European Medicines Agency

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# Work programme for the

# European Medicines Agency

# 2009

*Adopted by the Management Board on 11 December 2008*

**Please note that all figures given for 2009 in this document are estimates.**

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## Introduction by the Executive Director

**Thomas Lönngren**

The Agency's work programme is shaped by a number of trends, scientific, political and other developments that will dominate the Agency's environment in 2009. These developments include recently adopted and upcoming legislation vesting the Agency with new responsibilities, including legislation on advanced-therapy medicinal products, a revised regulation on variations to marketing authorisations and revised legislation on safe limits for residues of veterinary medicines in food. It is expected that the latter two pieces of legislation will come into effect during 2009.

The Agency operates in a global regulatory environment that is characterised, among other trends, by an increasing number of clinical trials conducted in countries where it is perceived that the application of good clinical practice does not yet have traditions as well established as those in the European Union, the US and other developed countries. In addition, the year 2008 saw some quality issues with products whose active ingredients were manufactured outside the EU. This will have an effect on the workload in the field of inspections, both for the EMEA and for the national competent authorities, and will add a new dimension to the EMEA's international commitments.

The Agency is experiencing continuing growth in the volume of work across various areas of its activities, including scientific advice, medicines for paediatric use, authorisation of vaccines against epidemic diseases of animals, transparency and international commitments, to name but a few.

The Agency's priorities have been set considering these and other factors affecting the Agency in 2009, and will centre around:

- further improving the effectiveness and efficiency of the Agency's core activities, including consolidation of the EMEA's international strategy in the light of global challenges;
- strengthening the European medicines network;
- continuing to improve the safety-monitoring of medicines for human and veterinary use;
- implementing and operating the new legislation on advanced-therapy medicinal products for human use, as well as other new legislation;
- fostering transparency, communication and provision of information;
- contributing to improved availability of medicines for human and veterinary use;
- contributing to an environment that stimulates innovation.

The Agency has been implementing various new parts of the pharmaceutical legislation over the course of a number of years. As a result, the Agency has grown into a complex organisation that is heavily dependent on effective and efficient information and communication technologies. At the same time, the EMEA has been allocating a significant part of its IT development and maintenance resources to the development and support of the EU Telematics systems. The results of various process-improvement initiatives, process analyses and staff surveys show that it is now time for the Agency to refocus some of its IT resources on improving corporate information systems as a step towards a fully electronic working environment. This commitment is reflected in the Agency's work programme and budget. Additionally, following internal preparatory work and consultation, the EMEA will adjust its organisational structure to enable the Agency to deliver on its mission in a more effective and efficient way.

As can be seen from this work programme, activities in the field of recently implemented legislation on paediatric medicines remain complex and dynamic. The Agency will continue to focus on further streamlining these activities, including the development of a paediatric research network.

The European medicines network is vital to the Agency's ability to deliver on its public-health mission and objectives. Continuous fostering and developing of the scientific capacity of the network is therefore the EMEA's perennial objective. This year, the Agency will further support collaboration

within the network and benchmarking activities (BEMA[1]), and will provide input into efforts aimed at strengthening the capacity of the network. Some of these objectives include improving the planning of scientific resources, progressing initiatives in the field of training and competence development, and assuring effective communication within the network.

Safety-monitoring of medicines is an area that is continuously being scrutinised, developed and strengthened. The EMEA, together with its partners, has developed and is implementing the European risk-management strategy (ERMS). An important part of the ERMS is the implementation of the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology (ENCePP). Preparatory work has been undertaken in 2008, and the Agency should be in a position to start commissioning pharmacoepidemiological studies in 2009. Another important project is the strengthening of the methodology for assessment of the benefit-risk balance of human and veterinary medicines throughout their lifespan. This work is being carried out both in internal fora and within the framework of the Innovative Medicines Initiative.

The EMEA has prepared for the creation of a new scientific committee — the Committee for Advanced Therapies — that will become fully operational in 2009. Having established the necessary procedures for the evaluation of applications and for the provision of other specific advice related to advanced-therapy medicinal products, the Agency will operate these procedures and will develop risk-management and pharmacovigilance activities in this new field of responsibility.

Significant effort is being made in the areas of communication, transparency and provision of information. The EMEA is under increasing pressure to ensure that its online presence can meet the needs of external stakeholders by publishing information via the web that is easy to find and consume. As a result, the Agency will re-launch its website towards the end of 2009, and will begin work to ensure that all public-facing websites managed by the Agency are easy to use and access by external stakeholders. In order to encompass and consolidate all transparency-related activities, the Agency, after consultation with partners and stakeholders, will develop a transparency policy. This will also facilitate the Agency's plans to provide access to safety and clinical trial-related information.

The Agency has been, and will continue to be, heavily involved in activities that support innovation and improve availability of medicines. In the field of innovation, the EMEA will dedicate its efforts and resources to the work of the Innovative Medicines Initiative and the European Technology Platform for Global Animal Health. Both initiatives attempt to improve medicinal product development processes and, therefore, are of importance to the Agency. As scientists from European and other countries work in the area of biomarkers, translational medicine and nanotechnologies, the EMEA will provide scientific input into these novel fields of medicinal product development.

The EMEA remains committed to improving the availability of veterinary medicines, and will focus its efforts in three major areas to achieve this. First, the Agency will work with stakeholders to promote and facilitate authorisation through the centralised procedure of vaccines against major epizootic diseases of animals, particularly avian influenza, bluetongue and foot-and-mouth disease. This will constitute a significant part of the Agency's contribution to the new Community Animal Health Strategy, 'Prevention is better than cure'. Second, the Agency will implement initiatives, in cooperation with the network, aimed at facilitating greater availability of veterinary medicines indicated for limited markets, including minor use/minor species, through the introduction of measures to assist companies at the time of authorisation. Third, the Agency will actively contribute to the work of the EU Commission, Community agencies and national competent authorities in relation to the assessment and, where appropriate, management of the potential risk to man arising from the use of antimicrobial agents as veterinary medicinal products. The Agency will coordinate the activities of its scientific committees with those of the network, to ensure the production of sound, scientific risk assessments that take into account the use of antibiotics in both man and animals.

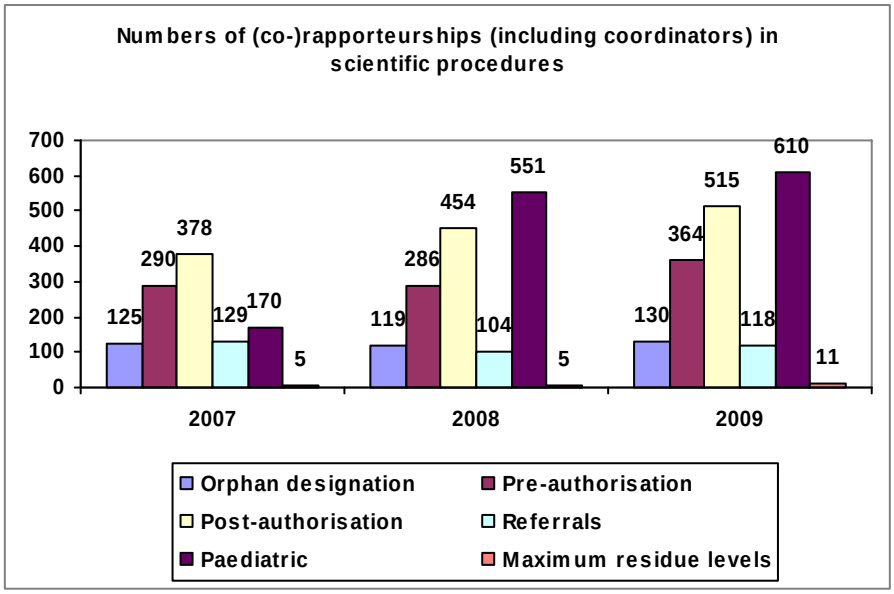
[1] Benchmarking of European medicines agencies (BEMA).

# 1. EMEA IN THE EUROPEAN SYSTEM

## *1.1 European medicines network*

The European medicines network[2] allows scientific resources to be mobilised and coordinated in a way that benefits patients throughout the EU. Support to the development of the European medicines network is a priority area for the Agency. The following trends and new issues will influence activities of the network in 2009:

- The network will increasingly be subject to a number of challenges over the next few years, especially with regard to the pressures on resources needed for the full implementation of new legislation on paediatric and advanced-therapy medicinal products.
- The Agency expects that the number of (co-)rapporteurs and coordinators from the European medicines network contributing to Agency procedures will increase by 15%, to 1,750[3].




*Objectives*

- Further enhance the overall quality and capacity of the European medicines network in terms of the availability of top-quality scientific expertise, quality-assurance and competence development.
- Contribute to the further development of the world-class medicines regulatory system by supporting Benchmarking of European Medicines Agencies (BEMA) activities:
  - provide assessors for the BEMA peer-review assessments;
  - organise training seminars for BEMA assessors from the national authorities and provide logistical support.
- Continue work with the Heads of Medicines Agencies to develop and plan the implementation of a strategy for regulatory and scientific training in the European medicines network.
- Facilitate training of assessors on evaluation of advanced therapies.

[2] Defined as the European Commission, the EMEA and the national competent authorities of the Member States.
[3] This figure includes the number of rapporteurs, co-rapporteurs and coordinators in the procedures mentioned in the chart. The figure does not include peer-reviewers or coordinators in the working parties, scientific advisory groups, etc.

- Review the revised (co-)rapporteur appointment procedure, taking into account experience gained and new legislation.
- Fully implement a framework for eCTD submissions and recommend eCTD submissions for all centralised procedures for medicines for human use (except for referrals) throughout the European medicines network.
- Implement the strategic plan to strengthen the scientific interaction among assessors' networks and learned societies (initiative stems from the Think-tank Report[4]).
- Following the ongoing review of the payment system to (co-)rapporteurs and, depending on the decision by the Management Board, possibly implement a new payment system in 2009.
- Start preparing the new EMEA road map to 2015 (adoption of the new road map planned in 2010).
- Implement the European Risk-Management Strategy (ERMS) in line with the 2008-2009 ERMS action plan.

## Meetings at the EMEA

### *Trends and new issues*

- The introduction of the new Committee for Advanced Therapies, together with the increasing complexity of tasks more generally, will contribute to the number of meetings and Member States' delegates visiting the Agency. Additional representatives from the candidate and potential candidate countries will attend appropriate meetings as observers.
- The Agency expects that the number of reimbursed delegates will increase by 6%, to 8,600, but that the number of meetings will remain at the 2008 level (around 600 meetings). The latter is due to reduced number of EU Telematics-related meetings and efforts to replace some of the conventional meetings with tele- and videoconferences or other alternative meeting solutions.

### *Objectives*

- Provide the best-possible support to delegates from Member States attending meetings, so as to achieve the same high level of satisfaction as expressed in previous years; develop methods to improve efficiency of reimbursement procedures where appropriate.
- In light of the high number of conventional meetings and pressure on national resources, further promote the use of communication tools as alternatives to conventional meetings, such as videoconferencing, desktop videoconferencing, teleconferencing, meeting webcasting and net meetings.

### *Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Satisfaction of delegates and interested parties regarding support provided by the EMEA | 95% of respondents to be satisfied or very satisfied |
| Percentage of delegates using MMS-E system | 80% |

## Preparations for future enlargement

### *Trends*

- An IPA (Instrument for Pre-accession Assistance) programme will be launched for supporting pre-enlargement activities, which have already started for Croatia, Turkey and the former Yugoslav

[4] 'Innovative drug-development approaches — Final report of the EMEA/CHMP think-tank on innovative drug development' (EMEA/127318/2007).

Republic of Macedonia, and which will be extended to the potential candidate countries in the Balkans such as Serbia, Albania, Bosnia-Herzegovina, Montenegro and Kosovo under UN MIK[5].

*Objectives and main initiatives*

- Facilitate the preparation for accession of the candidate countries and potential candidate countries. Where appropriate:
  - enable participation in EMEA meetings of observers from the countries concerned; provide training and organise conferences, workshops and seminars in the field of regulation of medicinal products;
  - set up measures aimed at facilitating the integration of the candidate and potential candidate countries' competent authorities into the EU telematics systems;
  - assess the level of harmonisation by each Balkan country with the EU acquis communautaire in the area of pharmaceuticals, in order to define suitable activities for providing the best support for each country;
  - provide best-possible support to the candidate and potential candidate countries, tailor-made to their needs, regarding harmonisation with the EU acquis communautaire.

## 1.2 European cooperation

This covers: contribution to new legislation initiated by Directorates-General of the European Commission; partnership with European Commission Directorates-General, namely DG Enterprise and Industry, DG Health and Consumer Protection, DG Research and DG Development; cooperation with EU Agencies, namely the European Centre for Disease Prevention and Control (ECDC), European Food Safety Authority (EFSA) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA); cooperation with the European Directorate for the Quality of Medicines and HealthCare (EDQM).

*Trends*

- Increasing antimicrobial resistance and associated reports on mortality and morbidity in EU citizens will increase the demand for development of niche products.
- Several high-level policy initiatives — such as the Pharmaceutical Forum activities (in particular those relating to the provision of information to patients), the Innovative Medicines Initiative and the 7th Framework Programme — as well as the follow-up to the European Commission report to the European Parliament and the Council on the current practice with regards to information provision (Article 88a of Directive 2001/83/EC, as amended) will necessitate increased interaction between the EMEA and the EU institutions.

*Objectives and main initiatives*

- Plan for an influenza pandemic simulation exercise in collaboration with national competent authorities to test the EMEA Pandemic Crisis Management Plan and associated procedures, and evaluate the EMEA's business-continuity measures.
- Continue collaboration with the European Commission in the areas of provision of information, research on and development of off-patent paediatric medicines, targeted medicinal products, rare diseases, products intended for non-EU markets, and projects on neglected diseases.
- Maintain EMEA's contribution and support to ongoing public health-related activities (activity relates to Road Map initiative).

[5] United Nations Interim Administration Mission in Kosovo.

- Continue collaboration with EU partners on risk-assessment activities.
- Maintain the database on medicinal products to be used against bioterrorism agents; cooperate with the ECDC in this area.
- Continue to support the ECDC project on harmonisation of vaccination schedules, and continue collaboration in the area of surveillance and pharmacovigilance of vaccines, antimicrobial resistance and pandemic planning.
- Engage with ECDC on matters relating to EU-wide oversight of infection risks associated with the use of advanced-therapy products.
- Continue the work of the scientific committees in the priority area of minimising the potential for the development of antimicrobial resistance through the use of antibiotics in humans and animals, in close cooperation with the Member States, the European Commission, EFSA and ECDC, as well as international organisations active in this area, such as the WHO, OIE, FAO and CODEX.
- Strengthen liaison with other scientific committees of EU institutions and agencies to ensure consistency of scientific opinions and to provide appropriate input when scientific committees prepare opinions.
- Contribute to EU and international work on anti-counterfeiting and parallel distribution, with particular focus on improving the distribution network (Road Map initiative).
- Prepare for the new MRL regulation, in liaison with the European Commission services concerned and Member States, and implement the new regulation, once adopted.
- Contribute to ongoing reflections within the European medicines network on the particular challenges that exist with respect to authorisation of veterinary medicines due to the small and fragmented nature of the market, and on how best the regulatory and legislative framework might be amended in future to deal with veterinary-specific requirements.

## *1.3 International cooperation*

These activities cover cooperation at European level, collaboration with the Organisation for Economic Co-operation and Development (OECD), cooperation with the European Directorate for the Quality of Medicines and HealthCare (EDQM), and at international level, EMEA participation in the International Conference on Harmonisation (ICH), work with the World Health Organization (WHO), the International Cooperation on Harmonisation for Veterinary products (VICH), the Codex Alimentarius, the World Organisation for Animal Health (OIE), work with the US Food and Drug Administration (FDA), the US Department of Agriculture (USDA) and the Japanese and Canadian authorities in the implementation of the confidentiality arrangements, and with other non-ICH regulatory authorities.

*Trends*

- The international visibility of the EMEA has developed rapidly and will continue to grow over time. Some regions of the world are interested in learning more about European operations and the network, as a possible model for their own regulatory development.
- The confidentiality arrangements with the US FDA are leading to increased collaboration in both the human and veterinary fields. With respect to human medicines, the same can be expected with the arrangements concluded in 2007 with Canada and Japan.
- Impact is expected from the 2007 initiative on administrative simplification, which covers a number of areas of work to be assessed.

*Objectives and main initiatives*

- Develop the Agency's international strategy, taking into account the changing pharmaceutical environment, increasing globalisation and existing international priorities.
- Review and further strengthen the collaboration with the FDA, the Japanese authorities and Health Canada in the context of the existing confidentiality arrangements with respect to human medicines, and with the FDA and Health Canada with respect to veterinary medicines.
- Explore, in collaboration with the European Commission, an extension of the international cooperation to other non-EU countries:
  - identify what additional cooperation activities (beyond the Visiting Experts programme and MRA collaboration) can be undertaken;
  - explore what activities can be undertaken within the framework of the Commission's arrangement on pharmaceuticals with China;
  - participate in discussions and liaise with fora regarding Ayurvedic medicinal products and traditional Chinese medicines, and in particular support the work of the EU-India Working Group on Pharmaceuticals and Biotechnology.
- Cooperate in the areas of pharmacovigilance, risk-management, clinical data-management, multidisciplinary topics and international standardisation activities in the framework of ICH, including Standards Development Organisations (SDOs) and the Council for International Organizations of Medical Sciences (CIOMS).
- Participate in WHO meetings and contribute to projects and workshops with regard to regulatory capacity-building; strengthen collaboration with the WHO in the context of pharmacovigilance and with regard to medicinal products intended for use outside the European Union; similarly, continue collaboration with the OIE in promoting initiatives to improve and harmonise standards for veterinary medicines at a global level.
- Continue international collaboration on worksharing and cooperation on all types of inspections with the FDA, WHO and other regulatory partners (Road Map initiative). See also Chapter 4 (Inspections).

## Certificates

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

*Trend*

- The number of certificate requests is expected to increase by approximately 20% (from 2,116 in 2008 to an estimated 2,590 in 2009), due to the increased number of approved marketing authorisations. Certificates within the framework of cooperation with the WHO and as a result of requests by SMEs are also expected to increase in 2009.

*Objective*

- Pursue discussions with the WHO on the possible acceptability of alternatives to paper certificates.

*Performance indicators*

| Performance indicator | Target |
|---|---|
| Percentage of certificates of medicinal products issued to requesting parties within the timeline | 90% compliance |

### Mutual-recognition agreements

Mutual-recognition agreements (MRAs) between the European Community and partner (third) countries include specific annexes relating to medicinal products and GMP. These allow EU Member States and the MRA partner to mutually recognise conclusions of inspections of manufacturers carried out by the respective inspection services of the other party, and to mutually recognise the manufacturers' certification of conformity to specifications for each batch without re-control at import.

The EMEA is responsible for implementation and operational aspects of these MRAs. MRAs with Australia, New Zealand, Switzerland, Canada and Japan are currently operational, but with slightly different provisions as to scope and applicability.

*Trends*

- Increase of the contribution of MRA partners to EudraGMP with a view towards exchanging GMP certificates and GMP-compliance information.
- Impact of implementation of ICH quality guidelines (quality risk-management, pharmaceutical quality systems) in EU GMP on the activities under the MRAs.

*Objectives and main initiatives*

- Complete the remaining evaluation work and follow-up with new Member States (Bulgaria and Romania) in the context of the European Community-Canada MRA.
- Further explore the practical implementation of EudraGMP on operation of exchange of information with MRA partners.
- Review the impact of implementation of ICH quality guidelines (quality risk-management, pharmaceutical quality systems) in EU GMP on the equivalency with MRA partners.

## *1.4 Communication and transparency*

Changes to EU pharmaceutical legislation in recent years have given the EMEA and the European network as a whole a wider mandate to increase the transparency of their activities and strengthen communication with their stakeholders. The areas of transparency and communication are a priority for the Agency.

*Trends*

- The Agency's stakeholders (patients, healthcare professionals, pharmaceutical industry, academia, learned societies and the press) expect an increasingly higher level of transparency, especially in relation to opinion-making and clinical trials.

- The Agency's stakeholders also expect to consume the EMEA's online information quickly and easily, in a format that they can readily use and understand.
- Access-to-documents activities will see a further substantial increase, with the number of requests expected to grow by around 42% (from 127 to 180 requests, where a single request may encompass hundreds of documents).
- The number of requests for information has been growing steadily over the years, and the nature of questions has become increasingly complex. The Agency estimates a 18% increase in requests for information (from 4,069 requests to 4,800).

### *Objectives and main initiatives*

- Implement the EMEA's 2008-2010 framework strategy for communications, taking into consideration the needs and expectations of external stakeholders.
- Re-launch the Agency's website (www.emea.europa.eu) to make it an efficient and user-friendly source of authoritative information on centrally authorised medicines.
- Implement the public-facing online information (PFOI) project across all public-facing EMEA-managed websites, including the Agency's main website (www.emea.europa.eu).
- Complete and implement the EMEA corporate-identity project.
- Develop an EMEA transparency policy, after consultation with the Agency's partners and stakeholders on the level of openness of EMEA activities.
  - Further increase EMEA transparency in relation to both product and non-product-related issues.
  - Further increase EMEA transparency with regard to the rationale for the Agency's scientific opinions.
  - Further reinforce the content of European public assessment reports to better reflect ethical issues related to clinical trials conducted in non-EU countries that are included in an initial application.
  - Engage in public debates on recommendations for biomarkers.
- Improve EMEA transparency on information relating to safety and to paediatric clinical trials.
  - Fully implement access policies for EudraVigilance data, subject to the resolution of data-quality issues.
  - Fully integrate the paediatrics component in the EudraCT database and provide public access via the web to specified data on paediatric clinical trials (Road Map initiative).
- Revise and subsequently implement the revised EMEA access-to-documents policy, following a public consultation launched in 2008.

For more information, please refer to Section 2.11.

### *Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of external requests for documents and information processed within established timelines | 95% |

## *1.5 Support for innovation and availability of medicines*

*Objectives and main initiatives*

- Conduct the following activities contributing to innovation and availability of medicines for human use: continued implementation of orphan and paediatric medicines policies, introduction of incentives for advanced therapies, provision of scientific advice (including that on biomarkers), provision of support to small and medium-sized enterprises (SMEs), operation of procedures shortening regulatory timeframes, stimulation of applications for products intended for non-EU markets in the context of cooperation with the WHO.
- Continue with the provision of advice on eligibility for pre-authorisation procedures of innovative types of medicinal products and with the provision of fora for discussion with stakeholders on innovative therapeutic approaches and new development methods, in line with the recommendation of the EMEA/CHMP think-tank report.
- Continue to cooperate with the European Commission on fostering innovation in the context of the Innovative Medicines Initiative (IMI), 7th Framework Programme and the European Technology Platform for Global Animal Health.
- Continue to work on promoting the availability of veterinary medicines by contributing to the implementation of the action plan arising from the HMA Taskforce on Availability, and by introducing a range of measures to promote the authorisation of products for limited markets (MUMS).
- Assist the European Commission in implementing the Action Plan for the new Community Animal Health Strategy, 'Prevention is better than cure', in particular by developing in cooperation with the CVMP measures to promote authorisation through the centralised procedure of vaccines against epizootic diseases such as foot-and-mouth disease, bluetongue and avian influenza.

