European Medicines Agency

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Work programme for the

European Medicines Agency

2006

Adopted by the Management Board on 15 December 2005

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Introduction by the Executive Director

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After celebrating the 10th anniversary of the EMEA, and following a challenging year of implementing the new EU pharmaceutical legislation, the Agency enters a new phase of its development.

The year 2006 is the first year of full operation of the revised pharmaceutical legislation. Modifications to the existing tasks, and the introduction of new ones, have put the EU regulatory system in a better position to ensure that safe and effective medicines, as well as adequate information about them, are available to European patients.

In the coming year, the Agency will continue to build on the priorities set out in its long-term strategy, and will focus on the following areas:

- Improving the safety of medicines to provide for better-protected patients;
- Contributing towards stimulating the innovation and research of medicines in the EU, to allow faster access to new therapies and technologies;
- Improving transparency, communication and provision of information;
- Strengthening the European medicines network.

The volume of applications to the Agency, and of associated tasks, will increase substantially in 2006. The complexity of the Agency's operations will also increase, due to the growing number of submissions associated with emerging therapies and technologies, and of requests for scientific advice relating to them. This will result in a higher demand on the Member States' national competent authorities to provide the necessary competences in these scientific areas.

Safety of medicines has been the Agency's priority for a number of years. Its ability to address and manage safety issues has now been strengthened, through provisions in the new legislation and the adoption of the Agency's long-term strategy. As a result, the Agency is in a better position to achieve its goals in this area. This year it will work to implement new risk-management tools stemming from the legislation and, among other initiatives, will develop an intensive drug-monitoring system. Shoulder-to-shoulder cooperation with the national competent authorities is vital to the success of these initiatives.

Owing to the new legislation, the Agency will assume full responsibility for evaluating medicines intended for the treatment of HIV/AIDS, cancer, diabetes and neurodegenerative disorders, which must now be authorised through the centralised procedure. This year, the EMEA also expects to receive the first authorisation applications for generic medicines for human use.

In 2006, the Agency will remain focused on the development and implementation of measures to promote the availability of medicines. Measures include the provision of free, high-quality scientific advice to companies developing orphan medicines or veterinary medicines intended for use in minor animal species. The Agency will also offer substantial support to small and medium-sized enterprises (SMEs) through its new SME Office, and will work with academia, learned societies and industry on issues relating to new technologies.

New regulatory procedures aimed at increasing access to medicines, including accelerated-assessment, conditional-marketing-authorisation and compassionate-use procedures, will also be applied. The EMEA will closely monitor the effectiveness and adequacy of all new tools, procedures and processes, and will fine-tune their operation to deliver the best results.

Patients and healthcare professionals need access to useful, targeted and easily understandable information about medicines. The Agency is working to provide information that contributes towards more effective and safer use of medicines, for the benefit of its stakeholders.

The Agency will make every effort to enhance cooperation between European partners on all activities relating to medicines, particularly those which contribute to the safety of patients in Europe and to the availability of new, effective and safe medicines.

In the increasingly global pharmaceuticals sector, the Agency's contributions to international scientific forums on harmonisation of the regulatory environment is significant. The Agency will continue to work with its international partners to create a more comprehensible regulatory environment and to improve access to medicines.

To ensure it manages the greater scope and complexity of its activities in the most efficient and effective way, the Agency will continue to develop its integrated quality-management system, with particular focus on optimising its processes and on effective use of its resources.

The priorities and key objectives for 2006 can be summarised as follows:

1. Safety of medicinal products for human and veterinary use

- Implement and strengthen the European risk-management strategy in close cooperation with the Member States
- Fully apply tools provided by the new legislation, including risk-management plans and the possibility of requesting specialised studies aimed at establishing safety profiles of medicinal products during the post-authorisation phase
- Work to establish a network for intensive monitoring of targeted medicines
- Full integration of the pharmacovigilance network between EU regulatory bodies

2. Access to medicines and stimulation of innovation and research

- Develop scientific-advice procedures to enable the Agency to give as much support as possible to companies developing medicinal products, by providing high-quality advice on issues of quality, safety and efficacy at the different stages of development
- Provide support to small and medium-sized enterprises, in accordance with the new legislative provisions, in order to contribute towards the promotion of innovation and research in this sector
- Continue efforts to increase the availability of veterinary medicines, particularly for minor species and minor uses
- Work to develop new pathways for EMEA interaction with top-quality experts from national competent authorities, academia, learned societies and industry to identify and discuss challenges relating to new technologies
- Contribute to the EU programme to reduce animal testing and to develop other modern approaches in the safety assessment of substances

3. Openness, communication and provision of information

- Provide high-quality information on medicinal products to patients and healthcare professionals, to provide for adequately informed patients and improve the availability of useful information to healthcare professionals
- Increase openness and transparency of the Agency's activities to underline the good corporate governance practised within the Agency and to allow interested parties to closely monitor the Agency's activities

4. The European medicines network

- Strengthen cooperation on common issues such as pharmacovigilance, scientific advice, support to small and medium-sized enterprises and information
- Work within the network to establish an EU communication strategy
- Work to ensure availability for the Agency of the highest quality expertise at the EU level for the evaluation of medicines and for monitoring and assessing their safety
- Establish an inventory of the available scientific expertise in the European medicines network; identify and complement insufficient expertise and plan for succession of established expertise
- Develop an EU competence-development strategy and strengthen competence-development at EU level

1 EMEA in the European system

1.1 Management Board

The Management Board will continue its focus in 2006 on:

- Performance-monitoring to help the Agency carry out tasks outlined in the legislation and achieve the aspirations outlined in its long-term strategy
- Additional aspects of the Agency's transparency and communication strategy, building on achievements in 2005
- Corporate governance and implementation of an integrated quality-management system to increase the effectiveness and operational efficiency of the Agency

To achieve the above objectives, the Management Board will:

- Adopt the Agency's work programme, budget and establishment plan for the year 2007, which will take into account priorities and objectives of the long-term strategy
- Receive an audit report and annual activity report with details on achievement of objectives relating to the principles of sound financial management
- Conduct analysis of the Executive Director's annual activity report, provide its opinion on the Agency's final accounts, and adopt the Agency's annual report

Management Board meetings in 2006	
Thursday 9 March	Thursday 28 September
Thursday 8 June	Tuesday 19 December

1.2 European medicines network

Close cooperation between all members of the European medicines network is paramount to its successful functioning, to its ability to provide safe and effective medicines to patients within optimal timelines, and to the creation of an effective regulatory environment which also stimulates research and innovation.

The European medicines network will focus its attention in 2006 on ensuring the availability of competences required to address the needs of new therapies and technologies. This will be done through identification of areas where expertise needs to be reinforced and through development of such expertise. Partners of the network will consider additional improvements aimed at optimising work.

Objectives:

- To assure the necessary supply of highest-quality scientific resources
- To improve the quality of the EU regulatory system and establish a network of excellence at EU level

Key initiatives to meet the objectives:

– Establishment of an EU-wide up-to-date inventory of the available scientific expertise for all aspects of human and veterinary medicines regulation, and identification of missing or insufficient

expertise
(Road Map action)

- Preparation of an EU competence-development strategy and involvement of academia and learned societies in the provision of high-quality specialist training to strengthen competence-development at EU level
(Road Map action)
- Carry out effective cooperation in the area of support to small and medium-sized enterprises, provision of scientific advice and information
- Support to the Heads of Agencies-Human, including the area of adequate resource-planning at EU level in order to predict and successfully address difficulties that could emerge in the future
- Support to the Heads of Agencies-Veterinary on strengthening the EU network of veterinary experts and all endeavours jointly undertaken to reinforce regulatory activities in the veterinary sector, especially pharmacovigilance under the European Surveillance Strategy (ESS)
- Conduct of self-assessment activities and peer-review visits within the context of the EU benchmarking system in order to support the established quality system of the European medicines network

1.3 Transparency and communication in the European medicines network

The Agency has a deep commitment to be a transparent, open and accessible organisation. In 2006, the Agency will build on achievements of the previous year and will concentrate its efforts in three areas: implementation of the EMEA communication strategy; efforts to enable greater openness as regards medicinal products submitted for evaluation (before they are authorised); active contribution to the development and implementation of the EU communication strategy.

Objectives:

- To further increase the level of transparency and openness of activities of the Agency and the European network
- To improve the EMEA's transparency on product-related issues

Key initiatives to meet the objectives:

- Contribution to the development of the EU communication strategy, following discussions with EMEA partners and stakeholders on the issues of transparency, communication and provision of information, and subsequent implementation of the strategy
(Road Map action)
- Further work on the implementation of legislation and Management Board decision on public access to the Agency's documents
- Publication of certain Management Board meeting documentation, and the holding of dedicated information sessions with interested parties
- Development of a best-practice guide clearly describing the interaction between the EMEA secretariat and the pharmaceutical industry and between the EMEA scientific committees and the pharmaceutical industry
(Road Map action)
- Preparation of recommendations to the EMEA Management Board on how to complement, in addition to the new legal provisions, the release of information on product-related issues
(Road Map action)

1.4 Integrated management at the Agency

The Agency is committed to full implementation of the EMEA integrated quality-management system and internal control standards. In 2006, the Agency will be in a position to consolidate measures implemented in previous years. The Agency will also see the establishment of a new audit advisory committee, following the tender carried out in 2005.

Objectives:

- To consolidate the implementation of the EMEA integrated quality-management system and improve the Agency's processes

Key initiatives to meet the objectives:

- Carry out review of processes in order to optimise their operation, implement rationalisation initiatives and achieve better overall cost-effectiveness of various activities
- Continued implementation of the standards for quality, for corporate risk-management and for internal control, in accordance with an agreed action plan
- Conduct of self-assessments in the context of the EU benchmarking system and implementation of actions resulting from findings in order to improve the EMEA management system
- Conduct of an annual management review to ensure the effectiveness and continued suitability of the integrated management system, and assess the need for change; carry out assessment of the level of implementation of internal control standards and perform annual review of audit reports
- Establishment of a complete audit advisory committee, following the tender announced in 2005
- Conduct of audits of the Agency's key processes to ensure implementation of the quality policy and integrated quality-management system

1.5 Small and medium-sized enterprises

An Office for Small and Medium-sized Enterprises (SME Office) has been created within the Agency with the sole remit of providing administrative and procedural assistance to SMEs that seek to develop and market new medicines for human and veterinary use. In 2006, the SME Office will establish contacts with SME companies, providing an interface to facilitate communication and access to regulatory and scientific advice. The Agency will introduce financial assistance for SMEs in the form of fee reductions/deferrals, and will publish a detailed user guide on aspects of particular relevance for SMEs.

Objective:

- To promote innovation and the development of new medicinal products by SMEs operating in the pharmaceutical sector

Key initiatives to meet the objective:

- Provision of administrative and procedural assistance by a dedicated SME Office at the Agency
- Publication of a 'User Guide' for SMEs
- Fee reductions for scientific advice, inspections and (for veterinary medicines) establishment of maximum residue limits
- Fee exemptions for certain administrative services of the EMEA
- Deferral of the fee payable for an application for marketing authorisation or related inspection

- Conditional fee exemption where scientific advice is followed and a marketing application is not successful
- Assistance with translations of the product information documents submitted in the application for marketing authorisation

1.6 European public-health activities

With regard to European public-health activities, the Agency:

- contributes to the development of new legislation initiated by the Directorates-General of the European Commission;
- works in partnership with the European Commission's DG for Enterprise and Industry, DG for Health and Consumer Protection and DG for Research;
- cooperates with EU Agencies, in particular: the European Food Safety Authority (EFSA), on issues relating to MRLs and veterinary medicinal products for food-producing animals, and issues relating to antimicrobial resistance; the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA); and the European Centre for Disease Prevention and Control (ECDC);
- cooperates with national competent authorities in areas such as training of assessors to strengthen the European network of regulatory authorities.

In 2006, the Agency will continue to allocate resources for the implementation of legislative provisions relating to the Agency's role in responding to bio-terrorism and pandemic threats. Specifications will be established for the creation of a database on bio-terrorism agents and treatments. Work in relation to the preparation of a new Regulation on advanced therapies will increase through 2006.

The Agency will continue its efforts to make contributions for minimising the development of resistance from the use of antimicrobials in human and veterinary medicines, and is active both at EU and at international level (WHO/OIE/Codex Alimentarius) in this respect.

The Agency's scientific committees will engage in activities in support of the EU programme to reduce animal testing and develop other modern approaches that will gradually change the way safety assessment is carried out.

The new legislation places greater emphasis on environmental risk-assessment for both human and veterinary medicinal products, which will now be required for all applications for marketing authorisation. For veterinary products, environmental risk-assessment will also be required as part of the benefit-risk assessment for renewal applications. The Agency will need to ensure adequate guidance is provided to Member States and marketing-authorisation holders.

Tasks and activities relating to the forthcoming Regulation on medicinal products for paediatric use will be defined and initiated prior to the Regulation's planned implementation for the beginning of 2007. This comprises procedures and activities in respect of the new Paediatric Committee and reflection on a European Network of Paediatric Research. In addition, the Paediatric Working Party will work on the draft content and format of Paediatric Investigation Plans. A Task Force to prepare for the implementation of the Regulation will be set up to ensure timely preparedness.

The Agency will continue to work on its crisis-management plan for pandemic influenza by holding training sessions for assessors of applications for such marketing authorisations and for Agency staff, and will undertake simulation exercises to validate the plan.

The Agency will provide support to the Innomed initiative of the European Commission through the recently created think-tank group on innovation.

Cooperation will continue with the European Directorate for the Quality of Medicines (EDQM) in the context of the sampling and testing programme, to ensure that high-quality medicines continue to be made available to patients.

1.7 Preparation for enlargement

The year 2006 will see an increase in pre-accession activities in view of the next wave of EU enlargement.

The Agency will take part in the PHARE multi-beneficiary programme on participation of Bulgaria and Romania in certain Community Agencies to support preparation of these countries for accession.

The Agency will work with the accession countries to ensure:

- a smooth transition to full participation in the work of the Agency's committees on accession;
- appropriate exposure and involvement in the EU telematics initiatives to foster compliance with legislative requirements (primarily, but not exclusively, Regulation (EC) No 726/2004 and Directive 2001/20/EC), and to enable Bulgaria and Romania to be a part of the electronic network on accession;
- that sufficient resources and planning are applied to the completion of the necessary translation checks to assure compliance with EU requirements on accession. This will include the operation of the Pre-Accession Linguistic Check Process (PALCII).

The Agency will also be involved in a PHARE multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in order to support preparation of these countries for accession. The project format will include participation in selected meetings, trainings, and organisation of specific conferences.

1.8 International cooperation

These activities cover cooperation at international level, namely coordination of EU participation in the International Conferences on Harmonisation (ICH and VICH), work with the World Health Organization, including on medicinal products for use in developing countries, Codex Alimentarius, OIE, the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA).

The Agency will continue to support the European contribution to international collaboration in the framework of ICH/VICH. Increased contribution of the Agency and the CHMP to ICH activities is planned for 2006. The Agency and the CVMP will play an active part in implementing the new phase-II strategy for VICH 2006-2010, concentrating on the maintenance of guidelines and some new topics.

The Agency will also liaise closely with the FDA and the USDA to exchange relevant information on human and veterinary medicines, particularly with regard to scientific advice, product assessments and pharmacovigilance information, in the context of the EU/FDA confidentiality arrangements. Changes that will be needed to improve this interaction will be implemented in 2006, following a review *(Road Map action)*.

The Agency will also cooperate with other non-EU competent authorities in Australia, Canada, Japan, New Zealand and Switzerland. The areas of cooperation will concern safety of medicines and inspections, among others. The Agency will continue the visiting experts programme.

2 Medicines for human use

Priorities for medicines for human use in 2006:

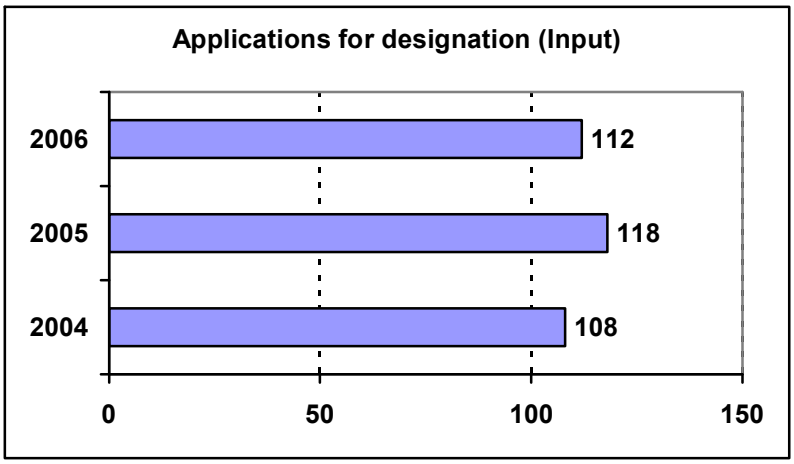
- Conduct effective marketing-authorisation procedures for medicinal products for human use. Manage first full year of implementation of new Community legislation, which includes full operation of new tools, such as accelerated-assessment, conditional-marketing-authorisation and compassionate-use procedures, and provision of opinions on medicinal products intended for non-EU markets. Monitor the implementation and, where necessary, take remedial action
- Continue to build on previous years' achievements in core business; continue to assure high-quality output of scientific assessments; assure scientific and regulatory consistency of processes to enable the provision of robust opinions by the Committee for Medicinal Products for Human Use (CHMP)
- Strengthen the focus on safety of medicines through ongoing implementation of the Agency's risk-management strategy, which includes full integration of new legislative tools, such as risk-management plans, but also looks at additional initiatives to build up an intensive drug monitoring system. Pan-European implementation of this approach in close collaboration with national competent authorities is vital for the success of the strategy and effective functioning of the EU pharmacovigilance system
- Contribute to the stimulation of innovation, research and development of new technologies by providing support to small and medium-sized enterprises, conducting pan-European discussions on various challenges emerging therapies will face, and fully integrating new Community legislation, including the provision of high-quality scientific advice
- Provide high-quality, timely, targeted and understandable information in all EU languages on medicinal products to patients and healthcare professionals, to contribute to the correct, safe and effective use of medicines
- Increase openness and transparency of the Agency's activities, to enable the public to closely monitor the Agency's activities, be informed of the Agency's initiatives and contribute constructively to the implementation of the Agency's mission
- Contribute to a further integration of herbal medicinal products in the European regulatory framework, in particular through a full implementation of applicable Community legislation

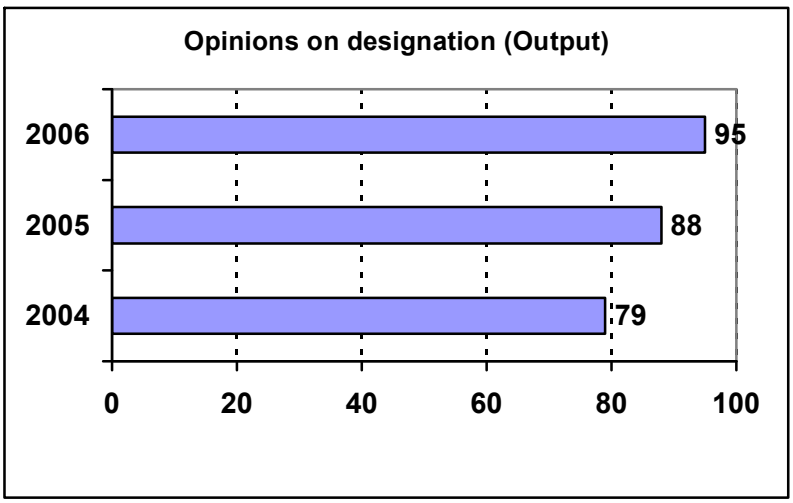
2.1 Orphan medicinal products

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

The Agency strives to meet the expectations of patients' organisations and sponsors, to meet the requirements of the legislation relating to small and medium-sized enterprises, and to create an environment for innovation and research through the orphan-medicinal-products policy. To this end, and taking into account the level of the orphan-medicinal-product fund (requested amount of EUR 5,900,000), as well as recommendations of the Committee on Orphan Medicinal Products (COMP), the Agency will propose fee reductions which will provide maximum possible incentives during the development and marketing-authorisation phases. Protocol assistance will remain a priority area for such incentives.

The fee reductions for products intended for rare diseases but authorised before the entry into force of Regulation (EC) No 141/2000 on orphan medicinal products will be brought into line with the policy for designated orphan medicines.





