The European Agency for the Evaluation of Medicinal Products

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WORK PROGRAMME FOR THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

2002

Adopted by the Management Board on 18 December 2001

The Work Programme for 2002 is presented by the Executive Director to the Management Board in accordance with Article 57(3) of Council Regulation (EEC) No 2309/93. It is forwarded to the European Parliament, Council, Commission and Member States. It is available on request in all official EU languages.

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EMEA key legislation and documents

Council Regulation (EEC) No 2309/93 (OJ L 214, 24.8.1993) created the EMEA and sets out its core tasks, including:

- the coordination of the **scientific evaluation** of the quality, safety and efficacy of medicinal products for **human and veterinary use** which are subject to Community marketing authorisation procedures;
- the transmission of **assessment reports, summaries of product characteristics, labels and package leaflets or inserts** for these medicinal products;
- the coordination of the **supervision, under practical conditions of use, of medicinal products** which have been authorised within the Community and the provision of advice on the measures necessary to ensure the safe and effective use of these products, in particular by evaluating and making available through a database information on adverse reactions to the medicinal products in question (**pharmacovigilance**);
- the provision of scientific opinions in respect of **maximum limits for residues** of veterinary medicinal products which may be accepted in foodstuffs of animal origin in accordance with Regulation (EEC) No 2377/90;
- coordinating the verification of compliance with the principles of **good manufacturing practice, good laboratory practice and good clinical practice**;
- upon request, providing technical and scientific support for steps to improve **co-operation between the Community, its Member States, international organisations and third countries** on scientific and technical issues relating to the evaluation of medicinal products;
- recording the **status of marketing authorisations** for medicinal products granted in accordance with Community procedures;
- providing technical assistance for the maintenance of a **database on medicinal products** which is available for public use;
- assisting the Community and Member States in the provision of **information to health care and veterinary professionals and the general public** about medicinal products which have been evaluated within the Agency;
- where necessary, **advising companies on the conduct of the various tests and trials** necessary to demonstrate the quality, safety and efficacy of medicinal products.

New legislation adopted since 1995 has added a number of responsibilities, including

- Designation of medicines for rare diseases (orphan medicines), with the creation of the Committee for Orphan Medicinal products (Council Regulation (EC) No 141/2000, OJ L 18, 22.1.2000, p. 1)
- Reinforcing the Agency's role in the verification of compliance of good clinical practice and the conduct of clinical trials (Council Directive 2001/20/EC, OJ L 121, 1.5.2001, p. 34)
- Reinforcing the Agency's role in the conduct of pharmacovigilance for medicines for veterinary and for human use and the creation of the EudraVigilance database for the transmission of adverse drug reactions (Commission Directives 2000/37/EC and 2000/38/EC, OJ L 139, 10.6.2000, p. 25 and p. 28)

Fees payable to the EMEA for services are set out in Council Regulation (EC) No 297/95, as last amended by Council Regulation (EC) No 2743/98 (OJ L No 345, 19.12.1998, p. 3).

Codification and revision of European pharmaceutical legislation

The European Parliament and Council of the European Union adopted codified Community rules on medicinal products for human and for veterinary use on 6 November 2001:

- Directive 2001/82/EC on the Community code relating to medicinal products for veterinary use (OJ L 311, 28.11.2001, p. 1)
- Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67)

Proposals for the revision of the European system for the authorisation and supervision of medicines were transmitted to the European Parliament and Council in November 2001 (COM(2001) 404 final, 26.11.2001). At the time of going to press the proposals had not been published in the Official Journal. The proposals are available on the web site of the European Commission Pharmaceuticals Unit: http://pharmacos.eudra.org/F2.

Introduction by the Executive Director

Thomas Lönngren

The European system for the authorisation and supervision of medicines, and the EMEA as part of that system, enters 2002 with a number of challenges ahead of it, building on initiatives begun in 2001 and on new enterprises to be undertaken in 2002.

The establishment of effective pharmacovigilance mechanisms for the supervision of medicines for both human and veterinary use is a major priority for the EMEA in 2002. Good progress was made in 2001, but there is a constant need for development. The cooperation of the EU institutions and of the national competent authorities will be central in achieving this important public and animal health objective.

There are a number of challenges that we will need to analyse and plan for their consequences. This includes the proposals to reform European Community pharmaceutical legislation and indeed the role of the EMEA itself. These reforms can be expected to come into force at the same time as the European Union welcomes new Member States. This is a unique opportunity to integrate the planning and preparation processes for these two events and one the EMEA will not hesitate to grasp.

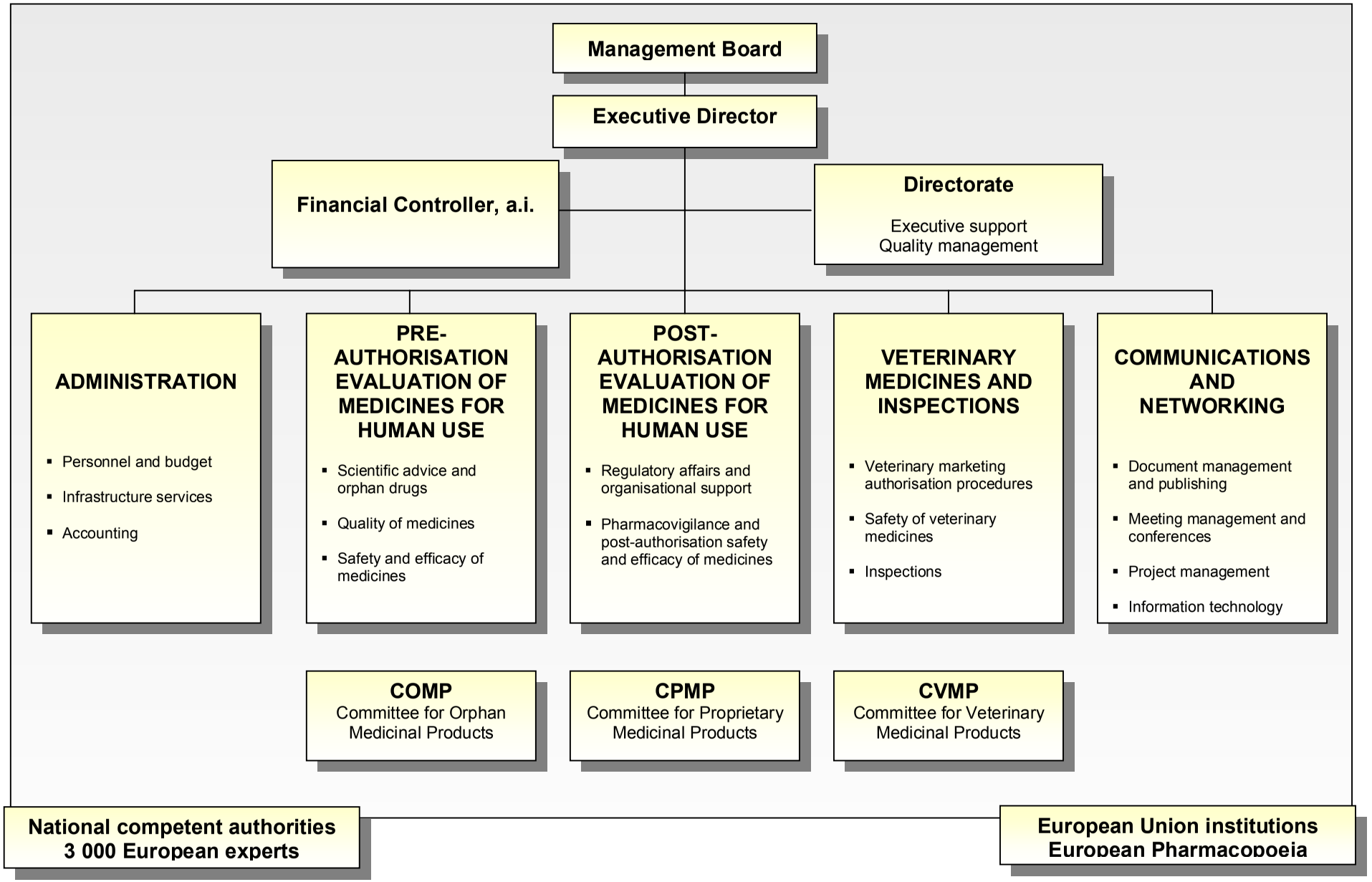
Our focus will also be on preparation for a number of other initiatives, including our future responsibility for the developments and operation of the Community's pharmaceutical regulatory IT strategy from 2003 onwards, the implementation of the Directive on clinical trials by 2004 at the latest and just as importantly the introduction of measures to further improve transparency of the regulatory system.

All this has to be taken against the background of an increasing workload for the Agency, the need to improve scientific advice to the European research-based pharmaceutical industry, develop our activities in relation to orphan medicinal products and our efforts for an anti-microbial resistance strategy for veterinary medicines.

Managing the demands of a complex Agency and the environment within which it operates is in itself a challenging task. This document sets out a programme for 2002 that will make demands on the staff of the EMEA and also colleagues in the national agencies with whom we work. The Agency's Management Board has approved an increased budget for 2002 that includes an additional 31 posts as part of its response to meeting the challenges of the 2002 work programme. I am working closely with heads of national agencies as they plan their own resource contributions to the European system.

The budget and resource demands for 2002 were put together early in 2001 for submission to the EU institutions. The environment has changed greatly since that time, with new workload demands made on the EMEA. We may need to return to the Management Board and the EU budgetary authority during the course of 2002 once we have a better understanding of the workload implications of some of these additional tasks.

Structure of the EMEA



Chapter 1
EMEA in the European system

The European system offers two routes for authorisation of medicinal products. The EMEA plays a role in both procedures:

- The centralised procedure is compulsory for medicinal products derived from biotechnology, and available at the request of companies for other innovative new products. Applications are submitted directly to the EMEA. At the conclusion of the scientific evaluation undertaken in 210 days within the Agency, the opinion of the scientific committee is transmitted to the European Commission to be transformed into a single market authorisation applying to the whole European Union.
- The decentralised procedure (or mutual recognition procedure) applies to the majority of conventional medicinal products and is based upon the principle of mutual recognition of national authorisations. It provides for the extension of marketing authorisations granted by one Member State to one or more other Member States identified by the applicant. Where the original national authorisation cannot be recognised, the points in dispute are submitted to the EMEA for arbitration. The opinion of the scientific committee is transmitted to the European Commission.

The European Commission adopts its decision with the assistance of a standing committee composed of representatives of the Member States.

1.1 Management Board

Overview of the Management Board

Chairman of the Management Board	Keith JONES
Vice-chairman of the Management Board	Gerhard Josef KOTHMANN

In addition to its responsibilities for ensuring appropriate standards of corporate governance, agreeing and monitoring implementation of the Agency's work programme and monitoring standards of performance, the Management Board has a number of specific priorities in 2002. These include advising the Executive Director on preparation for:

- Revision of the European marketing authorisation system
- Accession of new Member States to the European Union
- Revision of the level and structure of fees payable to the EMEA

The Board will meet four times a year. Heads of national agencies who are not members of the Board will be invited to attend when issues of common interest are discussed.

Management Board meetings in 2002
21 February
6 June
3 October
19 December

1.2 Network with national competent authorities

Useful web sites:

Heads of agencies for medicines for human use	*http://heads.medagencies.org*
Heads of agencies for medicines for veterinary use	*http://www.hevra.org*

The increasing workload expected for the EMEA in 2002 has an impact on the EU and EEA-EFTA states' national authorities that provide the scientific resources used for the evaluation and supervision of medicines. As this impact becomes increasingly important the EMEA intends to associate the national authorities more closely with its resource planning, in particular through the two heads of agencies groups responsible for human and veterinary medicines. The EMEA budget for 2002 provides for some € 23.3 million – about 33 % of the total budget – of payments by the EMEA to national authorities in return for scientific evaluation and supervision services.

Services provided by national authorities to the EMEA are governed by a contract. The contents and management of the standard contract and the general principles governing the relationship between the EMEA and the national authority will be reviewed in 2002.

The newly created Unit for Communications and networking at the EMEA will work towards the better coordination and running of the network between the Agency's partners. The Unit will focus on the communication tools and IT systems needed in particular to bring the Agency together with the 27 different national competent authorities. Details of the Unit's work programme can be found in Chapter 5.

With some 3 000 European experts available for the evaluation of medicines for human and veterinary use, new procedures for handling the nomination and management of the experts' database will be introduced. These procedures will include new procedures for verification of the declarations of interests of experts. In addition to the obligations set out in Council Regulation (EEC) No 2309/93 and the EMEA Code of Conduct, individual confidentiality undertakings will be concluded with each European expert.

1.3 Transparency and regulatory dialogue

The development of improved transparency and a communication policy is an important objective for the EMEA. New initiatives will be introduced in 2002 as part of the implementation of the recommendations of the 27 November 2000 EMEA workshop on transparency. These include:

- Proposals for the introduction of summaries of opinions adopted by the Committee for Proprietary Medicinal Products (CPMP) and Committee for Veterinary Medicinal Products (CVMP) for post-authorisation applications, in particular important changes made to the terms of the marketing authorisation and those impacting on the safety and use of medicines.

- Initiatives for publication of summaries of opinion of the Committee for Orphan Medicinal Products (COMP). In addition the COMP, through its Working Group with Interested Parties, will look at other initiatives to improve transparency.

The newly created press office will provide a focal point for the increasing media interest in the Agency and in the authorisation and supervision of medicines. The office will play a role in increasing awareness of the EMEA and the work of its scientific committees among healthcare professionals, users of medicines, patients, learned societies and EU institutions and national authorities.

The Agency will cooperate with the Office of the European Ombudsman concerning the planned revision of the EMEA Code of Conduct and other actions as requested.

1.4 Revision of EMEA fees

The EMEA will continue to collect data on the costs of the centralised procedure and in particular the costs of services provided by national competent authorities for rapporteurships and inspections.