### Small and medium-sized enterprises

Small and medium-sized enterprises (SMEs) operating in the human and veterinary pharmaceutical sectors are often innovative companies that can notably benefit from the pooling of scientific expertise at Community level. Regulation (EC) No 726/2004 and Commission Regulation (EC) No 2049/2005 make provisions for incentives in the form of fee reductions or deferments and administrative assistance from the Agency's SME Office. These are intended to reduce the cost for SMEs of marketing medicinal products authorised via the centralised procedure and the cost of establishing maximum residue limits for veterinary medicinal products.

*Trends*

- The activities of the SME Office are expected to steadily increase as new companies register for SME status.
- The introduction of the Advanced-Therapies Regulation is also expected to impact on the workload of the SME Office.

*Objectives and main initiatives*

- Ongoing financial, regulatory and administrative assistance to SMEs (including management of translations).
- Further support SMEs during the critical period between obtaining scientific advice and submitting a marketing-authorisation application, by providing more regulatory and administrative assistance to improve the success rate at the time of initial evaluation (Road Map initiative).
- Support SMEs with the electronic reporting of adverse drug reaction data.

## 1.6 Methodology and outcomes-assessment projects

*Trends and new issues*

- A need to develop the capacity for performing regulatory outcomes assessment in some areas is grounded in the EMEA Standards for Internal Controls, which require the Agency to carry out evaluation of its activities.
- Stakeholders put forward new demands to the Agency, such as requests for detailed justification of benefit-risk assessments performed by the Agency's committees, or the need to assess the impact of regulatory actions on public health.

*Pilot projects*

Taking the abovementioned trends into account, a number of relevant pilot projects have been identified, based on internal and external consultation, to be initiated/conducted in 2009:

- Develop and test tools and processes for balancing multiple benefits and risks as an aid to informed regulatory decisions about medicinal products (in collaboration with the London School of Economics, UK).
- Develop and test a concept for electronic structure and maintenance of key SPC drug information to be applied in e-prescribing services at point of healthcare (in collaboration with Karolinska Institutet, Sweden).
- Test alternative criteria for a signal of disproportionate reporting (SDR).
- Assess the content of benefit-risk communication – expectations from key opinion leaders (in collaboration with Kings College, UK).
- Assess the impact of establishing a maximum residue limit for muscle for injectable products.
- Assess the impact of scientific advice on the outcome of marketing-authorisation applications.
- Expand the Scientific Memory Database.
- Assess the evidence base for orphan drugs (collaboration with KCE, Belgian Healthcare Knowledge Centre, Belgium).
- Improve methodologies for assessing the post-marketing benefits and safety of medicinal products.

*Objectives*

- Initiate/conduct the pilot projects mentioned above.
- Further develop collaborative projects with European universities and other research organisations to enable the conduct of the abovementioned projects and enhance the visibility of the EMEA within the scientific community.

## 1.7 Integrated management at the EMEA

An integrated management system forms the backbone in providing management assurance about the Agency's processes and output. Central elements of this system, that is marked by continuous improvement, are: a quality management system; a risk management system; an Audit Advisory Committee; self-assessments, audits, internal controls and management reviews; benchmarking with partners in the European network of medicines agencies (BEMA); human resource management; business and financial management; health and safety, and environmental policies; and business continuity planning.

*Trends and new issues*

- The Management Board adopted the revised internal control standards, which now focus more on the effectiveness and efficiency of their implementation.
- A follow-up on the analysis of the outcome of the EMEA process-improvement exercise will be undertaken to allow the concepts of process improvement/better regulation to be integrated on a continual basis in the work of the Agency.
- The European Commission will carry out an evaluation of the Agency.
- Accommodation planning, management of office environment and meeting-room facilities, to match the requirements of the increases in staff numbers and delegates as well as of meetings; the number of visitors is forecast to increase by around 5%, from 43,000 in 2008 to an estimated 45,000 in 2009.
- 2009 will see the start of the second mandate of the Audit Advisory Committee (AAC), established by the Executive Director to provide independent advice on issues of corporate governance and oversight of the internal audit capability (IQM/Audit).

*Objectives and main initiatives*

- Ongoing management and administration activities, including personnel and budget management, accounting, management of infrastructure, the work of the verifying service, as well as management review, risk management, self-assessment, audit and control activities.
- Implement the revised internal control standards, and review and assess the effectiveness of their implementation.
- Carry out a review of the effectiveness and efficiency of the EMEA's integrated quality-management system.
- Assist the European Commission in its evaluation of the Agency and of the impact of the Agency's activities.
- Identify further (process) improvements in the various activities undertaken by the Agency, in order to gain efficiency and implement measures to improve the functioning of the EMEA.
- Ensure that the potential efficiency-gain measures identified for the various activities have been taken.
- Concentrate, in particular, on the areas of information and knowledge management, both with a view to improving business efficiency and ensuring effective business input into the ongoing development of new and improved IT support services.
- Fully implement the outcome of the analysis undertaken in 2008 as regards the need to introduce a reorganisation of the Agency.
- Further develop business-process training and enhanced scientific training to increase the knowledge of scientific administrators, particularly in the area of emerging and new therapies, by developing a syllabus and organising training, to include both in-house speakers and external training.

- Implement staff regulations, manage implementing rules and inform staff thereof.
- Progress the Agency's records-management project and begin the implementation phase.
- Advance the project to replace the finance and accounting system SI2 by an integrated resource-planning system (Enterprise Resource Planning).
- Progress business-continuity activities and review business-continuity and disaster-recovery measures to ensure that the offsite facilities and the telecommunications back-up are tested for their appropriateness to respond to any unforeseen event.
- Carry out a major refurbishment project for additional meeting rooms, delegate offices and office capacity.
- Conduct a feasibility study for EMEA's future office premises, prior to expiry of current lease.
- Review the environmental policy and the measurement of the environmental management system.

# 2. MEDICINES FOR HUMAN USE

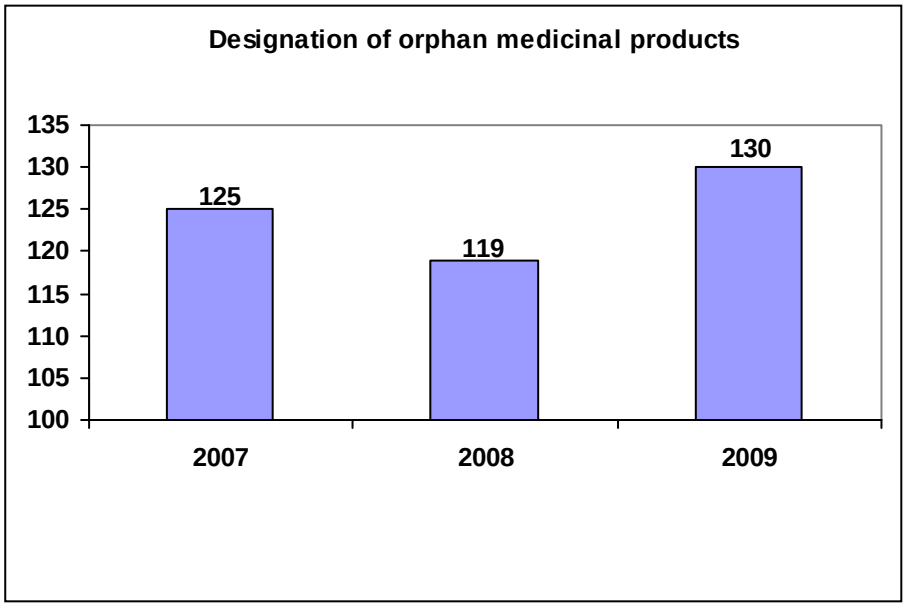
## *2.1 Orphan medicinal products*

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

The Agency contributes significantly to the creation of an environment that stimulates innovation, research and thus the availability of medicines to treat rare diseases, through the implementation of the orphan medicinal products policy. As part of this work, the Agency provides financial incentives during the development and initial marketing-authorisation phases, and, where the applicant is an SME, during the post-authorisation phase too. Protocol assistance remains a priority area for such incentives.

*Trends and new issues*

- Increased number of applications due to the impact of the Paediatric Regulation, the implementation of the common application form with the FDA, and possible impact of the Advanced-Therapies Regulation.
- Growing complexity of review of designation criteria prior to marketing authorisation (especially regarding 'personalised' medicines); increased number of challenges to orphan market exclusivity by companies with competitor products.




*Objectives and main initiatives*

- Ongoing management of core activities relating to the evaluation of applications for designation and development of related guidelines.
- Review experience with EMEA/US FDA common application form for orphan designation and its development.
- Further develop contacts with non-EU regulatory agencies with regard to international collaboration.

- Initiate activities with the US FDA in relation to annual reporting for designated orphan medicinal products.
- Implement the Commission guideline on Article 8(2) of Regulation (EC) No 141/2000 with respect to the review of the period of market exclusivity of orphan medicinal products.

*Performance indicators*

| Performance indicator | Target |
|---|---|
| Percentage of applications evaluated within the 90-day timeline | 100% of applications |
| Percentage of summaries of COMP opinions published within 1 month of the European Commission's decision on designation | 70% of summaries of opinion |

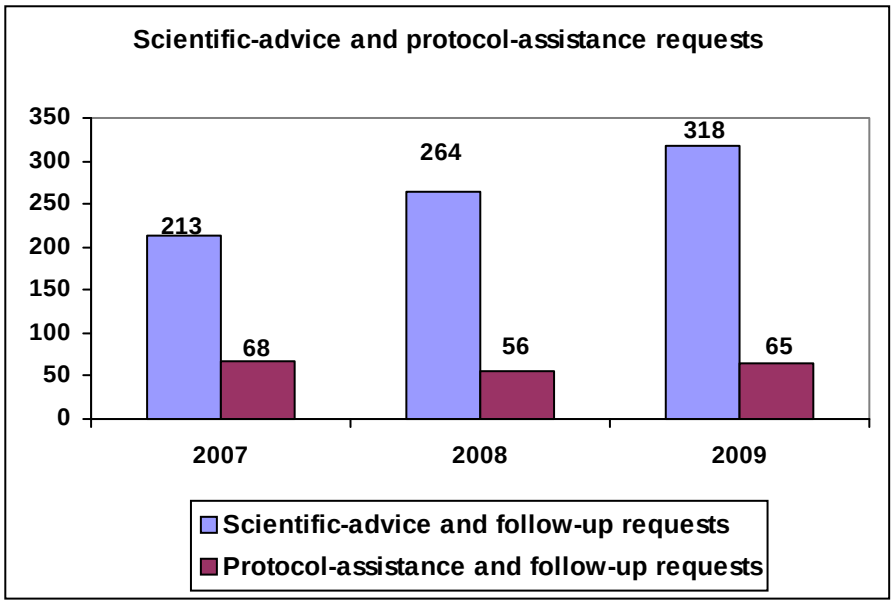
## 2.2 Scientific advice and protocol assistance

The Agency provides scientific advice and protocol assistance to sponsors during the phase of research and development of medicinal products. Scientific advice is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition, the Agency provides advice to sponsors of designated orphan medicines in the form of protocol assistance, which can include advice on the significant benefit of a product. The Agency has more recently introduced a qualification process for innovative development methods.

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

*Trends and new issues*

- An increase in the number of applications is expected, with a steady progression of questions on: alternative clinical-trial designs; comparability; biomarkers; advanced therapies; conditional marketing authorisation. There will be an increased number of scientific-advice requests in combined areas in both adult and paediatric development.
- An increase in clinical trials being carried out in low-income and developing countries relating to products under development for the European market is expected.



*Objectives*

- Ongoing management of core activities relating to the provision of quality scientific advice to applicants.
- Implement 'Think-tank report' initiatives:
  - complete implementation of a scientific-advice procedure on biomarkers to support the qualification process in drug development;
  - hold workshop with stakeholders on statistics in clinical trials;
  - implement a new procedure for urgent and minor scientific-advice follow-up.
- Monitor conduct of clinical trials in developing countries as part of scientific-advice activities.

*Performance indicators*

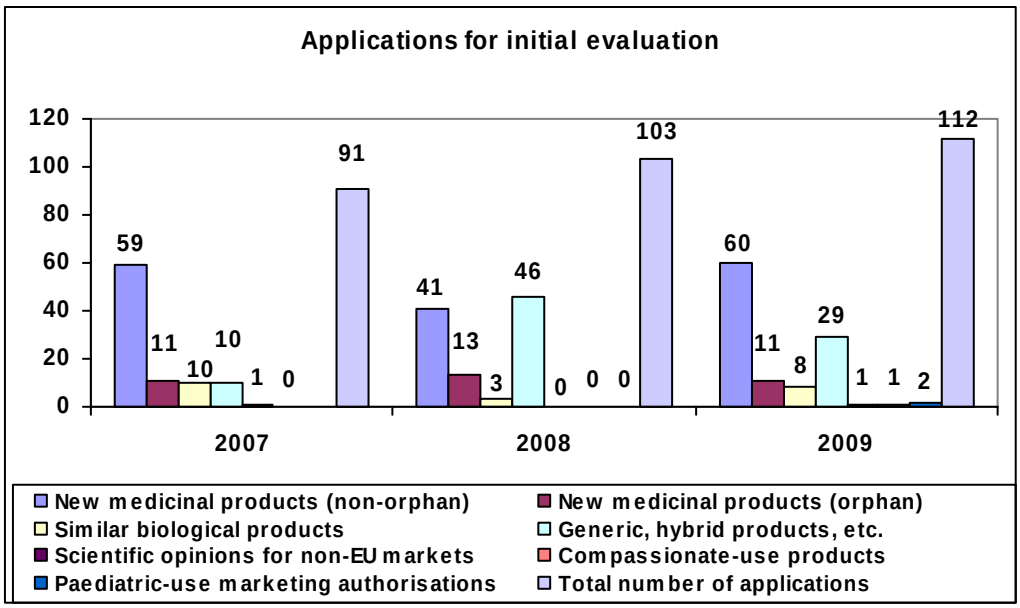
| **Performance indicator** | **Target** |
|---|---|
| Scientific-advice and protocol-assistance requests evaluated within the procedural timelines | 100% of requests |
| External experts involved in procedures | 50% of scientific-advice and protocol-assistance requests |

## 2.3 Initial evaluation

This covers EMEA activities relating to the processing of applications for centralised marketing authorisations, from pre-submission discussion with future applicants, through evaluation by the CHMP and the issuance of a scientific opinion, to the granting of a marketing authorisation by the European Commission. These activities result in the production of the European public assessment report (EPAR). Applications for certification of compliance with Community legislation of plasma master files (PMF) and vaccine antigen master files (VAMF) are processed in a similar manner, but without the production of an EPAR. Notified body consultations for blood derivatives and ancillary substances in medical devices are also referred to the EMEA.

*Trends and new issues*

- The initial-evaluation procedures and processes have become more complex, with different types of products involved and several levels of interaction arising from different regulations. Interaction between the CHMP, the Committee for Orphan Medicinal Products (COMP) and the Paediatric Committee (PDCO) will continue, and will now also incorporate the Committee for Advanced Therapies (CAT).
- Sponsors are carrying out more clinical trials in non-EU countries for submission in initial marketing-authorisation and variation applications. This requires particular analysis of data provided by applicants, and of the conditions in which those clinical trials have been conducted.
- Although the number of applications for products intended for non-EU markets (Article 58) may be limited, this activity relies on cooperation and new expertise from the EU network and the WHO. Malaria and vaccines remain of key importance, while interest in microbicides is on the increase.




*Objectives and main initiatives*

- Ongoing evaluation of marketing-authorisation applications.
- Further develop the quality-control elements for existing and new activities in relation to the assessment of marketing-authorisation applications in the centralised procedure (Road Map initiative):
  - implement quality-control elements for the validation of applications (including verification of compliance with the Paediatric Regulation), for advanced therapies and for compliance of clinical trials with ethical standards;
  - revise and expand controls of the quality of assessment reports and opinions across centralised applications.
- Strengthen the review and generation of opinions for generic, non-prescription and Article 58 products (Road Map initiative):
  - reinforce pre-submission activities to facilitate further the use of the centralised procedure for the abovementioned products.

*Performance indicators*

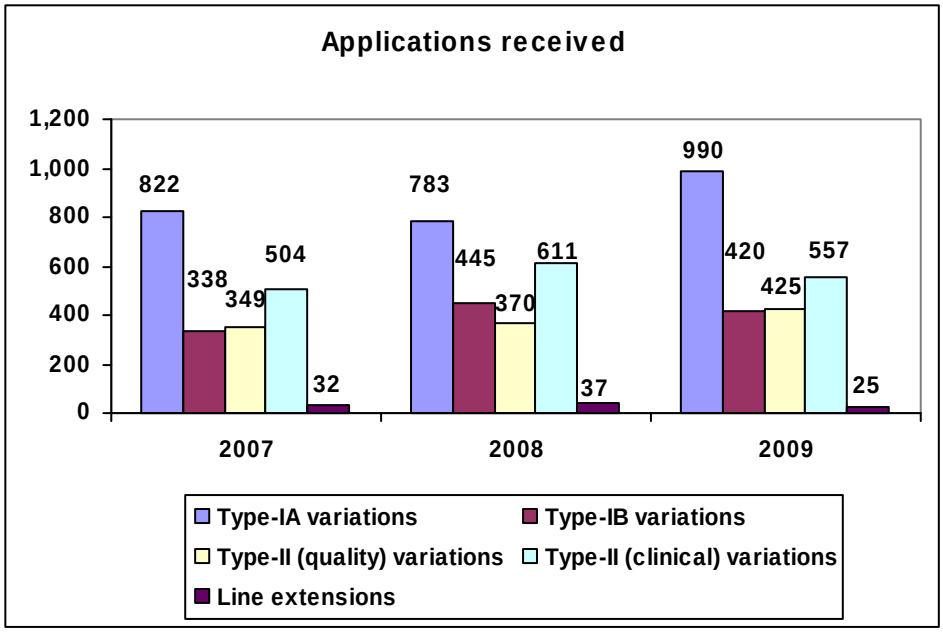
| **Performance indicator** | **Target** |
|---|---|
| Percentage of applications evaluated within the regulatory timeline: | |
| ▪ Marketing-authorisation applications | 100% of applications |
| ▪ Accelerated-assessment applications | 100% of applications |
| ▪ Plasma-master-file applications | 100% of applications |
| Percentage of opinions sent to the European Commission within the regulatory timeline of 15 days | 100% of applications |
| Percentage of risk-management plans (RMPs) that are peer reviewed by the EMEA as part of the assessment of the initial marketing-authorisation application | 80% of applications |

## 2.4 Post-authorisation activities

Post-authorisation activities relate to variations, line extensions and transfers of marketing authorisations. Variations to marketing authorisations can be either minor (type-IA or IB) or major (type-II) changes. These variations concern quality and (non-)clinical-related aspects, including extensions of indications.

*Trends and new issues*

- A further increase in variations is expected, in line with the growing number of centrally authorised products, including variations to similar biological and generic medicinal products. The number of variations resulting from the Paediatric Regulation is expected to increase in 2009 as a consequence of the impact of the regulation on post-authorisation procedures.
- Further to the publication of the revised Variations Regulation, preparatory work will be undertaken in terms of guideline and guidance development, as well as provision of training to facilitate the implementation of the new legal provisions.




*Objectives and main initiatives*

- Ongoing post-authorisation activities.
- Further strengthen the regulatory and scientific consistency of CHMP opinions and assessment reports:
  - introduce, in agreement with the CHMP, a peer-review system for the (co-)rapporteurs' assessment reports for major marketing-authorisation changes (type-II variations referring to extension of indication).
- Implement the revised Variations Regulation:
  - coordinate CHMP, CVMP, CMD(h), CMD(v) and EMEA input into the European Commission guidelines;
  - provide detailed guidance to stakeholders on revised variation procedures;
  - provide training to assessors on variation procedures.

*Performance indicators*

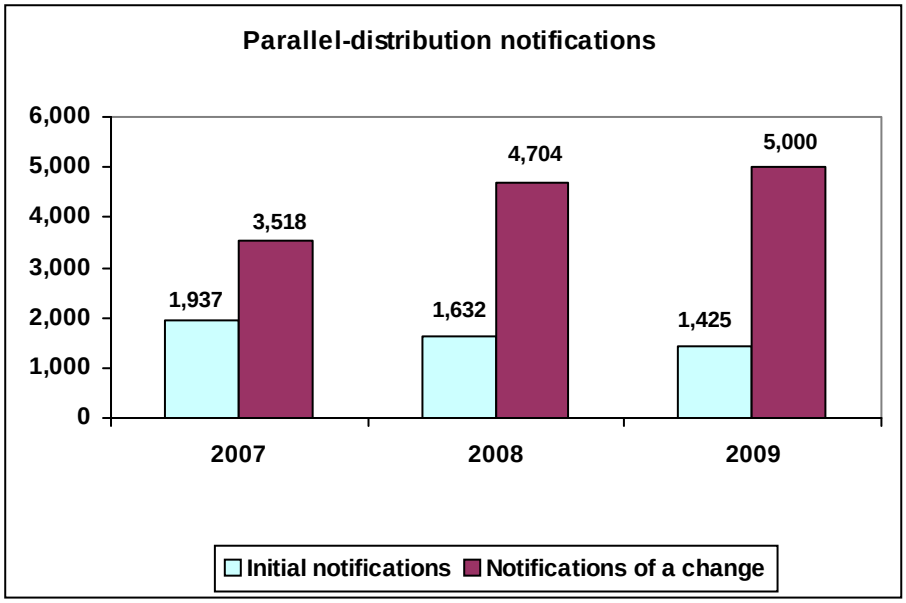
| Performance indicator | Target |
|---|---|
| Percentage of applications for post-authorisation procedures evaluated within the regulatory timelines | 100% of applications |
| Percentage of applications meeting the legal timeline of 27 days for the linguistic post-opinion check | 100% of applications |

## 2.5 Parallel distribution

Parallel distribution is the distribution of a centrally authorised medicinal product from one EU-EEA Member State to another by a pharmaceutical company independently of the marketing-authorisation holder. The task of the EMEA is to check compliance of products distributed in this way with the conditions laid down in Community legislation on medicinal products and the conditions laid down in the marketing authorisations of the products concerned.

*Trends and new issues*

- The number of initial notifications is expected to be slightly lower, and that of notifications of a change slightly higher, than in 2008.




*Objectives and main initiatives*

- Ongoing core activities (checking that the conditions laid down in the Community marketing authorisations are observed for parallel-distributed, centrally authorised medicinal products; providing guidance and information on parallel-distribution activities).
- Ensure compliance of the parallel distributors with the mandatory notification procedure and with the notices issued by the EMEA.
- Check the compliance of parallel-distributed products sampled in the framework of the sampling-and-testing programme with the notice issued by the EMEA.

