European Medicines Agency

EMEA/MB/442095/2006

Summary of the work programme for the

European Medicines Agency

2007

This document provides a summary of the Agency's work programme 2007. The Agency's full work programme 2007, which was adopted by the Management Board on 19 December 2006, can be found on the Agency's website: www.emea.europa.eu

Please note that figures for 2007 given in charts are estimates only.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu www.emea.europa.eu

Contents

Introduction by the Executive Director

Thomas Lönngren

The year 2007 will be the thirteenth year of operation of the EMEA and of its contribution towards the promotion and protection of public and animal health. The Agency welcomes the national competent authorities of the two new Member States, Bulgaria and Romania, as valued partners in the European medicines network. We look forward to fruitful cooperation with scientific experts from these countries to bring effective and safe medicines to all European citizens.

This EMEA work programme for 2007 has been shaped by a number of factors in the rapidly developing medicines regulation environment, most notably the entry into force of the legislation on paediatric medicines. This is an important new mandate for the EMEA, giving the Agency a significant role in stimulating the availability of safe and effective medicines for children. I wish to point out that this new area of responsibility will affect the existing core activities of the Agency — for example scientific advice, an area in which the Agency expects to receive 30% more requests than in 2006.

The Agency is facing a steady intensification of activities relating to the evaluation and supervision of medicinal products. In some areas, growth during 2006 was substantial, with an increased workload expected again in 2007. This intensification must be supported by improved cost-effectiveness of the Agency's operations and further improvement of its quality assurance systems. If the Agency is to continue to deliver on its commitment to high-quality results in all core areas, it must also be supported by a corresponding increase in finances, human resources and allocated national experts.

Promoting the safety of medicines has been an important area for the Agency over many years, and will remain a priority in 2007. Medicines agencies have traditionally relied on spontaneous reporting of adverse reactions, and the EMEA EudraVigilance database remains a key tool for this. However, we want to take this a step forward. In addition to the new tools we have already implemented, we want to work with Member State authorities and academic centres on establishing networks of experts to run intensive drug-monitoring programmes that will actively study the safety of targeted medicines.

The EMEA supports the objectives of the Lisbon agenda. Innovation and research are the primary driving forces for new medicines, and, consequently, motors for improved public and animal health. The Agency's efforts to support these objectives in 2007 will focus on: providing scientific advice; providing special support for small and medium-sized enterprises; conducting research into the consistency of the Agency's decision-making; and contributing to pan-European initiatives for facilitating innovative research.

The Agency considers the availability of the same, high-quality information about medicines in all official EU languages to be essential for their optimal use in all Member States. We will work closely with Member States and their experts to ensure that the information we provide is of the highest quality in all languages. We will also strive to improve our communications more generally, covering both our scientific and non-scientific activities. As part of this, we will further promote the participation of patients and healthcare professionals in our activities.

I would like to emphasise that these activities are only possible through the harmonious functioning of the European medicines network, with the EMEA and the national competent authorities working side by side. Fostering this spirit of cooperation and seeking practical solutions to present and future challenges brought by developments in our field will be my final, but nonetheless important, priority for 2007.

The priorities and key objectives for 2007 can be summarised as follows:

The Agency will conduct its core activities in the areas of authorisation and supervision of medicines for human and veterinary use to the highest quality standards. It will continuously assess the prioritisation of projects and activities to accommodate a considerably increased volume of activity, and effect improvements where necessary to ensure that high standards are maintained.

Additional priorities in 2007 will include:

Implementation of legislation on medicines for children

- Implement the new regulation on medicinal products for paediatric use, including the establishment of a new Paediatric Committee, delivering opinions and decisions on paediatric investigation plans and waivers, and providing information on paediatric clinical trials.

Safety of medicines for human and veterinary use

- Continue to apply a proactive approach to safety of medicines by initiating early assessment of the safety prior to authorisation, by monitoring implementation of risk-management plans after marketing authorisation, and by supervising the updating of such plans throughout the lifecycle of the product;
- Progress the implementation of the European Risk Management Strategy (ERMS), in close collaboration with the national competent authorities, leading to a more efficient system for supervising the safety of medicinal products;
- Further develop EudraVigilance, one of the main pillars of the ERMS, by implementing and starting the operation of quantitative signal-detection methods, by providing the Agency's stakeholders access to EudraVigilance information, and by setting up and implementing a network of academic centres for the intensive monitoring of targeted medicines;
- 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.

Stimulation of innovation

- Further maintain and improve measures for facilitating innovation and research, and thus increasing availability of medicines, in particular through: continuous support for the orphan medicinal products policy; the provision of scientific advice; support for micro, small and medium-sized enterprises; research into the impact and consistency of the Agency's decision making;
- Continue supporting the European Commission through the stages leading to the new regulation on advanced therapies; participate in the work of the Innovative Medicines Initiative for human medicines, the European Technology Platform for Global Animal Health for veterinary medicines, and in other international initiatives to improve drug development.

Earlier and improved availability of medicines

- Operate and increase the effectiveness of marketing authorisation procedures for facilitating availability of medicines, while maintaining the highest quality standards. These procedures include accelerated assessment, conditional marketing authorisation and compassionate use;
- Provide opinions on medicinal products intended for non-EU markets;

– Support further initiatives, once identified, to facilitate greater availability of veterinary medicines, particularly through measures to assist companies submitting applications for veterinary medicines which have limited markets or which are intended for diseases with regional distribution.

Transparency, communication and provision of information

– Further implement the EMEA transparency measures and increase the openness of the Agency's activities to underpin its corporate governance;

– Further improve the Agency's contribution towards the provision of high-quality and timely information on medicines in all official EU languages to patients and healthcare professionals; Contribute to the work of the Pharmaceutical Forum, particularly in the area of provision of information to patients;

– Promote the participation of patients and healthcare professionals in the work of the Agency.

The European medicines network

– Strengthen cooperation on pharmacovigilance, EU telematics, scientific advice, support to SMEs and communication;

– Further stimulate complementarities in the network and develop adequate work-sharing and resource-planning activities across the network;

– In light of the increasing tasks at the EU level and the arrival of novel therapies and technologies, work to ensure availability for the network of the highest-quality expertise at EU level for the evaluation of medicines and for monitoring and assessing their safety.

1 EMEA in the European system

1.1 European medicines network

The Agency looks forward to welcoming representatives of Bulgaria and Romania as full members of the European medicines network and active participants in the work of the Agency. In 2007, the European medicines network will continue its work to address trends relating to the growing complexity and the number of tasks performed at Community level, as well as the advent of novel therapies and technologies.

To address these trends, the EMEA, together with the national competent authorities, will work to strengthen the network of excellence and will cooperate to further develop resource-planning and work-sharing practices. Unmet training needs in critical areas will be identified and processes for advanced educational exchange will be established. Work will continue on implementing the vision outlined in the long-term strategies prepared by the EMEA and the national competent authorities.

1.2 Transparency, communication and provision of information

The Agency will complete the development of the communication and transparency strategy and begin its implementation during 2007. The Agency will focus its initiatives in the following areas: implementation of transparency and communication provisions relating to medicines for paediatric use and paediatric clinical trials; improving the provision of information on scientific non-product related issues; completion of the implementation of the legislation on access to documents; provision of access to information on adverse drug reactions contained in the EMEA EudraVigilance database; and provision of product-related information in the new Community languages, Bulgarian and Romanian, and, following expiry of the derogation, in Maltese. By developing these initiatives, the EMEA aims to promote the appropriate use of medicines and further contribute to patient safety.