The EMEA expects to be able to make a contribution to the European Commission during 2002 with regard to future changes in the structure of fees. In making its contribution, the Agency will also take into account the impact of future EU enlargement and the proposed revision of EMEA tasks and responsibilities.

The EMEA will keep under review the need to request an increase in the level of fees in 2002.

1.5 Review of the European marketing authorisation system

Useful web site:	
European Commission Unit for Pharmaceuticals: regulatory framework and market authorisations	*http://pharmacos.eudra.org/F2/home.html*

The EMEA will continue its analysis of the implications of the European Commission proposals for the revision of the European marketing authorisation system and they progress through the legislative process. The Agency will contribute as required to the work of the European Parliament and Council of the European Union as they begin their consideration of the proposals.

Work will in particular focus on the resource impact of the review and ensuring that the necessary structures and scientific resources can be put in place ready to implement the changes contained in the proposals once adopted. This will also have to take into account the enlargement of the European Union and expected advances in medical science.

1.6 Quality management

An important step towards an integrated quality management system for the EMEA will be achieved in 2002 with the incorporation of the quality manual in the newly installed electronic document management system. Another initiative in 2002 will be the development of co-auditing between the internal audit teams and the financial control team.

The quality management system will be underpinned by a number of internal audits to ensure continual improvement and a programme of management training, in accordance with the international standard ISO 9004:2000. Developments in the area of integrated resource management systems, European governance, accountability and performance measurement will be kept under review.

A third benchmarking workshop on good regulatory practices/quality management systems will be held on 7 May 2002. This will be organised with the participation of national competent authorities from the EU Member States and central and eastern European countries.

1.7 International partners

Useful web sites:

Pan-European Regulatory Forum	*http://perf.eudra.org*
International Conference on Harmonisation	*http://www.ifpma.org/ich1.html*
Veterinary International Conference on Harmonisation	*http://vich.eudra.org*
EMEA electronic submissions web site	*http://esubmission.eudra.org*

The second Pan-European Regulatory Forum (PERF II) continues until July 2002. Subject to further funding being made available by the European Commission PHARE programme, it is planned to continue the initiative – PERF III – until December 2003 to coincide with the expected first wave of accession of new Member States.

The objectives set for the forum in 1999 remain the same: The PERF is a targeted, pro-active approach to providing pre-accession assistance to participating candidate countries. The focus on practical implementation that is a feature of PERF II is planned to continue during PERF III.

The priority action areas in PERF II are:

- Implementation of Community pharmaceutical legislation and policy for medicines for human and for veterinary use (*'acquis communautaire')*
- Good manufacturing practice
- Pharmacovigilance
- Inter-agency training (quality systems, good regulatory practice and benchmarking; dossier assessment; telematics)
- Veterinary issues (including specific issues relating to quality, safety (including pharmacovigilance) and efficacy for veterinary medicines)

The proposal for PERF III includes workshops, secondments, joint visits, joint training sessions with staff from Member State competent authorities and a conference to mark the end of the programme.

The EMEA will continue to support initiatives under the two International Conferences for Harmonisation for human and for veterinary medicines (ICH and VICH). Particular efforts will be made towards the development of the electronic common technical document (eCTD) and participation in new initiatives on pharmacovigilance and gene therapy.

Within the VICH process, the EU will propose a concept paper to harmonise residue metabolism testing for veterinary medicines intended for use in food-producing animals.

The application tracking system developed jointly by the World Health Organisation (WHO) and the EMEA – SIAMED – will be further developed for general use at the EMEA in 2002. Data from all completed evaluation procedures will be loaded into SIAMED and the system will be used to track all new applications once it has been fully implemented.

The joint development between the EMEA and the WHO was partly motivated by the goal of developing a flexible tool that can be used to improve the information management capability of those competent authorities already using the older version of SIAMED, but also by the goal of making it available to a wider number of other national authorities in European and internationally in the medium to long-term.

As part of the Agency's policy of continual dialogue and exchange with regulatory authorities from around the world, a number of missions and visits will take place in 2002. The EMEA will continue to develop its collaboration with WHO in a number of fields and will participate in the WHO 10th International Conference of Drug Regulatory Authorities (ICDRA) scheduled to take place in Hong Kong in June 2002.

1.8 European Department for the Quality of Medicines

Useful web site: European Department for the Quality of Medicines/ European Pharmacopoeia *http://www.pheur.org*

The EMEA will continue to work closely with the European Pharmacopoeia in 2002. Representatives from the European Pharmacopoeia Secretariat will be invited to attend the meetings of the Joint CPMP/CVMP Quality Working Party and the ad hoc Meetings of GMP Inspection Services.

The importance of collaboration with respect to the European Department for the Quality of Medicines Certification of Suitability scheme will be recognised by the routine inclusion of this item in the agendas of the Quality Working Party in 2002. EMEA representatives will also participate at meetings of the European Pharmacopoeia Commission as a member of the European Commission delegation.

The programme for sampling and testing of centrally authorised products will continue in 2002, in collaboration with the EDQM. Products are included in the annual programme on the third anniversary of receipt of a Community marketing authorisation or when the scientific committees identify a specific need. Sampling and testing of the products is coordinated by EDQM and is carried out by the Network of Official Medicines Testing Laboratories of the EU and EEA-EFTA Member States. The 2002 programme will involve 32 products.

1.9 Financial control

EMEA Financial controller, a.i.	Claus CHRISTIANSEN

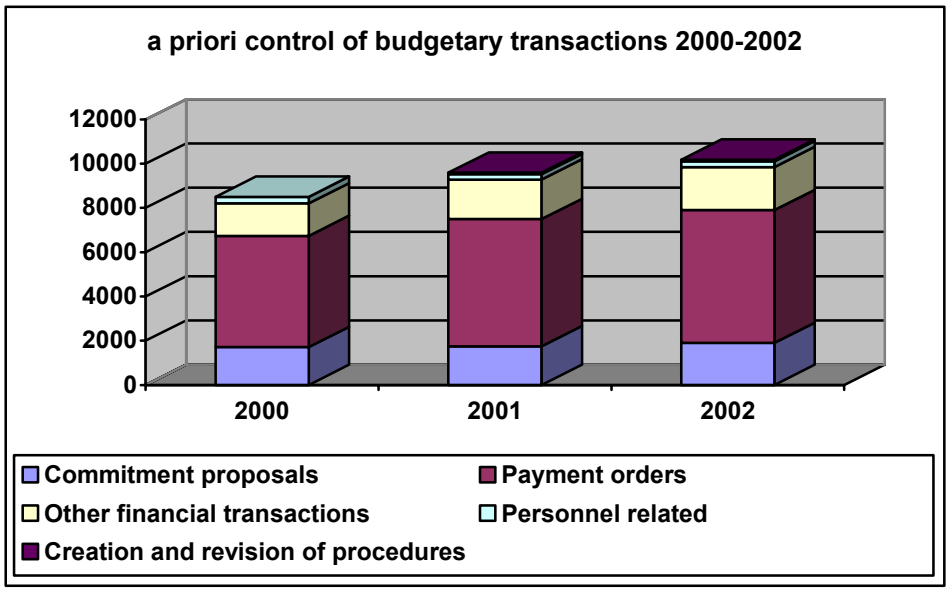
In line with other EU institutions, the financial control function at the EMEA is expected to be replaced in 2002 with a system of internal audits, most probably exercised by the services of the European Commission.

The process of implementing these changes is expected to take a number of years during which the European Commission will consult with the other EU bodies on the recasting of the financial regulation. Proposals for the necessary structural and other changes for the EMEA will be presented to the Management Board for approval.

Pending any changes, the Agency's interim financial controller will continue to ensure the application of the financial regulation and assist in the preparation for transition to the new system.

Targets for financial control in 2002 are:
- Handle 95 % of submissions within 2 days
- Handle 100 % of submissions within 5 days

Additional activities will include the delivery of opinions on financial systems and procedures, and, in cooperation with the IT sector, the development of a specific tool for financial control that links with the EMEA accounting system, SI2.



Chapter 2
Medicines for human use

Overview

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

Head of Unit	Patrick LE COURTOIS
Head of Sector for scientific advice and orphan drugs	Agnès SAINT RAYMOND
Head of Sector for quality of medicines	John PURVES
Head of Sector for safety and efficacy of medicines	Isabelle MOULON
Deputy Head of Sector for safety and efficacy of medicines	Marisa PAPALUCA AMATI

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

Head of Unit	Noël WATHION
Head of Sector for regulatory affairs and organisational support	Tony HUMPHREYS
Head of Sector for pharmacovigilance and post-authorisation safety and efficacy of medicines	Noël WATHION *(acting)*
Deputy Head of Sector for pharmacovigilance and post-authorisation safety and efficacy of medicines	Sabine BROSCH

Committee for Proprietary Medicinal Products

Chairman	Daniel BRASSEUR
Vice-Chairman	Eric ABADIE

Committee for Orphan Medicinal Products

Chairman	Josep TORRENT i FARNELL
Vice-Chairman	Yann LE CAM

Working parties and ad hoc groups

Biotechnology Working Party	Jean-Hugues TROUVIN
Efficacy Working Party	Barbara VAN ZWIETEN-BOOT
Pharmacovigilance Working Party	Fernando GARCIA ALONSO
Joint CPMP/CVMP Quality Working Party	Jean-Louis ROBERT
Safety Working Party	Beatriz SILVA LIMA
Scientific Advice Review Group	Markku TOIVONEN
ad hoc Working Group on Blood Products	Manfred HAASE
Herbal Medicinal Products Working Party	Konstantin KELLER

Priorities for medicines for human use in 2002:

- Manage the increase in workload for initial marketing authorisation and post-authorisation applications.

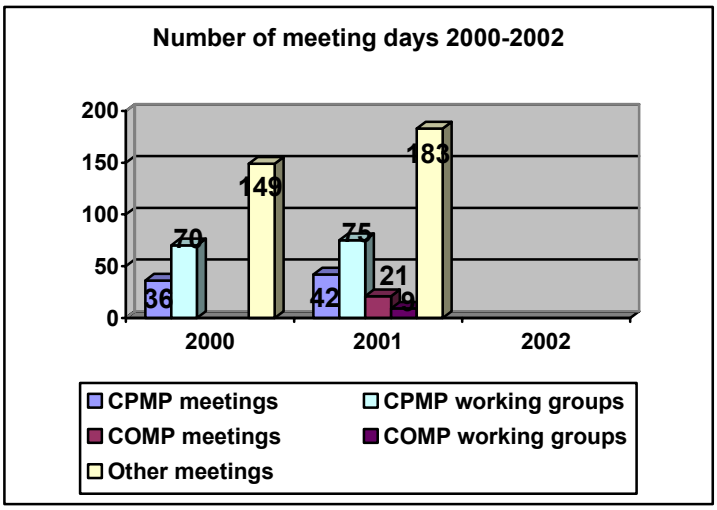
- Maintain and further improve the EudraVigilance database and the data processing network for the electronic reporting of individual case safety reports and strengthen the conduct of pharmacovigilance for centrally authorised medicinal products.

- Strengthen the provision and quality of scientific advice and protocol assistance available from the EMEA, in particular by focusing on streamlining of the procedures and encouraging companies to use the service.

- Manage the increase in workload for activities relating to orphan drug designation and strengthen policies directed towards orphan medicinal products.

- Improve the transparency of the regulatory process, with particular focus on the needs of patients, health professionals and other interested parties.

The workload arising from these priorities can be seen in the increase in meeting days forecast for 2002 and also in the significant rise in the number of reimbursed delegates expected in 2002, a significant number of which are experts for the evaluation of medicines for human use (see Section 5.3).



2.1 Initial evaluation

This covers the time from pre-submission discussion through to authorisation and the production of the European public assessment report (EPAR).

The number of applications for initial evaluation is expected to increase in 2002 with an expected 68 applications. An estimated 18 of the total applications are expected to be for orphan medicinal products.

Regulatory dialogue with applicants will be increased. Applicants are encouraged to request pre-submission meetings and where possible these will involve the rapporteur and co-rapporteur. During the evaluation process there will be increased opportunity for dialogue between applicants and their experts with the rapporteur, co-rapporteur, the European experts and the EMEA product team.

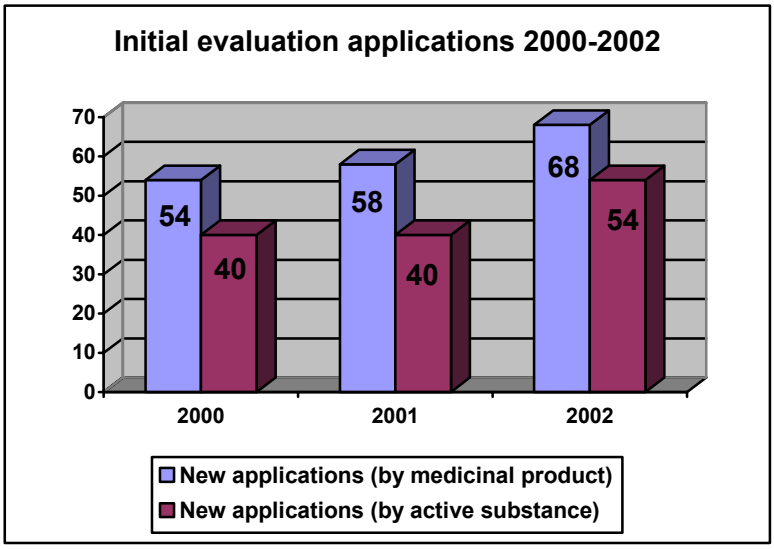
A scientific memory database will be further developed as part of EMEA quality assurance. The database provides guidance on past regulatory decisions, permitting a consistent approach across therapeutic areas. The database will also be used in the generation of performance indicators on the centralised procedure.

Small ad hoc expert working groups will be organised for some products during the evaluation phase to reinforce CPMP scientific expertise as appropriate.