*Performance indicators*

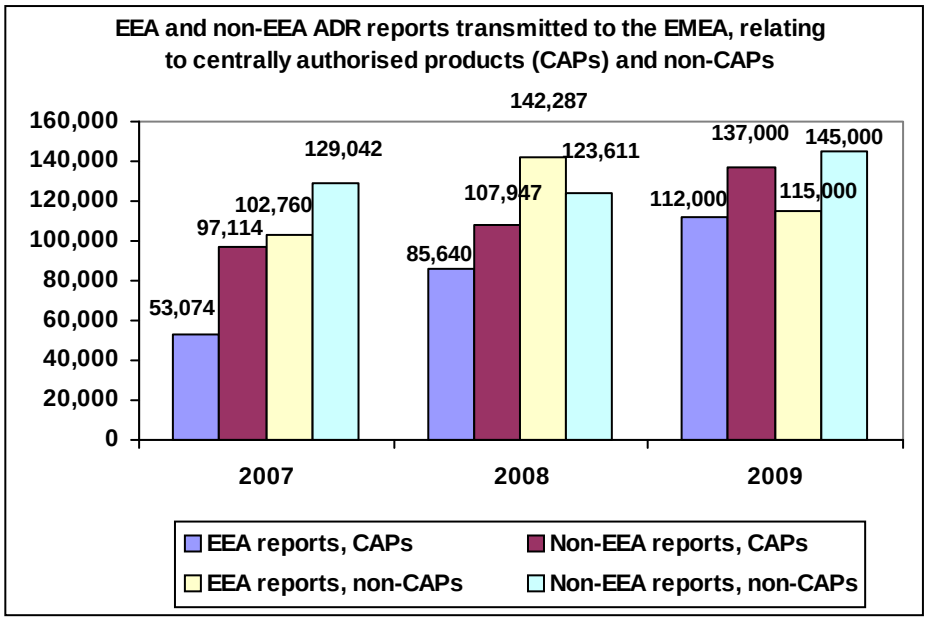
| Performance indicator | Target |
|---|---|
| Percentage of notifications checked for compliance within the regulatory timeline of 35 working days (validation and regulatory check) | 70% of applications |

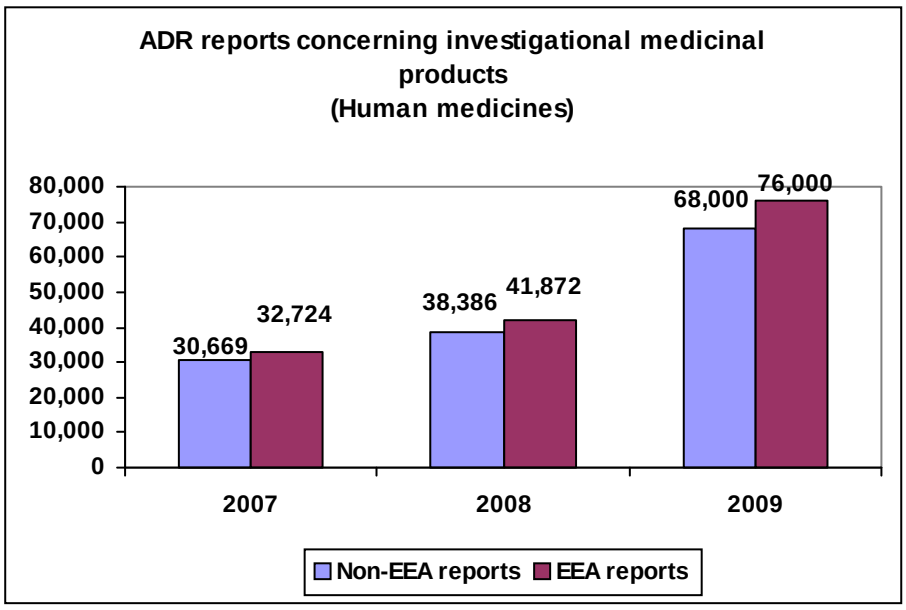
## 2.6 Pharmacovigilance and maintenance activities

Pharmacovigilance activities include the management of suspected adverse drug reactions in the pre- and post-authorisation phases (individual case safety reports, or ICSRs), periodic safety-update reports (PSURs) and risk-management plans (RMPs). Maintenance activities relate to post-authorisation commitments (specific obligations, follow-up measures), renewal applications, conditional renewals and annual reassessments.

*Trends and new issues*

- The workload resulting from the implementation of the Paediatric Regulation is expected to increase, as the Regulation comes into force for post-authorisation procedures in 2009.
- Building on the preparatory work undertaken in 2008, the Agency will implement the Advanced-Therapies Regulation with respect to the post-authorisation follow-up of efficacy, adverse reactions and risk-management.
- The impact of the legal proposals from the European Commission as a follow-up to the assessment of the European Community System of Pharmacovigilance will require adequate assessment by the EMEA.
- The Agency, together with its partners in the European medicines network, will deploy further initiatives in the context of the European Risk-Management Strategy (ERMS), taking into account the 2008-2009 ERMS action plan agreed at HMA level.






*Objectives and main initiatives*

- Ongoing core activities in relation to pharmacovigilance, including signal-detection for centrally authorised products, and maintenance activities (periodic safety-update reports, follow-up measures, specific obligations).
- Implement the ERMS, taking into account the 2008-2009 action plan agreed at HMA level:
  - implement and test the EU Regulatory System incident-management plan;
  - develop an EU Regulatory System communication strategy on emerging safety-related issues;
  - strengthen pandemic-influenza preparedness, and test the pandemic-influenza crisis-management plan.
- Maintain and strengthen the EudraVigilance system (including signal-detection and use of population databases) to support proactive pharmacovigilance (taking into account the ERMS initiatives).
- Implement the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology (ENCePP) as part of the continuous development of a functional network of centres for the intensive monitoring of targeted medicines (as part of the ERMS initiatives):
  - develop the priority areas identified by ENCePP members through the four dedicated working groups according to their agreed mandates, as follows: WG1 (Research standards, guidance and accreditation), WG2 (Transparency & independence), WG3 (Data sources & methodologies) and WG4 (Inventory of research centres);
  - launch a dedicated ENCePP web portal to provide general information on the project, an inventory of available research centres and data sources, and a members' forum;
  - start to commission pharmacoepidemiological studies to be performed through the network.
- If successful in the IMI call, undertake the necessary steps for the execution of the projects.
- Continue cooperation with the European Commission within the context of the 7th Framework Programme, by proposing research topics in the field of safety of medicines to address EU policy needs.
- Prepare for the implementation of the European Commission legal proposal for the revised EU pharmacovigilance framework, through an assessment of the impact on the EMEA.

*Performance indicators*

| Performance indicator | Target |
|---|---|
| Percentage of RMPs that are peer reviewed by the EMEA as part of the assessment of variations and line extensions that result in a significant change to a marketing authorisation | 80% of RMPs |
| Submission of outcome reports for post-authorisation commitments (PACs) to applicants/MAHs within 2 weeks of the CHMP meeting | 100% of reports |

## 2.7 Arbitration, Community referrals and opinions on scientific matters

Arbitration procedures (either under Article 29 of Directive 2001/83/EC as amended or Articles 6(12) and 6(13) of Commission Regulation (EC) No 1084/2003) are initiated because of disagreement between Member States, or because of disagreement of the marketing-authorisation holder with the Member States in the framework of the mutual-recognition (MRP) or decentralised procedures.

Article 30 referrals (Directive 2001/83/EC) are mainly initiated in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by the Member States.

Article 31 and 36 referral procedures (Directive 2001/83/EC) are mainly initiated in case of Community interest and generally for safety-related issues.

Article 16c(1)(c) referrals are initiated by Member States regarding herbal medicinal products with a traditional use of at least 30 years, including at least 15 years in the Community, in order to obtain an opinion on the adequacy of the evidence of long-standing use. Article 16(1)(4) referrals are initiated by Member States regarding herbal medicinal products with a traditional use of less than 15 years in the Community, in order to obtain an opinion on the eligibility for the simplified procedure.

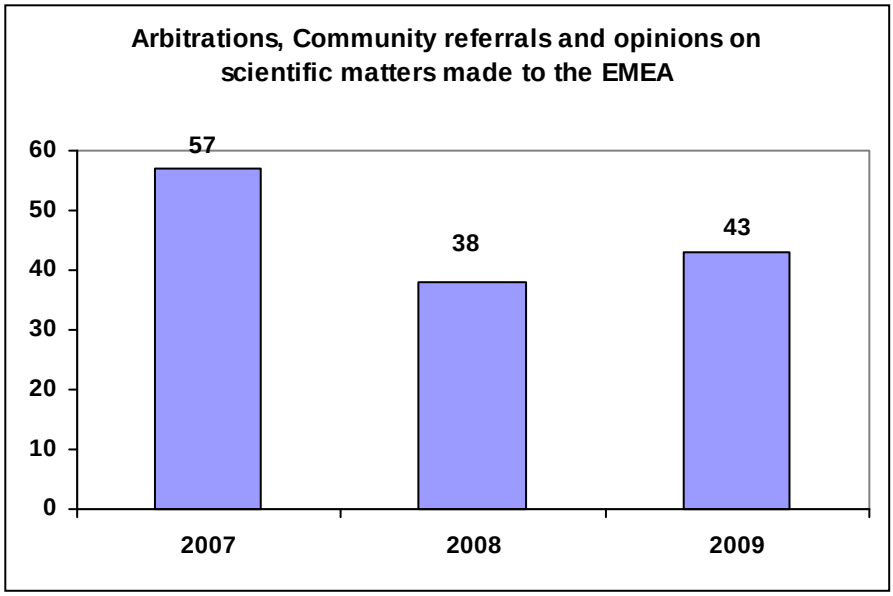
Article 107 of Directive 2001/83/EC, as amended, referrals are initiated to obtain a rapid CHMP opinion further to an envisaged suspension or revocation of the marketing authorisation (or optionally a variation to the marketing authorisation) of a medicinal product in a Member State as a result of pharmacovigilance data.

Article 5(3) procedures (Regulation (EC) 726/2004) require a CHMP opinion on any scientific matter raised by the EMEA, the European Commission or a Member State.

Article 29 procedures (Regulation (EC) No 1901/2006) require a CHMP opinion on authorisation of a new indication, new pharmaceutical form or new route of administration relating to paediatric use.

*Trends and new issues*

- The use of the mutual-recognition procedure in an enlarged European Union is expected to increase significantly. As a result, more products will be referred to the CMD(h). As consultation by the CMD(h) with the CHMP on scientific matters increases, the number of Article 29 (MRP) referrals triggered is expected to stabilise.
- The industry may continue to collaborate on the use of Article 30 referral procedures, with a view to simplifying the maintenance of marketing authorisations in the enlarged European Union.
- The activities in relation to safety-review procedures are expected to further increase, especially procedures following Article 107(2).




*Objectives and main initiatives*

- Ongoing core activities (effective evaluation of arbitrations and referrals).
- Streamline and improve procedures for the handling of referrals (Road Map initiative); further strengthen regulatory consistency:
  - publish public recommendations on the handling of Article 29 (MRP) and 30 referral procedures;
  - develop guidance, based on the 2008 experience gained with Article 29 paediatric procedures.
- Review and further improve the transparency and the provision of information on arbitration and referral procedures (Article 29, 30, 31 and 36) and safety-review procedures according to Article 107(2).

*Performance indicators*

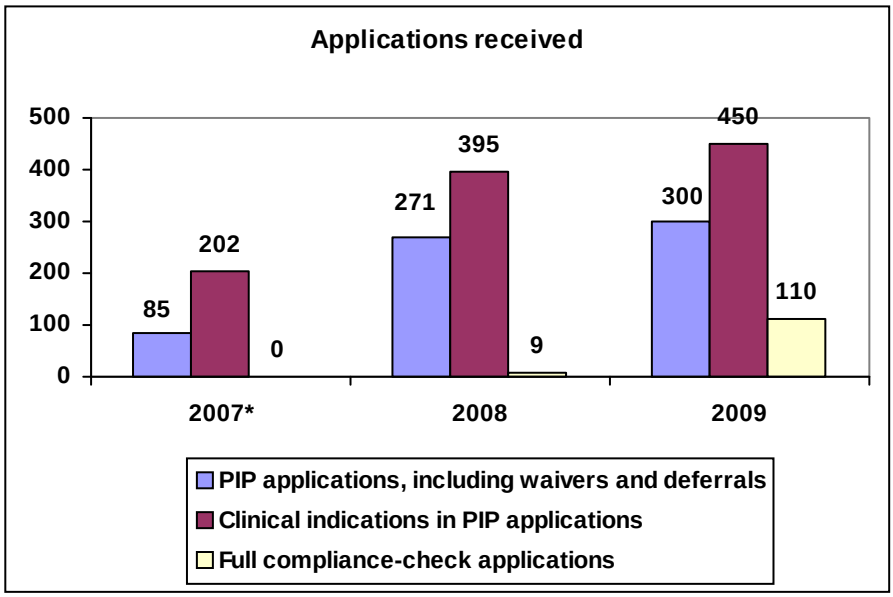
| **Performance indicator** | **Target** |
|---|---|
| Percentage of arbitrations and referrals evaluated within the legal timeline | 100% |
| Publication of question-and-answer documents for Community interest referral procedures (Articles 31, 36 and 107(2)) at the time of the CHMP opinion | 100% |
| Publication of the CHMP opinion and assessment report for Article 5(3) procedures at the time of the CHMP opinion | 100% |

## 2.8 Medicines for paediatric use

This covers EMEA activities relating to the assessment of, agreement of, and verification of compliance with, paediatric investigation plans (PIPs) and waivers by the Paediatric Committee of the EMEA in line with Regulation (EC) No 1901/2006 as amended, and other activities defined by the Regulation. The activities of the Paediatric Committee are strongly supported by the European network of medicines agencies. An agreed paediatric investigation plan may lead to information on the paediatric use of a medicine being included in a centralised or a national marketing authorisation for a new medicinal product and in a paediatric-use marketing authorisation for an off-patent product. Other activities also include the establishment of the European network of paediatric research, the provision of information on clinical trials performed in children and the establishment of an inventory of needs in the paediatric population.

*Trends and new issues*

- The number of PIP and waiver applications, which may cover several clinical indications, is expected to remain high. While in 2008 the number of requests for modifications of an agreed PIP was limited, with the increasing number of EMEA decisions on PIPs, an increase in modifications is expected in 2009.
- As PIP and waiver decisions were issued since the end of 2007, the number of requests for compliance-checks at the time of validation of new applications for a marketing authorisation, or of applications for a new indication, new pharmaceutical form or new route of administration, is expected to increase as well.
- The existing high level of support provided by the network of medicines agencies needs to be maintained.
- The Agency will have to prepare and make public the inventory of therapeutic needs. The inventory will be based on the results of the survey of existing use of medicines in children to be carried out by all Member States.




*2007 figures are for the period July to December.

*Objectives and main initiatives*

- Continue core activities relating to paediatric medicines (assessment of paediatric investigation plans and applications for waivers).
- Continue to streamline procedures for assessment of paediatric investigation plans, waivers and scientific advice in the light of experience gained since implementation of the Paediatric Regulation (Road Map initiative).
- Fully implement and streamline the procedure for validation of new marketing authorisations or applicable post-authorisation applications and, if appropriate, compliance-checks.
- Prepare the inventory of paediatric therapeutic needs.
- Establish the Paediatric Research Network, in line with the agreed strategy, by identifying existing networks, and initiate activities by defining recognition criteria.
- Develop risk-management and pharmacovigilance activities in the context of the Paediatric Regulation:
  - develop expert fora in order to investigate new sources and methods for the intensive monitoring of paediatric use of medicines;
  - coordinate appropriate expertise and networks in pharmacovigilance in order to support the field of paediatrics (including support to the Paediatric Committee).
- Monitor the number of paediatric indications in new marketing authorisations, the information in the summaries of product characteristics and patient leaflets, and extensions of indication granted.
- Discuss further possible collaboration between the EMEA/DG Research and National Institutes of Health/US FDA on paediatric trials in the context of the priority list of research into off-patent products.
- Increase liaison with paediatric learned societies on therapeutic needs when discussing proposed PIP applications.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Number of paediatric investigation plans or waiver opinions and decisions within legal timelines | 100% of opinions/decisions |
| Number of paediatric clinical trials entered in EudraCT database | 100% of paediatric clinical trials conducted |

## 2.9 Herbal medicinal products

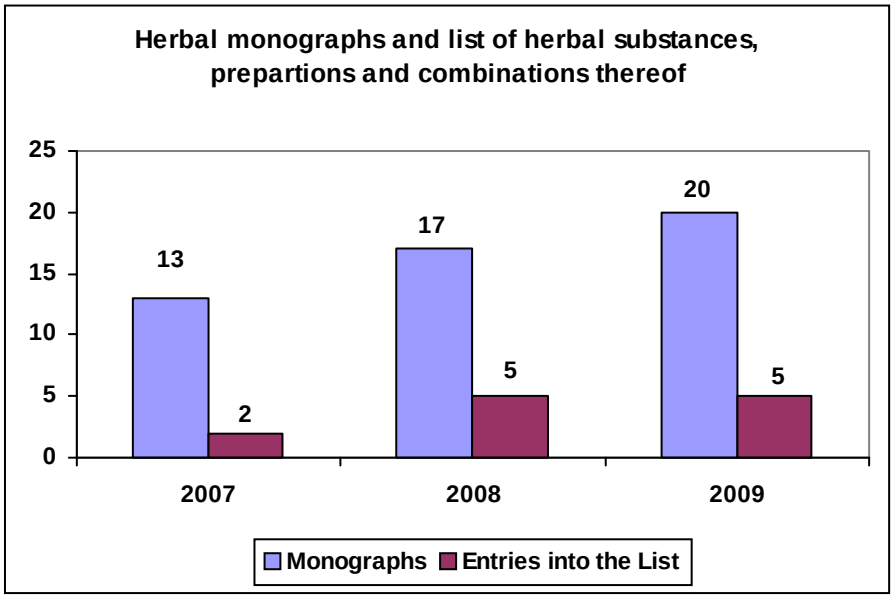
The Agency's activities in the area of herbal medicines include the provision by the Committee on Herbal Medicinal Products (HMPC) of scientific opinions on questions relating to herbal medicines, the establishment of Community herbal monographs for traditional and well-established herbal medicinal products, the establishment of a draft list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, the provision of opinions on herbal substances at the request of the CHMP, and the evaluation for referral and arbitration procedures of traditional herbal medicinal products.

*Trends and new issues*

- A possible extension of the scope of Directive 2004/24/EC, i.e. the simplified registration procedure, could be opened to other traditional products with a long-standing tradition of use in the EU, including certain products of animal origin.

*Objectives and main initiatives*

- Continue core activities relating to herbal medicines.
- Support the activities of the HMPC, its working party and drafting groups, in particular in view of the possible extension of the scope of the simplified registration procedure:
  - respond to a possible extension of the scope of the traditional-use simplified registration procedure in the EU in collaboration with the European Commission;
  - facilitate the cooperation of the HMPC with other EU bodies, in particular EFSA, in accordance with agreed terms of cooperation;
  - review and improve the process for producing Community herbal monographs and Community list entries.




*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Number of Community herbal monographs (finalised) | 20 herbal monographs |
| Number of Community list entries (finalised) | 5 Community list entries |

## 2.10 Advanced therapies and other emerging therapies and new technologies

This area of activity relates to advanced-therapy medicinal products (ATMPs: gene therapy, somatic cell therapy or human tissue engineered products) that fall within the scope of Regulation (EC) No 1394/2007. The main task of the Committee for Advanced Therapies (CAT), established by the Regulation, is to provide a draft opinion to the CHMP on the evaluation of each marketing-authorisation application submitted for an advanced-therapy medicinal product, to provide specific expertise, to advise the EMEA, CHMP and European Commission scientifically on any data related to advanced-therapy medicinal products, and to evaluate applications for certification of quality and non-clinical data. Other emerging therapies and new technologies that are outside the scope of the Regulation are also covered in this strategic area.

*Trends and new issues*

- Products within the scope of the Advanced-Therapies Regulation will have to be authorised through the centralised procedure; products already on the market in European Member States will have to be re-registered through the centralised procedure by 2011, for gene and cell therapies, and by 2012 for tissues.
- As the Regulation becomes fully operational, there will be more work in relation to the classification of these products. A new responsibility for the EMEA will be the certification of quality and non-clinical aspects. Although certification is only available to SMEs, it is anticipated that a substantial number of requests could be received in 2009. Scientific-advice requests in respect of new products and re-registration of advanced-therapy products will increase.
- The EMEA will run the secretariat for the Committee for Advanced Therapies, as well as new procedures, with a high level of interaction with the CHMP.
- Nanotechnology is a very rapidly developing field; regulatory standards for nanomedicines will need adjustment and additional guidance will be required.
- The drift versus more targeted therapies and the need for anticipating drug response – especially on the safety side – will require a more intense interaction between the authorities in charge of diagnostics and medicines during the clinical development of medicinal products.
- The implementation of the programme for the Innovative Medicines Initiative, and the outcome of platform studies under the 6th and 7th Framework Programmes, will impact on the workload of the Agency and national competent authorities in relation to regulatory appraisal. Increased consultation of regulatory authorities at the global level has been observed in relation to new biomarkers of 'omics' nature, and to other methods for promoting the development and approval of new medicinal products.

*Objectives and main initiatives*

- Operate new procedures for advanced-therapy medicinal products following entry into force of the Regulation:
  - process first marketing-authorisation applications, applications for certification of quality and non-clinical data, and requests for scientific advice; contribution to paediatric investigation plans and scientific recommendations on advanced-therapy classification.
- Support the Committee for Advanced Therapies in its first year of activities:
  - provide training to Committee members and experts on new procedures; ensure effective interaction between the Committee and other scientific committees, particularly the CHMP and its working parties.
- Extend the expertise on new emerging therapies and technologies (Think-tank Report initiative):
  - establish a group of experts on nanotechnologies in life sciences (Think-tank Report initiative);

- organise dedicated sessions to discuss, with stakeholders, translational medicines development and new methods, such as modelling and simulation, in particular for medicinal products falling within the mandatory scope of the centralised procedure;
- promote a public workshop in the field of new therapeutic approaches combining the use of medicinal products and devices (e.g. genomic testing and targeted therapies);
- reinforce the coordination between pharmaceuticals and devices authorities for the evaluation of targeted and combined medicinal products.

- Develop risk-management and pharmacovigilance activities in the context of the Advanced-Therapies Regulation.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of applications handled by the Committee for Advanced Therapies within the procedural timelines (allowing adoption of the opinion by the CHMP within the legal timeline of 210 days) | 100% of applications |
| Scientific recommendations on advanced-therapy classification provided within the legal timeline | 100% of requests |
| Certification of quality and non-clinical data issued within the procedural timelines | 100% of requests |
| Innovation Task Force briefing meetings organised within 60 days of receipt of a request | 80% of meetings |
| Percentage of regulatory-advice requests and ITF regulatory advice on new, emerging and borderline medicinal products (excluding ATMPs) given within 60 days | 80% of requests |

## 2.11 Working with patients and healthcare professionals

The Agency has implemented processes and procedures aimed at the provision of targeted, understandable and accessible information for patients and healthcare professionals. In addition to the transparency measures put in place as a consequence of the 2004 revision of the legislation (e.g. summaries of opinions, European public assessment reports, information on arbitrations and referrals, information on withdrawals of applications by applicants prior to opinion and on negative decisions, and summaries of EPARs written in a manner more understandable to the public), the Agency will extend the scope of publication of information to include paediatrics and advanced therapies.

The Agency coordinates the review of the quality of all product-related information submitted by sponsors and marketing-authorisation holders. This includes revision, by the Member States QRD experts, of the quality of translations of summaries of product characteristics, patient leaflets or package inserts and labelling.

*Trends and new issues*

- Implementation of the EMEA Road Map in the field of provision of information, according to the results of the consultation with the Agency's partners and stakeholders. The implementation will take into account any follow-up stemming from the Pharmaceutical Forum activities in relation to information-provision, as well as follow-up in relation to the European Commission report on the current practice concerning provision of information. Since the European Commission report may have major consequences on the Agency's operations, the impact of the legal proposal on the EMEA will be carefully assessed.
- The development of an EU network for medical information in the context of the EU regulatory system to further implement Community legislation on the provision of information will be an important priority. The operation of the EudraPharm database, especially as regards the population

of the database with initial information and the subsequent updating of such information, will be particularly important.

- The implementation of the new legislation on advanced therapies will increase the workload in this complex area, where the provision of understandable information to the public will be a challenge and will require specific competences.
- Implementation of the initiatives stemming from the recommendations of the EMEA/CHMP Working Group with Healthcare-Professionals' Organisations developed in 2008 will start in 2009.

