European Medicines Agency

EMEA/62913/2006

Summary of the work programme for the

European Medicines Agency

2006

This document provides a summary of the Agency's work programme 2006, adopted by the Management Board on 15 December 2005.

The full work programme 2006 in English can be found on the Agency's website: www.emea.eu.int

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

Contents

Introduction by the Executive Director

Thomas Lönngren

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 also 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. This year, the Agency 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 expects to receive the first authorisation applications for generic medicines this year, and 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.

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 contribution 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 processes and on effective use of 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 specialised studies on safety profiles of medicinal products post authorisation;
- 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 give as much support as possible to companies at the different stages of development of medicinal products;
- Provide support to SMEs 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 EMEA interaction with top-quality experts from national authorities, academia, learned societies and industry on challenges relating to new technologies;
- Contribute to the EU programme to reduce animal testing and develop other modern approaches for safety assessment of substances.

3. Openness, communication and provision of information

- Provide high-quality information to provide for adequately informed patients and improve the availability of useful information to healthcare professionals;
- Increase openness and transparency of activities to underline the good corporate governance of the Agency and allow interested parties to closely monitor its activities.

4. The European medicines network

- Strengthen cooperation on pharmacovigilance, scientific advice, support to SMEs and the provision of information;
- Work within the network to establish an EU communications strategy;
- Work to ensure availability for the Agency of the highest-quality expertise at EU level for evaluation of medicines and for monitoring and assessing their safety;
- Establish an inventory of 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.

Chapter 1 EMEA in the European system

The European medicines network

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

To carry out its mission relating to protection and promotion of public health, the Agency will draw on the best-available expertise in the EU and EEA-EFTA Member States to assess medicines, to provide high-quality scientific advice, to evaluate safety profiles of medicines and to develop important guidance documents.

In view of significant technological developments in the field of medicines, the European medicines network will focus its attention in 2006 on ensuring the long-term availability of competences to respond to the emergence of new therapies and technologies. This will be done by identifying areas where expertise needs to be reinforced and developed. In addition, the partners of the network will consider new ways to optimise the activities they perform, and will strengthen their efforts to provide high-quality information to patients and healthcare professionals throughout the EU.

A coordinated approach to continuous quality improvement across the European medicines network of more than 40 members is essential if we are to have strong quality-assurance systems in place. As part of this approach, the EMEA and national competent authorities have implemented the EU Benchmarking System, with its regular cycle of self-assessment activities and peer-review visits. The Agency's involvement in this cycle will continue in 2006.

Transparency, communication and provision of information to patients, healthcare professionals and users of medicines

The EMEA is deeply committed to being a transparent, open and accessible organisation. Providing targeted, understandable and accessible information to patients and healthcare professionals is an important element of that commitment, and will continue to be a priority for the Agency in 2006.

In the field of transparency, the Agency will build on the achievements of previous years, and will concentrate its efforts in three areas:

- Development and implementation of the EMEA transparency and communication strategy, as well as active contribution to the development and implementation of a transparency and communication strategy for the European medicines network;
- Greater openness and provision of information relating to medicinal products submitted to the Agency for evaluation, both before and after the granting of a marketing authorisation;
- Implementation of the Management Board decision on access to the Agency's documents, ensuring the widest possible public access.

As a result of measures implemented in 2005, the Agency now provides a wider range of information to the public about the medicinal products it evaluates. In addition to summaries of opinions, European public assessment reports (EPARs) and information on arbitrations and referrals, the Agency will now provide information on the withdrawal by applicants of applications prior to opinion and will produce summaries of EPARs written in a manner that is more understandable to the public.

In addition, a number of recommendations stemming from the Agency's work with patients' and consumers' organisations will be implemented, contacts with patients and healthcare professionals will be strengthened through development of specific frameworks, and a new working group with healthcare professionals will be established.

Development of the database containing information about authorised medicinal products in the EU will also continue. Once completed, the database will be a further source of authoritative information about medicines for patients, healthcare professionals and regulators.

Availability of medicines and innovation

In order to support innovation and research that leads to improved availability of medicines — and to promote access to them — the Agency will conduct a range of activities and implement a variety of tools, as follows:

- Further implementation of the orphan-medicines policy, whereby developers of designated orphan medicinal products — often derived from new technologies — enjoy reduced fees or fee waivers for a number of Agency procedures, thus stimulating the development of these products and increasing patients' access to them;

- Continued provision of scientific advice on issues relating to the quality, safety and efficacy of medicines during different stages of their development;

- Operation of new regulatory procedures, including accelerated-assessment, conditional-marketing-authorisation and compassionate-use procedures;

- Provision of free scientific advice to companies developing veterinary medicines for minor uses and minors species, as well as developing and implementing — in collaboration with Member State competent authorities — related guidelines, thus facilitating availability of such medicines;

- Provision of support and incentives to SMEs developing medicinal products;

- Commencement of discussions with academia, learned societies, industry and other parties on challenges relating to new technologies and therapies, plus implementation of practical proposals stemming from these fora, as part of the Agency's efforts to foster research into new technologies and rare diseases;

- Provision of regulatory input and advice to the European Commission's DG Research on innovation and technology platforms for human and veterinary medicines, aimed at supporting innovation and facilitating the availability of medicines.

Small and medium-sized enterprises

The Agency will implement the new legislation and guidelines concerning SMEs. Administrative and procedural assistance will be provided to SMEs by the dedicated SME Office within the Agency, which will become fully functional in 2006. Through this office, SMEs will be able to obtain fee reductions, exemptions or deferred payments for certain administrative and scientific services of the Agency, as well as assistance with translating product-information documents.

EU institutions, agencies and European and international partners

The Agency's continuing cooperation at the European level will include work with the EU institutions on the handling of pandemic threats, a project on innovative human and veterinary

medicines for Europe (technology platforms), and activities relating to the forthcoming regulations on medicinal products for paediatric use and on advanced therapies.

Regular contacts will be maintained with other decentralised agencies of the EU, in particular the European Food Safety Authority, the European Monitoring Centre for Drugs and Drug Addiction, and the European Centre for Disease Prevention and Control.