Initiatives will be taken with regard to improving the quality, consistency and readability of information given to health care professionals and patients. Greater emphasis will be placed on the quality of information documents (especially the summary of product characteristics and patient leaflets) during discussions with applicants. This will be accompanied by continuing efforts to improve the quality and consistency of CPMP assessment reports and EPARs.

A revised procedure for the linguistic review of product information will be implemented from the beginning of 2002. The aims are to provide better quality translations into all official EU languages and rationalise the use of resources available at the EMEA and at Member State level.

- Increase in initial evaluation work of 20 % in 2002 over 2001
- More focus on information to health care professionals and patients
- Consistency in assessments and opinions through development of the scientific memory database



Objectives:

- Adhere to regulatory timelines for active review time by the CPMP
- Publication of summaries of opinion at the time of adoption by the CPMP
- Rapid publication of EPARs after the European Commission decision granting marketing authorisation

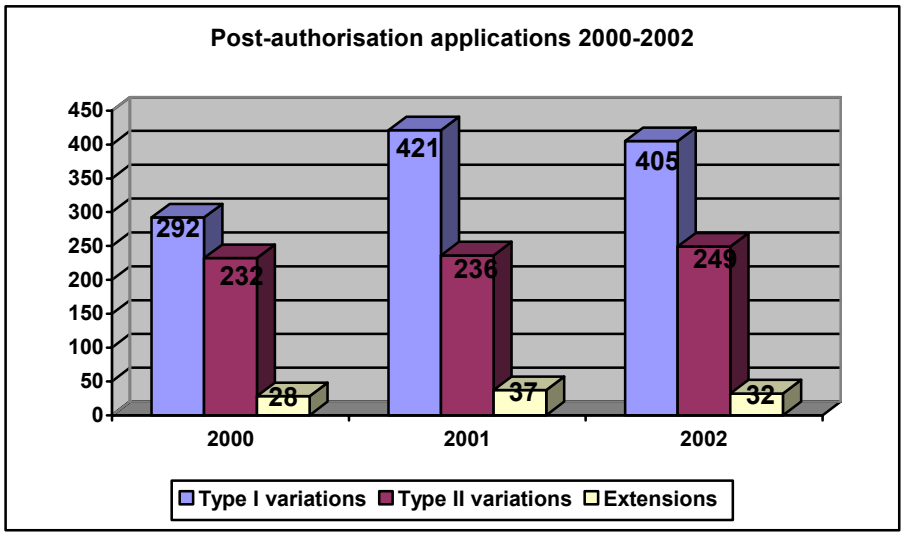
The CPMP will continue to meet in 2002 on a monthly basis. Efforts will be made to further improve the functioning of the Committee to allow it to handle an increasing workload and to prepare for future challenges, such as emerging therapies.

CPMP meetings in 2002
15-17 January
19-21 February
19-21 March
23-25 April
28-30 May
25-27 June
23-25 July
20-22 August[1]
17-19 September
15-17 October
19-21 November
17-19 December
[1] The CPMP will meet in August only if required Note: Rapporteurs and co-rapporteurs will be appointed at each meeting

2.2 Post-authorisation activities

This includes activities relating to variations, line extensions and transfers of marketing authorisation.

It is expected that the new legislation on variations to marketing authorisations will come into force in 2002. The impact on workload and resources for the EMEA secretariat of the new legislation will be kept under review.



Objectives:

- Adhere to regulatory timelines for the processing of type I, type II and line extension applications
- Keep workload evolution under review during 2002

2.3 Pharmacovigilance and maintenance activities

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

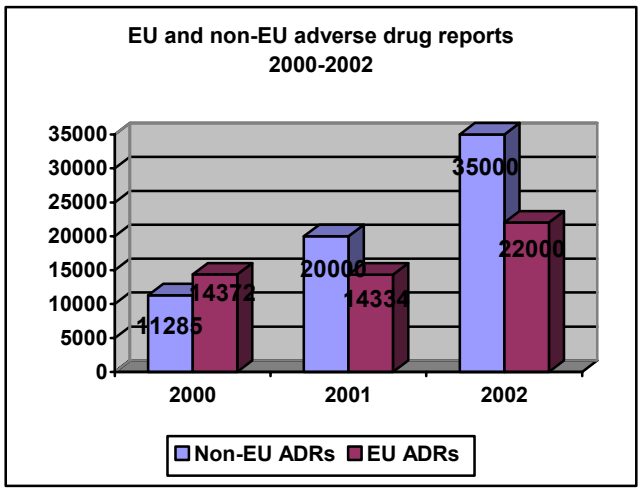
Pharmacovigilance objectives in 2002 include:

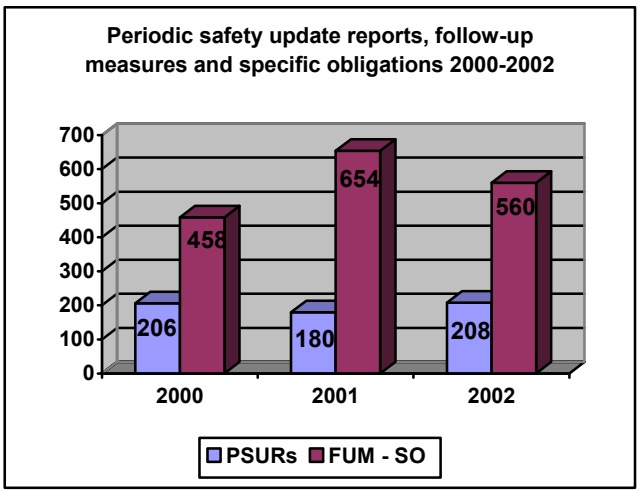
- Maintain, update and further improve the EudraVigilance database and the data processing network through the availability of new functionalities
- Manage all pharmacovigilance information (ADRs, PSURs) in a timely manner
- Strengthen the conduct of pharmacovigilance for centrally authorised medicinal products through a more in-depth and systematic review of information to allow early detection of signals

A significant challenge in 2002 will be the implementation of the electronic transmission of individual case safety reports in accordance with the policy paper adopted by the heads of national competent authorities.

Particular attention will be paid in 2002 to the monitoring of marketing authorisation holders' compliance with their post-authorisation commitments and obligations. A policy on compliance will be developed and implemented, to include systematic publication in EPARs of the compliance status of post-authorisation commitments.

- Increase in annual reassessments of marketing authorisations from 13 in 2001 to 19 in 2002
- Applications for renewal of marketing authorisations will remain stable with 20 applications in 2002 compared to 21 in 2001
- Increase in EU and non-EU ADRs and PSURs as the stock of centrally authorised products on the market increases





The number of non-EU ADRs has risen sharply in recent years and this is expected to continue in 2002. This is due to a number of factors including more medicinal products with Community marketing authorisations, more of these products are gaining authorisations outside the EU and possibly improved reporting of ADRs outside of the EU.

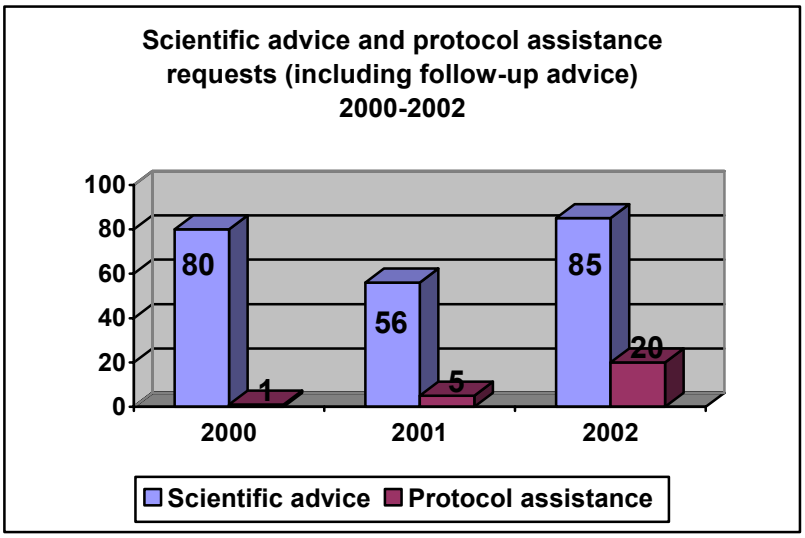
The post of Head of Sector for pharmacovigilance will be filled in early 2002.

2.4 Scientific advice

Scientific advice is provided through the Scientific Advice Review Group, a satellite group of the CPMP. The Group is supported by the Sector for scientific advice and orphan drugs. The Scientific Advice Review Group will meet 11 times in 2002, with meetings extended to 2 days each month. This is intended to allow improved interaction between the Group and companies requesting advice.

Particular attention will be focused on the development of protocol assistance for designated orphan medicinal products. The Group will be given the possibility of access to additional scientific expertise where necessary to provide better advice in the areas of rare diseases.

- Significant increases in the number of initial and follow-up scientific advice and protocol assistance requests in 2002



Objectives:

- Provide timely advice to companies in accordance with the agreed rules of procedure
- Monitor the impact of scientific advice and protocol assistance on subsequent applications for marketing authorisation

2.5 Arbitration and Community referrals

The number of arbitration referrals (under Article 29 of the Community Code for medicines for human use, formerly Article 10 of Council Directive 75/319/EEC, and Article 7(5) of Commission Regulation (EC) No 541/95) and the number of Community harmonisation referrals (under Article 30 of the Community Code, formerly Article 11 of Council Directive 75/319/EEC) is not expected to increase from 2001 levels.

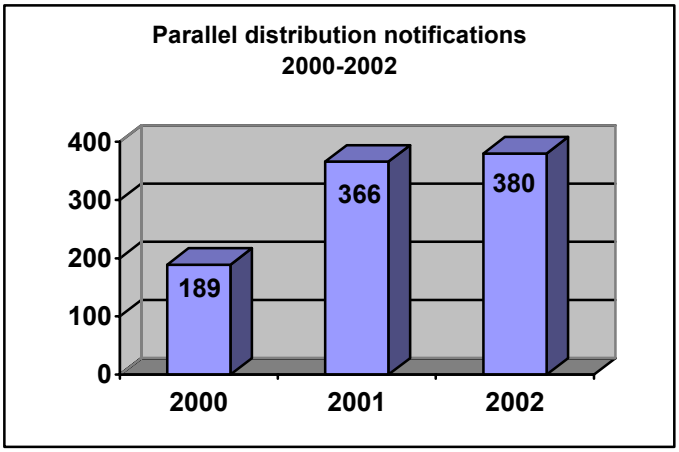
Following the decision taken by the heads of national competent authorities for human medicines, the Joint CPMP/MRFG working group on harmonisation of summary of product characteristics will continue its work in 2001 and will select candidates for harmonisation on a case by case basis among European brand leaders in major therapeutic areas.

The number of Community referrals related to pharmacovigilance concerns (under Articles 31 and 36 of the Community Code, formerly Articles 12 and 15a of Council Directive 75/319/EEC) is expected to remain stable compared to 2001.

Procedures began in 2002 will add to the already existing workload relating to procedures begun in 2000 and 2001.

2.6 Special services

The number of parallel distribution notifications continues to increase, with an estimated 380 expected in 2002. The current procedures and guidance documents for handling of notifications will be revised in 2002.



2.7 International activities

Activities with European institutions and Member States

- This includes participation at a number of forums chaired by the European Commission, including the Pharmaceutical Committee, the Notice to applicants group, Emacolex meetings of legal advisers of the competent authorities, various groups within the Community telematics structure, as well as any other relevant activity or meeting organised by or at the request of the European Commission.
- The two Units for the evaluation of medicines for human use also ensure adequate support to a number of EU initiatives and requests including the organisation of training sessions for assessors for national regulatory agencies.

- The Units also support EMEA participation to Joint Actions and collaboration with the European Monitoring Centre for Drugs and Drug Addiction based in Lisbon.
- Interaction will continue with the Office for Harmonization in the Internal Market (Trade marks and Designs) based in Alicante.

Activities with central and eastern European countries

- These activities are primarily organised through the Pan-European Regulatory Forum programme (PERF) and the different priority action areas relating to human medicines.
- Evaluations by the EMEA for centrally authorised medicines are recognised by the national authorities of central and eastern European countries through a simplified procedure at the request of the EU marketing authorisation holder. The operation of this simplified recognition procedure is dependent on a database managed by the EMEA. Updates to the database will continue in 2002.
- The Units will continue in 2002 to participate in the Visiting Experts Programme for experts from the different authorities of central and eastern European countries.
- The Units will contribute to other initiatives with a view to preparation for the accession of new Member States to the European Union.

Activities with other national competent authorities

- Activities with other national competent authorities are primarily focused on relations with the US Food and Drug Administration (FDA) and the Japanese Ministry of Health and Welfare.
- Working relations with the FDA will be strengthened with regular videoconferences between the EMEA and FDA, exchange of officials and participation in each other's meetings.
- EMEA interactions with the Japanese authorities will be strengthened in 2002, in particular through the exchange of officials.
- Relations with other regulatory authorities in Australia, Canada and other countries will be further explored and developed.

Participation in international forums

- One of the principal international forums is ICH and the EMEA will ensure adequate coordination and provision of expertise through its scientific committees. There will be two Steering Committee meetings in 2002 in Brussels and in Washington, DC.
- Collaboration with the World Health Organisation (WHO) will continue, in particular through interaction with the WHO Collaborating Centre for International Drug Monitoring as well as the WHO International Non-proprietary Name (INN) programme. This is especially important within the context of the work of the EMEA Invented Name Review Group discussions.