### *Objectives and main initiatives*

- Continue core activities relating to the provision of information and the quality-review of product information.
- Progress the implementation of the EMEA Road Map in the field of provision of information to EMEA stakeholders:
  - continue revising and improving product-related information published on the Agency's website, to make it an efficient and user-friendly source of authoritative information;
  - develop the framework for an EU network in the field of medical information.
- Further integrate the Agency's stakeholders (healthcare professionals, patients and consumers) in product-related activities:
  - continue the discussion on the recommendations from the EMEA/CHMP Working Group with Patients and Consumers' Organisations in relation to actions requiring an EU-wide approach, with the Member States and the European Commission;
  - analyse and monitor the degree of satisfaction of patients and consumers (based on performance indicators put in place in 2006), and of healthcare professionals;
  - begin to implement the recommendations of the EMEA/CHMP Working Group with Healthcare Professionals' Organisations;
  - reflect on how to further increase patients' involvement in EMEA activities, and consider the need to revise the framework on interaction.
- Implement and subsequently monitor the implementation of the information-provision requirements described in the new legislation on advanced therapies.
- Further improve the 2005 EMEA framework on the handling of translations of product-related information.
- Review the new policy on mock-ups and specimens, based on the analysis carried out in 2008.
- Contribute to increasing the quality and consistency of 'user consultation', by means of issuing relevant guidance in cooperation with the CMD(h).

### *Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of summaries of opinion published at the time of the CHMP press release | 90% of summaries of opinion |
| Percentage of initial EPARs published within 2 weeks of the Commission decision | 80% of marketing authorisations granted |
| Percentage of EPAR summaries in a language understandable to the public, published together with the EPAR | 90% of EPARs |
| Percentage of assessment reports published within 2 months following withdrawal of a marketing-authorisation application | 70% of assessment reports |
| Percentage of refusal assessment reports published within 2 weeks of | 70% of assessment reports |

| | |
|---|---|
| the Commission decision | |

## 2.12 Scientific committees, working parties and scientific advisory groups

*Trends*

- The EMEA committees are facing a higher number of procedures and increased complexity of applications, resulting from the extended legislation (paediatrics, advanced therapies, variations), and more complex interaction between the various committees.
- In accordance with the EMEA/CHMP Think-Tank recommendations, more flexible and easy-to-update documents will be generated in the form of reflection papers or question-and-answer documents, to complement or anticipate guidelines.
- A consistent approach to the generation of guidelines by the Agency will be further implemented.

*Objectives and main initiatives*

- Seek to better involve experts from the EU network and learned societies in scientific-committee and working-party activities (Think-Tank Report initiative):
  - finalise the policy on the involvement of experts, networks of excellence and learned societies;
  - extend the use of computer-assisted methods to involve experts and disseminate training (Think-Tank Report initiative).
- Organise consultation of stakeholders to define priority areas for guidelines.
- Review the transparency of the operation of EMEA scientific fora, and strengthen where necessary.
- Support and contribute to the CHMP work programme developed on the basis of the Think-tank Report.

Scientific-committee meeting dates can be found on the EMEA website at:
http://www.emea.europa.eu/meetings/committee.htm

## 2.13 Coordination group

The Agency provides secretarial support to the Coordination group for mutual recognition and decentralised procedures (human products) - (CMD)(h) - and its sub-groups/working groups, in accordance with the approved rules of procedure.

*Trends and new issues*

- There is an expectation that, over time, the decentralised procedure (DCP) will replace the mutual-recognition procedure (MRP), and in 2009, it is estimated that there will be more DCP applications than MRP applications. Consolidation of CMD(h) activities will continue, in particular in relation to referrals to the CMD(h) and to the list of products for SPC harmonisation, laid down on a yearly basis by the CMD(h).

*Main initiatives*

- Continue activities undertaken in previous years.
- Prepare the 2009 list of medicinal products for which a harmonised summary of product characteristics should be drawn up, and assess the impact of the implementation of the 2008 list.

- Support the CMD(h) in the activities arising from the implementation of the Paediatric Regulation (e.g. worksharing for the assessment of paediatric studies submitted in accordance with Articles 45 and 46 of Regulation (EC) No 1901/2006), the Advanced-Therapies Regulation (for products already available on national markets) and, depending on its entry into force, the revised variations legislation.

Coordination-group meeting dates can be found on the EMEA website at:
http://www.emea.europa.eu/meetings/committee.htm

## 2.14 Regulatory and organisational-support activities

The Agency provides regulatory and procedural advice to the pharmaceutical industry during the lifecycle of medicinal products, from scientific advice and pre-submission meetings with applicants through to post-authorisation and annual meetings with marketing-authorisation holders.

The Agency also works to continuously address regulatory and procedural issues affecting the EMEA committees, standing and temporary working parties, and associated groups. The Agency also provides support to applicants and marketing-authorisation holders with regard to the submission of applications and to related financial transactions.

*Objectives and main initiatives*

- Continue core activities relating to the provision of regulatory and procedural advice.
- Update existing guidance documents and develop new ones with regard to advanced-therapy medicines and to the updated Variations Regulation.
- Continue updating guidance documents focusing on the key steps of the centralised procedure.
- Implement agreed actions to reinforce benefit-risk assessment (Road Map initiative).
- Review external guidance documents to address eCTD and ePIM after experience gained in 2008.

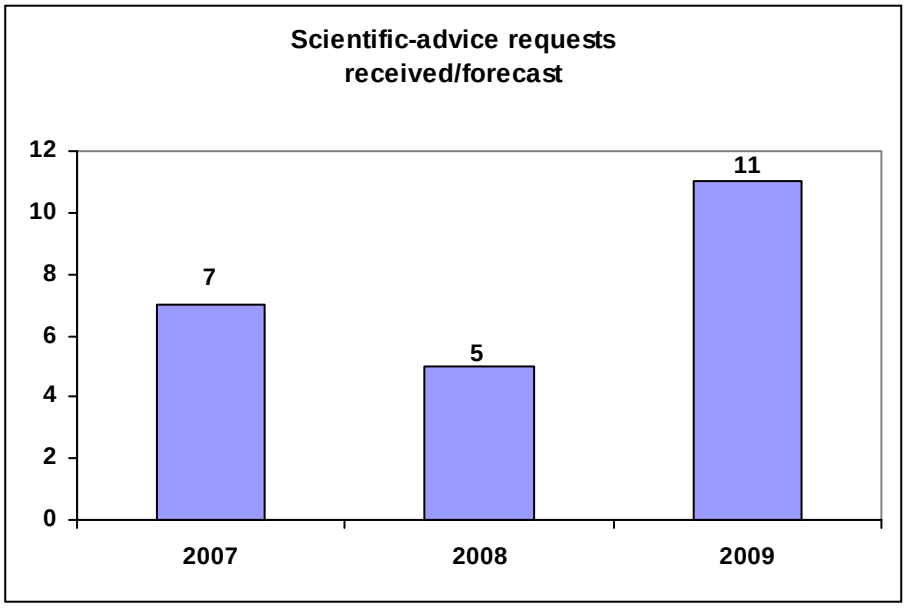
# 3. VETERINARY MEDICINES

## *3.1 Scientific advice*

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

*Trends and new issues*

- It is hoped that the improvements to the scientific-advice procedure will be recognised by potential applicants, and that the number of submissions made will increase gradually from the disappointingly low level in 2008 to 11 applications in 2009.
- A number of the applications are expected to be from SMEs, in view of the incentives put in place by the SME Regulation, and due to increased awareness resulting from the existence of the SME User Guide. Two such SME applications are forecast.
- There are expected to be applications for assessment of dossier requirements in relation to products for minor uses/minor species (MUMS)/limited markets, now that the guidelines on data requirements for MUMS are finalised.
- It is hoped that there will be a sustained increase for all types of scientific advice related to products for limited markets, in view of the measures to be implemented by the Agency to provide assistance to applicants in line with Article 79 of Regulation (EC) No 726/2004, including expanding the range of product types for which assistance is available.




*Objectives and main initiatives*

- Continue core activities relating to the provision of scientific advice and support to the Scientific Advice Working Party.

- Promote to potential applicants the Implementation Plan of the European Commission/FDA confidentiality arrangements with respect to providing parallel scientific advice with the FDA/USDA (Road Map initiative).
- Continue to explore, with potential applicants and with the CVMP, ways in which to enhance the attractiveness and effectiveness of the scientific-advice procedure.

*Performance indicators*

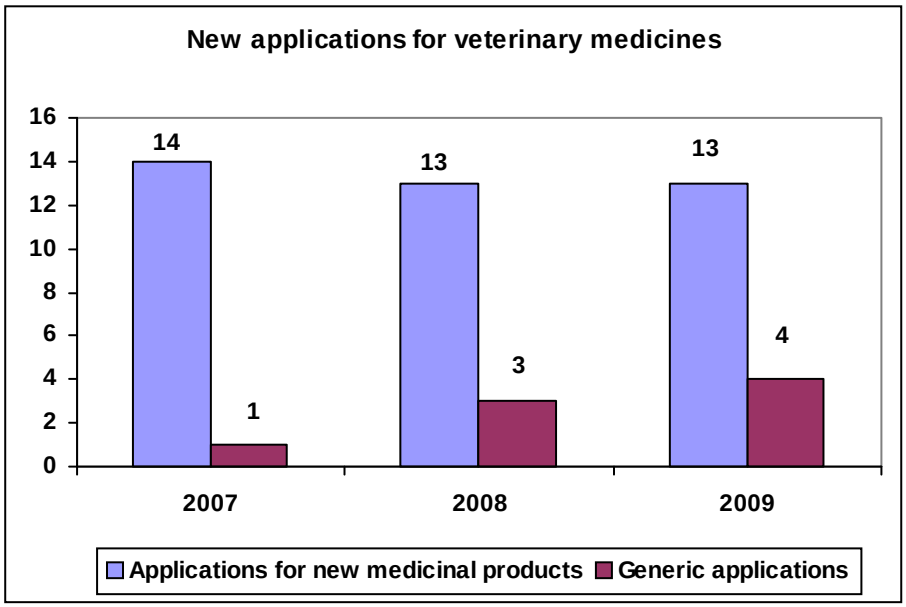
| Performance indicator | Target |
|---|---|
| Scientific-advice requests evaluated within the procedural timelines | 100% of applications |

## 3.2 Initial evaluation

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

*Trends and new issues*

- The Agency predicts a continuation of the long-term trend for a gradual increase in the number of applications for marketing authorisations when averaged out over several years. A total of 17 applications are currently forecast for 2009. In addition, this should be the first year of operation by the Agency of enhanced measures to provide support to companies submitting applications for limited markets and/or for regional diseases, which are expected to increase the number of applications for such products. The level of generics remains difficult to predict, but is expected to increase in line with the number of innovative reference products reaching the end of the 10-year period of data exclusivity, but also taking account of the market success of the pioneer product.
- The trend towards more vaccines for food-producing animals, particularly for emerging diseases, and 'lifestyle' pharmaceutical products for companion animals is expected to continue.



*Objectives and main initiatives*

- Continue core activities (evaluating applications for marketing authorisation, providing regulatory and procedural advice, preparing guidance).
- Strengthen the quality-assurance system in respect of CVMP procedures, through the following specific actions:
  - review the pilot phase of the project to implement peer review relating to the quality and consistency of scientific assessments, following 6 months of operation (Road Map initiative);
  - review the experience gained from the extended pilot phase of the revised procedure to streamline preparation of CVMP assessment reports and EPARs, following implementation for selected initial applications (Road Map initiative).
- Continue the survey of procedures with IFAH-Europe, to further assist in reacting to the IFAH Benchmarking survey conducted in 2006, using the updated questionnaire targeted at companies rather than individual products.
- Engage with the EU network in the review of the regulatory framework, with a view to developing proposals, for consideration by the European Commission, for improving the efficiency and effectiveness of authorisation procedures for veterinary medicinal products within the EU.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Products evaluated within the regulatory timeline of 210 days | 100% of applications |

## *3.3 Establishment of maximum residue limits*

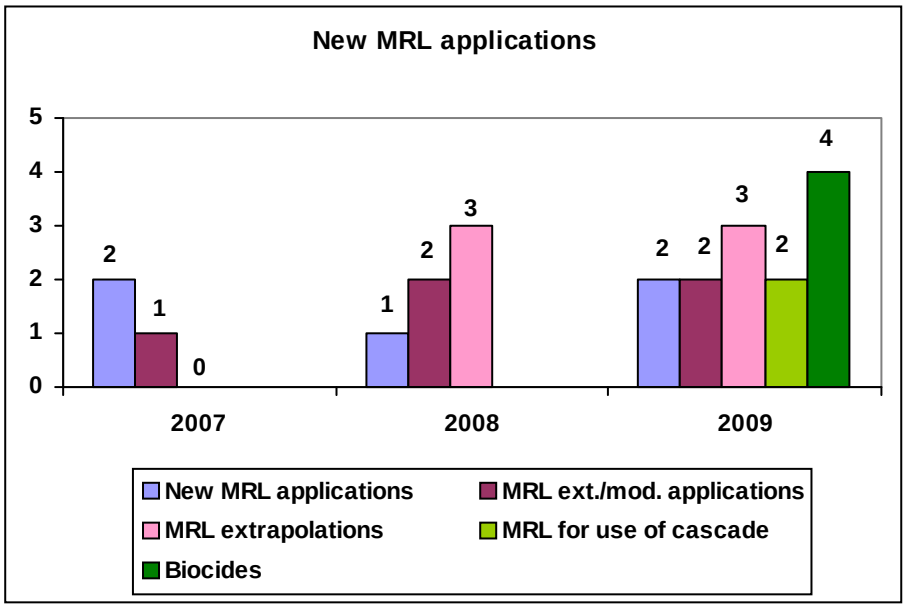
The use of veterinary medicinal products in food-producing animals may result in the presence of residues in foodstuffs obtained from treated animals. Before a veterinary medicinal product can be authorised, an evaluation of the safety of residues must be carried out. The Agency establishes maximum residue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

*Trends and new issues*

- The additional requirements for demonstrating safety to the consumer are expected to continue to act as a driver in the animal-health sector for reducing the number of new molecules developed for food-producing species and for maintaining the predominance of applications for products for the small-animal and biological sectors of the market. The number of applications for establishing MRLs in preparation for submission of marketing-authorisation applications for new veterinary medicines for food-producing animals is therefore expected to remain at a low level.
- Whilst the offer of the EMEA to extend MRLs to other species without a fee, by way of extrapolation if the scientific criteria described in CVMP guidance are met, has not been taken up to any great degree in recent years, it is expected that more such requests will be made by Member States, following the approval of the revised MRL legislation providing specific emphasis on extrapolations.
- The draft new MRL regulation foresees that Member States or the European Commission will be able to submit applications for the establishment of MRLs for substances that are intended for use under Article 11 of Directive 2001/82/EC (the 'cascade') and for which no MRLs have been established yet. This could concern molecules that have not yet been evaluated for safety of residues, as well as substances for which MRLs have been set in other species or tissues. As a

forecast, 2 applications for MRLs for such use of products under the cascade (new MRL or extension) are forecast.

- A considerable number of applications for the establishment of MRLs are expected in the future from Member States or the European Commission under Article 9 of the revised MRL regulation, in particular for substances included in biocidal products that are used in animal husbandry, for which MRLs should be established in accordance with Directive 98/8/EC, which will be stretched over several years. For the first year, 4 such applications are forecast.
- Applications for MRLs for products classified by the CVMP as indicated for limited markets may be forthcoming as a response to the assistance provided by the Agency in accordance with Article 79 of Regulation (EC) No 726/2004.




*Objectives and main initiatives*

- Continue core activities (high-quality assessment of MRL applications; extrapolation of MRLs to minor species; related activities).
- Further strengthen the review process by the CVMP, including MRL assessments.
- Implement changes introduced in the new MRL legislation, including revision of CVMP guidelines and procedures.

*Performance indicators*

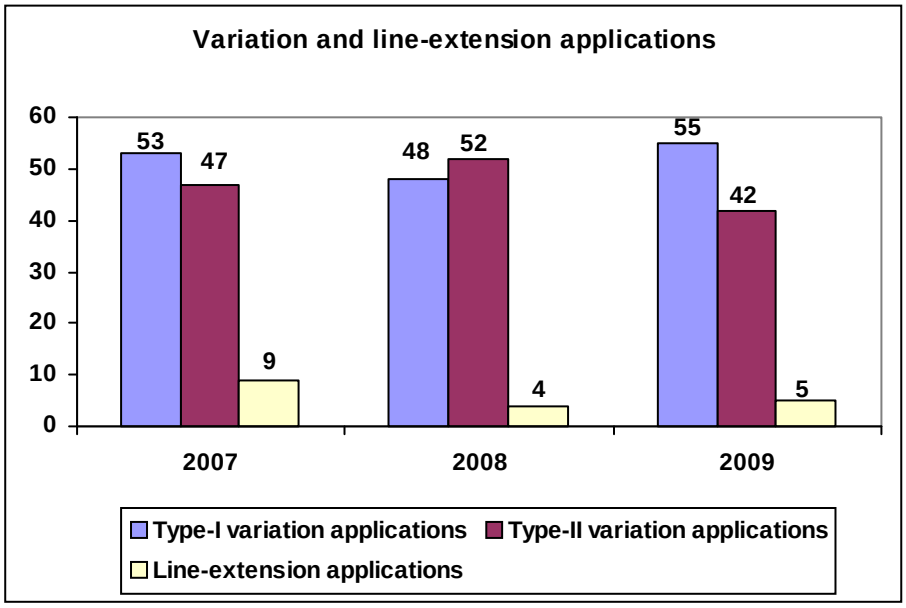
| **Performance indicator** | **Target** |
|---|---|
| Percentage of applications evaluated within the 120-day timeline | 100% of applications |

## 3.4 Post-authorisation activities

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

*Trends and new issues*

- The amount of work on post-authorisation activities, such as variations and line extensions, will increase in accordance with the total number of marketing authorisations and the increased number of products that will be on the market.




*Objectives and main initiatives*

- Continue core activities relating to the post-authorisation area.
- Continue to strengthen the quality and consistency of assessment of post-authorisation applications, particularly those for extensions.
- Implement the changes introduced in the review of the Variations Regulations:
  - carry out appropriate revision of SOPs and procedures;
  - provide input into procedural and classification guidance.

*Performance indicators*

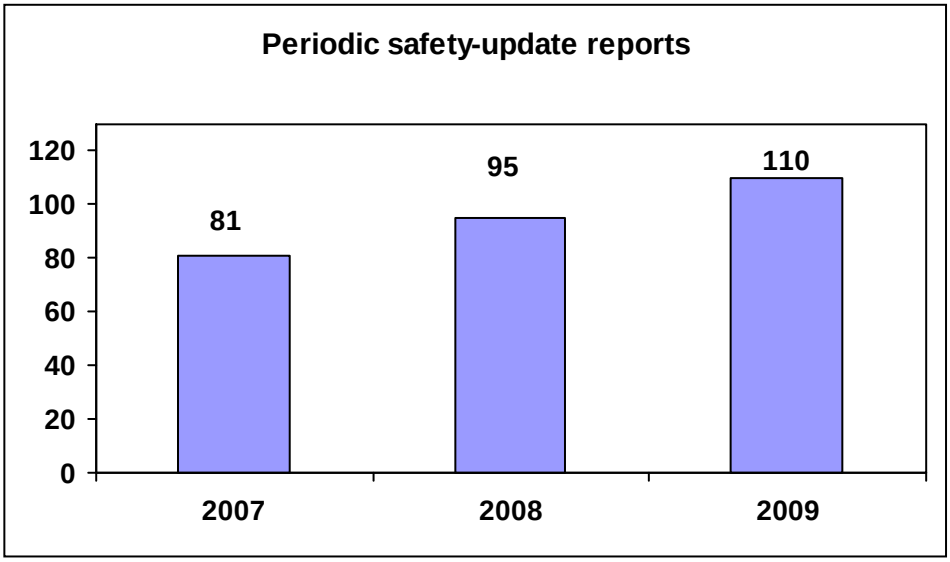
| Performance indicator | Target |
|---|---|
| Percentage of applications for type-I and type-II variations and line extensions evaluated within the regulatory timelines | 100% of applications |

## 3.5 Pharmacovigilance and maintenance activities

This activity relates to pharmacovigilance information, including suspected adverse reaction (SAR) reports and periodic safety-update reports (PSURs). Pharmacovigilance remains a high priority for the Agency in 2009, to ensure that post-authorisation monitoring and effective risk-management are continuously applied to veterinary medicines throughout the EU.

*Trends and new issues*

- The number of serious adverse reaction and human reaction reports has increased continuously over recent years. A further increase of 40% is expected during 2009, with the number of spontaneous reports received expected to be approximately 3,000, with approximately 110 PSURs being submitted.
- The full implementation of EudraVigilance Veterinary in 2008 will allow the Agency, the Member States and the veterinary pharmaceutical industry to improve and streamline the electronic exchange of pharmacovigilance information, and therefore to increase ready access to essential post-authorisation information for safeguarding public and animal health.
- Following the release of the EudraVigilance Veterinary Data Warehouse in 2008, the coordinating role of the Agency in processing and analysing pharmacovigilance information will be further rationalised, with the focus on optimising tools for signal detection, to establish the Agency's surveillance role within the EU (Road Map initiative), initially with emphasis on centrally authorised products.




*Objectives and main initiatives*

- Continue core activities relating to pharmacovigilance and maintenance.
- Collaborate fully with the Member States to optimise efficiency and harmonisation in the European medicines network for veterinary pharmacovigilance of all medicinal products authorised in the EU:
  - contribute to the European Surveillance Strategy (ESS);
  - ensure the effective functioning of the dual mandate of the CVMP Pharmacovigilance Working Party;

- provide training in relevant areas of pharmacovigilance, or contribute to training provided by others.

- Improve processing of pharmacovigilance information:
  - continue to improve signal-detection tools and procedures by making full use of the EudraVigilance Veterinary Data Warehouse, in accordance with the EudraVigilance Veterinary action plan;
  - develop the duplicate-detection engine to prohibit and detect the creation of duplicate reports in EudraVigilance Veterinary at data entry and when signals are generated.
- Support targeted pharmacovigilance:
  - finalise and implement the concept of risk-management plans for veterinary medicines (Road Map initiative).
- Implement the revised Rules Governing Medicinal Products in the European Union – Pharmacovigilance for Veterinary Medicinal Products, and provide training to Member States and industry (Volume 9B) (Road Map initiative).
- Further strengthen active communication to the professional community, as well as agree the approach for access to pharmacovigilance data for the general public (Road Map initiative).
- Continue initiatives with interested parties, in particular the Federation of Veterinarians of Europe, to train and advise practising veterinarians in the area of pharmacovigilance (Road Map initiative).
- Further strengthen active communication with industry.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of PSURs and SARs evaluated within the established timelines | 80% of PSURs; 100% of SARs |

## *3.6 Arbitration and Community referrals*

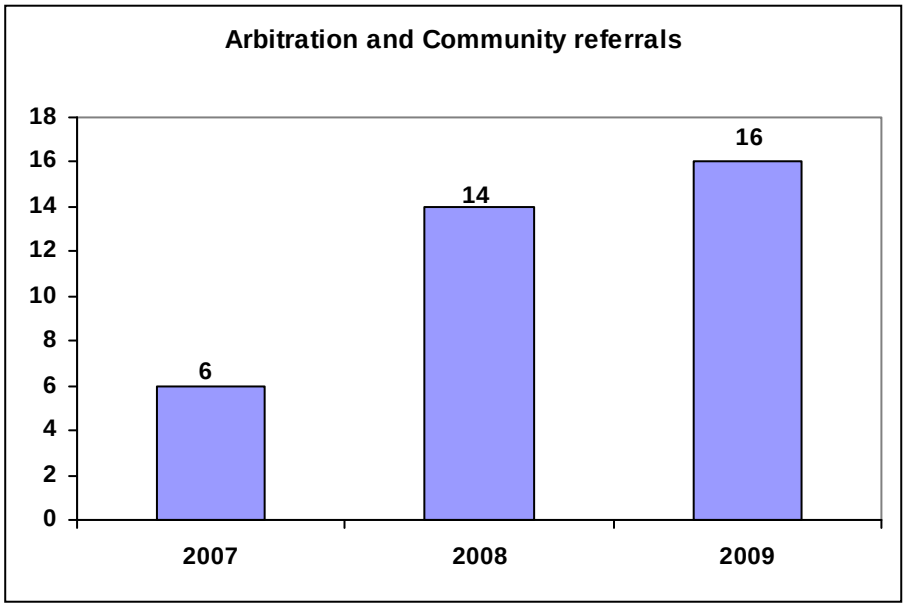
Arbitration procedures are initiated because of disagreement between Member States within the framework of the mutual-recognition or decentralised procedures (Article 33 of Directive 2001/82/EC, as amended).