Cooperation will also continue with the European Pharmacopoeia and with the European Directorate for the Quality of Medicines, in the context of the sampling and testing programme being operated to supervise the quality of centrally authorised medicinal products placed on the market.

Pre-accession activities in view of the next wave of EU enlargement, in 2007, will include operation of the pre-accession linguistic review process (PALC II) and CADREAC procedures, as well as participation in the PHARE multi-beneficiary programme, to facilitate the integration of Bulgarian and Romanian regulatory authorities in the work of the Agency.

Similar activities will start under the 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 and training courses, and organisation of specific conferences.

At the international level, the Agency will continue to coordinate the EU's participation in the International Conferences on Harmonisation (ICH and VICH), with an increased contribution expected from the Agency and its scientific committees in 2006. The Agency will also continue its work with the World Health Organization, Codex Alimentarius and OIE.

Cooperation between the EMEA and the US Food and Drug Administration will continue in the context of the EU-USA confidentiality arrangements, with primary focus on the parallel scientific-advice process and the exchange of safety-related information. Experience obtained so far will be reviewed and opportunities for improvement will be identified. The Agency will also work with the US Department of Agriculture to exchange relevant information on veterinary medicines.

Managing 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 the integrated management measures implemented over the years. To this end, the Agency will: conduct self-assessment activities as part of the EU benchmarking system, alongside its European partners; review the level of implementation of the internal control standards; conduct annual management-review activities; assess its achievements in the area of risk management; and assess the impact of improvements following audits. The Agency will also see the establishment of a new audit-advisory committee, following an open tender in 2005.

The EMEA plans to review its key processes in order to rationalise their functioning. Reviewing the efficiency of the Agency's operations is particularly important at this time, as it faces challenges resulting from the increased complexity and volume of its activities, from its wider scope of responsibilities, from the heightened expectations of its stakeholders, from challenges posed by the advent of new and more complex technologies, and from the continuing globalisation of the pharmaceutical sector.

With regard to the area of personnel-management, the Agency will work to implement the staff regulations and a new competence-development policy, and will direct professional-training management towards a continuous system of competence development, taking account of the

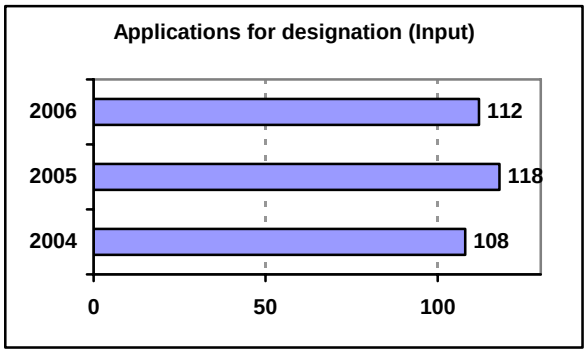
greater scientific orientation of the Agency. A staff-motivation exercise will be conducted in 2006, and the impact of actions developed as an outcome of the 2005 exercise will be evaluated.

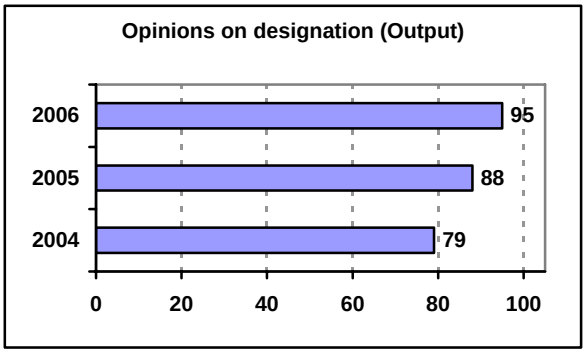
Chapter 2 Medicines for human and veterinary use

Orphan medicinal products for human use

The Agency's orphan-medicines policy is designed to support innovation and research, including that conducted by small and medium-sized enterprises. Taking into account the level of the orphan-medicinal-products fund (requested amount of EUR 5,900,000) and recommendations of the Committee for Orphan Medicinal Products (COMP), the Agency proposes fee reductions that will provide maximum possible incentives during the development and marketing-authorisation phases of orphan medicines.

Activities in terms of the number of applications for designation are expected to stabilise at the 2005 level, although the 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.





Scientific advice to enterprises

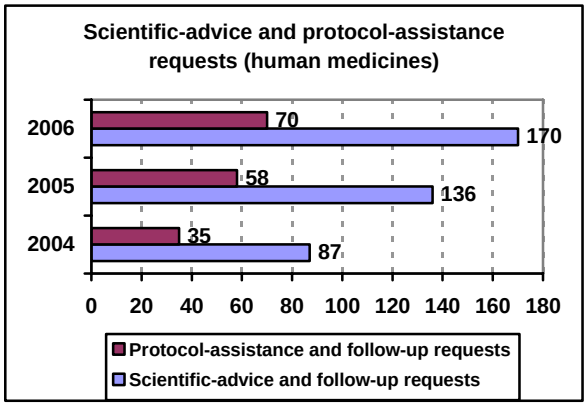
The provision of scientific advice is one of the most important ways in which the Agency can support innovation and research: analysis of the impact of scientific advice provided by the Agency shows that the procedure significantly increases the chances of obtaining a marketing authorisation.

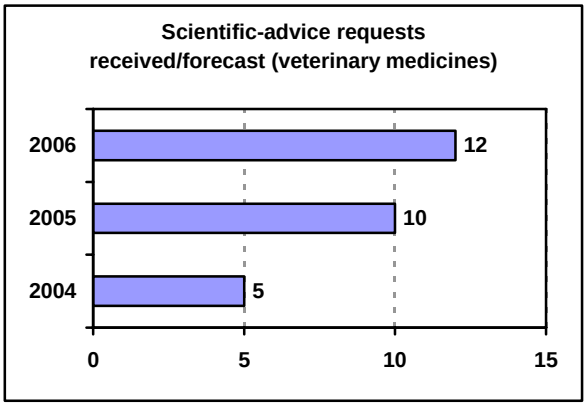
It is projected that the number of applications for scientific advice and protocol assistance (for designated orphan medicinal products) received in 2006 will be twice as high as in 2004; in particular, the ratio of scientific-advice requests relating to products for new therapies and technologies is expected to rise.

