



European Medicines Agency

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Summary of the work programme for the European Medicines Agency 2008

This document is a summary of the Agency's work programme for 2008. The Agency's full work programme for 2008, which was adopted by the Management Board on 13 December 2007, can be found on the Agency's website: www.emea.europa.eu

Please note that figures for 2008 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 16
E-mail: mail@emea.europa.eu <http://www.emea.europa.eu>

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INTRODUCTION BY THE EXECUTIVE DIRECTOR

Thomas Lönngren

The constantly evolving environment in which the Agency operates will shape its priorities and work in 2008. Elements affecting the environment include the adoption of new EU legislation in the field of pharmaceuticals, challenges faced by researchers in the development of new therapies, globalisation of the regulatory environment and steady intensification of work within the Agency's existing areas of responsibility.

While last year the Agency focused its efforts on implementing the Paediatric Regulation, the dominant regulatory issue in 2008 will be the implementation of a new regulation on advanced-therapy medicinal products. This will provide much-needed regulatory tools for improving the availability of innovative medicines in Europe. The EMEA will work throughout the year to prepare for its entry into force, by setting up a sixth scientific committee – the Committee for Advanced Therapies – and by introducing the necessary procedures for evaluating advanced-therapy medicines.

Increasing globalisation of the regulatory environment for medicines means that the EMEA needs to extend its activities in the international arena. The Agency will step up its interactions with international organisations and increase its contribution to scientific and regulatory discussions at the international level. This will include building on its successful collaboration with the US Food and Drug Administration (FDA) as a model for co-operation with the Japanese and Canadian authorities.

The European Union has launched a number of initiatives that aim to help researchers overcome certain bottlenecks in the development of medicines. The Agency will continue to contribute to these efforts, in particular through its support to the Innovative Medicines Initiative, the 7th Framework Programme and the European Technology Platform for Global Animal Health. In addition, the Agency will work to implement initiatives proposed by the EMEA/CHMP Think-Tank on innovative drug development, will continue its support to small and medium-sized enterprises, and will undertake projects to assess the impact and consistency of the Agency's scientific opinions.

The workload of the Agency continues to increase steadily, as a result of new regulatory initiatives and increasing activity in existing core areas of responsibility. On top of this, there is the increasing complexity of activities stemming from advances in pharmaceutical research and development techniques. The Agency and its partners in the European medicines network must ensure that they have the scientific resources necessary to address these challenges, both in the short term and further into the future. Work is progressing in this area and additional proposals on how to tackle this issue will be considered in the revised Road Map which the EMEA will develop to steer the Agency's course from 2010 to 2013.

Also important in 2008 will be a focus on initiatives to improve the monitoring of risks of medicines, facilitate the availability of medicines for human and veterinary use, and strengthen transparency, communication and provision of information to stakeholders, in particular patients and healthcare professionals.

PRIORITIES AND KEY OBJECTIVES FOR 2008

Improve the conduct of the Agency's core activities

- The effective conduct of the Agency's core responsibilities, in cooperation with all members of the European medicines network, in the areas of scientific advice, evaluation and supervision of medicinal products to the highest quality standards will continue to constitute the Agency's overall priority. This work is carried out in the face of increasing volume and complexity of activities. IT systems will be updated or newly developed to support the core activities.

Continue to improve the safety-monitoring of medicines for human and veterinary use

- Continue to apply a proactive approach to safety of medicines throughout their lifecycle, through initiatives undertaken in the context of the European Risk-Management Strategy (ERMS), in particular by implementing the ENCePP (European Network of Centres of Pharmacovigilance and Pharmacoepidemiology) project, by further developing EudraVigilance as a cornerstone of the EU Pharmacovigilance System, and by further improving the concept of risk-management plans for medicines for human use.
- Improve the methodology for determining benefit-risk balance of both human and veterinary medicinal products in order to improve predictability and consistency of the Agency's scientific opinions; place more emphasis on benefit-risk issues in the post-authorisation phase.
- Promote the supervision of veterinary medicines once authorised, through effective and targeted pharmacovigilance, including further development and use of the EudraVigilance veterinary database for continuous surveillance, and establishment of the concept of risk-management plans as it applies to the veterinary context.

Contribute to earlier availability of medicines for human and veterinary use

- Implement the new legislation on advanced-therapy medicinal products and establish a new Committee for Advanced Therapies.
- Consolidate and enhance activities relating to medicinal products for paediatric use, building on the experience gained in the first year of operation of new procedures; commence work on the implementation of the strategy for the network of paediatric research.
- Improve liaison with the World Health Organization and developing countries' regulatory authorities for the effective use of opinions on medicinal products intended for non-EU markets.
- Implement initiatives in cooperation with the Heads of Veterinary Medicines Agencies aimed at facilitating greater availability of veterinary medicines, particularly through measures to assist micro, small and medium-sized veterinary enterprises and companies seeking to authorise products for minor species and/or limited markets.

Contribute to the creation of an environment that stimulates innovation

- Continue the contribution to pan-European efforts to facilitate innovation and research, and thus to increase availability of medicines, in particular through participation in the work of the Innovative Medicines Initiative for human medicines, the European Technology Platform for Global Animal Health for veterinary medicines, and the continued implementation of recommendations of the EMEA/CHMP Think-Tank Group on innovative drug development.
- Conduct an assessment of the impact and consistency of the Agency's scientific opinions.

Strengthen the European medicines network

- Enhance collaboration with the Heads of Medicines Agencies and national competent authorities, thereby contributing to the network of excellence, in particular through initiatives in the fields of safety of medicines, resource planning, competence development, the medical information network,

transparency, communication, paediatric medicines and the benchmarking of European medicines agencies (BEMA).

- Continue to support the European Commission in implementing its 'Better Regulation' initiative in the field of pharmaceutical legislation.
- Continue implementation of the EMEA Road Map and contribute to the implementation of the Heads of Medicines Agencies strategy paper; commence preparation of the EMEA Road Map 2010-2013.

Foster transparency, communication and provision of information

- Develop and implement the EMEA communications strategy and information-related aspects of the EMEA Road Map in order to adapt the current EMEA information practices and improve the provision of information to all stakeholders.
- Improve the transparency of EMEA activities; provide access to EudraVigilance data, information on clinical trials, data held in EudraGMP and EMEA documents in general, in line with agreed access policies.
- Reinforce the Agency's interaction with patients and healthcare professionals, building on the initiatives undertaken in 2006 and 2007 and taking due account of satisfaction surveys.

Increase the Agency's contribution to international regulatory activities

- Review and further strengthen collaboration with the FDA in the context of the EU/US FDA confidentiality arrangements; implement the EU/Japanese Health Authorities and EU/Health Canada confidentiality arrangements.
- Focus on the international issues related to inspections, in particular with regard to avoiding where possible the duplication of inspections internationally; ensure consistency of standards for manufacture of active substances and finished products, and consistency of ethical standards for the conduct of clinical trials outside the EU.
- Maintain ongoing international cooperation in human and veterinary fields and explore possibilities for extending cooperation to other non-EU countries on important public-health matters.
- Participate in international standardisation activities.

1. EMEA IN THE EUROPEAN MEDICINES NETWORK

1.1. *European medicines network*

The Agency relies and draws on the scientific resources of the European medicines network to deliver its public-health mission. As such, the European medicines network is fundamental to the successful work of the Agency. Some of the challenges posed by the environment in which the Agency and its partners – the national competent authorities – operate relate to the increasing demand on scientific resources. This is due to the growing volume of core tasks of the Agency and of its partners in the network, and to the addition of new tasks vested by new legislation (e.g. the implementation of the new paediatric legislation in 2007 and the new legislation on advanced therapies in 2008). This trend is mirrored by the increased number of delegates from Member States attending meetings at the Agency. The Agency anticipates that the number of delegates coming to the Agency in 2008 will increase by 8% (to 8,400) and the number of meetings by 12% compared to 2007.

