future technologies, thus strengthening the European medicines network and increasing the overall quality and efficiency of its operation
- Stimulation of research and innovation in the area of medicines, emerging therapies and technologies in support of the Lisbon strategy for economic, social and environmental renewal, conclusions of the Competitiveness Council of 22 September 2003, resolutions of the Health Council of 1-2 December 2003 and the G10 recommendations
- Follow-up on initiatives to improve transparency and provide clear and understandable information to patients, healthcare professionals and the public
- Strengthening of the Agency's international collaboration

Initiatives outlined in the Agency's Road Map coupled with the implementation of the new pharmaceutical legislation will further contribute to the reinforcement of an effective and robust European regulatory system.

1.4 European medicines network

Trends:

- The European medicines network faces important opportunities as well as challenges stemming from political, institutional, legislative and, particularly, scientific developments, the result of the latter being the advent of new technologies for treatment of diseases
- The partners of the European medicines network have set themselves an important goal to enhance overall quality of the EU regulatory system. This encompasses making available top-quality scientific expertise and a robust quality assurance system
- Member State national competent authorities will receive about 30 % of the Agency's total budget in 2005 in return for scientific evaluation and inspection services performed for the EMEA. The total in 2005 is expected to reach € 33,498,000

Objective:

- To enhance the overall quality of the EU regulatory system through the availability of top-quality scientific expertise and an adequate quality assurance system, in close collaboration with national competent authorities

Key initiatives to meet the objective:

- Conduct joint planning to manage the resource implications arising from the new pharmaceutical legislation, the advent of new technologies and the increase in the number of scientific resource providers
- Revision of the 1997 'Statement of principles' document that sets out the basic principles of the partnership between the national competent authorities and the EMEA (including the standard contract for the performance of scientific and inspection services)
- Development and implementation of an EU benchmarking system, development of quality assurance systems for scientific committees and an improved peer review system
- Implementation of the EU risk management strategy
- Development of the EU transparency and communication strategies together with the Heads of Medicines Agencies

1.5 Transparency and communication in the European network

The new pharmaceutical legislation has given the EMEA and the European network as a whole a wider mandate to increase the transparency of its activities.

As a result of the initiatives in the area of transparency and communication, patients, healthcare professionals, academia, learned societies, the pharmaceutical industry and other stakeholders will have faster, easier access to a wider range of information regarding the activities of the Agency and the network. Corresponding strategies and policies will be prepared in 2005.

Objective:

- To increase the level of transparency of Agency and European network activities

Key initiatives to meet the objective:

- Establishment of a working party with the Heads of Medicines Agencies to address transparency and communication policy issues of the network

- Preparation of transparency and communication strategies and related policies that set out what, how and when information will be published
- Continuous implementation of EMEA transparency policy measures adopted by the EMEA Management Board in October 2003 relating to European public assessment reports, information on referral procedures, inspection-related activities, meeting summaries, summaries of opinions, and question and answer documents
- Progress interactions with the innovative, non-prescription and generic medicines industries
- Further development of the EMEA website, in particular with regard to improving access to information for the public. This includes making multilingual navigation possible and improving presentation, user friendliness and search tools

1.6 EU institutions, agencies and international partners

Trends:

- Cooperation with other public-health-oriented scientific and regulatory institutions and agencies at European Union level will develop further as a result of the increased responsibilities given to the Agency by the new European pharmaceutical legislation
- Anticipated enlargement of the European Union in 2007
- Increasing technological, industrial and regulatory globalisation, and need for global harmonisation activities
- Interest from around the world in the work of the EMEA and the European system is expected to increase, particularly following enlargement of the system to include 28 EU and EEA-EFTA countries
- Increasing bilateral cooperation with the US Food and Drug Administration following the signing of confidentiality arrangements in September 2003 and the similar agreement proposed with the US Department of Agriculture for certain classes of veterinary medicines

Key initiatives in this area:

- Continuous support to observers from candidate countries
- Relations and exchange of information with the European Parliament Environment, Public Health and Food Safety Committee. The Committee is expected to visit the EMEA in 2005
- Continuous collaboration with the Directorate-General for Enterprise on development of legislation relating to paediatric medicines, tissue engineering and the provision of information to the public
- Continuous collaboration with the Directorate-General for Health and Consumer Protection on biological threats and infectious diseases, and establishment of collaboration with the newly created European Centre for Disease Prevention and Control
- Contribution to the activities initiated by the Directorate-General for Research relating to emerging therapies and medicinal products for rare diseases and for developing countries
- Establishment of effective working relations with the European Food Safety Authority
- Contribution to the activities of the European Monitoring Centre for Drugs and Drug Addiction through extended contribution to EU joint actions
- Implementation of the early information function and cooperation with the European Directorate for the Quality of Medicines on the sampling and testing programme for centrally authorised products

- Work with the Agency's traditional partners on the EU-Japan-USA trilateral harmonisation of regulatory requirements for human and veterinary medicines (ICH and VICH)
- Continuation of work with the World Health Organization and the World Organisation for Animal Health (OIE), and participation in other international forums. Implementation of the guideline on the provision of scientific opinions in the context of cooperation with the WHO
- Implementation of an action plan for collaboration between the EMEA and the US Food and Drug Administration under the confidentiality arrangements, and close monitoring of all actions contained in this plan

1.7 Corporate governance – Integrated management system

Management and internal control systems are part of EMEA corporate governance and are consolidated in an integrated management system at the EMEA.

The Agency will work to implement the integrated quality management system agreed by the Management Board in 2004. This includes continuous improvement to its processes and interfaces with partners in the European network. The internal audit capability of the Agency periodically audits key processes, based on the priorities, the level of risk associated with the processes, and the results of previous audits.

The system of integrated audits is complemented by the work of the Agency's Audit Advisory Committee. The Committee was provisionally established in 2004 and will be fully functional in 2005. An open public procedure for the appointment of members of the Audit Advisory Committee will be launched in 2005.

In 2005, the Integrated Quality Management/Audit group will also have a training and coordination role in the EU benchmarking system, involving the national competent authorities of the European medicines network.

2 Medicines for human use

Priorities for medicines for human use in 2005:

- Establish new procedures necessary to implement the new pharmaceutical legislation (conditional approval, accelerated assessment, compassionate use, opinions for medicinal products not marketed in the EU (in collaboration with the WHO), scientific advisory groups, extended scope of the centralised procedure, etc.)
- Develop procedures for more systematic and repeated use of scientific advice and protocol assistance during the development of products, particularly for rare diseases and new therapies
- Establish procedures and a dedicated structure to provide support for small and medium-sized enterprises
- Establish scientific advisory groups, in particular for mandatory therapeutic fields of the centralised procedure
- Prepare for the submission of applications for biosimilar, generic and self-medication medicinal products
- Undertake the initial phase of the implementation plan for the EMEA Road Map to 2010 in relation to human medicines
- Further develop the EMEA risk management strategy, in particular as regards the concept of risk management plans and further implementation of the EudraVigilance project, including the reporting of adverse drug reactions in clinical trials
- Develop tools for the provision of information to patients and healthcare professionals, and strengthen interaction with the Agency's stakeholders
- Ensure high-quality functioning of core activities through effective management of the increasing workload and adherence to reduced regulatory timelines for pre and post-authorisation activities
- Strengthen the concept of lifecycle management and scientific consistency
- Contribute to EU public health strategies, including those relating to influenza pandemics, tissue-engineered products and paediatric medicines

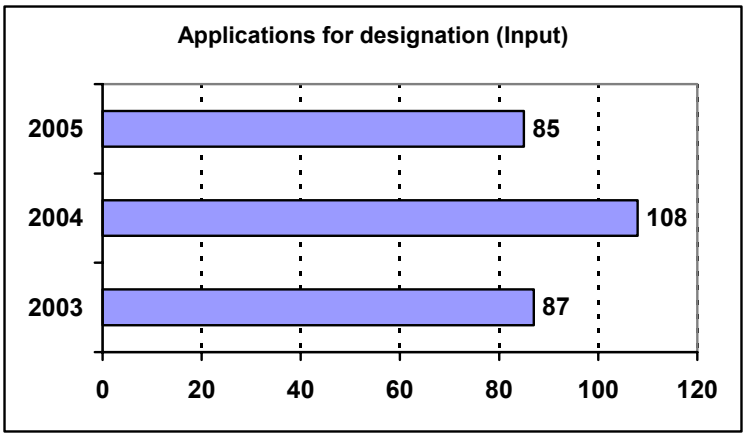
2.1 Orphan medicinal products

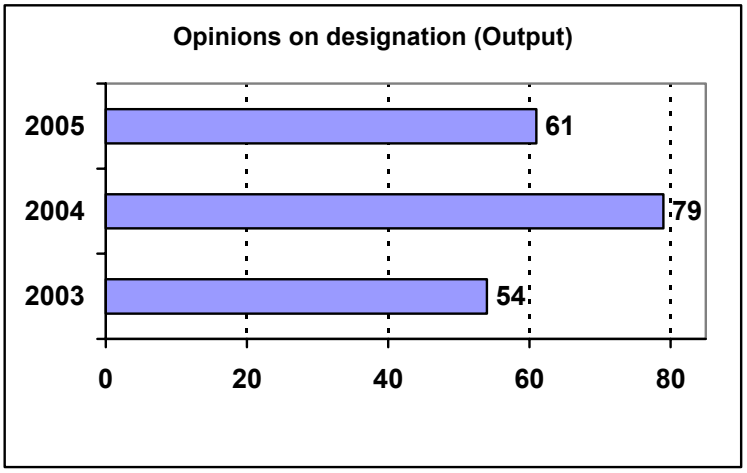
Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the European Community, or where for economic reasons such medicines would not be developed without incentives.

The special Community fund ('orphan drug fund') supports additional new applications and protocol assistance, as well as the post-authorisation activities that are necessary due to the increasing number of orphan medicinal products with Community marketing authorisations. The orphan drug fund allocated by the European Union budgetary authority for 2005 amounts to € 3,700,000.

In order to meet expectations from sponsors and patient organisations, and taking into account the level of the orphan drug fund, it is proposed, in line with recommendations of the Committee on Orphan Medicinal Products (COMP), that the level of fee reductions provide a maximum incentive during the development and registration phase, and should cover:

- 100 % of fees for protocol assistance
- 50 % of fees for initial applications for marketing authorisations and inspections
- 50 % of fees for post-authorisation applications and annual fees





Trends:

- Applications for designation are expected to remain stable at the pre-2004 level with 85 applications in 2005
- The post-designation workload is expected to increase by 35 % (the number of designated orphan medicinal products was 246 at the end of 2004)
- Management and follow-up of approximately 175 annual reports to be submitted in 2005 for designated orphan medicinal products
- More orphan medicinal products reach the stage of marketing authorisation. Therefore, there will be increased follow-up and assessment of designation criteria at the time of marketing authorisation
- Applications for designation are expected to include more complex emerging therapies

Objectives:

- To conduct quality orphan medicinal product designations and related activities and adhere to regulatory timelines

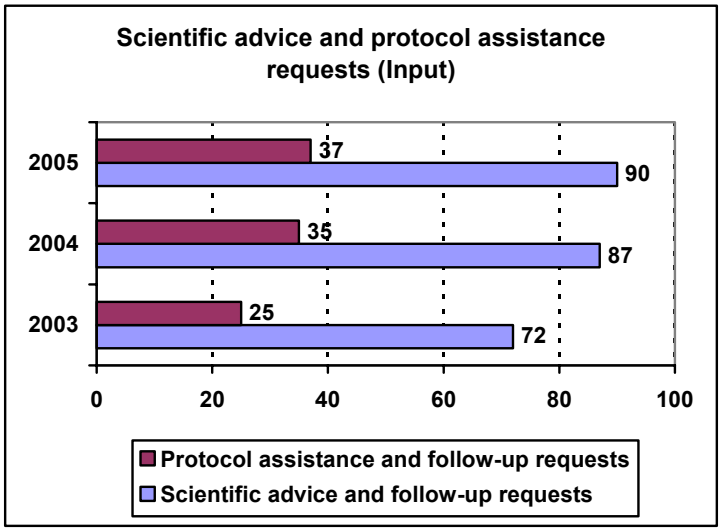
  The performance indicator for this objective is the percentage of applications evaluated within the 90-day timeline. The target is to have 100 % of applications evaluated within this time
- To improve transparency and provision of designation-related information to patients and other interested parties

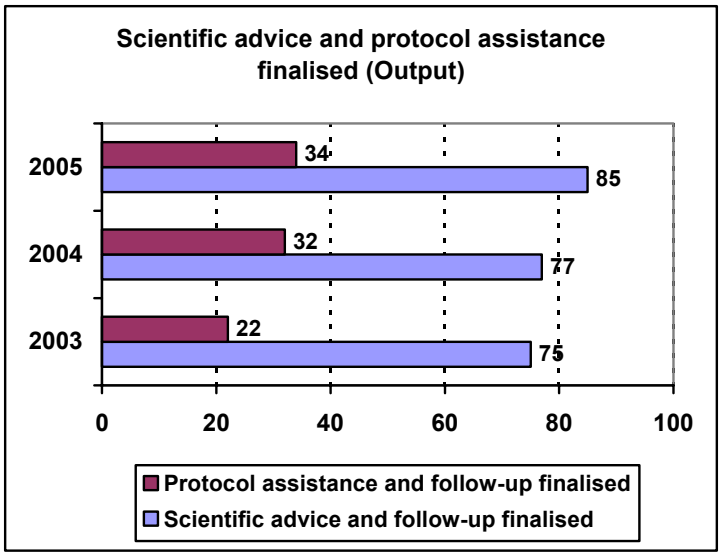
Key initiatives to meet the objectives:

- Continuous improvement of the designation procedure
- Setting-up of procedures for the assessment and re-evaluation of products five years from designation and/or removal from the Community register
- Support the Commission with the preparation of its five-year report on experience following the implementation of the orphan medicinal products regulation
- Implementation of transparency initiatives in the designation procedure in liaison with patients' organisations
- Faster release of the summary of opinion after Commission decision through improved consultation with patients' organisations

2.2 Scientific advice and protocol assistance

This relates to the provision of scientific advice and protocol assistance to sponsors during the research and development of medicinal products. Scientific advice is a priority area for the EMEA and is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition, the Agency provides advice to sponsors of designated orphan medicines. This advice is provided in the form of protocol assistance that can also include advice on the significant benefit of a product.





Trends:

- Steady increase in number of requests for scientific advice and follow-up requests as sponsors become more aware of its benefits
- Increase in number of requests for protocol assistance in line with an increase in the number of designated orphan medicinal products and on the basis of the recommendation to seek protocol assistance made by the COMP at the time of designation
- Overall workload to increase compared to 2004

The consequences of the new pharmaceutical legislation:

> The new legislation sets out the legal basis and enhanced responsibilities for the Agency in the area of scientific advice. The Executive Director is responsible for setting up administrative structures and procedures in consultation with scientific committees allowing the development of advice for undertakings, particularly regarding new therapies, on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products. To this end, the CHMP has already established a Scientific Advice Working Party (SAWP) that has the sole remit of providing scientific advice to undertakings.

Objectives:

- To implement the new legislative requirements in the area of scientific advice
- To provide quality scientific advice and protocol assistance to applicants and adhere to the defined timelines

  The performance indicator for this activity is the mean time between the start of the procedure and adoption of the advice letter. The target is to perform as well or better compared to the previous year
- To improve the scientific advice procedure and stimulate its use throughout the lifecycle of medicinal products, including the post-authorisation phase. The goal is to encourage all applicants in the field of new technologies and therapies to receive scientific advice
- To prepare for provision of specialised support to small and medium-sized companies

Key initiatives to meet the objectives:

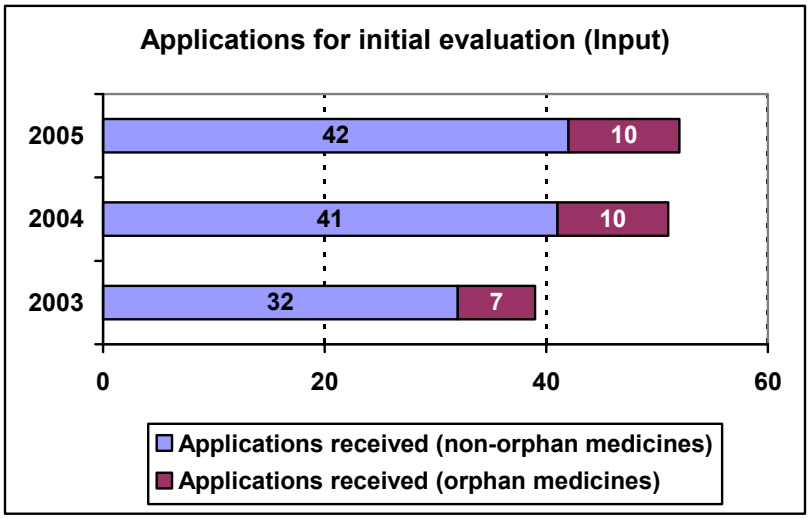
- Development of scientific advice procedures in line with the new legislation, including procedures for particular support for small and medium-sized enterprises and emerging therapies
- Increased involvement of external experts for both common and rare diseases
- Enhancement of liaison with working parties of CHMP and scientific advisory groups
- Implementation of a pilot programme for parallel scientific advice with the US Food and Drug Administration and monitoring of its effectiveness
- Continuous monitoring of the impact of scientific advice on the outcome of applications for marketing authorisations and analysis as part of the scientific memory and scientific advice databases

Scientific Advice Working Party

Following establishment of a standing scientific advice working party, modification to its structures and administrative procedures will be introduced in 2005. Eleven meetings will be held that will run for at least two full days. This will allow more time for discussion with companies requesting advice, for preparation of conclusions ahead of CHMP meetings, and for the provision of faster advice and assistance to sponsors.

2.3 Initial evaluation

The initial evaluation phase covers a number of EMEA activities ranging from pre-submission discussions with future applicants, through the evaluation by the Committee for Medicinal Products for Human Use (CHMP), to the granting by the European Commission of the product authorisation. The EMEA publishes a European public assessment report (EPAR) once the Commission decision has been taken.



Trends:

The number of initial applications for a marketing authorisation is expected to stabilise in 2005. Some reasons for this:

- The extended scope of the centralised procedure will be implemented in the fourth quarter of 2005 resulting in a minimal increase in the number of applications
- More biosimilar products are anticipated in 2005 compared to 2004
- The number of marketing authorisation applications for orphan medicinal products is expected to remain unchanged at 10 applications

Applications are expected in the context of cooperation with the WHO where the EMEA may be asked to provide an opinion on medicinal products intended exclusively for markets outside the Community.

The consequences of the new pharmaceutical legislation:

> The new requirements include the establishment of procedures for conditional marketing authorisations, accelerated assessment, compassionate use and for opinions on medicinal products intended for markets exclusively outside the EU (in collaboration with the WHO). The time for communication of opinion to the European Commission has been decreased considerably, which requires substantial review of the processes following the opinion of the scientific committee.
>
> In addition, the new legislation aims to help small and medium-sized enterprises to access the centralised procedure. To this end, the Agency will prepare to implement provisions regarding reduction in fees, deferment of the payment of fees, support for the translation of medical information, and administrative assistance to these enterprises.