Referrals are initiated either to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by Member States (Article 34 of Directive 2001/82/EC) or in cases where there is a Community interest or other safety-related issue (Articles 35 and 40 of Directive 2001/82/EC).

*Trends and new issues*

- The majority of referrals are expected to continue to relate to mutual-recognition or decentralised procedures (submitted under Article 33 and Article 34).
- A significant proportion of referrals relate to authorisation of generic products. Authorisation of generics is more complex for veterinary medicines than for human medicines, due to a number of additional factors that need to be considered, including use of the same product in different species, and consumer protection.
- It remains difficult to predict the number of referrals. During 2008 there was a considerable increase of referrals related to mutual-recognition or decentralised procedures for generics, with more than a doubling in the number of referrals. Since many of the divergences of view between Member States on authorisation of generics were resolved during 2008, it is expected that the number of referrals will remain at a more constant level in the future.

- It is expected that 1 or 2 referral procedures will be initiated under Article 34 or Article 35, due to discrepancies of withdrawal periods for veterinary medicinal products for food-producing animals, with the aim of harmonising withdrawal periods and ensuring consumer safety. These referrals usually concern large numbers of products and require considerable resources to process.
- Depending on the outcome of ongoing actions within the European regulatory network, one or more referrals to the CVMP may be initiated under Article 35, in relation to minimising the risk of the development of resistance arising from the use of antimicrobials in animals. If such referrals arise, they are likely to be extensive and relate to classes of antimicrobials encompassing large numbers of authorisations.




*Objectives and main initiatives*

- Continue core activities relating to the provision of high-quality opinions arising from arbitration and referral procedures.
- Continue to support efforts by the CVMP, CMD(v) and HMA to tackle issues that have a potential for disagreement in approach, and develop common understanding and harmonised guidance, as appropriate, with the aim of avoiding inappropriate referrals.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of arbitration and referral procedures managed within the legal timeline | 100% of procedures |

## 3.7 Scientific committee

The Committee for Medical Products for Veterinary Use (CVMP) is responsible for preparing the Agency's opinions on all questions concerning veterinary medicinal products, in accordance with Regulation (EC) No 726/2004.

*Objectives and main initiatives*

- The CVMP will continue its core task of providing opinions on veterinary medicinal products.
- The Committee will continue to contribute to various topics in the areas of public health, animal health and the availability of medicines. For more information on specific topics, please refer to Section 1.2 (European cooperation) and Section 1.5 (Support for innovation and availability of medicines). The CVMP working parties will continue to provide scientific support to the CVMP, in particular to develop and update guidelines, but also to provide advice on specific requests in relation to applications and technical or scientific enquiries from companies that are under consideration by both the CVMP and the Coordination Group. Following the expiry of the mandate for the temporary Working Party on Environmental Risk Assessment in 2009, a decision on the future role of this Working Party will be taken.
- The CVMP will establish appropriate procedures that result from the new MRL Regulation currently under discussion by the Council and the European Parliament, and implement the necessary changes resulting from this new piece of legislation.
- It is expected that the European Commission will publish a revision of Annex 1 to Directive 2001/82/EEC, to update the technical requirements for authorisation of veterinary medicinal products. This will result in a programme of updating of existing CVMP guidelines, which will start in 2009 and extend into 2010.
- Work will continue on reviewing the approach regarding residues at the injection site, in liaison with the European Commission and Member States, with the aim of providing a constructive contribution to the debate on this issue at international level.
- Liaison with other scientific committees, in particular those within EFSA, will be strengthened, to ensure consistency of scientific opinions for veterinary medicines and feed additives, and to provide appropriate input when EFSA scientific committees prepare opinions related to the use of veterinary medicinal products in the food chain or to animal health.
- The Committee will reflect on the experience gained since the last review of legislation on referral and arbitration procedures, with a view to capturing the lessons learnt, for the benefit of all parties.
- The Committee will adopt and subsequently implement its guideline on benefit-risk assessment, with the objective of introducing a more transparent and systemic methodology to its opinion-making process.

Scientific-committee meeting dates can be found on the EMEA website at:
http://www.emea.europa.eu/meetings/committee.htm

## 3.8 Coordination group

The Agency provides secretarial support to the Coordination group for mutual-recognition and decentralised procedures (veterinary products) - CMD(v) - and its sub-groups/working groups.

*Trend*

- In general, the Agency expects the growth in number of decentralised procedures observed in previous years will slow down in 2009. The number of mutual-recognition procedures will continue to be maintained, and the shift to more generics is expected to persist.

*Objectives*

- Assist the chair of the CMD(v) in identifying issues that affect the efficient working of the European medicines network at the level of the CMD(v), and promote the resolution of these issues through active liaison with the Heads of Medicines Agencies, CVMP, CMD(h) and interested parties.
- Assist the CMD(v) in reviewing its effectiveness in terms of mutual-recognition and decentralised procedures and general operation, and assist the implementation of actions for improvement following the 2008 review outcome. The Agency will focus particularly on regulatory and scientific memory.
- Implement any changes resulting from new or revised legislation that have an impact on the work of the CMD(v), in particular the new Variations Regulation.

Coordination-group meeting dates can be found on the EMEA website at:
http://www.emea.europa.eu/meetings/committee.htm

# 4. INSPECTIONS

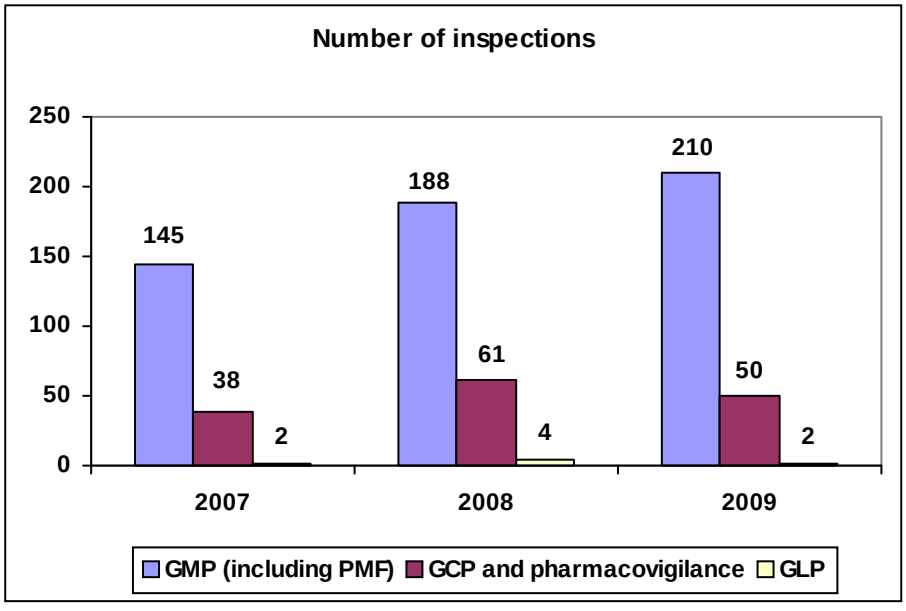
## *4.1 Inspections*

The EMEA coordinates the verification of compliance with the principles of good manufacturing practice (GMP), good clinical practice (GCP) and good laboratory practice (GLP), and with certain aspects of the supervision of authorised medicinal products in use in the European Community. It does this through inspections requested by the CHMP or CVMP in connection with the assessment of marketing-authorisation applications and/or the assessment of matters referred to these committees in accordance with EU legislation. These inspections may be necessary to verify specific aspects of the clinical or laboratory testing or manufacture and control of the product, and/or to ensure compliance with GMP, GCP or GLP and quality-assurance systems.

Similarly, the EMEA coordinates pharmacovigilance inspections requested by the scientific committees, and inspections of blood establishments within the plasma master file (PMF) certification framework. Communication and action by Member States in response to suspected quality defects and counterfeit medicines relating to centrally authorised medicines are also coordinated by the EMEA.

*Trends and new issues*

- GMP-inspection numbers are expected to increase by 10% relative to 2008 levels, which already represented a significant increase over 2007. The impact on GMP inspections as a consequence of activities stemming from the Advanced-Therapies Regulation and changes in variation provisions will need to be assessed in the light of further refinement of the associated provisions.
- GCP and pharmacovigilance inspections are expected to remain at similar levels to 2008, which represented a substantial increase over 2007. This reflects the agreed GCP policy on increasing numbers of routine inspections, increasing pharmacovigilance activity, and greater supervision of the conduct and ethical standards of clinical trials performed outside the EU. The impact on GCP inspections as a consequence of the activities relating to the Advanced-Therapies Regulation will also need to be taken into account.
- There is an increasing demand for international collaboration on worksharing on all types of inspections, as well as an increasing focus on risk-based approaches.
- New legislative proposals on counterfeits and pharmacovigilance are expected to impact approaches to GMP and pharmacovigilance inspections.



*Objectives and main initiatives*

- Continue core activities relating to effective coordination of inspections and management of quality defects.
- Progress pilot projects on joint inspections with the FDA and on collaboration on inspections of active pharmaceutical ingredients in third countries.
- Implement policies and procedures in the area of pharmacovigilance inspections (human and veterinary medicines) (Road Map initiative).
- Develop the Community database on manufacturing authorisations and GMP certificates (EudraGMP) (including the non-compliance module) and the corporate GXP database.
- Review procedures for quality-defect management and handling of rapid-alert information.
- Assess the impact of the Advanced-Therapies Regulation on GMP, GCP and pharmacovigilance activities, and review procedures in the light of experience.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Management of inspections within legislative timelines | 100% of inspections |
| Successful completion of collaborative inspections with the FDA | 1 by the end of 2009 |

## Meetings of GMDP[6], GCP, GLP and Pharmacovigilance Inspectors working groups, and of the Joint CHMP/CVMP Quality Working Party

*Main initiatives*

- Coordination of approaches to investigations and inspections arising from crises with potential impact throughout the Community, and follow-up to initiatives launched in 2008.
- Strengthen the approach to supervision of active substances and supply chains, in collaboration with international partners.
- Progress the development of risk-based approaches to inspection and inspection planning.
- Organise training activities on GCP, pharmacovigilance inspection and quality, with particular focus on advanced therapies, innovative approaches to manufacturing and control, and computerised systems used in clinical trials.
- Continue developing cooperation between inspection and assessment functions in all areas (GMP/quality, GCP/clinical assessment, pharmacovigilance).
- Conduct follow-up in relation to completion of the worksharing initiative on complex variations.
- Contribute to the development of guidelines and procedures to facilitate implementation of the new variations legislation (quality, manufacturing, pharmacovigilance).
- Finalise guidelines and Community procedures on GXP-related aspects of advanced-therapy legislation.
- Support capacity-building initiatives in the clinical-trial area and quality/manufacturing area involving regulators in developing countries.

[6] Good manufacturing and distribution practice.

## 4.2 Sampling and testing

The objectives of the sampling and testing programme, derived from the legal requirements, are to supervise the quality of centrally authorised medicinal products placed on the market, and to check compliance of these with their authorised specifications. 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 through the European Directorate for the Quality of Medicines and HealthCare (EDQM). A selection of centrally authorised products is included in each annual programme.

*Objectives and main initiatives*

- Continue core activities relating to the sampling and testing of centrally authorised products.
- Fully implement a risk-based approach for the 2010 programme.
- Implement provisions to ensure that parallel-distributed products are subject to sampling and testing.
- Review potential implications of advanced-therapy products on functioning of the sampling and testing programmes.
- Contribute to related work on risk-based approaches and coordination of non-centralised sampling and testing within the framework of the HMA's task force.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of planned products (43) actually tested | 95% of planned products |

## 4.3 Implementation of the Clinical-Trials Directives

*Objectives and main initiatives*

- Support the implementation of the Clinical-Trials Directive (2001/20/EC) and the GCP Directive (2005/28/EC) for human medicines, through the continued development of harmonised procedures.
- Implement agreed actions arising from the 2007 conference on clinical trials (Road Map initiative).
- Extend the functionality of the EudraCT database, with a focus on links to national competent authorities and transparency requirements.
- Review the outcome of GCP inspections performed to date, to identify trends and increase awareness of commonly found deficiencies.

# 5. EU TELEMATICS STRATEGY AND CORPORATE IT

## *5.1 EU telematics*

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

The implementation strategy concentrates on a number of projects with high European added value. These projects have been agreed as being EudraNet, EudraVigilance, EudraPharm, electronic submissions, EudraCT and Good Manufacturing Practice (GMP) databases. In addition, the Telematics Steering Committee has endorsed a set of horizontal services that are necessary to support the implementation of the systems mentioned.

The majority of activities in 2009 will be dedicated to the operation and support of the existing systems to agreed service levels. The development programme will be prioritised in accordance with the criteria set out in the EU Telematics Master Plan 2008-2013, as approved by the Management Board on 2 October 2008.

*Objectives and main initiatives*

- Seek to assure interoperability of information between the EU telematics systems and IT systems of national competent authorities. To this end, significant effort will be dedicated to the reference-data model and controlled terminology lists.
- Further improve EudraVigilance, with particular emphasis on the data-analysis system.
- Address re-coding of product references in safety reports, and cleaning of product data contained in the EudraVigilance medicinal-product dictionary, within a new project, EV data management.
- Continue to implement the recommendations of the Clinical Trials Facilitation Group, and the provisions of the Paediatrics Regulation.
- Continue work on the development of an electronic application form for use by NCAs and the EMEA, extended to all types of applications submitted to the EMEA.
- Continue work on the electronic product-information-management system, PIM.

In line with the EU Telematics Master Plan, development of EudraGMP will be temporarily suspended after delivery of version 2.0, and restarted in 2010. Similarly, there will be no further development of EudraPharm in 2009.

| **Performance indicator** | **Target** |
|---|---|
| Percentage of systems downtime | Max. 2% |
| Percentage of user satisfaction | Min. 80% |
| Delivery of projects against plan and budget | Min. 90% |
| Effective transition to production/operation | Min. 95% |
| Availability of services (excluding planned maintenance downtime) | Min. 98% |
| Response time to 80% of EU telematics service-desk requests[7] | Max. 2 hours[8] |
| Response time to 15% of EU telematics service-desk requests | Max. 1 day[8] |

[7] Excluding change requests for information systems.
[8] This target reflects the time required to fix the problem after it has been reported.

## 5.2 Implementation and operation of corporate IT

*Trends and new issues*

- Further development of corporate IT systems to meet the needs of the business, taking into account process-improvement proposals, is a priority for the Agency in 2009.
- The deployment of Unified Communications Systems, involving the integration of telephony, telecommunications, virtual meetings, collaboration tools, computer systems and business logic, is directly relevant to the EMEA environment.
- The requirement to provide and maintain a paperless meeting-room environment that is both effective and secure will remain valid in 2009.
- Complete the development and start the implementation of the communication and transparency strategies, taking into consideration the information needs and expectations of the Agency's stakeholders.

*Objectives and main initiatives*

- Continue core activities in the areas of corporate IT operation, maintenance and development.
- Ensure the provision of reliable and robust IT services to delegates, users of pan-European systems and EMEA staff:
  - progress the development of best-practice support processes, based on the IT Infrastructure Library (ITIL) service management.
- Design and build a new external EMEA website.
- Carry out an analysis of Agency-wide information architecture and information flow.
- Widen the scope of the SIAMED II project, with the objective of establishing an Agency data model for all product-related systems and processes.
- Build a new system to plan, manage, document and evaluate GXP inspections.
- Develop the full IP-telephony system, integrated with unified communications capability. This will include extending virtual-meetings solutions in line with specific meeting requirements.
- Enhance the electronic document and records-management systems.
- Continue development of the Enterprise Resource Planning System (the system replacing the Agency's financial accounting system, SI2) with a view to implementation in production in 2010.
- Improve the support and Service Desk functions, and the archiving and back-up of data, while maintaining a high level of security and confidentiality for all data held on EMEA systems.
- Conduct testing of the EMEA's business-continuity systems with users, on a regular basis, to ensure that they are effective in a disaster scenario.

*Performance indicators*

| **Performance indicator** | **Target** |
|---|---|
| Percentage of systems downtime | Max. 2% |
| Percentage of user satisfaction | Min. 80% |
| Delivery of IT projects against plan and budget | Min. 90% |
| Effective transition to production/operation | Min. 95% |
| Corporate availability of services (excluding planned maintenance downtime) | Min. 98% |
| Response time to 80% of corporate IT service-desk requests[7] | Max. 2 hours[8] |
| Response time to 15% of corporate IT service-desk requests | Max. 1 day[8] |

# ANNEXES

Annex 1 EMEA establishment plan 2007-2009

Annex 2 Revenue and expenditure overview 2007-2009

Annex 3 Committee working-party guidelines and working documents

Annex 4 EMEA contact points

Annex 5 Profiles of EMEA personalities

## *Annex 1 EMEA establishment plan 2007-2009*

| Function group & grade | Posts 2007 | | | | Posts 2008 | | Posts 2009 | |
|---|---|---|---|---|---|---|---|---|
| | Authorised | | Actual as per 31.12.2007 | | Authorised[9] | | Requested | |
| | Permanent posts | Temporary posts | Permanent posts | Temporary posts | Permanent posts | Temporary posts | Permanent posts | Temporary posts |
| AD 16 | - | 1 | - | 0 | - | 1 | - | 1 |
| AD 15 | - | 3 | - | 1 | - | 3 | - | 3 |
| AD 14 | - | 4 | - | 4 | - | 4 | - | 4 |
| AD 13 | - | 4 | - | 3 | - | 5 | - | 6 |
| AD 12 | - | 34 | - | 28 | - | 34 | - | 36 |
| AD 11 | - | 33 | - | 29 | - | 33 | - | 34 |
| AD 10 | - | 34 | - | 14 | - | 33 | - | 34 |
| AD 9 | - | 13 | - | 28 | - | 22 | - | 35 |
| AD 8 | - | 36 | - | 27 | - | 42 | - | 40 |
| AD 7 | - | 43 | - | 10 | - | 43 | - | 38 |
| AD 6 | - | 12 | - | 50 | - | 23 | - | 34 |
| AD 5 | - | 10 | - | 20 | - | 9 | - | 17 |
| *Total grade AD* | *0* | *227* | *0* | *214* | *0* | *252* | *0* | *282* |
| AST 11 | - | 0 | - | 0 | - | - | - | - |
| AST 10 | - | 6 | - | 2 | - | 6 | - | 6 |
| AST 9 | - | 2 | - | 2 | - | 2 | - | 5 |
| AST 8 | - | 10 | - | 3 | - | 11 | - | 12 |
| AST 7 | - | 14 | - | 12 | - | 14 | - | 15 |
| AST 6 | - | 30 | - | 16.5 | - | 33 | - | 38 |
| AST 5 | - | 32 | - | 14 | - | 34 | - | 39 |
| AST 4 | - | 54 | - | 18 | - | 56 | - | 46 |
| AST 3 | - | 24 | - | 53 | - | 26 | - | 30 |
| AST 2 | - | 10 | - | 26 | - | 21 | - | 25 |
| AST 1 | - | 32 | - | 60 | - | 26 | - | 32 |
| *Total grade AST* | *0* | *214* | *0* | *206.5* | *0* | *229* | *0* | *248* |
| **Grand Total** | **0** | **441** | **0** | **420.5** | **0** | **481** | **0** | **530** |

| | Actual as per 31.12.2007 | Planned FTE[10] 2008 | Planned FTE 2009 |
|---|---|---|---|
| **Contract agents** | 55 | 75 | 85 |
| **National experts** | 9 | 17 | 28 |

[9] Including Amending Budget 01-2008 (EMEA/MB/610696/2007).
[10] FTE = full-time equivalent.

## *Annex 2 Revenue and expenditure overview 2007-2009*

| | | 2007[11] | | 2008[12] | | 2009[13] | |
|---|---|---|---|---|---|---|---|
| | | € '000 | % | € '000 | % | € '000 | % |
| | **Revenue** | | | | | | |
| 100 | Fees | 111,753 | *67.61* | 126,318 | *69.07* | 138,966 | *73.65* |
| 200 | General EU contribution | 39,750 | *24.05* | 39,997 | *21.87* | 36,390 | *19.29* |
| 201 | Special EU contribution for orphan medicinal products | 4,892 | *2.96* | 6,000 | *3.28* | 5,500 | *2.91* |
| 300 | Contribution from EEA | 789 | *0.48* | 956 | *0.52* | 888 | *0.47* |
| 600 | Community programmes | 583 | *0.35* | 600 | *0.33* | 300 | *0.16* |
| 500+ 900 | Other | 7,522 | *4.55* | 9,024 | *4.93* | 6,645 | *3.52* |
| | | | | | | | |
| **TOTAL REVENUE** | | **165,289** | ***100.00*** | **182,895** | ***100.00*** | **188,689** | ***100.00*** |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Expenditure** | | | | | | | |
| **Staff** | | | | | | | |
| 11 | Staff in active employment | 46,252 | *29.07* | 53,911 | *29.48* | 56,661 | *30.03* |
| 13 | Mission expenses | 583 | *0.37* | 819 | *0.45* | 789 | *0.42* |
| 14 | Socio-medical infrastructure | 345 | *0.22* | 603 | *0.33* | 550 | *0.29* |
| 15 | Exchange of civil servants and experts | 1,182 | *0.74* | 2,112 | *1.15* | 4,350 | *2.31* |
| 16 | Social welfare | 47 | *0.03* | 105 | *0.06* | 105 | *0.06* |
| 17 | Entertainment and representation expenses | 36 | *0.02* | 38 | *0.02* | 38 | *0.02* |
| 18 | Staff insurances | 1,427 | *0.90* | 1,657 | *0.91* | 1,867 | *0.99* |
| | **Total Title 1** | **49,871** | ***31.34*** | **59,245** | ***32.39*** | **64,360** | ***34.11*** |
| **Building/equipment** | | | | | | | |
| 20 | Investment in immovable property, renting of building and associated costs | 15,562 | *9.78* | 19,468 | *10.64* | 17,081 | *9.05* |
| 21 | Expenditure on data-processing | 25,146 | *15.80* | 26,685 | *14.59* | 22,099 | *11.71* |
| 22 | Movable property and associated costs | 2,539 | *1.60* | 2,132 | *1.17* | 2,854 | *1.51* |
| 23 | Other administrative expenditure | 682 | *0.43* | 896 | *0.49* | 946 | *0.50* |
| 24 | Postage and communications | 767 | *0.48* | 1,048 | *0.57* | 978 | *0.52* |
| 25 | Expenditure on formal and other meetings | 62 | *0.04* | 79 | *0.04* | 90 | *0.05* |
| | **Total Title 2** | **44,758** | ***28.13*** | **50,308** | ***27.51*** | **44,048** | ***23.34*** |
| **Operational expenditure** | | | | | | | |
| 300 | Meetings | 7,144 | *4.49* | 7,746 | *4.24* | 8.939 | *4.74* |
| 301 | Evaluations | 53,490 | *33.61* | 60,406 | *33.03* | 66,419 | *35.20* |
| 302 | Translation | 3,182 | *2.00* | 4,001 | *2.19* | 4.245 | *2.25* |
| 303 | Studies and consultants | 81 | *0.05* | 90 | *0.05* | 80 | *0.04* |
| 304 | Publications | 69 | *0.04* | 499 | *0.27* | 298 | *0.16* |
| 305 | Community programmes | 531 | *0.33* | 600 | *0.33* | 300 | *0.16* |
| | **Total Title 3** | **64,497** | ***40.53*** | **73,342** | ***40.10*** | **80,281** | ***42.55*** |
| | | | | | | | |
| **TOTAL EXPENDITURE** | | **159,126** | ***100.00*** | **182,895** | ***100.00*** | **188,689** | ***100.00*** |

[11] Appropriation/Budget 2007 as per final accounts.
[12] Appropriation/Budget 2008 as of 31 December 2008.
[13] Appropriation/Budget DB 2009 as presented to the Management Board on 11 December 2008.