In order to address the pressures on scientific resources, the Agency and its partners will work to ensure long-term availability of top-quality scientific expertise (through establishment of an inventory of available expertise, and through various training and competence-development activities) and to develop further the common workload-planning practices. In addition, the operation of the scientific committees' working parties will be reviewed in order to evaluate whether it may be possible to rationalise the use of resources from the national competent authorities.

In the area of information technology, the Agency and its partners will work to increase the use of various IT tools that support collaboration. This includes implementation across all the committees of the electronic system for managing meeting documents and wider implementation of video- and teleconferencing facilities. The development of the electronic Application Form (eAF) for human medicinal products will be completed in 2008 (EU telematics project); A system to support the use of the eAF standard will also be developed and maintained by the Agency in connection with the centralised procedure.

The Agency will continue supporting the coordination groups for mutual-recognition and decentralised procedures (human and veterinary products). This includes support to the implementation of the referral procedure, development and maintenance of the memory of regulatory and scientific agreements, and activities arising from the paediatric medicines regulation.

The Management Board plans to review the system of remuneration for provision of scientific services to the EMEA in order to improve compliance with existing legislation. Care will be taken to ensure that a new system, if introduced, will promote cooperation and exchange of resources in the network.

1.2. *Transparency, provision of information and interaction with patients and healthcare professionals*

The Agency's Road Map contains a number of strategic objectives in the field of transparency and provision of information. The Agency is continuing its consolidation of existing practices and implementation of additional ones. As part of these initiatives, the EMEA plans to increase transparency in the field of non-product-related activities. This includes the publication of agendas and minutes of meetings of the Management Board, as well as of information from various EMEA committees on non-product-related issues; and providing access to the EudraVigilance database and to information on paediatric clinical trials (EU telematics project), in line with agreed access policies.

The legislation on access to documents has put significant pressure on the Agency's resources. The Agency forecasts that the number of requests for access will increase by around 68% to 155 requests (a single request may encompass hundreds of documents). Meanwhile, requests for other types of information are forecast to increase by a further 29%, to some 4,500 requests.

In the field of information provision, the Agency will consolidate related activities into the EMEA programme on provision of information. As part of this initiative, the EMEA will finalise the

development of its communication strategy and will consolidate the various communication tools into a communication 'platform'. This will help the EMEA to ensure that patients and healthcare professionals receive high-quality, targeted and timely information. The Agency's website will be at the forefront of this initiative. Work will continue on improving the website to enable easy access to information currently contained in various EMEA databases and other sources by stakeholders, in particular patients and healthcare professionals.

The Agency's interaction and engagement with patients and healthcare professionals will continue. The EMEA/CHMP working group with healthcare professionals' organisations will finalise recommendations that will improve these interactions. Collaboration with patients will continue, building on the success achieved in previous years. In addition to their participation in the work of certain EMEA committees and working parties, patients' representatives will continue to be involved in the review of documents developed for patients and the general public.

The Agency will develop the next phase of the EudraPharm database (EU telematics projects), introducing multilingual navigation and content, advanced search capability and better-structured product information.

1.3. Support for innovation and availability of medicines

The Agency contributes to the facilitation of innovation and availability of medicines through a number of its scientific activities, such as implementation of the orphan medicinal products policy, scientific advice, and management of accelerated assessment procedures, among others. In addition, the Agency is an active participant in EU-level initiatives, including the Innovative Medicines Initiative, European Technology Platform for Global Animal Health and the 7th Framework Programme.

In the field of human medicinal products, the Agency, in addition to the actions mentioned above, will focus on the implementation of the initiatives that the EMEA/CHMP Think-Tank on innovative drug development has elaborated. These initiatives include the establishment of procedures for the provision of advice on biomarkers and development of guidance for advanced-therapy medicinal products.

Another large area of activity will relate to the provision of support to small and medium-sized enterprises (SMEs) developing medicines for human and veterinary use. The Agency will continue to provide administrative and financial support to these enterprises and will facilitate electronic reporting by SMEs of adverse-drug-reaction data through the EudraVigilance system.

The EMEA will work with the Heads of Veterinary Medicines Agencies to implement initiatives to be adopted by the EMEA Management Board aimed at facilitating greater availability of veterinary medicines through a set of measures to assist companies seeking to authorise products for minor species and/or limited markets. The measures include providing free scientific advice as well as administrative and financial assistance similar to that given to SMEs.

1.4. European public- and animal-health activities

In 2008, the Agency will continue its work to tackle major public- and animal-health threats, including the development of antimicrobial resistance, pandemic influenza, avian influenza and other epizootic diseases such as bluetongue. Significant attention will be given to microbicides and to tropical, neglected, communicable and new emerging diseases.

The Agency will participate in the work relating to studies on off-patent medicinal products used in children, studies on the safety of medicines, and projects on rare diseases. This will be done within the context of the 7th Framework Programme.

This will be the sixth year of implementation by the Agency, with national competent authorities, of the EU telematics programme. The primary responsibility for implementation lies with the Agency, under the auspices of the telematics management structure. The Agency will advance projects such as EU Telematics Controlled Terms and Product Information Management (PIM), together with a number of other systems mentioned in the relevant sections of this work programme.

The Agency will also contribute to the implementation of the Clinical Trials Directive. A number of related guidelines will be further developed and support will be provided to the European Commission to follow up on the 2007 conference on implementation of clinical trials legislation. In addition, the Agency plans to upgrade the functionality of the EudraCT database as specified by the Clinical Trials Facilitation Group (EU telematics project).

The EMEA will also work in the field of environmental risk assessment and will provide support to programmes aimed at reducing animal testing.

1.5. Preparations for future enlargement

The EMEA will continue to work on a new transitional programme IPA (instrument for pre-accession) for supporting the participation of Croatia, Turkey and the Former Yugoslav Republic of Macedonia as observers in meetings, training courses, and workshops planned by the EMEA. These measures will familiarise the national competent authorities with the work performed by the EMEA's scientific committees and their working parties. The authorities will also be involved in the EU telematics programme.

1.6. International cooperation

The Agency's role in the international arena has grown substantially in recent years. In 2008, the Agency will continue its existing international activities and will aim to expand international collaboration. The EMEA will continue to be involved in the work of the ICH, VICH and Codex Alimentarius, will participate in international standardisation activities, and will further collaborate with the WHO, the World Organisation for Animal Health and other international organisations.

The Agency's work with its international partners will intensify, particularly in the context of the continued implementation of confidentiality arrangements with the US Food and Drug Administration (FDA), and implementation of the recently signed arrangements with the Japanese and Canadian health authorities.

Another area of the Agency's international work will relate to clinical trials and inspections. The number of clinical trials conducted in countries outside the EU is increasing. Taking this into account, and also considering the EU legislation aimed at improving the availability of medicinal products in children, the Agency will increase its supervision of the conduct and ethical standards of clinical trials performed outside the EU.

In the field of inspections, the EMEA will actively participate in the international discussions on worksharing and cooperation on all types of inspections with the FDA and WHO. The Agency hopes that these discussions will result in reduced duplication of international inspections and contribute to the efficient use of inspection resources.

The Agency, in accordance with a WHO scheme, issues certificates of medicinal products to support the work of health authorities outside the European Union, in particular in developing countries. The certificates confirm the marketing-authorisation status of products authorised through the centralised procedure. Health authorities rely on centralised assessments to support marketing in their own countries, thus facilitating the availability of medicines and avoiding the need for costly and double assessment work. The Agency expects that the number of certificate requests will increase in 2008 by 20%.