Objectives:

- To implement the new legislative requirements in the area of initial evaluation

- To improve scientific and regulatory consistency of opinions, adhere to regulatory timelines, and continue strengthening the operation of the initial evaluation procedure

  The performance indicator for this objective is the percentage of products evaluated within the regulatory timeline of 210 days. The target is 100 % of applications

- To prepare for provision of incentives to small and medium-sized enterprises
- To address specific needs for new technologies
- To provide timely and understandable product information to patients and healthcare professionals

  Performance indicators for this objective are:
  - percentage of summaries of opinion published at the time of publication of the press release following the CHMP meeting. The target is 90 % of summaries published at the time of the press release
  - percentage of European public assessment reports published within 14 days after Commission decision. The target is to publish 80 % of EPARs within the timeline

Key initiatives to meet the objectives:

- Preparation for inclusion of new mandatory therapeutic areas within the scope of the centralised procedure
- Introduction of the following new procedures foreseen in the new legislation: conditional marketing authorisation, accelerated assessment and compassionate use
- Preparation for progressive submission of applications for emerging therapies and new technologies, and for applications for self-medication and generic products
- Revision of current procedures, including incorporation of reduced timelines of communication of opinions to the Commission from 30 to 15 days
- Establishment of scientific advisory groups in the new mandatory therapeutic areas
- Implementation of legislative provisions in relation to financial incentives for SMEs and creation of a dedicated service within the Agency
- Definition of criteria of eligibility for extension of data exclusivity as provided in the new pharmaceutical legislation
- Further strengthening and maintenance of the quality assurance system in relation to the management of procedures and CHMP activities
- Provision of dedicated and up-to-date information on procedures for emerging therapies and technologies
- Implementation of the classification process for borderline products
- Publication of summaries of opinion and EPARs, together with the product information, in all official EU languages after the European Commission decision granting marketing authorisation
- Establishment of processes for preparation of summaries of EPARs written in a manner that is understandable to the public
- Establishment of a procedure for publication of information on withdrawal of applications and refusal of Community marketing authorisations

Plasma master files and vaccine antigen master files

Plasma master files (PMFs) and vaccine antigen master files (VAMFs) are separate documents from the dossier for a marketing authorisation. The certification of these Master Files in a system analogous to the centralised procedure leads to the issuance by the EMEA of a certificate of compliance with Community legislation that is valid throughout the European Community.

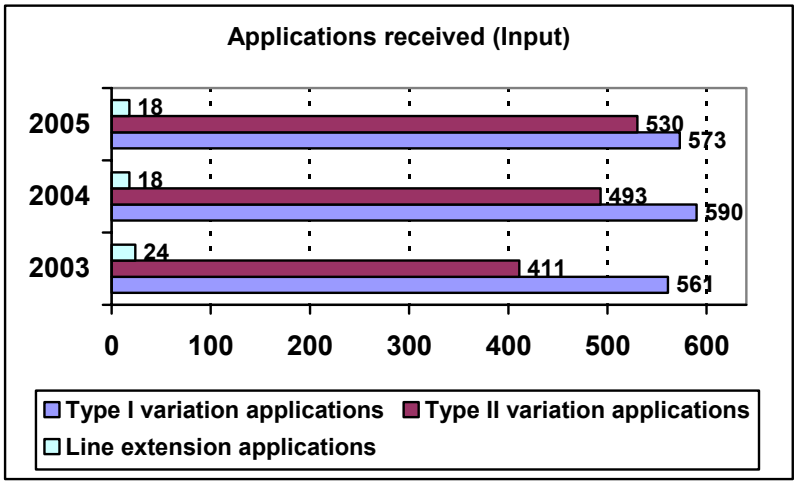
Procedures for the certification of PMFs and VAMFs were implemented in 2004. Following the first PMF applications received in 2004, seven applications are forecast for 2005. Variations to certificates of compliance are also expected. The first ten VAMF applications should be received in 2005.

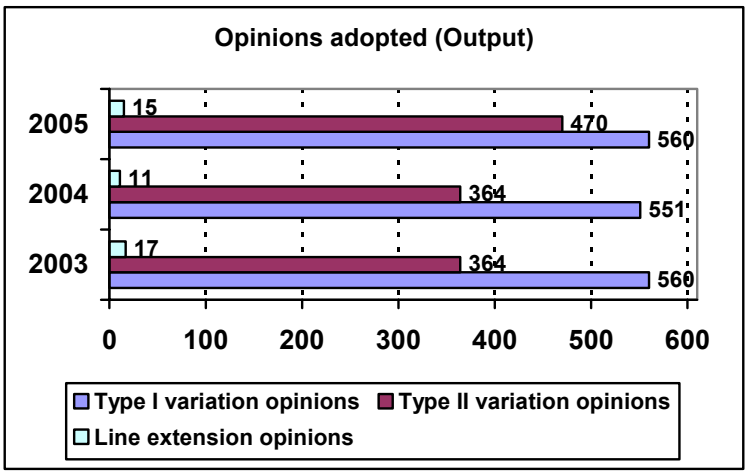
Objectives and key initiatives:

- To assess PMF and VAMF dossiers within the timelines laid down in the legislation
- Monitor the assessment procedures for PMFs and VAMFs, and review the procedures on the basis of experience gained

2.4 Post-authorisation activities

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





Trends:

- A continuous increase in the number of both type I and type II variations is anticipated due to the cumulative increase in the number of marketing authorisations granted. Post-authorisation activities on initial certification of plasma master files and vaccine antigen master files will develop
- Such increase will be influenced by the revised classification of variations and the status of implementation of new Community legislation on certification of plasma master files and vaccine antigen master files

Objectives:

- To increase the quality and the regulatory and scientific consistency of the evaluation of applications for line extensions, variations to and transfers of marketing authorisations, and adhere to regulatory timelines

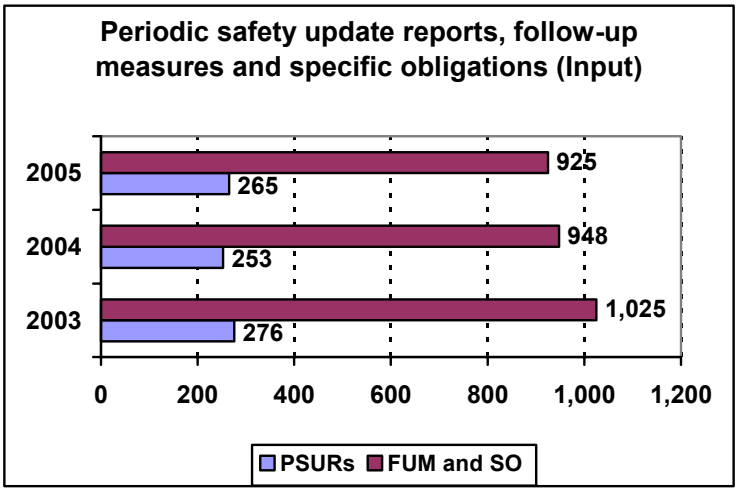
  The performance indicator for this objective is the percentage of applications evaluated within the 30, 60 or 90-day timeline (depending on the procedure). The target is to have 100 % of the applications evaluated within this timeline
- To improve the provision of information in the post-authorisation phase in accordance with the new legislation on variations

Key initiatives to meet the objectives:

- Revision of current procedures, including incorporation of reduced timelines for communication of opinions to the Commission from 30 to 15 days
- Revision, where necessary, of the Agency's management of minor variations, taking into account the first year's experience of the implementation of new Community legislation
- Publication of summaries of opinion for those post-authorisation activities which have an important impact on the use of the medicinal product; regular updating of European public assessment reports and publication of press releases regarding major post-authorisation activities

2.5 Pharmacovigilance and maintenance activities

These include activities related to pharmacovigilance information (adverse drug reaction reports and periodic safety update reports), follow-up measures, specific obligations, annual reassessments and renewal applications. It should be noted that pharmacovigilance is a priority area for the Agency and that, as a consequence, the EMEA will continue and further strengthen its efforts in order to ensure the safe use of products licensed in accordance with the centralised procedure.



Trends:

- Further strengthening of the Agency's coordinating role in the field of pharmacovigilance, as a result of the implementation of new Community legislation
- Increased electronic reporting both for ICSRs (individual case safety reports) and SUSARs (suspected unexpected serious adverse reactions) into the EudraVigilance database for all medicinal products, irrespective of the licensing route
- It is forecast that there will be some 1,700 ICSRs from the EU received electronically through the EudraVigilance post-authorisation module in 2005. An additional 51,800 ICSRs are expected from outside the EU. These estimates relate to centrally authorised products
- The forecast for electronic reporting for non-centrally authorised products in relation to EU and non-EU cases is 15,000
- Some 18,800 adverse drug reaction (ADR) reports for centrally authorised medicines are expected to be received by paper mail for EU cases, with an additional 3,390 ADR reports from outside the EU
- The forecast number of SUSAR reports for 2005 is 8,000
- The further development and implementation of EudraVigilance will relate to appropriate methodologies for data analysis, including data warehousing and data mining supporting signal detection, as well as the coordination and provision of training to the EMEA's business partners

The consequences of the new pharmaceutical legislation:

The new legislation sets forth provisions for the implementation of a risk management system as well as the possibility to set up a system of permanent follow-up of the risk/benefit balance. The legislative basis of pharmacovigilance inspections is now provided. In order to address urgent situations, a system of provisional measures is foreseen. Emphasis is put on transparency, communication and information on pharmacovigilance issues.

Objectives:

- To implement the EU review of pharmaceutical legislation, in particular as regards the reinforced coordinating role for the EMEA in the area of pharmacovigilance and provision of information on safety aspects
- To perform high-quality activities in the field of pharmacovigilance and adhere to required timelines
- To further implement the EMEA risk management strategy, as part of the EU risk management strategy
- To further implement the EudraVigilance project, including the SUSAR component, in particular as regards the implementation at Member State and pharmaceutical industry level, to achieve a more operational system. The target for 2005 is to have a majority of Member State competent authorities and a significant number of pharmaceutical companies reporting through the system

Key initiatives to meet the objectives:

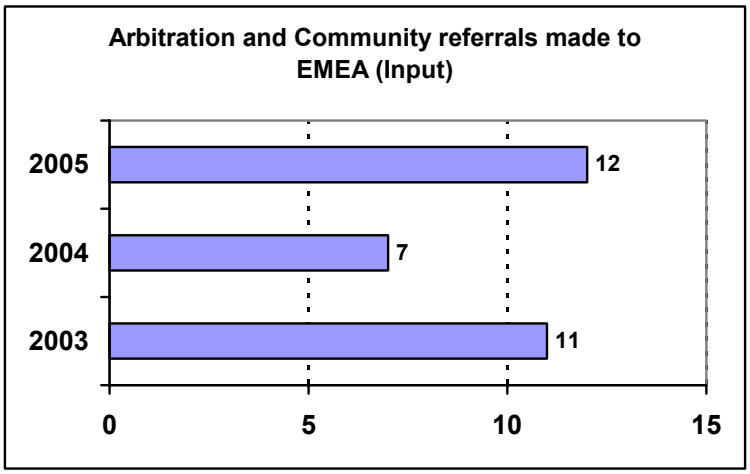
- Management and reinforcement of the procedure, introduced in 2004, for the handling of safety concerns, both pre- and post-authorisation, for centrally processed applications
- Adequate implementation of the concept of risk management plans
- Reinforcement of the scientific advice procedure to better address post-authorisation safety-related aspects
- Continued implementation and maintenance of the electronic transmission of ICSRs and support of the day-to-day operation and maintenance of the electronic ICSR transmission process for the pre- and post-authorisation phase via EudraVigilance
- Organisation of individual implementation meetings with each national competent authority (NCA) to further facilitate the electronic transmission of adverse reaction data between the NCAs and the EMEA
- Development and implementation of methodologies and tools for data analysis supporting signal detection; provision of adequate training to all users of the EudraVigilance system, including the new SUSAR component

2.6 Arbitration and Community referrals

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

Article 30 referrals are mainly initiated in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by the Member States.

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



Trends:

- The number of arbitrations and referrals under Articles 29 and 30 is expected to increase in 2005 compared to 2004
- The number of referrals related to pharmacovigilance concerns is expected to remain at the same level compared to 2004, although the impact of the new legislative provisions (e.g. the scope of these referral procedures) needs to be monitored
- Increase in workload as a result of the EU enlargement (handling of product information in 20 EU languages and possibility for additional referral procedures) and Commission decisions which involve specific commitments (pre-clinical trials, clinical trials, PSURs, post-marketing studies, registries) that need adequate follow-up

Objectives:

- To increase the quality, as well as the regulatory and scientific consistency, of the outcome of the scientific review. The goal is to shorten the procedure time for safety referrals
- To improve the availability of information in relation to Community referral procedures

Key initiatives to meet the objectives:

- Revision of the safety referral process in order to shorten the timeframe for finalisation of safety referral procedures
- Increased transparency on arbitration/referral procedures and consistent presentation of available information regarding arbitration/referral procedures irrespective of the legal basis of such procedures

2.7 Herbal medicinal products

The new legislation introduced a simplified registration procedure for traditional herbal medicinal products in the EU Member States and established a Committee on Herbal Medicinal Products (HMPC). The Agency's activities in the field of herbal medicinal products will help to harmonise procedures and provisions concerning herbal medicines laid down in the Member States and to integrate further herbal medicinal products in the European regulatory framework. In 2005, particular emphasis will be placed on preparations for the full mandate of the Committee.

Key initiatives:

- Preparatory work for the establishment of the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products
- Preparation of draft Community herbal monographs for herbal medicinal products with a well-established use
- Preparatory work in the area of procedures to be established in relation to the provision to Member States and European institutions of the best scientific opinion on questions related to herbal medicinal products, as well as to the adoption of opinions at the request of the Committee for Medicinal Products for Human Use
- Clarification of the requirements related to the content of a dossier for a registration application. Examples of areas where clarification is necessary include:
    - the format and content of the bibliographic review of safety data and expert report required as part of the documentation supporting an application for registration
    - the bibliography or expert evidence on the medicinal use throughout a period of at least 30 years (format and type of evidence) to support a registration application
    - demonstration that the pharmacological effects or the efficacy are made plausible on the basis of long-standing use and experience
- Clarification of the status of guidance prepared by the Herbal Medicinal Products Working Party between 1997 and 2004

2.8 Scientific committees

The Committee for Medicinal Products for Human Use

The yearly audit cycle of the Committee for Medicinal Products for Human Use (CHMP) will contribute to the culture of continuous process improvement at CHMP level. Building on the experience obtained in 2004, the CHMP will strengthen its interaction with patients through a further development of the activities undertaken at the level of the EMEA/CHMP Working Group with Patients' Organisations. Initiatives will include the finalisation of the recommendations on provision of information to patients. It is also planned to transform this working group into a standing working party. Interaction between the CHMP and healthcare professionals and learned societies will be further developed.

The CHMP will meet 11 times in 2005.

CHMP meetings in 2005	
17-20 January	25-28 July
14-17 February	No meeting in August

14-17 March	12-15 September
18-21 April	10-13 October
23-26 May	14-17 November
20-23 June	12-15 December

The Committee on Orphan Medicinal Products

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

The COMP will meet 11 times in 2005, with each meeting lasting two days, with the possibility to extend to three days, depending on the number and complexity of applications to be reviewed.

COMP meetings in 2005	
12-14 January	12-14 July
2-4 February	No meeting in August
2-4 March	7-9 September
6-8 April	18-20 October
10-12 May	9-11 November
14-16 June	7-9 December

The Committee on Herbal Medicinal Products

The Committee on Herbal Medicinal Products (HMPC) will meet six times in 2005.

HMPC meetings in 2005	
27-28 January	21 – 22 July
22-23 March	19 – 20 September
31 May – 1 June	22 – 23 November

Standing and temporary working parties

The working parties of the EMEA scientific committees responsible for medicinal products for human use are involved in the development and revision of guidelines, in the provision of recommendations and advice on medicinal products for which applications are made, and in marketing authorisation or post-authorisation activities, according to the specific area of responsibility of each group. This includes advice and recommendations on general public health issues related to medicinal products.

Key initiatives:

- CHMP standing and temporary working parties will continue to streamline their processes, improving their transparency and effectiveness. Following the implementation of the confidentiality arrangements with the US Food and Drug Administration, discussions will continue with the FDA regarding specific issues on the development of medicinal products
- Temporary working parties on new emerging therapies and new technologies, i.e. pharmacogenetics, gene therapy and cell therapy, will continue to meet in 2005 as the Agency is likely to receive applications in relation to emerging therapies. The committees are to be kept informed on scientific and technological development in this scientific area
- In anticipation of the EU legislation on paediatric medicines, which could be adopted in 2006, the Agency will continue to support the Paediatric Working Party in its work with individual companies to discuss the development of paediatric formulations and its work on the availability of information on medicines for use in children
- The EMEA will support the development of biosimilar medicinal products through the activities of the Comparability Working Party and the Biotechnology Working Party with the development of specific product guidelines
- The EMEA/CHMP Working Party with Patients' Organisations will meet regularly and provide a forum allowing patients to provide their input into the regulatory system
- Activities in relation to plasma and vaccine antigen master files and to medical devices containing biotechnology and blood-derived medicinal products will develop further
- The COMP ad hoc biotechnology group will support the designation process for emerging therapies, and the COMP group with interested parties will continue its activities on a regular basis
- The EMEA will provide support to workshops with stakeholders, in particular with academic research organisations, organised at the initiative of the COMP and CHMP, on new scientific and methodological aspects. In addition, the EMEA will organise training of national assessors on topics agreed with the Agency's scientific committees and EU national competent authorities

Main CHMP standing and temporary working parties in 2005	**Number of meetings**
Pharmacovigilance Working Party	12
Biotechnology Working Party	11
Joint CHMP/CVMP Quality Working Party	4
Blood Products Working Party	2
Efficacy Working Party (plenary)	4
Safety Working Party (plenary)	4

EMEA/CHMP Working Party with Patients' Organisations	3
Paediatric Working Party	6
Vaccine Working Party	6

2.9 Regulatory activities

Regulatory and procedural guidance

Regulatory and procedural advice is provided to the pharmaceutical industry during the lifecycle of medicinal products, from pre-submission meetings with applicants through to annual meetings with marketing authorisation holders. Guidance documents focusing on the key steps of the centralised procedure, as well as on issues of quality, safety and efficacy of medicinal products, are continuously developed and updated by the EMEA.