Trends:

- Activities are expected to stabilise at the 2005 level

- Outcome of the European Commission's report on orphan medicinal products regulation in early 2006 will be decisive for long-term trends and the potential evolution of the orphan policy at Community level, which may affect the Agency and its practices in the field of orphan medicinal products
- New term of the Committee on Orphan Medicinal Products (COMP) will start in April 2006, with the election of a new Chairperson and Vice Chairperson. This will require the secretariat to step up its support, to enable a fast and smooth transition of the new Committee
- New EMEA responsibilities and tasks derived from participation in the activities of the European Commission Working Group on Profitability of Orphan Medicinal Products (Article 8(2) of Regulation (EC) No 141/2000)
- Establish links between orphan designation-related activities and the newly created SME Office

Objectives:

- To conduct validation and evaluation of applications for orphan medicinal product designation according to the highest scientific and regulatory standards, and adhering to regulatory timelines
- To ensure effective advice on orphan medicines policy at EU level

Key initiatives to meet the objectives:

In addition to core activities relating to the evaluation of applications and development of related guidelines

- Follow-up, at the request of the European Commission, of pricing and reimbursement practices for orphan medicinal products in the Member States
- Tracking of availability and accessibility of orphan medicinal products throughout the EU
- Organisation of workshops on orphan medicinal products with interested parties in the EU, including research institutions and organisations, to foster research into rare diseases. These activities are also part of the implementation of the revised legislation on innovative therapies
- Implementation of new regulation and guidelines on SMEs in relation to orphan medicines
- Implementation of the revised procedure on the publication of summaries of COMP opinions

Performance indicators:

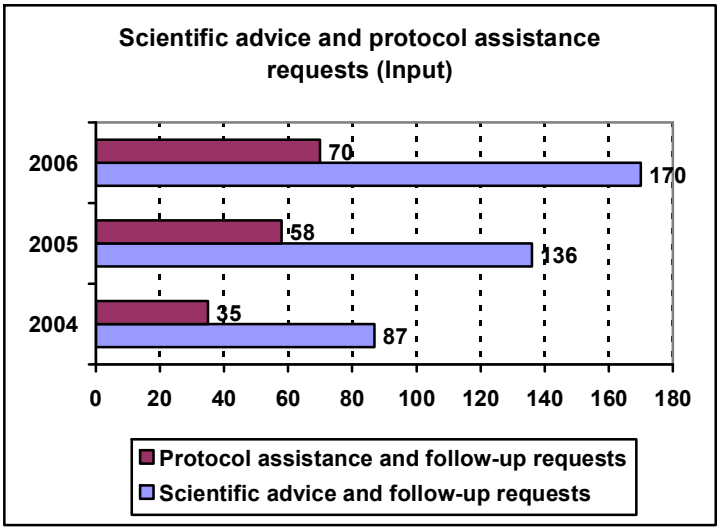
Performance indicator	**Target**
Percentage of applications evaluated within the 90-day timeline	100% of applications
Percentage of summaries of COMP opinions published within 1 month of the European Commission's decision on designation	80% of summaries of opinion
Percentage of orphan product designation procedures involving external experts	at least 70% of procedures

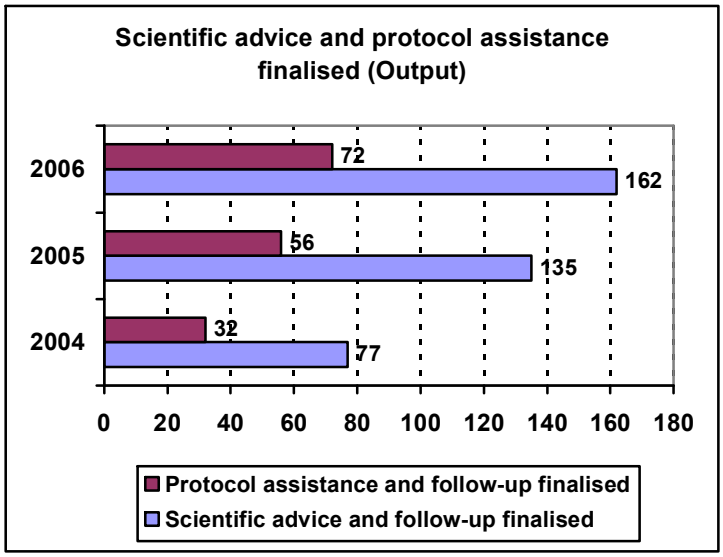
2.2 Scientific advice and protocol assistance

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

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

In 2006, in compliance with Regulation (EC) No 726/2004, improved scientific-advice and protocol-assistance procedures will be integrated into the working practices of the Agency, to enable smoother operation of the process, extend the scope, allow greater involvement of experts and increase the added value of the advice. Emphasis will be placed on efficient handling of the growing number of applications for scientific advice and protocol assistance, in particular with regard to the increasing ratio of scientific-advice requests relating to products for new therapies and technologies.





Trends:

- The implementation of the revised procedure for scientific advice and protocol assistance, and the overall increase in work volume for 2006, require adaptation of internal processes and resources
- Advent of new and first-in-class therapies and technologies requires new internal and external competences for new therapies, bioequivalence, risk-management, similarity and comparability of biotechnology products
- Wider scope of the centralised procedure, which includes new technologies and therapies, and the imminent advent of paediatric medicines as a result of the forthcoming paediatric regulation both impact on existing scientific-advice procedures

Objectives:

- To provide quality scientific advice and protocol assistance to applicants, and to adhere to the defined timelines
- To improve the scientific-advice procedure by

  increasing consistency between scientific advice and marketing-authorisation evaluation

  making the procedure faster, more transparent and interactive

  encouraging all applicants, including SMEs, in the area of new technologies and therapies to seek scientific advice

  anticipating the need for risk-management plans for new medicinal products

Key initiatives to meet the objectives:

In addition to core activities relating to the provision of scientific advice to applicants

- Implementation of revised scientific-advice and protocol-assistance procedures to deliver faster and improved results, including, in particular, earlier and greater involvement of internal and external experts, thereby strengthening the European medicines network
- Formalisation of peer review of scientific advice/protocol assistance and follow-up letters before final adoption by the Committee for Medicinal Products for Human Use (CHMP)
- Development of tools for better coordination between the centralised and national scientific advice

- Taking into account experience gained in 2005, implementation of necessary changes to the parallel scientific-advice procedure with the US Food and Drug Administration *(Road Map action)*
- Monitoring of the impact of scientific advice on the outcome of applications for marketing authorisations; analysis and preparation for further development of the scientific-memory and scientific-advice databases to include national advice *(Road Map action)*
- Preparation for implementation of new procedures to provide scientific advice in respect of paediatric medicines
- Organisation of a workshop with academia and industry on innovation in drug development

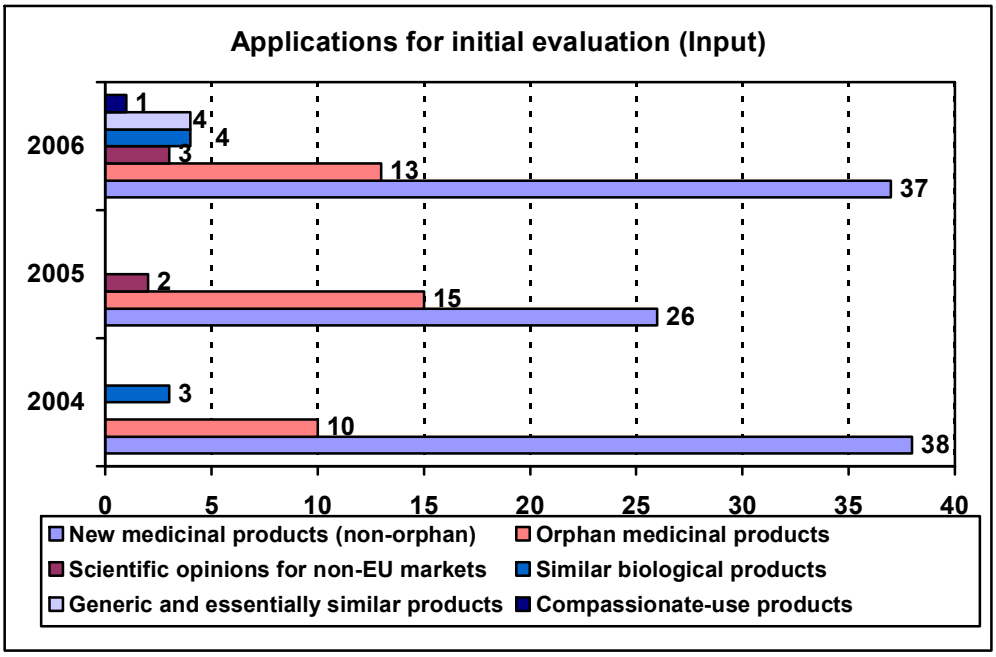
Performance indicators:

Performance indicator	**Target**
Scientific-advice and protocol-assistance requests evaluated within the procedural timelines	100% of requests
External experts involved in procedures	at least 70% of scientific-advice and protocol-assistance requests
Percentage of marketing-authorisation applications for new technology products having received scientific advice/protocol assistance	70% of applications

2.3 Initial evaluation

Initial evaluation covers activities relating to the processing of applications for medicinal products (orphan, non-orphan, similar biological (biosimilar) and generic) from pre-submission discussion with future applicants, through evaluation by the CHMP, to the granting of a marketing authorisation by the European Commission. These activities culminate in the production of the European public assessment report (EPAR). Initial evaluation also includes certification of plasma master files and vaccine antigen master files.

The highlights in 2006 for initial evaluation include four major areas: (1) consolidation of the new legislation and full use of procedures newly introduced in the Agency in 2005; (2) support of innovation and research, in particular through the support to small and medium-sized enterprises (SMEs) by the Agency's newly established SME Office and discussions with key parties on challenges relating to new technologies and therapies; (3) assuring the quality of assessments, including strengthened regulatory and scientific consistency through the stronger peer-review process and closer cooperation with the Agency's pool of partners; (4) evaluation by CHMP of risk-management plans (RMPs) which identify known and potential risks with the medicinal product so that risk-minimisation measures and other pharmacovigilance activities can be implemented proactively to protect public health. In addition, the Agency will implement a number of guidelines relating to similar biological medicinal products and will consolidate procedures relevant to chemical generics.



Trends:

- A change in the distribution of applications is anticipated in 2006 as a result of the changes to the legislation, in particular with respect to generic and biosimilar products, the compassionate-use procedure and scientific opinions for products intended for non-EU markets. There will be progressively more applications relating to new technologies and therapies; these applications will be complex
- In 2006, a few applications for biosimilar procedures and chemical generics are expected. Regarding non-prescription products, there could be some applications for a 'switch' from prescription status
- Applications are expected for pandemic-influenza vaccines, using the 'core dossier' concept
- Scientific opinions in collaboration with the World Health Organization are developing with a few applications each year. These opinions require resources and specific competences beyond usual applications
- The Agency forecasts receipt of 37 RMPs in relation to new marketing-authorisation applications in 2006

Objectives:

- To ensure high-quality processing and evaluation of marketing-authorisation applications and opinions, and to adhere to regulatory timelines
- To contribute to the protection of public health by proactively identifying safety concerns in marketing-authorisation applications for medicinal products and ensuring that appropriate pharmacovigilance activities and risk-minimisation processes are put in place prior to the authorisation
- To strengthen the quality-assurance system, including peer review of CHMP evaluations
- To contribute to the creation of an environment that stimulates research and innovation, while addressing the needs of small and medium-sized enterprises and requirements for medicinal products originating from new technologies
- To increase the provision of regulatory advice and guidance in order to allow the EMEA to adequately address more 'first-in-class' complex applications and issues stemming from generic and biosimilar applications

Key initiatives to meet the objectives:

In addition to the core activity of evaluating applications for marketing authorisation

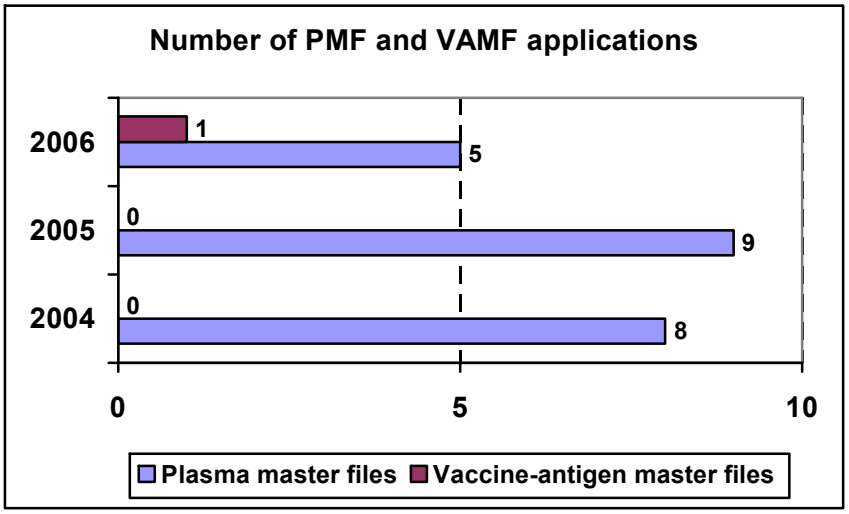
- Full application of newly introduced authorisation procedures, including conditional-marketing-authorisation, accelerated-assessment and compassionate-use procedures
- Development of pre-filing activities, particularly for procedures for conditional marketing authorisation, accelerated assessment, compassionate use and scientific opinions for products intended for non-EU countries
- Implementation of processes for generic medicines
  (Road Map action)
- Implementation of product-information-management project, which will allow easier and more effective handling of product information in all Community languages
- Revision of the scientific assessment procedure to assure the quality of assessments, with particular emphasis on initial assessments and the peer-review system
  (Road Map action)
- Further organisation of adequate competence development in the field of new technologies for staff from EU regulatory authorities, through involvement of academia and learned societies, to provide for continuous availability of required expertise
  (Road Map action)
- Provision of technical advice to the pharmaceutical industry and development of guidance documents focusing on key steps of the centralised procedure, as well as on quality, safety and efficacy of medicinal products
- Strengthening of the systematic involvement of academia and learned societies in development of guidance documents
  (Road Map action)
- Initiation of discussions with experts from national competent authorities, academia, learned societies and the pharmaceutical industry on all challenges relating to new technologies
  (Road Map action)
- Implementation of the procedure for the evaluation of RMPs in applications for marketing authorisations

Performance indicators:

Performance indicator	**Target**
Percentage of applications evaluated within the regulatory timeline of 210 days	100% of applications
Percentage of accelerated-assessment applications evaluated within the regulatory timeline of 150 days	100% of applications
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100% of applications
RMPs that are peer reviewed as part of the assessment of the initial marketing-authorisation application. Peer review of certain procedures is a part of the Agency's initiatives to assure high quality of assessment as outlined in its Road Map	70% of applications including an RMP

Plasma master files and vaccine-antigen master files

Plasma master files (PMF) and vaccine-antigen master files (VAMF) are separate documents from the dossier for a marketing authorisation. The certification of these master files uses a system analogous to the centralised procedure and leads to the issue, by the EMEA, of a certificate of compliance with Community legislation that is valid throughout the European Community.



Trend:

- The legislation regarding certification of vaccine antigen and plasma master files was implemented in 2004. The Agency forecasts no increase in applications for certification and re-certification (annual updates and variations) in 2006. The Agency will review and update certification procedures as a result of experience, to increase efficiency and use of resources

Objective:

- To ensure high-quality evaluation of plasma master file and vaccine antigen master file applications, adhering to regulatory timelines

Performance indicators:

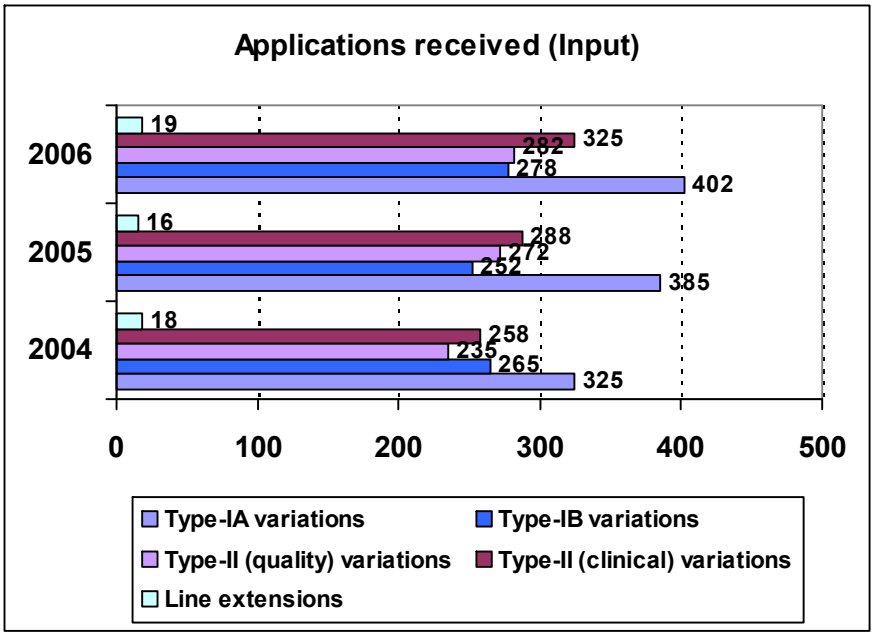
Performance indicator	Target
Percentage of plasma master file and vaccine antigen master file applications evaluated within the regulatory timeline	100% of applications

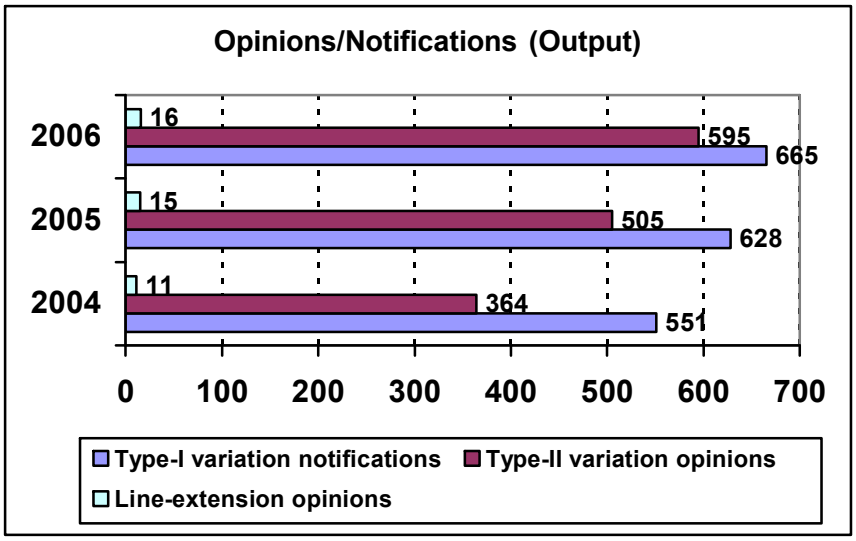
2.4 Post-authorisation activities

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

Emphasis will be placed on the full implementation of new Community legislation and monitoring of such implementation. Where necessary, action will be taken to further refine procedures as a result of experience and the growing number of applications. The regulatory and scientific consistency of CHMP opinions and assessment reports and their quality will be further improved. In addition, the

Agency will encourage marketing-authorisation holders to request pre-submission meetings to streamline the submission and review of line extensions and variation applications, thus facilitating the availability to patients of new indications and pharmaceutical forms.





Trends:

- As the number of authorised medicinal products grows each year (by around 35 new products), the number of type-II variations will continue to increase
- New work will involve variations to CHMP opinions on products intended exclusively for non-EU markets

Objectives and key initiatives:

In addition to the core activity of handling post-authorisation activities

- To implement new Community legislation, to monitor such implementation and to take remedial action where necessary

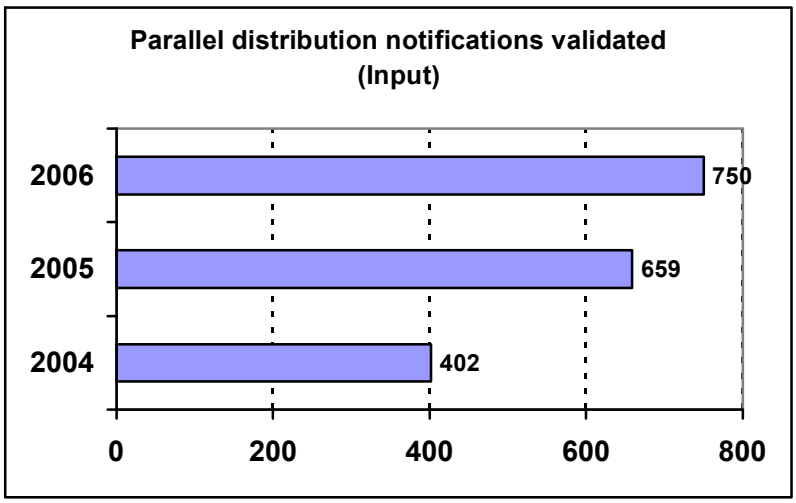
- To ensure high-quality management and evaluation of applications for variations, line extensions and transfers of marketing authorisations, and to adhere to regulatory timelines
- To strengthen the quality and the regulatory and scientific consistency of CHMP opinions and assessment reports
- To encourage applicants to request pre-submission meetings in case of significant changes and to share information on their future strategies
- To implement the product-information-management project, which will allow easier and more effective handling of product information in all official Community languages
- To review, in close collaboration with the Agency's partners and stakeholders, whether complementary process improvements, not requiring legislative changes, can be introduced in the area of variations to marketing authorisations
  (Road Map action)

Performance indicators:

Performance indicator	**Target**
Percentage of applications for type-I and II variations and line extensions evaluated within the regulatory timelines	100% of applications
Percentage of applications meeting the legal timeline of 15 days for the linguistic post-opinion checking procedure	100% of applications

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 significant 64% increase in validated parallel-distribution notifications was observed in 2005 due to the implementation of Community legislation on parallel distribution (mandatory EMEA notification procedure). The number of parallel-distribution notifications is forecast to increase by a further 14% in 2006. However, despite the mandatory nature of the notification procedure, compliance is still considered to be an issue. Hence, the forecast needs to be closely monitored.

Objectives and key initiatives:

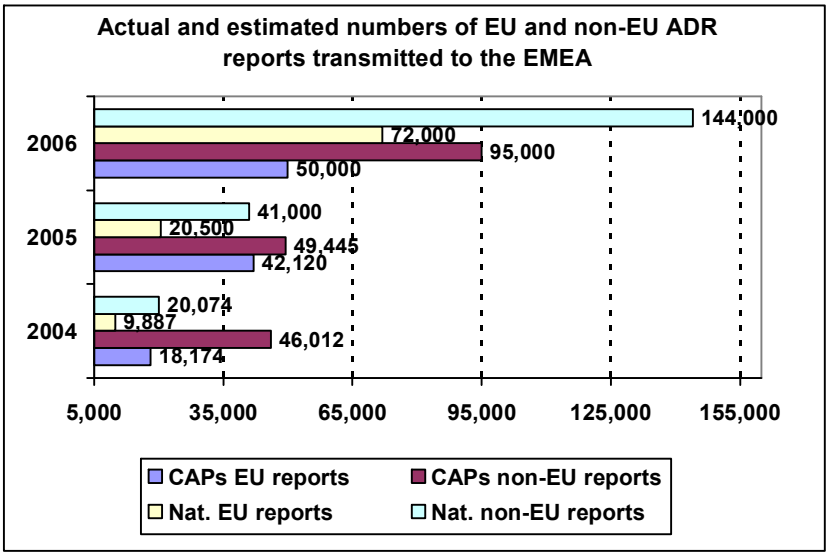
- To process parallel distribution notifications in accordance with the EMEA procedure, and to adhere to regulatory timelines
- To update the EMEA guidance on parallel distribution, taking into account the experience gained
- To define adequate performance indicators for various stages of the process, in consultation with the stakeholders

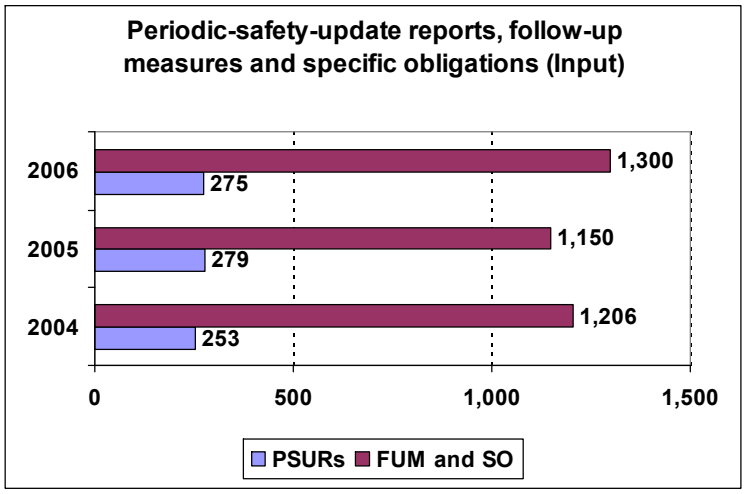
2.5 Pharmacovigilance and maintenance activities

This includes activities relating to pharmacovigilance information, such as adverse-drug-reaction (ADR) reports and periodic safety-update reports (PSURs), and to follow-up measures, specific obligations, annual reassessments and renewal applications.