Efficient handling of the process is, therefore, essential. In 2005, the Agency adapted its scientific-advice and protocol-assistance procedures to meet the requirements of the new legislation, resulting in reduced timelines, extended scope, greater involvement of experts, and increased added value of the advice. The improved procedures will allow smoother operation of the process, and will be fully integrated into the Agency's working practices in 2006.

The Agency will also prepare for the development of additional tools, including a scientific-memory database and a scientific-advice database.

The Agency also expects an increase in the number of scientific-advice requests for medicinal products for veterinary use, given the Management Board's decision to extend the period for free scientific advice for products for minor uses and minor species for a further period of 12 months. The Agency will seek feedback on the level of satisfaction with the new procedure for veterinary medicines.





Initial evaluation

Highlights in 2006 for initial evaluation of medicines for human use are expected in four main areas:

- Consolidating and fully operating the procedures introduced by the Agency in 2005, following the entry into force of the new EU pharmaceutical legislation. These include accelerated-assessment, conditional-marketing-authorisation and compassionate-use procedures, and the provision of scientific opinions on medicinal products intended for non-EU markets (in cooperation with the WHO). The Agency expects to receive a total of 59 initial applications (including ones for generic, biologically similar and compassionate-use products, and products intended for non-EU markets), which is a 44% increase on the previous year;

- Supporting innovation and research, in particular by providing support to SMEs and by discussing challenges relating to new technologies and therapies with key parties;

- Assuring the quality of assessments, including strengthened regulatory and scientific consistency. The peer-review process of the first phase of assessment will be strengthened and monitored. In addition to continuous improvement and revision of procedures, the Agency plans to strengthen cooperation with its pool of partners who can provide specialised knowledge and expertise, and to increase the size of that pool;

- Evaluating risk-management plans (RMPs). An important legislative change requires applicants to include an RMP in their application, to be evaluated by the Committee for Medicinal Products for Human Use (CHMP). The RMP identifies 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.

The Agency will fully embrace its responsibility to assess four classes of medicines for which authorisation must now be sought through the centralised procedure: those for HIV/AIDS, cancer, diabetes and neurodegenerative disorder.

The Agency will implement a number of adopted guidelines relating to similar biological (biosimilar) medicinal products, and will consolidate procedures for generic medicines. In 2006, the EMEA expects to receive the first applications for generic medicines through the centralised procedure. Changes in the legislation now make it possible to submit applications for the authorisation of non-prescription medicines through the centralised route.

In addition, the Agency will continue to evaluate applications for medicinal products intended for non-EU markets, as part of its cooperation with the World Health Organization. This is a

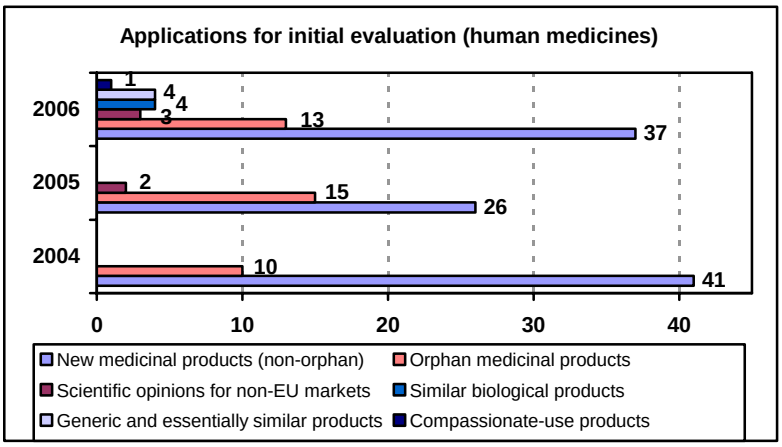
challenging legislative initiative, requiring new expertise on medicines and diseases not encountered in Europe.

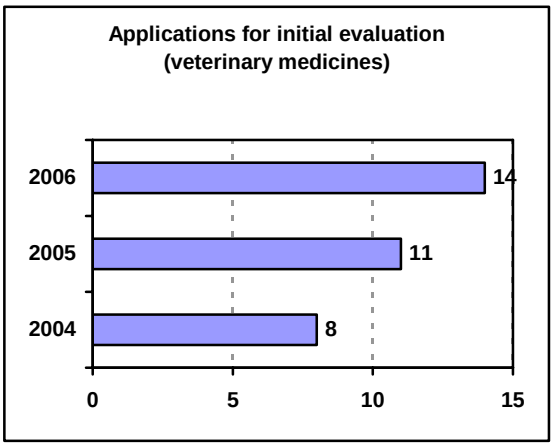
In the area of veterinary medicines:

- The Agency expects an increase in the number of applications for marketing authorisation. This is due mainly to the widened scope of the centralised procedure, new support available to companies considering applications for limited markets and/or for regional diseases and more generic applications expected as the data exclusivity period expires for centralised veterinary authorisations;

- The Agency is continuing the development of the scientific-memory database for centrally authorised veterinary medicines. The database will contribute towards improved consistency of scientific assessments;

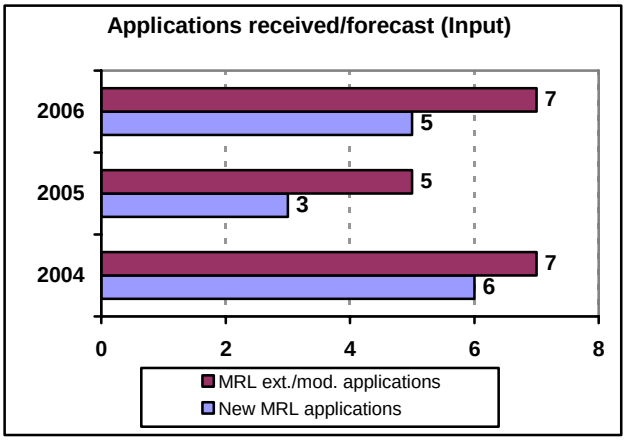
- The quality-assurance system will be strengthened by implementing recommendations resulting from the audit of the Committee for Medicinal Products for Veterinary Use (CVMP) conducted in October 2005.