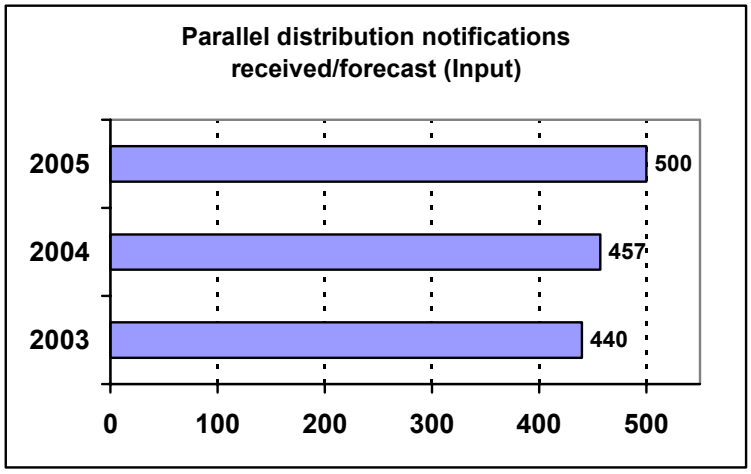
Key initiatives:

- During implementation of the new EU pharmaceutical legislation, significant emphasis will be made on the preparation of regulatory and procedural guidance, which will complement the ongoing review of the available guidance documents
- The EMEA will continue to support the European Commission in the updating and further development of the Notice to Applicants, providing advice on the centralised procedure and regulatory guidance for issues affecting the CHMP and its standing and temporary working parties

Details of all planned guidance documents are included in Annex 3.

Parallel distribution

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



Trend:

- A moderate increase in parallel distribution compared to 2004 is forecast. However, it should be noted that the implementation of the new Community legislation could result in a significant increase if parallel distributors were to systematically use the new legal provision. The situation, therefore, will be continuously monitored

Objectives and key initiatives:

- To process parallel distribution notifications in accordance with the EMEA procedure and adhering to regulatory timelines
- Update the EMEA guidance to parallel distributors taking into account the experience gathered
- Identification of areas for further improvement and implementation of necessary corrective actions

2.10 Provision of information to healthcare professionals and patients

The Agency has been given significant new responsibilities for the provision of information to patients and healthcare professionals. Emphasis is made on provision of information which is better adapted to its users. The Agency is in the process of revising its practices to make such information more understandable and accessible for both patients and healthcare professionals.

The new legislation, in addition, introduces requirements to provide information on withdrawals of applications by applicants prior to opinion and on refusals of marketing authorisations, to prepare summaries of European public assessment reports in a manner that is understandable to the public, and to distribute appropriate pharmacovigilance information.

Objective:

- To provide targeted, useful and accessible information to patients and healthcare professionals about the medicine-related aspects of the work of the Agency

Key initiatives to meet the objective:

- Establishment of a dedicated sector for medical information
- Finalisation of recommendations under development by the EMEA/CHMP Working Party with Patients' Organisations
- Achievement of consensus with the Agency's partners and stakeholders on the most adequate way to provide information on medicines to patients and healthcare professionals
- Continued development of the EuroPharm database to increase access to information on medicines available in the European Union
- Organisation of a dedicated workshop in the field of human medicines to discuss information and communication issues with healthcare professionals
- Establishment of a dedicated forum which would include the EMEA and Member State competent authorities, as well as the Agency's stakeholders, to discuss and propose the optimal way forward in providing information to patients and healthcare professionals from the European medicines network

2.11 International activities

Trends:

- The level of international activity is expected to continue to increase, taking into account the Agency's reinforced role in an enlarged European Union, resulting in an increasing interest in the Agency's work from non-EU regulatory authorities

Key initiatives:

- Interaction with the US Food and Drug Administration will be further developed through enhanced cooperation in the context of the confidentiality arrangements, e.g. in the fields of orphan medicinal products, scientific advice requests, new applications, pharmacovigilance, development of guidelines and the exchange of trainees and experts
- Interactions with Canada and Japan and other regulatory authorities will continue through the EMEA visiting experts programme
- Interaction and participation through scientific meetings and training with the WHO
- ICH activities will continue with two meetings in 2005, and reinforced support and coordination from the Agency will be provided in accordance with the new pharmaceutical legislation

2.12 Coordination group

The operation of the Mutual Recognition Facilitation Group (MRFG) will continue to be supported by the EMEA at its monthly meetings.

In November 2005, the MRFG will be replaced by the coordination group established by the new legislation. The EMEA is preparing for its new responsibility of providing secretarial support to the new coordination group, which will include:

- Proposal of meeting agendas, preparation and distribution of documents, provision of lists of positions taken on similar issues and follow-up to the meetings, including the preparation of monthly statistics related to the mutual recognition and decentralised procedures
- Phased introduction and maintenance of a memory of regulatory and scientific agreements and of the outcome of discussions regarding a specific mutual recognition or decentralised procedure
- Facilitation of liaison with other scientific working groups and with interested parties
- Secretarial assistance with preparation of annual reports, assistance with specific activities assigned to the coordination groups under their work programmes, and assistance in providing regulatory and legal support to the group's activities

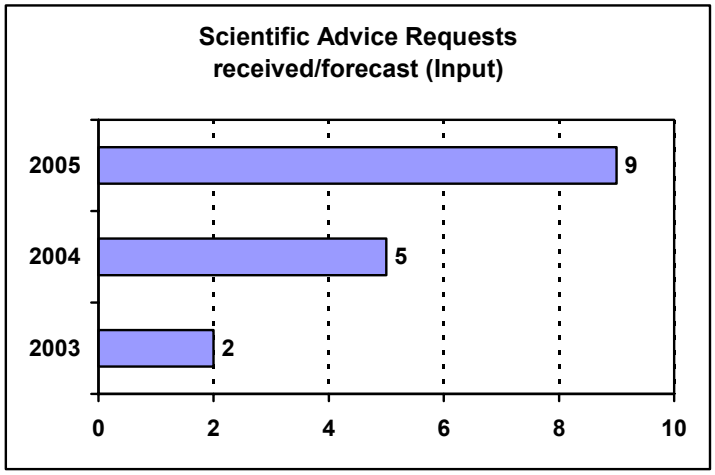
3 Veterinary medicines

Priorities for veterinary medicines in 2005:

- Encourage development of medicines for minor uses and minor species through implementation of the recommendations of the strategic action plan presented in the Committee for Medicinal Products for Veterinary Use (CVMP) Position Paper regarding Availability of Medicinal Products for Minor Uses and Minor Species, adopted in July 2004. Guidelines for consultation on the possible adaptation of data requirements for testing medicinal products for minor uses and minor species to facilitate their further authorisation will be drafted
- The EMEA will continue to fulfil its obligations under the new EU legislation with regard to coordination of pharmacovigilance responsibilities, with particular emphasis on effective communication to healthcare professionals and other interested parties. Electronic reporting of Adverse Drug Reactions for all veterinary medicines will be initiated under EudraVigilance Veterinary on 1 January 2005
- Establish a scientific memory database for centrally authorised medicinal products to underpin the quality and consistency of scientific assessment within the CVMP, thereby reinforcing the risk/benefit analysis prior to authorisation of new veterinary medicines
- Undertake the initial phase of the implementation plan for the EMEA Road Map to 2010 in relation to veterinary medicines, with particular emphasis on risk management of antimicrobial resistance, which may result from use of antimicrobials in animals, and on ensuring the adequacy of the environmental risk assessment in accordance with new EU legislation
- The EMEA and the CVMP will play an important part in contributing to the drafting of a new regulation and subsequent guidelines on residue control of veterinary medicines in food animals to succeed Council Regulation 2377/90

3.1 Scientific advice

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



Trends:

- Following a very useful exchange of views in 2004 with IFAH-Europe, the procedure and guidance for prospective applicants to request scientific advice have been considerably amended. The EMEA anticipates that interest in seeking such advice will continue and grow with the establishment of a new Scientific Advice Working Party for veterinary medicines
- Nine applications for scientific advice are expected this year
- Only a few applications for free scientific advice for products intended for minor uses/minor species have been received - for food animals

The consequences of the new pharmaceutical legislation:

The new legislation as regards the scientific advice described in section 2.2 of the work programme is equally applicable in both the human and veterinary medicinal product areas

Objectives:

- To implement the new legislative requirements in the area of scientific advice
- To provide quality scientific advice to applicants and adhere to regulatory timelines

  The performance indicator for this activity is the percentage of applications resulting in adoption of the advice letter within the 30, 60 or 90-day deadline (depending on the procedure). The target is to have 90 % of applications evaluated within this timeline
- To encourage the use of scientific advice by the veterinary medicinal products industry

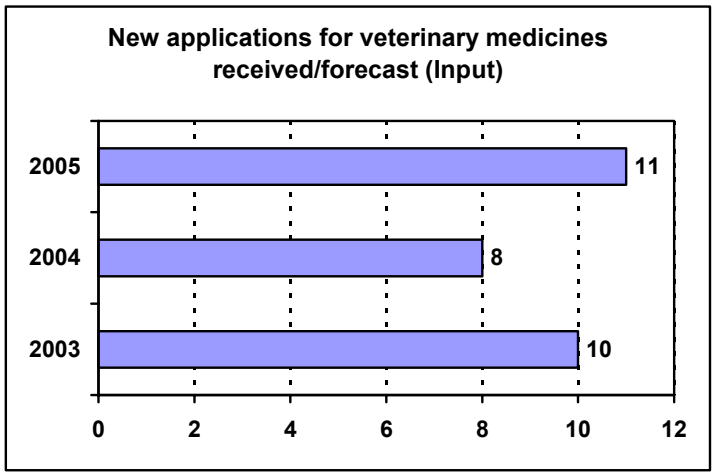
Key initiatives to meet the objectives:

- Provision of secretariat support to the scientific advice working party and support to potential applicants

- Proposal to the Management Board to approve an extension to the provision of free scientific advice to include products intended for use in minor uses and minor species that meet agreed criteria

3.2 Initial evaluation

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



Trends:

- The trend in applications through the centralised procedure continues, ensuring a steady supply of new and innovative medicines for veterinarians and animal owners throughout the Community
- There is only limited market growth foreseen in the veterinary pharmaceutical sector as a result of a reduction in the number of companies and industry's claims that investment in new products is being diverted into defensive research and development
- Despite this rather negative environment, there appears to be a small but steady flow of new products in the pipeline, with 11 full centralised applications forecast for 2005
- The trend in the number of generic applications which began in 2004 is anticipated to continue in 2005

The consequences of the new pharmaceutical legislation:

The new legislation in the area of evaluation of veterinary medicinal products introduces a number of important changes which have procedural, administrative and resource consequences for the Agency. The scope is broadened by the possibility of increased eligibility for the centralised procedure to include any veterinary medicine having importance for animal health throughout the Community. The legislation allows the committees to establish scientific advisory groups in connection with the evaluation of specific types of pharmaceutical products or treatments. Also, the time for communication of the CVMP opinion on medicinal products for veterinary use has been decreased to 15 days. This requires a substantial review of the procedure following the opinion of the CVMP.

Provisions regarding small and medium-sized enterprises are applicable in the field of veterinary medicinal products as well, and the Agency will need to provide support to veterinary companies with limited markets and to those licensing products for diseases with regional distribution. The

legislation also requires the Agency to provide information on withdrawal of an application by an applicant prior to opinion, and on refusal of marketing authorisation. The European public assessment reports will have to contain summaries written in a manner that is understandable to the public. These readability requirements will also be applicable to package inserts.

Objectives:

- To implement the new legislative requirements and increase the quality of assessment of such applications and adhere to regulatory timelines

  The performance indicator for this objective is the percentage of products evaluated within the regulatory timeline of 210 days. The target is 100 % of applications

- To provide timely and understandable product information to users and interested parties

  Performance indicators for this objective are:
  - percentage of summaries of opinion published at the time of publication of the press release following the CVMP meeting. The target is 90 % of summaries published at the time of the press release
  - percentage of European public assessment reports published within two weeks after Commission decision. The target is to publish 80 % of EPARs within the timeline

Key initiatives to meet the objectives:

- Provision of guidance to the CVMP on criteria to be considered when deciding whether an application for a product is eligible for the centralised procedure because it is "in the interests of patients and animal health at Community level" (Article 3(2)(b) of Regulation 726/2004)
- Integration into the CVMP assessment procedure of advice and recommendations of the scientific advisory group concerning applications for new antimicrobials
- Following the outcome of the CVMP audit in October 2004, implementation of its recommendations to strengthen the quality assurance system in relation to the CVMP procedures
- Establishment of a database to facilitate scientific memory analysis for all centralised applications submitted in the past 10 years, and for future applications, to allow for greater integrity, scientific quality and consistency of CVMP assessment reports
- Establishment of the necessary measures to provide assistance to companies producing veterinary products which have limited markets or are intended for diseases with a regional distribution (Article 79 of Regulation 726/2004)
- Preparation of EPAR summaries that are written so they are understandable to the public, and coordination with applicants to ensure package leaflets are similarly written in a manner comprehensible to the lay person

Management and organisation of the CVMP

The CVMP will meet 11 times during the year. The Committee will implement its newly adopted procedure intended to facilitate communication and dialogue between the Committee and interested parties, to fulfil obligations set out in the new legislation by putting in place the necessary arrangements to organise such exchanges and improve transparency as appropriate.

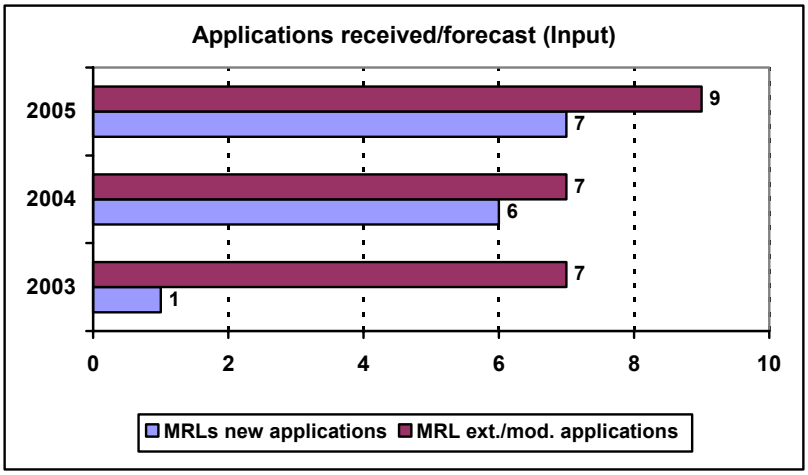
Following the audit of the CVMP conducted in October 2004, the Agency and Committee members will ensure the necessary responses to opportunities for improvement are implemented in full, to optimise the working practices of the Committee, its working parties and the secretariat.

CVMP meetings in 2005	
11-13 January	12-14 July
8-10 February	No meeting in August
8-10 March	6-8 September
12-14 April	4-6 October
17-19 May	8-10 November
14-16 June	6-8 December

3.3 Establishment of maximum residue limits

The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. The Agency therefore establishes maximum safe residue limits for pharmacologically active substances used in veterinary medicinal products in respect of all the various foodstuffs of animal origin, including meat, fish, milk, eggs and honey to provide for safe use of such foodstuffs.

Whilst the work to establish MRLs for the 'old' substances has all but finished, the secretariat continues to respond to a considerable number of enquiries for clarification and interpretation of the lists of MRLs in the Annexes to Council Regulation (EC) No 2377/90 from interested parties within and outside the Community. The document on frequently asked questions published on the EMEA website has facilitated this task and further steps will be undertaken to maximise the information available.



Trends:

- The number of requests for clarification on the list of MRLs is significant and is expected to remain at approximately 200
- Seven applications to establish MRLs for new substances in products for food animals are forecast, and the number of applications for extensions or modifications of MRLs is expected to increase to nine

- It is expected that further extrapolation of existing MRLs to additional species will continue as agreed within the CVMP's policy on minor uses and minor species as a direct response to specific applications from marketing authorisation holders

Objectives:

- To conduct quality assessments of MRL applications and related activities, and adhere to regulatory timelines

  The performance indicator for this objective is the percentage of applications evaluated within the 120-day timeline. The target is to have 100 % of applications evaluated within this timeline

- To provide timely information on MRLs to the public in accordance with agreed timelines

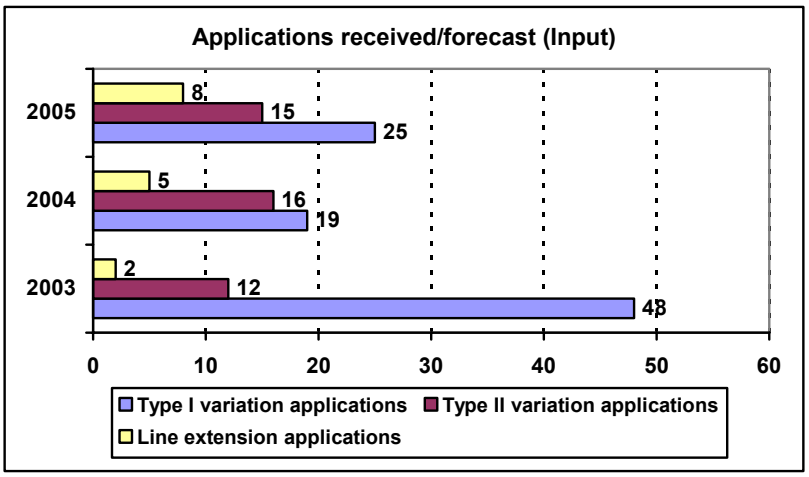
  Performance indicators for this objective are:
  - percentage of summaries of opinion published at the time of publication of the press release following the CVMP meeting. The target is 100 % of summaries published at the time of the press release
  - percentage of MRL summary reports published within 14 days after publication of Community MRLs. The target is to publish 80 % of summary reports within the timeline

- To provide timely information in response to queries from third parties on established MRLs in accordance with agreed timelines

  The performance indicator for this objective is the percentage of responses provided within 14 days. The target is to provide 95 % of responses within the timeline

3.4 Post-authorisation activities

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



Trends:

- The amount of work in post-authorisation activities such as variations and line extensions will increase steadily in line with the total number of marketing authorisations. Line extensions are likely to increase, with eight applications foreseen for 2005. Type I variations continue to grow in line with total marketing authorisations, with 25 anticipated for 2005. The number of type II variation applications remains at the previous year's level.

Objective:

- To provide quality opinions during post-authorisation activities adhering to regulatory timelines and to communicate post-authorisation information to interested parties

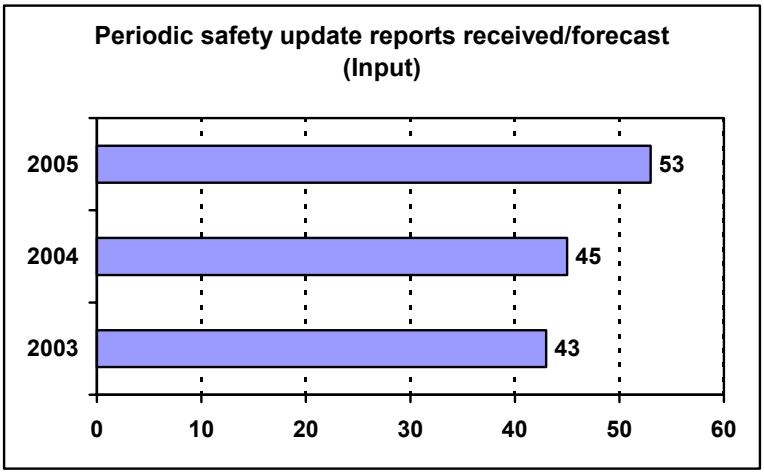
  The performance indicator for this objective is the percentage of applications evaluated within the 30, 60 or 90-day timeline (depending on the procedure). The target is to have 90 % of applications evaluated within these timelines

Key initiatives to meet the objective:

- Publication of summaries of opinion at the time of adoption by the CVMP
- Regular updating of EPARs in the post-authorisation phase for procedural and scientific aspects

3.5 Pharmacovigilance and maintenance activities

These include activities related to pharmacovigilance information (adverse drug reaction reports and periodic safety update reports). Pharmacovigilance remains a high priority of the Agency for 2005 to ensure that effective risk management is continually applied to post-authorisation monitoring of veterinary medicines throughout the EU.



