

The European Agency for the Evaluation of Medicinal Products

Work Programme 2001-2002

Adopted by the Management Board on 21-22 February 2001



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A great deal of additional information on the European Union is available on the Internet. It can be accessed through the Europa server (<http://europa.eu.int>)

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EMEA mission statement

The Work Programme for 2001-2002 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.

EMEA mission statement

To contribute to the protection and promotion of public and animal health by:

- *Mobilising scientific resources from throughout the European Union to provide high quality evaluation of medicinal products, to advise on research and development programmes and to provide useful and clear information to users and health professionals*
- *Developing efficient and transparent procedures to allow timely access by users to innovative medicines through a single European marketing authorisation*
- *Controlling the safety of medicines for humans and animals, in particular through a pharmacovigilance network and the establishment of safe limits for residues in food-producing animals*

New EMEA web site

<http://www.emea.eu.int>

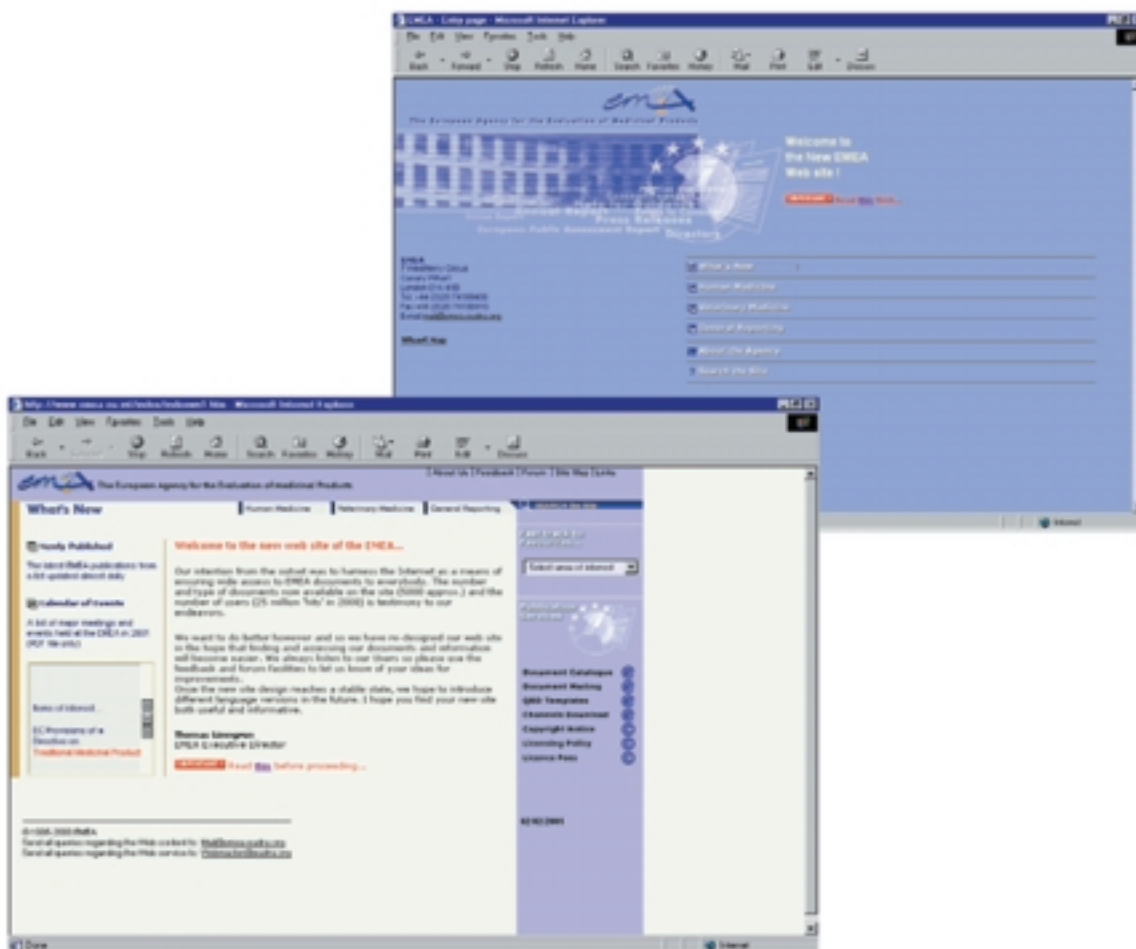
A new EMEA web site was launched at the beginning of 2001. The new site is designed to give improved access to the increasing number of documents available from the Agency.

Details of developments, events and news on EMEA activities are regularly posted on the web site.