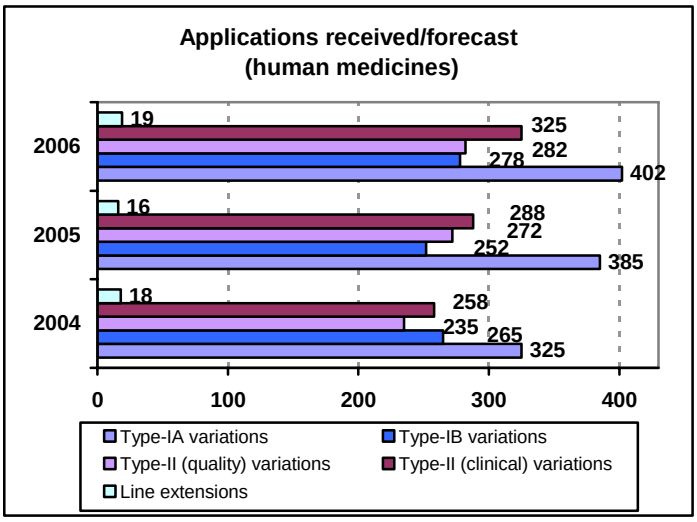
Establishment of maximum residue limits for veterinary medicines

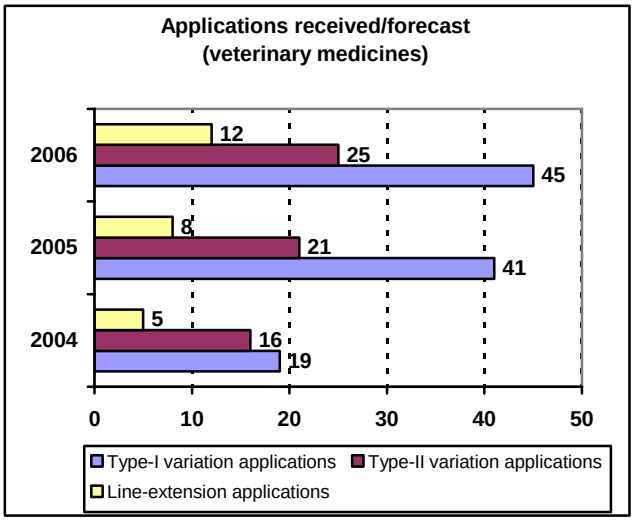
The Agency expects an increase in the number of extension or modification applications for maximum residue limits (MRLs) in 2006. This is a result of initiatives taken by the CVMP to facilitate the authorisation of products for minor uses and minor species. In 2006, the Agency will continue to extrapolate MRLs to minor species upon request by companies, in accordance with the CVMP policy on availability.



Post-authorisation activities

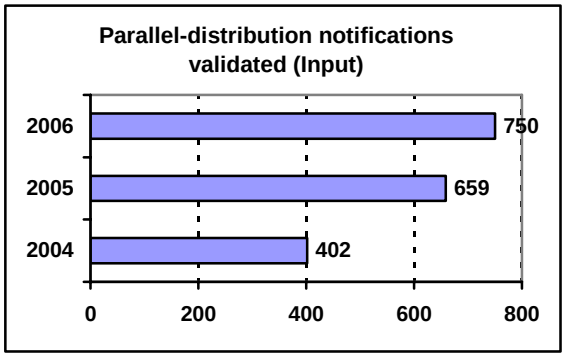
Emphasis will be placed on full implementation of the new Community legislation and on the monitoring of this implementation. Where necessary, action will be taken to further refine procedures as a result of experience gained and the growing number of applications. The regulatory and scientific consistency of scientific committees (CHMP and CVMP) 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-extension and variation applications, thus facilitating the availability of new indications and pharmaceutical forms.





Parallel distribution

A significant increase (64%) 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, reaching 750. However, despite the mandatory nature of the notification procedure, compliance is still considered to be an issue, and the forecast will be closely monitored.



Safety of medicines

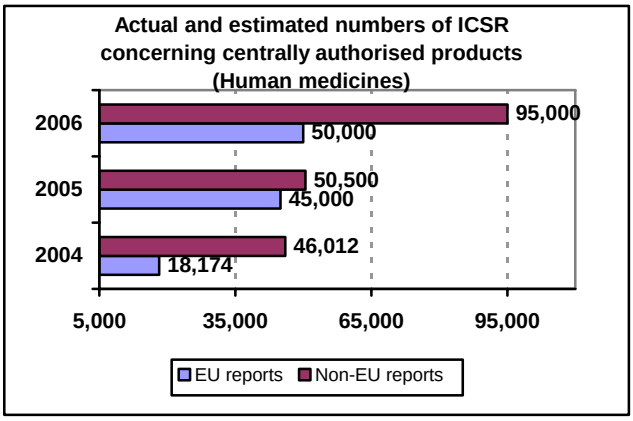
Monitoring the safety of medicines for human and veterinary use is a priority area for the EMEA. The related processes undergo continuous evaluation and improvement, with the close cooperation of the national competent authorities.

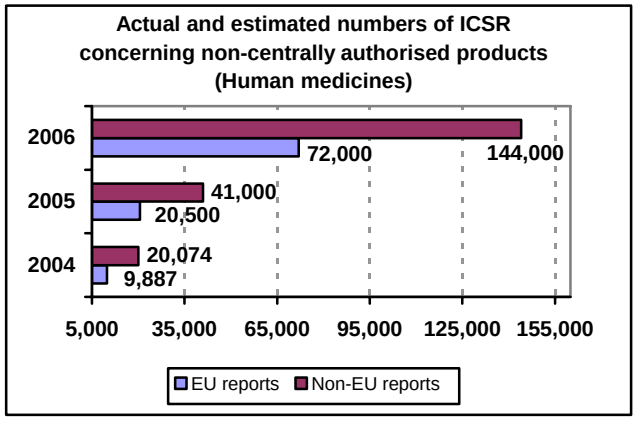
In the area of medicines for human use, the Agency will focus on fully integrating the new legislative requirements relating to pharmacovigilance into its processes, alongside further development and implementation of the European risk-management strategy.