Trends:

- Annual reports to be carried out for 37 products, prepared in cooperation with rapporteur and co-rapporteur
- Nine applications for renewal of marketing authorisation are forecast for 2005
- With the steady increase in products being authorised through the centralised procedure, the rise in adverse reaction reports and periodic safety update reports continues, with approximately 400 of the former and over 50 of the latter forecast for 2005
- Electronic reporting of adverse reactions in the veterinary sector will begin in January 2005 for the competent authorities, which will see a growth in development of electronic reporting by marketing authorisation holders as well
- The continuing responsibility for the organisation and support of the Veterinary Joint Implementation Group, the coordination of training, and the management of registration applications for access to EudraVigilance, as well as data collection, analysis, reporting and communication of electronic adverse reactions received from 1 January 2005, will place significant burdens on the small pharmacovigilance group in the veterinary sector. There will be a

continuous need for adaptation, maintenance and upgrading of the EudraVigilance database and data processing network, in collaboration with IT and project management teams at the Agency

- The trend for referral of issues resulting from pharmacovigilance reporting at Member State level to the CVMP will continue to grow, requiring the Committee's opinion for further actions to be taken as appropriate

The consequences of the new pharmaceutical legislation:

The new legislation sets forth provisions for the implementation of a risk management system, as well as for the possibility to set up a system for permanent follow-up of risk/benefit balance. The legislative basis for pharmacovigilance inspections is now provided. In order to address urgent situations, a system of provisional measures is foreseen. The legislation places emphasis on transparency, communication and provision of information on pharmacovigilance issues.

Objectives:

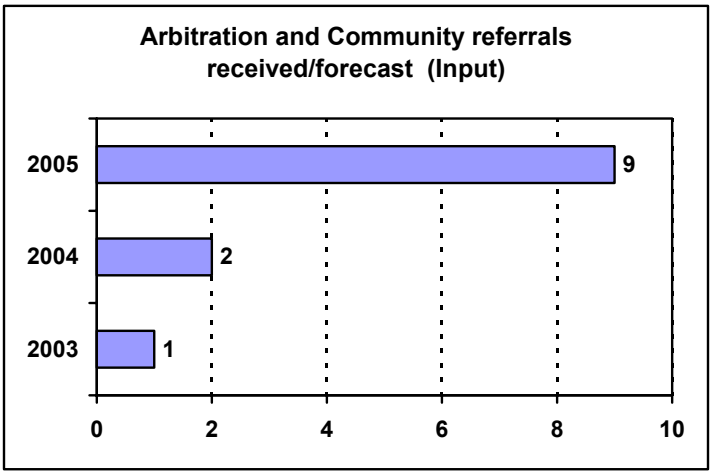
- To handle effectively and in a timely manner adverse reaction reports and PSURs for centralised products, in conjunction with rapporteur and co-rapporteur, for review by the CVMP, and to communicate information to the Commission, the Member States and the general public
- To implement EudraVigilance Veterinary effectively on 1 January 2005 for the competent authorities and by November 2005 for the Veterinary pharmaceutical industry
- To encourage greater exchange of information and dialogue on post-authorisation and safety of medicines, and to contribute to the effective utilisation of available EU resources in advancing effective pharmacovigilance for all veterinary medicines
- To implement new legislative mechanisms to optimise drug safety

Key initiatives to meet the objectives:

- Conduct analysis of adverse reaction reports and periodic safety update reports in a timely manner
- Provision of appropriate support to rapporteurs and co-rapporteurs
- Preparation of communication strategy, including annual report on pharmacovigilance for centralised products, for release to the Commission and Member States
- Management and monitoring of EudraVigilance Veterinary for its effective implementation of methodology for data analysis supported by automated signal detection
- Collaboration with the national competent authorities to evolve the European Surveillance Strategy
- Reporting and feedback on pharmacovigilance issues relating to centralised procedures to the Member States, interested parties and the public
- Continuing responsibility for Veterinary Joint Implementation Group coordination of training and applications for EudraVigilance, as well as data collection, analysis, reporting and communication of electronic adverse reactions received from 1 January 2005

3.6 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 case of Community interest and for safety-related issues (Articles 35 and 40 of Directive 2001/82/EC).



Trends:

- Enlargement of the Community to 25 Member States may mean that there is a greater challenge in reaching consensus in the mutual recognition procedure, with the potential for an increase in referrals to the CVMP for arbitration (Article 33) on the grounds of potential risk to human or animal health, or to the environment
- New legislation requires that Member States agree within the coordination group on a list of medicinal products for which harmonised summaries of product characteristics shall be prepared to promote harmonisation of veterinary medicines authorised in the EU. The Committee will be asked to act upon such referrals to harmonise summaries (Article 34 referral) once the Agency and Commission have agreed on finalisation of the list and timing of actions required. This list should be submitted by the Member States by 30 April 2005 and is expected to be rather extensive
- It is to be expected that further referrals shall be received, mainly concerning safety of medicines where Community interest is of primary concern (Article 35)

Objectives:

- To contribute to the promotion of harmonisation of authorisation of veterinary medicines in the EU
- To provide timely and quality opinions arising from arbitration and referral procedures

Key initiatives to meet the objectives:

- Reach agreement on a final list and a timetable for the list of medicinal products for SPC harmonisation with the Commission, following recommendations from the coordination group
- Coordination of the necessary workload for the initiation of such referrals that can be handled by the secretariat and CVMP in 2005

- Address procedural, regulatory and scientific issues arising from the mutual recognition procedure, including best practice guide for standard operating procedures for all such referrals

3.7 Regulatory activities

EU institutions and regulatory affairs

The Agency will continue to work closely with the relevant European institutions in the field of veterinary medicinal products, particularly the European Commission, and will work to increase the level of collaboration already established with the European Food Safety Authority during the previous year.

There will be continued cooperation with the Commission on reinforcing contributions to international activities where the Commission is involved, and provision of technical support in such forums as appropriate.

The Agency will maintain its commitment to support the Heads of Medicines Agencies (Veterinary) on strengthening the EU network of veterinary experts and all endeavours undertaken jointly to reinforce regulatory activities in the veterinary sector.

The Veterinary Unit will liaise closely with the Center for Veterinary Medicines (CVM) in the US Food and Drug Administration and with the United States Department of Agriculture to implement practical arrangements for advancing the Confidentiality Arrangements for exchange of information and documents agreed between the US and EU in late 2004.

Interested parties

The Agency will capitalise on its previously successful initiatives to maintain contacts and exchanges with interested parties, and aims to fulfil its obligations in accordance with new legislation to facilitate greater communication and dialogue on matters of common interest. The CVMP's procedure adopted in October 2004 to facilitate such communication and dialogue (EMEA/CVMP/329/04-Final) will be fully implemented and will progress the following initiatives:

- Presentations by senior representatives of interested parties
- Discussions on work programmes of CVMP working parties and scientific advisory groups
- Exchange of views between interested parties regarding guidelines
- Discussion of interested parties with working parties and/or ad hoc groups on specific technical/scientific issues
- Invitation by the CVMP, its working parties or scientific advisory groups to interested parties on specific technical/scientific issues
- Continued organisation of Infodays, focus groups and bilateral meetings

Standing and temporary working parties

The CVMP will continue to consider the need, when appropriate, for new guidelines, based on prior consideration of concept papers, subject to the widest consultation. The Agency will consult with the European Commission on responses to IFAH-Europe concerning their representation to the Commission expressing fears about the excessive development of guidelines in the veterinary sector.

The working parties and scientific advisory groups will support the CVMP with its provision of scientific input to the Commission and other Community institutions on request, with regard to animal health issues of concern to the Community.

The working party on Environmental Risk Assessment will advise the CVMP on implementation of specific requirements in the new legislation concerning any risk of undesirable effects on the environment resulting from the use of veterinary medicinal products. The working party will develop a technical guidance document prepared in cooperation with Member States and industry to facilitate implementation of the CVMP/VICH guideline.

CVMP working parties and ad hoc groups in 2005	**Number of meetings**
Immunologicals Working Party	4
Efficacy Working Party	3
Pharmacovigilance Working Party	6
Safety Working Party	4
Joint CHMP/CVMP Quality Working Party	4
Working party on Environmental Risk Assessment	3
Scientific advisory group on Antimicrobials	4
Scientific Advice Working Party	11

3.8 International activities

The Agency continues its role in coordinating the input and participation of the EU at VICH, and will be represented at the VICH 3 conference scheduled to take place in Washington DC in May 2005.

There will be continued technical support to the Commission in its membership of Codex Alimentarius, and the Agency and CVMP will continue their representation at other international forums, including the WHO, OIE and FAO.

The level of international interest in the Agency's veterinary activities of regulatory authorities from outside the EU is expected to be high, and support to these various organisations will continue.

3.9 Coordination group

The Agency is preparing for its new responsibility for the provision of secretarial support to the newly created coordination group, established according to the new legislation in 2005. For more information please refer to section 2.12.

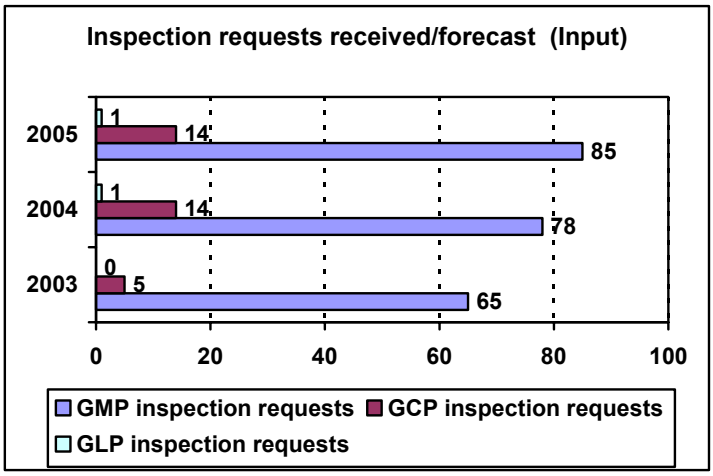
4 Inspections

Priorities for inspections in 2005:

- The major priority for 2005 will be to prepare for the implementation of the pharmaceutical legislative review, in particular the new requirements for GMP for starting materials and the setting-up of a database on manufacturing authorisations and GMP certificates
- Support the implementation activities relating to GCP inspections under the Clinical Trials Directive 2001/20/EC for human medicines and the directive on GCP, in particular the implementation of the second phase of the EudraCT database
- Support the European contribution to international discussions on GMP/quality systems in cooperation with the FDA and within the ICH and VICH framework
- Coordination of activities in the context of the joint audit programme for GMP inspectorates to ensure maintenance of consistent quality standards and harmonised approaches
- Work on implementation of mutual recognition agreements is expected to move towards consolidation as all agreements, with the exception of that with the US, become fully operational. Completion of the internal evaluation work with new Member States in the context of the Canadian mutual recognition agreement
- Coordinate and manage effectively the requests for GMP, GCP, pharmacovigilance and GLP inspections relating to applications for products through the centralised procedure within the timeframe laid down in Community law and to the standards required by the Agency's quality management system
- Implementation of an action plan for revision of the sampling and testing programme for centrally authorised products, in cooperation with EDQM, to streamline activities and focus resources taking a risk-based approach. Improvement of general transparency and communication between all stakeholders
- Provide support to all 25 Member States to optimise compliance with Community requirements in relation to GMP and GCP and Pharmacovigilance, and cooperate on planning initiatives to secure the allocation of sufficient resources for the conduct of inspections throughout the EU and in third countries
- Impact of new approach to WHO cooperation in the context of the certification scheme

4.1 Inspections

The EMEA coordinates the verification of compliance with the principles of Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP), and with certain aspects of the supervision of authorised medicinal products in use in the European Community, through inspections requested by the CHMP or CVMP in connection with the assessment of marketing authorisation applications and/or the assessment of matters referred to these committees in accordance with Community legislation. These inspections may be necessary to verify specific aspects of the clinical or laboratory testing or manufacture and control of the product and/or to ensure compliance with GMP, GCP or GLP and quality assurance systems. Similarly, the EMEA coordinates pharmacovigilance inspections requested by the scientific committees and inspections of blood establishments within the Plasma Master File (PMF) certification framework. Communication and action by Member States in response to suspected quality defects relating to centrally authorised medicines are also coordinated by the EMEA.



Trends:

- Requests for GMP and PMF (plasma master file) inspections are expected to increase by 10 % in 2005. This builds on a previous increase of 20 % relative to the number forecast for 2004. The increase is due in part to inspections in the context of plasma master file and vaccine antigen master file certification, but also to the effect of an increase in applications at the end of 2004
- Requests for GMP re-inspections of manufacturing sites are expected to form a high proportion of GMP requests in 2005, and coordination of responses to quality defects of centrally authorised products is also expected to increase due to the greater number of authorised products and increased awareness of the effects of deviations
- Requests for GCP and pharmacovigilance inspections are not expected to increase from their 2004 level as the rise in number for that year was already significant
- Implementation of Directive 2001/20/EC and of the new legislation will add to demands on community inspection resources
- Impact of Process Analytical Technologies on quality aspects of assessment and inspection
- Cooperation on the ICH/FDA initiative on quality systems/GMP is expected to build on the need for interaction between GMP inspectors and quality assessors

The consequences of the new legislation:

> The new pharmaceutical legislation requires the introduction of a number of new processes in the inspection field. The legislation provides for compliance with GMP requirements by manufacturers of active substances and for the establishment of a database containing information on GMP certificates and on manufacturing authorisations.

Objectives and key initiatives:

- To implement the new legislation in the fields of GMP, in particular with respect to active substances
- To provide support for the integration of new Member States in the GMP, GCP and GLP work of the Agency and to contribute to international cooperation and harmonisation activities
- To develop a database on manufacturing authorisations and GMP certificates
- To implement confidentiality arrangements with the FDA on inspection-related activities

Ad hoc groups of GMP, GCP inspections and joint CHMP/CVMP Quality Working Party

The ad hoc group of GMP inspection services will meet four times in 2005. The focus of its work will be on the continued harmonisation of inspection procedures and GMP interpretation, as well as on GMP implications of the new Community blood and GCP directives. This harmonisation work will include the development of GMP guidelines on products used as gene and cell therapies. The development of guidelines and procedures resulting from the GMP impact of the review of legislation will form a significant part of the work plan in 2005.

The ad hoc group of GCP inspection services will meet four times in 2005. In addition to general harmonisation work on approaches to GCP inspection, focus will be on consolidation of procedures to support the implementation of the Clinical Trials Directive and the Commission directive on GCP. There will also be further development of the interaction between the inspection and assessment functions so that best use can be made of the inspection resource available in the Community.

The joint CHMP/CVMP Quality Working Party will also meet four times in 2005 as it continues with the development of EU quality guidelines. The impact of new approaches to manufacturing and control methods (PAT) will be addressed in the framework of the EU PAT team.

4.2 Implementation of the Clinical Trials Directive

Trends:

- The Council Directive on the conduct of clinical trials on medicinal products for human use came into force on 1 May 2004
- Implementation of Directive 2001/20/EC and of the Commission Directive on GCP at EU level will require continued support to the development of harmonised procedures within the ad hoc group of GCP inspection services

Objectives and key initiatives:

- To provide support to the implementation of the clinical trials legislation, in particular with respect to GCP inspection
- Implementation of the first modules of Lot 2 of EudraCT
- Development of GCP inspection-related procedures and guidelines

4.3 Mutual recognition agreements

Objectives:

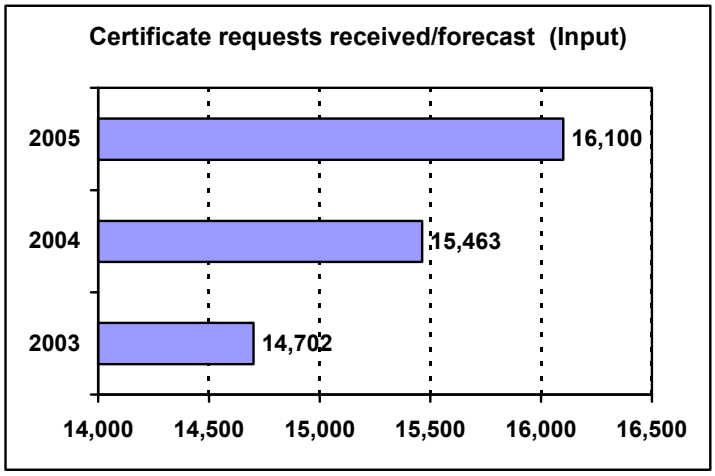
- To consolidate operational aspects of the respective MRAs (all agreements, with the exception of that with the US, are fully operational at least within the old Member States)
- To complete inclusion of the new Member State authorities in the MRAs (EC-Canada)
- To expand the scope of the EC-Japan agreement

Key initiatives to meet the objectives:

- Completion of the internal evaluation work with new Member States (the EC-Canada MRA)
- Provision of assistance to the new Member States for external evaluations (the EC-Canada MRA)
- Expansion of scope of the MRA with Japan to include sterile medicinal products and biologicals

4.4 Certificates

Numbers of certificate requests are expected to continue to increase as the pool of centrally authorised products is growing. The main objective for 2005 is to manage the increased workload and issue certificates according to required timelines.



4.5 Sampling and testing

The programme for sampling and testing centrally authorised products will continue in 2005, with 37 human and veterinary products to be tested.

New Member States will participate for the first time in the sampling part of the programme. Communication of programmes and results to stakeholders will increase due to the agreed greater transparency. The agreed action plan for revision of the programme requires an update of all documentation and SOPs at both the EMEA and EDQM.

5 EU telematics strategy and information technology

The European Union Telematics strategy for pharmaceuticals is agreed between Member States, the EMEA and the European Commission. In order to implement European pharmaceutical policy and legislation, the various initiatives aim to increase efficiency and enhance transparency, and support and facilitate the operation of procedures established by legislation.

The implementation strategy concentrates on a number of projects with high European added value. These projects have been agreed as being EudraNet, EudraVigilance, the EuroPharm database, electronic submissions, implementation of the Clinical Trials Directive and the good manufacturing practice database.

EU telematics is a priority area for the Agency. A large number of important telematics projects are carried out by the Agency concomitantly. Implementation of the projects in 2005 will advance the Agency towards the goal of collecting all information about adverse drug reactions electronically and conducting automatic signal detection. This will help the Agency to monitor the safety pattern of authorised medicines more effectively and to make more timely decisions.

In addition, EU regulators will have instant access to information about ongoing clinical trials in Europe and information about the status of GMP certificates and manufacturing authorisations. Once completed, the EuroPharm database will help healthcare professionals, patients and the general public to access up-to-date and reliable information about medicinal products available on the EU market.

Major corporate IT programmes for 2005 include an electronic document management system and a meeting management system. Improvement of the two programmes will enable the Agency to manage the organisation of meetings more effectively. The document management system allows for better implementation of requirements of the Agency's quality policy, helps to manage the large number of documents being created by the Agency, and will automate certain publishing and communication activities.