The Agency will take part in the work of the Pharmaceutical Forum, and will continue the development of the EudraPharm database, containing information about centrally authorised products.

The Agency will also continue its efforts to develop and strengthen interaction with and the participation of the Agency's stakeholders — healthcare professionals, patients and consumers — in the work of the Agency. To this end, the Agency has established a working group with healthcare professionals, which will prepare a framework for interaction with healthcare professionals' organisations.

1.3 Support for innovation and access to medicines

The Agency will remain focused on the objectives of the Lisbon agenda. It will continue to implement the policy on micro, small and medium-sized enterprises (SMEs), which are often innovative companies working in the field of new technologies and emerging therapies; will continue to provide high-quality scientific advice to companies developing medicinal products; will support the development of orphan medicinal products; and will actively participate in the Innovative Medicines Initiative. The latter aims to address bottlenecks in the development of medicines, and may have a strong and wide-reaching impact on how research in medicines is done in the future. The Agency's task-force on innovation will continue its work, and the EMEA/CHMP think-tank on innovation will finalise its report in the beginning of the year.

The EMEA will continue its initiatives aimed at improving the availability of veterinary medicines for minor uses and minor species. It will work with the Heads of Veterinary Medicines Agencies on availability and will provide support to the European Technology Platform for Global Animal Health,

which aims to accelerate the development of novel animal-health products for both major and minor markets. The Agency will also develop measures to assist companies with authorisation of products for minor markets.

1.4 Emerging therapies and new technologies

The Agency is active in the field of advanced therapy medicinal products such as gene therapy, somatic cell-therapy and human tissue-engineered products. It also deals with other emerging therapies and new technologies that are not within the scope of the upcoming regulation on advanced therapies and which will strongly influence the Agency's work in this field.

To better prepare itself and the network for the advent of new therapies and technologies, the Agency will promote early dialogue with sponsors of potential applications for advanced therapies and emerging products and technologies. It will extend the dialogue with academia and society at large to identify expertise, expectations and bottlenecks relating to the area of new treatment solutions. Following discussion with stakeholders and interested parties, work will start on establishing a 'Strategic plan for new technologies'.

1.5 European public health activities

Important areas of interaction with the European Commission on public-health issues will include: work associated with the legislation and initiatives relating to advanced therapies; support on the updating and further development of the Notice to Applicants; work within the framework of the public-private partnership aimed at providing quality information to patients; and assistance in revision of legislation governing variations to marketing authorisations.

The Agency will continue its work in respect of, and maintain readiness for, a potential influenza pandemic, including through training and simulation activities and measures to promote the authorisation through the centralised procedure of safe and effective vaccines for control of avian influenza in birds. In addition, it will develop the concept of the 'multistrain' dossier to promote authorisation of vaccines against antigenically variable viruses such as avian influenza, bluetongue and foot-and-mouth disease.

The EMEA will continue ongoing activities in areas including: EU programme to reduce animal testing and develop modern approaches to safety assessment of medicines, minimisation of the occurrence of antimicrobial resistance, and environmental risk-assessment for medicinal products. Cooperation will continue with the partner EU agencies and the European Directorate for the Quality of Medicines.

1.6 Preparations for future enlargement

The Agency will participate in the multi-beneficiary programme dedicated to supporting the participation of Croatia and Turkey in the work of certain Community agencies. The aim of the Agency's activities will be to build contacts and relationships between Croatia and Turkey and the EMEA. This programme will allow the two countries to prepare themselves for participation in the activities of the EMEA and to develop the confidence of the existing Members States in the systems in place in the two candidate countries.

1.7 International cooperation

The Agency's activities in the international arena include: coordination of EU experts' participation in the International Conference/Cooperation on Harmonisation (ICH and VICH) and the 7th ICH Conference, as well as work with the World Health Organization (for example, on medicinal products for use in developing countries), the Codex Alimentarius, the World Organisation for Animal Health, the US Food and Drug Administration (FDA) and the US Department of Agriculture.

The Agency will continue its successful and useful cooperation with the FDA and will introduce measures to deepen this cooperation by consolidating procedures for parallel scientific advice. The Agency will also liaise with responsible US institutions to exchange relevant information on veterinary medicines.

The EMEA, together with the European Commission, plans to continue preliminary discussions with the Japanese medicines agency (MHWL/PMDA) in order to explore the possibility of setting up confidentiality arrangements similar to those concluded with the FDA.

1.8 Integrated management at the Agency

The Agency's highlights for this year will include completion of the two-year process-improvement exercise. The objective of the exercise is to optimise key Agency processes, improve the cost-effectiveness of its operations, improve performance and boost customer and stakeholder satisfaction. Some outcomes of these initiatives will contribute to the ongoing discussion on planning of activities at the level of the European medicines network.

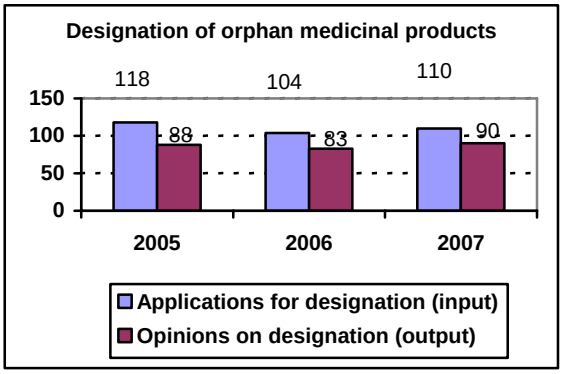
As in previous years, the Agency will carry out a number of self-assessment activities, internal audits and stakeholder surveys, and will introduce a system for 360-degree evaluation of management.

2 Medicines for human and veterinary use

2.1 Orphan medicinal products for human use

Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting a small number of patients in the European Community. Incentives are provided because such medicines might, for economic reasons, not otherwise be developed. In order to meet the expectations of patients' organisations and sponsors and the requirements of the legislation, and to create an environment for innovation and research in this area, the Agency will continue to provide incentives during the development and initial marketing authorisation phases. Protocol assistance will remain a priority area for these incentives.

In addition to its evaluation of orphan-designation applications, the Agency will collaborate with international partners, particularly through increased provision of protocol assistance in parallel with the US Food and Drug Administration.



2.2 Scientific advice and protocol assistance

Human medicines

Scientific advice and protocol assistance are key areas of activity for the Agency, in particular with respect to fostering new innovative technologies and therapies and as a means to facilitate and improve earlier availability of medicinal products.

A trend seen in scientific advice is the high interest shown by industry, with a significant increase in the number of requests from year to year translating into a high workload and, thus, the need for effective management of procedures. Another trend is the advent of new technologies and emerging therapies, for which the Agency and the network will begin preparations.