Further interaction will develop in the areas specified by the European Commission. Among these, the Agency will participate in discussions regarding Ayurvedic and traditional Chinese medicines.

1.7. Integrated management at the Agency

The Agency's integrated quality policy has been in operation for ten years, and its robust, integrated quality-management system is subject to continuous improvement. In 2008, the Agency plans to consolidate the outcomes of its two-year process-improvement exercise and will continue to implement

measures to optimise key processes, improve cost-effectiveness of the Agency's operations, and achieve higher satisfaction for the Agency's stakeholders.

The EMEA receives, creates and manages a large amount of documents. The EMEA decided to review existing practices and to introduce necessary changes to improve the efficiency and effectiveness of the document- and information-management processes. A separate programme encompassing all information-management activities in the Agency will be launched to implement this objective.

The Agency will carry out activities to assess the impact and consistency of its scientific opinions. With this in mind, the EMEA will conduct a few pilot projects related to benefit-risk assessment, risk communication and scientific memory. Depending on the outcome, the projects may have an impact on certain aspects of how the Agency evaluates and supervises medicines and delivers its services to its stakeholders.

In order to ensure that the Agency is able to operate key processes in case of a disaster or an unforeseen event of any kind, the Agency has developed a business-continuity plan. Work in this area will continue and the next phase of business-continuity solutions, including IT aspects, will be implemented.

In the area of information technology, the Agency will progress the deployment of best-practice-support processes based on the IT Infrastructure Library (ITIL) service management. This approach will assist with the provision of reliable and robust IT services to staff, delegates and all users of pan-European systems.

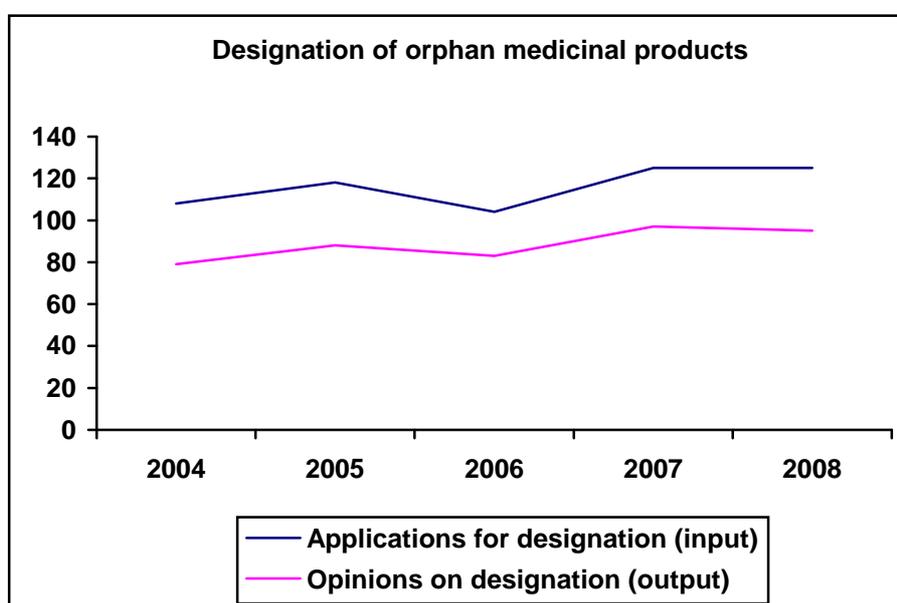
The Agency will implement further changes in its internal control system in order to make the system more efficient and effective.

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 Union. The Agency provides financial incentives because such medicines might, for economic reasons, not otherwise be developed. In addition, such medicines benefit from market exclusivity. The Agency plans to streamline the implementation of legislative requirements regarding the review of profitability of such medicines after their authorisation, in the light of a new Commission guideline.

The Agency also plans to work with the US FDA to implement the process for parallel designation of orphan medicinal products. This work is carried out in the context of the confidentiality arrangements with the US FDA.



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. The graph below demonstrates that this activity has experienced strong growth over the years.

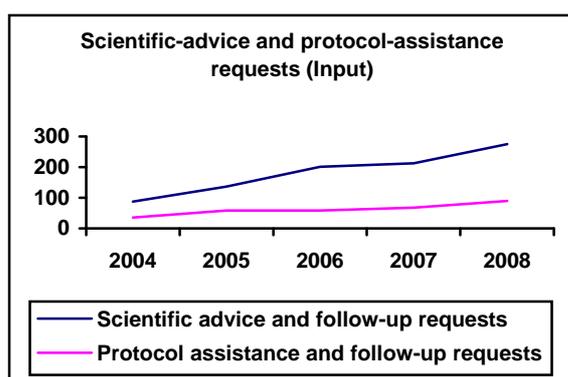
The Agency anticipates that the number of requests for scientific advice and protocol assistance will continue to increase in 2008. The variety of scientific-advice requests will also increase, from advice on products subject to the centralised procedure, to alternative clinical-trial design, to programmes for products intended for non-EU markets.

In addition to ongoing activities in this field, the Agency will review how to expand its scientific-advice database with information on scientific advice given by national competent authorities. This would help to further promote exchange of information within the European medicines network.

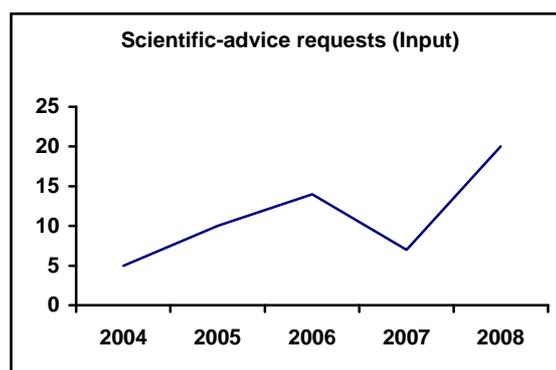
The EMEA plans to set up a new procedure for advice on biomarkers. Once implemented, the advice given will facilitate certain aspects of the conduct of clinical trials and may potentially contribute to earlier availability of novel medicines.

Veterinary medicines

The Agency’s Management Board has introduced a set of measures to support the availability of medicinal products for veterinary use. Measures include the provision of free scientific advice to veterinary companies developing medicines for minor uses or minor species. Another type of advice relates to the assessment of dossier requirements in relation to products for limited markets. The Agency expects that these measures will contribute to the number of requests for scientific advice in 2008 reaching 20.



Human medicines



Veterinary medicines

2.3. Initial evaluation

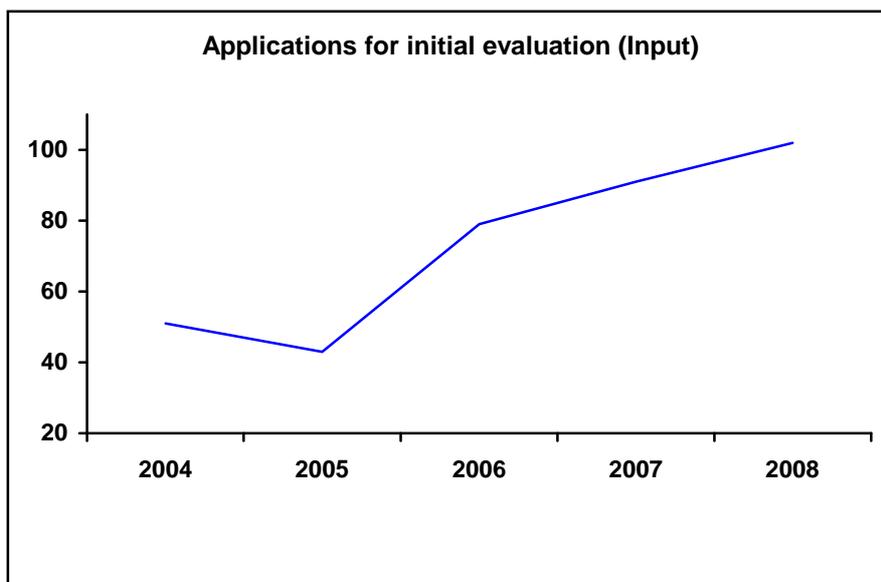
Human medicines

The number of applications for initial marketing authorisation has doubled over the last four years. In 2008, the scope of the mandatory centralised procedure will extend to products for autoimmune diseases and other immune dysfunctions and viral diseases. The Agency will handle applications for these products from 20 May 2008.