2.8 Orphan medicinal products

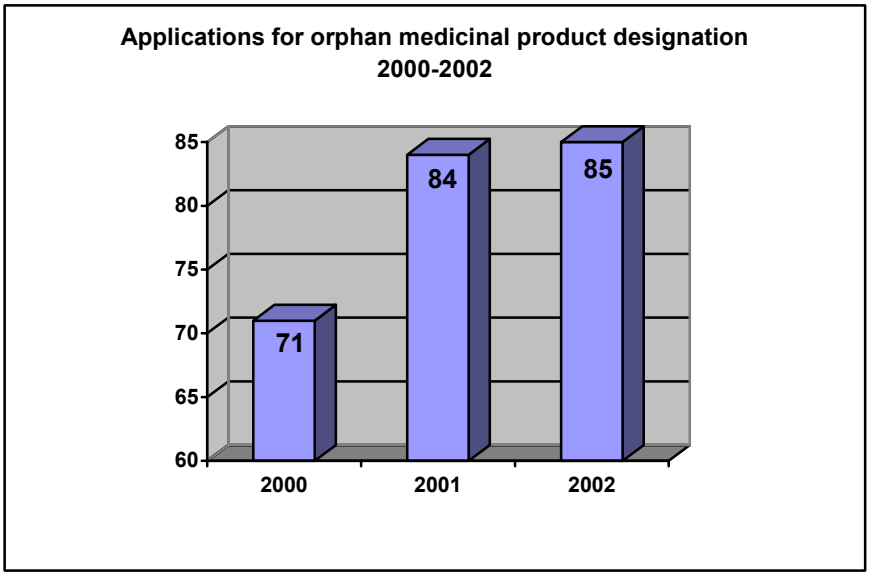
The Committee for Orphan Medicinal Products (COMP) is responsible for making recommendations to the European Commission for the designation of orphan medicinal products for rare diseases. The COMP is responsible for advising the European Commission on the development of an orphan drug policy and for providing assistance in liaison with international partners and patient organisations in this respect. The Committee is supported by the Sector for scientific advice and orphan drugs.

The number of applications for orphan drug designation in the EU and for the related activities are already much more higher than initially planned when drawing up the legislation and can be estimated to be considerably higher than forecasted when the legislation was adopted at the end of 1999. These activities will continue to increase in 2002.

The Committee for Orphan Medicinal Products will meet 11 times in 2002, meeting for 2 days each month.

COMP meetings in 2002
22-23 January
26-27 February
25-26 March
29-30 April
22-23 May
19-20 June
17-18 July
No meeting in August
11-12 September
8-9 October
14-15 November
12-13 December

- Increase in number of applications for orphan medicinal product designation in 2002 to 85
- Full implementation of the orphan drug legislation (Regulation (EC) No 141/2000) with new activities such as annual reports for designated products, follow-up and assessment of designation criteria at the time of application for marketing authorisation
- Increased activities in relation to the provision of information to patient organisations and interested parties (academia, health professionals and sponsors), including the publication of summaries of opinion at the time of the European Commission decision



Objectives:

- Adhere to regulatory timelines for applications for opinions from the COMP on orphan drug designation
- Publication of summaries of opinion at the time of decision on designation by the European Commission

2.9 CPMP and COMP working parties and ad hoc groups

The working parties of the EMEA scientific committees responsible for medicinal products for human use are involved in the development and revision of guidelines, the provision of recommendations and advice on medicinal products for which applications are made for orphan drug designation, scientific advice, protocol assistance, marketing authorisation or post-authorisation activities, according to the specific area of responsibility of each committee. This includes advice and recommendations on general public health issues related to medicinal products such as transmissible spongiform encephalopathy (TSE) or Creutzfeld-Jakobs's Disease (CJD), or viral safety on plasma derivatives.

This activity also supports the work of the national competent authorities in the functioning of the mutual recognition procedure.

- Increase in CPMP guidelines from 50 in 2001 to close to 60 in 2002 including ICH-derived CPMP guidelines
- Additional expertise may be required – in the form of ad hoc groups or individual experts – to assist the Committees and working parties. This could include the availability of additional pharmacovigilance expertise to strengthen the conduct of pharmacovigilance at EU level or the establishment of therapeutic groups to support activities related to the clinical development of medicinal products

CPMP working parties and ad hoc groups in 2002	Number of meetings	New guidelines	Ongoing guidelines	Guidelines for publication
Pharmacovigilance Working Party	8	4	17	6
Biotechnology Working Party	9	11	26	14
Joint CPMP/CVMP Quality Working Party	4	7	13	16
Blood Products Working Group	3	4	17	6
Efficacy Working Party (including therapeutic groups)	8	9	39	20
Safety Working Party	3	2	14	11
Scientific Advice Review Group	11	n/a	n/a	n/a

Continuous developments in medical and pharmaceutical science, the emergence of new therapies and new public health challenges or threats have led the CPMP to establish new ad hoc groups. As with the working parties, these groups of specific experts will prepare guidelines, give advice to the Committee on particular questions related to medicinal products or general policy on identified topics.

- 10 ad hoc groups will meet in 2002
- The ad hoc groups concern paediatrics, oncology, anti-HIV medicines, comparability of biotechnology products, pharmacogenetics, xenogenic cells, gene therapy, anti-bioresistance, vaccines and biological threats

The CPMP will continue through its satellite groups (Invented Names Review Group, Organisational Matters Group, Meeting of the chairmen of the CPMP and working parties) to improve the functioning of the Committee and of the centralised procedure.

COMP working parties

The COMP working parties provide the committee with advice on aspects of the designation criteria for orphan status such as the relevance of significant benefit assumptions particularly for medicinal products of biological or biotechnology origin or on the epidemiological aspects related to the estimation of the number of patients affected by the disease ('prevalence').

The COMP Biotech Working Party will meet 3 to 6 time and the COMP Epidemiology Working Party will meet up to 4 times, according to requests.

Herbal Medicinal Products Working Party

- 3 meetings in 2002
- Develop a number of guidance documents in accordance with the Group's mandate adopted by the EMEA Management Board on 18 December 2001

The working documents of the Herbal Medicinal Products Working Party offer guidance for the evaluation of herbal medicines in order to promote consumer protection and facilitate mutual recognition in the Member States.

2.10 Mutual recognition facilitation group

Useful web site:	
Heads of agencies for medicines for human medicines	*http://heads.medagencies.org*
European product index	*http://mri.medagencies.com/prodidx*

The operation of the Mutual Recognition Facilitation Group (MRFG) will continue to be supported by the EMEA at its monthly meetings held on the day preceding the start of CPMP meetings.

Chapter 3
Veterinary medicines

Overview

Unit for the veterinary medicines and inspections

Head of Unit	Peter JONES
Head of Sector for veterinary marketing authorisation procedures	Jill ASHLEY-SMITH
Deputy Head of Sector for veterinary marketing authorisation procedures	Melanie LEIVERS
Head of Sector for safety of veterinary medicines	Kornelia GREIN
Head of Sector for inspections	Sheila KENNEDY *(acting)*

The work programme for inspections can be found in Chapter 4.

Committee for Veterinary Medicinal Products

Chairman of the CVMP	Steve DEAN
Vice-Chairman of the CVMP	Gérard MOULIN

Working parties and ad hoc groups

Efficacy Working Party	Liisa KAARTINEN
Immunologicals Working Party	David MACKAY
Pharmacovigilance Working Party	Cornelia IBRAHIM
Joint CPMP/CVMP Quality Working Party	Jean-Louis ROBERT
Safety Working Party	Christian FRIIS
ad hoc Group on Antimicrobial Resistance	Margarita ARBOIX

Priorities for veterinary medicines in 2002:

- Finalise the installation, testing and implementation of the EudraVigilance database in the veterinary medicines sector for reporting of serious adverse reactions.

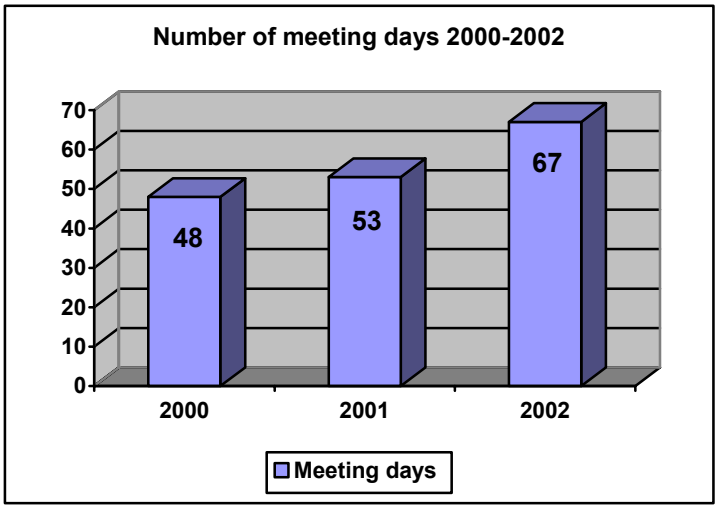
- Following completion of the consultation period initiated in October 2001, adopt final guidelines for the testing and authorisation of antimicrobials in veterinary medicine in compliance with the risk management strategic plan adopted by the CVMP in 2000 (EMEA/CVMP/818/99-final).

- Meet the Agency's obligations in successfully finalising the PERF II programme in respect of all agreed priority action areas relating to procedures for veterinary medicinal products.

- Ensure the adequate provision of EU expertise into the VICH initiative at a critical time, with particular emphasis on finalising the pharmacovigilance, safety testing and environmental impact assessment guidelines, as well as full support of the VICH 2 conference in Japan in October 2002.

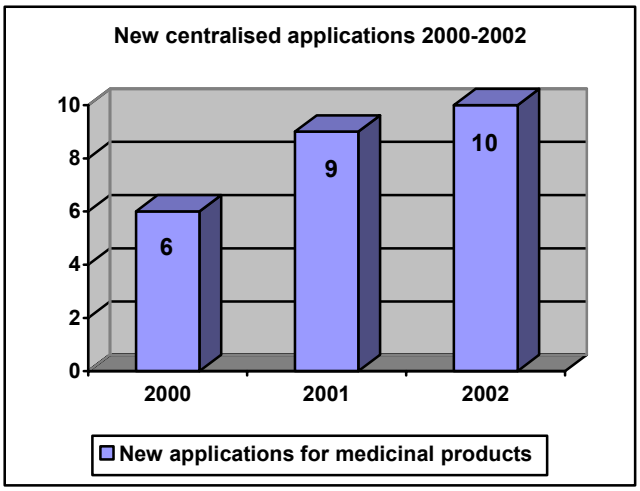
- Guarantee the processing of all applications in relation to the centralised procedure and maintenance activities for all veterinary medicinal products and the establishment of maximum residue limits within the legal timeframes and in a professional and efficient manner, and in accordance with the Agency's quality management system.

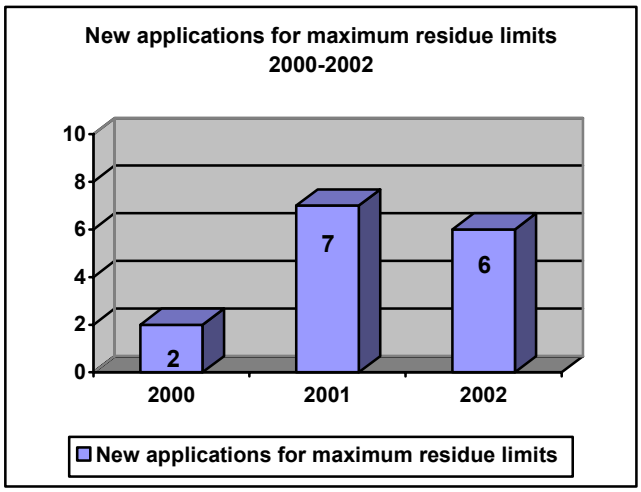
The increase in number of meeting days for the CVMP, working parties and ad hoc groups reflects the increased workload for veterinary medicines in 2002.



3.1 Initial evaluation

- Based on preliminary forecasts received from industry, a small increase in the number of applications for centralised authorisations is expected with 10 in applications in 2002
- Applications for new MRL applications are similarly expected to remain relatively stable with 6 in 2002
- Under the impetus of the EMEA quality management system, the Unit will develop a regulatory database that will be used to maximise consistency of guidance to industry. A scientific memory database is also under consideration as part of EMEA quality assurance





Objectives:

- Adhere to regulatory timelines for active review time by the CVMP
- Publication of summaries of opinion at the time of adoption by the CVMP
- Rapid publication of EPARs after the European Commission decision granting marketing authorisation

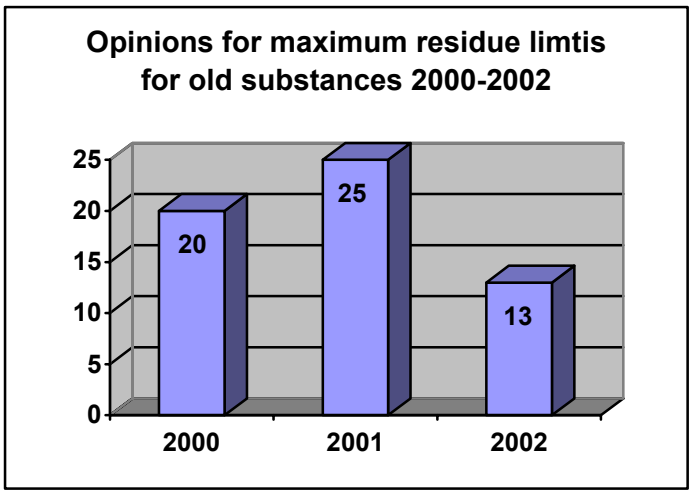
The CVMP will continue to meet on a monthly basis in 2002.