## *Annex 3 Committee working-party guidelines and working documents*

In addition to the guidelines listed below, the EMEA scientific committees and their working parties actively contribute on behalf of the European Union to the development of guidelines by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

### CHMP Biologics Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CPMP/BWP/2879/02 | CHMP position statement on Creutzfeldt-Jakob Disease and plasma-derived and urine-derived medicinal products | Guideline to be revised |
| EMEA/CPMP/BWP/269/95, rev 3 | Note for guidance on plasma-derived medicinal products | Revision to be finalised |
| CHMP/BWP/452081/07 | Addendum on the replacement of rabbit pyrogen testing by an alternative test for plasma derived medicinal products | To be finalised and incorporated in guideline EMEA/CPMP/BWP/269/95, rev 3 |
| EMEA/CPMP/BWP/3794/03 | Guideline on the scientific data requirements for a plasma master file (PMF) | Finalisation of template for evaluation report |
| EMEA/CHMP/BWP/188268/05 | Guideline on validation of immunoassay for the detection of antibody to human immunodeficiency virus (anti-HIV) in plasma pools | Maintenance of guideline |
| EMEA/CHMP/BWP/188270/05 | Guideline on validation of immunoassay for the detection of Hepatitis B virus surface antigen (HBsAg) in plasma pools | Maintenance of guideline |
| EMEA/CPMP/BPWP/BWP/561/03 | Note for guidance on the warning on transmissible agents in summary of product characteristics (SPC) and package leaflets for plasma-derived medicinal products | Possible revision of guideline |
| Ref. 3AB1A, Dec 1994 | Production and quality control of medicinal products derived by recombinant DNA technology | Maintenance of guideline |
| EMEA/CHMP/BWP/49348/2005 | Guideline on similar biological medicinal products containing biotechnology derived proteins as active substances: quality issues | Maintenance of guideline |
| | Guideline on immunogenicity of biotechnological medicinal products | Development of quality aspects of guideline |
| EMEA/CHMP/ BWP/261157/2008 | Guideline on production and quality control of monoclonal antibodies | Maintenance of guideline |
| EMEA/CPMP/BWP/268/95 | Guideline on virus validation studies: the design, contribution and interpretation of studies validating the inactivation and removal of viruses | Maintenance of guideline |
| EMEA/CHMP/BWP/388681/2005 | Guideline on virus safety evaluation of biotechnological investigational medicinal products | Maintenance of guideline |

| Reference Number | Document Title | Status |
|---|---|---|
| CPMP/BWP/1793/01 | Note for guidance on the use of bovine serum used in the manufacture of human biological medicinal products | Maintenance of guideline |
| | Guideline on biological quality aspects of biological medicinal products to be used in clinical trials | Guideline to be developed |
| EMEA/CHMP/BWP/271475/2006 | Guideline on potency testing of cell based immunotherapy medicinal products for human use | Maintenance of guideline |
| EMEA/CPMP/BWP/3354/99 | Note for guidance on the production and quality control of animal immunoglobulins and immunosera for human use | Maintenance of guideline |
| 3AB7A, Dec 1994 | Note for guidance on the use of transgenic animals in the manufacture of biological medicinal products for human use | Guideline to be reviewed |
| EMEA/CHMP/BWP/48316/2006 | Guideline on the quality of biological active substances produced by stable transgene expression in higher plants | Maintenance of guideline |
| EMEA/CHMP/BWP/304831/2007 | Manufacture and control of allergens including recombinant allergens | Finalisation of guideline following public consultation |
| CPMP/BWP/2517/00 | Points to consider on the reduction, elimination or substitution of thiomersal in vaccines | Maintenance of guideline |
| EMEA/CPMP/BWP/214/96 | Guideline on harmonisation of requirements for influenza vaccines | Maintenance of guideline |
| CPMP/BWP/2289/01 | Points to consider on the development of live attenuated influenza vaccines | Maintenance of guideline |
| EMEA/CPMP/BWP/2758/02 | Note for guidance on pharmaceutical aspects of the product information for human vaccines | Maintenance of guideline |

## CHMP Blood Products Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CPMP/BPWG/1561/99<br>EMEA/CPMP/BPWG/1625/99<br>EMEA/CPMP/BPWG/198/95 rev. 1<br>EMEA/CPMP/BPWG/1619/99 | Note for guidance on the clinical investigation and core SPC of recombinant and plasma derived Factor VIII and IX products | Guidelines to be finalised |
| EMEA/CPMP/BPWG/388/95 rev 1<br>EMEA/CPMP/BPWG/859/95 rev 2 | Note for guidance on the clinical investigation and core SPC of human normal immunoglobulin for intravenous administration (IVIg) | Guidelines under revision |
| | Note for guidance on the clinical investigation and core SPC of alpha-proteinase inhibitor | Release of concept papers |
| | Guideline on the clinical investigation of recombinant Factor VIIa (eptacog) | If needed, release of concept paper |
| | Note for guidance on the clinical investigation and core of human C1 inhibitor | If needed, release of concept paper |

## CHMP Efficacy Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| | Guideline on gastroparesis and gastroesophageal reflux disease (GERD) | For consideration |
| CPMP/EWP/1080/00 | Revision of guideline on clinical Investigation of medicinal products in the treatment of diabetes mellitus | Draft guideline to be released for consultation |
| CHMP/EWP/141426/2008 | Addendum to the note for guidance on evaluation of medicinal products indicated for the treatment of bacterial infections to specifically address the clinical development of new agents to treat disease due to Mycobacterium tuberculosis | For finalisation of addendum |
| CHMP/EWP/30039/2008 | Guideline on the clinical evaluation of direct acting antiviral agents intended for treatment of chronic hepatitis C | For finalisation |
| CPMP/EWP/1343/01 | Points to consider on the clinical evaluation of new agents for invasive fungal infections | For finalisation |
| CPMP/EWP/633/02 Rev. 1 | Guideline on the clinical development of medicinal products for treatment of HIV infection | For finalisation |
| CPMP/EWP/558/95 Rev 1 | Guideline on evaluation of medicinal products indicated for treatment of bacterial infections | Concept paper |
| CPMP/EWP/205/95 Rev. 3 | Annex to the guideline on the evaluation of anticancer medicinal products in man on haematology malignancies | For finalisation |
| | Guideline on lupus and lupus nephritis | For consideration |
| CHMP/EWP/566954/2007 | Concept paper on the development of a CHMP guideline on the clinical investigation of medicinal products for the treatment of pulmonary hypertension | Release of draft guideline for consultation |
| | Reflection paper on the need for outcome studies | For consideration |
| CPMP/EWP/238/95 Rev. 1 | Guideline on clinical investigation of medicinal products in the treatment of hypertension | Release of draft guideline for consultation |
| CPMP/EWP/3020/03 | Concept paper on the need for revision of the note for guidance on clinical investigation of medicinal products in the treatment of lipid disorders | Release of draft guideline for consultation |
| CPMP/EWP/714/98 Rev.1 | Note for guidance on clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease | For consideration |
| CPMP/EWP/3020/03 | Note for guidance on clinical investigation of medicinal products in the treatment of lipid disorders | Concept paper on the need for a paediatric addendum |
| CPMP/EWP/238/95 Rev. 1 | Note for guidance on clinical investigation of medicinal products in the treatment of hypertension | Draft guideline |

| Reference Number | Document Title | Status |
|---|---|---|
| CPMP/EWP/4891/03 | Guideline on the clinical investigation of medicinal products for treatment of ankylosing spondylitis | For finalisation |
| CPMP/EWP/784/97 | Points to consider on clinical investigation of medicinal products for the treatment of osteoarthritis | Release of draft guideline for consultation |
| CPMP/EWP/552/95 Rev. 2 | Guideline on the evaluation of medicinal products in the treatment of primary osteoporosis | Addendum on secondary disease to be considered |
| CHMP/EWP/356538/2005 | Guideline on the development of new products for the treatment of nicotine dependence | For finalisation |
| CHMP/EWP/356538/2005 | Concept paper on the development of a guideline on the development of new products for the treatment of tobacco and alcohol dependence | Release of draft guideline for consultation |
| CHMP/EWP/20119/08 | Concept paper on the development of guideline on the treatment of attentional deficit hyperactivity disorder (ADHD) | Release of draft guideline for consultation |
| | Guideline on premenstrual dysphoric disorders | Concept paper |
| | Guideline on clinical investigation of hypnotic medicinal products (3CC27 a) | Release of draft guideline for consultation |
| CPMP/EWP/566/98 Rev. 1 | Note for guidance on clinical investigation of medicinal products in the treatment of epileptic disorders | Release of draft guideline for consultation |
| CPMP/EWP/565/98 | Points to consider on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis | Revision to be considered |
| CPMP/EWP/QWP/1401/98 Rev. 1 | Guideline on the investigation of bioequivalence | For finalisation |
| CPMP/EWP/560/95 | Note for guidance on the investigation of drug interactions | Draft guideline |
| CHMP/EWP/81927/07 | Guideline on the clinical development of medicinal products for cystic fibrosis | For finalisation |
| CPMP/EWP/4151/00 | Guideline on the requirements for clinical documentation for orally inhaled products (OIP) and Appendix 1 | For finalisation |
| CPMP/EWP/2922/01 | Guideline on clinical investigation of medicinal products in the treatment of asthma | Revision to be considered |
| CPMP/EWP/562/98 | Guideline on clinical investigation of medicinal products in the chronic treatment of patients with chronic obstructive pulmonary disease (COPD) | Revision to be considered |
| CHMP/EWP/12052/20080 | Harmonisation and update of the clinical aspects in the authorised conditions of use for radiopharmaceuticals and other diagnostic medicinal products | Draft core SPCs |
| EMEA/509951/2006 | Guideline on conditional marketing authorisation | Draft annex on methodological considerations |
| CHMP/EWP/7799/2007 | Concept paper on the development of a CHMP guideline on extrapolation results in clinical studies to the EU | Draft guideline |

| Reference Number | Document Title | Status |
|---|---|---|
| | population | |
| CPMP/EWP/1119/98 Rev. 1 | Guideline on the evaluation of diagnostic agents | For finalisation |
| EMEA/CHMP/EWP/321180/2008 | Appendix 1 to the guideline on diagnostics on imaging | Finalisation of appendix |
| CHMP/EWP/240/95 Rev.1 | Guideline on fixed-combination medicinal products | Finalisation of guideline |
| CPMP/EWP/1776/99 | Points to consider on missing data | Draft guideline |
| | Concept paper on pegylated and liposomal formulations | Draft guideline |
| | Concept paper on analytical validation of bioequivalence studies | Draft guideline |
| EMEA/CHMP/BMWP/170734/2008 | Concept paper on the need for revision of the annex to guideline on biosimilar medicinal products containing biotechnology-derived proteins as active substance – non-clinical and clinical issues: Guidance on biosimilar medicinal products containing recombinant erythropoietins | For finalisation |
| EMEA/CHMP/BMWP/118264/2007 | Guideline on similar biological medicinal products containing low molecular weight heparins- non-clinical and clinical issues | For finalisation |

## CHMP Gene Therapy Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| CPMP/BWP/3088/99 | Revision of the note for guidance on quality, preclinical and clinical aspects of gene transfer medicinal products | Start of the revision after finalisation of the revision of Annex 1, Part IV of Directive 2001/83/EC, as amended |
| EMEA/GTWP/58311/2007 | Guideline on the quality, preclinical and clinical aspects of medicinal products containing genetically modified cells | For finalisation |
| EMEA/GTWP/60436/2007 | Guideline on clinical monitoring and follow-up of patients exposed to gene therapy/gene transfer medicinal products | For finalisation |
| EMEA/GTWP/405677/2006 | Guideline on live recombinant vector vaccines | For finalisation |
| | Guideline for DNA vaccines | Release of draft guideline for consultation |
| EMEA/CHMP/GTWP/587488/2007 | Reflection paper on quality, pre-clinical and clinical issues relating specifically to recombinant adeno-associated viral vectors | For finalisation |
| | Reflection paper on the framework for non-clinical bridging studies after introducing changes during development | For finalisation |
| | Reflection papers and question and answer documents on current topics in gene therapy | Current issues under discussion include different viral vectors, dose ranging studies, emerging products in the field |

## CHMP Pharmacogenomics Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| | Guideline on the use of pharmacogenomics in pharmacokinetic studies | Release of draft guideline for consultation |
| | Reflection paper on co-development of pharmacogenomic biomarkers and test platforms | Release of reflection paper for consultation |
| | Reflection paper on statistical and methodological issues associated with pharmacogenomic biomarkers | Release of reflection paper for consultation |
| | Reflection paper on genomics and personalised medicines | Release of reflection paper for consultation |

## CHMP Pharmacovigilance Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| - | Volume 9A of the Rules Governing Medicinal Products in the European Union – Revision 2008 | To be finalised after public consultation |
| - | Volume 9A of the Rules Governing Medicinal Products in the European Union – Revision 2009 (inc. revision of Ch. I.3, II.2.A, II.2.B; guidance on lack of efficacy reporting for products other than vaccines) | To be developed for public consultation and to be finalised thereafter |
| CHMP/PhVWP/503449/2007 | Conduct of Pharmacovigilance for Vaccines for Pre- and Post-Exposure Prophylaxis Against Infectious Diseases | To be finalised after public consultation |
| - | Guidance in relation to the need for contraception after exposure to medicinal products with teratogenic potential | To be developed for public consultation and to be finalised thereafter |
| - | Guidelines in relation to public communication of pharmacovigilance information | To be developed for public consultation and to be finalised thereafter |
| CPMP/PhVWP/135/00 | Standard Operating Procedure for the Review of CPMP Scientific Advice by the CPMP Pharmacovigilance Working Party | To be revised with view to Risk Management Plans, if considered necessary in the light of experience gained |
| - | ICH-E2B(R3): Clinical Safety Data Management – Data Elements for Transmission of Individual Case Safety Reports | Contribution to the project to develop ICH-E2B into an international standard (ISO/CEN) |
| CHMP/ICH/309348/2008 | ICH-E2F: Development Safety Update Reports | Contribution to finalisation following public consultation |
| - | ICH-M1: Medical Dictionary for Drug Regulatory Activities (MedDRA) | Contribution to MedDRA maintenance and user guidance documents |
| - | ICH-M5: Data Elements and Standards for Drug Dictionaries | Contribution to the project to develop ICH-M5 as international standard (ISO/CEN) |
| - | ICH-M6: Standard Operating Procedures for Maintenance of ICH Terminology Lists | Contribution to this ICH Guideline |

| Reference Number | Document Title | Status |
|---|---|---|
| - | Documents on improved working practices, document management and communication tools, also regarding the interactions and co-operation CHMP-PhVWP, HMPC-PhVWP, PDCO-PhVWP, CMD(h)-PhVWP and HMA-h-PhVWP | To be developed |
| - | Internal guidance on PSUR assessment | To be developed |
| - | Policies for transparency of pharmacovigilance matters at the level of the PhVWP | To be developed |
| - | Procedures for responses to requests from members of the public for access to documents held by Competent Authorities or the EMEA | To be developed |
| - | Other CHMP, EMEA, EC guidance and working documents (not developed under the lead of the PhVWP) | Contributions as requested |

## CHMP Safety Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CHMP/SWP/150115/2006 | Guideline on detection of early signals of drug-induced hepatotoxicity in non-clinical studies | For finalisation |
| CPMP/SWP/104/99 | Note for guidance on repeated dose toxicity | For finalisation |
| EudraLex vol. 3B3BS1A | Note for guidance on single dose toxicity | For finalisation |
| CPMP/372/01 | Points to consider on the non-clinical assessment of the carcinogenic potential of insulin analogues | Possible revision depending on ICH S6 |
| CPMP/SWP/398/01 | Note for guidance on photosafety testing | For finalisation |
| EMEA/CHMP/431994/2007 | Genotoxic impurities: question and answer document | Possible revision |

## CHMP Similar Biological (Biosimilar) Medicinal Products Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| CHMP/BMWP/496286/06 | Guideline on similar biological medicinal products containing low molecular weight heparins | For finalisation |
| EMEA/CHMP/BMWP/301636/2008 | Revision of guideline on similar medicinal products containing recombinant erythropoietins | Release of draft guideline for external consultation followed by finalisation |
| | Annex on monoclonal antibodies for the CHMP guideline on immunogenicity assessment of therapeutic proteins | Preparation of concept paper |
| | Reflection paper on expansion of the regulatory framework for similar biological medicinal products to more | Preparation of concept paper |

| Reference Number | Document Title | Status |
|---|---|---|
| | complex biologicals | |
| | Reflection paper on development of similar biological medicinal products in novel expression systems (e.g. transgenic plants). | Preparation of concept paper |
| | Guideline on similar medicinal products containing recombinant interferon alpha | For finalisation |

## CHMP Vaccine Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| | Concept paper on clinical investigation of influenza vaccines in children | Possible concept paper |
| | Guidance for fast track procedure for seasonal strain update of live attenuated influenza vaccines (LAIV) | Possible concept paper |
| | Guideline on live recombinant vector vaccines | Release for consultation |
| | Guidance for DNA vaccines | Release for consultation |
| | Reflection paper on the application of reverse vaccinology | Possible concept paper |
| | Reflection paper on seasonal influenza vaccines – clinical data for annual strain update | Release for consultation |
| | Reflection paper on pre-pandemic influenza vaccines – clinical data for strain change | Release for consultation |
| EMEA/CPMP/VEG/4986/03 | Guideline on submission of marketing authorisation applications for pandemic influenza vaccines through the centralised procedure | Maintenance of guideline |
| EMEA/CPMP/VEG/4717/03<br>EMEA/CHMP/VWP/263499/06 | Guideline on dossier structure and content for pandemic influenza marketing authorisation application. | For finalisation |
| | Guideline on influenza vaccines prepared from viruses with the potential to cause a pandemic and intended for use outside of the core dossier context. | Maintenance of guideline |
| EMEA/CHMP/VWP/164653/05 | Guideline on clinical evaluation of new vaccines | Maintenance of guideline |
| EMEA/CHMP/VWP/382702/06 | Annex to guideline on clinical evaluation of new vaccines | Maintenance of guideline |
| EMEA/CHMP/VEG/134716/2004<br>EMEA/CHMP/VWP/244894/2006 | Guideline on adjuvants in vaccines for human use; Explanatory note on immunomodulators for the guideline on adjuvants in vaccines for human use | Maintenance of guideline |
| EMEA/CHMP/VWP/12544/2008. | Core SPC for influenza vaccines with avian strains with a pandemic potential for human use | For finalisation |
| EMEA/CHMP/VEG/193031/04 | Core SPC for pandemic influenza vaccines | Maintenance of guideline |

## CHMP Working Party on Cell-based Products

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CPMP/CPWP/1199/02 | Guideline on xenogeneic cell-based medical products | For finalisation |
| | Guideline on post-marketing surveillance of cell-based medicinal products | Planned development of guideline |
| | Reflection paper on stem cell products | Planned |
| | Guideline on clinical aspects specific to regenerative medicines | Preparation of draft guideline |
| | Reflection paper on the practical application of the risk analysis approach for cell-based medicinal products | Preparation of reference paper |
| | Guideline on scientific requirements for certification of quality and non-clinical data for advanced therapy medicinal products | Planned |

## CHMP Working Group with Healthcare Professionals' Organisations

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/384343/2007 | Framework on interaction between EMEA and healthcare professionals' organisations | Under preparation |
| EMEA/42240/2007 | Criteria to be fulfilled by healthcare professionals' organisations involved in EMEA Activities | Under preparation |
| EMEA/421182/2006 | Mandate and Rules of Procedure (revision) | Under preparation |
| | Rules for involvement of healthcare professionals in EMEA activities. | Planned for 1Q2009 |
| | Document on benefit/risk information on medicines | Under preparation |
| EMEA/185036/2008 | Recommendation and proposals for action | Released for 3-month consultation |

## CHMP Name Review Group

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/531570/2008 | Criteria for NRG objections based on potential risk to confusion with names of suspended or withdrawn/revoked Marketing Authorisations (MA) | For finalisation |

## Committee for Advanced Therapies (CAT)

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CAT/454446/2008/rev.0 | Committee for Advanced Therapies Rules of Procedures | Draft, to be discussed at the January meeting and adopted in January/February 2009 |

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/164968/2008 Rev.0 | Procedural guidance for the evaluation of advanced therapy medicinal product in accordance with Article 8 of Regulation (EC) No 1394/2007 | Draft. To be discussed at CAT In January/February 09 for possible adoption |
| EMEA/164968/2008 Rev.0 | Procedural guidance on the certification of quality and non-clinical data for small and medium-sized enterprises developing advanced therapy medicinal products | Draft. To be adopted in June 09 |
| EMEA/164968/2008 Rev.0 | Procedural guidance for scientific recommendation on classification of advanced therapy medicinal products in accordance with article 17 of Regulation (EC) No 1394/2007 | Draft. To be discussed at CAT in January/February 2009 and adopted in May 2009 |

## Committee on Herbal Medicinal Products (HMPC)

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/HMPC/CHMP/CVMP/287539/ 2005 Rev.1 | Guideline on declaration of herbal substances and herbal preparations in herbal medicinal products/traditional herbal medicinal products | Revision 1 on declaration in the package leaflet and labelling for finalisation 1-2 Q |
| EMEA/HMPC/186645/2008 | Reflection paper on level of purification of extracts to be considered as herbal preparations | For finalisation 1-2 Q |
| | Guideline on selection of test materials for genotoxicity testing for traditional herbal medicinal products | To be developed (for release for public consultation 1-2 Q) |
| | Guidance on comparability of herbal substances/ preparations (e.g. extracts using different solvents) | To be developed |
| | Guidance on constituents of known therapeutic activity and criteria for standardised extracts | To be developed |
| | Guidance on stability testing for herbal products/preparations | To be developed |
| EMEA/HMPC/85114/2008 | Reflection paper on ethanol content in herbal medicinal products and traditional herbal medicinal products | For finalisation 1-2 Q |
| | Guideline on preparation of herbal teas | To be developed |