The EMEA shall continue to ensure that necessary risk-minimisation measures have been put in place prior to the granting of marketing authorisations for medicinal products. Necessary changes in the assessment process have been made over the last year to meet this goal. This activity is strengthened through the peer review of assessment reports, which also includes the review of risk-management plans.

More and more clinical trials are conducted in countries outside the EU. This trend, coupled with the requirements of legislation that aims to improve the availability of medicines for children, increases the need for the Agency to ensure that due care is given to ethical standards in clinical trials performed in non-EU countries. This will continue to be done as part of the review process for initial marketing authorisations and will be reflected in the European public assessment reports (EPARs).

The provision of understandable and clear information about medicines is an important goal for the Agency. A number of activities are underway with this goal in mind. In the area of initial evaluation of medicines, the Agency will work to improve the content and presentation of information in the assessment report of the Committee for Medicinal Products for Human Use and in the EPARs. The documents will be improved in the light of stakeholders’ expectations.



A detailed graph showing the number of applications split into product types can be found in the full version of the work programme, section 2.3.

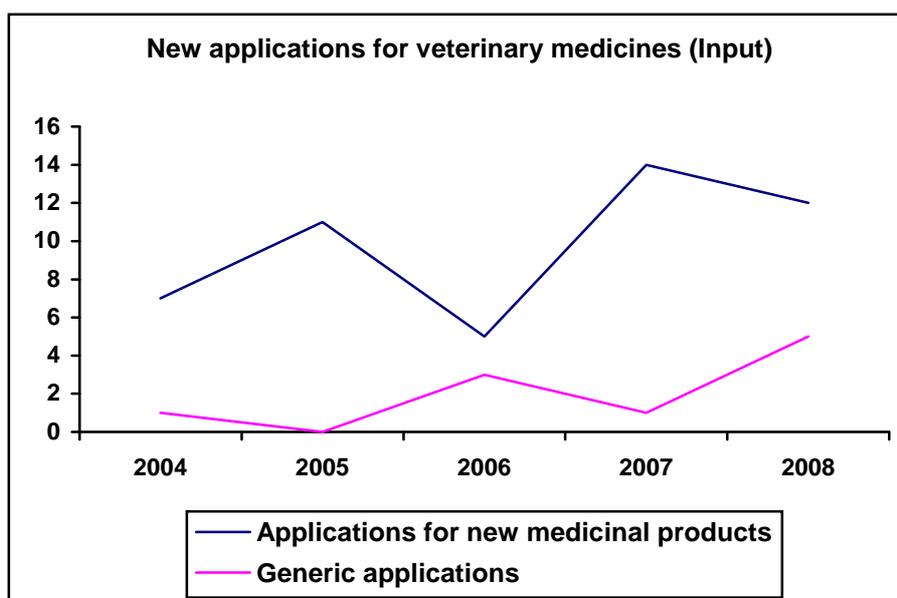
Veterinary medicines

The Agency expects a continuation of the long-term trend for a gradual increase in the number of applications for marketing authorisation of veterinary medicinal products. To strengthen this trend and to facilitate the availability of medicines, the Agency will work with the Heads of Veterinary Medicines Agencies to implement new measures to provide support to companies considering applications for limited markets and/or for regional diseases. This may contribute to a higher number of applications for such products.

As seen in the graph below, the level of generic medicines is expected to increase gradually. This trend is in line with the number of innovative reference products reaching the end of the 10-year period of data exclusivity.

The focus of additional activities in the area of evaluation of veterinary medicines will include further improvement of the quality-assurance system in respect of the procedures of the Committee for Medicinal Products for Veterinary Use (CVMP) and establishing systems for peer review of the quality and consistency of scientific assessments.

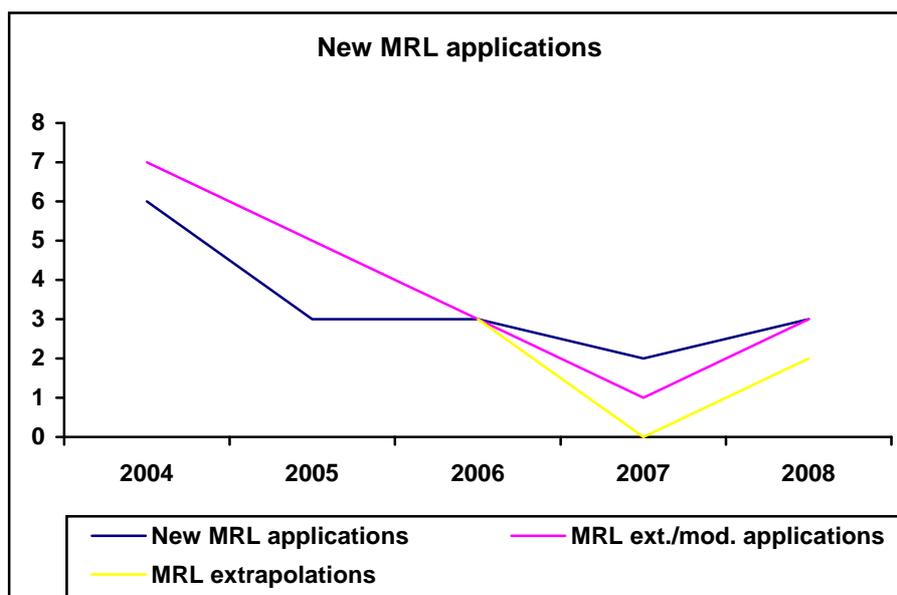
As part of its corporate governance, the Agency seeks feedback from its stakeholders about their experience with the Agency and its procedures. This provides the information necessary for the Agency to introduce needed improvements. As part of this initiative, the Agency will launch a revised survey with IFAH-Europe of its procedures for authorisation of veterinary medicinal products. This will help the Agency to clarify areas of concern to some parts of the industry that were identified in the IFAH Benchmarking survey conducted in 2006.



2.4. Establishment of maximum residue limits for veterinary medicines

Within the animal-health industry, priorities are expected to remain directed predominantly towards the small-animal and immunologicals sectors of the market. Consequently, the number of new veterinary pharmaceutical medicines for food-producing animals will remain at a low level. Nonetheless, applications for MRLs for products classified by the CVMP as indicated for limited markets may be forthcoming in response to the assistance provided by the Agency for these types of products.

The number of extensions has remained low over recent years, despite the initiatives taken by the CVMP to facilitate the authorisation of products for minor uses and minor species. This situation is expected to continue for 2008. Similarly, since the offer by the EMEA to extend MRLs to other species without a fee (by way of extrapolation, provided the scientific criteria are met) was not taken up in 2007, only a small number of such requests for extrapolation are expected in 2008.