CVMP meetings in 2002
8-10 January
12-14 February
12-14 March
16-18 April
14-16 May
11-13 June
9-11 July
13-15 August[1]
10-12 September
8-10 October
12-14 November
10-12 December

[1] *Only if required*

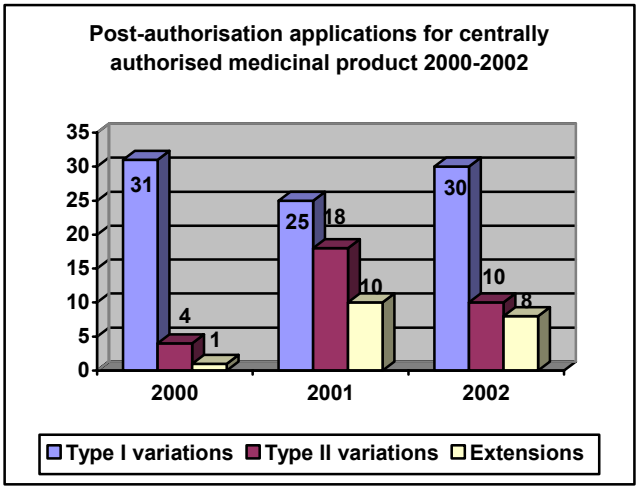
3.2 Establishment of maximum residue limits for old substances

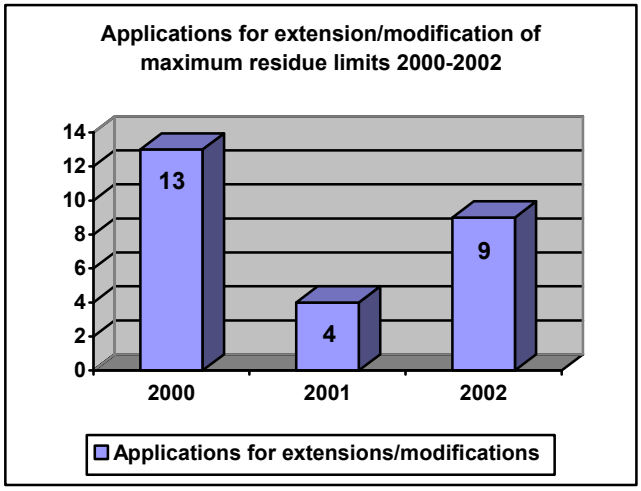
Work related to the establishment of definitive MRLs for old substances with provisional MRLs and placed in Annex III of Council Regulation (EC) No 2377/90 will continue in 2002. Thirteen substances remain pending.



3.3 Post-authorisation activities

- Post-authorisation activities will continue at a steady pace in line with the increased number of products authorised through the centralised procedure
- The number of expected variations is expected to return to normal levels following increases in 2001 as part authorisation holders' demonstration of compliance with the TSE guideline





Objectives:

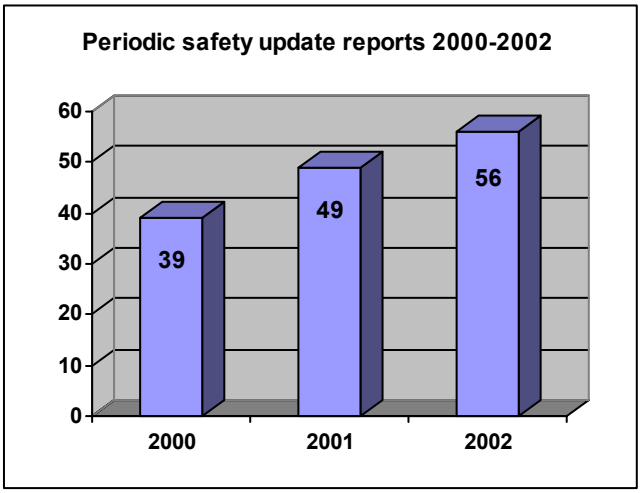
- Adhere to regulatory timelines for the processing of type I, type II and extension applications for marketing authorisations and for MRLs
- Keep workload evolution under review during 2002

3.4 Pharmacovigilance and maintenance activities

Maintenance activities relating to the post-authorisation surveillance of veterinary medicines will steadily rise in 2002. This is in line with the increase in the number of centrally authorised veterinary medicines. The level of pharmacovigilance activities will intensify in 2002.

Testing for the installation and implementation of the EudraVigilance pharmacovigilance database for veterinary medicines will be carried out. The system is expected to become operational during 2002.

- Annual reassessment will be carried out for 23 authorised medicinal products in 2002
- The number of periodic safety update reports (PSURs) submitted is expected to increase to 56
- 5 applications for renewal of marketing authorisations are expected



3.5 Scientific advice

The veterinary pharmaceutical industry makes relatively little use of the scientific advice services available and a maximum of 2 requests can be expected in 2002; 1 for the development of a new veterinary medicinal product and 1 relating to the establishment of the maximum residue limit for a new substance used in veterinary medicinal products.

3.6 Arbitration and Community referrals

Three arbitrations and Community referrals are forecast in 2002.

3.7 Interested parties

The secretariat commits to continued liaison and cooperation with interested parties to CVMP to underpin the spirit of transparency to ensure regular meetings on a quarterly basis with the Committee, as well as Infodays on topics of key interest, capitalising on the success of these meetings in the past.

In addition, focus groups of experts from the CVMP and interested parties will be convened to consider specific topics mutually agreed to by the Committee and interested parties.

3.8 International activities

The main international activities for the Unit for veterinary medicines and the CVMP in 2002 are:

Activities with European institutions and Member States

- Participation at a number of groups chaired by the European Commission, including the Veterinary Pharmaceutical Committee, the Notice to applicants group and meetings of heads of national competent authorities for veterinary medicines (HEVRA)

Activities with central and eastern European countries

- These activities are primarily organised through the Pan-European Regulatory Forum programme (PERF) and the different priority action areas relating to veterinary medicines

Participation in international forums

- The EMEA will ensure adequate coordination and provision of expertise to the VICH process. There will be two Steering Committee meetings in 2002, one in Washington, DC to be followed by another in association with the second VICH conference in Tokyo in October 2002
- The EMEA will continue to provide scientific expertise either as part of the European Commission delegation or in its own capacity to the Codex Alimentarius Commission, the World Health Organisation and other international forums

3.9 Working parties and ad hoc groups

Immunologicals Working Party

- 4 meetings in 2002
- Finalisation of guidance on harmonisation requirements for low and high potency and batch consistency of vaccines, and on vectored vaccines
- Revision of guidance on transmissible spongiform encephalopathy, on compliance with the European Pharmacopoeia, on equine influenza and on claims for veterinary vaccines

Efficacy Working Party

- 3 meetings in 2002
- Finalisation of guidance on antimicrobials for veterinary use, ectoparasiticide guidance for sheep, cattle and goats
- Consultation on VICH target animal safety guideline and preparation of a fluid therapy guideline

Pharmacovigilance Working Party

- 6 meetings in 2002
- Finalise and develop a number of measures for the implementation of the EudraVigilance database, including the VEDDRA list of clinical terms to take into account harmonisation at VICH, the electronic transmission and management of pharmacovigilance information and for the optimisation of drug monitoring
- Finalise development of a common reporting form for suspected adverse drug reactions, in cooperation with interested parties

Safety Working Party

- 5 meetings in 2002
- Assess responses to lists of questions in relation to provisional MRLs for old substances
- Develop guidelines as part of preparation for CVMP contribution to VICH
- Finalise revision of guidelines on safety evaluation of antimicrobial substances regarding the effect on human gut flora

Joint CPMP/CVMP Quality Working Party

- 4 meetings in 2002
- Guideline on modified release oral and transdermal dosage forms
- Development of guidance on near infra-red spectroscopy
- Revision of guidance on the European Drug Master File and other CVMP guidance documents

ad hoc Group on Antimicrobial Resistance

- 3 meetings in 2002
- Finalise guidance on pre-authorisation surveillance testing to satisfy regulatory requirements as part of the application for marketing authorisation

3.10 Veterinary mutual recognition facilitation group

Useful web site:
Heads of agencies for medicines for veterinary use *http://www.hevra.org*

The Unit will continue to provide secretariat support to the Veterinary Mutual Recognition Facilitation Group (VMRFG). The Group is responsible for the facilitation of applications within the mutual recognition procedure and is chaired on a rotating basis by a representative of the Member State holding the presidency of the European Union.

With the significant increase in workload that has occurred in this area and that foreseen in 2002, a national expert on secondment has been appointed to the EMEA to provide full-time support to the VMRFG.

Chapter 4
Inspections

The Sector for inspections is part of the Unit for Veterinary medicines and inspections	
Head of Sector	Sheila KENNEDY *(acting)*
ad hoc Meeting of GMP Inspection Services	Sheila KENNEDY and Katrin NODOP
ad hoc Meeting of GCP Inspection Services	Fergus SWEENEY

Priorities for inspections in 2002:

- Consolidate on significant progress made to date in advancing mutual recognition agreements (MRA). In particular, to prepare for implementation of the agreement with Japan through a confidence building phase; to continue work in implementing the agreement with the USA; to coordinate the operational agreements with Australia and New Zealand; and to progress the practical implementation of the MRAs with Canada and Switzerland.

- To manage the ad hoc Meetings of good manufacturing practice (GMP) and good clinical practice (GCP) Inspection Services, and work on continuing harmonisation of inspection processes in the EU. To continue contacts on good laboratory practice (GLP) inspections with the EMEA scientific committees and GLP inspectors in order to progress the procedures and concept.

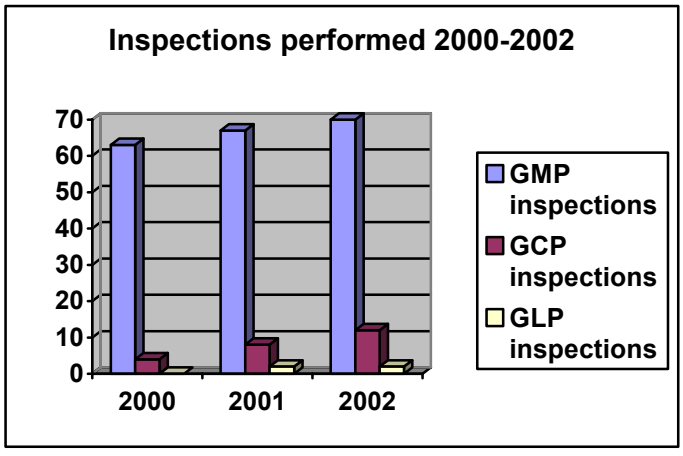
- Meet the Agency's obligations in successfully finalising the PERF II programme in respect of all agreed priority action areas relating to inspections and good manufacturing practices.

- Guarantee the processing of all requests for inspections within the legal timeframes and in a professional and efficient manner, and in accordance with the Agency's agreed quality standards.

Inspections

The number of requests for good manufacturing practice (GMP) inspections is expected to remain stable, with 70 inspections expected in 2002. The workload in dealing with associated product defect will continue to be significant.

The number of good clinical practice (GCP) inspections is forecast to rise in 2002 to 12 and provision for 2 good laboratory practice (GLP) inspections has been made in the event that these are requested by the scientific committees.



The ad hoc Group of GMP Inspectors will meet on 5 occasions in 2002, and will focus on the development of guidance on GMP issues and harmonisation of inspection procedures with a view to strengthening Member State inspection systems and increasing mutual confidence between Member States. Emphasis will be given to the implementation of the EU joint audit programme in the coming year.

The ad hoc Group of GCP Inspectors will also meet 5 times in 2002. The emphasis of the group will be on practical implementation of the procedures for GCP inspection in support of the centralised procedure. This includes working with assessors on the processes needed to initiate inspections, during review of the dossier, and the benefits to be obtained. There will also be significant work involved in preparation of guidelines for the clinical trial directive.

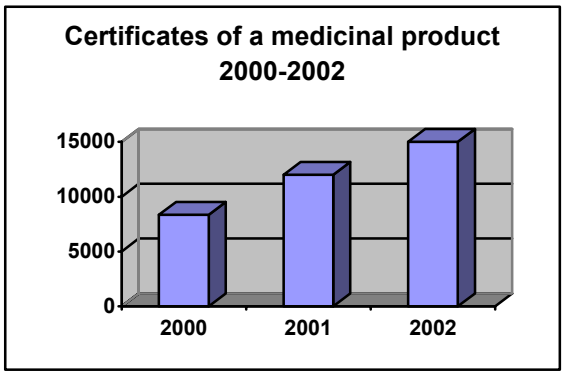
Work on the contract between the EMEA and the Italian Ministry of Health to assist Italy in training of inspectors and joint inspections will continue in 2002.

Mutual recognition agreements

Work will continue in 2002 on mutual recognition agreements (MRA), in particular in relation to the commencement of the 18-month preparatory work phase with regard to the MRA with Japan. The timing of the activities in the agreement with the USA remains uncertain, with a possible extension of the confidence-building phase for a further two years.

Certification of medicinal products

A significant increase of about 25 % for requests for certificates of medicinal products is expected in 2002. This is primarily due to the increasing number of centrally authorised medicines and to variations, extensions and renewals in connection with these authorisations.



Implementation of Council Directive 2001/20/EC

Guidance will be prepared for the implementation of the future clinical trials directive (Council Directive 2001/20/EC, OJ L 121, 1.5.2001, p. 34). Work will include development of specifications for the clinical trials database foreseen in the legislation. The EMEA has indicated its willingness to act as rapporteur for the development of the guideline on the clinical trials database, including the database for serious ADR reporting, as foreseen by Article 11(3) of the Directive.

This is a new area of activity for the EMEA not foreseen in the original budget request to the EU budget authority.

Chapter 5
Administration and support activities

Administration Unit	
Head of Unit	Andreas POTT
Head of Sector for personnel and budget	Frances NUTTALL
Head of Sector for infrastructure services	Sara MENDOSA (acting)
Head of Sector for accounting	Gerard O'MALLEY
Communications and networking Unit	
Head of Unit	*Post vacant*
Head of Sector for document management and publishing	Beatrice FAYL
Head of Sector for meeting management and conferences	Sylvie BÉNÉFICE
Head of Sector for project management	Tim BUXTON (acting)
Head of Sector for information technology	Michael ZOURIDAKIS
Deputy Head of Sector for information technology	David DRAKEFORD

The Administration Unit is now composed of three sectors, including a new sector dealing with infrastructure services. The sector brings together a number of services that were previously under different responsibilities within the EMEA, in particular facilities management, archiving, reprographics and mail room services.