Monitoring the safety of medicines is a priority area for the EMEA. The related processes undergo continuous evaluation and improvement, with the close cooperation of the national competent authorities.

In 2006, the Agency will focus on fully integrating the new legislative requirements in the field of pharmacovigilance into the Agency's processes, in particular the novel concept of risk-management plans. The Agency will progress the implementation of the European risk-management strategy (ERMS) according to the two-year rolling plan and will continue the development of the EudraVigilance system. The Agency expects that all national competent authorities will be fully reporting electronically by the end of 2006, which is reflected in the forecast increase of electronic reports in the chart below. The Agency will also work to develop and implement policies on access to data included in EudraVigilance.





Trends:

- With the implementation of new Community legislation, the electronic reporting save in exceptional circumstances of suspected serious adverse reactions in form of individual case safety reports (ICSRs) became mandatory as of 20 November 2005,. Therefore, the EMEA is expecting to receive a substantial proportion of all EU and non-EU ICSRs electronically, in the EudraVigilance Post-Authorisation Module (EVPM). Paper reporting should be minimal in 2006. In addition, with the broadening of the scope of the centralised procedure, the Agency is expecting a significant increase each year in the number of ICSRs involving centrally authorised products
- It is forecast that an estimated 50,000 ICSRs[1] from the EU involving centrally authorised medicinal products will be received in 2006. In addition, an estimated 95,000 ICSRs for these products are expected from outside the EU
- The number of ICSRs received electronically for non-centrally authorised products (EU and non-EU cases combined) is expected to be 216,000
- The number of suspected unexpected serious adverse reactions (SUSARs) from clinical trials for 2006 to be reported in form of ICSRs to the EudraVigilance Clinical Trial Module (EVCTM) is expected to be 64,000
- New Community legislation introduced the concept of risk-management plans. The workload is expected to be considerable. In addition to the plans for new products, it is likely that safety issues arising with products already authorised through the centralised procedure will lead to additional requests for risk-management plans. Updating of agreed plans will add to the number of risk-management plans being reviewed
- An increased number of procedures under Article 20 of Regulation (EC) No 726/2004 due to safety concerns over centrally authorised products is forecast. Some of these procedures will be initiated to streamline regulatory actions for centrally authorised and national products in case of class-related safety concerns.

Objectives:

- To contribute to the best-evidence approach in pharmacovigilance, leading to safer medicines on the EU market, by taking additional initiatives to arrive at an intensive drug-monitoring system, complementing the existing spontaneous reporting system
- To contribute to the protection of public health by proactively identifying safety concerns for centrally authorised medicinal products and ensuring that appropriate pharmacovigilance activities and risk-minimisation processes are put in place
- To further support the scientific activities of the CHMP with respect to the identification of new safety signals and with the scientific assessment of the data contained in EudraVigilance by releasing a first production version of the EudraVigilance data warehouse and web-reporting tools
- To make further progress in the electronic reporting of ICSRs to EVCTM and EVPM in the Community in accordance with EU and international standards
- To continue work on the implementation of the provisions of Community legislation with regard to public access to data contained in EudraVigilance, taking into account EU legislation, individual data protection and the protection of commercially confidential information
- To ensure high-quality management and evaluation of the various post-authorisation commitments and adhere to established timelines

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[1] With the implementation of the mandatory electronic reporting the presentation of the adverse reaction reports will be based on the number of ICSRs received taking into account the EudraVigilance Clinical Trial Module (EVCTM) and the EVPM.

Key initiatives to meet the objectives:

In addition to the Agency's core activities in relation to pharmacovigilance and maintenance activities

- Full application of new Community provisions, with particular emphasis on the risk-management-plan concept. Application of legislative provision enabling the request of specialised studies aimed at further elucidating the safety profiles of medicinal products during the post-authorisation phase
- Implementation of the ERMS in accordance with the rolling two year work programme through cooperation with NCAs
- Revision of the ERMS through the ERMS facilitation group to bring it more in line with the new legal provisions and to adequately respond to the outcome of the European Commission's assessment of the EU pharmacovigilance system
- Revision of procedures (such as the CHMP handling of safety concerns in the post-authorisation phase for centrally processed applications) to effectively incorporate the concept of risk-management plans in the evaluation process
- Initiation of discussions with the European Centre for Disease Prevention and Control (ECDC) on the development of methods and processes appropriate to the conduct of high-quality post-authorisation studies for vaccines
  (Road Map action)
- Discussion with all concerned stakeholders on the most adequate conduct of post-authorisation safety studies
  (Road Map action)
- Establishment of a network of centres to be involved in intensive monitoring of targeted medicines
  (Road Map action)

Performance indicators:

Performance indicator	**Target**
Percentage of ICSRs for centrally authorised products (CAPs) transmitted electronically	100% of ICSRs
Percentage of ICSRs for non-CAPs transmitted electronically	60% of ICSRs
RMPs that are peer reviewed as part of the assessment of updates to the initial marketing authorisation and of the assessment of variations and line extensions which result in a significant change in a marketing authorisation. Peer review of certain procedures is a part of the Agency's initiatives to assure high quality of assessment as outlined in its long-term strategy	70% of RMPs
Percentage of PSURs and post-authorisation commitments evaluated within the established timeline of 60 days	80% of PSURs and post-authorisation commitments

2.6 Arbitration and Community referrals

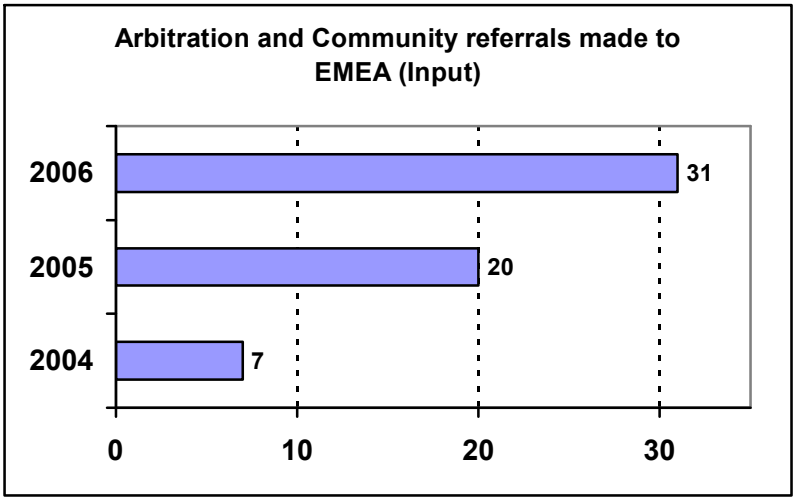
Arbitration procedures (either under Article 29 of Directive 2001/83/EC as amended or Articles 6(12) and 6(13) of Commission Regulation (EC) No 1084/2003) are initiated because of disagreement

between Member States or because of disagreement of the marketing-authorisation holder with the Member States in the framework of the mutual-recognition or decentralised procedures.

Article 30 referrals are mainly initiated in order to obtain harmonisation of authorisations for medicinal products authorised in the Community.

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

In the area of arbitrations and Community referrals the Agency will concentrate on two goals in 2006. The first one will include introduction of further improvements to referral procedures dealing with the safety of medicines so as to shorten the time between initiation of the referral procedure and adoption of the Committee's opinion. This is in line with the Agency's priorities in the area of safety of medicinal products. The second goal is to effectively manage arbitrations and referrals.



Trends:

- An increase in referrals and arbitrations is expected from full implementation of the New Community legislation in the area of Mutual Recognition and Decentralised Procedures. Referral procedures which are not restricted by consensus within the CMD(h) are expected to proceed to arbitration at the CHMP. In addition the CMD(h) will draw up the list of medicinal products, agreed by Member States, the European Commission and the Agency, for which harmonised product information should be drawn up. The impact on the number of referrals is, however, difficult to predict
- The number of referrals relating to pharmacovigilance concerns is also expected to increase. Considering the new legal provisions, it is expected that referrals relating to pharmacovigilance concerns will concern therapeutic classes rather than individual products
- A new procedure has been introduced by Community legislation (Article 107 of Directive 2001/83/EC as amended) requiring a CHMP opinion further to the suspension or revocation of the marketing authorisation of a medicinal product in a Member State as a result of pharmacovigilance data

Objectives and key initiatives:

- To perform high-quality and timely evaluations for referral and arbitration procedures
- To shorten the procedure time for safety referrals, to meet the new legal timeframes
- To strengthen the quality and the regulatory and scientific consistency of CHMP opinions and assessment reports

- To further increase transparency on arbitration and referral procedures
- To fully implement the newly introduced procedure under Article 107
- To improve the availability of procedural guidance in relation to arbitration and referral procedures

Performance indicators:

Performance indicator	**Target**
Percentage of arbitration and referral procedures evaluated within the legal timeline	100% of procedures
Average overall time for Community-interest referrals	Time to be 10% shorter than in 2004
Publication of 'question and answer' document for Community-interest referrals and procedures under Article 107 at the time of CHMP opinion	100% of community interest referrals and Article 107 procedures

2.7 Herbal medicinal products

The Agency's involvement in the field of herbal medicinal products has significantly increased since the entry into force of the new Community legislation and the establishment of the new Committee on Herbal Medicinal Products (HMPC) in 2004.

Objectives and key initiatives:

- To fully implement Community legislation applicable to the Committee on Herbal Medicinal Products
- To provide Member States and European institutions with the best-possible scientific opinion on questions relating to herbal medicinal products
- To establish a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, for subsequent publication by the European Commission
- To establish Community herbal monographs for traditional herbal medicinal products, as well as for well-established herbal medicinal products
- To provide opinions on herbal substances at the request of the Committee for Medicinal Products for Human Use in accordance with timelines set out in Community legislation
- To update guidance on the content of dossiers for applications to register the traditional medicinal use of herbal medicinal products, taking into account experience gained in the Member States and in the HMPC
- To establish a framework and tools to ensure high-quality and timely evaluations for referral and arbitration procedures on traditional herbal medicinal products
- To provide Member States, upon request, opinions on the adequacy of the evidence of the long-standing use of a traditional herbal medicinal product and, in particular, in cases where the product has been used in the Community for less than 15 years but is otherwise eligible for traditional-use registration
- To provide applicants any scientific advice or opinion on traditional herbal medicinal products
- To strengthen interaction with the World Health Organisation (WHO) on its traditional-medicines programme
  (Road Map action)

Performance indicators:

Performance indicator	Target
Establish Community herbal monographs	20 herbal monographs established
Establish a list of herbal substances, preparations and combinations thereof	30 entries to the list
Percentage of referrals processed in a timely manner and in accordance with the agreed procedure	100% of referrals

2.8 Scientific committees, working parties and scientific advisory groups

The Committee for Medicinal Products for Human Use

The Committee for Medicinal Products for Human Use (CHMP) is responsible for scientific evaluation and provision of scientific opinions to the European Commission for the authorisation and maintenance of medicinal products. Scientific opinions will also be provided in collaboration with the World Health Organization for products destined for developing countries. The Committee provides scientific advice and protocol assistance to pharmaceutical enterprises during the process of medicines development. The Committee also provides scientific opinions on medicinal products involved in arbitration and referral procedures, on medicinal products intended for use outside the European Union, and on any matter relating to the evaluation of medicinal products at the request of the European Commission or the Executive Director of the Agency. Furthermore, work is undertaken in the field of harmonisation of technical requirements for pharmaceutical regulation.

The CHMP will meet 11 times in 2006, with each meeting lasting four days.

CHMP meetings in 2006	
23-26 January	24-27 July
20-23 February	No meeting in August
20-23 March	18-21 September
24-27 April	16-19 October
29 May-1 June	13-16 November
26-29 June	11-14 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 on liaison with international partners and patients' organisations on this issue. The Committee will start a new mandate in April 2006.

The COMP will meet 11 times in 2006, with each meeting lasting up to three days.

COMP meetings in 2006	
10-12 January	11-13 July
7-9 February	No meeting in August
7-9 March	5-7 September
4-6 April	3-5 October
16-18 May	8-10 November
13-15 June	5-7 December

The Committee on Herbal Medicinal Products

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

The HMPC will meet 6 times in 2006 with each meeting lasting one and a half days.

HMPC meetings in 2006	
11-12 January	12-13 July
8-9 March	6-7 September
11-12 May	25-26 October

Standing and temporary working parties and scientific advisory groups

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

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

The Agency will continue to develop an integrated approach to the work of working parties and to the development of requirements, particularly as concerns new and emerging therapies and technologies, including advanced therapies. As a result of the requirements of the new legislation regarding the

scientific role of the Agency's secretariat, and continued efforts to improve the quality of scientific opinions, the Agency will strengthen regulatory and scientific support to the various working parties.

A notable increase in the number of meeting days is planned for the Scientific Advice, Cell-Based Products, Gene Therapy, Pharmacogenetics and Paediatric Working Parties. This increase relates to the expected growth in the number of scientific-advice applications, activities in the field of emerging therapies and new technologies, and preparation for implementation of the new legislation on medicinal products for paediatric use. The increased activity in this area is also due to the need for scientific advisory groups to cover the new mandatory fields of the centralised procedure.

Working parties will continue to meet in smaller groups to draft and review guidance documents. On 1 September 2005, a new 'Procedure for European Union guidelines and related documents within the pharmaceutical legislative framework' came into operation. The activities of working parties will be rationalised, since they are now also required to assess the impact on stakeholders and regulatory authorities of the guidelines they develop.

The Agency, in collaboration with working parties and the European medicines network, will continue to organise workshops on specific topics and provide training to assessors.

CHMP standing and temporary working parties	**Number of meetings in 2006**
Biologics Working Party	11
Blood Products Working Party (plenary)	2
Efficacy Working Party (plenary)	4
Gene Therapy Working Party	4
Joint CHMP/CVMP Quality Working Party	4
Paediatric Working Party	6
Pharmacogenetics Working Party	4
Pharmacovigilance Working Party	11
Safety Working Party (plenary)	4
Scientific Advice Working Party	11
Vaccine Working Party	6
Working Party on Cell-Based Products	5
Working Party on Similar Biological Medicinal Products	4
EMEA/CHMP Working Group with Healthcare Professionals' Organisations	2
EMEA/CHMP Working Group with Patients' and	4

Consumers' Organisations	

CHMP scientific advisory groups	**Number of meetings in 2006**
Anti-infectives	3
Cardiovascular system	3
Central nervous system	3
Diabetes/endocrinology	3
Diagnostics	2
HIV/viral diseases	3
Oncology	6

CHMP associated groups	**Number of meetings in 2006**
(Invented) Name Review Group	11
CHMP/EMEA Implementation Task Force	8
Working Group on Quality Review of Documents	4
Quality Review of Documents Subgroup	11

COMP working groups	**Number of meetings in 2006**
Biotechnology Working Group	2
Working Group with Interested Parties	3

HMPC working parties and associated groups	**Number of meetings in 2006**
Working Party on Monographs/List[2]	6

[2] Working party on the establishment of Community herbal monographs and the preparation of a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

Drafting Group on Quality	6
Drafting Group on Organisational Matters	6

2.9 Provision of information to patients and healthcare professionals

Provision of information is a priority area for the Agency. The Agency implemented processes and procedures in 2005 aimed at the provision of targeted, understandable and accessible information for patients and healthcare professionals. In addition to summaries of opinions, European public assessment reports (EPARs), and information on arbitrations and referrals, the Agency now provides a wider range of information, including information on withdrawals of applications by applicants prior to opinion and on negative decisions, as well as summaries of EPARs written in a manner more understandable to the public.

These processes and procedures were developed and applied by the end of 2005; the Agency will streamline them in 2006. A number of recommendations stemming from the work with patients' and consumer organisations will be implemented and contacts with healthcare professionals will be strengthened.

Objective:

- To strengthen interaction with patients, healthcare professionals and interested parties, and provide them with targeted, high-quality and easily understandable and accessible information on medicinal products and related authorisation, arbitration and referral procedures in a timely manner

Key initiatives to meet the objective:

In addition to the core activities relating to publication of summaries of opinions, European public assessment reports, public statements and question and answer documents

- Implementation of new Community legislation relating to the provision of information, building on achievements in 2005
- Development and implementation of specific frameworks on the interaction between the EMEA and stakeholders (patients' and consumer organisations, and healthcare professionals)
- Further development of the database of authorised medicinal products in the European Union. The development of the database will not be finalised in 2006. However once completed, the database will enable the EMEA and national competent authorities to provide comprehensive information on medicinal products to patients and healthcare professionals
- Implementation of recommendations affecting only the Agency, as agreed by the EMEA/CHMP Working Group with Patients' and Consumers' Organisations
  (Road Map action)
- Establishment of a Working Group with Healthcare Professionals to facilitate communication with them on defining optimal ways for providing timely and useful information
  (Road Map action)
- Implementation and monitoring of the revised EMEA handling of translations of product-related information for centrally authorised products in all Community languages

Performance indicators:

Performance indicator	Target
Percentage of summaries of opinions published at the time of the CHMP press release	90% of summaries of opinions
Percentage of initial European public assessment reports (EPARs) published within 2 weeks of the Commission decision	80% of marketing authorisations granted
Percentage of summaries of EPAR in language understandable by the public published together with the EPAR	80% of EPARs
Percentage of EPARs published within 2 months following withdrawal	70% of EPARs
Percentage of reports on arbitrations and referrals published within 1 month of the Commission decision	70% of reports

2.10 Coordination group

The year 2006 is the first full year of operation of the Coordination Group for Mutual-Recognition and Decentralised Procedures (human products) (CMD(h)) established by new Community legislation. The Agency will provide secretarial support to the CMD(h) and its working parties. This will include:

- Preparation and distribution of documents, provision of lists of positions taken on similar issues and follow-up to meetings, including preparation of monthly statistics relating to the mutual-recognition and decentralised procedures
- Facilitation of liaison with other scientific working groups and with interested parties
- Secretarial assistance for the preparation of annual reports and assistance on specific activities assigned to the CMD(h) under their work programmes, as well as assistance in providing regulatory and legal support to CMD(h) activities
- Preparation of the list of medicinal products for which a harmonised Summary of Product Characteristics (SPC) should be drawn up

The CMD(h) will meet 11 times in 2006, with each meeting lasting two days

CMD(h) meetings in 2006	
23-24 January	24-25 July
20-21 February	No meeting in August
20-21March	18-19 September
24-25 April	16-17 October
29-30 May	13-14 November
26-27 June	11-12 December

CMD(h) working parties and subgroups in 2006	Number of meetings
Subgroup on CTS	6
Working Group on Harmonisation of SPCs	8
Joint Pharmacovigilance WP/CMD(h) WG	4

2.11 Regulatory activities

The Agency provides regulatory and procedural advice to the pharmaceutical industry during the lifecycle of medicinal products, from scientific advice and pre-submission meetings with applicants through post-authorisation and annual meetings with marketing-authorisation holders. It will continue to update and develop guidance documents focusing on the key steps of the centralised procedure, as well as on issues of quality, safety and efficacy of medicinal products, to facilitate use of the centralised procedure and support submission of required quality applications.

The Agency also works to continuously address the regulatory and procedural issues affecting the EMEA committees, standing and temporary working parties, and associated groups, as well as providing guidance and monitoring the operational implementation of the new Community pharmaceutical legislation. It will continue to support the European Commission in the updating and further development of the Notice to Applicants and in providing advice on the centralised procedure.