2.5. Post-authorisation activities

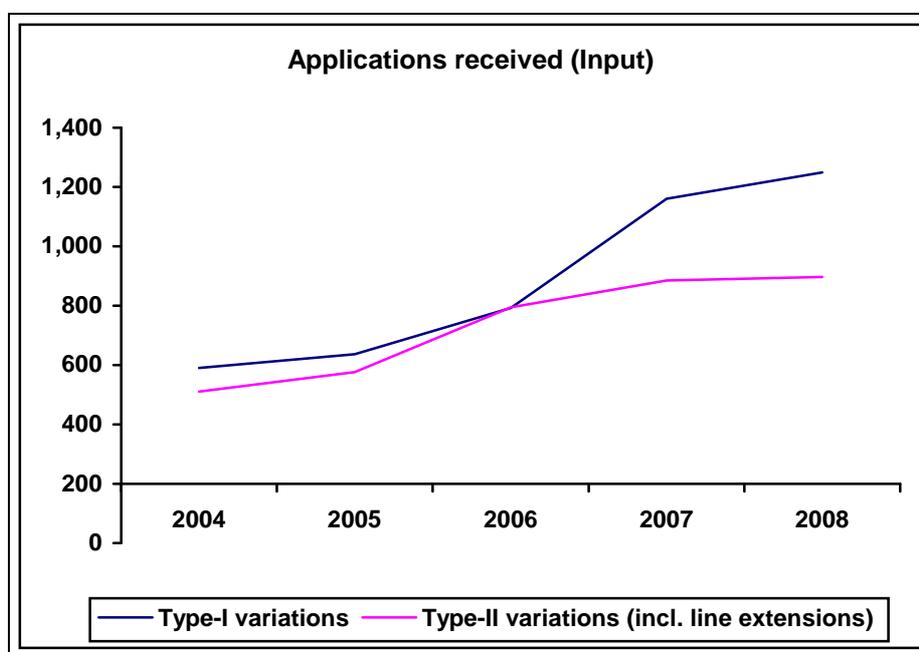
Human medicines

The number of variations is growing every year. This is due to the fact that more products are authorised and subsequently more variations are submitted. This trend will be further strengthened as a consequence of the implementation of the paediatric legislation.

The Agency's focus in 2008 in the area of variations will be on the establishment of a new procedure for variations of generic and similar biological medicinal products in order to allow the implementation of changes to the product information subsequent to changes to the reference product, hence ensuring consistency. This will also include development of guidance documents for applicants.

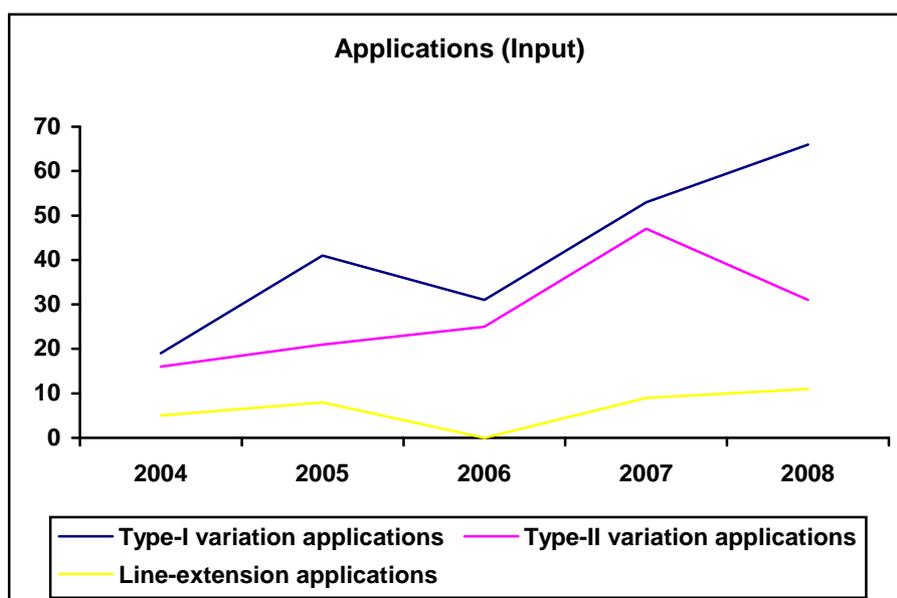
In order to help the pharmaceutical industry improve the quality of their submissions, the Agency will identify common application difficulties encountered by the industry and will provide necessary feedback.

As described earlier, the Agency will also ensure that due account is taken of ethical standards in clinical trials performed in non-EU countries, as part of the assessment of post-authorisation applications.



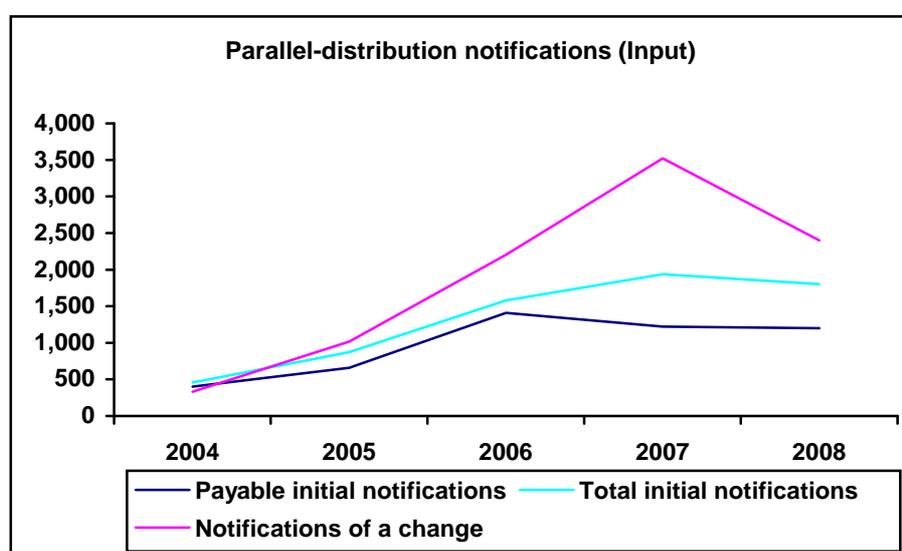
Veterinary medicines

The Agency expects that the number of variations and line extensions in the veterinary field will also increase in accordance with the increased number of products that will be on the market. The main focus in this area will be the further strengthening of the quality and consistency of assessment of post-authorisation applications, in particular, extensions. This will be done through the implementation of a new process to streamline preparation of CVMP assessment reports and the creation and updating of European public assessment reports (EPARs).



Parallel distribution

The number of initial notifications received in 2008 is expected to be comparable to that for 2007. In 2008, the Agency, in addition to its core activities in the area of parallel distribution, will verify compliance with the mandatory notification procedure by parallel distributors. This will be done in collaboration with the national competent authorities.



2.6. Pharmacovigilance and maintenance activities

Human medicines

The main factors influencing the Agency's activities in the area of pharmacovigilance relate to the implementation of the paediatric and advanced therapy legislation.