The newly created Communications and networking Unit is focused on provision of services aimed at the Agency's partners, including the provision of information to the public and extensive logistical and technical support to national competent authorities. It is also responsible for provision of IT services for the EMEA.

5.1 Administration

Personnel and budget

The personnel service will experience a marked increase in workload in for the selection and recruitment of new staff foreseen in the 2002 budget. In addition, the sector will deal with the replacement of staff that resign and the continuing administration of entitlements for existing, new and leaving staff.

It is expected that a total of about 65 new members of staff will join the EMEA in 2002. The Agency's personnel database will be further developed in 2002.

The Agency's human resources management policy will be overhauled in 2002. This will include
- Improvements to recruitment patterns through widening of the scope of publications of employment opportunities at the EMEA
- Development of more family-friendly employment patterns
- Development of training and competence development for staff members, including specific professional training to enable staff to retain potential for mobility with regard to other European Union bodies and the private sector

Work towards the formalisation of the Agency's personnel policy in a single document will be progressed, in line with the recommendation of the European Court of Auditors.

In addition to the ongoing budget planning and monitoring activities, the sector will transfer the EMEA budget to a VAT-neutral system.

Infrastructure services

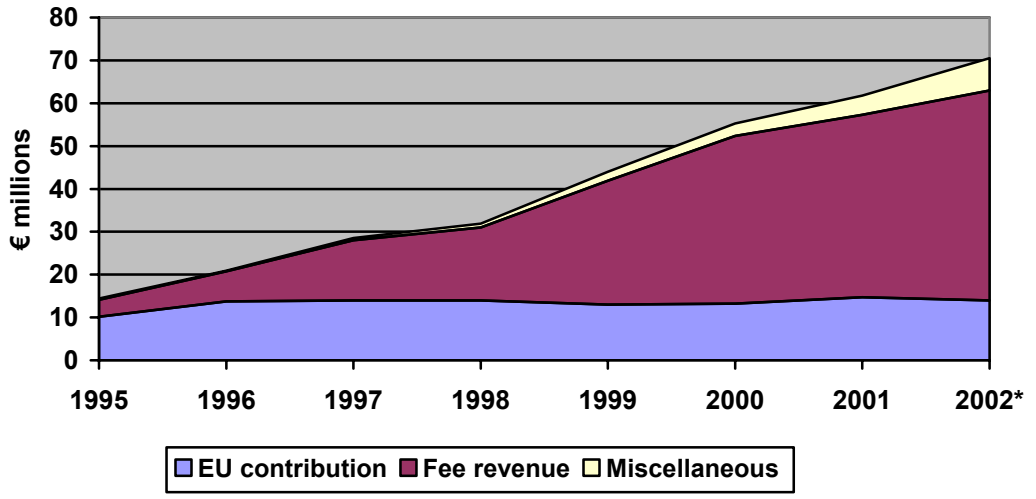
The service has a number of projects in 2002, including

- Develop and implement a business continuity plan
- Acquisition and refurbishment of the 6th floor at the EMEA offices, together with associated works elsewhere in the EMEA offices
- Develop an archive database for files stored offsite from the EMEA
- Installation of a digital photocopying network
- Installation of digital closed-circuit television

Accounting

Key objectives in 2002 include:

- Revise the EMEA Financial Regulation in line with the reform of the financial regulations of the European Union institutions
- Improve the process for reimbursement of meeting expenses for delegates at the EMEA
- Upgrade the internal accounting software, including integration into other finance-related systems at the EMEA
- Further develop analytical accounting and activity costing information as part of the costing exercise



(*) Budget for 2002 adopted by the Management Board 18 December 2001.

5.2 Document management and publishing

The sector is responsible for publishing, cataloguing, distributing and conserving EMEA documents. These activities include quality management (particularly in the areas of translations, product information quality and the coherence of regulatory documents) and logistics (the EMEA library, physical and electronic archiving).

Priorities in 2002 are:

- Continue the implementation of the electronic document management system: The whole Agency will be transferred to the new system during the early part of 2002 in order to be able to take advantage of the improvement in accessibility of documents that the system offers. Once this has been achieved, work will be undertaken to implement electronic workflows for a selected number of areas of activity in the Agency. The implementation will continue in order to complete electronic workflows wherever appropriate throughout the Agency before the end of 2004.

- Contribute to the development of information publishing on the EMEA web site and manage the expected increase in documents. The sector will also contribute to the ongoing supervision and management of the site.

- Implement a new publication strategy to ensure faster publication of key documents, including the launch of a tender for local printing of key documents such as annual reports and work programmes.

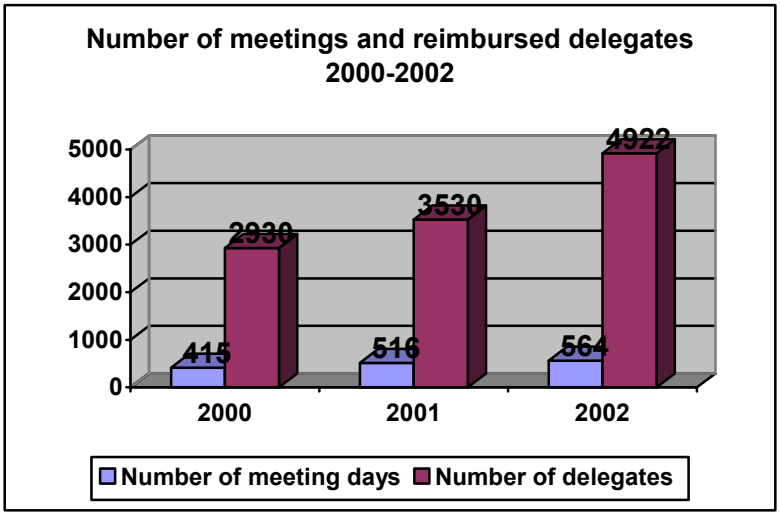
- Manage the document dissemination service, with the target of dealing with 95 % of requests for documents within 48 hours. The number of requests is expected to rise from 3 200 in 2001 to 4 000 in 2002, despite the increase in availability of documents on the web site.

5.3 Meeting management and conferences

The Sector is responsible for ensuring efficient support for EMEA meetings by providing the best possible facilities and services and constantly improving the resources available, as well as assisting delegates with logistics and practical arrangements.

Priorities in 2002 are:

- Develop new forms of meetings, particularly in view of the increase in number of meetings held at the EMEA and the future enlargement of the European Union
- Complete implementation of the computerised meetings management system. Review procedures for reimbursement of delegates to assist with the expected increase in number of delegates
- Support operation of the Pan-European Regulatory Forum (PERF), particularly with the provision of documentation, technical reports and conference proceedings
- Implement videoconferencing capacities to improve and maximise the participation by experts in the work of the scientific committees, working parties and mutual recognition facilitation groups



The rise in number of reimbursed delegates in 2002 will come from an increased number of ad hoc meetings related to the evaluation of medicinal products for human use, increased use of experts in the designation process for orphan medicines and also from preparation and implementation of a number of special projects, in particular relating to the Agency's future role in the Community pharmaceuticals regulatory IT strategy.

5.4 Project management

The Sector has been set up in order to provide a single point within the Unit for Communications and networking to coordinate and manage individual projects whose objectives are aligned with those of the Unit. These objectives may be summarised as the facilitation of communications within the European regulatory network, focusing on the communication tools, IT systems and logistical support required.

The overall objectives for 2002 will be to structure and proceed with the projects, both new and old, for which it will have responsibility. The Sector will manage both internal EMEA projects and Europe-wide projects as part of the European network. These projects include:

- Management and organisation of the Pan-European Regulatory Forum
- Implementation of the electronic Common Technical Document (eCTD) format for submission of applications for marketing authorisations
- Implementation of the product information management project (PIM). This is a project to define an exchange standard for the electronic submission of product information included in the summary of product characteristics, the patient information leaflet and product packaging
- Implementation of the EudraVigilance system
- Implementation of an EMEA electronic document management system
- Preparation for the EuroPharm database, a database of information on all products authorised within the EU
- Development of a clinical trials database

5.5 Information technology

The sector's mission is to supply reliable and robust information technology (IT) services to the Agency. These services include appropriate levels of operational support, internal development activities, and technical support for projects with an external focus. The EMEA has agreed to take on responsibility for the majority of the pan-European information technology projects and services with effect from January 2003 in accordance with a strategy proposal and implementation plan developed by the European Commission. This constitutes a major change in the scope of the Agency's IT activities with consequences during 2002 (as the Agency puts in place the necessary structures and resources to assume the new responsibilities) and 2003, as the EMEA consolidates the changes effected during 2002 and takes on its new responsibilities in full.

Internal services

During 2002, the IT sector will seek to achieve the following:

Function	Activity	Applications & equipment
Operational support	- Ensure a minimum a minimum internal system availability of 98% of IT services during EMEA working hours	Contribute to the business continuity/disaster recovery project
	- Provide helpdesk facilities in accordance with the levels of service required by the Agency	Equip and connect the 6th floor;
	- Execute the replacement of obsolete equipment and applications in accordance with the defined lifecycle criteria	Replace screens; design and implementation of storage area network; contribute to definition of an electronic archiving policy
Development	- Implement upgrades to customised applications as required by new releases of the underlying proprietary applications	Personnel database; Sincom 2
	- Develop and implement upgrades to bespoke and customised applications in production at the EMEA in accordance with the priorities defined by EMEA management	Scientific memory database; Scientific advice database; Orphan drug database; experts database; ActiTrak
	- Develop or continue the development of new applications in accordance with the priorities defined by EMEA management	Meetings management system
Project support and management	- Technical support in the development and implementation of major projects	PIM and the eCTD; SIAMED; electronic document management system

European initiatives and activities

The IT sector will undertake the activities set out below in support of the European initiatives and activities

Initiative	Activities
EudraNet	- Preparation for the assumption of operational responsibility from January 2003 - Chair of the EudraNet Telematics Implementation Group
EudraVigilance	- Operational support to ensure 99% system availability - Management and support of development contractors for the implementation of phases 2 and 3 of the project, including the electronic gateway - Coordination of the testing pilot group including participants from Member States and industry - Chair of the EudraVigilance Telematics Implementation Group
EuroPharm database	- Technical assistance in the specification of the data model and user requirements - Technical assistance in ensuring appropriate compatibility of data field definitions across all pan-European projects - Technical assistance with the trial implementation of the database in conjunction with the nominated developer
Electronic submission	- Technical assistance and support in setting up the necessary systems to receive electronic submissions in accordance with the eCTD - Technical assistance and support in the definition and implementation of the applications necessary to manage data that has been electronically submitted - Technical assistance and support in the definition and implementation of the applications necessary to work with data that has been electronically submitted

Annexes

1. **EMEA establishment plan 2000– 2002**
2. **EMEA budget summaries 2000 – 2002**
3. **EMEA contact points and reference documents**
4. **Profiles of EMEA personalities**

Annex 1
EMEA establishment plan 2000 – 2002

	2000	2001		2002
Category and Grade	**Occupied as at 31.12.2000**	**Authorised for 2001**	**Occupied as at 31.12.2001**	**Authorised for 2002**
A1	--	--	--	--
A2	--	1	1	1
A3	4	5	4	5
A4	24	29	26	29
A5	22	27	24	28
A6	25	25	24	29
A7	23	24	24	30
A8	--	--	--	--
TOTAL A	**98**	**111**	**103**	**122**
B1	3	4	4	4
B2	4	8	8	9
B3	6	9	9	11
B4	5	6	5	9
B5	5	5	5	8
TOTAL B	**23**	**32**	**31**	**41**
C1	13	14	14	15
C2	13	14	13	19
C3	37	44	42	44
C4	--	--	--	4
C5	--	--	--	--
TOTAL C	**63**	**72**	**69**	**82**
D1	1	1	1	1
D2	4	4	4	5
D3	--	--	--	--
D4	--	--	--	--
TOTAL D	**5**	**5**	**5**	**6**
TOTAL POSTS	**189**	**220**	**208**	**251**

Allocation of posts		
	Allocation in 2001	Allocation in 2002
Directorate and financial control	11	11
Directorate total	*11*	*11*
Administration Unit		
Head of Unit team	2	2
Sector for Personnel and budget	10	11
Sector for Infrastructure services	17	19
Sector for Accounting	6	7
Reserve posts	2	--
Unit total	*37*	*39*
Unit for the Pre-authorisation Evaluation of Medicines for Human Use		
Head of Unit team	2	2
Sector for Scientific advice and orphan drugs	12	14
Sector for Quality of medicines	19	21
Sector for Safety and efficacy of medicines	16	19
Reserve posts	--	1
Unit total	*49*	*57*
Unit for the Post-authorisation Evaluation of Medicines for Human Use		
Head of Unit team	2	2
Sector for Regulatory affairs and organisational support	22	24
Sector for Pharmacovigilance and post-authorisation safety and efficacy of medicines	27	35
Reserve posts	--	--
Unit total	*51*	*61*
Unit for Veterinary Medicines and Inspections		
Head of Unit team	4	4
Sector for Veterinary marketing authorisation procedures	8	10
Sector for Safety of veterinary medicines	7	8
Sector for Inspections	14	14
Reserve posts	--	--
Unit total	*33*	*36*
Communication and Networking Unit		
Head of Unit team	2	2
Sector for Document management and publishing	9	10
Sector for Meeting management and conferences	8	9
Sector for Project management	5	6
Sector for Information technology	15	19
Reserve posts	--	--
Unit total	*39*	*46*
Additional posts in general reserve	--	1
Total number of posts	**220**	**251**

Annex 2
EMEA budget summaries 2000 – 2002

The summarised comparative budget statements for 2000 to 2002 are as follows:
(Amounts expressed in euro)