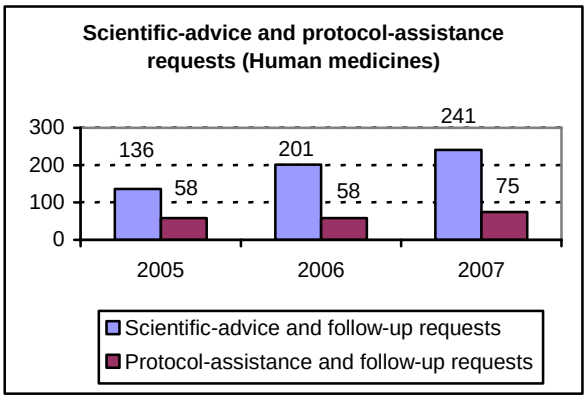
A significant task for the Agency in 2007 is to implement the paediatric medicines regulation by ensuring effective cooperation between the Scientific Advice Working Party and the new Paediatric Committee. The Agency anticipates around 50 requests for scientific advice relating to paediatric medicines. A second key task will relate to the development of risk-management plans at the time when scientific advice is sought.

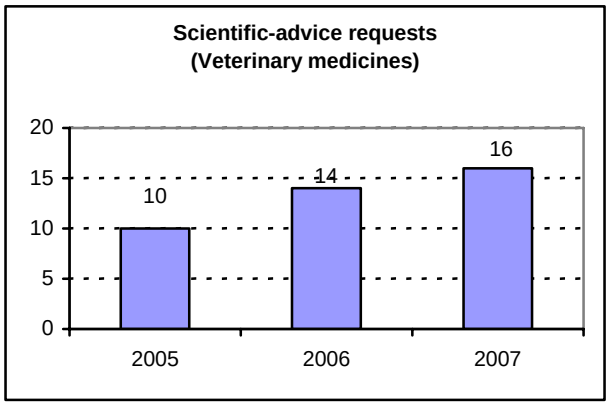
Veterinary medicines

The number of submissions for scientific advice for veterinary medicines will increase to 16 for 2007. This is a result of recognition and appreciation by potential applicants of improvements to the

veterinary scientific advice procedure, as well as growing confidence in the industry through experience with the procedure.

The Agency will introduce additional information-technology tools to track applications for veterinary scientific advice, and will measure the level of satisfaction with the new procedure in order to make additional improvements, if needed.



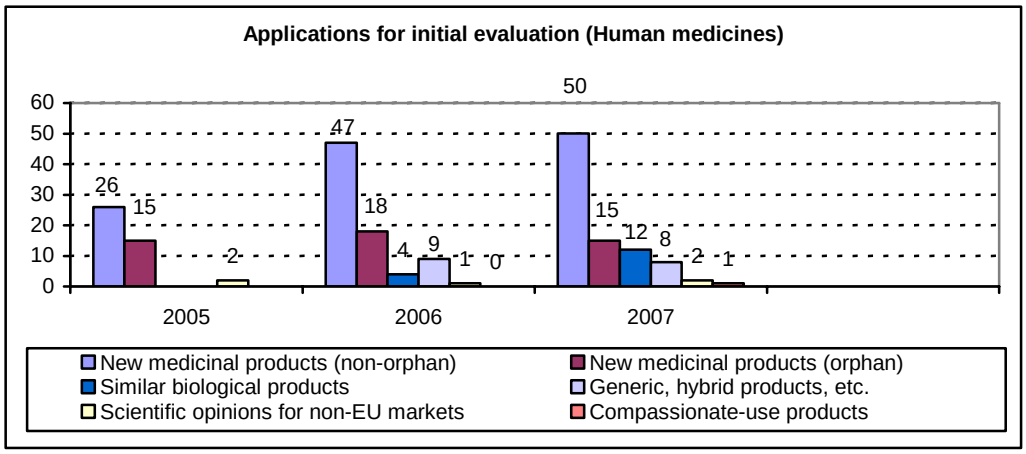


2.3 Initial evaluation

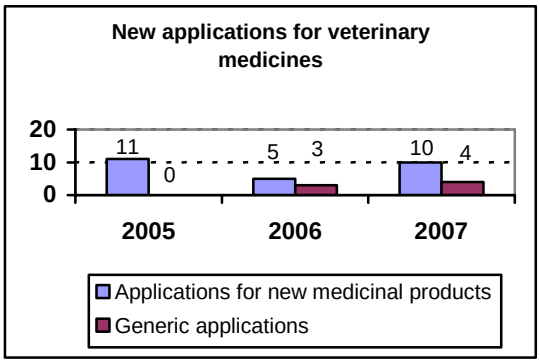
Human medicines

The number of applications and related workload has increased over the last years. This increase is due, to a large extent, to the entry into force of the new legislation modifying the scope of procedures and introducing new procedures. The large number of applications received in 2006 will have a significant impact on the workload in 2007 since procedures run over several months.

Thanks to the new legislation, the Agency was able to introduce a number of procedures which provide faster availability of most-needed medicines and assure high quality of the results of the work performed. The procedures include: pre-authorisation procedure for risk-management plans, conditional marketing authorisation, accelerated assessment, procedures for generic and similar biological products, procedures for compassionate use and for products intended for non-EU markets. The Agency will review the effectiveness of the procedures and will reinforce the link between scientific advice and marketing authorisation application phases.



The Agency expects that the overall number of applications for veterinary medicinal products will remain at around 14 applications in 2007. In addition to evaluation of the applications, the Agency plans to continue strengthening the quality-assurance system as well as the scientific and regulatory consistency of scientific assessments in 2007. This will be done through various initiatives, which will also include development and maintenance of a scientific memory database. In order to ensure that scientific issues are fully discussed prior to submission, and thus to avoid premature applications in the veterinary area, the Agency will hold pre-submission meetings involving the rapporteur, co-rapporteur and necessary experts.

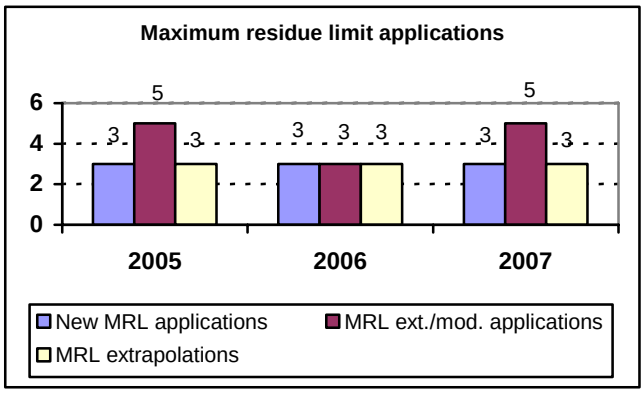


2.4 Establishment of maximum residue limits

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.

The number of new veterinary medicines for food-producing animals is expected to remain relatively stable, and the number of new MRL applications is predicted to remain constant, with 3 applications being forecast. Despite initiatives taken by the CVMP[1] to facilitate the authorisation of products for minor uses and minor species, the number of associated extensions and modifications has remained stable over the last years — a situation likely to continue in 2007, with 5 applications being predicted.

In addition to evaluation of applications for MRLs, the Agency will provide assistance to the Commission with the review of Regulation (EEC) No 2377/90 laying down a Community procedure for the establishment of MRLs for veterinary medicinal products in foodstuffs of animal origin.