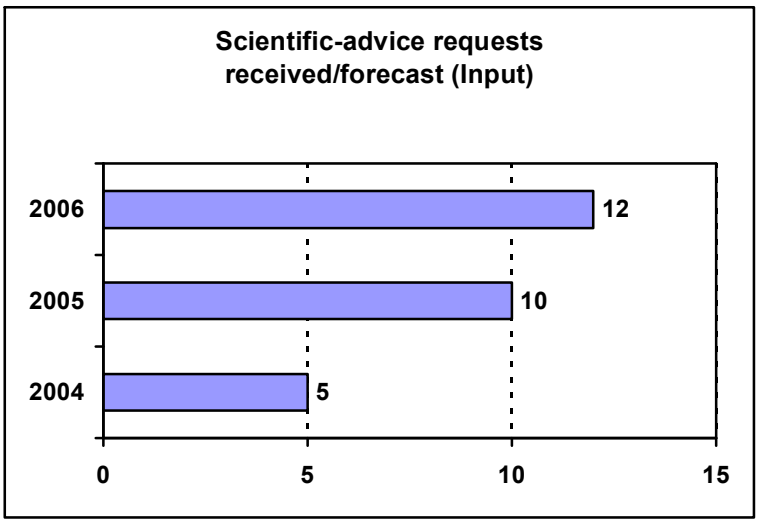
3 Veterinary medicines

Priorities for veterinary medicines in 2006:

- To capitalise on efforts initiated in late 2005 to fulfil the Agency's obligations with regard to coordinating the supervision of veterinary medicines once authorised, through effective implementation of pharmacovigilance as well as through the dissemination of information on adverse drug reactions in accordance with the principles laid down in the new Regulation and Directive
- To continue collaboration with Member State agencies on the European Surveillance Strategy (ESS) to continuously develop pharmacovigilance systems capable of achieving high standards of public and animal-health protection for all veterinary medicinal products
- To ensure the adequate resourcing and implementation of measures to meet the requirements of the amended Veterinary Directive, which requires an impact-assessment of the potential risks posed to the environment for each new marketing-authorisation application for veterinary medicinal products and the consideration of the risk to the environment in the benefit-risk assessment of renewal applications
- To provide effective technical and procedural secretarial support to the newly created Veterinary Coordination Group on Mutual-Recognition and Decentralised Procedures to ensure its efficient and strategic operation as required in the new Directive
- To support further initiatives, once identified, to facilitate greater availability of medicines, particularly through involvement in the Global Technology Platform on Animal Health
- To implement measures agreed by the Management Board to provide assistance to companies — particularly those classed as SMEs — submitting applications for veterinary medicines in the centralised procedure which have limited markets or which are intended for diseases with regional distribution, as required in the new Regulation
- To prepare for and manage the predicted increase of referrals to the CVMP where there has been failure to reach agreement in the mutual-recognition/decentralised procedures, as well as a likely increase of referrals for harmonisation of SPCs (Article 34) as identified in the list under discussion by Member States and the Commission
- To manage the workload and adhere to regulatory guidelines for pre- and post-authorisation activities for veterinary applications and those in respect of MRLs and modifications/extensions

3.1 Scientific advice

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



Trends:

- It is anticipated that, as the improvements to the scientific-advice procedure are recognised and appreciated by potential applicants, the number of submissions made will increase to around 12 per year. This figure also takes into account the decision of the Management Board to extend the period for free scientific advice for MUMS products by a further 12 months

Objectives and key initiatives:

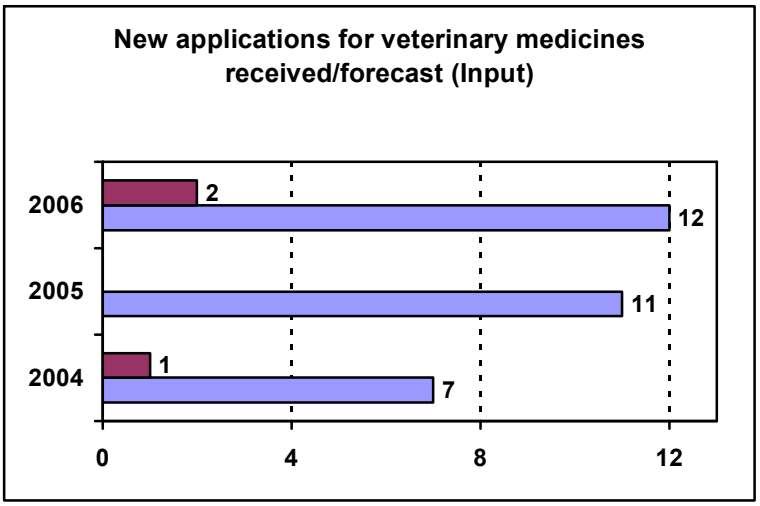
- To provide quality scientific advice to applicants and adhere to regulatory timelines. A questionnaire will be sent to all applicants in order to gain feedback on the level of satisfaction with the new procedure
- To provide effective support to the Scientific Advice Working Party, taking account of the experience gained with the new standard operating procedure, the updated web guidance document and the mandate to streamline the service provided and increase the attractiveness of this service to Industry

Performance indicators:

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

3.2 Initial evaluation

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



Trends:

- The number of applications for new products through the centralised procedure has increased somewhat over the past few years. Two aspects of the new legislation are considered relevant here: the increased scope of the procedure in the new Regulation (Article 3(2)) foresees applications for the centralised procedure being eligible if the medicines concerned are considered to be in the interest of public and animal health in the Community; secondly, support is now available to companies considering applications for limited markets and/or for regional diseases

  Some reflection suggests that companies previously not considering the centralised procedure — because of the cost involved in fulfilling the requirements of Community authorisation in 25 Member States — may now be tempted to submit dossiers to the EMEA. In addition, there is now the possibility of submitting applications for immunological products for diseases where there is a Community interest
- Generic applications for centralised products, which began in 2004, are expected to continue in 2006
- As a result of all these factors, the number of applications is forecast to grow by 27%, to a total of 14

Objective:

- To ensure high-quality processing and evaluation of marketing-authorisation applications and opinions, and to adhere to regulatory timelines

Key initiatives to meet the objective:

- Further development of the scientific-memory database, with implementation expected in the second half of the year, to assist in ensuring consistency of scientific assessments
- Provision of appropriate and timely regulatory and procedural advice and guidance documents to the pharmaceutical industry, to optimise use of the centralised procedure under the scope of the new Regulation

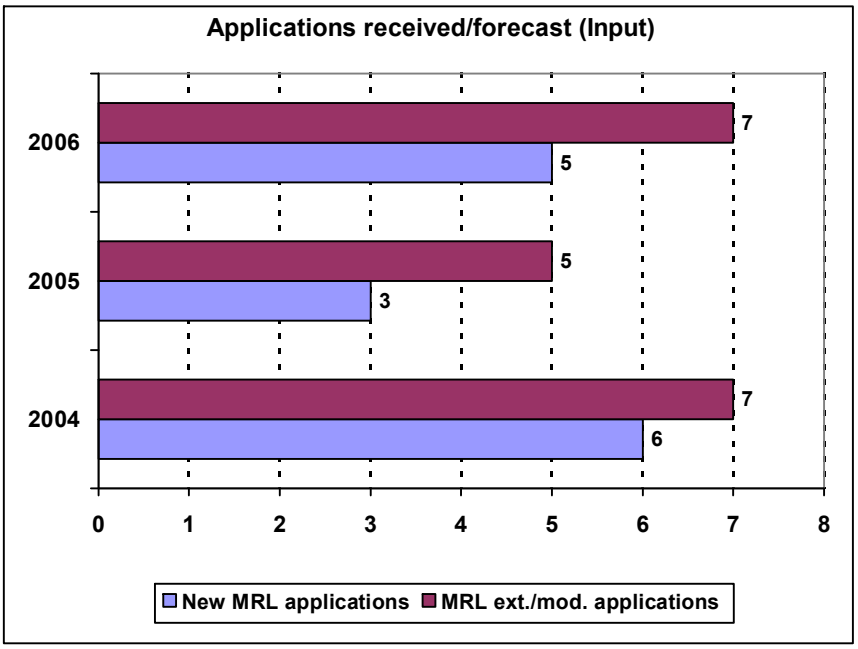
- Preparation and publication of EPAR summaries in line with the requirements of the new Regulation
- Following the outcome of the CVMP audit in October 2005, implementation of its recommendations to strengthen the quality-assurance system in respect of CVMP procedures

Performance indicators:

Performance indicator	Target
Percentage of products evaluated within the regulatory timeline of 210 days	100% of applications
Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days	100% of applications

3.3 Establishment of maximum residue limits

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



Trends:

- The number of new MRL applications is expected to remain consistent with previous years, with 5 applications forecast
- However, the numbers of extensions and modifications may grow, particularly as initiatives taken by the CVMP to facilitate the authorisation of products for minor uses and minor species come into play; 7 applications for extensions and modifications are forecast

Objectives and key initiatives:

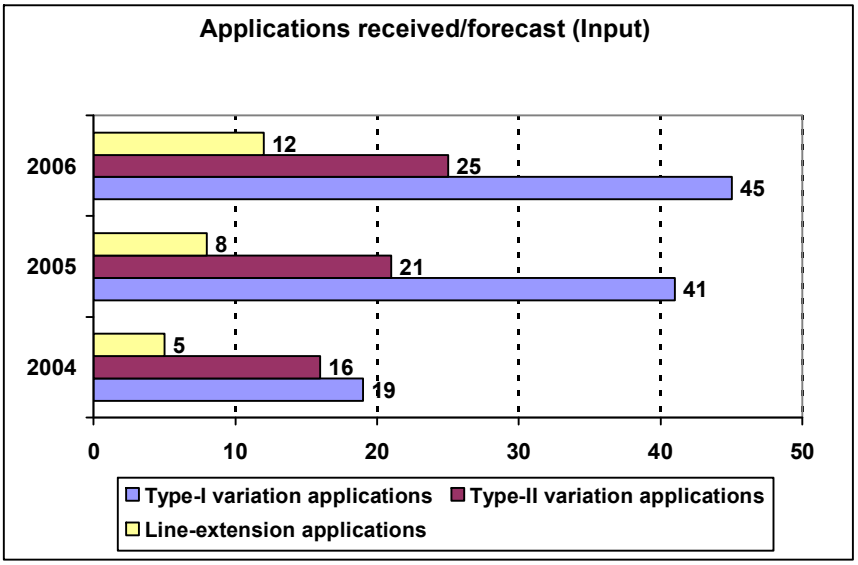
- To ensure high-quality assessment of MRL applications and related activities, and to adhere to regulatory timelines
- To continue to extrapolate MRLs to minor species upon request by companies, in accordance with the CVMP policy on availability

Performance indicators:

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

3.4 Post-authorisation activities

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



Trends:

- The amount of work on post-authorisation activities is expected to increase steadily in accordance with the total number of marketing authorisations and the increased number of products that will be on the market.

Objective:

- To ensure high-quality assessment of post-authorisation applications, and to adhere to regulatory timelines

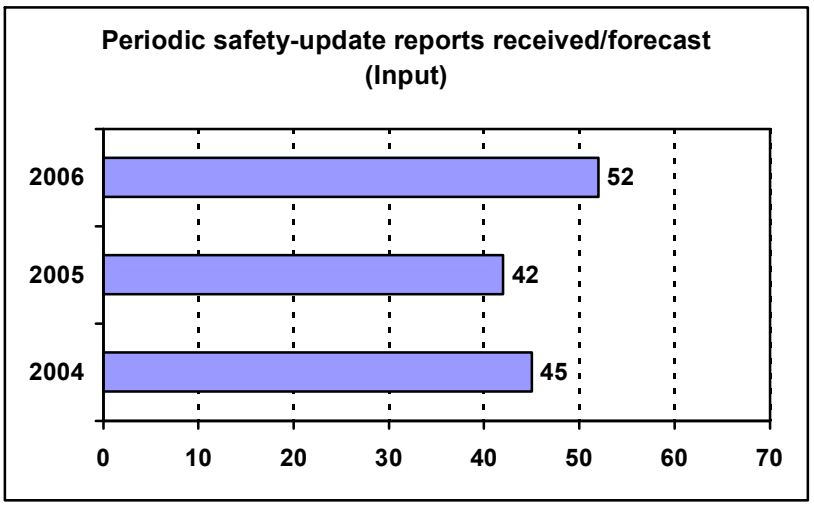
Performance indicators:

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

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

3.5 Pharmacovigilance and maintenance activities

This includes activities relating to pharmacovigilance information, including adverse-drug-reaction reports (ADRs) and periodic safety-update reports (PSURs). Pharmacovigilance remains a high priority of the Agency for 2006, to ensure that effective risk-management is continuously applied to post-authorisation monitoring of veterinary medicines throughout the EU.



Trends:

- The continuing emphasis on the safety of veterinary medicines in the post-authorisation phase and the need to adopt a continuing risk-management approach to this important issue will feature highly on the list of priority activities in the 2006 plan for veterinary medicines
- With an anticipated 80 centralised products being commercialised by 2006, the number of serious adverse reaction reports can be expected to rise to well over 400, with approximately 52 PSURs being submitted as well
- Following the full switch to electronic reporting by all Member States, a number of activities relating to further training and the provision of assistance to Member States and Industry will be required. Furthermore, in order to identify safety signals, the EMEA will have to provide assistance to Member States on the import of product-related data and analysis of pharmacovigilance data
- With the need to meet the Agency's obligations to the outside world on pharmacovigilance reporting and communication as explicitly stated in the new Regulation, a considerable increase in data analysis with EudraVigilance and subsequent reporting and greater transparency is expected. The Agency will continue to improve on its communication to the public, and will encourage a reporting culture through its collaborative efforts with interested parties and Member States
- The impact of the new legal provisions on 'automatic referrals' for any urgent pharmacovigilance measure by a Member State under Article 78 of Directive 2001/82/EC as amended is difficult to estimate at present. Twenty CVMP procedures for such urgent provisional measures are forecast

Objectives and key initiatives:

- To ensure high-quality conduct of pharmacovigilance activities for centrally authorised veterinary medicinal products

- To collaborate fully and work with Member States in the European Surveillance System to foster a joint approach to optimising the efficiency of EU veterinary pharmacovigilance for all medicinal products authorised in the Community
- Provision of assistance to Member States on the import of product-related data and on the analysis of pharmacovigilance data to identify any signals
- Provision of training, maintenance and assistance to Member States and Industry in the area of pharmacovigilance reporting, following the full switch to electronic reporting
- Continuation of initiatives with interested parties (Federation of Veterinarians of Europe) to train and advise practising veterinarians in the area of pharmacovigilance

Performance indicators:

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

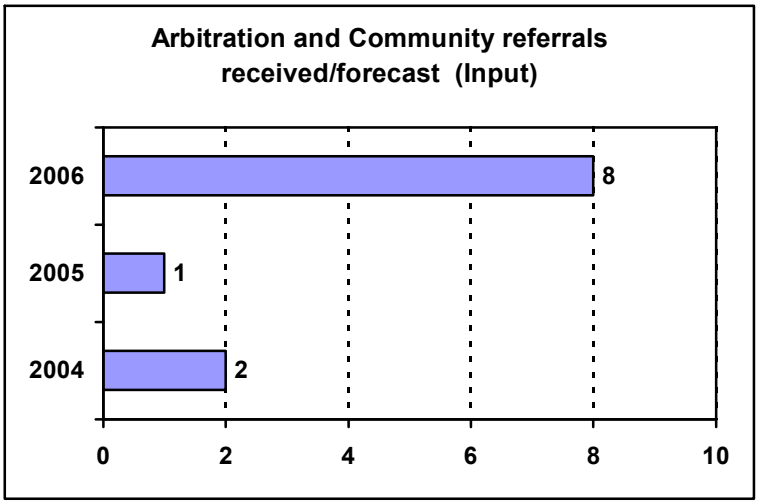
3.6 Availability of medicines

The EMEA will continue its initiatives aimed at improving the availability of medicines through application of principles agreed and implemented, as defined in the CVMP's 'Position paper regarding availability of products for minor uses and minor species (MUMS)' (EMEA/CVMP/477/03-Final). In this context, the CVMP will finalise the guidelines on adaptation of data requirements for the quality, safety and efficacy of products for minor uses and minor species, which will subsequently be implemented, in full collaboration with Member State competent authorities, to ensure a harmonised approach.

The EMEA will participate in providing input and advice to the Heads of Medicines Agencies-Veterinary's task force on availability and to the Global Technology Platform for Animal Health, ensuring that attention is given to the Community priority for an increased number of medicinal products for minor uses and minor species within the EU. As required by the new Regulation, the Agency shall provide assistance to companies intending to submit applications through the centralised procedure for products which have limited markets or that are intended for diseases of a regional nature.

3.7 Arbitration and Community referrals

Arbitration procedures are initiated because of disagreement between Member States within the framework of the mutual-recognition procedure (Article 33 of Directive 2001/82/EC, as amended). Referrals are initiated either in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States (Article 34 of Directive 2001/82/EC) or in cases where there is a Community interest or other safety-related issue (Articles 35 and 40 of Directive 2001/82/EC).



Trends:

- In accordance with the new Directive, automatic referrals to the CVMP for arbitration are expected to begin in early 2006. The number of referrals that will be initiated is difficult to predict, but the frequency of withdrawals under the current system indicates that there will be approximately 5
- Following a consultation process, the list of products to be agreed for harmonisation of the SPC to be submitted by the coordination group to the Commission, as required by the new Directive, will be finalised. The number of products concerned is difficult to forecast at present. The list will focus on consumer safety and availability issues. Actual referrals to the CVMP are expected to begin towards the end of the year 2006 (forecast 2), and will be phased over a period of several years
- The number of referrals triggered by safety concerns where there is a Community interest is expected to remain at a low level
- In total, 8 arbitrations/referrals are expected to be submitted to the CVMP in 2006, which is a significant increase on the 2005 number

Objective:

- To ensure provision of quality opinions arising from arbitration and referral procedures, and to adhere to regulatory timelines

3.8 Scientific committee

The Committee for Medicinal Products for Veterinary Use (CVMP) will need to reflect on its performance in meeting its obligations under the new legislation, and continue to respond to opportunities for improvement arising from the second audit of the CVMP that took place on 3-7

October 2005. From the EMEA Road Map stem, in particular, requirements for strengthening of the quality of assessments and improvement of the information provided to the public.

The CVMP will need to consider and discuss the possible need for additional scientific advisory groups beyond the antimicrobials one established in July 2004.

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

CVMP meetings in 2006	
17-19 January	18-20 July
14–16 February	No meeting in August
14-16 March	12-14 September
19-20 April	10-12 October
16-18 May	8-10 November
20-22 June	12-14 December

Working parties

The CVMP will review the mandate and operation of its standing and temporary working parties to establish whether the Committee is adequately served by their activities. In particular, the Committee will need to consider the need for new working parties to deal with emerging therapeutic and new technologies, if by early 2006 there is evidence of such a need in the veterinary sector, and whether the term of the Environmental Risk-Assessment Working Party should be extended.

The Committee will reflect on the operation of its Scientific Advisory Group on Antimicrobials and determine if its mandate is appropriate as it stands or whether change is appropriate, depending on the environment for non-human-resistance development.

CVMP working parties and ad hoc groups in 2006	**Number of meetings**
Efficacy Working Party	4
Immunologicals Working Party	3
Pharmacovigilance Working Party	6
Safety Working Party	4
Joint CHMP/CVMP Quality Working Party	4
Environmental Risk-Assessment Working Party	4
Scientific Advice Working Party	11
Scientific Advisory Group on Antimicrobials	4

3.9 Coordination group

The coordination group secretariat will have been established at the EMEA at the end of 2005. A significant increase in workload for the new coordination group, and greater reliance on the formal secretariat provided by EMEA staff, is expected in 2006. The Agency's support for the Coordination Group for Mutual-Recognition and Decentralised Procedures will include:

- Preparation of meeting documents and conduct of follow-up to meetings
- Facilitation of liaison with EMEA committees/working groups and interested parties
- Preparation of the texts of the agreements, and of any other texts related to the role of the CMD(v) in liaison with the responsible CMD(v) member and/or CMD(v) expert(s)
- Assisting the Chairperson in the preparation of the annual reports on mutual-recognition and decentralised procedures
- Assisting the Chairperson in monitoring compliance with the time periods laid down by legislation in relation to referrals to the CMD(v)
- Facilitation of the necessary contacts between the CMD(v) and the person responsible for the placing a product on the market
- Preparation of monthly statistics relating to the mutual-recognition and decentralised procedures
- Provision of support from regulatory/legal staff with experience in the mutual-recognition and decentralised procedures

The CMD(v) will meet 11 times in 2006, with each meeting lasting two days:

CMD(v) meetings in 2006	
19-20 January	20-21 July
16-17 February	No meeting in August
16-17 March	14-15 September
20-21 April	12-13 October
18-19 May	9-10 November
22-23 June	14-15 December

4 Inspections

Priorities for inspections in 2006:

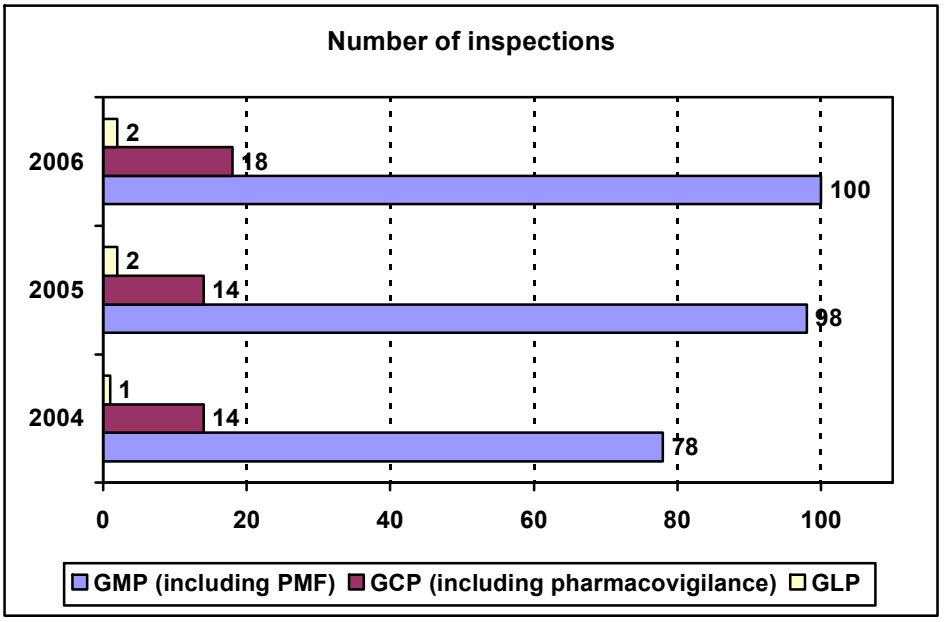
- The main priority for 2006 will be to implement the new pharmaceutical legislation, particularly the new requirements for GMP for active substances and certain excipients, and requirements for the establishment of a database on manufacturing authorisations and GMP certificates
- To strengthen the coordination of inspections in the context of the PMF and VAMF certification schemes
- To continue activities to support the clinical trials directive (2001/20/EC) and the GCP directive (2005/28/EC) for human medicines, in particular the implementation of activities relating to GCP inspections and GMP requirements and the next phase of the EudraCT database
- To ensure maintenance of consistent quality standards and harmonised approaches through coordination of activities in the context of the ad hoc GMP inspectors meetings and the joint audit programme for GMP inspectorates
- To coordinate and manage effectively requests for GMP, GCP, pharmacovigilance and GLP inspections relating to applications through the centralised procedure, within the timeframes laid down in Community legislation and to the standards required by the Agency's quality-management system
- To implement a more risk-based approach to the selection of products for inclusion in annual testing programmes. Improvement of general transparency and communication between all stakeholders
- To coordinate communication and community action with respect to suspected defects or suspected counterfeits of centrally authorised medicinal products
- To strengthen cooperation between Member States on inspection performance and outcomes in order to optimise compliance with Community requirements in relation to GMP, GCP, GLP and, in particular, pharmacovigilance
- To facilitate innovation and continuous improvement of pharmaceutical manufacturers in the context of manufacturing and control methods, through the work of the Process Analytical Technology (PAT) team, ICH cooperation, implementation of quality risk management approaches and in the context of the EU-FDA confidentiality arrangements