The growing number of meetings managed by the Agency and increasing number of delegate days will require the development of meeting technologies such as IP telephony, videoconferencing and web streaming.

Trends:

- Entry into force of the new legislation, requiring considerable effort to set up structures, processes and tools for the changed regulatory environment
- Increased complexity of managing multilingual submissions of product information due to the increase in number of languages following enlargement and to tighter deadlines introduced by the new legislation
- Concurrent development work on all EU telematics projects will have to be carried out, and five of the EU telematics systems – EudraNet, EudraVigilance, EudraCT, EuroPharm and e-Submission – will have to be operated, supported and maintained

Objectives:

- To take forward Eudra projects in a consistent, well-structured manner, and to put in place the modifications to systems and services necessary to successfully implement the new legislation. Delivery of first production versions of the EuroPharm medicines information system, the EudraVigilance data warehouse and pharmacointelligence tools, and the product information management system (PIM), plus completion of phase 2a of the European Clinical Trials registration database system (EudraCT). Preparatory work to provide access to dedicated information contained in the EudraVigilance database to healthcare professionals, marketing

authorisation holders and the public. The attainment of these objectives will be measured against delivery of the systems on time, within budget, and to specification

- To provide high-quality service, including extended helpdesk facilities, of EU telematics to the EMEA's partners on an ongoing basis. Service quality will be measured by a number of performance indicators, such as systems availability, helpdesk response times and problem resolution times
- To progress the development of a programme of corporate projects (25 out of 50 corporate IT projects) while providing support to all IT activities related to the Agency's increased responsibility. The achievement of these objectives will be monitored through key performance indicators, such as systems availability, response times and on-time delivery, within budget and to specifications, for new or improved information systems
- To consider new and innovative ways of applying technological solutions to conducting meetings, including promoting greater use of videoconferencing and web streaming
- To improve business continuity arrangements, i.e. to put in place the necessary infrastructure and processes to guarantee that the Agency's core business will not be interrupted for more than one working day

Key initiatives to meet the objectives:

- Operation, maintenance, support and further development of five EU telematics projects: EudraNet, EudraVigilance, EudraCT, EuroPharm and e-Submission
- Bringing of EuroPharm into production, including data from as many competent national authorities as wish to contribute
- Definition and establishment of the dictionaries to be implemented centrally, together with an agreed process for managing dictionary maintenance
- A pilot implementation of the data warehouse and business intelligence applications for EudraVigilance
- Implementation of Lot 2A of EudraCT as a production version
- Operation, maintenance, support and further development of two important sub-systems: product information management system (PIM) and user identity management, together with legally enforceable digital signatures. Implementation of a first production version of the PIM system for 21 November 2005
- Development of the database on manufacturing authorisations and GMP certificates
- Completion of the construction of an EU telematics data centre with high availability, high scalability and good performance

6 Support activities

6.1 Administration

The activities in the administration area relate to a number of functions, which include managing revenue, expenditure and accounts according to existing rules and regulations, conducting recruitment procedures, and managing and administering staff and seconded personnel, as well as providing and running the necessary infrastructure services for effective functioning of the Agency. The activities entail close cooperation with the European Parliament and the Council (Budgetary Authority), as well as with the Commission and the Court of Auditors, on matters relating to administration, the budget, personnel, and rules and regulations on finances, audit and accounting. For this reason, the Administration unit maintains regular contacts with the above institutions and with the other European agencies.

Particular challenges in the year 2005 will be:

- A changed working environment following the review of the Agency's founding regulation
- The implementation of a new fee regulation
- The implementation of a new accounting system
- The integration of delegates, staff and experts from the new Member States, and the extension of the Agency's office and conference space to accommodate new staff, delegates and experts following the entry into force of the new legislation
- The implementation of an improved activity-based budgeting database and budgetary planning
- The implementation of a new competence-development policy

Personnel and budget

Objectives:

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

Key initiatives to meet the objectives:

- Consolidation of the new Staff Regulations
- Enhancement of the activity-based budgeting system
- Professional training management directed towards a continuous system of competence development, taking account of the enhanced scientific role of the Agency
- Conduct of recruitment procedures
- Implementation of the 2005 budget
- Budget process for 2006 budget

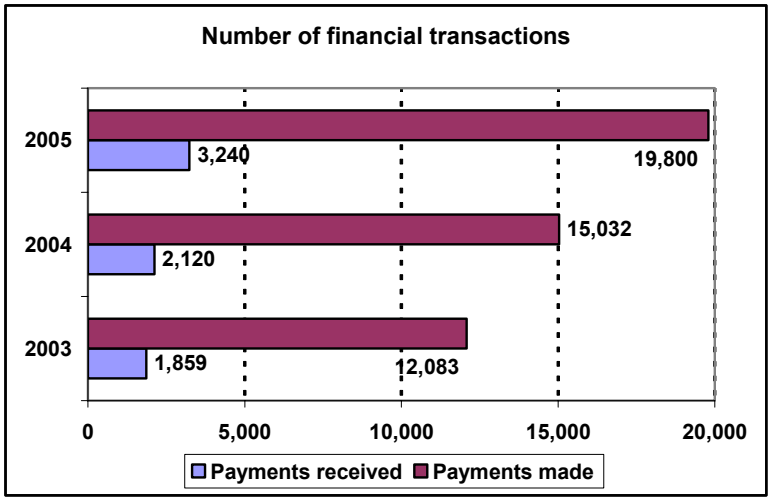
	2003 final	2004 final	2005 projected
Workload			
Total staff	287	314	379
EMEA budget	€ 84,179,000	€ 99,089,103	€ 110,160,000
Selection procedures	23	27	30
Mission claims	950	897	1,000
Salary payments	3,300	3,715	4,200
Staff movements	77	127	115

Accounts

Objectives and key initiatives:

- To maintain the accounts, make payments and collect revenue in accordance with the procedures laid down in the financial regulation
- To manage efficiently the cash resources of the Agency and maintain relationships with the Agency's banks
- To maintain and develop financial and budgetary accounting systems and reporting tools, including security and helpdesk components
- Provision of accurate and timely financial information to management
- Implementation of inventory accounting system
- Requirement to produce financial accounts based on generally accepted accounting principles by 2005

The table below gives an overview of the likely workload in accounts in 2005. The biggest impact on future workload estimated for 2005 will be the implementation and management of new invoicing and financial accounting systems.



Infrastructure Services at the EMEA

The area of infrastructure services at the EMEA covers a wide range of services, including security, telecommunications, reception, switchboard, archiving, mail, reprographics, technical assistance to meeting rooms, confidential waste, health & safety, fire and emergency plans, business continuity planning, inventory, office equipment and supplies, maintenance, refurbishment and fitting out, and management of the catering facilities.

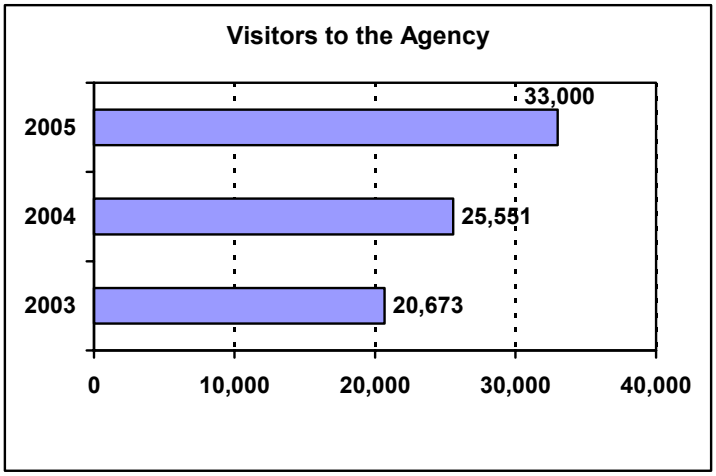
Objective:

- To ensure a safe and efficient work environment for staff, delegates and visitors

Key initiative to meet the objective:

- Business continuity plan – the exercising and testing of the plan will be carried out
- Expansion of accommodation for both offices and meetings
- Streamlining the procurement procedure and the management of contracts
- Review of audiovisual and interpretation equipment in the meeting rooms
- Focus on health & safety in the workplace
- Managing the impact of the enlargement on the various services in the area of infrastructure

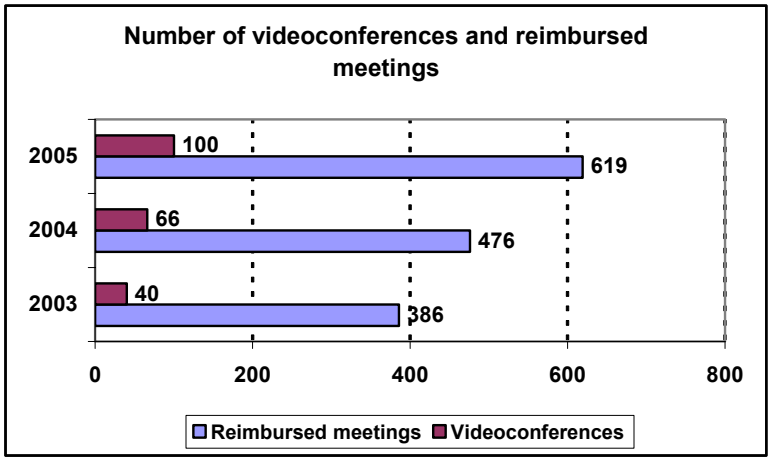
The work in the area of infrastructure is directly linked to the increase in staff, meetings, telecommunications activities and visitors to the Agency. The maintenance of six floors at 7 Westferry Circus is highly labour intensive as it includes all the facilities on each of the floors, plus mechanical and engineering services.

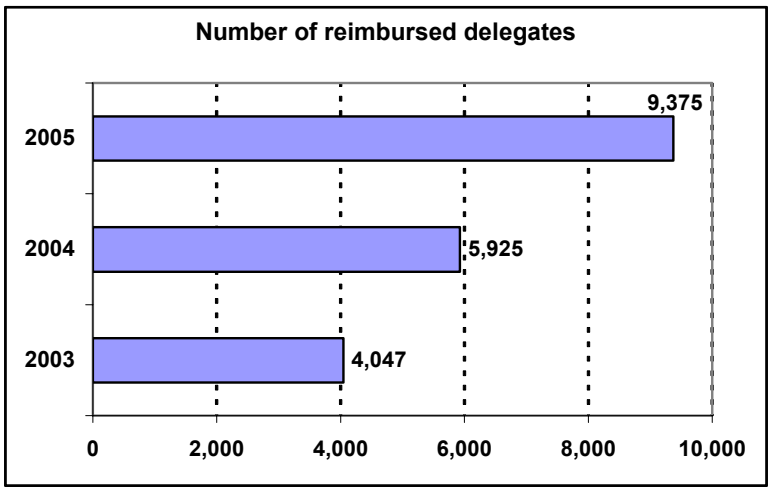


6.2 Meetings and conferences at the EMEA

The EMEA ensures efficient support for meetings organised by the Agency, provides facilities and services, and constantly improves the resources available. The Agency assists delegates with logistics and practical arrangements. This includes 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 area of meeting management and conferences will experience a significant increase in its activities in 2005. This increase is a result of the 2004 enlargement, entry into force of new legislation which introduces a new committee, new scientific groups and the setting of new priorities, and a result of the established role of the Agency not only in the EU but also in the international regulatory forum. The Agency plans to re-engineer and reinforce its processes related to meeting management. It will not only streamline and automate a number of related procedures but will also explore alternatives to physical meetings.





Trends:

- 30 % increase in the number of meetings to be organised due to the additional new committee and related working party meetings, as well as the planned increase in the number of scientific advice oral explanation meetings and meetings with companies
- Increase in the number of travel and hotel booking requests to manage
- 60 % increase in the reimbursement of meeting expenses to delegates, national authorities and suppliers

Objectives and key initiatives:

- To streamline and optimise the organisation of meetings to achieve the highest possible standard. To enhance the efficiency of reimbursement procedures
- To provide the best possible support and assistance to delegates attending meetings
- Processing the delegates' expenses reimbursement within two weeks after the meeting ends
- Development of a meeting management system to automate the meeting management process
- Development of meeting broadcasting and wider implementation of video- and teleconferencing to facilitate communication and reduce the number of reimbursed meetings
- Setting up a 'visitors' centre' on the EMEA website, including information such as the Delegate manual
- Development of a Conference Guide for EMEA staff, external delegates and experts, linked to the meeting management system and containing all relevant information surrounding conferences

6.3 EMEA document management and publishing

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

The objective for 2005 in the area of document management and publishing is to support the Agency's full compliance with all regulatory and quality requirements in the areas of records and document management and to ensure the application of best practice.

2005 will be 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 will have procedural and resource implications.

Implementation of the electronic document management system remains 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. Development and implementation of document management, records management and mail registration policies will be undertaken in 2005.

Annexes

1. **EMEA establishment plan 2003–2005**
2. **Revenue and expenditure overview 2003–2005**
3. **Guidelines and working documents in 2005**
4. **EMEA contact points**
5. **Profiles of EMEA personalities**

Annex 1
EMEA establishment plan 2003-2005

Category & Grade	TEMPORARY POSTS		
	Occupied as per 31.12.2003	Authorised for 2004	Requested for 2005
A*16	-	-	-
A*15	1	1	1
A*14	5	5	7
A*13	-	-	4
A*12	28	32	33
A*11	32	37	32
A*10	31	39	34
A*9	-	-	11
A*8	30	32	32
A*7	-	-	41
A*6	-	-	-
A*5	-	-	-
Total grade A	*127*	*146*	*195*
B*11	-	-	-
B*10	6	6	6
B*9	-	-	-
B*8	8	10	10
B*7	11	15	12
B*6	12	15	12
B*5	8	9	9
B*4	-	-	2
B*3	-	-	8
Total grade B	*45*	*55*	*59*
C*7	-	-	-
C*6	17	19	19
C*5	19	27	23
C*4	39	51	47
C*3	4	7	6
C*2	-	-	2
C*1	-	2	21
Total grade C	*79*	*106*	*118*
D*5	-	-	-
D*4	2	2	2
D*3	3	5	5
D*2	-	-	-
Total grade D	*5*	*7*	*7*
Total Staff	**256**	**314**	**379**

Annex 2
Revenue and expenditure overview 2003-2005

The summarised comparative budget statements for 2003 to 2005 are as follows:
(Amounts expressed in euro)

	2003 (31.12.2003)		**2004** (30.11.2004)		**2005** (draft budget)	
	€	*%*	€	*%*	€	*%*
Revenue						
Fees	56,742,000	*67.41*	67,000,000	*67.62*	77,455,000	*70.31*
General EU contribution	12,300,000	*14.61*	17,500,000	*17.66*	17,900,000	*16.25*
Special EU contribution for IT Telematics strategy	7,000,000	*8.32*	7,500,000	*7.57*	7,500,000	*6.81*
Special EU contribution for orphan medicinal products	3,100,000	*3.68*	3,500,000	*3.53*	3,700,000	*3.36*
Contribution from EEA	558,000	*0.66*	573,000	*0.58*	530,000	*0.48*
Contribution from EU programmes	1,530,000	*1.83*	p.m.	*0*	p.m.	*0*
Other	2,949,000	*3.50*	3,016,103	*3.04*	3,075,000	*2.79*
TOTAL REVENUE	**84,179,000**	**100.00**	**99,089,103**	**100.00**	**110,160,000**	**100.00**
Expenditure						
Staff						
Salaries	27,352,500	*32.49*	32,286,000	*32.57*	35,876,000	*32.57*
Interim and other support persons	1,845,000	*2.19*	2,346,000	*2.37*	2,695,000	*2.45*
Other staff-related expenditure	2,355,000	*2.80*	2,503,000	*2.53*	2,759,000	*2.50*
Total Title 1	*31,553,000*	*37.48*	*37,135,000*	*37.47*	*41,330,000*	*37.52*
Building/equipment						
Rent/charges	5,686,000	*6.76*	5,664,000	*5.72*	8,698,000	*7.90*
Expenditure on data processing	9,517,000	*11.31*	11,179,000	*11.28*	8,931,000	*8.10*
Other capital expenditure	1,959,000	*2.33*	1,638,000	*1.65*	2,023,000	*1.84*
Postage and communications	418,000	*0.50*	505,000	*0.51*	580,000	*0.53*
Other administrative expenditure	2,075,000	*2.46*	3,157,000	*3.19*	4,030,000	*3.66*
Total Title 2	*19,655,000*	*23.35*	*22,143,000*	*22.35*	*24,262,000*	*22.03*
Operational expenditure						
Meetings	3,946,800	*4.70*	6,803,103	*6.87*	7,439,000	*6.75*
Evaluations	26,810,800	*31.85*	31,175,000	*31.46*	35,673,000	*32.38*
Translation	701,000	*0.83*	1,485,000	*1.50*	1,001,000	*0.91*
Studies and consultants	27,000	*0.03*	100,000	*0.10*	200,000	*0.18*
Publications	78,000	*0.09*	248,000	*0.25*	255,000	*0.23*
EU programmes	1,407,000	*1.67*	p.m.	*0*	p.m.	*0*
Total Title 3	*32,971,000*	*39.17*	*39,811,103*	*40.18*	*44,568,000*	*40.45*
TOTAL EXPENDITURE	**84,179,000**	**100.00**	**99,089,103**	**100.00**	**110,160,000**	**100.00**

Annex 3
Guidelines and working documents in 2005

CHMP Biotechnology Working Party

Reference number	Document title	Status
EMEA/410/01 Rev 3	Note for guidance on minimising the risks of TSE transmission via medicinal products	Work to be continued in 2005
--	Guideline on similar medicinal products containing biotechnology derived proteins as active substances: Quality issues	To be finalised in 2005
--	Guideline on development of potency assays for tumour cell line based medicinal products	Work to be continued in 2005
--	Guideline on the use of transgenic animals in the manufacture of biological medicinal products for human use *(revision)*	To be finalised in 2005
CPMP/BWP/764/02	Points to consider on quality aspects of medicinal products containing active substances produced by stable transgene expression in higher plants	To be finalised in 2005
--	Description of strength of insulin analogues	Concept paper and recommendations to be developed and completed in 2005
--	Manufacture and control of recombinant allergens	Concept paper for preparation of guideline to be developed
--	CPMP recommendations on transmissible agents and urinary derived medicinal products	To be finalised in 2005
--	Guideline on similarity of orphan medicinal products	Guideline to be finalised in 2005
--	Position paper on cumulative stability requirements for vaccines	Work to be continued in 2005
CPMP/BWP/2289/01	Points to consider on the development of live attenuated influenza vaccines	Revision to start in 2005
--	Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products: development of additional guidance for lentiviral vectors	Work to be continued in 2005

CHMP Blood Products Working Party

Reference number	Document title	Status
CPMP/BPWG/220/02	Guideline on the clinical investigation of von Willebrand factor	To be finalised in 2005 after further consultation on related core SPC
CPMP/BPWG/388/95 Rev 1	Note for guidance on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	Revision expected to be released for consultation in 2005 and finalised in 2006