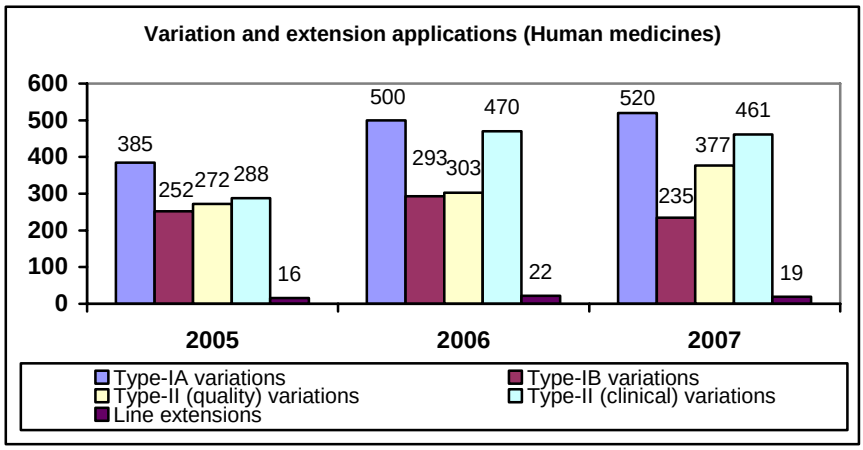
[1] Committee for Medicinal Products for Veterinary Use (CVMP).

2.5 Post-authorisation activities

Human medicines

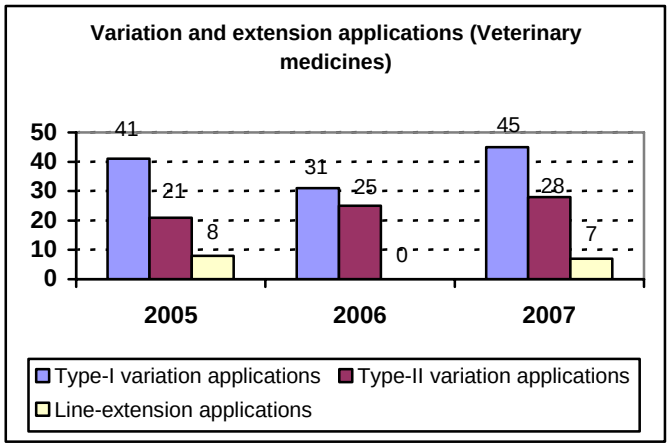
The number of type-I and II variations will change in line with the growing number of centrally authorised products. The Agency expects to receive in 2007 the first variations to similar biological products and first updates of opinions given to medicinal products intended for non-EU markets.

The Agency will review its post-authorisation activities during the ongoing process-improvement exercise to further increase efficiency. Work will continue on strengthening the quality and the regulatory and scientific consistency of CHMP[2] opinions and assessment reports in the post-authorisation phase, building on improvements introduced in 2006.



Veterinary medicines

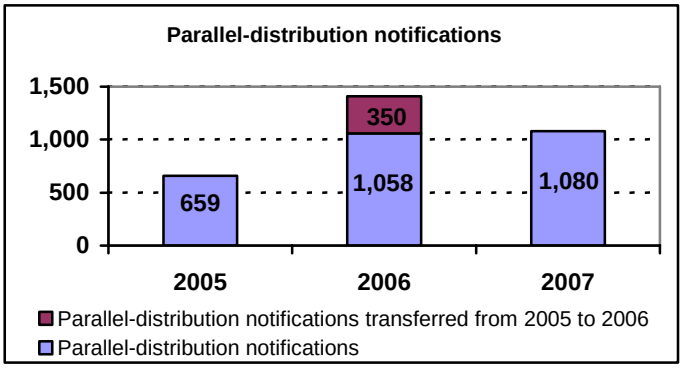
The Agency expects that the number of applications in the post-authorisation area of veterinary medicines will remain largely unchanged. In addition to evaluation of received applications, the Agency will continue the provision of information on post-authorisation activities. As part of the activities, the EMEA will prepare EPAR[3] summary updates for line extensions that lead to major changes in the indications or conditions of use. To further advance the implementation of the revised legislation, the procedure for monitoring the actual placing on the market of authorised products will be implemented.



[2] Committee for Medicinal Products for Human Use (CHMP).
[3] European public assessment report (EPAR).

Parallel distribution

The EMEA expects that the number of parallel-distribution notifications for 2007 will stabilise at approximately 1,000. In addition to handling notifications, the Agency plans to review and update its guidance on parallel distribution to improve the efficiency of parallel-distribution notification processes, and will publish parallel-distribution notifications issued by the EMEA on its website.



2.6 Pharmacovigilance and maintenance activities

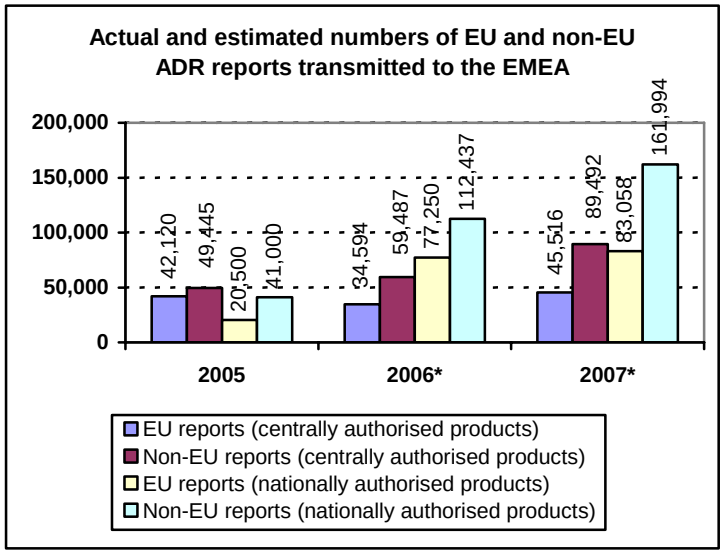
Safety of medicines is a priority area for the EMEA and the Agency will continue to strengthen its efforts to ensure the safe use of centrally authorised medicinal products. The Agency will concentrate its efforts in three areas:

Firstly, the Agency will further improve the EudraVigilance database and individual case safety reporting. Although there has been a major increase in electronic reporting of ICSRs over the last two years, the EMEA will continue its initiatives to speed up the implementation of such reporting. It will also address aspects relating to data quality and stakeholders' compliance with expedited reporting timelines. The detection, evaluation and tracking of potential safety issues will be reinforced through the availability of the EudraVigilance Data Warehouse and Analysis System.

Secondly, the EMEA will continue to work with the national competent authorities to establish an intensive drug monitoring system. The work will be carried out in the context of the European Risk Management Strategy (ERMS), and will include the development of additional activities and the implementation of agreed initiatives. The EMEA and the network partners will establish a rolling two-year work plan for the period 2007-2009 and will take forward a project designed to set up a network of academic centres for the intensive monitoring of targeted medicines.

Finally, the Agency plans to grant access to adverse drug reaction data to the stakeholders. The level of access will take into account the requirement to guarantee personal data protection as well as the commercial confidentiality of some of the data stored in EudraVigilance.

Maintenance activities relating to post-authorisation commitments (specific obligations, follow-up measures), renewal applications and annual reassessments are expected to continue at last year's rate.



* With the implementation of the mandatory electronic reporting of ICSRs and the EudraVigilance Data Warehouse and Analysis System, a new method has been developed to present the number of ICSRs received/expected over time. This new method has been used for the numbers as of 2006.