	2000[1] (31.12.2000)		2001[2] (31.12.2001)		2002[3] (18.12.2001)	
Revenue						
Fees	39 154 000	*70.82%*	45 771 000	*69.49%*	49 000 000	*69.46%*
General EU contribution	13 200 000	*23.88%*	14 700 000	*22.32%*	14 000 000	*19.84%*
Special EU orphan medicinal product contribution	1 000 000	*1.81%*	600 000	*0.91%*	3 300 000	*4.68%*
Contribution from EEA	245 220	*0.44%*	287 640	*0.44%*	310 000	*0.44%*
Contribution from EU programmes (PERF)	217 000	*0.39%*	2 314 360	*3.51%*	1 632 000	*2.31%*
Other	1 471 000	*2.66%*	2 193 000	*3.33%*	2 305 000	*3.27%*
TOTAL REVENUE	**55 287 220**	*100.00%*	**65 866 000**	*100.00%*	**70 547 000**	*100.00%*
Expenditure						
Staff						
Salaries	18 493 000	*33.45%*	20 615 000	*31.30%*	24 952 000	*35.37%*
Interim and other support persons	1 058 000	*1.91%*	1 414 000	*2.15%*	1 905 000	*2.70%*
Other staff-related expenditure	1 350 000	*2.44%*	1 683 640	*2.56%*	1 776 000	*2.52%*
Total title 1	*20 901 000*	*39.80%*	*23 712 640*	*36.00%*	*28 633 000*	*40.59%*
Building/equipment						
Rent/charges	5 212 220	*9.43%*	5 149 000	*7.82%*	5 936 000	*8.41%*
Expenditure on data processing	2 423 500	*4.38%*	4 293 000	*6.52%*	2 570 000	*3.64%*
Other capital expenditure	2 353 000	*4.26%*	1 658 000	*2.52%*	1 170 000	*1.66%*
Postage and communications	480 000	*0.87%*	617 000	*0.94%*	394 000	*0.56%*
Other administrative expenditure	1 593 000	*2.88%*	1 829 000	*2.78%*	1 925 000	*2.73%*
Total title 2	*12 061 720*	*21.82%*	*13 546 000*	*20.57%*	*11 995 000*	*17.00%*
Operational expenditure						
Meetings	3 270 000	*5.92%*	4 110 000	*6.24%*	4 320 000	*6.12%*
Evaluations	18 682 500	*33.79%*	21 308 000	*32.35%*	23 333 000	*33.07%*
Translation	*p.m.*	*0.00%*	428 000	*0.65%*	359 000	*0.51%*
Studies and consultants	5 000	*0.01%*	225 000	*0.34%*	85 000	*0.12%*
Publications	150 000	*0.27%*	190 000	*0.29%*	190 000	*0.27%*
EU programmes	*217 000*	*0.39%*	2 346 360	*8.20%*	1 632 000	*2.31%*
Total title 3	*22 324 500*	*40.38%*	*28 607 360*	*43.43%*	*29 919 000*	*42.41%*
TOTAL EXPENDITURE	**55 287 220**	*100.00%*	**65 866 000**	*100.00%*	**70 547 000**	*100.00%*

Notes
(1) Final appropriations for the 2000.
(2) Final appropriations for 2001.
(3) Budget for 2002 as adopted by the Management Board on 18.12.2001.

Annex 3
EMEA guidelines for 2002

The following documents are intended to be finalised or released for consultation in 2002.

CPMP Biotechnology Working Party

Document title
Revision of Note for guidance on minimising the risks of TSE transmission via medicinal products
CPMP recommendations on vCJD and plasma derived medicinal products – CPMP recommendations on transmissible agents and urinary derived medicinal products
Note for guidance on the use of bovine serum used in the manufacture of human biological medicinal products
Note for guidance on the production and quality control of animal immunoglobins and immunosera for human use
Cell culture inactivated influenza vaccines – Annex to Note for guidance on harmonisation of requirements for influenza vaccines
EU recommendations for the influenza vaccine composition for the season 2002/2003
Plasma master file: Contribution to part S.2.3 of the structure of the dossier for applications for marketing authorisation – control of starting materials for the production of plasma-derived medicinal products

CPMP Blood Products Working Party

Document title
Note for guidance on the clinical investigation of plasma derived antithrombin products
Core summary of product characteristics for plasma-derived antithrombin products
Note for guidance on the clinical investigation of human normal immunoglobulin for intramuscular and subcutaneous use
Core summary of product characteristics for human normal immunoglobulin for intramuscular and subcutaneous use
Note for Guidance on the clinical investigation of plasma derived fibrin sealants
Core summary of product characteristics for plasma derived fibrin sealants
Note for guidance on the clinical investigation of von Willebrand factor
Core summary of product characteristics for von Willebrand factor
Note for guidance on the clinical investigation of alpha$_1$ antitrypsin
Core summary of product characteristics for alpha$_1$ antitrypsin
Core summary of product characteristics for the following specific immunoglobulins**:** ▪ Human varicella-zoster immunoglobulin i.v. ▪ Human cytomegalovirus immunoglobulin i.v. ▪ Human rabies immunoglobulin i.m. ▪ Human tetanus immunoglobulin i.m. ▪ Human tick-borne encephalitis immunoglobulin i.m. ▪ Human measles immunoglobulin i.m. ▪ Human rubella immunoglobulin i.m.
Core summary of product characteristics for Hepatitis B immunoglobulin
Revision of core summary of product characteristics for human normal immunoglobulin for intravenous use – addition of indication for treatment of parvovirus B19 infection
Revision of core summary of product characteristics for human plasma derived factor VII products and human plasma prothrombin complex
Revision of core summary of product characteristics for factor VIII inhibitor bypassing fraction
Warning on transmissible agents for patient leaflets and summary of product characteristics
Revision of core summary of product characteristics for human anti-D immunoglobulin for intravenous and/or intramuscular use (CPMP/BPWG/574/99)

CPMP Efficacy Working Party

Document title
Note for guidance on clinical investigation of medicinal products for the treatment of diabetes mellitus
Note for guidance on clinical investigation of anti-depressive agents
Note for guidance on clinical investigation of medicinal products for pain treatment
Position paper on new modified formulations of acetyl salicylic acid in the secondary prevention of cardiovascular events
Note for guidance on clinical investigation of medicinal products for treatment of peripheral arterial occlusive disease
Concept paper on the revision of the Note for guidance on evaluation of new anti-bacterial medicinal product (CPMP/EWP/558/95) and the Note for guidance on the pharmacodynamic section of the summary of product characteristics for antibacterial products
Points to consider on biostatistical/methodological issues arising from CPMP discussion on licensing applications: Adjustment for multiplicity and related topics
Points to consider on biostatistical/methodological issues arising from CPMP discussion on licensing applications: Adjustment for baseline covariates
Points to consider on the clinical investigation of medicinal products in the treatment of asthma
Note for guidance on the clinical investigation of medicinal products for the treatment of urinary incontinence in women
Note for guidance on the evaluation of medicinal products for treatment of migraine
Appendix to the CPMP Note for guidance on the clinical investigation of medicinal products in the treatment of schizophrenia, on methodology of clinical trials concerning the development of depot preparations of approved medicinal products in schizophrenia
Note for guidance on the evaluation of medicinal products indicated for thrombolysis in acute myocardial infarction
Addendum on acute cardiac failure to the CPMP Note for guidance on clinical investigation of medicinal products in the treatment of acute cardiac failure
Note for guidance on the evaluation of medicinal products for the treatment of dyslipoproteinaemia
Points to consider on clinical investigation of slow-acting anti-rheumatic medicinal products in rheumatoid arthritis
Points to consider on irritable bowel syndrome
Points to consider document on the evaluation of new anti-fungal agents for invasive fungal infections
Points to consider on biostatistical/methodological issues arising from CPMP discussion on licensing applications: Choice of delta
Points to consider on the requirements for clinical documentation for metered dose inhalers
Addenda for neuropathic pains to be considered
Clinical investigation of hypnotic medicinal products
Clinical Investigation of Medical Products in the Treatment of Generalised Anxiety Disorder, Panic Disorder and Obsessive-compulsive DisorderRevision
Note for guidance on Anthiarrhythmics
Note for guidance on Clinical investigation of steroid contraceptives in women
Clinical Investigation of Corticosteroids Intended for use on the Skin.
Note for guidance on Pharmacokinetic Studies in man
Points to consider on Live attenuated influenza vaccines
Guidance on requirements for pharmaceutical/clinical documentation for Cell culture influenza vaccines
Points to consider on xenogeneic cell therapy
Note for guidance on comparability of medicinal products containing biotechnology-derived proteins as active substance
Note for guidance on the use of medicinal products during pregnancy: need for post-marketing data
Note for guidance on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling
Revision of the Note for guidance on harmonisation of requirements for influenza vaccines

CPMP Safety Working Party

Document title
Revision of Note for guidance on carcinogenic potential (3BS7a, Volume 3B, 1998, p. 63)
Note for guidance on photosafety testing
Points to consider document on the need for assessment of reproductive toxicity of human insulin analogues
Discussion paper on environmental risk assessments of non-GMO containing medicinal products for human use
Non-clinical documentation of medicinal products with 'well-established use'
Note for guidance on the need for non-clinical testing of pharmaceuticals in juvenile animals
Discussion paper on the non-clinical safety studies to support single low dose clinical screening studies in man
Note for guidance on specification limits for residues for heavy metal catalysts in medicinal products
Points to consider on xenogeneic cell therapy
Note for guidance on comparability of biotechnology products pre-clinical and clinical issues
Points to consider on the assessment of the potential for QT interval prolongation by non-cardiovascular medicinal products
Note for guidance on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling

CVMP Efficacy Working Party

Document title
Antimicrobials for veterinary use
Summary of product characteristics for antimicrobial products
Ectoparasiticide guidance for sheep, cattle and goats
Fluid therapy

CPMP Pharmacovigilance Working Party

Document title
Revision of Note for guidance on the conduct of pharmacovigilance for centrally authorised products
Revision of crisis management plan regarding centrally authorised products for human use
Guidance document for the implementation of the position paper on compliance with pharmacovigilance regulatory obligations
Contribution to Note for guidance on the use of medicinal products during pregnancy: Need for post-marketing data
Contribution to CPMP Points to consider document on xenogeneic cell therapy
Proposals for revision to Standard operating procedure on urgent safety restrictions for medicinal products authorised through the mutual recognition procedure

CVMP Immunologicals Working Party

Document title
Harmonisation requirements for low and high potency and batch consistency of vaccines
Harmonisation requirements for low and high potency and batch consistency of vectored vaccines
Requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products
Revision: transmissible spongiform encephalopathy
Revision: compliance with the European Pharmacopoeia
Revision: equine influenza
Revision: claims for veterinary vaccines
VICH: Biologicals: testing of residue formaldehyde
VICH: Biologicals: testing of residual moisture

CVMP Pharmacovigilance Working Party

Document title
VICH: Pharmacovigilance of veterinary medicinal products: Management of adverse event reports
VICH: Pharmacovigilance of veterinary medicinal products: Management of periodic summary update reports
VICH: Pharmacovigilance of veterinary medicinal products: Controlled list of terms
Processing of renewals in the centralised procedure

CVMP Safety Working Party

Document title
Safety evaluation of antimicrobial substances regarding the effects on human gut flora
VICH: Pre-approval information for registration of new medicinal products for food producing animals with respect to antimicrobial resistance
VICH: Studies to evaluate the safety of residues of veterinary drugs in human food: Carcinogenicity testing
Pre-authorisation studies to assess the potential for resistance resulting from the use of antimicrobial veterinary medicinal products

Joint CPMP/CVMP Quality Working Party

Document title
In-use stability testing of veterinary medicinal products
Use of near infrared spectroscopy by the pharmaceutical industry
Modified release oral and transdermal dosage forms
Revision: European Drug Master File

Annex 4
EMEA contact points

Pharmacovigilance and product defect reporting

The constant monitoring of the safety of medicines after authorisation ('pharmacovigilance') is an important part of the work of the national competent authorities and EMEA. The EMEA receives safety reports from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use	Noël WATHION Direct telephone (44-20) 74 18 85 92 E-mail: noel.wathion@emea.eu.int
For matters relating to pharmacovigilance for medicinal products for veterinary use	Barbara FREISCHEM Direct telephone (44-20) 74 18 85 81 E-mail: barbara.freischem@emea.eu.int
For product defect and other quality-related matters	Francisco PEÑARANDA FERNANDEZ Fax number for defective product rapid alerts (44-20) 74 18 85 90 E-mail: francisco.penaranda@emea.eu.int

Certificates of a medicinal product

The EMEA issues certificates of a medicinal product in conformity with the arrangements laid down by the World Health Organisation. These certify the marketing authorisation and good manufacturing status of medicinal products in the EU and are intended for use in support of marketing authorisation applications in and export to non-EU countries.

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use	Jonna SUNELL-HUET Direct telephone (44-20) 74 18 84 65 E-mail: certificate@emea.eu.int

Documentation services

A wide range of documents has now been published by the EMEA, including press releases, general information documents, annual reports and work programmes. These and other documents are available either on the Internet at *http://www.emea.eu.int* or by writing to:

Subscription Service
European Agency for the Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
UK - London E14 4H

A subscription service is available for all EMEA public documents, distributing documents electronically or in paper form.