## HMPC Working Party on Community monographs and Community list

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/HMPC/234463/2008 | Community herbal monograph on Absinthii herba | For finalisation 1-2 Q |
| EMEA/HMPC/98717/2008 | Community herbal monograph on Althaeae radix | For finalisation 1-2 Q |
| EMEA/HMPC/591648/2007 | Community herbal monograph on Boldi folium | For finalisation 1-2 Q |
| EMEA/HMPC/105536/2008 | Community herbal monograph on Centaurii herba | For finalisation 1-2 Q |

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/HMPC/114586/2008 | Community herbal monograph on Hamamelis folium | For finalisation 1-2 Q |
| EMEA/HMPC/225319/2008 | Community herbal monograph on Hippocastani semen | For finalisation 1-2 Q |
| EMEA/HMPC/600668/2007 | Community herbal monograph on Polypodii radix | For finalisation 1-2 Q |
| EMEA/HMPC/508015/2007 | Community herbal monograph on Urticae folium | For finalisation 1-2 Q |
| EMEA/HMPC/600717/2007 | Community herbal monograph on Cimicifugae rhizoma | For finalisation 3-4 Q |
| EMEA/HMPC/332350/2008 | Community herbal monograph on Echinaceae pallidae radix | For finalisation 3-4 Q |
| EMEA/HMPC/114583/2008 | Community herbal monograph on Hamamelis cortex | For finalisation 3-4 Q |
| EMEA/HMPC/114584/2008 | Community herbal monograph on Hamamelis folium et cortex, distillate | For finalisation 3-4 Q |
| EMEA/HMPC/101304/2008 | Community Herbal Monograph on Hyperici herba | For finalisation 3-4 Q |
| EMEA/HMPC/331653/2008 | Community herbal monograph on Salviae folium | For finalisation 3-4 Q |
| EMEA/HMPC/212895/2008 | Community herbal monograph on Taraxaci radix cum herba | For finalisation 3-4 Q |
| EMEA/HMPC/585558/2007 | Community herbal monograph on Valerianae radix/Lupuli flos | For finalisation 3-4 Q |
| | Community herbal monograph on Curcumae longae rhizoma | Draft to be released for public consultation 1-2 Q |
| | Community herbal monograph on Juniperi fructus | Draft to be released for public consultation 1-2 Q |
| | Community herbal monograph on Urticae radix | Draft to be released for public consultation 1-2 Q |
| | Community herbal monograph on Agrimoniae herba | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Arnicae flos | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Capsella bursapastoris herba | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Carvi fructus | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Centellae herba | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Cynarae folium | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Echinaceae angustifolia radix | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Echinaceae purpureae radix | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Gentianae radix | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Hederae helices folium | Draft to be released for public consultation 3-4 Q |

| Reference Number | Document Title | Status |
|---|---|---|
| | Community herbal monograph on Mate folium | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Myrrha (Commiphora molmol) | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Oleae folium | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Orthosiphonis folium | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Quercus cortex | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Rosmarini folium | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Solanum dulcamara | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Thymi aetheroleum | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Thymi herba/Primulae radix | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Violae tricoloris herba | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Vitis viniferae folium | Draft to be released for public consultation 3-4 Q |
| | Community herbal monograph on Zingiberis rhizoma | Draft to be released for public consultation 1-2 Q |

## Committee for Orphan Medicinal Products (COMP)

| Reference Number | Document Title | Status |
|---|---|---|
| | Document on implementation of Article 8.2 of Regulation (EC) 141/2000 | Planned |

## EMEA Human Scientific Committees Working Party with Patients' and Consumers' Organisations

| Reference Number | Document Title | Status |
|---|---|---|
| | Document on benefit/risk information on medicines | Under preparation |

## Other EMEA scientific-committee and working-party guidelines

| Reference Number | Document Title | Status |
|---|---|---|
| | Procedural advice on recommendations on unforeseen variations according to Article 5 of the new Variations Regulation | New guideline –to be published 1Q2009 |
| | Updated Post-Authorisation Procedural Advice to reflect the detailed operation of the new Variations Regulation in the Centralised Procedure | Revision to be finalised 3Q2009 |

## EMEA contribution to EC Guidelines

| Reference Number | Document Title | Status |
|---|---|---|
| | Guideline on the detailed classification of variations, according to the new Variations Regulation | New guideline - contribution to be finalised by Feb 2009 |
| | Guideline on the procedural elements for the implementation of the new Variations Regulation | New guideline - contribution to be finalised by Feb 2009 |

## CVMP Efficacy Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CVMP/28510/2008 | Dossier requirements for oncology products<br>Multidisciplinary guideline: Involved WPs are EWP, SWP , QWP and ERAWP | New guideline<br>Guideline to be finalised after consultation (Q3 2009) |
| EMEA/CVMP/019/00-Rev.1 | Conduct of bioequivalence studies for veterinary medicinal products<br>Multidisciplinary guideline: involved WPs are EWP, SWP and QWP | Revision of existing guideline<br>Draft Guideline to be prepared for adoption by CVMP for public consultation (Q2-3 2009)<br>Focus Group meeting with interested parties scheduled for Q1 2009 |
| | Veterinary medicinal products controlling Varroa destructor parasitosis in bees | Revision of existing guideline<br>Draft Guideline to be prepared for adoption by CVMP for public consultation (anticipated for Q2-3 2009) |
| | Guideline on Efficacy of veterinary medicinal products for use in farmed aquatic species | Revision of existing guideline<br>Draft Guideline to be prepared for adoption by CVMP for public consultation (anticipated for Q4 2009)<br>Focus Group meeting with interested parties scheduled for Q3-4 2009 |
| | Conduct of efficacy studies for NSAIDs (EMEA/CVMP/273/01) | Revision of existing guideline<br>Draft Concept paper for the revision of guideline to be prepared for adoption by CVMP for public consultation (Q3-4 2009) |
| | Statistical principles for veterinary clinical trials (EMEA/CVMP/83804/2005) | Revision of existing guideline<br>Draft Concept paper for the revision of guideline to be prepared for adoption by CVMP for public consultation (Q3-4 2009) |

## CVMP Environmental Risk Assessment Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| | Environmental information for the SPC and risk mitigation. Consideration of effectiveness of risk mitigation practices and SPC standard risk | Concept paper to be released for public consultation |

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| | mitigation phrases (section 4.5.iii of the SPC) and environmental information (section 5.3) and on EPAR and Scientific Discussion templates in respect to environmental risk assessment | |
| | Dossier requirements for bibliographic applications<br>Multidisciplinary Guideline: Involved WPs are EWP, SWP and ERAWP | Concept paper to be released for public consultation (following revision of Annex I of 2001/82/EC) |
| EMEA/CVMP/28510/2008 | Dossier requirements for oncology products<br>Multidisciplinary guideline: Involved WPs are EWP, SWP, QWP and ERAWP | Guideline to be finalised after consultation (Q3) |

## CVMP Immunologicals Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CVMP/552/02 | Guideline on EU requirements for batches with maximum and minimum titre or batch potency for developmental safety and efficacy studies | Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended |
| EMEA/CVMP/IWP/219089/2006 | Guideline on requirements for in-use stability claims | Guideline to be adopted for implementation Q3/4 2009 |
| EMEA/CVMP/IWP/205712/2006 | Guideline on preparation of master seeds to replace established master seeds already used in authorised immunological veterinary medicinal products (IVMPs) | Guideline to be adopted for implementation Q3/4 2009 |
| - | Guideline on the need for requiring data to demonstrate the influence of maternally derived antibodies on the vaccination of very young animals | Draft Guideline to be released for consultation by IWP/CVMP Q1/2 2009 |
| - | Revised Guideline on requirements for combined veterinary vaccines | Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended |
| - | VICH Guideline for the tests on the presence of extraneous viruses in veterinary viral vaccines | EU contribution to development of guideline |
| - | VICH Guideline on the detection of mycoplasma | EU contribution to development of guideline |
| | Guideline on the requirements for multistrain dossiers | Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended |
| | Validation of batch potency tests and establishing pass criteria | Concept paper to be released for consultation by IWP/CVMP Q1/2 2009 |
| | Revision of all guidelines for IVMPs | Draft Guideline to be released for consultation by IWP/CVMP following the revision of Annex I of Directive 2001/82/EC as amended |

## CVMP Pharmacovigilance Working Party (PhVWP-V)

| Reference Number | Document Title | Status |
|---|---|---|
| | Volume 9B of the Rules Governing Medicinal Products in the European Union – Pharmacovigilance of veterinary medicinal products | Finalisation of the draft Volume 9B further to end of public consultation upon request from the European Commission |
| EMEA/CVMP/471721/2006 | Recommendation on the use of data contained in EudraVigilance and EudraVigilance Veterinary (EVVet) | To be developed on basis of the Concept paper on the same topic, the results on pilot monitoring undertaken by the PhVWP-V subgroup, and considering the final policy on transparency of the data. Following finalisation of the guidance, it is foreseen for inclusion in Volume 9B. |
| EMEA/CVMP/VICH/647/01 | VICH GL30: Pharmacovigilance of Veterinary Medicinal Products: Controlled list of terms | To be finalised in 2009, on basis of the VICH position paper developed in 2007 |
| EMEA/CVMP/VICH/123940/2006 | VICH GL35: Pharmacovigilance of Veterinary Medicinal Products: Electronic standards for transfer of data | Possible update in 2009 following developments related to GL35 (HL7/ISO) and GL30 (GL30, GL35 and GL42 are considered as one package) |
| EMEA/CVMP/VICH/355996/05 | VICH GL42 Step 7: Guideline on pharmacovigilance of veterinary medicinal products: data elements for submission of adverse event reports | Possible update in 2009 following developments related to GL35 (HL7/ISO) and GL30 (GL30, GL35 and GL42 are considered as one package) |
| EMEA/CVMP/413/99 – Rev. 5<br>EMEA/CVMP/891/04 – Rev. 3<br>EMEA/CVMP/553/03 – Rev. 3<br>EMEA/CVMP/PhVWP/556/04- Rev. 1 | Annual review of Standard lists used for reporting suspected adverse reactions | Expected date(s) of drafting/expert group: 23 April 2008. |
| EMEA/CVMP/552/03 | Guideline on Harmonising the approach to causality assessment for adverse reactions to veterinary medicinal products | Concept paper to be finalised in 2008 aiming at revision of the guideline, which is then converted to a CVMP recommendation. The revised recommendation will be considered for inclusion in Volume 9B in due course. |
| | Concept paper on detailed descriptions of risk management systems for medicinal products for veterinary use | Concept paper to be finalised in 2008 for public consultation. |

## CVMP Safety Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CVMP/SWP/355689/2006 | Guideline on the assessment of pharmacological / pharmacodynamic data to establish a pharmacological ADI | Guideline to be finalised after consultation (Q3/Q4) |
| EMEA/CVMP/28510/2008 | Dossier requirements for oncology products<br>Multidisciplinary guideline: Involved WPs are EWP, SWP, QWP and ERAWP | Guideline to be finalised after consultation (Q3) |
| - | Revision of the guideline on user safety | Revised guideline to be finalised after consultation (Q4) |

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|---|---|---|
| - | Project to address the question of how to approach the issue of pharmacological activity of excipients | Reflection paper / guideline to be developed following consultation with EC (tbc) |
| EMEA/CVMP/330382/2007 | Conduct of bioequivalence studies for veterinary medicinal products<br>Multidisciplinary guideline: Involved WPs are EWP, SWP and QWP | Draft guideline to be prepared for adoption by CVMP for public consultation (Q2-3) |
| - | Review of alternative reference limits | Continue developing reflection papers during 2009 (not for publication) |
| - | Dossier requirements for bibliographic applications<br>Multidisciplinary Guideline: Involved WPs are EWP, SWP and ERAWP | Concept paper to be released for public consultation (following revision of Annex I of 2001/82/EC) |
| - | Guideline on establishment of withdrawal periods for milk producing animals during the dry period (and relevant parts of SPC guideline) | Update may be required following further consideration at SWP and CVMP |
| - | (VICH) Guideline on metabolism and residue kinetics:<br>Study to identify the nature and quantity of residues<br>Study requirements to demonstrate residue depletion<br>Validation requirements for analytical methods used in residue studies<br>Harmonisation of scientific model assumptions<br>Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals | Support to EU position during 2009 |
| - | (VICH) Guideline on elaboration of Acute Reference Dose for Veterinary Medicinal Products | Support to EU position during 2009 |
| EMEA/CVMP/VICH/467/03 | (VICH) Guideline on the microbiological ADI | Support to EU position during 2009 |

## CVMP Scientific Advice Working Party

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CVMP/172329/04-Rev.2 | EMEA guidance for companies requesting scientific advice | Review SOP and Guidance document in 2008/9 and revise where necessary in view of experience gained with the procedure |
| SOP/V/4016 | SOP on Scientific Advice to be given by the CVMP for veterinary medicinal products | Review SOP and Guidance document in 05/2009 and revise where necessary in view of experience gained with the procedure |

## CVMP Scientific Advisory Group on Antimicrobials

| Reference number | Document title | Status |
|---|---|---|
| EMEA/CVMP/SAGAM /81730/2006 | Use of 3rd and 4th generation cephalosporins in food-producing animals in the European Union: development of resistance and impact on human and animal health (revised position paper) | Document to be finalised during 2009 following revision of comments received during 2008 in the consultation phase. |
| | Use of macrolides, lincosamides and streptogramins in food-producing animals in the European Union: development of resistance and impact on human and animal health (concept paper to be prepared) | Publication of concept paper during 2009 |
| | Considerations on MRSA. Publication of a report during 2009 on MRSA assessing the impact of use of antimicrobials in livestock and companion animals on the risk of colonization or infection with MRSA and providing a reflection on therapeutic options for animals related to the issue. This action will be coordinated with the EFSA and ECDC. | Publication of reflection paper during 2009 in addition to a document coordinated with EFSA and ECDC on MRSA |
| | Considerations on MRSI/P in companion animals (concept paper to be prepared) | Publication of concept paper during 2009 |

## CVMP General

| Reference Number | Document Title | Status |
|---|---|---|
| EMEA/CVMP/248499/2007-CONSULTATION-Rev.1 | Guideline on the evaluation of the benefit-risk balance of veterinary medicinal products | Adopted by CVMP October 2008 for release for second consultation (end of consultation 31 January 2009) |

## Joint CHMP/CVMP Quality Working Party

| Reference number | Document title | Status |
|---|---|---|
| | Guideline on Pharmaceutical Development of Medicines for Paediatric Use | Release of a draft guideline for public consultation |
| CPMP/QWP/3309/01<br>EMEA/CVMP/961/01 | CPMP/CVMP Note for Guidance on the use of near infrared spectroscopy by the Pharmaceutical Industry and the Data to be forwarded in the Part II of the Dossier for a Marketing Authorisation | Finalisation of revision to take account of advances in this area |
| CPMP/ICH/367/96 &<br>3A Q11a Vol. IIIA | CPMP and CVMP Guidelines on Specifications | Discussion on the impact of new technologies and approaches as described in ICH Guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems) on |
| CHMP/QWP/848/96 &<br>EMEA/CVMP/126/95 | CPMP/CVMP Guideline on Process Validation | |

| Reference number | Document title | Status |
|---|---|---|
| CPMP/QWP/486/95 &<br>EMEA/CVMP/598/99 | Guideline on manufacture of the finished dosage form | current concepts |
| CPMP/QWP/130/96rev 1 &<br>EMEA/CVMP/541/03 | Chemistry of the new active substance | |
| CPMP/QWP/3015/99 &<br>EMEA/CVMP/QWP/339588/2005 | CPMP and CVMP Guidelines on Parametric Release | Publication of a Concept Paper on the revision of the CPMP guideline to take into account Real Time Release concepts.<br>Then similar consideration of the CVMP guideline. |
| EMEA/CHMP/CVMP/QWP/450653/2006 | Assessment of the Quality of Medicinal Products Containing Existing/Known Active Substances (H & V) | Finalisation after end of public consultation |
| EMEA/CVMP/QWP/544467/2007 | CVMP Guideline on the quality aspects of single-dose veterinary spot-on products | Finalisation after end of public consultation |
| EMEA/CVMP/28510/08 | CVMP Guideline on dossier requirements for anticancer medicinal products for dogs and cats | Contribution to finalisation after end of public consultation |
| EMEA/CVMP/134/02 Rev 2<br>CPMP/QWP/227/02 Rev 1 | CHMP/CVMP Guideline on Active Substance Master File - introduction of an Annex for Herbal Medicinal Products, on referral by the HMPC | Finalisation of the revision (introduction of an Annex for Herbal Medicinal Products) |
| EudraLex 3AQ21A (Human) | Guideline on radiopharmaceuticals based on monoclonal antibodies | Publication of the concept paper for revision of the guideline and then release of the draft revised guideline for public consultation |
| EMEA/CHMP/167068/2004-ICH | ICH Guideline on Pharmaceutical Development (Q8) | Contribution to the development of an annex |
| EMEA/CHMP/167068/2004-ICH<br>EMEA/INS/GMP/157614/2005-ICH<br>ICH Q10 | ICH Guidelines on Pharmaceutical Development (Q8), Quality Risk Management (Q9) and Pharmaceutical Quality System (Q10) | Contribution to the implementation in the EU |
| EMEA/CVMP/VICH/581467/2007 | VICH Guideline on Bracketing and matrixing designs for stability testing of new veterinary drug substances and medicinal products (GL45) | Finalisation after end of public consultation |
| EMEA/CVMP/016/00 | CVMP Guideline on the conduct of bioequivalence studies for veterinary medicinal products | Contribution to revision of the guideline prior to its release for consultation |
| | Guideline on Setting Specifications for Related Impurities in Antibiotics | Release of a draft guideline for public consultation |

## *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 from outside concerning centrally authorised medicinal products, and coordinates action relating to the safety and quality of medicinal products.

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| For matters relating to pharmacovigilance for medicines for human use | **Sabine BROSCH**<br>Direct telephone: (44-20) 74 18 85 69<br>E-mail: pharmacovigilance@emea.europa.eu |
| For matters relating to pharmacovigilance for medicines for veterinary use | **Fia WESTERHOLM**<br>Direct telephone: (44-20) 74 18 85 81<br>E-mail: vet-phv@emea.europa.eu |
| For product-quality defects and recalls | Website: www.emea.europa.eu/inspections/defectinstruction.html<br>E-mail: qdefect@emea.europa.eu<br>Direct telephone: (44-20) 7523 7676<br>Fax: (44-20) 74 18 85 90<br>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.

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| SME office contact point | **Melanie CARR**<br>Direct telephone: (44-20) 74 18 85 75/84 63<br>Fax: (44-20) 75 23 70 40<br>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.

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| For enquiries concerning certificates for centrally authorised medicines for human or veterinary use | Direct telephone: (44-20) 75 23 71 07<br>Fax: (44-20) 74 18 85 95<br>E-mail: certificate@emea.europa.eu |

**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 Union.

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| For enquiries concerning PMF certificates | **Silvia DOMINGO ROIGÉ**<br>Direct telephone: (44-20) 74 18 85 52<br>Fax: (44-20) 74 18 85 45<br>E-mail: PMF@emea.europa.eu |
| For enquiries concerning VAMF certificates | **Ragini SHIVJI**<br>Direct telephone: (44-20) 74 18 8698<br>Fax: (44-20) 74 18 85 45<br>E-mail: VAMF@emea.europa.eu |

**Documentation services**

The EMEA publishes a wide range of documents, including press releases, general information documents, annual reports and work programmes.

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| These and other documents are available: | On the Internet at: www.emea.europa.eu<br>By e-mail request to: info@emea.europa.eu<br>By fax to: (44-20) 7418 8670<br>By writing to:<br>**EMEA Documentation service**<br>European Medicines Agency<br>7 Westferry Circus, Canary Wharf<br>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 by e-mail to: europeanexperts@emea.europa.eu

**Press office**

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| Press officers | **Martin HARVEY ALLCHURCH**<br>**Monika BENSTETTER**<br>Telephone: (44-20) 74 18 84 27<br>E-mail: press@emea.europa.eu |

## *Annex 5 Profiles of EMEA personalities*

**Pat O'Mahony, Chair of the Management Board, n. Irish**

**Education**: Pat O'Mahony is a qualified veterinary surgeon from University College Dublin with a post-graduate research Masters Degree in Veterinary Medicine. Pat was awarded an MBA degree from the Michael Smurfit Graduate School of Business, University College Dublin, in 2001.

**Career to date**: Pat O'Mahony is Chief Executive at the Irish Medicines Board, a position he took up in December 2002. Having initially spent a number of years in private practice and four years as Technical Manager in the pharmaceutical industry in Ireland and the UK, Pat worked in public health and was Director of Consumer Protection for five years at the then newly established Food Safety Authority of Ireland. He has been a member of the EMEA Management Board since 2003, and Chair since 2007. He is also a member of the Board of the Food Safety Authority of Ireland, and a member of the Board of the Irish National Accreditation Board.

**Vice-chair of the Management Board**

To be elected.

**Thomas Lönngren, Executive Director, n. Swedish**

**Education**: Qualified pharmacist from the University of Uppsala Faculty of Pharmacy. MSc in social and regulatory pharmacy. Post-graduate studies in management and health economics. Honorary Member of the Pharmaceutical Society of Great Britain since 2003 and Honorary Fellow of the Royal College of Physicians since 2004. In recognition of his work in regulatory science, in 2008 he was awarded an honorary PHD by the University of Uppsala.

**Career to date**: From 1976 to 1978, lecturer at University of Uppsala. Dr Lönngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990, during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1984 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He has been Executive Director of the EMEA since January 2001.

### *EMEA scientific committees*

**Eric Abadie, Chair of the CHMP, n. French**

**Education**: Qualified medical doctor from the University of Paris.

Post-graduate qualifications in internal medicine, endocrinology, diabetology and cardiology. He also holds an MBA.

**Career to date**: From 1981 to 1983 Dr Abadie held a number of clinical and laboratory positions, before joining the pharmaceutical industry in 1983. He was director of medical affairs of the French pharmaceutical trade association from 1985 to 1993. He returned briefly to the pharmaceutical industry from 1993 to 1994, before joining the French medicines agency in 1994 as director of pharmacotherapeutic evaluation, until 2007. Currently, he works as a scientific adviser to the General Director at AFSSAPS.

He became a member of the CHMP in 1997, and was elected as Vice-chair in 2001. He was elected as Chair in 2007. He has been a consultant in cardiology and diabetology since 1984.

**Tomas Salmonson, Vice-chair of the CHMP, n. Swedish**

**Education**: Qualified pharmacist from University of Uppsala, Sweden. Post-graduate research at School of Pharmacy, UCSF, San Francisco. Obtained a PhD in internal medicine 1990 (pk/pd of erythropoietin) from Uppsala University.

**Career to date**: Following his PhD, Dr Salmonson worked for nine months as a visiting assessor at the Therapeutic Goods Administration, Canberra. Upon returning to Sweden in 1991, he was appointed head of section, Pharmacokinetics, at the Medical Products Agency (MPA), Sweden. He joined the pharmaceutical industry for a short period in 1994-95. On his return to the MPA, he was appointed head of Pre-clinical and Clinical unit I. He was also acting Director at the MPA for 18 months, and became a member of the CPMP in 1999.

Dr Salmonson was elected as Vice-chair in 2007.