4.1 Inspections

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

- GMP and PMF inspection numbers are expected to remain constant with respect to 2005. This takes into account an unexpected rise in activity during 2005 that is unlikely to be maintained, as well as the possibility of some inspections of active substances in accordance with the new GMP requirements
- GCP and pharmacovigilance inspections are expected to increase taking into account the new pharmaceutical legislation. Pharmacovigilance inspections, both routine and 'for cause', are an important element of regulatory authorities' actions relating to risk-management of pharmaceuticals
- Further development of policy, procedures, shared expertise and increased use of the pharmacovigilance inspection process will be required
- Work on implementation of the EudraGMP database of manufacturing authorisations and GMP certificates is expected to demand significant resources in 2006

- GLP inspections are expected to continue to rise due to the number of studies coming from Canada where no GLP monitoring authority exists. However, the overall numbers will remain low (2-3)

Objectives and key initiatives:

- To coordinate and manage effectively requests for GMP, GCP, pharmacovigilance and GLP inspections relating to applications for products through the centralised procedure, and to adhere to regulatory timelines
- To complete the implementation of legislative and procedural requirements in the area of GMP for active substances and certain excipients *(Road Map action)*
- To coordinate activities and optimise the joint audit programme for GMP inspectorates *(Road Map action)*
- To publish a report on the major deficiencies found during GMP and PMF inspections
- To roll out the first production version of the EU-wide database on manufacturing authorisations and GMP certificates (EudraGMP) *(Road Map action)*
- To strengthen the coordination of inspections in the context of the plasma master file and vaccine antigen master file certification schemes *(Road Map action)*
- To contribute to international harmonisation discussions, in particular on quality systems
- To coordinate any necessary communication and follow-up actions relating to suspected quality defects of centrally authorised products
- Counterfeits: the Agency's Inspections Sector will continue to liaise with the EU medicines enforcement officers on their work to investigate the incidence of counterfeit medicines, especially those authorised centrally. The sector will provide expert input into any investigation and/or enquiry to which it may be asked to contribute, as well as assisting with sampling and testing activities, if required, and coordinating any necessary recalls relating to centrally authorised products

Performance indicators:

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

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

The three main working parties (GMP, GCP and QWP) under the responsibility of the Agency's Inspections Sector will each meet four times in 2006. Related training activities on GCP and quality will also be organised. A meeting of the ad hoc GLP inspection services will be convened to address feedback arising from the SOP on GLP inspections published in 2004. Highlights of their activities will include: the harmonisation of inspection procedures and processes, particularly those relating to inspections of active substances and pharmacovigilance; development of guidelines resulting from the impact of new Community GCP and blood legislation, and from the new pharmaceutical legislation, including revised annexes on radiopharmaceuticals, herbal medicinal products, medicinal gases and biological products. Other work on GMP guidelines will include revision of requirements for manufacture of sterile medicinal products and the need for dedicated facilities for certain product types. A joint GMP/GCP group will address an update on GMP requirements for investigational medicinal products. The Quality Working Party will, additionally, review assessment experiences and existing guidelines with a view towards greater rationalisation of dossier requirements. Cooperation between inspection and assessment functions will continue to be developed, particularly through the work of the Process Analytical Technology team, discussions on minor deviations and marketing

authorisation requirements and joint sessions with GMP inspectors/quality assessors and GCP inspectors/clinical assessors. *(Road Map action)*

4.2 Mutual-recognition agreements

Mutual-recognition agreements (MRAs) between the European Community and partner (third) countries include specific annexes relating to medicinal products and GMP. These allow EU Member States and the MRA partner to mutually recognise conclusions of inspections of manufacturers carried out by the respective inspection services of the other party, and to mutually recognise the manufacturers' certification of conformity to specifications for each batch without re-control at import. The EMEA is responsible for implementation and operational aspects of these MRAs. MRAs with Australia, New Zealand, Switzerland, Canada and Japan are currently operational, but with slightly different provisions as to scope and applicability.

Objectives and key initiatives:

- Harmonisation of operational aspects of the respective mutual-recognition agreements (MRAs)
- Completion of the remaining internal evaluation work and follow-up with new Member States in the context of the EC-Canada MRA
- Continuation of external evaluations in the context of the MRA with Canada
- Impact of EudraGMP database on operation of exchange of information with MRA partners

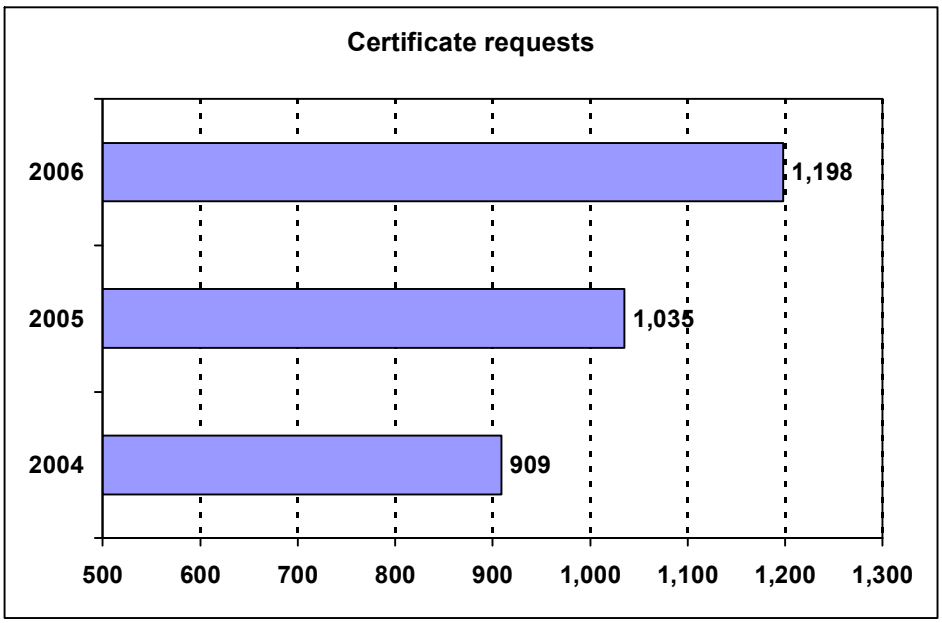
4.3 Certificates of medicinal products

The purpose of the EMEA scheme for certificates of medicinal products is to support the work of health authorities outside the European Union, in particular in developing countries. EMEA certificates are issued by the Agency, on behalf of the European Commission, to confirm the marketing-authorisation status of products authorised by the European Commission through the centralised procedure or of products for which a centralised application has been submitted to the EMEA. The certificates also confirm compliance with good manufacturing practice (GMP) at the manufacturing site(s) where the medicinal product is produced. Health authorities can rely on centralised assessments to support marketing in their own countries, thus facilitating access to these medicines and avoiding the need for costly and duplicative assessment work.

The number of certificate requests is expected to increase by 16%, due to the increased number of approved marketing authorisations. The Agency has a mandate to provide opinions on medicinal products intended for use exclusively in markets outside the EU (cooperation with the WHO) and, work in this area during 2006 will have an impact on the scope of the certification scheme. Similarly, the provision of certificates free of charge to small and medium-sized enterprises (SMEs) will be accommodated. The Agency will continue to work on rationalisation of the process, including staff allocation, IT developments and follow-up to the removal of the legalisation step formerly performed by the European Commission's UK representation.

Performance indicators:

Performance indicator	**Target**
Percentage of certificates issued to requesting parties within the published timeline	95% compliance
Successful removal of legalisation step	Q1 2006



4.4 Sampling and testing

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

The sampling and testing programme for centrally authorised products will continue in 2006, enabling the quality of medicinal products on the market in the EEA to be controlled, using the expertise of the EEA official medicines-control network. Close collaboration between the EMEA, the EDQM and the national authorities in the programme continues to prove invaluable in assuring effective and continued post-marketing surveillance of the quality of medicines.

Objectives and key initiatives:

- To conduct sampling and testing of centrally authorised products
- To implement a new strategy for the testing of medicinal products to accommodate a more risk-based approach to the selection of products for inclusion in annual testing programmes
- Consolidation and simplification of procedures for the sampling and testing programme
- Negotiation of a new contract for the coordination of sampling and testing programmes

Performance indicators:

Performance indicator	**Target**
Number of planned products (34) actually tested	95% of planned products

4.5 Implementation of the clinical trials directives

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

- Further development of GCP-inspection-related procedures and guidelines, to enable greater harmonisation of procedures and practices *(Road Map action)*
- Assistance in the area of competence development
- Support to the operation of the EudraCT database (Lot 1) and completion of the implementation of the next phase of the database (Lot 2)
- Facilitation of dialogue on interpretation of GMP in the context of investigational medicinal products, feeding this into relevant guidance development as required

5 EU telematics strategy

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

The implementation strategy concentrates on a number of projects with high European added value. These projects have been agreed as being EudraNet, EudraVigilance, the database of authorised medicinal products in the EU, electronic submissions, implementation of the clinical trials directive and the good manufacturing practice database.

EU telematics remains a priority area in 2006, which will be the fourth year of implementation by the Agency, with national competent authorities, of the programme of projects described in the Telematics Implementation Plan. The primary responsibility for implementation lies with the Agency, under the auspices of the telematics management structure.

In 2006, development work on all EU telematics projects and sub-projects needs to be continued or started. At the same time, five of the EU telematics systems, namely EudraNet, EudraVigilance, EudraCT, the database of authorised medicinal products in the EU and the Product Information Management (PIM) Review System, will have to be operated, supported, maintained and further developed.

The Agency will advance the work on the new database of GMP certificates and manufacturing authorisations, and will complete the construction of an EU telematics data centre with high availability, high scalability and good performance.

Objectives:

- To progress the development of EU telematics projects (to meet project success criteria)
- To provide high-quality service in EU telematics, including helpdesk facilities, to the EMEA's partners on an ongoing basis

Key initiatives and anticipated project deliverables for telematics in 2006 are as follows:

Project	**Initiatives/deliverables**
The database of authorised medicinal products in the EU	▪ In production with: – Extended data set in place; in addition, product information (SPC, PIL, labels) included in the database for a subset of centrally authorised products – Data in use from those Member States who have provided their product data and signed a memorandum of understanding on data exchange and maintenance – Extended search capability ▪ Creation of different areas (public, protected etc.); it is planed to provide public access by September 2006
EudraVigilance, data warehouse and business intelligence	▪ Regular production releases of EudraVigilance Human and Veterinary ▪ Release of two production versions of data warehouse and business intelligence tools for signal detection and evaluation: for human medicinal products – March 2006, for veterinary – September 2006 ▪ Access to EudraVigilance Human and Veterinary by all marketing-authorisation holders, healthcare professionals, veterinarians and

	the general public
Product information management (PIM)	▪ Second version in production in second quarter 2006 of: – PIM review system – PIM Light authoring tool ▪ Third version in production of: – PIM data exchange standard
EudraGMP	▪ The first production version to be ready for use in the third quarter of 2006
EudraCT	▪ Completion of implementation of the next phase of database with version 3.0.0 to be released in April 2006 and version 4.0.0 in June 2006
Implementation of e-submissions	▪ Date, from which electronic-only submission of MAAs and variations for the centralised procedure is possible, established
Infrastructure	▪ First establishment of central dictionaries
Reference-data model used as a reference for current and future databases and projects	▪ Incremental versions delivered

Performance indicators:

Performance indicator	**Target**
Project management in EU telematics	
Project delivery in accordance with stated timelines	All projects
Project delivery in line with the anticipated budget	All projects
Project deliverables perceived as being in line with expectations	All projects
Provision of service in EU telematics	
Availability of services (excluding planned maintenance downtime) (during EMEA office hours)	98%
Response time to 80% of EU telematics IT helpdesk requests	4 hours*
Response time to 15% of EU telematics IT helpdesk requests	2 days*
Response time to 80% of EudraNet and EudraLink IT helpdesk requests	3 hours*
Response time to 15% of EudraNet and EudraLink IT helpdesk requests	1.5 days*

* These targets reflect the time required to fix the problem.

6 Support activities

6.1 Administration

The Administration Unit has responsibility for a broad range of functions, which includes: managing revenue, expenditure and accounts according to existing rules and regulations; conducting recruitment procedures; managing and administering staff and seconded personnel, including management of continued professional training; and providing and running the necessary infrastructure services for effective functioning of the Agency. The activities entail close cooperation with the European Parliament, Council (Budgetary Authority), Commission and Court of Auditors on matters relating to administration, the budget, personnel, and rules and regulations on finances, audit and accounting. The Administration Unit maintains regular contacts with these institutions and, additionally, with the other European Agencies.

Activities in the administration area will be particularly shaped by three new factors in 2006: the changed working environment following implementation of the new founding regulation, the implementation of new financial accounting rules and modifications to the accounting systems, and the finalisation of the extension of the Agency's premises.

Personnel and budget

The principal activities in the personnel and budget area include:

- Developing the EMEA's human and financial resources and managing them in a timely and accurate manner, including personnel administration, recruitment procedures and professional training, as well as providing information to staff and other concerned persons on these matters
- Managing and developing the human and financial resources of the Agency in accordance with best practice
- Developing further and efficiently managing internal rules and regulations
- Cooperating closely with the European Parliament, Commission, Council and European Agencies on the basis of European standards set by the staff regulations and the financial regulation
- Adapting administrative structures and procedures to the changing environment, particularly to new developments concerning human-resource management, information, and EU rules and regulations

In addition to the core activities mentioned above, the following activities/initiatives will be undertaken in 2006:

- Implementation of implementing rules under the new staff regulations
- Development of an online applications system for external candidates
- Implementation of a new competence-development policy
- Professional-training management directed towards a continuous system of competence development, taking account of the greater scientific orientation of the Agency
- Assessment of financial competency and any training needs
- Implementation of improved activity-based budgeting database and budgetary planning

	2004 final	2005 estimated	2006 projected
Workload			
Total staff	314	379	424
EMEA budget	€ 99,089,103	€ 111,835,000	€ 123,551,000
Selection procedures	27	41	32
Mission claims	897	1,173	1,150
Salary payments	3,715	4,613	5,000
Staff movements	127	329	350

Accounts

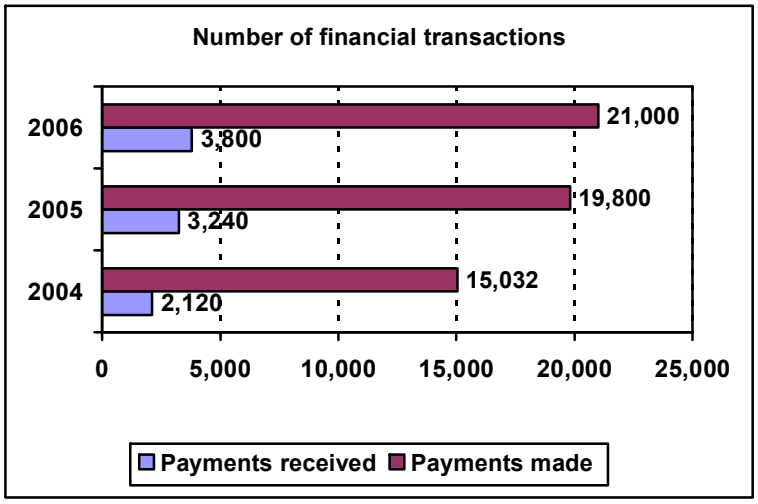
The principal activities in the accounts areas include:

- Maintaining the accounts, making payments and collecting revenue in accordance with the procedures laid down in the financial regulation
- Efficiently managing the cash resources of the Agency and maintaining relationships with the Agency's banks
- Maintaining and developing financial and budgetary accounting systems and reporting tools, including security and helpdesk
- Providing accurate and timely financial information to management

In addition to the core activities in the accounts area, the following activities will be undertaken in 2006:

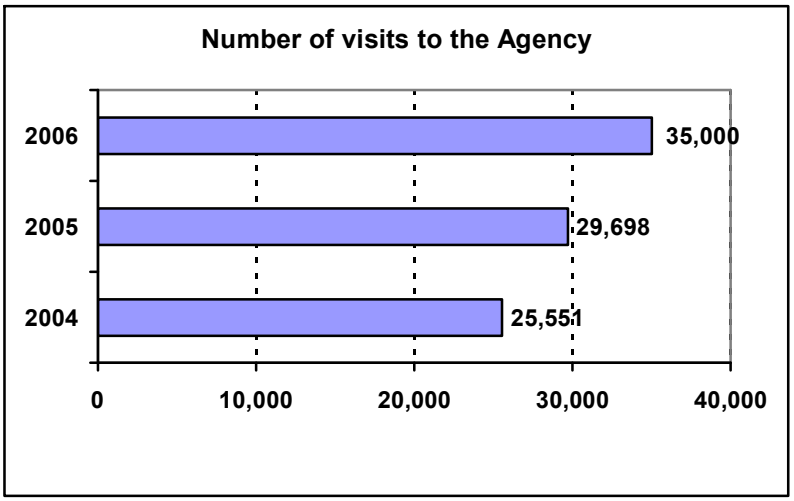
– Specification, selection and implementation of a new integrated accounting system, including fee invoicing, accrual accounting and integration with other administrative systems

– Development of accrual-based accounting (ABAC) and European-agency-management-system (EAMS) projects



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 for meeting rooms, confidential waste, health and safety, fire and emergency plans, business-continuity planning, inventory, office equipment and supplies, maintenance, refurbishment and fitting-out, and management of the catering facilities.



The Agency's work in the infrastructure area is directly linked to the increase in numbers of staff, meetings, telecommunications activities and visitors to the Agency. The maintenance of the Agency's premises is highly labour intensive as it includes all the facilities on each of the floors, plus mechanical and engineering services. A major refurbishment project will take place in 2006 for the additional office capacity acquired for EMEA expansion.

Objectives and key initiatives:

- To manage and ensure sustained functioning of the EMEA infrastructure and building environment
- To undertake major refurbishment project to increase meeting facilities for the Agency's scientific committees and working groups and accommodate new staff following entry into force of the new legislation
- Development of a strategy for any future expansion and reorganisation of the EMEA offices
- Implementation of e-procurement following Commission guidelines
- Revision of security procedures
- Exercising and conduct of continuous testing of the business-continuity plan
- Streamlining the procurement procedure and the management of contracts
- Focus on health & safety in the workplace

6.2 Information technology

The smooth operation of internal EMEA information technology systems is critical to the Agency's ability to perform its tasks. The Agency ensures provision of reliable and robust IT services to its staff, delegates and all users of pan-European systems. It provides efficient support and helpdesk services to the Agency's corporate users. The Agency also ensures archiving and back-up of data, and maintains a high level of security and confidentiality for all data held on EMEA systems. In addition, new services and improvements to the infrastructure as required from business and users alike are constantly introduced, taking into account prevailing technological trends to ensure that infrastructure and facilities are continually improved.

In addition to the maintenance and operational support of EU telematics applications and the development of the new EU telematics projects described earlier, the Agency's efforts and resources in the IT area will be applied to the operation, support, maintenance and development of a number of corporate and business-continuity projects.

Objectives:

- To progress the development programme for corporate projects
- To provide a high level of operational support to all IT activities relating to the Agency's increased responsibility, as well as to provide a reliable and robust IT service to EMEA staff and delegates

Key initiatives to meet the objectives:

- Enhancement of data-centre-management services
- Further development and operational support of the corporate IT programme (see the table below)
- Enhancement of business-continuity IT facilities to support a range of disaster-recovery scenarios
- Development and operational support of a number of internal databases relevant to the Agency's core business activities
- Implement the change to the newly created "europa.eu" domain for websites and e-mail addresses in accordance with the requirement of the European Parliament and Council Regulation

Distribution of workload between different maintenance activities and projects:

	2006 forecast
Maintenance activities	
Provide operational support and data-centre-management services, including EDMS support, applications support (corporate and EU telematics), corporate helpdesk, back-up, servers, SAN and LAN; apply patches and bug fixes to the OS; operate, support and maintain all existing hardware and software of the Agency; ensure virus protection; etc.	49%
Development of new projects	
Business continuity – IT deployment	16%
EMEA core corporate development (SIAMED, online form-evaluation for personnel/recruitment, website development (Portal), SI2, etc.)	13%
Fitting-out of 2nd and 7th-floor IT infrastructure	8%
Web development (including content-management-system pilot)	8%

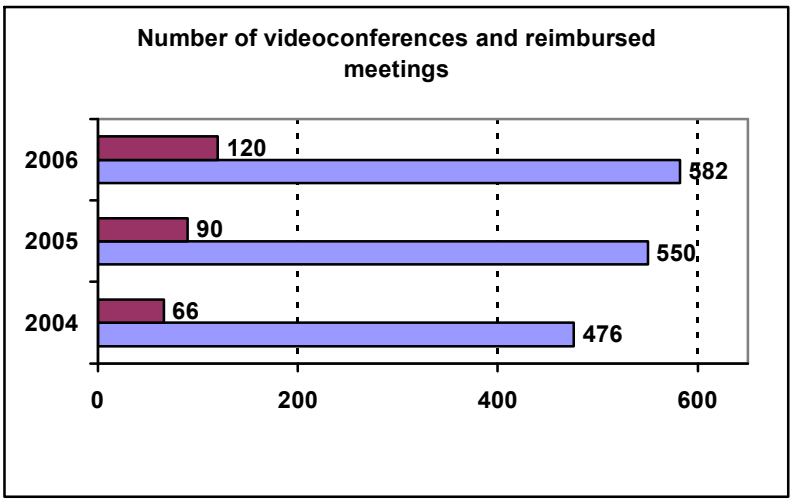
	2006 forecast
EDMS enhancements	3%
Data centre and enterprise-management services deployment	3%
Total	**100%**

Performance indicators:

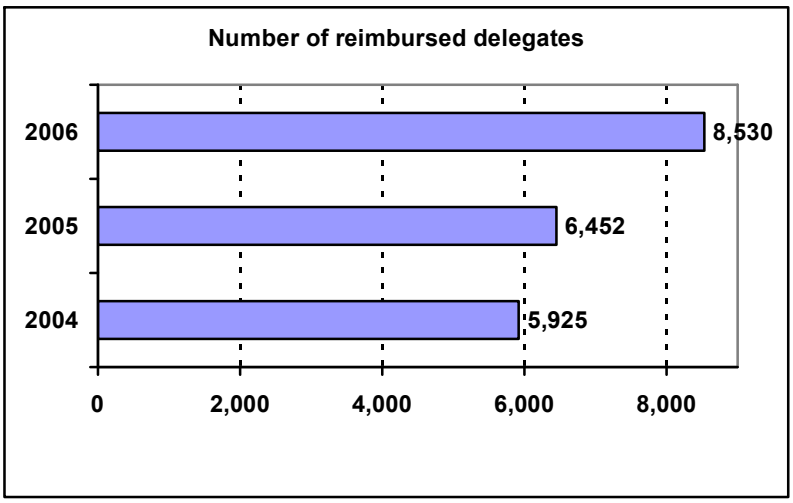
Performance indicator	Target
Corporate availability of services (excluding planned maintenance downtime)	99.5%
Response time to 80% of corporate IT helpdesk requests	2 hours*
Response time to 15% of corporate IT helpdesk requests	1 day*

6.3 Meetings and conferences at the EMEA

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



* These targets reflect the time required to fix the problem.