Reference number	Document title	Status
CPMP/BPWG/198/95 Rev 1	Note for guidance on the clinical investigation of recombinant Factor VIII and IX products (CPMP/BPWG/1561/99) and the Note for guidance on the clinical investigation of human plasma derived Factor VIII and IX products	Revision expected to be released for consultation in 2005 and finalised in 2006
CPMP/BPWG/575/99	Note for guidance on the clinical investigation of human anti-D immunoglobulin for intravenous and/or intramuscular use	Review and possible revision of the guideline. If revision is required, expected to be released for consultation in 2005 and finalised in 2006
CPMP/BPWG/278/02	Core SPC for von Willebrand factor	Core SPC released for further consultation in 2004 and to be finalised in 2005
CPMP/BPWG/3726/02	Core SPCs for human varicella immunoglobulin i.v.	Core SPC released for 6 months' consultation in 2003 and to be finalised in early 2005
CPMP/BPWG/4222/02	Core SPC for human plasma derived hepatitis-B immunoglobulin for intramuscular use	Core SPC released for 6 months' consultation in 2003 and to be finalised in early 2005
CPMP/BPWG/4027/02	Core SPC for human plasma derived hepatitis-B immunoglobulin for intravenous use	Core SPC released for 6 months' consultation in 2003 and to be finalised in early 2005
CPMP/BPWG/3735/02	Revision of core SPC for human plasma prothrombin complex	Core SPC released for 6 months' consultation in 2003 and to be finalised in early 2005
CPMP/BPWG/859/95 Rev 2	Core SPC for human normal immunoglobulin for intravenous administration (IVIg)	Revision expected to be released for consultation in 2005 and finalised in 2006
CPMP/BPWG/574/99	Core SPC for human anti-D immunoglobulin for intravenous and/or intramuscular use	Review and possible revision of core SPC. If revision is needed, revision expected to be released for consultation in 2005 and finalised in 2006
CPMP/BPWG/1619/99	Core SPC for human plasma derived and recombinant coagulation Factor VIII products	Revision expected to be released for consultation in 2005 and finalised in 2006
CPMP/BPWG/1625/99	Core SPC for human plasma derived and recombinant coagulation Factor IX products	Revision expected to be released for consultation in 2005 and finalised in 2006
--	Guideline on warning on transmissible agents for SPCs and patient leaflets	Work to be continued in 2005

CHMP Vaccine Working Party

Reference number	Document title	Status
CPMP/VEG/15/04	Guideline on clinical evaluation of vaccines	Revision expected to be released by mid 2005
CHMP/VEG/193031/2004	Core SPC for pandemic influenza vaccines	To be released in January 2005 for 3 months' consultation. To be finalised by Q3 2005
EMEA/CPMP/VEG/17/03/v3/ Consultation	Guideline on requirements for evaluation of new immunological "adjuvants" in vaccines	To be finalised in 2005
--	Guideline on product information for	Work to start in 2005

Reference number	Document title	Status
	vaccines: Sections 4 and 5	
--	Guidance on the development of vaccines against emerging and re-emerging diseases such as SARS, pathogens potentially used in bioterrorism, monovalent polio vaccines	Work to be considered in 2005

CHMP Efficacy Working Party

Reference number	Document title	Status
CPMP/EWP/3635/03	Guideline on clinical investigation of medical products in the treatment of social anxiety disorder (social phobia)	To be finalised in 3/4Q 2005
--	Concept paper for the development of a guideline on clinical investigation of medical products in the treatment of post-traumatic stress disorder	To be adopted in 1/2Q 2005
CPMP/EWP/561/98-Rev 1	Guideline on the clinical investigation of medicinal products for the treatment of multiple sclerosis	Draft revision 1 to be released for consultation in 1/2Q 2005
CPMP/EWP/553/95	Guideline on medicinal products in the treatment of Alzheimer's disease	Revision to be considered in 2005
CPMP/EWP/234/95-Rev 1	Guideline on the clinical investigation of antianginal medicinal products in stable angina pectoris	Revision to be finalised in 2/3Q 2005
CHMP/EWP/1470/04	Guidance on clinical investigation of medicinal products for secondary prevention of cardiovascular events	To be released for consultation in 2/3Q 2005
--	Questions and answers document on fixed combination of antihypertensive and lipid lowering agents	To be released for consultation in 1/2Q 2005
CPMP/EWP/519/98-Rev 1	Guideline on clinical investigation of steroid contraceptives in women	Revision to be finalised in 1/2Q 2005
CPMP/EWP/4891/03	Guideline on clinical investigation of medicinal products for the treatment of ankylosing spondylitis	To be released for consultation in 1/2Q 2005
CPMP/EWP/422/04	Guideline on clinical investigation of medicinal products for treatment of juvenile arthritis	To be released for consultation in 1/2Q 2005
CPMP/EWP/468/04	Guideline on clinical investigation of medicinal products for treatment of psoriatic arthritis	To be released for consultation in 1/2Q 2005
CPMP/EWP/021/97-Rev 1	Guideline on hormone replacement therapy	Revision to be finalised in 3/4Q 2005
CPMP/EWP/281/96-Rev 1	Guideline on clinical investigation of drugs used in weight control	Draft revision 1 to be released for consultation in 1/2Q 2005
EMEA/CPMP/EWP/552/95-Rev 2	Guideline on postmenopausal osteoporosis in women	Draft revision 2 to be released for consultation in 1/2Q 2005
CPMP/EWP/4713/03	Guideline on the clinical investigation of medicinal products for the treatment of sepsis	To be released for consultation in 1/2Q 2005
CPMP/EWP/6172/03	Guideline on the clinical investigation	To be released for consultation in

Reference number	Document title	Status
	of medicinal products for the treatment of hepatitis B	1/2Q 2005
CPMP/EWP/2158/99	Guideline on Biostatistical/methodological issues arising from CHMP discussion on marketing authorisation applications: Choice of non-inferiority margin	To be released for consultation in 1Q 2005
CPMP/EWP/2459/02	Guideline on the use of statistical methods for flexible design and analysis of confirmatory clinical trials	To be released for consultation in 1/2Q 2005
CPMP/EWP/226/02	Guideline on clinical pharmacokinetic investigation of the pharmacokinetics of peptides and proteins	To be released for consultation in 1/2Q 2005
CPMP/EWP/968/02	Guideline on the evaluation of the pharmacokinetics of medicinal products in the paediatric population	To be released for consultation in 1/2Q 2005
CPMP/EWP/2339/02	Guideline on the evaluation of the pharmacokinetics of medicinal products in patients with hepatic impairment	To be released for consultation in 1/2Q 2005
--	Concept paper for the development of a guideline on the evaluation of the pharmacokinetics of highly variable medicinal products	To be adopted in 1/2Q 2005
CPMP/EWP/4937/03	Guideline on the clinical investigation of antiemetic medicinal products for use in oncology	To be released for consultation in 1/2Q 2005
CHMP/EWP/1068/04-Rev 1	Guideline on the evaluation of anticancer medicinal products in man	Draft version 1 to be released for consultation in 1/2Q 2005
CPMP/EWP/5872/03	Guideline on data monitoring committee	To be finalised in 2/3Q 2005
CHMP/EWP/6235/04	Guideline on clinical investigation of medicinal products for the prophylaxis of venous thromboembolism in non-surgical patients	Draft revision 1 to be released for consultation in 1/2Q 2005
CPMP/EWP/555/95-Rev 1	Guideline on clinical trials with haematopoietic growth factors for the prophylaxis of infection following myelosuppressive or myeloablative therapy	Draft revision 1 to be released for consultation in 1/2Q 2005
CPMP/EWP/504/97-Rev 1	Guideline on clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome	Draft revision 1 to be released for consultation in 2/3Q 2005
--	EWP Reflection paper on clinical trials in small populations	To be finalised in 1Q 2005
EMEA/CHMP/1889/04	Guideline on the use of medicinal products during pregnancy: need for post-marketing data	To be finalised in 2/3Q 2005
CPMP/EWP/239/95	Guideline on the clinical requirements for locally applied, locally acting products containing known constituents	Revision to be considered in 2005
CPMP/EWP/240/95	Guideline on fixed combination medicinal products	Revision to be considered in 2005
CPMP/EWP/560/95	Guideline on the investigation of drug interactions	Revision to be considered in 2005

Reference number	Document title	Status
CPMP/EWP/1119/98	Guideline on the evaluation of diagnostic agents	Revision to be considered in 2005
CHMP/ICH/2/04	ICH E14 the clinical evaluation of QT/QTs interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs	EWP contribution

CHMP Pharmacovigilance Working Party

Reference number	Document title	Status
EC Volume 9 2001	Notice to marketing authorisation holders	Revision to be released for public consultation by April 2005
EC Volume 9 2001	Procedure for competent authorities on the undertaking of pharmacovigilance activities	Revision to be released for public consultation by April 2005
EC Volume 9 2001	CPMP Note for Guidance on the rapid alert system and non-urgent information system in pharmacovigilance	Revision to be released for public consultation by April 2005
EC Volume 9 2001	Note for Guidance on the conduct of pharmacovigilance for centrally authorised products	Revision to be released for public consultation by April 2005
EC Volume 9 2001	Note for Guidance on the conduct of pharmacovigilance for medicinal products authorised through mutual recognition	Revision to be released for public consultation by April 2005
EC Volume 9 2001	Principles of providing the World Health Organization with pharmacovigilance information	Revision to be released for public consultation by April 2005
-	CHMP Guideline on the conduct of pharmacovigilance for medicines used by children	To be released for public consultation by Q4 2005
-	CHMP Guideline on the conduct of pharmacovigilance for vaccines	Concept paper to be transmitted to CHMP by Q4 2005
-	CHMP Guideline for the preparation of assessment reports on periodic safety update reports	Draft to be transmitted to CHMP by Q2 2005
-	Guideline on criteria for recall and repackaging following urgent safety restriction and variation procedures	Work to be continued in 2005
CHMP/PhVWP/3897/03	CHMP Guideline on handling direct healthcare professional communication for medicinal products for human use	To be released for public consultation by Q2 2005
-	Guideline on handling public statements on matters relating to the safety of medicinal products for human use	Concept paper to be transmitted to CHMP by Q2 2005
-	Guidance on risk management tools and risk communication	Contribution to EMEA and HMA activities
-	Other documents on working practices and work-sharing as well as new document management and communication/information exchange/tracking tools, in particular	Work to be continued in 2005

Reference number	Document title	Status
	with view to implementing the EU Risk Management Strategy and the revised PhVWP mandate of September 2003	
-	Good Pharmacovigilance Practice (GVP)	Work to be continued in 2005
CPMP/PhVWP/135/00	Standard Operating Procedure for the Review of CPMP Scientific Advice by the CPMP Pharmacovigilance Working Party	Revision to be considered in 2005
-	Policy for the transmission of PhVWP Recommendations and Assessment Reports for mutually recognised and purely nationally authorised products to marketing authorisation holders	Work on Concept paper to be continued in 2005
CPMP/PhVWP/1618/01	Position Paper on Compliance with Pharmacovigilance Regulatory Obligations	Contribution to EMEA and HMA activities on follow-up and implementation of revised legislation
CPMP/ICH/4679/02	ICH-E2C Addendum	To be incorporated in revised Volume 9 (see above)
CPMP/ICH/3945/03	ICH-E2D: Post-Approval Safety Management: Definitions and Standards for Expedited Reporting and Good Case Management Practices	To be incorporated in revised Volume 9 (see above)
CPMP/ICH/5716/03	ICH-E2E: Pharmacovigilance Planning	To be incorporated in revised Volume 9 (see above)
-	ICH-M1: Medical Dictionary for Drug Regulatory Activities (MedDRA)	Contribution to maintenance and guidance on the use of MedDRA at request of EC
EC December 1999	Notice to Applicants – Guideline on the Summary of Product Characteristics	Discussion of comments received on revision to be released for public consultation in 2005
-	EudraVigilance – Definition of pre-defined queries for signal generation and usage of the data warehouse	Contribution to draft prepared by EudraVigilance Working Groups
-	CHMP Guideline on Risk Assessment of Medicinal Products on Human Reproductive and Development Toxicities: From Data to Labelling	Contribution (see SWP)
CPMP/BWP/2289/01	Points-to-Consider on the Development of Live Attenuated Influenza Vaccines	Contribution, if requested (see BWP)
-	Note for Guidance on Quality, Pre-clinical and Clinical Aspects of Gene Transfer Medicines – Lentiviral Vectors	Contribution, if requested (see BWP)
MRFG March 2001	Standard Operating Procedure on Urgent Safety Restrictions for Medicinal Products Authorised through Mutual Recognition Procedure	Need for comments in the light of experience to be considered in 2005
Commission Directive/…/EC	Technical Requirements for Blood and Blood Components (including those used for medicinal products derived from human blood and plasma)	Contribution to development of haemovigilance procedures and mechanisms for interaction between haemovigilance and pharmacovigilance systems if requested

CHMP Safety Working Party

Reference number	Document title	Status
CPMP/SWP/4447/00	Guideline on environmental risk assessments for pharmaceuticals	To be re-released for consultation in 4Q 2004/1Q 2005
CPMP/SWP/5199/02	Guideline on the limits for genotoxic impurities	To be finalised in 1Q 2005
CPMP/SWP/1094/04	Guideline on the evaluation of control samples for toxicokinetic parameters in toxicology studies: checking for contamination with the test substance	To be re-released for consultation in 1Q 2005
CPMP/SWP/799/95	Guideline on the non-clinical documentation for mixed marketing authorisation applications	To be finalised in 2Q 2005
EMEA/CHMP/SWP/149188/2004	Guideline on the need for pre-clinical testing of human pharmaceuticals in juvenile animals	To be released for consultation in 1Q 2005
EMEA/CHMP/SWP/94227/2004	Guideline on investigation of dependence potential of medicinal products	To be released for consultation in 1Q 2005
--	Guideline on the non-clinical development of fixed combinations of medicinal products	To be released for consultation in 3Q 2005
EMEA/CHMP/SWP/5382/2003	Guideline on the nonclinical testing for inadvertent germline transmission of gene transfer vectors	To be released for consultation in 2Q 2005
EMEA/CHMP/SWP/178958/2004	Guideline on drug-induced hepatotoxicity	To be released for consultation in 3Q 2005
CPMP/SWP/QWP/4446/00	Guideline on specification limits for residues of metal catalysts in medicinal products	To be re-released for consultation in 2005
--	Guideline on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling	To be released for consultation in 3Q 2005
--	Guideline on the assessment of carcinogenic and mutagenic potential of anti-HIV medicinal products	To be released for consultation in 3Q 2005
--	Guideline on the investigation of mitochondrial toxicity of HIV-therapeutics in vitro	To be released for consultation in 3Q 2005
--	Reflection paper on genotoxicity testing of antisense oligodeoxynucleotides	To be released in 1Q 2005
CPMP/SWP/2599/02 Rev 1	Position paper on the non-clinical safety studies to support clinical trials, with a single low dose of a compound	Possible revision in 2005
CPMP/372/01	Points to consider on the non-clinical assessment of the carcinogenic potential of insulin analogues	Possible revision in 2005
CPMP/SWP/104/99	Note for guidance on repeated dose toxicity	Possible revision in 2005
CPMP/SWP/997/96	Note for guidance on pre-clinical evaluation of anticancer medicinal products	Possible revision in 2005
--	Pharmacokinetics and metabolic	Possible revision in 2005

Reference number	Document title	Status
	studies in the safety evaluation of new medicinal products in animals	
CHMP/ICH/423/02 Revised	ICH S7B: The nonclinical evaluation of the potential for delayed ventricular repolarization (QT interval prolongation) by human pharmaceuticals	SWP contribution
EMEA/CHMP/167235/2004	ICH S8: Immunotoxicology studies	SWP contribution

Scientific Advice Working Party

Reference number	Document title	Status
EMEA/H/4260/01 Rev 2	EMEA Guidance for companies requesting scientific advice (SA) and protocol assistance (PA)	Revision 3 expected in 1Q 2005
EMEA/H/238/02 Rev 1	EMEA Guidance for companies requesting protocol assistance regarding scientific issues	Revision 2 expected in 1Q 2005

Paediatrics Working Party

Reference number	Document title	Status
--	Discussion paper on the need for investigation of immune system	To be finalised in 2Q 2005
--	Discussion papers on other important organs to be considered when developing medicinal products in neonates complementary to the paper already published on renal maturation (e.g. hepatic, central nervous system)	To be finalised in 4Q 2005
--	The Paediatrics Working Party will be consulted at an early stage of the drafting of guidelines which are relevant to paediatric population developed by any CHMP working parties	

Invented Name Review Group

Reference number	Document title	Status
CPMP/328/98 Rev 4	Guidelines on the acceptability of invented names for medicinal products processed through the centralised procedure	Revision to be finalised in 2005

CVMP Efficacy Working Party

Reference number	Document title	Status
CVMP/EWP/049/04	Guideline on reduced efficacy requirements for minor species or minor indications	Adopted by EWP in October 04, under discussion at CVMP
EMEA/CVMP/461/04	Concept paper on dossier requirements for bibliographic applications	Joint concept paper adopted by EWP and SWP, under discussion by CVMP
--	VICH Target animal safety – pharmaceuticals	EU Comments in preparation of VICH Guideline
EMEA/CVMP/1008/04	Guideline - Prudent use of anthelminics in relation to resistance	Guideline to be developed after consultation of concept paper
--	Standard statements for the SPC of certain classes / types of veterinary medicinal products	Internal guideline to be developed
--	Revision of guideline for fixed combination products	Guideline to be prepared
--	Concept paper on dossier requirements for oncology products	Concept paper to be prepared
--	Target animal safety requirements for corticosteroids	Concept paper to be prepared
--	Target animal safety requirements for substances with disorder dependant dose effect	Concept paper to be prepared

CVMP Immunologicals Working Party

Reference number	Document title	Status
--	Guideline on EU requirements for batches with maximum and minimum titre or batch potency for developmental safety and efficacy studies	To be finalised following revision of Annex I of Directive 2001/82/EC
--	Reduced requirements for IVMPs intended for minor species or minor indications	To be finalised following revision of Annex I of Directive 2001/82/EC
--	Proposed approach for the consideration of substances other than active ingredients present in veterinary medicinal products	Position paper to be developed
--	Concept paper on requirements for combined veterinary vaccines	Concept paper to be prepared
--	User safety guideline	Guideline to be developed
--	Concurrent administration of IVMPs in view of determining day X to be 14 days and consequent revision of the SPC guideline for immunologicals	Concept paper to be prepared
--	The impact of maternally derived antibodies on vaccination	Concept paper to be prepared
--	Preparation of new master seeds	Concept paper to be prepared
--	Requirements for in-use stability claims	Concept paper to be prepared

Reference number	Document title	Status
--	Immunity induced by bacterial vaccines	Concept paper to be prepared