The novel concept of risk-management plans (RMPs) introduced by the new legislation will require adequate evaluation, both in the pre- and post-authorisation phases. The workload on RMPs will be considerable in the post-authorisation phase, taking into account the need for updates of RMPs agreed at the time of authorisation. In addition, reviews of RMPs (including risk-minimisation measures and other pharmacovigilance activities) to identify known and potential risks with the medicinal product will be required for some variations and line extensions which result in a significant change in a marketing authorisation. Existing procedures (such as the CHMP handling of safety concerns for centrally processed applications) will be revised to effectively incorporate the concept of RMPs in the evaluation process. The most appropriate involvement of specialised expertise in the various processes will have to be carefully considered during such revision.

Further development of the European risk-management strategy will target the implementation of the new legislation, complementary implementation initiatives (in the fields of risk detection, risk assessment, risk minimisation and risk communication, and in insufficiently developed fields of pharmacovigilance such as paediatrics and vaccines) and further strengthening of the EU pharmacovigilance system. This should result in a more intensive drug-monitoring system. A two-year rolling work plan on the detailed initiatives to be undertaken up to mid 2007 has been established.

Further development of the EudraVigilance system (comprising an electronic database and data-processing network for adverse drug reactions) is paramount to the successful implementation of the strategy and will, therefore, remain at the top of the Agency's agenda in the field of safety of medicines. The Agency expects that all national competent authorities will be reporting electronically to the EudraVigilance system by the end of 2006, which is reflected in the forecast increase of electronic reports in the chart below. Finally, the policies concerning public access to the data included in EudraVigilance will be defined, taking into account the protection of individual and commercially confidential data.



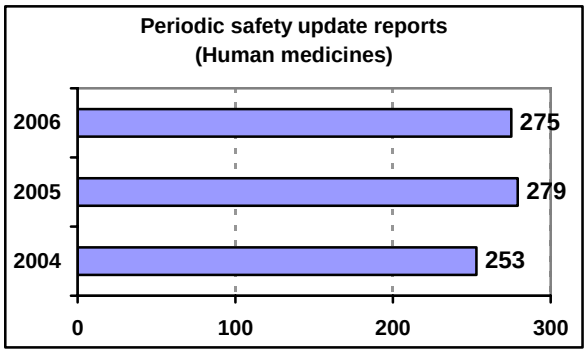


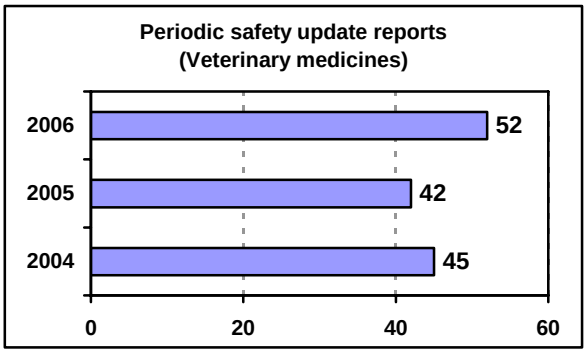
The continuing emphasis on the safety of veterinary medicines in the post-authorisation phase and the need to adopt a continuing risk-management approach to this important issue will feature highly on the list of priority activities in 2006.

Following the full switch to electronic reporting of adverse drug reactions (ADRs) to veterinary medicines for all Member States in 2005, 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.

In addition, the Agency will collaborate fully and work with the Member States' veterinary regulatory authorities in the European Surveillance System to foster a joint approach to optimising efficiency in EU veterinary pharmacovigilance for all medicinal products authorised in the Community.

With the need to meet the Agency's obligations to provide more transparent veterinary pharmacovigilance reporting and communication to the outside world, as explicitly stated in the new Regulation, a considerable increase in data analysis with EudraVigilance and subsequent reporting is expected. The Agency will continue to improve on its communication to the public and encourage a reporting culture through its collaborative efforts with interested parties and the Member States.



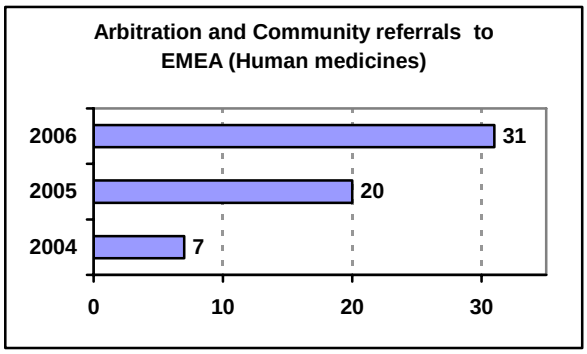


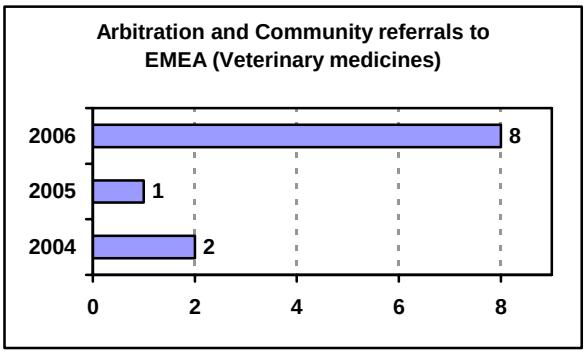
Arbitrations and referrals

In the area of arbitrations and Community referrals relating to medicines for human use, the Agency will concentrate on two goals in 2006. The first 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. The Agency will also establish a framework and tools for evaluation of referral and arbitration procedures relating to traditional herbal medicinal products.