Trends:

- The number and complexity of tasks and responsibilities undertaken by the Agency in 2006 will result in an increase in the number of meetings and number of experts participating in them
- The number of reimbursed meetings is forecast to grow by 5% in 2006
- The number of reimbursed delegates will grow by 33% in 2006

Objectives and key initiatives:

In addition to the core activities in the area of meetings management

- To put in place procedures for the organisation of emergency meetings. Such meetings would be organised within 24 hours, whether on working days, weekends or national holidays. A need for this type of meeting may emerge, for example, in the case of a pandemic-influenza outbreak
- Further development of the meetings-management system, which will increase efficiency of meetings management. The new system will automate the management of meeting documents, such as invitations, participants' lists and reimbursement forms. The system will incorporate a tracking system for hotel and travel details. In addition, online booking will be made available to delegates
- To facilitate external relationships and to develop the use of up-to-date communication tools, such as video-conferencing, teleconferencing, broadcasting and net meetings. Further development of new forms of meetings broadcasting and wider implementation of video- and teleconferencing
- Development of a 'visitors' centre' on the Agency's website. The site will contain the delegate manual and information about planning and preparation procedures, rooms and facilities, interpretation and languages, technical support, hotel and travel arrangements, reimbursement status, etc.
- Conducting a bi-annual survey to evaluate the level of service support, travel booking and accommodation provided to delegates by the Meeting-management & Conferences Sector

Performance indicators:

Performance indicator	Target
Processing and payment of delegate reimbursements within one month after the meeting ends	80% of reimbursements handled within specified timeframe
Implementation of the Meeting Management System	Fully operational
Delegates' satisfaction regarding travel and accommodation bookings	95%
Assistance and satisfaction of interested parties (EMEA, delegates, national competent authorities, suppliers)	95%

6.4 EMEA document management and publishing

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

Objectives and key initiatives:

In addition to the core activities in the document management and publishing area

- To finalise development and implement records and document management policies
- To facilitate the increase in electronic document use and dissemination through the Internet
- To finalise and continue implementation of the access-to-documents policy, and review the copyright policy
- To implement processes for the management of translation services on behalf of small and medium-sized enterprises

Performance indicators:

Performance indicator	Target
Percentage of requests processed within 48 hours	95%
Percentage of translations processed within established timelines	100%

Annexes

1. **EMEA establishment plan 2004–2006**
2. **Revenue and expenditure overview 2004–2006**
3. **Guidelines and working documents in 2006**
4. **EMEA contact points**
5. **Profiles of EMEA personalities**

Annex 1
EMEA establishment plan 2004 - 2006

(until 30 April 2006)

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

[3] As authorised by the Budgetary Authority and adjusted by the Management Board on 15 December 2005

(as from 1 May 2006)

Category & Grade	**TEMPORARY POSTS**		
	Occupied as per 31.12.04	Authorised for 2005	Authorised for 2006[4]
AD 16	-	-	1
AD 15	1	1	3
AD 14	5	7	4
AD 13	-	4	4
AD 12	32	33	34
AD 11	37	32	33
AD 10	39	34	34
AD 9	-	11	13
AD 8	36	32	32
AD 7	-	41	43
AD 6	-	-	12
AD 5	-	-	-
Total grade AD	*150*	*195*	*213*
AST 11	-	-	-
AST 10	6	6	6
AST 9	-	-	2
AST 8	8	10	10
AST 7	11	12	14
AST 6	31	31	30
AST 5	33	32	32
AST 4	50	51	54
AST 3	11	19	23
AST 2	-	2	10
AST 1	-	21	30
Total grade AST	*150*	*184*	*211*
Total Staff	**300**	**379**	**424**

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

Annex 2
Revenue and expenditure overview 2004-2006

		2004[5]		2005[6]		2006[7]	
		€'000	%	€'000	%	€'000	%
Revenue							
Fees		67,350	*67.76*	77,455	*69.26*	83,580	*67.65*
General EU contribution		17,000	*17.11*	17,900	*16.01*	22,000	*17.81*
Special EU contribution for IT telematics strategy		7,500	*7.55*	7,500	*6.71*	8,000	*6.48*
Special EU contribution for orphan medicinal products		3,985	*4.01*	5,000	*4.47*	4,000	*3.24*
Contribution from EEA		537	*0.54*	530	*0.47*	650	*0.53*
Community programmes		91	*0.09*	250	*0.22*	550	*0.45*
Other		2,922	*2.94*	3,200	*2.86*	4,771	*3.86*
TOTAL REVENUE		**99,385**	*100*	**111,835**	*100*	**123,551**	*100*
Expenditure							
Staff							
11	Staff in active employment	31,774	*32.84*	37,738	*33.74*	40,638	*32.89*
13	Mission expenses	452	*0.47*	616	*0.55*	556	*0.45*
14	Socio-medical infrastructure	281	*0.29*	447	*0.40*	485	*0.39*
15	Exchange of civil servants and experts	750	*0.78*	1,280	*1.14*	1,099	*0.89*
16/17	Social welfare, entertainment and representation expenses	26	*0.03*	86	*0.08*	28	*0.02*
18	Staff insurances	867	*0.90*	1,189	*1.06*	1,230	*1.00*
	Total Title 1	*34,150*	*35.31*	*41,356*	*36.98*	*44,036*	*35.64*
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	8,296	*8.58*	12,934	*11.57*	15,071	*12.20*
21	Expenditure on data processing	13,964	*14.43*	10,922	*9.77*	11,642	*9.42*
22	Movable property and associated costs	627	*0.65*	1,602	*1.43*	1,020	*0.83*
23/25	Other administrative expenditure	568	*0.59*	917	*0.82*	833	*0.67*
24	Postage and communications	423	*0.44*	730	*0.65*	800	*0.65*
	Total Title 2	*23,878*	*24.69*	*27,105*	*24.24*	*29,366*	*23.77*
Operational expenditure							
300	Meetings	5,347	*5.53*	6,133	*5.48*	6,731	*5.45*
301	Evaluations	32,008	*33.09*	35,492	*31.74*	39,559	*32.02*
302	Translation	1,110	*1.15*	1,064	*0.95*	2,945	*2.38*
303	Studies and consultants	80	*0.08*	180	*0.16*	170	*0.14*
304	Publications	141	*0.15*	255	*0.23*	194	*0.16*
305	Community programmes	0	*0.00*	250	*0.22*	550	*0.45*
	Total Title 3	*38,686*	*40.00*	*43,374*	*38.78*	*50,149*	*40.59*
TOTAL EXPENDITURE		**96,714**	*100*	**111,835**	*100*	**123,551**	*100*

[5] Final accounts 2004.
[6] Appropriation/Budget 2005 as of 31 December 2005.
[7] Appropriation/Budget 2006 as adopted by the Management Board on 15 December 2005

Annex 3
Guidelines and working documents in 2006

CHMP Biologics Working Party

Reference number	Document title	Status
EMEA/410/01	Revision of Note for guidance on minimising the risks of TSE transmission via medicinal products	Review of Guideline to be continued in 2006
CPMP/BWP/269/95	Note for guidance on Plasma-derived medicinal products	Revision of guideline expected in 2006 with release for consultation in 2007
CPMP/BWP/3794/03	Guideline on the scientific data requirements for a plasma master file (PMF)	Revision of guideline with release for consultation in Q1 2006
CHMP/BWP/188268/05	Guideline on validation of immunoassay for the detection of antibody to human immunodeficiency virus (Anti-HIV) in plasma pools	Released for consultation in September 2005 Finalisation of guideline in 2006
CHMP/BWP/188270/05	Guideline on validation of immunoassay for the detection of Hepatitis B virus surface antigen (HbsAg) in plasma pools	Released for consultation in September 2005 Finalisation of guideline in 2006
CPMP/BPWG/BWP/561/03	Note for Guidance on the Warning on transmissible agents in Summary of Product Characteristics (SPCs) and Package Leaflets for Plasma-derived medicinal products	Review of guideline in Q1/2 2006, if revision needed, release for consultation in Q3/4 2006
EMEA/CPMP/BWP/2879/02	CHMP Position Statement on Creutzfeldt-Jakob Disease and plasma derived and urine-derived medicinal products	Review and update in Q1/2 2006
EMEA/CPMP/BWP/3752/03	CPMP Position Statement on West Nile Virus and plasma-derived medicinal products	Review of position statement in 2006
EMEA/CHMP/BWP/329312/2005	Guideline on similar biological medicinal products containing biotechnology derived proteins as active substances: Quality issues	Finalisation of guideline in Q1 2006
Ref. 3AB4A/Rev. Dec 1994	Revision of the Guideline on Production and Quality Control of Monoclonal Antibodies	Revision of guideline expected to be released in Q2/3 2006
	Interferons and neutralising antibodies in multiple sclerosis. Development of a common assay methodology	Work to be continued in 2006
	Concept paper on development of assays for neutralising antibodies for biotech medicinal products	Development of concept paper in 2006
	ICH guideline on manufacturing process development and validation for biological / biotechnological substances	Contribution to development of guideline in 2006
EMEA/CHMP/BWP/388681/2005	Guideline on Virus Safety Evaluation of Biotechnological Investigational Medicinal Products	Guideline expected to be released for consultation in Q2 2006
	Guideline on biological quality aspects of biological medicinal products to be used in Clinical Trials	Development of concept paper in Q2/3 2006
CPMP/BWP/1793/01	Note for Guidance on the use of bovine serum used in the manufacture of human biological medicinal products	Review of guideline in Q2/3 2006
	Guideline on potency testing of cell based immunotherapy medicinal	Guideline expected to be released for consultation in Q3 2006

Reference number	Document title	Status
	products for human use	
3AB7A	Note for guidance on the Use of transgenic animals in the manufacture of biological medicinal products for human use	Review of guideline expected in Q3/4 2006
EMEA/CHMP/BWP/1711/00	Guideline on quality aspects of medicinal products containing active substances produced by stable transgene expression in higher plants	Finalisation of guideline in 2006
EMEA/CHMP/BWP/124446/2005	Guideline on Potency Labelling for Insulin Analogue containing Products with Particular Reference to the use of "International Units" or "Units"	Finalisation of guideline expected in Q2/3 2006
CPMP/BWP/214/96	Guideline on harmonisation of requirements for influenza vaccines	Review of guideline expected in Q2/3 2006
	Guideline on stability data for cumulative storage periods for vaccines/intermediates	Development of concept paper expected in Q2/3 2006
EMEA/CPMP/BWP/2758/02	Note for guidance on pharmaceutical aspects of the product literature for human vaccines	Review of guideline expected in Q2/3 2006
EMEA/CHMP/BWP/3088/99	Note for guidance on Quality, Preclinical and Clinical aspects of gene transfer medicinal products	Review of guideline expected in Q1/2 2006
CPMP/BWP/1700/01	Points to Consider on xenogeneic cell therapy products	Review of guideline expected in Q2/3 2006
CPMP/BWP/41450/98	The Manufacture and Quality Control of Human Somatic Cell Therapy Medicinal Products	Review of guideline expected in Q2/3 2006
	Scientific requirements for the environmental risk assessment for gene therapy medical products	Development of concept paper and guideline jointly with GTWP/SWP in Q1/2 2006
	Influenza vaccines: strain selection	Propose recommendations in 2006
EMEA/CHMP/135148/04	Environmental Risk Assessments for Medicinal products containing, or consisting of, Genetically Modified Organisms (GMOs) (Module 1.6.2)	Released for consultation in January 2005 Finalisation of guideline in 2006
	Commission consultation on the need for a community legal framework on advanced therapies	Scientific input into development of technical annexes in Q1/2 2006

CHMP Blood Products Working Party

Reference number	Document title	Status
CPMP/BPWG/388/95 rev. 1	Note for guidance on the Clinical investigation of Human normal immunoglobulin for intravenous administration (IVIg)	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/1561/99	Note for guidance on the Clinical investigation of recombinant Factor VIII and IX products	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/198/95 rev. 1	Note for guidance on the Clinical investigation of human plasma derived Factor VIII and IX products	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/575/99	Note for guidance on the Clinical investigation of human anti-D immunoglobulin for intravenous and/or intramuscular use	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/283/00	Note for guidance on the Clinical investigation of Human normal immunoglobulin for subcutaneous and intramuscular use	Review and possible revision of the guideline after experience with its use. Concept Paper in 2006

Reference number	Document title	Status
CPMP/BPWG/2656/01	Note for guidance on the Clinical investigation of α1- Antitrypsin Products	If guideline needed, Concept Paper in 2006
CPMP/BPWG/BWP/561/03	Note for guidance on the Warning on transmissible agents in SPCs and package leaflets for plasma-derived medicinal products	Review of guideline
CPMP/BPWG/4222/02	Core SPC for Human plasma Derived Hepatitis-B Immunoglobulin for Intramuscular Use	Core SPC to be finalised in early 2006
CPMP/BPWG/4027/02	Core SPC for Human plasma Derived Hepatitis-B Immunoglobulin for Intravenous Use	Core SPC to be finalised in early 2006
CPMP/BPWG/859/95 rev. 2	Core SPC for Human normal immunoglobulin for intravenous administration (IVIg)	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/574/99 rev. 1	Core SPC for Human anti-D immunoglobulin for intramuscular use	Revision expected to be released for consultation in 2006 and finalised in 2007
CHMP/BPWP/319615/2005	Core SPC for Human anti-D immunoglobulin for intravenous use	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/1619/99	Core SPC for Human plasma derived and recombinant coagulation Factor VIII products	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/1625/99	Core SPC for Human plasma derived and recombinant coagulation Factor IX products	Revision expected to be released for consultation in 2006 and finalised in 2007
CPMP/BPWG/282/00	Core SPC for Human normal immunoglobulin for subcutaneous and intramuscular use	Review and possible revision of the SPC after experience with its use. Concept Paper in 2006
CPMP/BPWG/2657/01	Core SPC on Human α1- Antitrypsin for intravenous use	If core SPC needed, Concept Paper in 2006
CHMP/BPWP/122007/2005	Core SPC for Human plasma derived fibrinogen products	Concept paper released for consultation in 2005. Core SPC to be prepared in 2006 for release for consultation.

CHMP Efficacy Working Party

Reference number	Document title	Status
CHMP/EWP/205/95/Rev.3	Guideline On The Evaluation Of Anticancer Medicinal Products In Man	Implementation of major changes following public consultation; adoption expected in 1/2Q 2006
CPMP/EWP/633/02/Rev. 1	Guideline on the Clinical Development of Medicinal Products for Treatment of HIV Infection	Released for consultation in February 2005. Finalisation expected in 1Q 2006
CPMP/EWP/4937/03	Guideline on the clinical investigation of Antiemetic medicinal products for use in Oncology	Released for consultation in February 2005. Finalisation expected in 1/2Q 2006
CPMP/EWP/553/95/Rev. 1	Guideline on Medicinal Products in the Treatment of Alzheimer's Disease	Concept Paper adopted in 4Q 2005
CPMP/EWP/563/95/Rev. 1	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Parkinson's Disease	Concept paper adopted in 4Q 2005
CPMP/EWP/3635/03	Guideline on Clinical Investigation of Medicinal Products in the Treatment of Social Anxiety Disorder (Social Phobia)	Released for consultation in November 2004. Finalisation expected in 1/2Q 2006
CHMP/EWP/356538/2005	Concept Paper for the development of a Guideline on the development of new products for the treatment of Tobacco and Alcohol Dependence	Concept paper adopted 4Q 2005

Reference number	Document title	Status
CPMP/EWP/788/01	Update of the paediatric section in the Guideline on the Clinical Investigation of Medicinal Products for the treatment of Migraine	Finalisation expected 1Q 2006
CPMP/EWP/252/03	Update of the paediatric section in the Guideline on the Clinical Investigation of Medicinal Products intended for the treatment of Neuropathic Pain	Finalisation expected 1Q 2006
CPMP/EWP/561/98/Rev. 1	Revision of Guideline on the clinical investigation of medicinal products for the treatment of Multiple Sclerosis	Draft revised guideline released for consultation in September 2005. Finalisation expected 3/4Q 2006
	Reflection Paper on Gender Effects in Cardiovascular Medicinal Products	Reflection paper expected 1/2Q 2006
CHMP/EWP/327726/2005	Concept Paper on the Development of a CHMP Guideline on the evaluation of the Medicinal Substances Contained in Drug-Eluting (Medicinal Substance-Eluting) Coronary Stents within the Framework of a Consultation Procedure for Combination Products	Concept Paper expected 1Q 2006
CPMP/EWP/237/95/Rev. 1	Guideline on Antiarrhythmics	Revision to be considered in 2006
CPMP/EWP/234/95/Rev. 1	NfG on the clinical investigation of antianginal medicinal products in stable angina pectoris	Released for consultation in June 2005. Finalisation expected 1/2Q 2006
	Guideline on Ulcerative Colitis	Concept paper expected 1/2 Q 2006
CPMP/281/96/Rev. 1	Revision of Guideline on Clinical Investigation of drugs used in Weight Control	Draft revised Guideline expected to be released for consultation in 2/3Q 2006
CPMP/EWP/2284/99/Rev. 1	Points to Consider on Clinical Investigation of Medicinal Products for the Management of Crohn's Disease	Concept paper on the need for revision expected 1/2Q 2006
CPMP/EWP/4713/03	Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Sepsis	Draft guideline was released for external consultation in May 2005. Finalisation expected 2/3Q 2006
CPMP/EWP/6172/03	Guideline on the Clinical Investigation of Medicinal Products for the Treatment of Hepatitis B	Draft guideline was released for external consultation in February 2005. Finalisation expected 1/2Q 2006
CPMP/EWP/4891/03	Guideline on clinical investigation of medicinal products for treatment of Ankylosing spondylitis	Draft guideline was released for external consultation in June 2005. Finalisation expected 3/4Q 2006
CPMP/EWP/422/04	Guideline on clinical investigation of medicinal products for treatment of Juvenile Arthritis	Draft guideline was released for external consultation in June 2005. Finalisation expected 3/4Q 2006
CPMP/EWP/468/04	Guideline on clinical investigation of medicinal products for treatment of Psoriatic Arthritis	Draft guideline was released for external consultation in June 2005. Finalisation expected 3/4Q 2006
CPMP/EWP/552/95/Rev. 2	Revision of Guideline on Postmenopausal Osteoporosis in Women	Draft revised guideline expected to be released for consultation in 1/2Q 2006
CPMP/EWP/2459/02	Guideline on the use of statistical methods for flexible design and analysis of confirmatory clinical trials	Release for 6-months consultation expected 1Q 2006
CHMP/EWP/83561/2005	Guideline on Clinical Trials in Small Populations	Draft Guideline released for consultation in March 2005. Finalisation expected 2/3Q 2006
CPMP/EWP/226/02	Guideline on clinical pharmacokinetic investigation of the pharmacokinetics of peptides and proteins	Released for consultation in July 2005. Finalisation expected 2/3Q 2006
CPMP/EWP/968/02	Guideline on the evaluation of the pharmacokinetics of medicinal products in the paediatric population	Release for consultation expected 1/2Q 2006
CHMP/EWP/195220/2005	Guideline on Reporting the Results of Population Pharmacokinetic Analyses	Release for consultation expected in 1/2Q 2006
	Guideline on the evaluation of the pharmacokinetics of highly variable	Concept paper expected 1Q 2006

Reference number	Document title	Status
	medicinal products	
	Concept Paper on Pharmacogenetics in PK Studies	Concept paper expected 1Q 2006
CPMP/EWP/504/97/Rev. 1	Revision of Guideline on clinical investigation of medicinal products in prevention and treatment of Acute Respiratory Distress Syndrome	Released for consultation in September 2005. Finalisation expected 3/4Q 2006
CHMP/EWP/6235/04	Guideline on clinical investigation of medicinal products for the prophylaxis of venous thromboembolism in non-surgical patients	Released for consultation in May 2005. Finalisation expected 3/4Q 2006
CPMP/EWP/555/95/Rev. 1	Revision of Guideline on clinical trials with haematopoietic growth factors for the prophylaxis of infection following myelosuppressive or myeloablative therapy	Draft revised guideline expected to be released for consultation in 1/2Q 2006
CPMP/EWP/707/98/Rev. 1	Revision of Points to consider on Clinical Investigation of Medicinal Products for Prophylaxis of Intra- and Post-operative Venous Thromboembolic Risk	Draft guideline to be released for consultation 3/4Q 2006
	Multidisciplinary Guidelines developed by Other Working Parties	EWP Contribution
ICH E14	The clinical evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs	Input into follow-up on the Guideline

CHMP Gene Therapy Working Party

Reference number	Document title	Status
CHMP/SWP/273974/2005	Guideline on non-clinical testing for inadvertent germline transmission of gene transfer medicinal products.	Released for 6-month consultation in November 2005. Finalisation expected 3Q 2006
CHMP/GTWP/203821/2005	Guideline on non-clinical studies prior to clinical use of gene therapy medicinal products.	Concept paper adopted November 2005. Draft guideline expected to be released for consultation in 3/4Q 2006
CHMP/GTWP/203831/2005	Guideline on scientific requirements for the environmental risk assessment of gene therapy medicinal products.	Concept paper adopted November 2005. Draft guideline expected to be released for consultation in 3/4Q 2006
	Reflection paper on retroviral and lentiviral vectors issues (benefits and risks, insertional mutagenesis)	Reflection paper expected 2/3Q 2006
	Gene therapy vaccines, including vectors and naked DNA	Reflection paper to be considered in conjunction with VWP and BWP
CPMP/BWP/3088/99	Note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products.	Survey of current relevant issues for recommendation of update or addendum
	ICH Considerations for the minimization of the risk of germline transmission	GTWP contribution