Veterinary medicines

Safety of veterinary medicines in the post-authorisation phase and the need to implement and further improve a risk-management approach to this important issue will continue to be a high priority for the Agency in 2007. It is expected that over 70 centrally authorised veterinary products will be available by 2007. The Agency forecasts the number of serious adverse reaction reports will rise to well over 400, with 64 PSURs[4] being submitted (54 were submitted in 2006).

To step up the provision of veterinary pharmacovigilance information, the Agency plans to increase reporting on pharmacovigilance information to the stakeholders. The planned development of the analytical and reporting functions of the EudraVigilance Data Warehouse will support this goal.

The Agency will collaborate closely with Member States in the European Surveillance Strategy (ESS) to foster a joint approach to optimising the efficiency of EU veterinary pharmacovigilance for all medicinal products authorised in the Community. Together with the Member States, the Agency will continue to work on encouraging a reporting culture on pharmacovigilance issues.

2.7 Arbitration and Community referrals

Human medicines

The Agency expects a significant increase in the number of arbitration and referral procedures in particular in the number of Article 29 arbitrations (relating to difference in opinions at the Member State level). The implementation of Article 5(3) and Article 107(2) procedures which are new legal provisions will be monitored carefully.

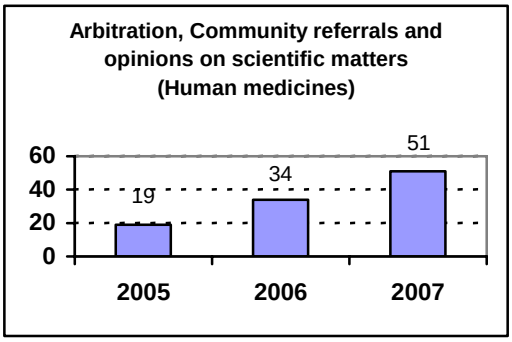
The Agency will focus on the effective management of referral and arbitration procedures, and will work to further strengthen the quality and the regulatory and scientific consistency of CHMP opinions and assessment reports. With this in view, a number of guidance documents will be developed.

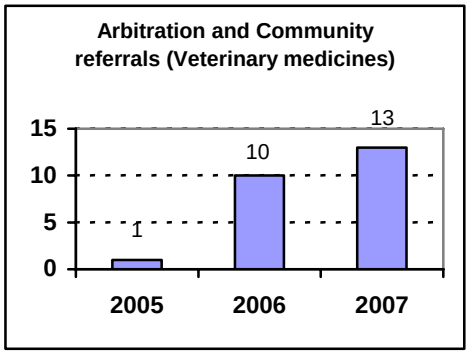
The Agency will publish Q&A documents at the time of adoption of the CHMP opinion, thus ensuring transparency on arbitration and referral procedures.

[4] Periodic safety-update reports (PSURs).

Veterinary medicines

The Agency expects that a total of 13 arbitrations/referrals will be submitted to the CVMP in 2007 — three more than in 2006 — including twelve referrals following mutual recognition and decentralised procedures. The number of referrals triggered by safety concerns where there is a Community interest is expected to remain low, with only 1 predicted for 2007. The Agency will focus on ensuring the quality of opinions arising from arbitration and referral procedures, and will work to adhere to regulatory timelines. The Agency will ensure optimal coordination between concerned parties to minimise 'unnecessary' referrals.





2.8 Medicines for children

The Agency will receive entirely new responsibilities in the field of paediatric medicines. The EMEA Paediatric Committee will conduct assessment of, agreement on, and verification of compliance with, paediatric investigation plans and waivers. An agreed paediatric investigation plan may lead to information on the paediatric use of medicines being included in a centralised or national marketing authorisation for new medicinal products, and in a paediatric-use marketing authorisation for off-patent products.

To undertake the above tasks, the EMEA will establish a new scientific committee (the Paediatric Committee) and related processes. The EMEA will also begin the gradual establishment of a European network for paediatric research. It will develop, with the Commission and Member States, guidelines for transparency of the paediatric clinical-trials database.

The Agency estimates around 400 requests or applications relating to paediatric activities (such as paediatric investigation plans, waivers and scientific advice) will be received in the first year of activity. In addition, the work on paediatric investigation plans will impact on activities within other areas, including scientific advice, quality and post-authorisation areas, as well as risk-management plans.

Work will also commence in the area of paediatric pharmacovigilance. A number of related guidelines will be implemented, and expert fora for the investigation of new sources and methods for intensive monitoring of the paediatric use of medicines will be established.

2.9 Herbal medicinal products

The Agency's Committee on Herbal Medicinal Products (HMPC) provides scientific opinions on questions relating to herbal medicines, establishes Community herbal monographs for traditional and well-established herbal medicinal products, and prepares a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products. It also provides opinions on herbal substances at the request of the CHMP and conducts referral and arbitration procedures involving traditional herbal medicinal products.

In 2007 the Agency plans to develop 20 herbal monographs and make 10 entries into the list of herbal substances, preparations and combinations thereof. However, the achievement of these targets is critically dependent on the availability of adequate bibliographic data and on resources made available at NCA level to support their review. Availability or lack thereof will have a direct impact on the productivity of the HMPC in 2007 and beyond.

The Agency will also update interested parties on the operations of the HMPC, with particular emphasis on prioritisation of herbal substances identified for list entry/monograph development.

2.10 Scientific committees, working parties and scientific advisory groups

A renomination of the majority of the CHMP, CVMP and HMPC members will take place in May 2007, following completion of their three-year term. The Agency will work to ensure timely and smooth transitions from the former Committees. A fifth scientific committee, the Paediatric Committee, will be established in the second quarter of 2007. Work will continue on improving the cost-effectiveness of arrangements for working parties, including a review of their mandates, the distribution of work, and the support provided by the secretariat. Expertise needed in the working parties will be addressed together with the Heads of Medicines Agencies.

2.11 Coordination group

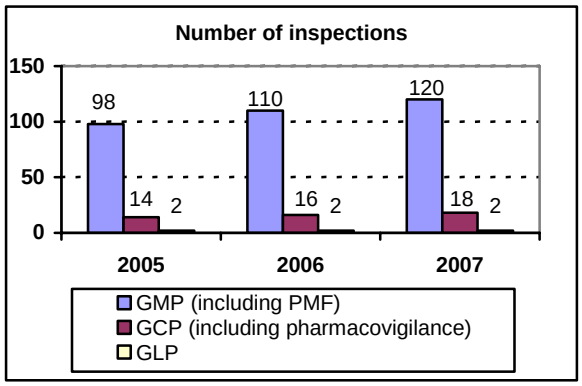
The Agency provides secretarial support to the Coordination groups for mutual recognition and decentralised procedures (human and veterinary products) (CMD)(h) and CMD(v)), and to their sub-groups/working groups, in accordance with the approved rules of procedure. In 2007, the Agency will seek to consolidate these activities, based on a review of the experience gained from the first year of operation of the CMD(h) and CMD(v).

3 Inspection activities

3.1 GMP, GCP, GLP and pharmacovigilance inspections

Both GMP[5] and PMF[6] inspections numbers are expected to rise relative to 2006. This takes into account the increasing number of authorised products requiring re-inspection, increasing numbers of variations, the impact of generic applications, and new requirements for GMP for active substances.