Taking into account the change in the legislation regarding automatic referrals and the development of lists of medicinal products for which a harmonised summary of product characteristics (SPC) should be drawn up, an increase in arbitrations/referrals for both human and veterinary medicines is expected.





Herbal medicinal products for human use

The Agency will continue its work to fully implement recent Community legislation on herbal medicinal products and to provide Member States and EU institutions with the best-possible scientific opinion on questions relating to herbal medicinal products. As an important element of the harmonised approach to the scientific assessment of herbal medicinal products in the EU, the Committee on Herbal Medicinal Products (HMPC) will pay particular attention in 2006 to establishing Community herbal monographs, as well as to preparing entries to the draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. In addition, the HMPC will continue its work on updating the guidance for the content of applications to register the traditional medicinal use of herbal medicinal products.

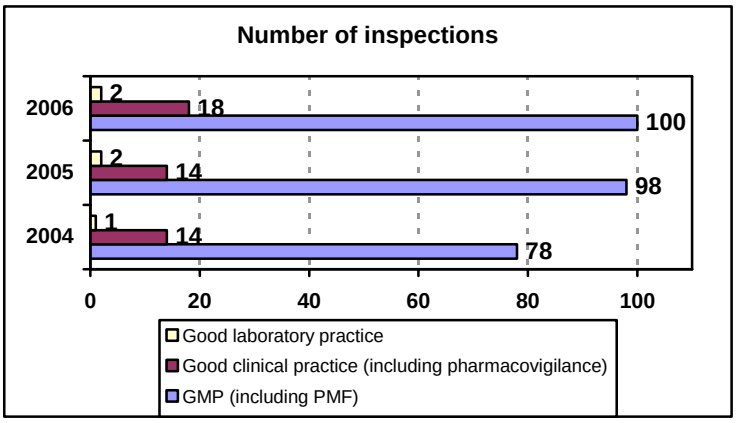
Coordination groups for mutual-recognition and decentralised procedures (human and veterinary products)

The year 2006 is the first full year of operation of the Coordination Groups for Mutual-Recognition and Decentralised Procedures (CMDs) established by the new Community legislation. The Agency will provide secretarial support to the CMDs and their working parties, whose responsibilities will include: preparation and distribution of documents; provision of lists of positions taken on similar issues; follow-up to meetings; facilitation of liaison with other scientific working groups and with interested parties; assistance on preparation of annual reports; specific activities assigned to the CMDs under their work programmes; assistance in providing regulatory and legal support to CMD activities; coordination of the 60-days procedure for discussion in case of disagreement between Member States in mutual-recognition or decentralised procedures; and preparation of the list of medicinal products for which a harmonised SPC should be drawn up.

Chapter 3 Inspections

Inspections

The Agency expects the number of inspections to remain stable in 2006. During the year, the Agency will complete its implementation of legislative and procedural requirements in the area of good manufacturing practice (GMP) for active substances and certain excipients. It will also roll out the first production version of the EU-wide database on manufacturing authorisations and GMP certificates. The EMEA will contribute to international harmonisation discussions on quality systems and implementation of quality risk-management and pharmaceutical development. The EMEA will liaise with EU medicines-enforcement officers on their work to investigate the incidence of counterfeit medicines.



The Agency will also continue to support implementation of the clinical trials directive and will further develop relevant procedures and guidelines, and support the operation and further development of the clinical trials database.

The Agency's inspection-related working parties will: harmonise inspection procedures and processes, in particular those relating to inspections of active substances and to pharmacovigilance; develop guidelines in light of the requirements of Community legislation on clinical trials and blood; and continue to work on GMP guidelines on products used as gene and cell therapies.

In order to rationalise dossier requirements, the Joint CHMP/CVMP Quality Working Party will review assessment experiences and existing guidelines.

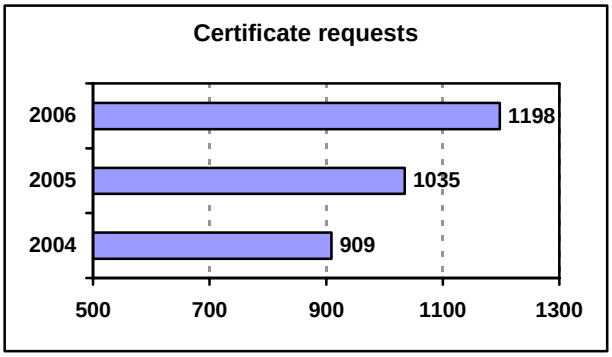
Innovation and continual improvement in the context of manufacturing and control methods will be facilitated through the work of the Process Analytical Technology (PAT) team.

National competent authorities are expected to complete the remaining internal evaluation work and follow-up with new Member States in the context of the EC-Canada mutual-recognition agreement. The Agency also expects good progress on external evaluations carried out by Canada by the end of the year.

Certificates of medicinal products

The number of certificate requests is expected to increase by 16%, due to the increased number of approved marketing authorisations. The Agency's mandate to provide opinions on medicinal products intended for use exclusively in markets outside the EU (cooperation with the WHO) 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 will be accommodated. The Agency will continue to work on rationalisation of the process and will follow up on the removal of the legalisation step formerly performed by the European Commission.



Sampling and testing

The sampling and testing programme for centrally authorised products will continue in 2006, using the expertise of the EEA's network of official medicines-control laboratories, enabling the quality of medicinal products on the market in the EEA to be controlled. Close collaboration between the EMEA, the European Directorate for the Quality of Medicines and the national authorities in this programme continues to prove invaluable in assuring effective and continued post-marketing surveillance of the quality of medicines. In 2006, the Agency will work with its partners 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.

Chapter 4 EU telematics strategy

The main priorities for 2006 are: continued development and modification of systems to implement the new legislation; reliable operation of the EU telematics systems and related services; and continued analysis and development of the EU telematics IT projects.