CHMP Paediatrics Working Party

Reference number	Document title	Status
	Draft Concept paper on the impact of lung and heart immaturity when investigating medicinal products	Concept paper to be finalised by 1Q 2006 and draft Guideline expected to be released by 3Q 2006

Reference number	Document title	Status
	intended for neonatal use	
	Draft Concept paper on the impact of brain immaturity when investigating medicinal products intended for neonatal use	Concept paper to be finalised by 2 Q 2006 and draft Guideline expected to be released by 4Q 2006
	Draft Guideline on the impact of liver immaturity when investigating medicinal products intended for neonatal use	Draft Guideline to be released 2Q 2006
	Reflection Paper: Formulations of Choice for the Paediatric Population	Update reflection paper following comments received from consultation period in 1Q 2006 Develop as Guidance documents in 3 Q 2006
	Assessment of Paediatric Needs: - chemotherapy (part II) - migraine - nephrology (particularly diuretics) - anaesthesiology/sedation - diabetes type II - obstructive lung diseases - psychiatry (mainly anti-depressants/neuroleptics).	Expected to be released for consultation 3/4Q 2006

CHMP Pharmacogenetics Working Party

Reference number	Document title	Status
EMEA/382026/2005	Concept Paper on Pharmacogenetics in PK Studies	Concept paper expected 1Q 2006
EMEA/MB/374230/2005	Reflection Paper on Biobanks Issues Regarding Pharmacogenetics	Expected to be finalised 3Q 2006
EMEA/381019/2005	Reflection paper on the use of genomics in clinical intervention trials to explore interaction between treatment and genomic traits	Draft Reflection paper expected 3Q 2006
	ICH Guideline on the Terminology in Pharmacogenetics	Concept paper expected 2 Quarter 2006 Draft guideline expected 4Q 2006
EMEA/MB/374230/2005	Guideline on Pharmacogenetics briefing meetings	Expected to be finalised 1Q 2006

CHMP Pharmacovigilance Working Party

Reference number	Document title	Status
-	Volume 9A of the Rules Governing Medicinal Products in the EU	To be finalised in 2006 in light of comments received during public consultation
-	Conduct of Pharmacovigilance for Centrally Authorised Products (Chapter II.2.A of Volume 9A)	Revision reflecting new Community legislation and the EU Risk Management Strategy to be released for public consultation in 2006
-	Crisis Management Plan for Centrally Authorised Products (Chapter II.2.B of Volume 9A)	Revision reflecting new Community legislation and the EU Risk Management Strategy to be released for public consultation in 2006
EMEA/CHMP/235910/2005	CHMP Guideline on the Conduct of Pharmacovigilance for Medicines Used by the Paediatric Population	To be finalised in 2006 in light of comments received during public consultation

Reference number	Document title	Status
-	CHMP Guideline on the Conduct of Pharmacovigilance for Vaccines	To be drafted in 2006 after completion of public consultation of the Concept Paper (CHMP/PhVWP/372004/2005)
-	CHMP Guideline on Handling Direct Healthcare Professional Communication for Medicinal Products for Human Use	To be released for public consultation in 2006
-	*Other Guidelines in relation to public communication of pharmacovigilance information*	Various concept papers and guidelines Development of in the context of the EMEA communication and transparency strategy in order to implement new Community legislation
-	Criteria for recall and repackaging following urgent safety restriction and variation procedures	Criteria to be developed for discussion by CHMP
-	Good Pharmacovigilance Practice	Drafting to be continued

EudraVigilance Expert Working Group and EudraVigilance Steering Committee

Reference number	Document title	Status
Eudralex: Volume 9A Chapter III	'Guidelines for Marketing Authorisation Holders, Competent Authorities and the Agency on the Electronic Exchange of Pharmacovigilance Information in the EU'	Revision reflecting new community legislation with regard to electronic reporting of adverse reactions
	EudraVigilance Access Policies	To be finalised
	EudraVigilance Signal Detection Methods and tools	To be finalised
	EudraVigilance Signal Detection and Data Analysis training material	To be prepared
	Electronic Reporting of ICSRs and EudraVigilance training material	Revision
ICH E2B (R)	E2B(R): Revision of the E2B(M) ICH Guideline on Clinical Safety Data Management Data Elements for Transmission of Individual Case Safety Reports	This guideline provides additional information and clarification as well as some modifications to the ICH E2B guideline signed-off on July 17, 1997 and modified as E2B(M) guideline in November 2000. It incorporates adjustments based on the experience gained after the implementation of the guideline in the three regions. It is recommended that the reader reviews this document as well as the companion document M2 ICSR Message Specification.
ICH M5	M5: Data Elements and Standards for Drug Dictionaries	This guideline has been released for consultation under Step 2 of the ICH process on 10 May 2005. The lack of internationally harmonized standards related to core sets of medicinal product information and medicinal product terminology is hindering the scientific evaluation and comparison of product data as well as healthcare. This applies in particular to the area of pharmacovigilance, where the exchange and management of

Reference number	Document title	Status
		medicinal product information in expedited and periodic adverse reaction reports at the international level is a key aspect of ensuring drug safety. This document provides guidance on the harmonized standards that are being proposed by the ICH M5 EWG to facilitate the exchange and practical use of medicinal product data by regulators and pharmaceutical industry.
ICH M5 Controlled Vocabularies	ICH M5 Controlled Vocabularies Routes of Administration	Revision
ICH M5 Controlled Vocabularies	ICH M5 Controlled Vocabularies Pharmaceutical Dose Forms	To be finalised
ICH M5 Controlled Vocabularies	ICH M5 Controlled Vocabularies Units and Measurements	Revision
ICH M5 Controlled Vocabularies	ICH M5 Active Ingredients	To be finalised
ICH Terminology Maintenance	ICH Terminology Maintenance Options Paper	To be prepared
ICH M2	ICH M2 Message specifications for E2B(R) and M5 business requirements	To be finalised

CHMP Safety Working Party

Reference number	Document title	Status
CPMP/SWP/4447/00	Guideline on Environmental Risk Assessment of Medicinal Products for Human Use	Guideline re-released for consultation in January 2005. Finalisation expected 1Q 2006
CPMP/SWP/5199/02	Guideline on the Limits for Genotoxic Impurities	Draft Guideline re-released for consultation in June 2004. Finalisation expected 1Q 2006
EMEA/CHMP/SWP/149188/2004	Guideline on the Need for Pre-clinical Testing of Human Pharmaceuticals in Juvenile Animals	Draft Guideline released for consultation in 4Q 2005. Finalisation expected 4Q 2006
EMEA/CHMP/SWP/178958/2004	Guideline on Drug-Induced Hepatotoxicity	Draft Guideline expected to be released for consultation in 2Q 2006
EMEA/CHMP/SWP/258498/2005	Guideline on the Non-Clinical Development of Fixed Combinations of Medicinal Products	Draft Guideline released for consultation in 4Q 2005. Finalisation expected 3Q 2006
CPMP/SWP/QWP/4446/00	Guideline on Specification Limits for Residues of Metal Catalysts in Medicinal Products	Draft Guideline expected to be re-released for consultation in 2Q 2006
EMEA/CHMP/SWP/203927/2005	Guideline on Risk Assessment of Medicinal Products on Human Reproductive and Development Toxicities: from Data to Labelling	Draft Guideline expected to be released for consultation in 2Q 2006
EMEA/CHMP/SWP/94227/2004	Guideline on the Investigation of Dependence Potential of Medicinal Products	Draft Guideline released for consultation in 2Q 2005. Finalisation expected 2Q 2006
EMEA/CPMP/SWP/2877/00	Guideline on the Assessment of Carcinogenic and Mutagenic Potential of anti-HIV Medicinal Products.	Draft Guideline expected to be released for consultation in 2Q 2006
EMEA/CHMP/SWP/5382/2003	Note for Guidance on the Quality, Preclinical and Clinical Aspects of Gene Transfer Medicinal Products:	Draft Annex released for consultation in 4Q 2005. Finalisation of Annex expected 4Q 2006

Reference number	Document title	Status
	Annex on Nonclinical Testing for Inadvertent Germline Transmission of Gene Transfer Vectors	
	Guideline on NRTI-Induced Mitochondrial Toxicity	Draft Guideline expected to be released for consultation in 4Q 2006
	Guideline on A Reduced Toxicology Package to Support Early Clinical Investigative Studies	Concept paper expected to be adopted by the CHMP in 2Q 2006
CPMP/372/01	Points to Consider on the Non-Clinical Assessment of the Carcinogenic Potential of Insulin Analogues	Possible revision
CPMP/SWP/104/99	Note for Guidance on Repeated Dose Toxicity	Possible revision
Eudralex vol. 3B3BS1A	Note for Guidance on Single Dose Toxicity	Possible revision
ICH S7B	Non Clinical Studies for Assessing Risk of Repolarisation Associated Ventricular Tachyarrhythmia	SWP contribution
	ICH Consideration Paper for the minimisation of the risk of germline transmission	SWP contribution

CHMP Scientific Advice Working Party

Reference number	Document title	Status
	Standard Questions & Answers documents for frequently asked questions on various topics to be defined.	To be developed in collaboration with the relevant working parties

CHMP Similar Biological (Biosimilar) Medicinal Products Working Party

Reference number	Document title	Status
EMEA/CHMP/42832/05	Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues	Finalisation 1Q 2006 after consultation phase
EMEA/CHMP/94528/05	Annex Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues: Guideline on similar biological medicinal products containing Somatropin	Finalisation 1Q 2006 after consultation phase
EMEA/CHMP/94526/05	Annex Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues: Guideline on similar biological medicinal products containing recombinant Erythropoietins	Finalisation 1Q 2006 after consultation phase
EMEA/CHMP/32775/05	Annex Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – non-clinical and	Finalisation 1Q 2006 after consultation phase

Reference number	Document title	Status
	clinical issues: Guideline on similar biological medicinal products containing recombinant human Insulin	
EMEA/CHMP/31329/05	Annex Guideline similar biological medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues: Guideline on similar biological medicinal products containing recombinant Granulocyte-Colony Stimulating Factor	Finalisation 1Q 2006 after consultation phase
EMEA/CHMP/94526/05	Annex Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues: Guideline on similar biological medicinal Products containing recombinant α-Interferons	Concept Paper planned to be released for consultation 2Q 2006, guideline to be released for consultation 4Q 2006
EMEA/CHMP/BMWP/246511/2005	Guideline on Immunogenicity Assessment of Biological/Biotechnology-Derived Proteins	Concept Paper released for consultation January 2005, guideline to be released for consultation 4Q 2006
(CPMP/3097/02)	Note for Guidance on Comparability of medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues	Revision released for 3-months consultation 3Q 2005

CHMP Vaccine Working Party

Reference number	Document title	Status
CPMP/VEG/15/04	Guideline on clinical evaluation of vaccines	Released for consultation in May 2005 Finalisation of revision in 2006
	Guidance on the development of vaccines against emerging or re-emerging diseases, such as SARS, pathogens potentially used for bioterrorism, monovalent polio vaccines to be used in the event of a re-occurrence of polio in the post-eradication period.	New guideline, as required
CPMP/BWP/2289/01	Points to Consider on the Development of Live Attenuated Influenza Vaccines	Revision of points to consider document to include guidance for a pandemic scenario.
CPMP/1100/02	Note for guidance on the development of vaccinia based vaccines against smallpox	Possible revision
	Guideline on requirements for evaluation of therapeutic vaccines	New guideline
EMEA/CHMP/VEG/134716/2004	Guideline on adjuvants in vaccines for human use	Revision or publication of explanatory note

CHMP Working Party on Cell-based Products

Reference number	Document title	Status
	Guideline on quality, preclinical and clinical testing of tissue-engineered products	New guideline
	Guideline on quality, preclinical and clinical testing of human cell therapy medicinal products	New guideline, incorporating and replacing BWP guidance CPMP/BWP/41450/98: Points to consider on the manufacture and quality control of human somatic cell therapy medicinal products

CHMP Working Group with Patients' and Consumers' Organisations

Reference number	Document title	Status
EMEA/149479/2004/Final	Recommendations and proposals for action	Implementation planned for 2006
EMEA/14610/04/Final	Criteria to be fulfilled by Patients' and Consumers' Organisations involved in EMEA activities	Criteria-based evaluation of Patients' and Consumers' Organisations with interest in EMEA activities planned for 2006

CHMP Invented Name Review Group

Reference number	Document title	Status
CPMP/328/98 Rev 5	Guidelines on the acceptability of invented names for medicinal products processed through the centralised procedure	Revision to be finalised in 2006

CVMP Efficacy Working Party

Reference number	Document title	Status
EMEA/CVMP/EWP/117899/2004-CONSULTATION	Guideline on Efficacy and Target Animal Safety Data Requirements for Veterinary Medicinal Products intended for Minor Uses and Minor Species	Consulation ended 31 October 2005 To be finalised Q1 2006 – Q2 2006
EMEA/CVMP/83804/2005-CONSULTATION	Fixed combinations of veterinary pharmaceutical products Multidisciplinary guideline: Involved WPs are EWP, SWP and ERAWP	End of consultation 30 April 2006 To be finalised Q2 2006 – Q3 2006
-	Guideline on the SPC for anthelmintics	To be released for consultation Draft Guideline to be prepared for adoption by CVMP in Q2 2006
-	Dossier requirements for oncology products Multidisciplinary guideline: Involved WPs are EWP, SWP and ERAWP	Consultation of concept paper ended 30 September 2005 Draft Guideline to be prepared for adoption by CVMP in 2007
EMEA/CVMP/005/00-Rev.1	Testing and evaluation of the efficacy of antiparasitic substances for the treatment of tick and flea infestations in dogs and cats	Revision of existing guideline Draft guideline to be prepared for public consultation
-	Dossier requirements for bibliographic applications Multidisciplinary Guideline: Involved WPs are EWP, SWP and CMDV	Concept paper to be released for public consultation (tbc)
-	Alternatives to animal testing	Working party considerations during 2006
-	Conduct of efficacy studies for NSAIDs	Revision of existing guideline Concept paper to be developed in 2006
-	VICH Target Animal Safety – Pharmaceuticals	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)

CVMP Environmental Risk Assessment Working Party

Reference number	Document title	Status
-	Technical Guidance Document on the environmental impact assessment of veterinary medicinal products (issues where the VICH Phase II document recommends “seek regulatory guidance”)	Guideline expected to be finalised by Q2 2006 – Q3 2006 following public consultation
-	Technical Guidance Document on the environmental risk assessment of veterinary medicinal products (issues where the VICH Phase II document recommends “seek regulatory guidance”)	Guideline to be released for public consultation by Q1 2006
-	Implementation of the new legal provisions regarding environmental risk assessment (Directive 2001/82/EC, amended by 2004/28/EC)	Proposals to be developed by Q1 2006
-	Alternatives to animal testing	WP considerations to be developed by Q2 2006

CVMP Immunologicals Working Party

Reference number	Document title	Status
-	Reduced requirements for IVMPs intended for minor species or minor indications	Draft Guideline to be prepared for adoption by CVMP Q1 2006
-	User Safety Guideline	Draft Guideline to be prepared for adoption by CVMP Q1 2006
-	Guideline on EU requirements for batches with maximum and minimum titre or batch potency for developmental safety and efficacy studies.	Draft Guideline to be prepared for adoption by CVMP (following revision of Annex I of Directive 2001/82/EC)
-	Proposed approach for the consideration of substances other than active ingredients present in veterinary medicinal products.	Draft Guideline to be prepared for adoption by CVMP Q4 2006
-	Procedure to be followed when a batch of a vaccine finished product is suspected to be contaminated with Bovine Viral Diarrhoea (BVD) virus	Concept paper to be released for public consultation Q1 2006
-	Requirements for Combined Veterinary Vaccines	Concept paper to be released for public consultation Q1 2006
-	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 released for public consultation Q1 2006
-	Requirements for in-use stability claims	Concept paper to be developed Q1 2006
-	Preparation of new master seeds	Concept paper to be developed Q1 2006
-	The impact of Maternally Derived Antibodies on vaccination	Concept paper to be developed Q4 2006
-	Immunity induced by bacterial vaccines	Concept paper to be developed Q4 2006
-	Validation of patch potency tests and establishing pass criteria	Concept paper to be developed Q4 2006
-	VICH Guideline on Target Animal Safety for Veterinary Biological Products.	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)
-	VICH Guideline on examination of live veterinary vaccines for reversion to virulence	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)
-	VICH Guideline for the tests on the presence of extraneous viruses in veterinary viral vaccines	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)
-	VICH Guideline on the detection of mycoplasma	Draft Guideline to be prepared for public consultation (EU contribution to development of guideline)

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMEA/CVMP/413/99-Rev.2	VEDDRA List of clinical terms for reporting adverse reactions in animals to veterinary medicines	To be revised as per PhVWP-V work program for 2006 (VEDDRA sub-group to meet May 06, adoption by PhVWP Jul 06 & CVMP Sept 06)
EMEA/CVMP/891/04	VEDDRA List of clinical terms for reporting Suspected Adverse Reactions in Human Beings to veterinary medicinal products	To be revised as per PhVWP-V work program for 2006 (VEDDRA sub-group to meet May 06, adoption by PhVWP Jul 06 & CVMP Sept 06)
EMEA/CVMP/553/03	List of species and breeds for electronic reporting of adverse reactions in veterinary pharmacovigilance	To be revised as per PhVWP-V work program for 2006 (VEDDRA sub-group to meet May 06, adoption by PhVWP Jul 06 & CVMP Sept 06)
EMEA/CVMP/900/03	Guideline on a strategy for triggering pharmacovigilance investigations preceding regulatory actions by EU competent authorities	Update required to take into account the to be agreed harmonised approach on the use of EudraVigilance Veterinary data
EMEA/CVMP/143/99-Rev.1	Note for Guidance: Conduct of pharmacovigilance for veterinary medicinal products authorised through the mutual recognition procedure	Update required to take into account the to be agreed harmonised approach on the use of EudraVigilance Veterinary data
-	Guideline on PSUR assessment [further to the review of the EU pharmaceutical legislation]	Concept paper has been prepared in 2005 (EMEA/CVMP/PhVWP/145320/05) Following the consultation period the development of the guideline will be initiated
-	Guideline on the use of data contained in EudraVigilance and EudraVigilance Veterinary (EVvet) [further to the review of the EU pharmaceutical legislation]	To be developed further to clarification of the EMEA responsibilities regarding evaluation of data contained in EudraVigilance and transparency of the data by the Commission
-	Guideline on ongoing risk/benefit evaluation [further to the review of the EU pharmaceutical legislation]	On the basis of a concept paper it will also be considered whether this guidance may be incorporated in the above guideline on PSUR assessment
CVMP/VICH/547/00	VICH GL24: Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Reports	To be finalised Q1 2006
CVMP/VICH/646/01	VICH GL29: Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (PSUs)	To be finalised Q1 2006
CVMP/VICH/647/01	VICH GL30: Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms	To be finalised Q1 2006.
	VICH GL35: Pharmacovigilance of Veterinary Medicinal Products: Electronic standards for transfer of data	To be finalised Q1 2006.
EMEA/CVMP/PhVWP/110607/2005-CONSULTATION	Veterinary Pharmacovigilance in the EU – A simple guide to reporting adverse reactions	Released for consultation April 2005. End of consultation 18 October 2005. To be adopted in 2006.
EMEA/CVMP/PhVWP/145320/2005-CONSULTATION	Concept Paper on a Periodic Safety Update Report (PSUR) assessment guideline for veterinary medicinal products	Released for consultation July 2005. End of consultation 30 September 2005. To be adopted in 2006.