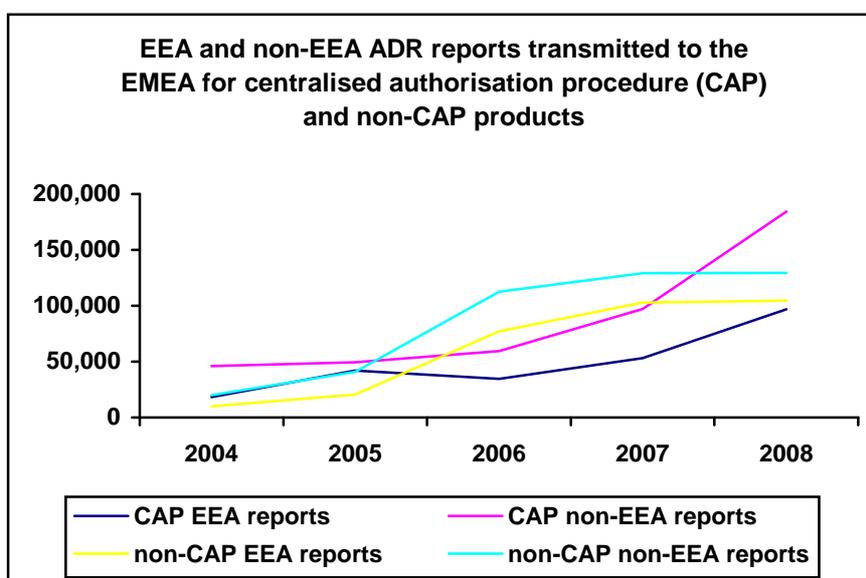
In order to strengthen active pharmacovigilance, the Agency, together with its partners in the European medicines network, is implementing the European Risk-Management Strategy. One of the main activities in 2008 will be to prepare for the implementation of the project on the European Network of

Centres for Pharmacovigilance and Pharmacoepidemiology (ENCePP). The primary focus in 2008 will be the development of general principles, standards, quality assurance and transparency-related aspects, which subsequently will be applied across the network of these centres.

Another area of activity will relate to the continued improvement of the EudraVigilance database. This will be done through the implementation of the EudraVigilance Action Plan, which helps the European medicines network to improve the quality of data submitted to the database. Additional functionalities will be added to the database and known defects resolved in the course of 2008 (EU telematics project). The Agency will also progress the validation of the EudraVigilance data-analysis system (EU telematics project).

The legislation requires the Agency to provide access to EudraVigilance data by its stakeholders. This requirement contributes to the Agency's initiatives in the area of transparency and provision of information. As a response to this requirement, the Agency is developing the EudraVigilance Access Policy, which it plans to finalise in 2008. Steps will be taken to prepare for its implementation.

To assure high quality standards for the assessment of risk-management plans for paediatric medicines, the Agency will extend the existing peer-review system to the field of paediatric medicines. In preparation for the implementation of legislation on advanced-therapy medicinal products, the Agency will develop guidance in the fields of post-authorisation follow-up on efficacy, adverse reactions and risk-management of these products.



Veterinary medicines

In order to complete the development of EudraVigilance Veterinary, the Agency's Management Board adopted the EudraVigilance Veterinary Action Plan. Implementation of the plan will allow the Agency, the Member States and the veterinary pharmaceutical industry to improve and streamline the electronic exchange of pharmacovigilance information. This will in turn increase access to essential post-authorisation information and will better equip the network for safeguarding public and animal health.

An improved tool that will help the Agency and its partners to rationalise the processing of pharmacovigilance information – the EudraVigilance Veterinary Data Warehouse (EU telematics project) – will be implemented in 2008. The Agency will then continue to elaborate data-analysis and signal-detection tools that will enhance the Agency's surveillance role within the regulatory network of the European Union.

As for human medicinal products, the Agency will carry out preparatory work to provide access to EudraVigilance Veterinary data by the professional community and the general public.

The Agency and the Member States will continue their collaboration on the implementation of the European Surveillance Strategy. The strategy helps the partners to optimise the efficiency in the EU regulatory network for veterinary pharmacovigilance of all medicinal products authorised in the Community.

2.7. Sampling and testing

The quality of centrally authorised medicinal products placed on the market is supervised through the sampling and testing programme. This ensures that the products actually on the market continue to meet public- and animal-health requirements. Sampling from the market in different countries is carried out by national inspectorates and testing is performed by official medicines-control laboratories coordinated by the European Directorate for the Quality of Medicines and HealthCare (EDQM). The Agency plans to have 42 centrally authorised products verified for quality and compliance with authorised specifications.

2.8. Arbitration and Community referrals

Human medicines

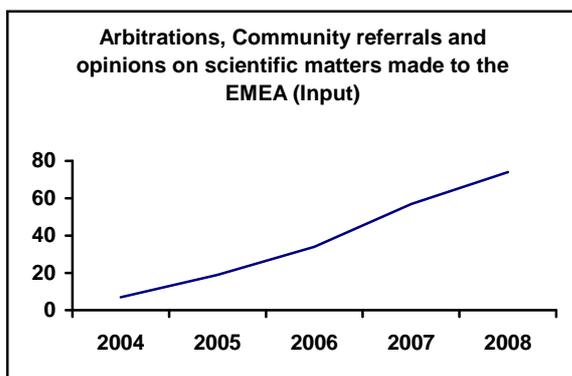
This area of activity has experienced strong growth over the years, but it remains difficult to forecast the volume of arbitrations and referrals. However, the Agency expects that the number of referrals due to differences in opinion at Member State level in the framework of mutual-recognition procedures will be similar to that of 2007. On the other hand, it is expected that marketing-authorisation holders will make more voluntary use of the summary of product characteristics (SPC) harmonisation procedure to streamline the harmonisation of product information and optimise post-approval maintenance of their products across the EU.

Based on the initial experience during 2007, there is a clear trend for an increase in referral procedures in the context of the suspension or revocation of marketing authorisations as a result of the evaluation of pharmacovigilance data.

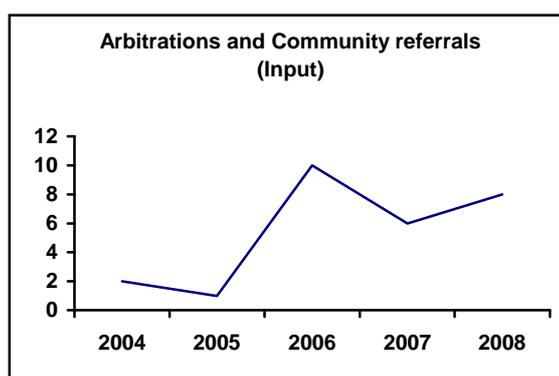
Referrals concerning new indications, new pharmaceutical forms or new routes of administration relating to paediatric use are a new legislative tool. The number of procedures is difficult to predict and the impact on the workload of the CHMP and EMEA secretariat will be carefully monitored.

Veterinary medicines

The number of arbitrations and referrals remains difficult to predict, but the increasing trend since the introduction of the new legislation is expected to continue. It is anticipated that the majority of referrals will continue to relate to arbitrations that are due to differences in opinion at the Member State level within the framework of the mutual-recognition or decentralised procedures. The Agency also expects to receive some referrals relating to harmonisation within the Community of the conditions of authorisation of already authorised products, to Community interests, and to other safety-related issues. The anticipated increase is partly due to the fact that many of the arbitrations relating to applications for generic products also lead to simultaneous Community-interest referrals, as this represents the only way that Member States can address issues relating to safety and efficacy that arise during the procedure.