In 2006, development work on a number of EU telematics projects and sub-projects needs to be continued. At the same time, five of the EU telematics systems — EudraNet, EudraVigilance, EudraCT, the database of authorised medicinal products in the EU, and the product-information-management application, PIM, — will have to be operated, supported, maintained and further developed. The Agency will advance the work on the new database for GMP certificates and manufacturing authorisations, and will complete the construction of an EU telematics data centre with high availability, high scalability and good performance.

The EU telematics programme is delivering improved communication and better access to data. As the programme advances, the benefits, including those listed below, become more apparent

- The suite of business intelligence and statistical tools within EudraVigilance will enable safety data relating to products on the market and under development in Europe to be monitored, analysed and acted upon in an increasingly sophisticated manner; an interim data warehouse and business intelligence solution for medicinal products for human use will be made available to all EU/EEA regulators in March 2006. The corresponding suite for veterinary medicines will be rolled out in September 2006.
  Two to three new upgrade versions of the main EudraVigilance application (7.1, 7.2, 7.3) will be released in the course of 2006.

- The database of authorised medicinal products in the EU will make authoritative, up-to-date information on all these products available to regulators, health professionals and the general public; while the current version of the application is already available to EU regulators, public access will be provided by September 2006. In addition to 33 core data elements, product information (SPC, PIL, labels) will be included in the database for a subset of centrally authorised products. Information on nationally authorised products may be included for those Member States who have provided their product data and signed a memorandum of understanding on data exchange and maintenance. By the end of the year, advanced query facilities will be provided.

- Both EudraCT (the clinical-trials database) and EudraGMP (the database of GMP certificates and manufacturing authorisations) will provide EU regulators a single source of information for these domains for the whole of the European Union; two new versions of EudraCT will be released during 2006 (3.0.0 in April 2006, 4.0.0 in June 2006). The first production version of EudraGMP will be ready for use in the third quarter of 2006.

- Subject to the outcome of the analysis of business processes, the EMEA will accept electronic-only submissions of applications for marketing authorisations in the eCTD format towards the end of the year. New versions of the PIM light authoring and review tools will be released at the end of April.

- Secure and reliable communication within the EU regulatory network is assured through EudraNet and the infrastructure supporting the systems.

Chapter 5 Support activities

Information technology

In addition to the maintenance and operational support of corporate and EU telematics applications — and the development of new EU telematics projects — 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.

The priorities for the Agency's IT activity relate to the continued provision of quality services in corporate IT, meetings-management and conferences, and electronic document-management and publishing.

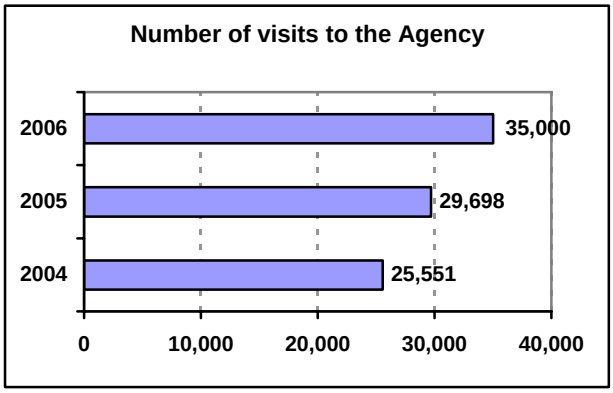
The Agency will progress its work on IP telephony, web-streaming, video-streaming and other audiovisual-meetings systems, to support the Agency's objectives in the area of meetings-management. The Agency may also need to implement the changeover to the newly created "europa.eu" domain for websites and e-mail addresses to meet the requirement of the European Parliament and Council Regulation.

Development of corporate applications will concentrate on the completion of phase III of the Meetings Management System (end of March), the continuing update of the corporate product database and tracking system SIAMED to include provisions of the new medicines legislation, and its migration to a different technical platform, and further work on a number of smaller systems such as the contracts database.

The existing business-continuity arrangements will be improved to support a range of disaster-recovery scenarios.

Infrastructure

The Agency's work in the infrastructure area is directly linked to the increased number of meetings, visitors to the Agency, telecommunications activities and staff. The Agency plans to undertake a major refurbishment project to increase meeting facilities for the Agency's scientific committees and working groups, following entry into force of the new legislation. Taking into account further changes of the Agency's regulatory and legal environment, the Agency will develop a strategy for any future expansion and reorganisation of its offices. The Agency will conduct exercises and continually test its business-continuity plan, to ensure its proper functioning.



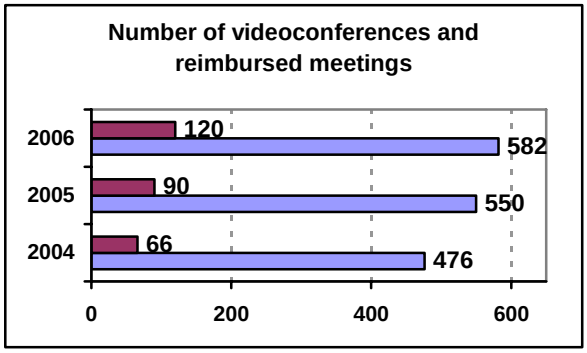
Meetings at the EMEA

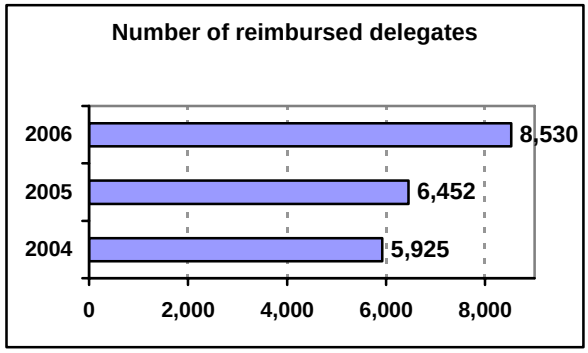
Meeting forecasts for 2006 again point to a significant increase in the number of meetings and delegate-days. The number of meetings is forecast to increase by 5% and the number of reimbursed delegates by 33%.

Given this significant growth in activity, the Agency will develop its meetings-management system to make online booking facilities available to delegates, thereby increasing the efficiency and effectiveness of this process.