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMEA/CVMP/413/99-Rev 1	VEDDRA List of clinical terms for reporting adverse reactions in animals to veterinary medicines	To be revised as per PhVWP-V work programme for 2005 (VEDDRA sub-group to meet May 05, adoption by PhVWP July 05 & CVMP Sept. 05)
EMEA/CVMP/183/96	Pharmacovigilance of veterinary medicinal products	Consultation ended 17 Sept. 04, under revision by PhVWP- V for adoption in 1Q 2005
EMEA/CVMP/900/03	Triggering pharmacovigilance investigations	Consultation ended 16 Dec. 04, under revision by PhVWP- V for adoption in 1Q 2005
EMEA/CVMP/891/04	VEDDRA List of clinical terms for reporting suspected adverse reactions in human beings to veterinary medicinal products	Consultation ends 18 Apr. 2005 subsequent revision by PhVWP-V
EMEA/CVMP/893/04	EU Veterinary suspected adverse reaction report form for veterinarians and health professionals	Consultation ends 18 Apr. 2005 subsequent revision by PhVWP-V
--	Review of volume 9	Under discussion in view of revised pharmaceutical legislation
--	Simple guide to veterinary pharmacovigilance	Under development by the PhVWP-V
--	Guideline on the use of data contained in EudraVigilance and EudraVigilance Veterinary (EVvet)	Concept paper to be developed in 2005
--	Development of concepts and criteria for analysis of data contained in EudraVigilance Veterinary (tailoring of the EVvet Data warehouse requirements)	Concept paper to be developed in 2005

CVMP Safety Working Party

Reference number	Document title	Status
EMEA/CVMP/543/03	User safety guideline	Consultation ended 18 Oct 04, under revision by SWP-V for adoption in 1Q 2005
--	Minor use – minor species: finalisation of revised guidelines with regard to the minimum data requirements for 'minor use – minor species' products	Under development by SWP-V
--	Concept paper on guidance on the approach on how to prove whether a substance is capable of pharmacological action or not	To be prepared during 2005
--	Concept paper on alternative reference limits/exposure assessment	To be prepared during 2005
--	Concept paper on guideline on the assessment of pharmacological/pharmacodynamic data to establish a pharmacological ADI	To be prepared during 2005
--	Concept paper on impact of analytical methods on Commission Decision 2002/657/EC compared with current analytical requirements for the establishment of MRLs	To be prepared during 2005
--	Development of document on basis for extrapolation of MRLs: gathering of information allowing to establish a scientific basis from 'absorption, distribution, metabolism and excretion' similarities/differences	To be prepared during 2005

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
--	Further guidance on interpretation of the data from guideline CVMP-VICH GL27, guidance on pre-approval information for registration of new veterinary medicinal products for food-producing animals with respect to antimicrobial resistance (CVMP/VICH/644/01)	Concept paper to be adopted for consultation during 2005
--	Guidance on dossier requirements regarding antimicrobial resistance for companion animals	Concept paper to be prepared during 2005
--	Need for revision of the current SPC guideline to give precise recommendation on prudent use and restrictions based on resistance data evolving from the SPC guideline	Considerations of the Scientific group to be prepared during 2005

Joint CHMP/CVMP Quality Working Party

Reference number	Document title	Status
CPMP/QWP/155/96	CPMP Guideline on pharmaceutical development	Possible revision once the ICH initiatives on Q8 and Q9 have been stabilised, at step 2
CPMP/QWP/3015/99	CPMP Guideline on parametric release	Possible revision once the ICH initiatives on Q8 and Q9 have been stabilised, at step 2 (in collaboration with GMP inspectors)
--	CHMP Guideline for the requirements to the quality part of a request for authorisation of a clinical trial	To be finalised following end of consultation
--	CHMP Guideline for formulations of choice for paediatric population	Development of a new document with PEG (Paediatrics Working Party)
EMEA/CVMP/1041/04	CVMP Guideline on quality data requirements for veterinary medicinal products for minor uses or minor species (MUMS)	Adopted by QWP in October 04, under discussion at CVMP
--	CHMP Guideline on dry powder inhalers and pressurised metered dose inhalers to include nasal products, products for nebulisation and hand-held nebuliser products	To be revised and updated (jointly with Health Canada)
CPMP/QWP/4359/03 EMEA/CVMP/205/04	CPMP/CVMP Note for guidance on plastic primary packing materials	To be finalised following end of consultation, the revision and update of 3AQ10a
--	CHMP Guideline on dosing delivery of injectable liquids	To be finalised in 2005
--	CHMP Concept paper and guideline on quality requirements for manufacturing in and distribution from climatic zones 3 and 4	To be finalised following end of consultation
CPMP/QWP/576/96 EMEA/CVMP/373/04	CVMP and CHMP Guideline on stability testing for applications for variations to a marketing authorisation	To be finalised following end of consultation
--	CHMP/CVMP Procedure on handling and assessment of active substance master files (ASMF, syn. European drug master file, EDMF)	Clarification of applicability to well-defined active substances
CPMP/QWP/419/03	Guideline on excipients, antioxidants and antimicrobial preservatives	To be finalised following end of public consultation
CPMP/SWP/QWP/4446/00	Guideline on specification limits for residues of heavy metal catalysts	To be finalised (with SWP) following end of public consultation
CPMP/SWP/5199/02	Guideline on the limits of genotoxic impurities	To be finalised (with SWP) following end of public consultation
--	Guideline on radiopharmaceuticals	The existing 1991 guideline to be revised to include a section on Positron Emission Tomography (PET)
ICH Q8	ICH Guideline on pharmaceutical development	EU Comments in preparation of ICH Guideline
ICH Q9	ICH risk management	EU Comments in preparation of ICH Guideline
ICH Q10	ICH quality system approach initiative	EU Comments in preparation of ICH Guideline

Reference number	Document title	Status
CPMP/ICH/367/96	CPMP/CVMP guideline on specifications	Possible revision once the ICH initiatives on Q8 and Q9 have been stabilised, at step 2
VICH GL3 (R)	VICH Guideline on stability testing of new veterinary drug substances and medicinal products	EU Comments in preparation of revised VICH Guideline
VICH GL10 (R) & GL 11 (R)	VICH Guidelines on impurities in new veterinary drug substances and impurities in new veterinary medicinal products	EU Comments in preparation of revised VICH Guidelines
EMEA/VICH/810/04 (VICH GL39)	VICH Guideline on specifications: test procedure and acceptance criteria for new drug substances and new drug products: Chemical substances	EU Comments in preparation of VICH Guideline after consultation
EMEA/VICH/811/04 (VICH GL40)	VICH Guideline on specifications: test procedure and acceptance criteria for biological/biotechnological products	EU Comments in preparation of VICH Guideline after consultation

Committee on Orphan Medicinal Products (COMP)

Reference number	Document title	Status
ENTR/6283/00 Rev 3	Guideline on the format and content of applications for designation as orphan medicinal products and on the transfer on designations from one sponsor to another	To be released for consultation in 4Q 2005
EMEA/COMP/66972/2004	Guideline on elements required to support the medical plausibility and the assumption of significant benefit for an orphan designation	Released for consultation September 2004. Deadline for comments March 2005

Committee on Herbal Medicinal Products (HMPC)

Reference number	Document title	
CPMP/QWP/2819/00 (EMEA/CVMP/814/00)	Revised guideline on quality of herbal medicinal products	To be finalised in 2Q 2005
CPMP/QWP/2820/00 (EMEA/CVMP/815/00)	Revised guideline on specifications: test procedures and acceptance criteria for herbal drugs, herbal drug preparations and herbal medicinal products	To be finalised in 2Q 2005
--	Guideline on the format and content of applications for registration of the traditional use of herbal medicinal products	To be released for consultation in 3Q 2005
--	Review of guidance documents prepared by the Herbal Medicinal Products Working Party (1997-2004)	To be finalised in 3Q 2005
--	Guideline on the evidence of safety and efficacy required for traditional and well-established herbal medicinal products	To be released for consultation in 4Q 2005
--	SOP and template for Community herbal monographs	To be finalised in 4Q 2005
--	SOP and template for List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products	To be finalised in 4Q 2005
--	Reflection paper on the pharmacovigilance of herbal medicinal products	To be released for consultation in 4Q 2005

Annex 4
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 and outside the EU concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use	Panos TSINTIS **Direct telephone: (44-20) 75 23 71 08** **E-mail: panos.tsintis@emea.eu.int**
For matters relating to pharmacovigilance for medicinal products for veterinary use	Barbara FREISCHEM **Direct telephone: (44-20) 74 18 85 81** **E-mail: barbara.freischem@emea.eu.int**
For product defect 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	Ragini SHIVJI **Direct telephone: (44-20) 75 23 71 47** **Fax: (44-20) 74 18 85 45** **E-mail: ragini.shivji@emea.eu.int**

Documentation services

A wide range of documents are 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 email request to **info@emea.eu.int**
- by fax to **(44-20) 7418 8670**
- by writing to:

  EMEA Documentation service
  European Medicines Agency
  7 Westferry Circus
  Canary Wharf
  London E14 4HB
  UK

European experts list

Approximately 3,500 European experts are used by the EMEA in its scientific evaluation work. The list of these experts is available for examination on request at the EMEA offices.

Requests should be sent in writing to the EMEA
or to E-mail: **europeanexperts@emea.eu.int**

Integrated quality management

IQM adviser

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

Press office

Press officer

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

Annex 5
Profiles of EMEA personalities

Hannes Wahlroos, Chairman of the Management Board, b. 7 July 1952, n. Finnish

Education: Professor Wahlroos is a qualified pharmacist (pharmacology) from the University of Helsinki and holds a PhD (SocPharm) from the University of Kuopio. Postgraduate studies in management, leadership and administration.
Career to date: From 1973 to 1979, Professor Wahlroos served as a pharmacist and a researcher in several pharmacies, at the University of Helsinki and in the pharmaceutical industry. In 1979 he joined the National Board of Health, where he acted as senior pharmaceutical inspector and head of the pharmaceuticals department. Professor Wahlroos was appointed director-general of the National Agency for Medicines (NAM) in 1993. As the first director-general of the NAM he was responsible for establishing the Agency's strategies and working operations. From 1993 to 1994 he acted as the vice-chairman of the EFTA Expert Group on Pharmaceuticals and from 1994 to 1995 as the chairman of the Nordic Council on Medicines. Professor Wahlroos had a central role in the pharmaceutical sector in the preparations for the accession of Finland to the EU in 1995. He has been a member of the EMEA management board since 1995. He was elected chairman of the board in May 2004.

Jytte Lyngvig, Vice-Chairman of the Management Board, b.13 October 1953, n. Danish

Education: Graduate in chemical engineering from the Technical University of Denmark. Postgraduate studies include a PhD in socio-economic planning.
Career to date: From 1976 to 1980, Dr Lyngvig was research assistant and lecturer at the Technical University of Denmark. She worked at the Danish Environment Ministry from 1979 to 1985, first as a consultant and later as an official, before moving to the City of Copenhagen Environment Protection Agency until 1988. Dr Lyngvig has 12 years' private-sector experience in the transport and consultancy industries and was appointed chief executive officer of the Danish Medicines Agency in 2000. She joined the EMEA Management Board in the same year, was elected vice-chairman in 2003 and re-elected vice-chairman following the EU enlargement in 2004.

Thomas Lönngren, Executive Director, b. 16 December 1950, n. Swedish

Education: Qualified pharmacist from the University of Uppsala Faculty of Pharmacy. MSc in social and regulatory pharmacy. Postgraduate studies in management and health economics. Honorary member of the Pharmaceutical Society of Great Britain since 2003 and honorary fellow of the Royal College of Physicians since 2004.
Career to date: From 1976 to 1978, lecturer at the University of Uppsala. Mr Lönngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990, during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1982 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as director of operations and later as deputy director-general. He has been executive director of the EMEA since January 2001.

EMEA scientific committees

Daniel Brasseur, Chairman of the CHMP, b. 7 June 1951, n. Belgian

Education: Qualified medical doctor from the Free University of Brussels. Postgraduate degree in paediatrics and a PhD in nutrition.
Career to date: From 1976 to 1986, Dr Brasseur worked as a paediatrician at the University Sint Pieter Hospital in Brussels. He moved briefly to the pharmaceutical industry from 1986 to 1987, before returning to clinical work at the Queen Fabiola Children's University Hospital in Brussels as head of the nutrition and pharmacodynamics unit, a post he continues to hold today. He joined the Pharmaceutical Inspectorate of the Belgian Ministry of Public Health as head of medical assessors in 1997. He was appointed a member of the CHMP in 1997. Dr Brasseur has held a number of teaching posts and is currently professor of nutrition and nutrition-related diseases at the Free University of Brussels. He was re-elected chairman of the CHMP in 2004.

Eric Abadie, Vice-Chairman of the CHMP, b. 14 July 1950, n. French

Education: Qualified medical doctor from the University of Paris. Postgraduate qualifications in internal medicine, endocrinology, diabetology and cardiology. He also holds an MBA.
Career to date: From 1981 to 1983, Dr Abadie held a number of clinical and laboratory positions, before joining the pharmaceutical industry in 1983. He was director of medical affairs of the French pharmaceutical trade association from 1985 to 1993 and returned to industry until 1994. He joined the French medicines agency in 1994 as director of pharmacotherapeutic evaluation, a post he holds today. Dr Abadie has been a consultant in cardiology and diabetology since 1984. He was re-elected as vice-chairman of the CHMP in 2004.

Gérard Moulin, Chairman of the CVMP, b. 18 October 1958, n. French

Education: PhD in microbiology from the University of Lyon.
Career to date: From 1981 to 1984, Dr Moulin worked in the Bovine Pathology Laboratory in Lyon. In 1984, he joined the Veterinary Medicines Laboratory in Fougères where he was assessor and rapporteur for marketing authorisation dossiers. He was also responsible for a laboratory unit. In 1997, he was appointed head of the pharmaceuticals assessment unit of the French veterinary agency (AFSSA-ANMV). In 2002, he was appointed director-delegate of international affairs. He has been a CVMP member since 1997; he was elected vice-chairman of the CVMP in 2001. He was first elected chairman of the CVMP in January 2003 and was re-elected in 2004.

Johannes Hoogland, Vice-Chairman of the CVMP, b. 22 February 1956, n. Dutch

Education: Degree in analytical chemistry from the University of Amsterdam, 1984, followed by a PhD in biochemistry from the University of Amsterdam, 1988.
Career to date: Worked for the food industry (1976-1977), biological laboratory of the Free University of Amsterdam (1977-1978). Employed by the Ministry of Agriculture, Nature Management and Fisheries in 1988; from 1988 to 1998 by the State Institute for Quality Control of Agricultural Products (RIKILT-DLO) as an assessor for veterinary medicinal products and feed additives, research on development of analytical methods and development of quality systems for agricultural production; from 1998 to the present by the Bureau Registratie Diergeneesmiddelen (BRD). CVMP member since 1998 and chairman of the CVMP ad hoc group for environmental risk assessment. He was re-elected vice-chairman of the CVMP in 2004.

Josep Torrent i Farnell, Chairman of the COMP, b. 2 May 1954, n. Spanish

Education: Qualified pharmacist and degree in medicine and surgery from the University of Barcelona, as well as postgraduate courses in pharmacology and toxicology, public health and European institutions. Specialist in internal medicine and clinical pharmacology. Doctorate in clinical pharmacology from the Autonomous University of Barcelona (UAB).
Career to date: From 1977 to 1990, Professor Torrent i Farnell worked in internal medicine and clinical pharmacology in Spain and was assistant professor of pharmacology at the UAB. From 1990 to 1994, he was technical counsellor in clinical evaluation and pharmacology at the Spanish Ministry of Health, a member of the CPMP Efficacy Working Party and involved in the Efficacy Group of the ICH. In 1992, he became professor of clinical pharmacology and therapeutics and director of the masters/diploma course on European registration of medicinal products (UAB). He joined the EMEA in 1995 as principal scientific administrator and from 1996 to 1998 he was head of sector for new chemical substances. In 1998 he was coordinator-director for the creation of the Spanish Medicines Agency and executive director of the Spanish Medicines Agency from 1999 to 2000. He was re-elected chairman of the Committee on Orphan Medicinal Products in May 2003. In November 2000, he became director-general of the Advanced Centre of Services and Training for Health and Life Sciences, Dr Rober Foundation (UAB).

Yann Le Cam, Vice-Chairman of the COMP, b. 15 July 1961, n. French

Education: Master's degree in business administration from the Institut Superieur de Gestion in Paris. Executive master of business administration from the Centre de Perfectionnement aux Affaires at HEC-CPA, in Jouy-en-Josas, France, in 2000.
Career to date: Mr Le Cam has 19 years of professional experience, and personal commitment, in non-governmental health and medical research organisations in France, Europe and the United States in the fields of cancer, HIV/AIDS and genetic diseases. He has three daughters, the eldest of whom is affected by cystic fibrosis. From 1992 to 1998 he served as director-general of AIDES Fédération Nationale. He later joined the French Neuromuscular Diseases Association (AFM) as special adviser to its president, to stimulate public health policy on rare diseases and to create the French Alliance Maladies Rares, an umbrella of 134 patients' organisations. He co-founded the International Alliance of Patient Organisations (IAPO) based in London, and served as vice-chairman from 1997 to 2000. He served on the management board of the French National Agency for Health Evaluation and Hospital Accreditation (ANAES) from 2000 to 2004, and on its executive committee from 2002 to 2004. He is a co-founder of the European Organisation for Rare Diseases (EURORDIS) of which he has been the chief executive officer since 2001. He was re-elected vice-chairman of the COMP in June 2003.

Konstantin Keller, Chairman of the HMPC, b. 19 February 1954, n. German

Education: Pharmacist, doctorate in natural sciences (pharmacognosy) from the University of Saarbrücken.
Career to date: From 1978 to 1982, Dr Keller worked as a research and teaching assistant at the Institute for Pharmacognosy and Analytical Phytochemistry of the University of Saarbrücken. After serving as a pharmacist (Captain) in a pharmaceutical control laboratory of the German Army, he joined the former German Federal Health Office in 1983. His main activities since then have been related to the review of old substances and the assessment of complementary/alternative medicines. He currently holds the positions of director and professor at the Federal Institute for Drugs and Medical Devices. He is the head of the 'Particular therapies' division, which is in charge of the pharmaceutical und clinical assessment of herbal, homeopathic and anthroposophic products.
Dr Keller is a member of the American Society of Pharmacognosy and of the International Society for Medicinal Plant Research.

Heribert Pittner, Vice-Chairman of the HMPC, b. 19 January 1948, n. Austrian

Education: Qualified medical doctor from the University of Graz. Postgraduate degree in pharmacology; associate professor in pharmacology and toxicology at the University of Vienna.
Career to date: Dr Pittner worked in the pharmaceutical industry from 1972 to 1985 where he discovered the pharmacological properties of the beta 1 - adrenoceptor antagonist celiprolol. In 1986 he joined the Austrian drug regulatory authority; since 2003 he has been deputy head of the drug authorisation department of the Austrian Ministry of Health and Women. Dr Pittner joined the Herbal Medicinal Products Working Party (HMPWP) in 1999 and was vice-chairman of the HMPWP from 2002 until 2004. Dr Pittner was also a CPMP delegate from 1995 to 1997 and from 2001 until April 2004; since May 2004 Dr Pittner has been a CHMP delegate.