The Agency will work to carry out GMP, GCP[7], GLP[8] and pharmacovigilance inspections within the required timelines and to the required quality level. Additional efforts will focus on addressing the impact of legal and procedural requirements on various inspection areas, on integration of certain ICH concepts (quality risk-management, design space, etc.) in assessment and inspection areas, and on analysis of GMP, PMF inspection and quality-defect findings in previous years.



The Agency will organise training activities on GCP and Quality/GMP and will further develop the cooperation between inspection and assessment functions, particularly through the work of the Process Analytical Technology team and joint sessions with GMP inspectors/Quality assessors and GCP inspectors /Clinical assessors.

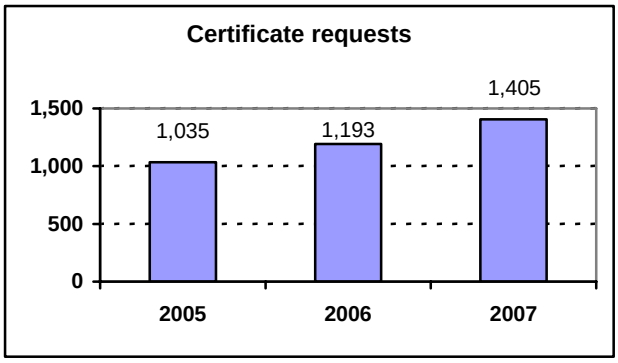
The Agency will continue its support for the implementation of directives on GCP and will further work on the preparation of guidelines and Community procedures associated with implementation of GMP-related aspects of the new legislation.

Mutual recognition agreements (MRAs) with Australia, New Zealand, Switzerland, Canada and Japan are currently operational, but with slightly different provisions as to scope and applicability. The Agency expects to complete the remaining internal evaluation work and follow-up with new Member States in the context of the EC-Canada MRA, which will now include Bulgaria and Romania. The external evaluations will continue into late 2007. The Agency expects to complete the implementation of the full scope of the GMP Annex with EC-Japan MRA and maintenance arrangements.

[5] Good manufacturing practice (GMP).
[6] Plasma master file (PMF).
[7] Good clinical practice (GCP).
[8] Good laboratory practice (GLP).

3.2 Certificates of medicinal products

The Agency issues certificates of medicinal products to support the work of health authorities outside the European Union, in particular in developing countries. The Agency expects an 18% increase in the number of certificate requests due to the increasing number of approved marketing authorisations. Certificates within the framework of cooperation with the WHO and certificates for SMEs are also expected to increase in 2007. The Agency will rationalise the certification process in 2007.



3.3 Sampling and testing

The sampling and testing programme for centrally authorised products will continue in 2007, and will enable the quality of medicinal products on the market in the EEA to be monitored, using the expertise of the EEA official medicines-control laboratories network. Close collaboration between the EMEA, the European Directorate for the Quality of Medicines and the national authorities in the programme continues to prove invaluable in assuring effective and continued post-marketing surveillance of the quality of medicines.

The Agency plans to test 40 products in 2007. Work will be done to progress a risk-based approach to the selection of products and parameters for testing in view of generic applications and advances in technology (Process Analytical Technology), and the Agency will review a ‘one-laboratory testing scheme’ concept and assess its possible introduction for biological products.

4 EU telematics strategy

As part of the implementation of the European pharmaceutical policy and legislation, the Agency was given responsibility to implement the EU telematics strategy. The strategy aims 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, EudraPharm, electronic submissions, clinical trials and good manufacturing practice databases. In addition, there is a set of horizontal services that are necessary to support the implementation of the systems mentioned.

The majority of EU telematics systems will be in use at the beginning of 2007. These systems are evolving in line with communicated requirements. The table below provides an overview of the development of the systems in 2007.

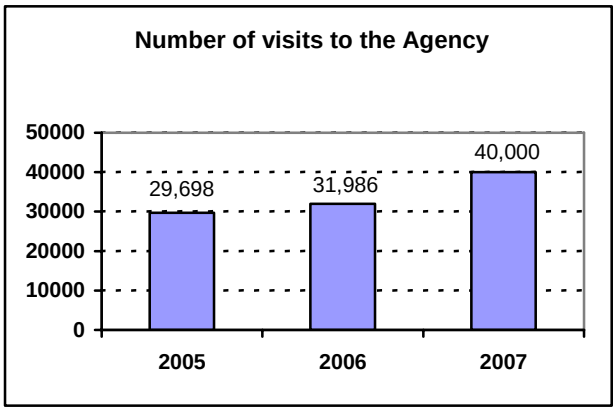
System or process	2007 milestones
EudraNet *(In production)*	Bringing inspections agencies into service over EudraNet where these are not part of the national competent authority. Implementation of advanced network-management and performance services. Provision of additional EudraNet back-up systems.
EudraPharm *(In production)*	In line with the legislation, development will focus on products authorised using the centralised procedure in this first phase. Quarterly releases are anticipated, implementing increases in functionality in the areas of search, use by specific audiences, data entry, interaction with other systems and use of controlled vocabularies.
EudraVigilance *(In production)*	Up to three releases are planned, implementing increases in functionality in the product dictionary, the first part of signal tracking and access by specific audiences.
Eudra Data Warehouse *(In pre-production)*	Regular releases throughout the year are foreseen, putting into place reporting against the requested pre-defined queries for pharmacovigilance (in respect of both human and veterinary products).
EudraCT *(In production)*	Work will include background upgrading of the underlying infrastructure followed by the delivery of improved systems for importing and exporting sets of data. This will result from routine maintenance activities.
EudraCT-Paediatrics Database *(At inception)*	This database is in the first stages of the design process. During 2007, it is anticipated that the high-level design will be completed, that the system will be prototyped, and that work on the first production version will be initiated.
EudraGMP *(In final testing)*	The first version of this database will be delivered early in 2007. Work on the next version will be postponed to 2009.
European Review System *(Pre-installation)*	Following the tender procedure in 2006, it is anticipated that over the year, the system will be installed in agencies across the European Economic Area that require it.
PIM (Product Information Management) *(In pilot production)*	Subject to successful conclusion of pilot activities for both new marketing authorisation applications and post-authorisation activities, the system will go into full production during the year. One or two new releases of both the review and light authoring systems are anticipated. Except for specification, work on extending the system to mutual recognition and decentralised procedures has been postponed to 2008-2009.
EU Telematics Controlled Terms *(2nd Proof of Concept concluded)*	This system is intended to act as a central repository for controlled terms for the European medicines network. A production system is anticipated that will be able to make available sets of controlled terms, subject to the establishment of a formal process for the control of such terms.

5 Support activities

5.1 Infrastructure services at the EMEA

The number of meetings and increasing number of staff due to the growing responsibilities of the Agency made it necessary for the Agency to acquire additional office space in 2006. The Agency will design, plan and carry out refurbishment projects in the new space to make it fully equipped for the needs of the Agency's delegates and staff.

The Agency will attend to the implementation and exercising of business-continuity plans in 2007, as well as to the organisation of health and safety awareness campaigns. E-procurement tools, systems and procedures will be introduced and developed in 2007. In addition to four outsourced contracts (switchboard/reception; audiovisual technicians; security guarding; and catering), the Agency will consider outsourcing reprographics and ancillary services in 2007.