Documents available include:

- European public assessment reports for all centrally authorised products for human and veterinary use
- Summary reports for maximum residue limits of veterinary medicines in food of animal origin
- Guidelines from the scientific committees
- Regulatory guidance
- General reporting and information documents, including annual reports and work programmes
- Press releases and public statements
- Links to other related sites

Annex 3 details some of the key EMEA documents.



Introduction by the Executive Director

Thomas Lönngren

I am pleased to present my first work programme as EMEA Executive Director. I start with firm foundations built by my predecessor, Fernand Sauer, who did so much to establish the Agency since its creation. The EMEA is well managed, but inevitably all organisations are constantly in need of development and management care. This is all the more important for the EMEA as it goes into review process and looks ahead to the challenges of EU enlargement.

Aside from my arrival, there were many changes at the beginning of 2001. New chairmen of the Management Board and the scientific committees were elected and I am confident that under Keith Jones, Daniel Bresseur and Steve Dean, the Management Board, CPMP and CVMP will be able to face the challenges ahead. A number of internal changes have also been made, particularly with the creation of two units dealing with evaluation of medicines for human use.

I believe that there are many issues that can be tackled in 2001-2002 within the current legislative framework before the revision is implemented. In particular there will be the challenge of an increased workload of incoming new applications, in particular as a result of the orphan drugs legislation, efforts to put in place pharmacovigilance system, improvements to scientific advice, reorganisation of working methods of scientific committees, PERF, information technology and communication.

The working methods of the CPMP and CVMP will need to be looked at again in 2001, not only to streamline their operation, but also to prepare for the future. Looking ahead to the many new developments in medicines technology and the expected benefits of the human genome project, we will need to prepare ourselves to face the challenges of new and exciting therapies.

In 2002 expecting increases in workload and call for improved scientific output from the EMEA evaluation and information technology and communication. This will necessarily have finance and resource implications to cope with the system and manage it well – not just within the EMEA and its scientific committee, but also at the level of the national experts involved in the review and maintenance.

The on-going EU review of the system, on the basis of a Commission proposal expected in Spring 2001, is an opportunity for all interested parties to examine how to build on our past successes to ensure a higher level of public and animal health into the future. All this must be done in a global perspective, particularly looking at the needs of our future Member States, research and development activities in Europe and the increasing complexity of the research-based pharmaceutical industry.