CVMP Safety Working Party

Reference number	Document title	Status
EMEA/CVMP/66781/200-CONSULTATION	Guideline on Safety and Residue Data Requirements for Veterinary Medicinal Products intended for Minor Uses or Minor Species	Consulation ended 31 October 2005 To be finalised Q1 2006 – Q2 2006
EMEA/CVMP/83804/2005-CONSULTATION	Fixed combinations of veterinary pharmaceutical products Multidisciplinary guideline: Involved WPs are EWP, SWP and ERAWP	End of consultation 30 April 2006 To be finalised Q2 2006 – Q3 2006
-	Guideline on the approach on how to prove whether a substance is capable of pharmacological action or not	Draft Guideline to be developed Q1 2006 – Q2 2006
-	Guideline on the assessment of pharmacological/pharmacodynamic data to establish a pharmacological ADI	Draft Guideline to be developed Q1 2006 – Q2 2006
-	Dossier requirements for oncology products Multidisciplinary guideline: Involved WPs are EWP, SWP and ERAWP	Draft Guideline to be prepared for adoption by CVMP in 2007
-	Extrapolation of MRLs and gathering of information allowing to establish a scientific basis from "Absorption, Distribution, Metabolism and Excretion" similarities/differences	Working Party considerations Q1 2006 – Q2 2006
-	Approach for the establishment of provisional MRLs to ensure adequate safety margin while awaiting completion of further studies	Working Party considerations Q1 2006
-	Conditions for use of faecal binding studies for the establishment of microbiological ADI	Working Party considerations Q1 2006 – Q2 2006
-	Dossier requirements for bibliographic applications Multidisciplinary Guideline: Involved WPs are EWP, SWP and CMDV	Action: Concept paper to be released for public consultation *(tbc)*
-	Alternative reference limits	Working Party considerations Q1 2006 – Q2 2006
-	Guideline on metabolism and residue kinetics	Support to EU position in VICH during 2006

CVMP Scientific Advice Working Party

Reference number	Document title	Status
EMEA/CVMP/854/02-Rev.1	EMEA guidance for companies requesting scientific advice	Review SOP and Guidance document in 2006 and revise where necessary in view of experience gained with the procedure

CVMP Scientific Advisory Group on Antimicrobials

Reference number	Document title	Status
-	Further guidance on pre-approval information according to VICH GL27	Draft Guideline to be developed by 2Q 2006

Reference number	Document title	Status
-	Revision of SPC antimicrobials guideline	Draft Guideline to be developed by 2Q 2006
-	Support of the EU position on the VICH topic: Standardization of Antimicrobial Susceptibility Testing Methodology and Interpretive Criteria	Support to EU position during 2006

CVMP General

Reference number	Document title	Status
EMEA/CVMP/064/05	Guideline on the Summary of Product Characteristics for Immunological Veterinary Medicinal Products	Consultation ended 31 December 2005 To be adopted 2006
EMEA/CVMP/065/05	Guideline on the summary of product characteristics for Pharmaceutical Veterinary Medicinal Products	Consultation ended 31 December 2005 To be adopted 2006

Joint CHMP/CVMP Quality Working Party

Reference number	Document title	Status
CPMP/QWP/3309/01 CVMP/961/01	Note for Guidance on the use of near infrared spectroscopy by the Pharmaceutical Industry and the Data to be forwarded in the Part II of the Dossier for a Marketing Authorisation	Revision to take account of advances in this area
CPMP/QWP/155/96	CPMP Guideline on pharmaceutical development	Revision following finalisation of ICH Q8
CPMP/QWP/3015/99	CPMP Guideline on Parametric Release	Revision following finalisation of ICH Q8, in collaboration with GMP inspectors
CPMP/ICH/367/96.	CPMP Guideline on Specifications	Revision following finalisation of ICH Q8
CHMP/QWP/185401/2004	CHMP Guideline for the Requirements to the Quality part of a request for authorisation of a clinical trial.	Finalisation of the guideline
EMEA/CVMP/128710/2004 – CONSULTATION corr	Guideline on Quality data requirements for Veterinary Medicinal Products for Minor Uses or Minor Species (MUMS).	Finalisation following end of the consultation
	CVMP Guideline on Parametric Release based on the existing CPMP Guideline (CPMP/QWP/3015/99).	Publication of draft Guideline and finalisation following end of public consultation.
EMEA/CHMP/QWP/49313/2005 corr.	Guideline on the pharmaceutical Quality of Inhalation and Nasal Products.	Revised jointly with Health Canada. Finalisation following end of public consultation. Q2 2006
	CHMP Guideline on the Suitability of the Graduation of Delivery Devices for Liquid Dosage Forms.	Finalisation following end of public consultation. Q3 2006
(EMEA/CVMP/134/02 Rev 1, CPMP/QWP/227/02 Rev 1).	Guideline on Active Substance Master File Introduction of an Annex for Herbal Medicinal Products, on referral by the HMPC (see section V.5).	Publication of revised Guideline for public consultation.. Q1 2006
(CPMP/QWP/419/03).	Guideline on excipients, antioxidants and antimicrobial preservatives	Finalisation following end of public consultation.

Reference number	Document title	Status
CPMP/SWP/QWP/4446/00.	Guideline on specification limits for residues of heavy metal catalysts	Finalisation with SWP, following end of public consultation.
(CPMP/SWP/5199/02).	Guideline on the limits of genotoxic impurities	Finalisation with SWP, following end of public consultation.
Eudralex 3AQ20A	Radiopharmaceuticals	Revision of the 1991 guideline on to include a section on Positron Emission Tomography (PET). Development of a Guideline following release of Concept Paper.
EMEA/CHMP/167068/2004-ICH	Guideline on pharmaceutical development (Q8)	Contribution to finalisation of ICH Guideline, following public consultation
EMEA/INS/GMP/157614/2005-ICH,	Contribution to finalisation of ICH Guideline on risk management (Q9), following public consultation	Contribution to finalisation of ICH Guideline, following public consultation
ICH Q10	Contribution to Quality Systems initiative (ICH Q10)	Contribution to ICH concept paper and Guideline
EMEA/CVMP/VICH/899/99–Rev.1	Guideline on Stability testing of new veterinary drug substances and medicinal products, GL3 (R)	Contribution to finalisation of VICH Guideline, following public consultation
CVMP/VICH/837/99-Rev.1-Consultation CVMP/VICH/838/99-Rev.1-Consultation	Guidelines of impurities in new veterinary drug substances and impurities in new veterinary medicinal products, GL10 (R) and GL 11 (R)	Contribution to finalisation of VICH Guideline, following public consultation
EMEA/CVMP/VICH/810/04-Rev.1	Guideline on specifications: test procedures and acceptance criteria for new drug substances and new drug products: Chemical substances, GL 39	Contribution to finalisation of VICH Guideline, following public consultation
EMEA/CVMP/VICH/811/04-Rev.1	Guideline on specifications: test procedures and acceptance criteria for biological/biotechnological products, GL 40	Contribution to finalisation of VICH Guideline, following public consultation

Committee on Orphan Medicinal Products

Reference number	Document title	Status
	Guideline on application of Article 8 of Regulation (EC) 141/2000	New guideline

Committee on Herbal Medicinal Products (HMPC)

Reference number	Document title	Status
EMEA/HMPC/166326/2005	Final 'Guideline on the clinical assessment of fixed combinations of herbal substances/herbal preparations'	To be released in 1Q 2006
EMEA/HMPC/104613/2005	Draft 'Guideline on the assessment of clinical safety and efficacy in applications for marketing authorisation for well-established herbal medicinal products or for registration of traditional herbal medicinal products'	To be released in 1Q 2006
EMEA/HMPC/32116/2005	Draft 'Guideline on non-clinical documentation for well-established and traditional herbal medicinal products – Guidance to facilitate mutual recognition and use of bibliographic data'	To be released in 1Q 2006
	Draft 'Template assessment report for the establishment of Community herbal monographs and/or for the inclusion of herbal substances, preparations or combinations thereof in the Community list'	To be released in 1Q 2006
	Draft 'Guideline on CTD for traditional herbal medicinal products'	To be released in 1Q 2006
	Draft 'Template for submission by a Member State of a request for advice on scientific and technical issues relating to the evaluation of (traditional) herbal medicinal products	To be released in 1Q 2006
	Draft procedure and timelines for the submission of a proposal for inclusion in the Communiyt list of herbal substances, preparations and combinations thereof	To be released in 2Q 2006
	Draft 'Guideline on interpretation of requirements to show medicinal use throughout a period of 30 years'	To be released in 2Q 2006
	Draft procedure and templates for the adoption of an opinion of the Committee on the adequacy of the evidence of the long-standing use of a herbal medicinal product, or of a corresponding product, at the request of a Member State	To be released in 2Q 2006
	Draft procedure and templates for the adoption of an opinion of the Committee on a herbal medicinal product, which has been used in the Community for less than 15 years but is otherwise eligible for traditional use registration	To be released in 2Q 2006
	Draft procedure and templates for the adoption (and transmission to the CHMP) of an opinion of the Committee on the herbal substance(s) contained in a herbal medicinal product referred to the Agency under Chapter 4 of Title III of Community Code	To be released in 2Q 2006
EMEA/HMPC/287539/2005	Draft 'Guideline on the declaration of herbal substances/herbal preparations in herbal medicinal products/traditional herbal medicinal products in the SPC'	To be released in 1Q 2006
	Guidance on fumigation of herbal	To be released in 2Q 2006

Reference number	Document title	Status
	substances	
	Guidance on quality assessment of herbal multicomponent mixtures	To be released in 2Q 2006

HMPC Working Party on Community monographs and Community list

Reference number	Document title	Status
EMEA/HMPC/340719/2005	Final Community herbal monograph on Valerian root (Valeriana, radix)	To be released in 1Q 2006
EMEA/HMPC/340849/2005	Final Community herbal monograph on Linseed (Linum, semen)	To be released in 1Q 2006
EMEA/HMPC/340857/2005	Final Community herbal monograph on Ispaghula husk (Plantago ovata, tegumentum)	To be released in 1Q 2006
EMEA/HMPC/340861/2005	Final Community herbal monograph on Ispaghula seed (Plantago ovata, semen)	To be released in 1Q 2006
EMEA/HMPC/340865/2005	Final Community herbal monograph on Psyllium seed (Plantago afra et Plantago indica, semen)	To be released in 1Q 2006
EMEA/HMPC/340779/2005	Final Community list entry on Valerian root (Valeriana, radix)	To be released in 1Q 2006
EMEA/HMPC/340854/2005	Final Community list entry on Linseed (Linum, semen)	To be released in 1Q 2006
	Draft Community herbal monograph/ Community list entry on Birch leaf (Betula pendula et Betula pubescens, folium)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Caraway fruit (Carum, fructus)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Purple coneflower herb (Echinacea, herba)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Eleutherococcus (Eleutherococcus, radix)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Fennel (Foeniculum, fructus)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Devil's claw (Harpagophytum procumbens et Harpagophytum zeyheri, radix)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Hop strobile (Humulus, flos)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Melissa leaf (Melissa, folium)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Peppermint oil (Menthae aetheroleum)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Peppermint leaf (Menthae folium)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Passion flower (Passiflora, herba)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Primula root (Primula veris et Primula elatior, radix)	To be released in 2006

Reference number	Document title	Status
	Draft Community herbal monograph/ Community list entry on Blackcurrant leaf (Ribes, folium)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Willow bark (Salix purpurea, Salix daphnoides et Salix fragilis, cortex)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Senna leafs (Cassia senna, folium)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Senna pods (Cassia senna, fructus)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Nettle leaf and Nettle herb (Urtica dioica et Urtica urens, folium/herba)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Nettle root (Urtica dioica et Urtica urens, radix)	To be released in 2006
	Draft Community herbal monograph/ Community list entry on Ginger (Zingiber, rhizoma)	To be released in 2006

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 EMEA. The EMEA receives safety reports from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use	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	Fia WESTERHOLM Direct telephone: (44-20) 74 18 85 81 E-mail: fia.westerholm@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 Organisation. These certify the marketing authorisation and good manufacturing status of medicinal products in the EU and are intended for use in support of marketing authorisation applications in and export to non-EU countries.

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use	E-mail: certificate@emea.eu.int Fax: (44-20) 74 18 85 95

PMF/VAMF EMEA certificates

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

For enquiries concerning PMF certificates	Silvia DOMINGO ROIGÉ Direct telephone: (44-20) 74 18 85 52 Fax: (44-20) 74 18 85 45 E-mail: silvia.domingo@emea.eu.int
For enquiries concerning VAMF certificates	Antoon Gijsens Direct telephone: (44-20) 75 23 7114 Fax: (44-20) 74 18 85 45

E-mail: antoon.gijsens@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, n. Finnish

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

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

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

Thomas Lönngren, Executive Director, n. Swedish

Education: Qualified pharmacist from the University of Uppsala Faculty of Pharmacy. MSc in social and regulatory pharmacy. Post-graduate studies in management and health economics. Honorary Member of the Pharmaceutical Society of Great Britain since 2003 and Hornorary Fellow of the Royal College of Physicians since 2004.
Career to date: From 1976 to 1978, lecturer at University of Uppsala. Mr Lönngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990 during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1982 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He is Executive Director of the EMEA since January 2001.

EMEA scientific committees

Daniel Brasseur, Chairman of the CHMP, n. Belgian

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

Eric Abadie, Vice-chairman of the CHMP, n. French

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

Gérard Moulin, Chairman of the CVMP, n. French

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

Johannes Hoogland, Vice-chairman of the CVMP, n. Dutch

Education: Degree in analytical chemistry from the University of Amsterdam 1984, followed by PhD 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 Ministry of Agriculture, Nature Management and Fisheries since 1988; from 1988 to 1998 by 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 present by Bureau Registratie Diergeneesmiddelen (BRD). CVMP member since 1998 and chairman of the ad hoc Group for environmental risk assessment of CVMP. He was re-elected as vice-chairman of the CVMP in 2004.

Josep Torrent i Farnell, Chairman of the COMP, 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 1977-1990, Prof. Torrent i Farnell worked in internal medicine and clinical pharmacology in Spain and was Assistant Professor of Pharmacology at UAB. From 1990 to 1994, he was Technical Counsellor in Clinical Evaluation and Pharmacology at the Spanish Ministry of Health, 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 1999-2000. He was re-elected chairman of the Committee for 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, n. French

Education: Master 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 health and medical research non-governmental 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 advisor to its president, to stimulate public health policy on rare diseases and to create the French Alliance Maladies Rares, an umbrella of 134 patient 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 is the Chief Executive Officer since 2001. He was re-elected vice-chairman of the COMP in June 2003.

Konstantin Keller, Chairman of the HMPC, n. German

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

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

Education: Qualified medical doctor from the University of Graz. Post-graduate degree in pharmacology, Associate Professor in pharmacology and toxicology from the University of Vienna.
Career to date: Dr Pittner worked in the pharmaceutical industry from 1972 to 1985 where he discovered the pharmacological properties of the beta 1 - adrenoceptor antagonist celiprolol. In 1986 he joined the Austrian drug regulatory authority; since 2003 he is 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 has been vice-chairman of the HMPWP from 2002 until 2004. Moreover Dr Pittner has been CPMP delegate from 1995 to 1997 and from 2001 until April 2004; since May 2004 Dr Pittner is CHMP delegate.

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

Patrick Le Courtois, Head of Unit, n. French

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

Agnès Saint Raymond, Head of Sector for orphan drugs and scientific advice, n. French

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

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

Education: Qualified medical doctor from the University of Wuerzburg, Germany. Board certified specialist in Pharmacology and Toxicology (Bavarian Chamber of Physicians). Associate Professor for Pharmacology and Toxicology in the University of Wuerzburg.
Career to date: Since 1984 Prof Vamvakas held positions in the Department of Pharmacology and Toxicology of the University of Wuerzburg and in the Department of Pharmacology in the Medical Centre of the University of Rochester NY, USA. He joined the EMEA in May 1999 and one of his major activities in recent years was the establishment of Orphan Drug designation and Protocol Assistance in the EMEA. He has a continuing teaching appointment for Pharmacology and Toxicology in the University of Wuerzburg. He was appointed acting Deputy Head of Sector for scientific advice and orphan drugs in October 2004.

John Purves, Head of Sector for quality of medicines, n. British

Education: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. PhD in pharmaceutical microbiology from the University of Strathclyde, Glasgow.
Career to date: From 1972 to 1974, Dr Purves worked in the pharmaceutical industry. Between 1974 and 1996, he held posts in the UK Medicines Division and the Medicines Control Agency, including inspector of pharmaceutical manufacture, reviewer of dossiers and manager of the Biotechnology and Biological Unit. He was the UK representative at the Biotechnology Working Party, involved in the

generation of many guidelines relating to biotechnology and biological products. He joined the EMEA in August 1996 as Head of Sector for biotechnology and biologicals. He was appointed Head of Sector for quality of medicines in January 2001.

Xavier Luria, Head of Sector for safety and efficacy of medicines, n. Spanish

Education: Qualified medical doctor from the Autonomous University of Barcelona. Postgraduate fellowship in internal medicine and postgraduate qualifications in pharmaceutical medicine, in biostatistics and in clinical pharmacology, drug development and regulation.
Career to date: Dr Luria worked as a general practitioner and internal medicine physician, as assistant of the Physiology Department (Autonomous University of Barcelona), and assistant in gastrointestinal and psychosomatic disorders. In 1987, he joined a pharmaceutical company as a medical doctor in clinical research and in 1990 became Head of Clinical Research. In 1995 he was nominated Medical Director with responsibility for clinical development, biometry, pharmacovigilance and global medical affairs. He has been a member of working groups in the Spanish (Farmaindustria) and European (EFPIA) pharmaceutical industry associations. He participated in a number of ICH initiatives and was also a member of the DIA Steering Committee Europe until 2004. He joined the EMEA in December 2005 as Head of Sector for safety and efficacy of medicines.

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

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

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

Noël Wathion, Head of Unit, n. Belgian

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

Tony Humphreys, Head of Sector for regulatory affairs and organisational support, n. Irish

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

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

Education: Qualified in medicine from Sheffield University in 1983. Post-graduate qualifications in internal medicine (FRCP) and pharmaceutical medicine (FFPM).
Career to date: Six years of clinical experience in UK hospitals, 5 years as Director of Pharmacovigilance and Regulatory Affairs at Astra Pharmaceuticals in the UK and a total of 7 years at the UK Medicines and Healthcare Products Regulatory Agency (MHRA). Prior to his appointment as Unit Manager in Pharmacovigilance, he held a number of positions in both pre- and post-authorisation areas and was also the UK delegate to the CPMP Pharmacovigilance Working Party. Dr Tsintis joined EMEA as Head of Sector, Pharmacovigilance and post-authorisation safety and efficacy of medicines in March 2002.

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

Education: Masters Degree in pharmacy and Doctor of Natural Sciences Degree in pharmacology from the University of Vienna. Post-graduate studies in pharmacology at the University of Melbourne and Auckland.
Career to date: From 1988 to 1992, Dr Brosch worked as an assistant professor at the Department of Pharmacology and Toxicology at the University of Vienna, where she was specialised in electrophysiology. In 1992 she moved to the Pharmacovigilance Department at the Austrian Ministry of Health and completed a 6-month regulatory traineeship in the Pharmaceuticals Unit of the European

Commission in 1995. She joined the EMEA in November 1996 and was appointed Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines in January 2001.

Isabelle Moulon, Head of Medical Information Sector, n. French

Education: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology and metabolic diseases. Post-graduate studies in nutrition, statistics and methodology.
Career to date: Worked as a clinical endocrinologist in hospital until 1987 and then joined the Directorate of Pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the EMEA in July 1995. She was responsible for Scientific Advice until December 2000. She was appointed Head of Sector for Safety and Efficacy of Medicines in January 2001. Since September 2005 she has taken up new responsibilities as Head of the Medical Information Sector.

Unit for Veterinary medicines and inspections

David Mackay, Head of Unit, n. British

Eductation: Graduated in veterinary medicine from the Royal Veterinary College, London. MSc in Immunology from the University of Birmingham and a PhD in Veterinary Immunology from the Royal Veterinary College, University of London. Member of the Royal College of Veterinary Surgeons of the United Kingdom.
Career to date: After a period in general veterinary practice in the UK, Dr Mackay returned to academia to gain an MSc followed by a PhD in veterinary immunology. This was followed by work as a research scientist, first for industry and subsequently as an expert in exotic viral diseases of livestock at the Pirbright Laboratory of the Institute for Animal Health, UK. Dr Mackay then worked for four years in regulatory affairs at the Veterinary Medicines Directorate, finishing in post of Director of Licensing. He then returned to Pirbright as Head of Laboratory before taking up the post as Head of Unit in February 2006.

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

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

Melanie Leivers, Deputy Head of Sector for veterinary marketing authorisation procedures, n. British

Education: Graduate in biochemistry and pharmacology from Leeds University. Post-graduate diploma in European Community law from King's College, London.
Career to date: Miss Leivers worked for the Milk Marketing Board for England and Wales (MMB) as a Liaison Chemist for 5 years prior to being appointed Assistant Director of the MMB/Federation of Agricultural Cooperatives office in Brussels, representing all sectors of agricultural cooperation to the European institutions. Following this she worked for a short-term contract at the European Commission (DG XI) and then in industry at Pfizer (formerly SmithKline Beecham Animal Health) as a regulatory affairs manager. Miss Leivers joined the EMEA in February 1996 and was appointed Deputy Head of Sector in June 2001.

Kornelia Grein, Head of Sector for safety of veterinary medicines, n. German

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

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

Emer Cooke, Head of Sector for inspections, n. Irish

Education: Qualified Pharmacist with Masters degree in Pharmaceutical Chemistry and Masters in Business Administration (MBA) from Trinity College Dublin. Member of the Pharmaceutical Society of Ireland.
Career to date: Ms. Cooke worked in a number of positions within the Irish pharmaceutical industry before joining the Irish Medicines Board as a pharmaceutical assessor in 1988. Following graduation with a MBA degree in 1991, she joined EFPIA, the European pharmaceutical industry association as Manager of Scientific and Regulatory Affairs. Her responsibilities there included coordination of regulatory aspects of European procedures and International Conference on Harmonisation (ICH) activities. After a three-year stay in Prague, Czech Republic, where she worked as a consultant on European pharmaceutical matters as well as continuing her work with EFPIA, she joined the Pharmaceuticals Unit of the European Commission in September 1998. Her responsibilities there included coordination of ICH activities, relations with the FDA, pharmaceutical aspects of mutual recognition agreements, GMP and inspection-related matters, orphan medicinal products, preparatory work on a regulation on paediatric medicinal product and issues relating to EU enlargement. She joined the EMEA as Head of the Inspections Sector in July 2002.

Communications and networking Unit

Hans-Georg Wagner, Head of Unit, n. German

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

Beatrice Fayl, Head of Sector for document management and publishing, n. Danish

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

Sylvie Bénéfice, Head of Sector for meeting management and conferences, n. French

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

Tim Buxton, Head of Sector for project management, n. British

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

David Drakeford, Head of Sector for information technology, n. Irish

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

Riccardo Ettore, Deputy Head of Sector for information technology, n. Italian

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

Administration Unit

Andreas Pott, Head of Unit, n. German

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

Frances Nuttall, Head of Sector for personnel and budget, n. Irish

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

Sara Mendosa, Head of Sector for infrastructure services, n. British

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

Gerard O'Malley, Head of Sector for accounting, n. Irish

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

Services attached to the Executive Director

Martin Harvey Allchurch, Head of Executive Support, n. British

Education: Law degree from the University of Dundee, UK. Masters degree in European and international law from the Vrije Universiteit Brussel, Belgium.
Career to date: After a traineeship with the European Commission 1991-92, Martin Harvey Allchurch worked as a European affairs consultant in Brussels from 1992 to 1995. During this time he also worked as contributing editor for a European affairs publication and as Brussels correspondent for an American pharmaceutical journal. He joined the EMEA in September 1995. He was nominated as press officer in September 2001 and appointed Head of Executive Support in January 2004.

Vincenzo Salvatore, Head of Legal Sector, n. Italian

Education: Law degree from the University of Pavia (I), Ph.D. in European Law from the European University Institute of Florence (I), *Avvocato*, Chair Professor of International Law.
Career to date: From 1991 to 2004 Mr. Salvatore experienced as qualified lawyer in private practice both arbitration and litigation dealing mainly with public procurement, competition, international trade and contracts. He worked also as research assistant in International law at the University of Pavia from 1992 to 1999, Associate Professor of International Law at the University of Insubria (Varese) from 1999 to 2003 and Chair Professor of International Law at the same University since 2004. He joined the EMEA as Head of Legal Sector on 16 November 2004.

Marijke Korteweg, Integrated quality management advisor, n. Belgian

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