Human medicines



Veterinary medicines

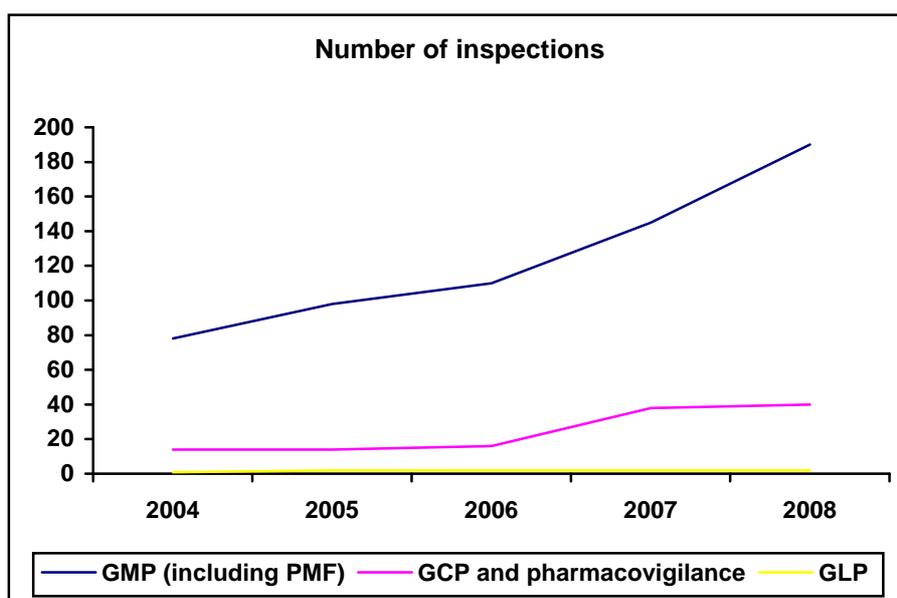
2.9. GMP, GCP, GLP and pharmacovigilance inspections

GMP inspection numbers will continue their steep growth, with a further 30% increase expected compared to 2007. 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. In addition, a number of inspections to support plasma-file certification are planned, contributing to about 15% of the total number.

GCP and pharmacovigilance inspections are expected to rise relative to previous years, taking into account the GCP policy on increasing numbers of routine inspections and increasing pharmacovigilance activity, as well as the need for greater supervision of the conduct and ethical standards of clinical trials performed outside the EU.

The Agency will discuss worksharing and cooperation on all types of inspections with its international partners, as part of efforts to address the increasing demand for international collaboration in this area and to avoid duplication of effort and resources.

The Agency also plans to finalise the remaining work arising from the 2004 legislative review. The Community database of manufacturing authorisations and GMP certificates, EudraGMP, will be expanded to contain a module with negative inspection outcomes (EU telematics project).



The Agency is responsible for operational aspects of mutual-recognition agreements (MRA) between the European Community and partner (third) countries. These agreements are in operation with Australia, New Zealand, Switzerland, Canada and Japan, and allow the conclusions of inspections of manufacturers carried out by respective inspection services to be mutually recognised. In this context, the remaining evaluation work in Bulgaria and Romania is expected to be completed as part of the MRA between the European Commission and Canada.

3. SPECIFIC MEDICINAL PRODUCT AREAS

3.1. Medicines for children

Following receipt of the first applications for paediatric investigation plans (PIPs) and waivers during 2007 – the first year of implementation of the regulation on paediatric medicines – the number of applications is expected to be maintained during 2008, with around 400 clinical indications in new PIP and paediatric-waiver applications.

As part of the task of implementing the paediatric legislation, the Agency will begin to implement the strategy on the network of paediatric research. In 2008, the Agency expects that standards for the quality of the network will be agreed and that the Coordinating Group for the network of existing networks will be set up.

In addition, the Agency plans to provide public access to information on paediatric clinical trials by the end of 2008, to create further transparency in this area (EU telematics project).

Cooperation with the US FDA also covers paediatric medicinal products. The Agency plans to make further progress on parallel review of the development of paediatric medicines with this international partner.

Collaboration with Member States in the area of medicines for children will also cover information on off-label paediatric use of medicines in Member States, and the implementation of a strategy for the exchange of paediatric information.

3.2. 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; establishes a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products; provides opinions on herbal substances as needed; and evaluates referrals and arbitrations concerning traditional herbal medicinal products.

The European Commission published in 2007 a report on the status of the implementation of the legislation on traditional herbal medicinal products. The Agency will support the European Commission in any necessary follow-up to the report.

In order to review and improve the process for producing Community herbal monographs and entries to the aforementioned list, the EMEA will explore the possibility of involving academia alongside the resources made available by the European medicines network.

The HMPC plans to establish 20 monographs and 10 list entries this year.

3.3. Advanced therapies and other emerging therapies and new technologies

The new legislation on advanced-therapy medicinal products will enter into force by the end of 2008. Consequently, the area of advanced therapies will present a big area of change for the Agency in 2008 and 2009. In preparation for the entry into force of the new legislation, the Agency will establish a new, sixth, scientific committee in 2008, and will develop the necessary procedures for the assessment of advanced-therapy medicinal products.

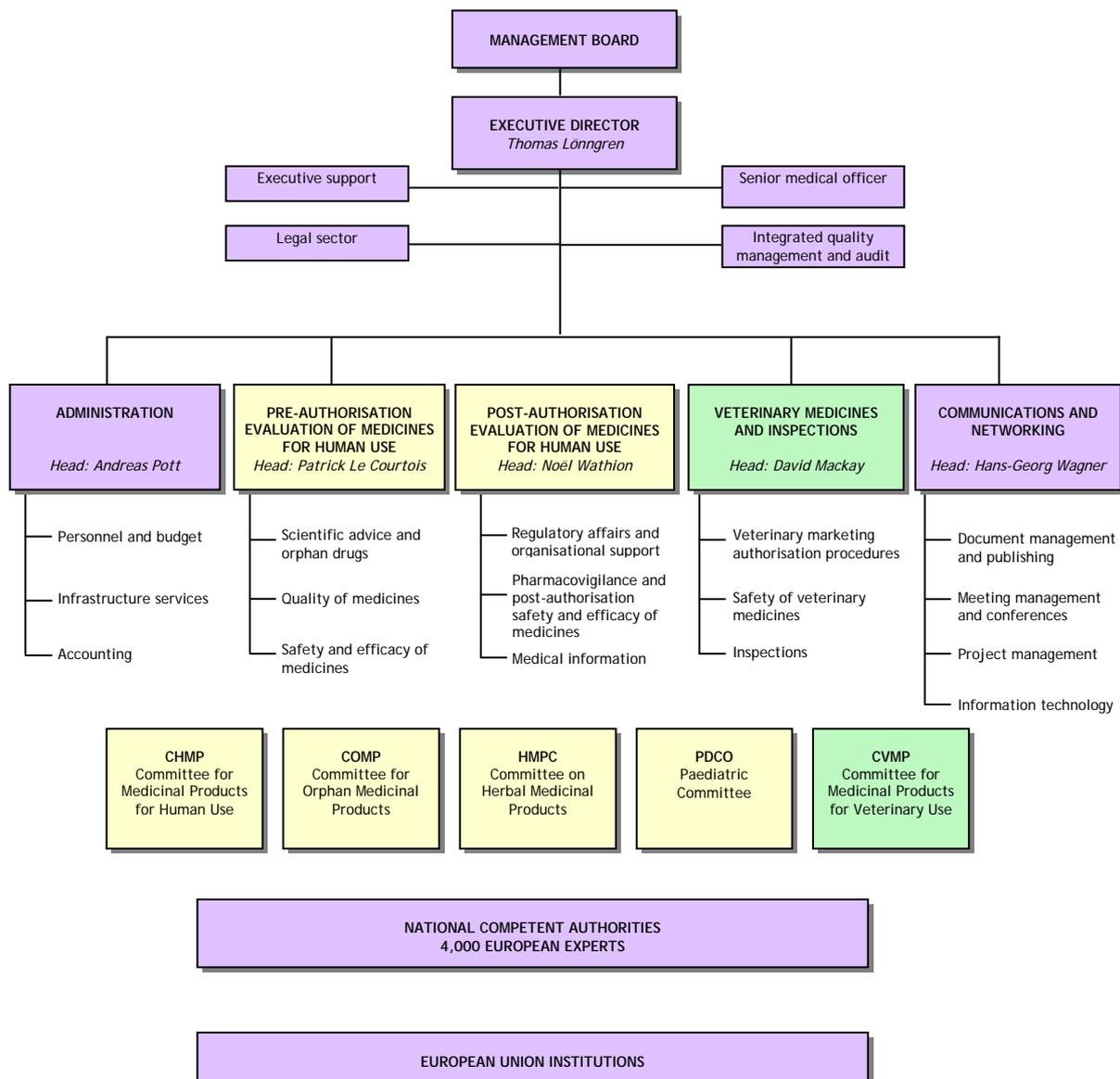
In order to ensure high-quality assessment of the new types of applications, the Agency will review the scientific expertise available in the Agency and its committees and, if needed, will seek complementary expertise/experience in close collaboration with Member States.