**Gérard Moulin, Chair of the CVMP, n. French**

**Education**: PhD in Microbiology from the University of Lyon.

**Career to date**: From 1981 to 1984, Dr Moulin worked in the Bovine Pathology Laboratory in Lyon. In 1984, he joined the Veterinary Medicines Laboratory in Fougères, where he was assessor and rapporteur for marketing-authorisation dossiers. He was also responsible for a laboratory unit. In 1997, he was appointed as Head of the pharmaceuticals assessment unit of the French veterinary agency (AFSSA-ANMV). In 2002, he was appointed as Director-delegate of international affairs, and in 2006, he became Head of the Marketing Authorisation Department. He has been a CVMP member since 1997, and was elected Vice-chair of the CVMP in 2001. He was first elected as Chair of the CVMP in January 2003, and was then elected chair of the new CVMP in 2004, following the publication of the review of the EU legislation, and re-elected in 2007.

**Anja Holm, Vice-chair of the CVMP, n. Danish**

**Education**: Veterinarian (DVM) from the Royal Veterinary and Agricultural University of Copenhagen in January 1994.

**Career to date**: From 1991 to 1993, Dr Holm worked at the department of toxicology at H. Lundbeck A/S in Copenhagen. From 1994 to 1998, she was a veterinary practitioner (small and large animals) in Denmark. In 1998, she was employed by the Danish Medicines Agency as safety and efficacy assessor for veterinary medicinal products, including immunologicals. From 2001-2002 she joined the research section of the Virology Department at the Danish Veterinary Institute. In 2002, she returned to the Danish Medicines Agency as senior scientific officer, where she is involved in centralised, MRP and national procedures, clinical trials and pharmacovigilance. Member of CVMP since January 2004. Member of Pharmacovigilance Working Party from 1998-2003 and again in 2006. Member of Immunologicals Working Party from 2004-2006. Member of the Scientific Advice Working Party since 2004. Elected as Vice-chair of CVMP in October 2006.

**Kerstin Westermark, Chair of the COMP, n. Swedish**

**Education**: Qualified medical doctor from the University of Uppsala. PhD in endocrinology. Specialist in internal medicine and endocrinology. Professor of internal medicine at the University of Uppsala.

**Career to date**: From 1980 to 1996, Dr Westermark worked as a practitioner and a senior consultant in the Department of Internal Medicine of the University Hospital of Uppsala, and held a position as head of the Endocrinology and Diabetes section (1995 to 1996). In 1996, Dr Westermark joined the Medical Products Agency (MPA) of Sweden as a senior consultant in the Clinical Trials Department. She was head of department from 1997 to 2005, and since 2005 has been a senior expert at the MPA.

Since 1999, Dr Westermark has been a senior medical lecturer at the Department of Medical Sciences of the University of Uppsala, and in 2008, she became adjunct professor.

Dr Westermark has been a COMP member since 2000, and was elected as Chair in June 2006.

**Birthe Byskov Holm, Vice-chair of the COMP, n. Danish**

**Education**: Qualified lawyer from the University of Copenhagen.

**Career to date**: From 1973 to 1980, Mrs Byskov Holm worked as an officer in the Tax Ministry and Administration in Denmark. In 1980, she became head of office in the Department of Internal Revenue and, in 1990, regional director of Customs and Tax in Denmark. Since 2002, she has worked for a private law firm.

Mrs Byskov Holm is a member of the Danish Osteogenesis Imperfecta Society and the Danish Alliance for Rare Disorders.

Mrs Byskov Holm has been a COMP member since 2003, and was elected Vice-chair in June 2006.

**Konstantin Keller, Chair of the HMPC, n. German**

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

**Ioanna Chinou, Vice-chair of the HMPC, n. Greek**

**Education**: Pharmacist, doctorate in Pharmacognosy, University of Athens, Greece, post-doctorate at the University of Nantes, France (Laboratoire de Recherche Therapeutique en Cancerologie - Lab. de Chimie Organique).

**Career to date**: From 1990, Lecturer, and, since 2002, Assoc. Prof. at the University of Athens, School of Pharmacy, Div of Pharmacognosy and Chemistry of Natural Products. Her main research activities have been related to phytochemical studies (isolation, structure elucidation) of bioactive natural products, including bee-keeping products.

Dr Chinou has been Vice-chair of the Committee of Greek Pharmacopoeia since 2003, and external assessor for herbal medicinal products at the Greek Medicines Agency.

Dr Chinou joined the HMPC (Herbal Medicinal Products Committee) in 2005 and was elected as Vice-chair of the HMPC Working Party on Community Lists and Monographs (MLWP) in January 2006.

She is the reviewer of more than 20 international journals, a member of many scientific societies (PSE, GA, ISP, AFERP, etc.) and author of several publications and chapters in scientific books.

**Daniel Brasseur, Chair of the PDCO, n. Belgian**

**Education**: Qualified medical doctor from the Free University of Brussels. Post-graduate degree in paediatrics and a PhD in nutrition.

**Career to date**: From 1976 to 1986, Dr Brasseur worked as a paediatrician at the University Sint Pieter Hospital in Brussels. He moved briefly to the pharmaceutical industry from 1986 to 1987, before returning to clinical work at the Queen Fabiola Children's University Hospital in Brussels as head of the nutrition and pharmacodynamics unit, a post he continues to hold today. He joined the Pharmaceutical Inspectorate of the Belgian Ministry of Public Health as head of medical assessors in 1997. He was appointed as a member of the CPMP in 1997. Dr Brasseur has held a number of teaching posts and is currently professor of nutrition and related diseases at the Free University of Brussels. He was CHMP Chair from 2001 to May 2007. He was elected Chair of the PDCO in September 2007.

**Gérard Pons, Vice-chair of the PDCO, n. French**

**Education**: Qualified medical doctor from the University of Paris (Xavier Bichat). Post-graduate degree in Paediatrics. PhD in pharmacology.

**Career to date**: Professor Pons held positions in paediatric pharmacology at the University of Minnesota, USA, and in France. He is currently the Head of Department of perinatal and paediatric pharmacology of Cochin St Vincent de Paul Hospital, and professor of clinical pharmacology at University Rene Descartes, Paris. He is President of the European Society for Developmental Perinatal and Paediatric Pharmacology. He is also the coordinator of the French paediatric research network (RIPPS) and the Chair of the French paediatric committee. He was elected Vice-chair of the PDCO in September 2007.

**Christian Schneider, Chair of the CAT, n. German**

**Career to date**: Dr Schneider is a physician by training, specialising in immunology and rheumatology. He is currently head of division for EU cooperation/microbiology at the Paul-Ehrlich-Institut (PEI), in Langen, Germany. His areas of expertise include: quality and safety of biological medicines, including ATMPs; clinical trials and risk-mitigation strategies for first-in-man clinical trials; non-clinical development of biotechnology-derived medicinal products; unwanted immunogenicity of therapeutic proteins; concepts for comparability exercise for biotechnological medicinal products. Dr Schneider is a member of the Committee for Medicinal Products for Human Use (CHMP) and the Scientific Advice Working Party (SAWP), and is also Chair of the Biosimilar Medicinal Products Working Party (BMWP).

**Paula Salmikangas, Vice-chair of the CAT, n. Finnish**

**Career to date**: Dr Salmikangas is a biochemist. She is Senior Researcher, responsible for marketing authorisations of biological medicinal products, at the National Agency for Medicines, in Finland. She is also Associate Professor in Biochemistry, University of Helsinki. Her area of expertise is cell and molecular biology of various inherited diseases.

Dr Salmikangas is also the Chair of the Cell-based Products Working Party (CPWP) and a member of the Biologics Working Party (BWP).

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

**Patrick Le Courtois, Head of Unit, n. French**

**Education**: Qualified medical doctor from the University of Paris. PhD in public health from the University of Bordeaux. Post-graduate degrees in tropical medicine, clinical research and epidemiology.

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

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

**Education**: Qualified medical doctor from the University of Paris. Post-graduate qualifications in paediatrics and methodology.

**Career to date**: Dr Saint Raymond held a position as paediatrician in a teaching paediatric hospital in Paris, followed by a number of years working for a number of pharmaceutical companies. In 1995, she joined the French Medicines Agency as Head of Unit for pharmaco-toxico-clinical assessment. She joined the EMEA in January 2000 and was appointed Head of Sector for scientific advice and orphan drugs in December 2001, a Sector which includes the EMEA Office for Small and Medium-Sized Enterprises since December 2005. Dr Saint Raymond was acting Head of Sector for safety & efficacy from October 2004 to December 2005. She is also in charge of issues relating to medicines used in children and the implementation of the European regulation on medicinal products for paediatric use.

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

**Education**: Qualified medical doctor from the University of Wuerzburg, Germany. Board certified specialist in Pharmacology and Toxicology (Bavarian Chamber of Physicians). Associate Professor for Pharmacology and Toxicology in the University of Wuerzburg.

**Career to date**: From 1984, Professor Vamvakas held positions in the Department of Pharmacology and Toxicology of the University of Wuerzburg and in the Department of Pharmacology in the Medical Centre of the University of Rochester, NY, USA. He joined the EMEA in May 1999, and one of his major activities in recent years was the establishment of orphan-drug designation and protocol assistance at the EMEA. He has a continuing teaching appointment for Pharmacology and Toxicology in the University of Wuerzburg. He was appointed acting Deputy Head of Sector for scientific advice and orphan drugs in October 2004 and is more specifically in charge of scientific advice.

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

**Education**: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. PhD in pharmaceutical microbiology from the University of Strathclyde, Glasgow.

**Career to date**: From 1972 to 1974, Dr Purves worked in the pharmaceutical industry. Between 1974 and 1996, he held posts in the UK Medicines Division and the Medicines Control Agency (MHRA -

formally known as Medicines Control Agency), including inspector of pharmaceutical manufacture, reviewer of dossiers, and manager of the Biotechnology and Biological Unit. He was the UK representative of the Quality Working Party and Biotechnology Working Party, involved in the generation of many guidelines relating to quality, biotechnology and biological products. He joined the EMEA in August 1996 as Head of Sector for biotechnology and biologicals. He was appointed Head of Sector for quality of medicines in January 2001.

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

**Education**: Qualified medical doctor from the Autonomous University of Barcelona. Post-graduate fellowship in internal medicine and post-graduate qualifications in pharmaceutical medicine, in biostatistics and in clinical pharmacology, drug development and regulation.

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

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

**Education**: Qualified as medical doctor in Rome in July 1978. Specialist in internal medicine. Post-graduate studies in cardiology and endocrinology.

**Career to date**: From 1978 to 1983, research fellow at the State University of Rome in the areas of clinical immunology, oncology and cellular immunology. From 1984 to 1994, at the Pharmaceutical Department of the Italian Ministry of Health, she was in charge as medical director of the Operative Centre for Community Procedures, and was Italian member of the former Committee for Proprietary Medicinal Products (CPMP), and was also involved in a number of ICH activities. She joined the EMEA in October 1994. She acted as scientific secretary of the Biotechnology Working Party until December 2000. She was appointed Deputy Head of Sector for safety and efficacy of medicines in January 2001, and since then she has also been in charge of EMEA activities in the field of innovation, emerging therapies and technologies, Community referrals and the coordination of scientific training.

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

**Noël Wathion, Head of Unit, n. Belgian**[14]

**Education**: Qualified pharmacist from the Free University of Brussels.

**Career to date**: Mr Wathion first worked as pharmacist in a retail pharmacy. He was later appointed to the Pharmaceutical Inspectorate (Ministry of Social Affairs and Public Health) in Brussels as a Chief Inspector, acting as the Secretary of the Belgian Medicines Commission. He is a former Belgian Member of both the CPMP and CVMP, and representative on the Pharmaceutical Committee, Standing Committee and Notice to Applicants working group. He joined the EMEA in August 1996 as Head of Sector for regulatory affairs and pharmacovigilance, and was appointed Head of the Human

[14] Currently directly responsible for post-authorisation safety & efficacy.

Medicines Evaluation Unit in September 2000. Further to the restructuring of the Human Medicines Evaluation Unit in 2001, he was appointed Head of Unit for the Post-authorisation evaluation of medicines for human use.

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

**Education**: Qualified as a pharmacist, BSc (Pharm), and was granted a Masters degree in pharmaceutics in the research area of microencapsulation from Trinity College Dublin.

**Career to date**: Since qualifying in 1983, Mr Humphreys has worked in the area of development pharmaceutics for a national branded generics manufacturer and an international research and development company. In 1991, he joined the International Regulatory Affairs Division of Glaxo Group Research Limited, where he was responsible for the development and submission of a series of international registration applications in a number of therapeutic areas. He joined the EMEA in May 1996 and was appointed Head of Sector for regulatory affairs and organisational support in January 2001. Within this capacity, he is currently responsible for provision of secretariat support to the CHMP, CMD(h), CHMP and NRG, and provision of regulatory advice and guidance concerning human medicinal products, both pre- and post-authorisation, within the EMEA and to applicants/marketing-authorisation holders. Furthermore, he is responsible for provision of organisational support to the operations of the Human Units, together with supervision of parallel-distribution notifications received by the EMEA.

**Peter Arlett, Head of Sector for pharmacovigilance and risk management, n. British**

**Education**: Qualified in medicine from University College London (UCL) in 1991, and after specialising in hospital medicine, in 1994 became a Member of the Royal College of Physicians (MRCP) of London. In 2002 became a Member of the Faculty of Pharmaceutical Medicine (MFPM) of the Royal College of Physicians of London, and in 2004 also became Honorary Senior Lecturer in the Department of Medicine at UCL. In 2007 became a Fellow of the Faculty of Pharmaceutical Medicine (FFPM) of the Royal College of Physicians of London.

**Career to date**: After his basic training in medicine, he worked as a hospital physician in Oxford and at the Hammersmith Hospital (Imperial College). Joined the UK Medicines Control Agency (now MHRA) in 1996, where he had various responsibilities as a specialist assessor and manager. In 2001, he was appointed UK delegate to the European Committee for Human Medicinal Products (CHMP). In 2003, he joined the Pharmaceuticals Unit, DG Enterprise and Industry of the European Commission as Principal Administrator, where his responsibilities included: international relations, pharmacovigilance (including lead responsibility for the revision of legislation), implementation of new pharmaceutical legislation, medicines for children (including lead responsibility for the new Paediatric Regulation). He joined the EMEA in 2008.

**Sabine Brosch, Deputy Head of Sector for pharmacovigilance and risk management, n. Austrian**

**Education**: Masters Degree in pharmacy and Doctor of Natural Sciences Degree in pharmacology from the University of Vienna. Post-graduate studies in pharmacology at the University of Melbourne and Auckland.

**Career to date**: From 1988 to 1992, Dr Brosch worked as an assistant professor at the Department of Pharmacology and Toxicology at the University of Vienna, where she specialised in electrophysiology. In 1992, she moved to the Pharmacovigilance Department at the Austrian Ministry of Health. She completed a six-month regulatory traineeship in the Pharmaceuticals Unit of the European Commission in 1995. She joined the EMEA in November 1996 and was appointed Deputy

Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines in January 2001.

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

**Education**: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology and metabolic diseases. Post-graduate studies in nutrition, statistics and methodology.

**Career to date**: Worked as a clinical endocrinologist in hospital until 1987 and then joined the Directorate of Pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the EMEA in July 1995. She was responsible for Scientific Advice until December 2000. She was appointed Head of Sector for Safety and Efficacy of Medicines in January 2001. She has been Head of the Medical Information Sector since September 2005.

*Unit for Veterinary medicines and inspections*

**David Mackay, Head of Unit, n. British**

**Education**: Graduated in veterinary medicine from the Royal Veterinary College, London. MSc in Immunology from the University of Birmingham and a PhD in Veterinary Immunology from the Royal Veterinary College, University of London. Member of the Royal College of Veterinary Surgeons of the United Kingdom. Honorary professor of the Royal Veterinary College, London.

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

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

**Education**: Graduated in pharmacology from Kings College, London University. Qualified as a veterinary surgeon from the Royal Veterinary College, London University. Member of the Royal College of Veterinary Surgeons of the United Kingdom.

**Career to date**: From 1987 to 1994, Dr Ashley-Smith was employed in the veterinary pharmaceutical industry, first as a technical adviser and subsequently as a registration manager. In 1994, she joined the UK Veterinary Medicines Directorate as senior veterinary assessor in the pharmaceuticals and feed additives team. She participated as UK CVMP member from 1996 until joining the EMEA in July 1997 as Head of Sector.

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

**Education**: Graduate in biochemistry and pharmacology from Leeds University. Post-graduate diploma in European Community law from King's College, London.

**Career to date**: Miss Leivers worked for the Milk Marketing Board for England and Wales (MMB) as a Liaison Chemist for 5 years prior to being appointed Assistant Director of the MMB/Federation of Agricultural Cooperatives office in Brussels, representing all sectors of agricultural cooperation to the European Institutions. Following this, she worked on a short-term contract at the European

Commission (DG XI) and then in industry at Pfizer (formerly SmithKline Beecham Animal Health) as a regulatory affairs manager. Miss Leivers joined the EMEA in February 1996 and was appointed Deputy Head of Sector in June 2001.

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

**Education**: Doctorate in natural sciences (organic chemistry) from the Free University of Berlin. Diploma in chemistry and qualified pharmacist from the Free University of Berlin.

**Career to date**: From 1976 to 1981, Dr Grein held a position at the Free University of Berlin in Germany teaching and conducting research. This was followed by positions as a pharmacist. In 1987, she joined the German Environmental Agency as scientific administrator involved in risk assessment of industrial chemicals. Seconded to the European Commission in 1992, she was involved in the implementation of the EU legislation on existing chemicals and international harmonisation activities, and coordinated the development of the EU approach to risk assessment for chemicals. In 1995, she returned to Germany to the Ministry for Environment as senior administrator. She joined the EMEA in April 1996 as Head of Sector.

**Head of Sector for inspections**

This post is currently vacant.

*Communications and networking Unit*

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

**Education**: Doctorate in natural sciences (applied physics and materials science) from Saarbruecken University, Diploma in physics from Tuebingen University, Master of Arts (mathematics) from the University of Cambridge, UK.

**Career to date**: Dr Wagner was a research and teaching assistant at Saarbruecken University from 1976 to 1981. He later taught as a lecturer and senior lecturer at the same university until he joined the European Commission in Luxembourg in January 1986, where he was responsible for a number of groups in the technical support division of the Euratom Safeguards Directorate. Dr Wagner was appointed head of sector for IT in the same service in 1993. He joined the EMEA on 1 May 2002.

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

**Education**: Bachelor of Arts in languages and linguistics at the University of East Anglia and post-graduate degree in librarianship and information science at University of Wales.

**Career to date**: Ms Fayl held various positions as a documentalist in several European countries, the latest from 1988 to 1995, setting up and running the documentation service in the European Commission Delegation to Norway and Iceland. Ms Fayl joined the EMEA in April 1995.

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

**Education**: Doctorate in Physical Sciences from Montpellier University, Doctorate in Physical Organic Chemistry from Montpellier University, Qualified in research management from Montpellier University; Masters degree in physical organic chemistry from Montpellier University; Degree in biochemistry from Nice University.

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

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

**Education**: Bachelor of Laws from the University of Birmingham, qualified as a Member of the Institute of Chartered Accountants in England and Wales.

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

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

**Education**: Honours degree in experimental physics, and MSc in electronic engineering from Trinity College Dublin.

**Career to date**: David Drakeford worked with Telecom Eireann, where he managed the implementation of a national data communication network. In 1987, he joined Coopers & Lybrand, where he was a senior management consultant specialising in the management and financial control of large, primarily IT-related, projects. He was also involved in numerous multinational project-management and business-analysis assignments, including managing the implementation of a worldwide information-management system for clinical trials on behalf of a Switzerland-based pharmaceutical company. He joined the EMEA in February 1997, and has been Head of Sector IT since 2003.

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

**Education**: Diploma in conference interpretation and translation from Scuola Superiore per Interpreti, Milan.

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

*Administration Unit*

**Andreas Pott, Head of Unit, n. German**

**Education**: Masters Degree in political science, history and English from the University of Hamburg. Certificat de Hautes Etudes Européennes (economics) from the College of Europe, Bruges.

**Career to date**: From 1972 to 1989, Mr Pott held a number of teaching and research posts, including a research fellowship at the Institute of Peace Research and Security Policy, University of Hamburg. He joined the Secretariat of the European Parliament in 1989, serving on the secretariats of the

Committee on Research, Technological Development and Energy, of the Committee on Budgets and latterly of the Parliament's Bureau and Conference of Presidents. He moved to the Translation Centre for Bodies of the European Union in 1999 as Head of the Department for Interinstitutional Cooperation. He joined the EMEA in May 2000.

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

**Education**: Master of Science in economics and Bachelor of Science in public administration from Trinity College Dublin.

**Career to date**: Ms Nuttall held several posts in the Irish Civil Service, serving in the Departments of Health, Finance and the Office of Public Works. Ms Nuttall then served with the Food and Agriculture Organisation of the United Nations from 1990 to 1995. She joined the EMEA in May 1995.

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

**Education**: Business studies and languages at Loughborough Polytechnic

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

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

**Education**: Bachelor of Commerce from University College Dublin. Fellow of the Institute of Chartered Accountants in Ireland. Censor Jurado de Cuentas and Member of the Registro Oficial de Auditores de Cuentas in Spain.

**Career to date**: From 1971 to 1974, Mr O'Malley completed articles in Dublin. From 1974 to 1985, he was an audit manager in Spain with Ernst and Young, and from 1985 to 1995, he was Financial Controller at Johnson Wax Española. He joined the EMEA in April 1995.

*Services attached to the Executive Director*

**Hans-Georg Eichler, Senior Medical Officer, n. Austrian**

**Education**: MD from the Vienna University Medical School, Austria, Master of Science in toxicology from the University of Surrey, Guildford, UK.

**Career to date**: Professor Eichler has been Professor and Chair of Clinical Pharmacology at the Medical University of Vienna, Austria, since 1992. In 2003, he assumed the position of Vice Rector for Research and International Relations. He received his clinical training at the Vienna University Hospital and the Poison Control Centre, as well as at Stanford University in USA. He did research in several institutions in the USA, the UK and South Africa, and gained experience in outcomes research as a visiting professor at the world headquarters of Merck & Co. Professor Eichler was a member of several medical advisory boards at the Austrian Ministry of Health. From 2000 to 2006, he was President of the Vienna School of Clinical Research. Professor Eichler was a member of the Committee for Orphan Medicinal Products from April 2000 to June 2002, and has twice served as a member of the CHMP Scientific Advice Working Party. He was appointed Senior Medical Officer of the EMEA on 1 February 2007.

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

**Education**: Law degree from the University of Dundee, UK. Masters degree in European and international law from the Vrije Universiteit Brussel, Belgium.

**Career to date**: After a traineeship with the European Commission from 1991-92, Mr Harvey Allchurch worked as a European affairs consultant in Brussels, from 1992 to 1995. During this time, he also worked as contributing editor for a European affairs publication and as Brussels correspondent for an American pharmaceutical journal. He joined the EMEA in September 1995. He was nominated as press officer in September 2001, and appointed Head of Executive Support in January 2004.

**Vincenzo Salvatore, Head of Legal Sector, n. Italian**

**Education**: Law degree from the University of Pavia, Italy. PhD in European Law from the European University Institute of Florence, Italy. Avvocato, Chair Professor of International Law.

**Career to date**: From 1991 to 2004, Professor Salvatore experienced as qualified lawyer in private practice both arbitration and litigation, dealing mainly with public procurement, competition, international trade and contracts. He worked also as research assistant in International Law at the University of Pavia, from 1992 to 1999, Associate Professor of International Law at the University of Insubria (Varese), from 1999 to 2003, and Chair Professor of International Law at the same University since 2004. He joined the EMEA as Head of the Legal Sector on 16 November 2004. He was appointed as Data Protection Officer in July 2005.

**Head of Sector internal audit capability**

This post is currently vacant.