Existing facilities and services for videoconferencing over the Internet will be extended and improved. A pilot project for the introduction of Internet telephony (voice over IP) will be started. A pilot exercise for web meetings will run during the first half of 2006 to examine the potential benefits of this approach.

The Agency will implement procedures for the organisation of emergency meetings. The Agency will be able to organise meetings within 24 hours, on any day of the week. A need for this type of meeting may emerge, for example, in the event of a pandemic-influenza outbreak.





Document management and publishing

The Agency will continue upgrading its electronic document management system, as this forms the bedrock for effective publishing of core business information to the Web interface, and will undertake the necessary development of records management (including retention policies) and mail registration.

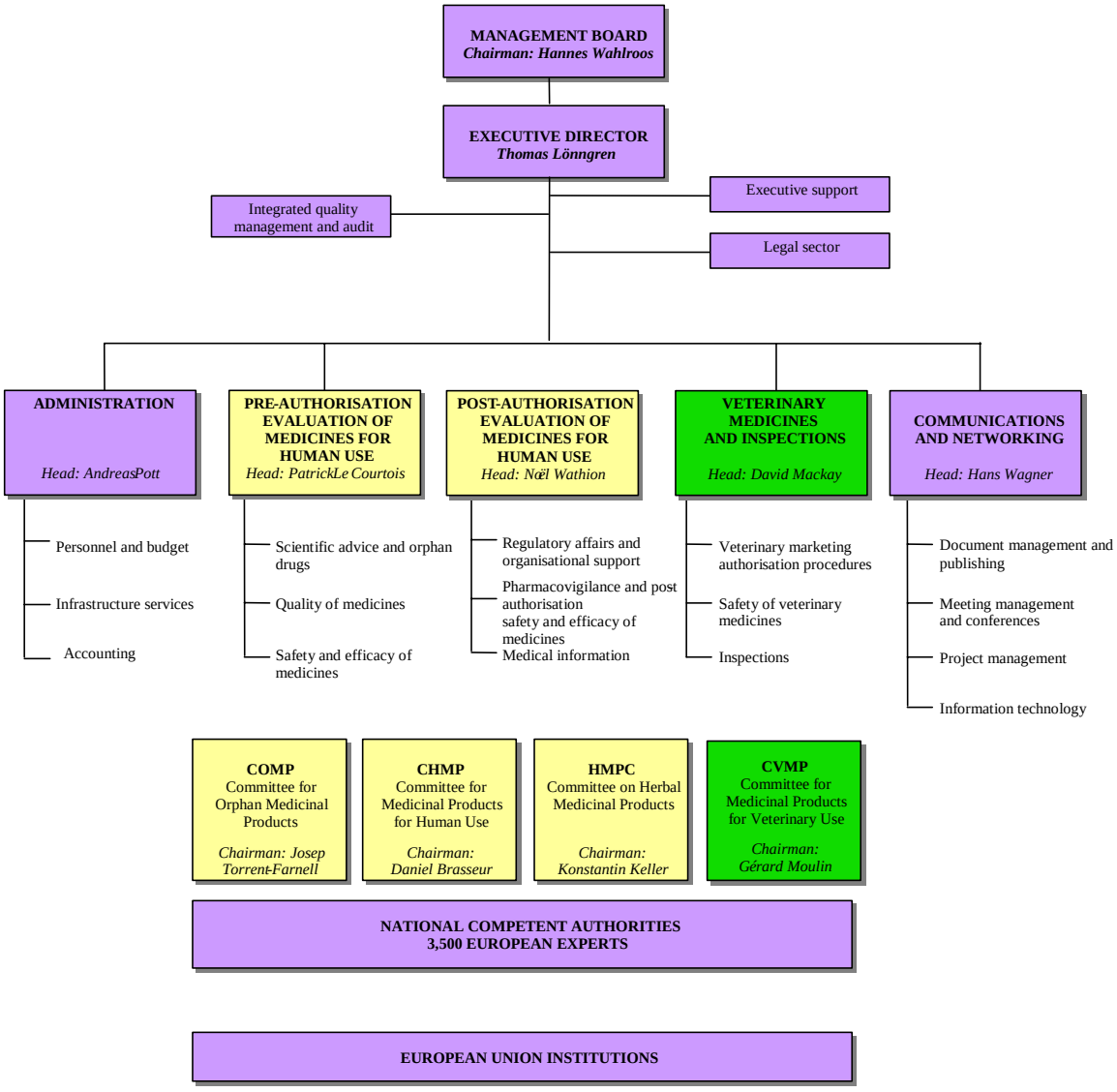
The European Commission has issued new regulations on transparency and will be reviewing European copyright laws. This comes in response to heightened public awareness and a subsequent demand for the re-use of information. The Agency therefore needs to revisit its policy on access to documents and related copyright issues.

As part of the Agency's mission to provide information to interested parties, the Agency will work to improve the quality of translations. To that effect, the EMEA will investigate translation memory, with the attendant requirement for the development of a translation-terminology database.

Annexes

1. **EMEA structure**
2. **EMEA establishment plan 2004-2006**
3. **Revenue and expenditure overview 2004-2006**
4. **Management Board and scientific committee meeting dates in 2006**
5. **EMEA contact points**

Annex 1
EMEA structure



Annex 2
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[1]
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**

[1] 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[2]
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**

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

Annex 3
Revenue and expenditure overview 2004-2006

		2004[3]		2005[4]		2006[5]	
		€'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*
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*

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

Annex 4
Management Board and scientific committee meeting dates in 2006

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

Committee for Medicinal Products for Human Use meetings	
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

Committee on Orphan Medicinal Products meetings	
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

Committee on Herbal Medicinal Products meetings	
11-12 January	12-13 July
8-9 March	6-7 September
11-12 May	25-26 October

Committee for Medicinal Products for Veterinary Use meetings	
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

For more details about the mandates, composition and other information on the EMEA Scientific Committees, Scientific Advisory Groups and Working Parties please refer to the Agency's website at: www.emea.eu.int

Annex 5
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