Further information can be obtained from the above address or from	Iro MAVROPOULOS Direct telephone (44-20) 74 18 85 82 E-mail: subscriptions@emea.eu.int
Requests for general information packs should be sent to	Amanda BOSWORTH Direct telephone (44-20) 74 18 84 08 E-mail: amanda.bosworth@emea.eu.int

European experts lists

The list of European experts is available for examination on request at the EMEA offices. Requests may be made either in writing to the EMEA or sent to the following e-mail addresses:

Human medicines' experts list	human_experts@emea.eu.int
Veterinary medicines' experts list	vet_experts@emea.eu.int
Inspectors' experts list	inspectors_experts@emea.eu.int

Press office

Press officer	Martin HARVEY Direct telephone (44-20) 74 18 84 27 E-mail: martin.harvey@emea.eu.int

Annex 5
Profiles of EMEA personalities

Keith Jones, Chairman of the Management Board, b. 14 October 1937, n. British

Education: Dr Jones is qualified in medicine and has held posts in clinical medicine and research at UK teaching hospitals. He then trained as a toxicologist in the agrochemical industry.
Career to date: Dr Jones went on to spend 22 years in industry as Head of the Medical Department at Fisons Agrochemical Divisions, Head of Safety Assessment and Clinical Pharmacology at Beecham Pharmaceuticals and Executive Director, Medical Affairs at Merck Sharp and Dohme in the USA. In 1991 Dr Jones was appointed Chief Executive of the UK Medicines Control Agency, and is presently the UK delegate to the EU Pharmaceutical and Standing Regulatory Committees, and a member of the EU Scientific Steering Committee within the European Commission Directorate-General for Public health and consumer protection. He is currently visiting Professor of Pharmacology at the School of Pharmacy University of London and has published widely. Dr Jones joined the EMEA Management Board in 1995 and was elected chairman of the Board in 2001.

Gerhard Josef Kothmann, Vice-Chairman of the Management Board, b. 23 July 1943, n. German

Education: Qualified veterinary surgeon from the University of Hanover.
Career to date: After a period of general veterinary practice, Dr Kothmann joined the German Federal Research Centre for Animal Virus Diseases in 1970 and the veterinary administrative service for Lower Saxony in 1972. He moved to the German Federal Ministry for Health in 1975 where he has served in various posts, including in the division responsible for veterinary pharmaceutical sector, and in 1990 he collaborated in the reconstruction of the veterinary services in the new federal Länder. He was appointed Chief Veterinary Officer in 1991. Dr Kothmann joined the EMEA Management Board in 1996 and was elected vice-chairman in 2000.

Thomas Lönngren, Executive Director, b. 16 December 1950, 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.
Career to date: From 1976 to 1978, lecturer at University of Uppsala. Mr Lönngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990 during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1982 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He is Executive Director of the EMEA since January 2001.

EMEA scientific committees

Daniel Brasseur, Chairman of the CPMP, b. 7 June 1951, n. Belgian

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

Eric Abadie, Vice-chairman of the CPMP, b. 14 July 1950, n. French

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

Steve Dean, Chairman of the CVMP, b. 2 August 1951, n. British

Education: Qualified veterinary surgeon from the Royal Veterinary College, London. Diploma in veterinary radiology.
Career to date: Mr Dean has spent periods of time in general veterinary practice, as a lecturer in anatomy and radiology at the Royal Veterinary College, London and in technical and business positions in the veterinary pharmaceutical industry. During his employment with industry he worked in a variety of product areas including anthelmintics, hormones, growth promoters and veterinary immunology. He is currently Director of Licensing at the Veterinary Medicines Directorate in the UK and is a past Chairman of the Veterinary Mutual Recognition Facilitation Group. He was appointed a member of the CVMP in August 1999.

Gérard Moulin, Vice-chairman of the CVMP, b. 18 October 1958, 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). Since 1997 he is an active participant in the CVMP and VMRF group.

Josep Torrent i Farnell, Chairman of the COMP, b. 2 May 1954, n. Spanish

Education: Qualified Pharmacist and Degree in medicine and surgery from the University of Barcelona as well as postgraduate courses in pharmacology and toxicology, public health and European institutions. Specialist in internal medicine and clinical pharmacology. Doctorate in clinical pharmacology from the Autonomous University of Barcelona (UAB).
Career to date: From 1977-1990, Prof. Torrent i Farnell worked in internal medicine and clinical pharmacology in Spain and was Assistant Professor of Pharmacology at UAB. From 1990 to 1994, he was Technical Counsellor in Clinical Evaluation and Pharmacology at the Spanish Ministry of Health, Member of the CPMP Efficacy Working Party and involved in the Efficacy Group of the ICH. In 1992, he became Professor of Clinical Pharmacology and Therapeutics and Director of the Masters/Diploma course on European Registration of Medicinal Products (UAB). He joined the EMEA in 1995 as Principal Scientific Administrator and from 1996 to 1998 he was Head of Sector for new chemical substances. In 1998 he was coordinator Director for the creation of the Spanish Medicines Agency and Executive Director of the Spanish Medicines Agency from 1999-2000. He was elected Chairperson of the Committee for Orphan Medicinal Products in May 2000. In November 2000, he became Director-General of the Advanced Centre of Services and Training for Health and Life Sciences, Dr. Rober Foundation (UAB).

Yann Le Cam, Vice-chairman of the COMP, b. 15 July 1961, n. French

Education: He is a graduate in business administration from the Institut Supérieur de Gestion in Paris. He also holds an MBA from the Centre de Perfectionnement aux Affaires, Groupe HEC-CPA, 2000, Jouy-en-Josas, France.
Career to date: Mr Le Cam has 15 years of professional experience and personal commitment in health and medical research non-governmental organisations in France, Europe and the United States in the fields of cancer, AIDS and genetic diseases. He served as Director-General of AIDES Fédération Nationale from 1992 to 1998. He later joined the French Neuromuscular Diseases Association (AFM) as Special Advisor to stimulate public health policy on rare diseases, to create the French Alliance Maladies Rares, a national umbrella organisation of 70 patients associations, and to advise the European Organisation for Rare Disorders (Eurordis), based in Paris. He is also the Vice-Chairman of the International Alliance of Patients Organisations (IAPO) based in London. Mr Le Cam has three daughters, the eldest of whom is affected by cystic fibrosis.

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

Patrick Le Courtois, Head of Unit, b. 9 August 1950, 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 education. In 1990, he joined the Pharmacy Directorate of the French Ministry of Health and in 1993 the French Medicines Agency as CPMP rapporteur, Head of Unit of European Procedures and from January 1995 as a French CPMP delegate. He joined the EMEA in September 1997 and was appointed Head of Sector for new chemical substances in June 1998 and Head of Sector for orphan drugs and scientific advice in January 2001.

Agnès Saint Raymond, Head of Sector for orphan drugs and scientific advice, b. 7 September 1956, n. French

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

John Purves, Head of Sector for quality of medicines, b. 22 April 1945, n. British

Education: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. PhD in pharmaceutical microbiology from the University of Strathclyde, Glasgow.
Career to date: From 1972 to 1974, Dr Purves worked in the pharmaceutical industry. Between 1974 and 1996, he held posts in the UK Medicines Division and the Medicines Control Agency, including inspector of pharmaceutical manufacture, reviewer of dossiers and manager of the Biotechnology and Biological Unit. He was the UK representative at the Biotechnology Working Party, involved in the generation of many guidelines relating to biotechnology and biological products. He joined the EMEA in August 1996 as Head of Sector for biotechnology and biologicals. He was appointed Head of Sector for quality of medicines in January 2001.

Isabelle Moulon, Head of Sector for safety and efficacy of medicines, b. 9 March 1958, n. French

Education: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology. Post-graduate studies in statistics, methodology and nutrition.
Career to date: Worked as a clinical endocrinologist in a French 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 appointed Head of Sector for safety and efficacy of medicines in January 2001.

Marisa Papaluca Amati, Deputy Head of Sector for safety and efficacy of medicines, b. 12 October 1954, n. Italian

Education: Degree in medicine and surgery from the University of Rome. Specialist in internal medicine. Post-graduate studies in cardiology and endocrinology.
Career to date: From 1978 to 1983 Dr Papaluca worked as a research fellow in the State University of Rome on projects in the area of clinical immunology, oncology and cellular immunology. From 1984 to 1994, as medical director of the Pharmaceutical Department of the Italian Ministry of Health, she was in charge of the Operative Centre for Community Procedures and was an Italian member of the former Committee for Proprietary Medicinal Products. Dr Papaluca has acted as EU rapporteur for an ICH efficacy topic and as a member of the International CIOMS Working Groups I and II on pharmacovigilance. She joined the EMEA in October 1994. She was appointed Deputy Head of Sector for safety and efficacy of medicines in January 2001.

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

Noël Wathion, Head of Unit, b. 11 September 1956, n. Belgian

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

Tony Humphreys, Head of Sector for regulatory affairs and organisational support, b. 12 December 1961, n. Irish

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

Noël Wathion, Acting Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines

Sabine Brosch, Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines, b. 17 August 1963, n. Austrian

Education: Masters Degree in pharmacy and Doctor of Natural Sciences Degree in pharmacology from the University of Vienna. Post-graduate studies in pharmacology at the University of Melbourne and Auckland.
Career to date: From 1988 to 1992, Dr Brosch worked as an assistant professor at the Department of Pharmacology and Toxicology at the University of Vienna, where she was specialised in electrophysiology. In 1992 she moved to the Pharmacovigilance Department at the Austrian Ministry of Health and completed a 6-month regulatory traineeship in the Pharmaceuticals Unit of the European Commission in 1995. She joined the EMEA in November 1996 and was appointed Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines in January 2001.

Unit for Veterinary medicines and inspections

Peter Jones, Head of Unit, b. 9 August 1947, n. British

Education: Graduated in veterinary medicine from the Faculty of Veterinary Science at Liverpool University and is a Member of the Royal College of Veterinary Surgeons of the United Kingdom.
Career to date: After several years in general veterinary practice in the United Kingdom and Canada, Dr Jones joined the pharmaceutical industry in the animal health sector. He has held a number of appointments in research and regulatory affairs in multinational companies and, most recently, as Senior Director of International Regulatory Affairs for Animal Health Products for Merck Sharp and Dohme in New Jersey, USA. He joined the EMEA in June 1995, and was appointed Head of the Veterinary Unit in December of the same year and took on responsibility for information technology in January 2000. He is EU coordinator in the VICH.

Jill Ashley-Smith, Head of Sector for veterinary marketing authorisation procedures, b. 18 December 1962, n. British

Education: Graduated in pharmacology from Kings College, London University. Qualified as a veterinary surgeon from the Royal Veterinary College, London University.
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.

Melanie Leivers, Deputy Head of Sector for veterinary marketing authorisation procedures, b. 1 December 1958, n. British

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

Kornelia Grein, Head of Sector for safety of veterinary medicines, b. 24 July 1952, n. German

Education: Qualified chemist and pharmacist from the Free University of Berlin. PhD in organic chemistry from the Free University of Berlin.
Career to date: From 1976 to 1987, Dr Grein held positions in Germany as scientific assistant at the Free University of Berlin and as pharmacist. In 1987 she joined the German Environmental Agency as scientific administrator. Seconded to the European Commission in 1992, she returned to Germany to the Ministry for Environment in 1995. She was involved in the EU classification and labelling scheme and risk assessment of chemical substances, as well as in the harmonisation activities on these topics both within the EU and OECD. She joined the EMEA in April 1996.

Sheila Kennedy, Acting Head of Sector for inspections, b. 2 June 1959, n. Irish

Education: Honours degree and PhD in microbiology from University of Dublin, Trinity College. Postgraduate diploma in industrial pharmaceutics, University of Brighton.
Career to date: From 1985 to 1987, Dr Kennedy was employed as Section Head of Microbiology Research and Development in a multinational pharmaceutical company. From 1987 to 1992 she worked as a quality control microbiologist in a number of different pharmaceutical companies with responsibility for all aspects of microbiological quality control. Between 1992 and 1994, she was employed by the European Federation of Pharmaceutical Industries and Associations (EFPIA) as an Assistant in the Scientific, Technical and Regulatory Affairs, responsible for Quality and Biotechnology related matters. She joined the EMEA in October 1996 and has been acting Head of the Inspections Sector from March 2001.

Communications and networking Unit

Head of Unit

Post vacant

Beatrice Fayl, Head of Sector for document management and publishing, b. 9 October 1959, 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 in Norway. Ms Fayl joined the EMEA in April 1995.

Sylvie Bénéfice, Head of Sector for meeting management and conferences, b. 28 December 1954, n. French

Education: Doctorate of Science in physical sciences; qualification in research management; PhD in physical organic chemistry; Masters degree in physical organic chemistry; Degree in biochemistry.
Career to date: From 1982 to 1986, Dr Bénéfice was a researcher at the University of Montpellier, France. In 1986 she joined the French National Scientific Research Centre (CNRS) as *Chargé de recherche 1st Class* and became officer for European affairs in 1991. From 1993 to 1997 she was seconded to the European Commission (DG XII) 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, Acting Head of Sector for project management, b. 27 February 1959, n. British

Education*:* Batchelor 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 acting Head of Sector in September 2001.

Michael Zouridakis, Head of Sector for information technology, b. 8 February 1958, n. Swedish

Education: MSc in computer science and BSc in business administration and economics at the University of Gothenburg.
Career to date: From 1985 to 1989, Mr Zouridakis held various positions in the field of information technology as programmer, systems analyst and project manager, working as a senior consultant from 1990 to 1992. In 1993 he became Director of Information Systems/Information Technology at Astra AB in Greece. He joined the EMEA in April 1998.

David Drakeford, Deputy Head of Sector for information technology, b. 4 December 1957, n. Irish

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

Administration Unit

Andreas Pott, Head of Unit, b. 14 April 1949, 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, b. 11 November 1958, 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, Acting Head of Sector for infrastructure services, b. 23 January 1950, 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 acting head of sector in September 2001.

Gerard O'Malley, Head of Sector for accounting, b. 14 October 1950, 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.

Press office

Martin Harvey, Press officer, b. 20 October 1966, n. British

Education: Law degree from the University of Dundee, UK. Masters degree in European and international law from the Vrije Universiteit Brussel, Belgium.
Career to date: After a traineeship with the European Commission 1991-92, Martin Harvey 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 working in the office of the Executive Director. He was nominated as press officer in September 2001.