5.2 Information technology

Agency activities in the information technology area will seek to address the growing requirement to provide and maintain a paperless meeting room environment, high levels of service availability and good quality of IT service.

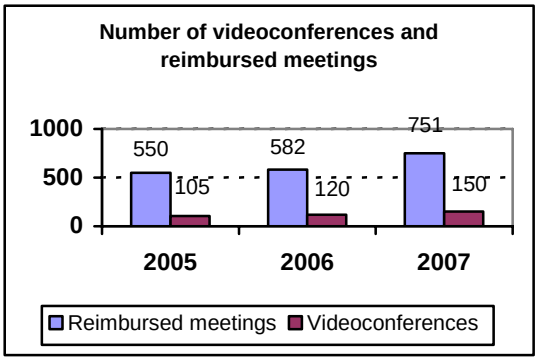
To respond to the growing number of meetings and visiting delegates, and to rationalise resource use, the Agency will progress the development of integrated videoconferencing and other virtual meetings solutions, in line with specific meeting requirements. These projects will be complemented by work to enhance the electronic document management system (Managing Meeting Documents, e-Collaboration and setting up workflows), which will rationalise processes linked to managing meeting-related documentation. The Agency also plans to improve the electronic records management system, to include mail registration and electronic archiving solutions. In addition, the implementation of a business-continuity IT solution will be advanced to support a range of disaster-recovery scenarios.

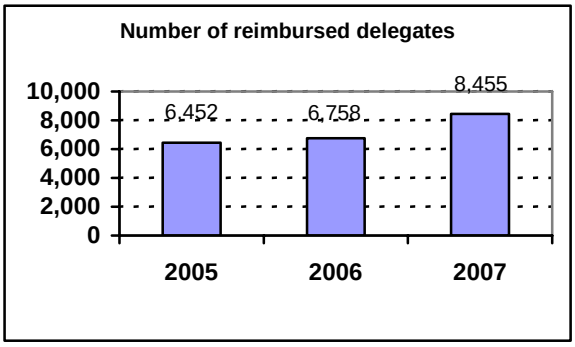
To ensure high quality of IT projects, the Agency will progress the deployment of best-practice support processes based on the IT Infrastructure Library (ITIL) service management. This will enable the Agency to ensure the provision of reliable and robust IT services to its staff, delegates and all users of pan-European systems.

5.3 Meetings and conferences at the EMEA

The factors influencing the growing number of meetings to be held at the Agency in 2007 include: the increasing responsibilities of the Agency (paediatric legislation); a growing interest in the centralised procedure (leading to more meetings with applicants); activities in the field of innovation; and intensified cooperation in the network (including training activities). The increase also takes into account activities postponed from 2006, as well as participation of representatives of candidate countries in meetings, training courses and conferences.

The Agency estimates an increase in the number of reimbursed meetings by 30% and the number of reimbursed delegates by 25% in 2007.





To respond to the increasing number of meetings, and to improve the meetings-organisation workflow and procedures, the Agency will focus on two aspects: streamlining the management of meetings and providing alternative meeting solutions. Streamlining of meeting management will be achieved by enhancing the Agency's Meeting Management System to include a tracking system for hotel and travel details and, via the EMEA website, online booking facilities for delegates. The MMS financial module will speed up the process of reimbursing delegates and provide clearer information to delegates and national competent authorities.

With regard to alternative meeting solutions, the Agency will work to extend videoconferencing and broadcasting of meetings to national competent authorities and EMEA experts. If justified, desktop videoconferencing facilities will be developed and pilot web broadcasts of scientific meetings may be carried out in 2007.

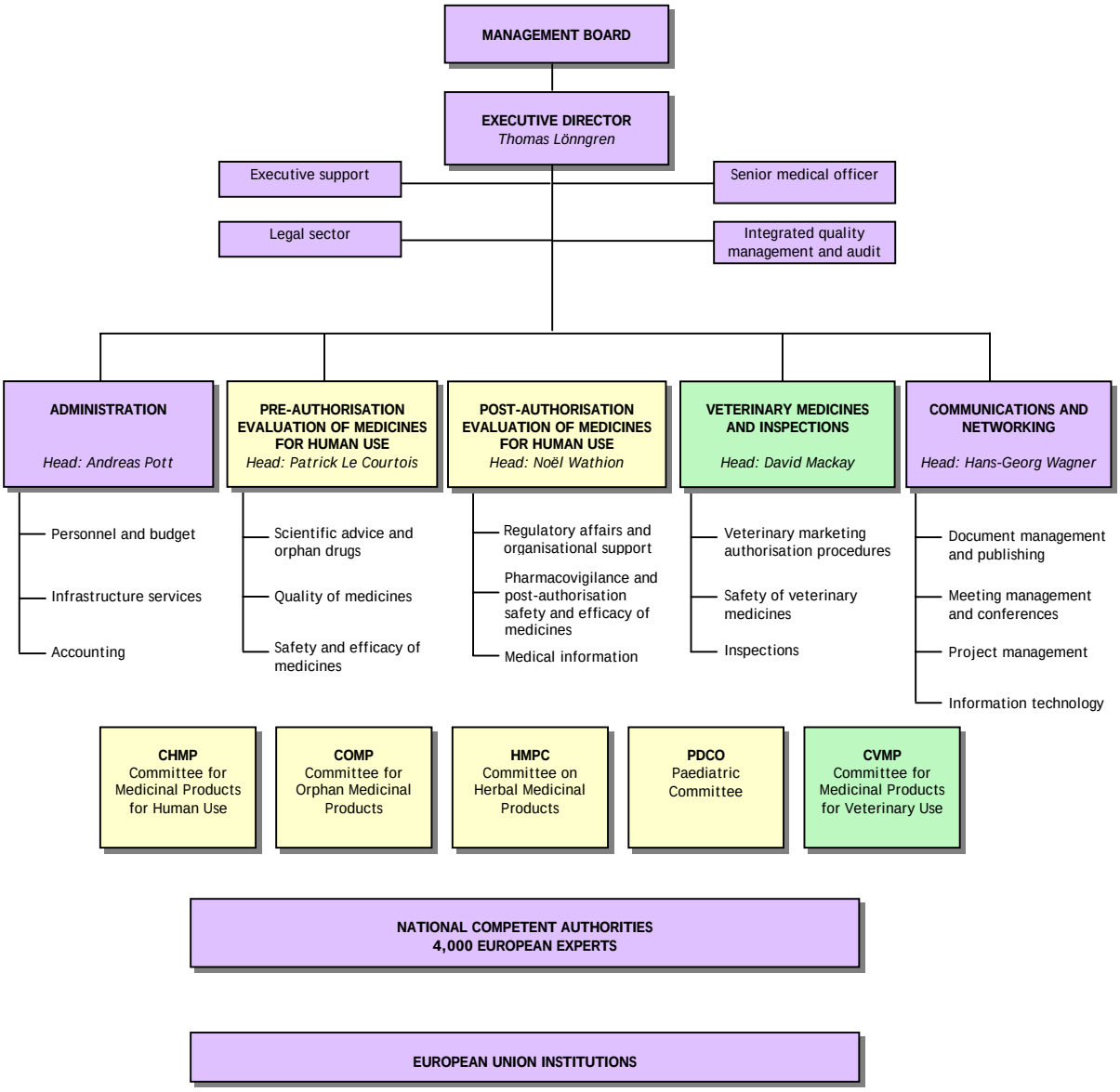
5.4 EMEA document management and publishing

The Agency faces challenges in the area of document management stemming from the next wave of EU enlargement, which will impact on multilingual communication and translation activities, and implementation of the legislation on access to documents. The volume of translations is expected to increase to 40,950 pages — 95% more than in 2006. In addition, following the entry into force of the legislation on access to documents, the Agency expects there to be 100 such requests, compared to 50 requests in 2006 (a single request may encompass hundreds of documents).