The Agency will also maintain and further strengthen dialogue with all stakeholders through joint workshops with the European Commission on both the regulatory and scientific aspects of advanced-

therapy medicinal products. A number of guidance documents on advanced-therapy medicinal products and new technologies will be developed in consultation with interested parties. These will include links between specific therapies such as gene, cell-therapy and tissue-engineered products, and nanomedicines.

ANNEXES

Annex 1 EMEA structure



Annex 2 EMEA establishment plan 2006-2008

Function group & Grade	Occupied as per 31.12.06		Authorised for 2007		Requested for 2008 ¹	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	1	-	1	-	1
AD 15	-	3	-	3	-	3
AD 14	-	3	-	4	-	4
AD 13	-	4	-	4	-	5
AD 12	-	33	-	34	-	34
AD 11	-	33	-	33	-	33
AD 10	-	33	-	34	-	33
AD 9	-	11	-	13	-	20
AD 8	-	32	-	36	-	41
AD 7	-	38	-	43	-	43
AD 6	-	8	-	12	-	22
AD 5	-	-	-	10	-	9
<i>Total grade AD</i>	<i>0</i>	<i>199</i>	<i>0</i>	<i>227</i>	<i>0</i>	<i>248</i>
AST 11	-	-	-	-	-	-
AST 10	-	6	-	6	-	6
AST 9	-	2	-	2	-	2
AST 8	-	10	-	10	-	11
AST 7	-	12	-	14	-	14
AST 6	-	30	-	30	-	33
AST 5	-	29	-	32	-	34
AST 4	-	50	-	54	-	56
AST 3	-	20	-	24	-	26
AST 2	-	9	-	10	-	19
AST 1	-	28	-	32	-	26
<i>Total grade AST</i>	<i>0</i>	<i>196</i>	<i>0</i>	<i>214</i>	<i>0</i>	<i>227</i>
Grand Total	0	395	0	441	0	475

¹ Excluding the six additional posts for paediatrics legislation as per decision of the Management Board (EMEA/MB/244582/2007).

Annex 3 Revenue and expenditure overview 2006-2008

	2006 ²		2007 ³		2008 DB ⁴	
	€'000	%	€'000	%	€'000	%
Revenue						
Fees	94,556	67.03	108,570	66.56	126,318	72.89
General EU contribution	22,107	15.67	20,174	12.37	14,589	8.42
EU contribution for SME policy	1,826	1.29	3,015	1.85	3,695	2.13
EU contribution for paediatrics policy	0	0.00	2,647	1.62	4,944	2.85
EU contribution for IT Telematics strategy	8,000	5.67	13,808	8.47	8,772	5.06
Special EU contribution for orphan medicinal products	6,633	4.70	6,000	3.68	6,000	3.46
Contribution from EEA	618	0.44	904	0.55	765	0.44
Community programmes	498	0.35	706	0.43	600	0.35
Other	6,820	4.84	7,289	4.47	7,624	4.40
TOTAL REVENUE	141,059	100.00	163,113	100.00	173,307	100.00

Expenditure							
Staff							
11	Staff in active employment	40,544	29.78	47,259	28.97	54,411	31.40
13	Mission expenses	525	0.39	660	0.40	639	0.37
14	Socio-medical infrastructure	399	0.29	459	0.28	603	0.35
15	Exchange of civil servants and experts	1,002	0.74	1,205	0.74	2,437	1.41
16	Social welfare	3	0.00	55	0.03	55	0.03
17	Entertainment and representation expenses	30	0.02	37	0.02	38	0.02
18	Staff insurances	1,205	0.89	1,457	0.89	1,657	0.96
	<i>Total Title 1</i>	<i>43,709</i>	<i>32.10</i>	<i>51,132</i>	<i>31.35</i>	<i>59,840</i>	<i>34.53</i>
Building/equipment							
20	Investment in immovable property, renting of building and associated costs	17,159	12.60	16,740	10.26	15,618	9.01
21	Expenditure on data processing	14,490	10.64	25,460	15.61	20,502	11.83
22	Movable property and associated costs	1,011	0.74	3,148	1.93	1,617	0.93
23	Other administrative expenditure	632	0.46	792	0.49	861	0.50
24	Postage and communications	661	0.49	983	0.60	1,048	0.60
25	Expenditure on formal and other meetings	54	0.04	75	0.05	79	0.05
	<i>Total Title 2</i>	<i>34,007</i>	<i>24.98</i>	<i>47,198</i>	<i>28.94</i>	<i>39,725</i>	<i>22.92</i>
Operational expenditure							
300	Meetings	6,093	4.48	7,144	4.38	8,156	4.71
301	Evaluations	49,431	36.31	53,632	32.88	60,406	34.85
302	Translation	2,110	1.55	3,183	1.95	4,001	2.31
303	Studies and consultants	150	0.11	100	0.06	80	0.05
304	Publications	114	0.08	74	0.05	499	0.29
305	Community programmes	534	0.39	650	0.40	600	0.35
	<i>Total Title 3</i>	<i>58,431</i>	<i>42.92</i>	<i>64,783</i>	<i>39.72</i>	<i>73,742</i>	<i>42.55</i>
TOTAL EXPENDITURE		136,147	100.00	163,113	100.00	173,307	100.00

² Appropriation/Budget 2006 as per final accounts.

³ Appropriation/Budget 2007 as of 31 December 2007.

⁴ Appropriation/Draft Budget 2008 as adopted by the Management Board on 13 December 2007.

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 the EMEA. The EMEA receives safety reports and product-quality-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

Sabine BROSCH
Direct telephone: (44-20) 74 18 85 69
E-mail: pharmacovigilance@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: vet-phv@emea.europa.eu

For product quality defects and recalls see www.emea.europa.eu/inspections/defectinstruction.html
for instructions and contact points

E-mail: qdefect@emea.europa.eu
Direct telephone: (44 20) 75 23 70 75
Fax: (44-20) 74 18 85 90
Out-of-hours telephone: (44) 78 80 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.

SME Office contact point:

Melanie CARR
Direct telephone: (44-20) 74 18 85 75/84 63
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 Organization. These certify the marketing-authorisation and good-manufacturing status of medicinal products in the EU and are intended for use in support of marketing-authorisation applications in, and export to, non-EU countries.

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

E-mail: certificate@emea.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: PMF@emea.europa.eu

For enquiries concerning VAMF certificates

Ragini SHIVJI
Direct telephone: (44-20) 74 18 86 98
Fax: (44-20) 74 18 85 45
E-mail: VAMF@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 e-mail request to info@emea.europa.eu
- by fax to (44-20) 74 18 86 70
- by writing to:

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

European experts list

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
at the address above or by e-mail 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