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

Patrick Le Courtois, Head of Unit, b. 9 August 1950, n. French

Education: Qualified medical doctor from the University of Paris. PhD in public health from the University of Bordeaux. Postgraduate degrees in tropical medicine, clinical research and epidemiology.
Career to date: From 1977 to 1986, Dr Le Courtois worked as a general practitioner and as director of a medical centre in Paris. In 1986 he joined the University of Bordeaux and was involved in various research areas in public health, including epidemiology, clinical research, pharmacovigilance, tropical and infectious diseases, health economy and health education. In 1990 he joined the pharmacy directorate of the French Ministry of Health and in 1993 joined the French Medicines Agency as CPMP rapporteur, was head of unit for European procedures and from January 1995 was a French CPMP delegate. He joined the EMEA in September 1997 where he was appointed head of sector for new chemical substances in June 1998 and head of sector for orphan drugs and scientific advice in January 2001. Further to the restructuring of the Human Medicines Evaluation Unit in 2001, he was appointed head of unit for the pre-authorisation evaluation of medicines for human use, in March 2001.

Agnès Saint Raymond, Head of Sector for orphan drugs and scientific advice and Acting Head of Sector for safety & efficacy of medicines, b. 7 September 1956, n. French

Education: Qualified medical doctor from the University of Paris. Postgraduate qualifications in paediatrics and methodology.
Career to date: Dr Saint Raymond held a position as paediatrician in a teaching paediatric hospital in Paris, followed by a number of years working for a number of pharmaceutical companies. In 1995 she joined the French Medicines Agency as head of unit for pharmaco-toxico-clinical assessment. She joined the EMEA in January 2000 and was appointed head of sector for scientific advice and orphan drugs in December 2001. She is also in charge of issues relating to medicines used in children and has been acting head of sector for safety & efficacy since October 2004.

Spiros Vamvakas, Acting Deputy Head of Sector for orphan drugs and scientific advice, b. 4 September 1960, n. German/Greek

Education: Qualified medical doctor from the University of Würzburg, Germany. Board-certified specialist in pharmacology and toxicology (Bavarian Chamber of Physicians). Associate professor for pharmacology and toxicology in the University of Würzburg.
Career to date: From 1984 Professor Vamvakas held positions in the department of pharmacology and toxicology at the University of Würzburg and in the department of pharmacology at the Medical Centre of the University of Rochester NY, USA. He joined the EMEA in May 1999 and one of his major activities in recent years was the establishment of orphan drug designation and protocol assistance in the EMEA. He has a continuing teaching appointment for pharmacology and toxicology at the University of Würzburg. He was appointed acting deputy head of sector for scientific advice and orphan drugs in October 2004.

John Purves, Head of Sector for quality of medicines, b. 22 April 1945, n. British

Education: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. PhD in pharmaceutical microbiology from the University of Strathclyde, Glasgow.
Career to date: From 1972 to 1974, Dr Purves worked in the pharmaceutical industry. Between 1974 and 1996 he held posts in the UK Medicines Division and the Medicines Control Agency, including those of inspector of pharmaceutical manufacture, reviewer of dossiers, and manager of the biotechnology and biological unit. He was the UK representative of the Biotechnology Working Party, involved in the generation of many guidelines relating to biotechnology and biological products. He joined the EMEA in August 1996 as head of sector for biotechnology and biologicals. He was appointed head of sector for quality of medicines in January 2001.

Marisa Papaluca Amati, Deputy Head of Sector for safety and efficacy of medicines, b. 12 October 1954, n. Italian

Education: Qualified as a medical doctor in Rome in July 1978. Specialist in internal medicine. Postgraduate studies in cardiology and endocrinology.
Career to date: From 1978 to 1983, research fellow at the State University of Rome on projects in the area of clinical immunology, oncology and cellular immunology. From 1984 to 1994, as medical director at the pharmaceutical department of the Italian Ministry of Health, she was in charge of the Operative Centre for Community Procedures, was the Italian member of the former Committee for Proprietary Medicinal Products (CPMP), and was also involved in ICH activities. She joined the EMEA in October 1994. She acted as scientific secretary of the Biotechnology Working Party until December 2000. She was appointed deputy head of sector for safety and efficacy of medicines in January 2001, and since then has been in charge of EMEA activities in the field of innovation, emerging therapies & technologies, and the coordination of scientific training.

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

Noël Wathion, Head of Unit, b. 11 September 1956, n. Belgian

Education: Qualified pharmacist from the Free University of Brussels.
Career to date: Mr Wathion first worked as a pharmacist in a retail pharmacy. He was later appointed to the Pharmaceutical Inspectorate (Ministry of Social Affairs and Public Health) in Brussels as a chief inspector, acting as the secretary of the Belgian Medicines Commission. He is a former Belgian member of both the CPMP and CVMP and representative on the Pharmaceutical Committee, Standing Committee and Notice to Applicants working group. He joined the EMEA in August 1996 as head of sector for regulatory affairs and pharmacovigilance and was appointed head of the Human Medicines Evaluation Unit in September 2000. Further to the restructuring of the Human Medicines Evaluation Unit in 2001, he was appointed head of unit for the post-authorisation evaluation of medicines for human use.

Tony Humphreys, Head of Sector for regulatory affairs and organisational support, b. 12 December 1961, n. Irish

Education: Qualified as a pharmacist, BSc (Pharm) and was granted a master's degree in pharmaceutics in the research area of microencapsulation from Trinity College Dublin.
Career to date: Since qualifying in 1983, Mr Humphreys has worked in the area of development pharmaceutics for a national branded generics manufacturer and an international research and development company. In 1991 he joined the International Regulatory Affairs Division of Glaxo Group Research Limited where he was responsible for the development and submission of a series of international registration applications in a number of therapeutic areas. He joined the EMEA in May 1996 and was appointed head of sector for regulatory affairs and operational support in January 2001.

Panos Tsintis, Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines, b. 18 September 1956, n. British

Education: Qualified in medicine from Sheffield University in 1983. Postgraduate qualifications in internal medicine (FRCP) and pharmaceutical medicine (FFPM).
Career to date: Six years of clinical experience in UK hospitals, five years as director of pharmacovigilance and regulatory affairs at Astra Pharmaceuticals in the UK and a total of seven years at the UK Medicines Control Agency. Prior to his appointment as unit manager in pharmacovigilance, he held a number of positions in both pre- and post-authorisation areas, and was also the UK delegate to the CPMP Pharmacovigilance Working Party. Dr Tsintis joined the EMEA as head of sector, pharmacovigilance and post-authorisation safety and efficacy of medicines in March 2002.

Sabine Brosch, Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines, b. 17 August 1963, n. Austrian

Education: Master's degree in pharmacy and doctor of natural sciences degree in pharmacology from the University of Vienna. Postgraduate studies in pharmacology at the Universities of Melbourne and Auckland.
Career to date: From 1988 to 1992, Dr Brosch worked as an assistant professor at the department of pharmacology and toxicology at the University of Vienna, where she specialised in electrophysiology. In 1992 she moved to the pharmacovigilance department at the Austrian Ministry of Health and

completed a six-month regulatory traineeship in the pharmaceuticals unit of the European Commission in 1995. She joined the EMEA in November 1996 and was appointed deputy head of sector for pharmacovigilance, post-authorisation safety and efficacy of medicines in January 2001.

Isabelle Moulon, Head of Sector for medical information, b. 9 March 1958, n. French

Education: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology and metabolic diseases. Postgraduate studies in nutrition, statistics and methodology. **Career to date**: Worked as a clinical endocrinologist in a French hospital until 1987 and then joined the directorate of pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the EMEA in July 1995. She was responsible for scientific advice until December 2000. She was appointed head of sector for safety and efficacy of medicines in January 2001. Since October 2004 she has been in charge of establishing the new sector for medical information.

Unit for Veterinary medicines and inspections

Peter Jones, Head of Unit, b. 9 August 1947, n. British

Education: Graduated in veterinary medicine from the faculty of veterinary science at Liverpool University and is a member of the Royal College of Veterinary Surgeons of the United Kingdom.
Career to date: After several years in general veterinary practice in the United Kingdom and Canada, Dr Jones joined the pharmaceutical industry in the animal health sector. He has held a number of appointments in research and regulatory affairs in multinational companies both in the UK and overseas. He joined the EMEA in June 1995, and was appointed head of the veterinary unit in December of the same year, and took on responsibility for the inspections sector in January 2002.

Jill Ashley-Smith, Head of Sector for veterinary marketing authorisation procedures, b. 18 December 1962, n. British

Education: Graduated in pharmacology from King's College London. Qualified as a veterinary surgeon from the Royal Veterinary College, University of London. Member of the UK Royal College of Veterinary Surgeons.
Career to date: From 1987 to 1994, Dr Ashley-Smith was employed in the veterinary pharmaceutical industry, first as a technical adviser and subsequently as a registration manager. In 1994, she joined the UK Veterinary Medicines Directorate as senior veterinary assessor in the pharmaceuticals and feed additives team. She participated as UK CVMP member from 1996 until joining the EMEA in July 1997.

Melanie Leivers, Deputy Head of Sector for veterinary marketing authorisation procedures, b. 1 December 1958, n. British

Education: Graduate in biochemistry and pharmacology from Leeds University. Postgraduate diploma in European Community law from King's College London.
Career to date: Miss Leivers worked for the Milk Marketing Board for England and Wales (MMB) as a liaison chemist for five years, prior to being appointed assistant director of the MMB/Federation of Agricultural Cooperatives office in Brussels, representing all sectors of agricultural cooperation to the European institutions. Following this she worked on a short-term contract at the European Commission (DG XI) and then in industry at Pfizer (formerly SmithKline Beecham Animal Health) as a regulatory affairs manager. Miss Leivers joined the EMEA in February 1996 and was appointed deputy head of sector in June 2001.

Kornelia Grein, Head of Sector for safety of veterinary medicines, b. 24 July 1952, n. German

Education: Qualified chemist and pharmacist from the Free University of Berlin. PhD in organic chemistry from the Free University of Berlin.
Career to date: From 1976 to 1981, Dr Grein held a position at the Free University of Berlin in Germany teaching and conducting research. This was followed by positions as a pharmacist. In 1987, she joined the German Environmental Agency as scientific administrator involved in risk assessment of industrial chemicals. Seconded to the European Commission in 1992, she was involved in the implementation of the EU legislation on existing chemicals and coordinated the development of the EU approach on risk assessment for chemicals. She was also involved in international harmonisation

activities on this subject. In 1995 she returned to Germany to the Ministry for Environment as scientific administrator. She joined the EMEA in April 1996.

Emer Cooke, Head of Sector for inspections, b. 9 April 1961, n. Irish

Education: Qualified pharmacist with a master's degree in pharmaceutical chemistry and a master's degree in business administration (MBA) from Trinity College Dublin. Member of the Pharmaceutical Society of Ireland.
Career to date: Ms Cooke worked in a number of positions within the Irish pharmaceutical industry before joining the Irish Medicines Board as a pharmaceutical assessor in 1988. Following graduation with an MBA degree in 1991, she joined EFPIA, the European pharmaceutical industry association, as manager of scientific and regulatory affairs. Her responsibilities there included coordination of regulatory aspects of European procedures and International Conference on Harmonisation (ICH) activities. After a three-year stay in Prague, Czech Republic, where she worked as a consultant on European pharmaceutical matters as well as continuing her work with EFPIA, she joined the pharmaceuticals unit of the European Commission in September 1998. Her responsibilities there included coordination of ICH activities, relations with the FDA, pharmaceutical aspects of mutual recognition agreements, GMP and inspection-related matters, orphan medicinal products, preparatory work on a regulation on paediatric medicinal products and issues relating to EU enlargement. She joined the EMEA as head of sector for inspections in July 2002.

Communications and networking Unit

Hans-Georg Wagner, Head of Unit, b. 29 November 1948, n. German

Education: Doctorate in natural sciences (applied physics and materials science) from Saarbrücken University; diploma in physics from Tübingen University; master of arts (mathematics) from the University of Cambridge, UK.
Career to date: Dr Wagner was a research and teaching assistant at Saarbrücken University from 1976 to 1981. He later taught as a lecturer and senior lecturer at the same university until he joined the European Commission in Luxembourg in January 1986. There he was responsible for a number of groups in the technical support division of the Euratom Safeguards Directorate. Dr Wagner was appointed head of sector for IT in the same service in 1993. He joined the EMEA on 1 May 2002.

Beatrice Fayl, Head of Sector for document management and publishing, b. 9 October 1959, n. Danish

Education: Bachelor of Arts in languages and linguistics at the University of East Anglia and postgraduate degree in librarianship and information science at the University of Wales.
Career to date: Ms Fayl held various positions as a documentalist in several European countries, the latest from 1988 to 1995, setting up and running the documentation service at the European Commission Delegation in Norway. Ms Fayl joined the EMEA in April 1995.

Sylvie Bénéfice, Head of Sector for meeting management and conferences, b. 28 December 1954, n. French

Education: Doctorate of science in physical sciences; qualification in research management; PhD in physical organic chemistry; master's degree in physical organic chemistry; degree in biochemistry.
Career to date: From 1982 to 1986, Dr Bénéfice was a researcher at the University of Montpellier, France. In 1986 she joined the French National Scientific Research Centre (CNRS) as *Chargé de recherche 1ère classe* and became officer for European affairs in 1991. From 1993 to 1997, she was seconded to the European Commission (DG XII) as scientific secretary for COST actions in the field of chemistry, with responsibility for coordination of research networks and organisation of scientific conferences and workshops in Europe. She joined the EMEA in September 1997.

Tim Buxton, Head of Sector for project management, b. 27 February 1959, n. British

Education*:* Bachelor of law from the University of Birmingham, qualified as a member of the Institute of Chartered Accountants in England and Wales.
Career to date*:* Tim Buxton completed articles with Touche Ross & Co. in London in 1987. After a year in merchant banking, he was finance director of a private company from 1988 to 1995. He undertook long-term assignments as a management consultant until January 1997, when he joined the EMEA. He was appointed head of sector on 1 May 2002.

David Drakeford, Head of Sector for information technology, b. 4 December 1957, n. Irish

Education: Honours degree in experimental physics and MSc in electronic engineering from Trinity College Dublin.
Career to date: David Drakeford worked with Telecom Eireann where he managed the implementation of a national data communication network. In 1987, he joined Coopers & Lybrand where he was a senior management consultant specialising in the management and financial control of large, primarily IT-related, projects. He was also involved in numerous multinational project management and business analysis assignments, including managing the implementation of a worldwide information management system for clinical trials on behalf of a Swiss-based pharmaceutical company. He joined the EMEA in February 1997.

Riccardo Ettore, Deputy Head of Sector for information technology, b. 8 April 1953, n. Italian

Education: Diploma in conference interpretation and translation from Scuola Superiore per Interpreti, Milan.
Career to date: Mr Ettore joined the European Commission as conference interpreter in 1976. During the 1980s, he developed a computer system to support the complex task of editing and managing the assignment of European Commission interpreters to meetings. By 1987, he had gradually moved from full-time interpreting to full-time software development. His published works include scores of articles in computer journals during the 1980s and several popular software packages. He joined the EMEA in May 1995 and was appointed deputy head of sector in July 2003.

Administration Unit

Andreas Pott, Head of Unit, b. 14 April 1949, n. German

Education: Master's degree in political science, history and English from the University of Hamburg. Certificat de Hautes Etudes Européennes (economics) from the College of Europe, Bruges.
Career to date: From 1972 to 1989, Mr Pott held a number of teaching and research posts, including a research fellowship at the Institute of Peace Research and Security Policy, University of Hamburg. He joined the secretariat of the European Parliament in 1989, serving on the secretariats of the Committee on Research, Technological Development and Energy, of the Committee on Budgets and, latterly, of the Parliament's Bureau and Conference of Presidents. He moved to the Translation Centre for Bodies of the European Union in 1999 as head of the department for interinstitutional cooperation. He joined the EMEA in May 2000.

Frances Nuttall, Head of Sector for personnel and budget, b. 11 November 1958, n. Irish

Education: Master of science in economics and bachelor of science in public administration from Trinity College Dublin.
Career to date: Ms Nuttall held several posts in the Irish Civil Service, serving in the Departments of Health, Finance and the Office of Public Works. Ms Nuttall then served with the Food and Agriculture Organisation of the United Nations from 1990 to 1995. She joined the EMEA in May 1995.

Sara Mendosa, Head of Sector for infrastructure services, b. 23 January 1950, n. British

Education: Business studies and languages at Loughborough Polytechnic
Career to date: From 1975 to 1990, Mrs Mendosa held a number of posts at the European Commission in Luxembourg, including the Conference Service, the Office for Official Publications and the Statistical Office. In 1991 Mrs Mendosa was transferred to the London office of the European Commission Representation in the UK. She joined the EMEA in November 1994 and was nominated head of sector in November 2002.

Gerard O'Malley, Head of Sector for accounting, b. 14 October 1950, n. Irish

Education: Bachelor of commerce from University College Dublin. Fellow of the Institute of Chartered Accountants in Ireland. Censor Jurado de Cuentas and Member of the Registro Oficial de Auditores de Cuentas in Spain.
Career to date: From 1971 to 1974, Mr O'Malley completed articles in Dublin. From 1974 to 1985, he was an audit manager in Spain with Ernst and Young and from 1985 to 1995 he was financial controller at Johnson Wax Española. He joined the EMEA in April 1995.

Services attached to the Executive Director

Martin Harvey Allchurch, Head of Executive Support, b. 20 October 1966, n. British

Education: Law degree from the University of Dundee, UK. Master's degree in European and international law from the Free University of Brussels, Belgium.
Career to date: After a traineeship with the European Commission, from 1991 to 1992, Martin Harvey Allchurch worked as a European affairs consultant in Brussels, from 1992 to 1995. During this time he also worked as contributing editor for a European affairs publication and as Brussels correspondent for an American pharmaceutical journal. He joined the EMEA in September 1995. He was nominated press officer in September 2001 and appointed head of executive support in January 2004.

Vincenzo Salvatore, Head of Legal Sector, b. 8 August 1963, n. Italian

Education: Law degree from the University of Pavia, Italy; PhD in European Law from the European University Institute of Florence, Italy; *Avvocato*, chair professor of international law.
Career to date: Mr Salvatore acted as a private practice lawyer from 1991 to 2004, dealing with arbitration and litigation cases mainly in the fields of public procurement, competition, international trade and contracts. He worked also as research assistant in international law at the University of Pavia from 1992 to 1999, as associate professor of international law at the University of Insubria (Varese) from 1999 to 2003, and as chair professor of international law at the same University since 2004. He joined the EMEA as head of the legal sector in November 2004.

Marijke Korteweg, Integrated quality management adviser, b. 29 May 1947, n. Belgian

Education: PhD (Chemistry) and PhD (Biochemistry), University of Ghent, Belgium. Fellow of the Institute of Quality Assurance, UK.
Career to date: After 10 years of fundamental prostaglandin research she joined the pharmaceutical industry in 1981 as a clinical research associate. In 1984 Dr Korteweg created the regulatory compliance/quality assurance audit department for the European pharmaceutical R&D division of Bristol-Myers Squibb, later becoming director of worldwide regulatory compliance (auditing). She was editor for the ICH GCP guideline from February 1992 until its adoption in May 1996. Dr Korteweg joined the EMEA in August 1997 and has acted as EMEA quality manager since July 1998. She has led the Agency's integrated quality management system and internal audit system since November 1999. She was appointed integrated quality management adviser in January 2004.