To respond to these changes, the Agency will improve its electronic document management system (EDMS), which is important for effective publishing of core business information to the web interface. This will be coupled with further developments in document management, records management (including retention policies) and mail registration activities. The Agency will re-examine its translation policies, to take into account the increase in multilingual communication activities, and will develop the terminology and translation memory databases. The latter will help to maintain and improve the quality of translations of non-product information documents.

Annexes

Annex 1 EMEA structure



Annex 2 EMEA establishment plan 2005-2007

Function Group & Grade	**TEMPORARY POSTS**		
	Occupied as per 31.12.05	Authorised for 2006	Authorised for 2007
AD 16	-	1	1
AD 15	1	3	3
AD 14	6	4	4
AD 13	4	4	4
AD 12	33	34	34
AD 11	32	33	33
AD 10	34	34	34
AD 9	10	13	13
AD 8	31	32	36
AD 7	37	43	43
AD 6	-	12	12
AD 5	-	-	10
Total Function Group AD	*188*	*213*	*227*
AST 11	-	-	-
AST 10	6	6	6
AST 9	-	2	2
AST 8	9	10	10
AST 7	12	14	14
AST 6	27	30	30
AST 5	29	32	32
AST 4	46.5	54	54
AST 3	14	23	24
AST 2	2	10	10
AST 1	4	30	32
Total Function Group AST	*149.5*	*211*	*214*
Total Staff	**337.5**	**424**	**441**

Annex 3 Revenue and expenditure overview 2005-2007

		2005[9]		2006[10]		2007[11]	
		€ '000	%	€ '000	%	€ '000	%
Revenue							
Fees		71,895	*65.72*	92,580	*66.76*	105,870	*68.51*
General EU contribution		19,588	*17.91*	20,174	*14.55*	20,174	*13.05*
EU contribution for SME policy		0	*0.00*	1,826	*1.32*	3,015	*1.95*
EU contribution for Paediatrics policy		0	*0.00*	n/a	*0.00*	2,647	*1.71*
EU contribution for IT Telematics strategy		7,500	*6.86*	8,000	*5.77*	9,164	*5.93*
Special EU contribution for orphan medicinal products		6,110	*5.59*	7,400	*5.34*	6,000	*3.88*
Contribution from EEA		535.94	*0.49*	650	*0.47*	798	*0.52*
Community programmes		0	*0.00*	760	*0.55*	490	*0.32*
Other		3,767	*3.44*	7,286	*5.25*	6,380	*4.13*
TOTAL REVENUE		**109,396**	*100.00*	**138,676**	*100.00*	**154,538**	*100.00*
Expenditure							
Staff							
11	Staff in active employment	36,463	*33.98*	41,376	*29.84*	47,708	*30.87*
13	Mission expenses	560	*0.52*	586	*0.42*	610	*0.39*
14	Socio-medical infrastructure	436	*0.41*	440	*0.32*	499	*0.32*
15	Exchange of civil servants and experts	726	*0.68*	1,119	*0.81*	1,375	*0.89*
16	Social welfare	6	*0.01*	155	*0.11*	240	*0.16*
17	Entertainment and representation expenses	52	*0.05*	31	*0.02*	24	*0.02*
18	Staff insurances	1,065	*0.99*	1,214	*0.88*	1,457	*0.94*
	Total Title 1	*39.307*	*36.63*	*44,921*	*32.39*	*51,913*	*33.59*
Building/equipment							
20	Investment in immovable property, renting of building and asset costs	12,475	*11.62*	17,260	*12.45*	16,606	*10.75*
21	Expenditure on data processing	10,889	*10.15*	14,623	*10.54*	18,223	*11.79*
22	Movable property and asset costs	1,482	*1.38*	1,057	*0.76*	3,148	*2.04*
23	Other administrative expenditure	540	*0.50*	756	*0.55*	792	*0.51*
24	Postage and communications	624	*0.58*	684	*0.49*	983	*0.64*
25	Expenditure on formal and other meetings	4	*0.00*	74	*0.05*	75	*0.05*
	Total Title 2	*26,015*	*24.24*	*34,454*	*24.84*	*39,827*	*25.77*
Operational expenditure							
300	Meetings	5,825	*5.43*	6,355	*4.58*	7,298	*4.72*
301	Evaluations	34,727	*32.36*	49,827	*35.93*	51,089	*33.06*
302	Translation	1,043	*0.97*	2,215	*1.60*	3,593	*2.32*
303	Studies and consultants	150	*0.14*	170	*0.12*	150	*0.10*
304	Publications	122	*0.11*	124	*0.09*	178	*0.12*
305	Community programmes	132	*0.12*	610	*0.44*	490	*0.32*
	Total Title 3	*42,000*	*39.13*	*59,301*	*42.76*	*62,798*	*40.64*
TOTAL EXPENDITURE		**107,322**	*100.00*	**138,676**	*100.00*	**154,538**	*100.00*

[9] Final accounts 2005
[10] Appropriation/Budget 2006 as of 31 December 2006
[11] Appropriation/Budget 2007 as adopted by the Management Board on 19 December 2006

Annex 4 EMEA contact points

Pharmacovigilance and product quality 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 reportsand product defect 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.europa.eu
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.europa.eu
For product quality defects and other recalls see www.emea.europa.eu/inspections/defectinstructions.html for instructions and contact points.	Fax: (44-20) 74 18 85 90 Out of hours telephone: (44-7880) 55 06 97

SME Office

The SME office has been set up within the agency to address the particular needs of smaller companies. The office aims to facilitate communication with SMEs through dedicated personnel within the agency who will respond to practical or procedural enquiries, monitor applications, and organise workshops and training sessions for SMEs. Any comments on the content of this draft SME User Guide should also be forwarded to the SME office.

SME office contact point:	Melanie CARR Direct telephone: (44-20) 74 18 85 75/86 43 Fax: (44-20) 75 23 70 40 E-mail: smeoffice@emea.europa.eu

Certificates of a medicinal product

The EMEA issues certificates of a medicinal product in conformity with the arrangements laid down by the World Health 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.europa.eu Direct telephone: (44-20) 75 23 71 07 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.europa.eu

For enquiries concerning VAMF certificates

Peter Richardson
Direct telephone: (44-20) 75 23 7114
Fax: (44-20) 74 18 85 45
E-mail: peter.richardson@emea.europa.eu

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.europa.eu
- by email request to info@emea.europa.eu
- by fax to (44-20) 7418 8670
- by writing to:

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

European experts list

Over 4 000 experts are used by the EMEA in its scientific evaluation work. The list of these European 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.europa.eu

Integrated quality management – Internal audit

IQM adviser

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

Press office

Press officer

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