Thomas Lönngren

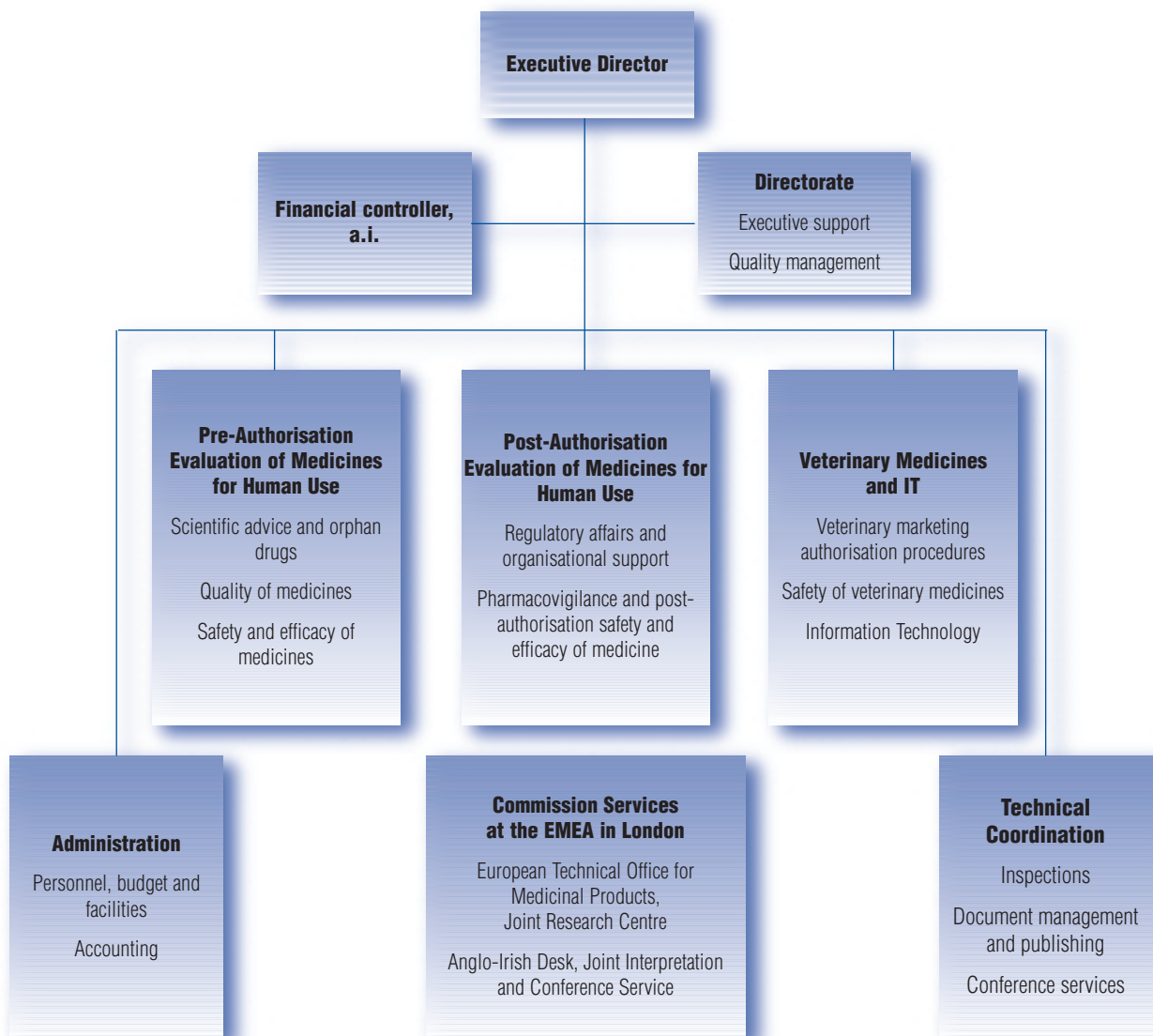


Structure of the EMEA

EMEA and the European network



EMEA Organisation



Chapter 1

EMEA in the European system

The EMEA is the central part of the pan-European network bringing together national structures for the authorisation and supervision of medicines for human and veterinary use. Our network of partners also includes the general public and the users of medicines, the pharmaceutical industry, health care professionals and our international partners.

One of the fundamental tasks of the EMEA is to facilitate appropriate communication throughout this network to strengthen and reinforce the procedures and competence of the system to deliver a high level of public and animal health.

EMEA in 2001-2002:

- Activities will increase as the number of applications increases
- Post-marketing activities will increase as a consequence of the increased number of centrally authorised medicinal products
- New activities relating to orphan drugs, Pan-European Regulatory Forum II, ICH and VICH, clinical trials, medical devices containing blood derivatives
- Increased need for communication, transparency and information technology development
- Re-organisation of the human medicines' units and work of the Committee for Proprietary Medicinal Products (CPMP) in order to strengthen the scientific consistency of opinions

All this results in a need for an increase in staff and financial resources for the EMEA. An overview of resources for 2001-2002 is given in Annexes 1 and 2.

1.1 Management Board

Overview of the Management Board

Chairman of the Management Board

Keith JONES

Vice-Chairman of the Management Board

Gerhard KOTHMANN

Priorities for the Management Board in 2001 and 2002 will include:

- Finalise EMEA transparency policy
- Prepare for the revision of EMEA fees in 2002, in particular through the costing exercise
- Contribute to the revision of the European marketing authorisation system, including the challenges of EU enlargement

The Board will continue to 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 2001	Management Board meetings in 2002
21-22 February	20 February
6 June	5 June
4 October	2 October
18 December	11 December

Within the context of the European Economic Area and following an exchange of letters, representatives of Liechtenstein will begin to officially participate at the Management Board as observers in 2001. Liechtenstein will also be able to nominate members and representatives for EMEA scientific committees and their working parties.

1.2 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 EMEA scientific review process relies on the European experts nominated by national competent authorities. The expected increases in workload and the broadening of scientific challenges in 2001 and 2002 will have resource implications that will need to be addressed by the EMEA Management Board and by the Heads of Agencies groups.

Support to the work of the mutual recognition facilitation groups for human and veterinary medicines will in particular include the completion in 2001 of new meeting and conference facilities at the EMEA, including a videoconferencing suite. Other areas for support will be explored with the heads of agencies groups in 2001.

The information technology and communication links between the EMEA and national authorities will be reinforced in a number of areas in 2001 and 2002, particularly as part of the implementation of the European pharmacovigilance system.

A benchmarking exercise will begin in 2001 to compare good regulatory practices and quality management systems of competent authorities both in the European Economic Area and central and eastern European countries. It is hoped that the initiative will be extended to our other international partners. The first meeting will be held at the EMEA on 5 March 2001.

1.3 Transparency and regulatory dialogue

Following the EMEA workshop on transparency of 27 November 2000, the Management Board will consider measures to improve the transparency of the EMEA regulatory process.

Dialogue with interested parties and the scientific committees will continue in 2001 and 2002. Meetings between the EMEA and CPMP interested parties will follow a new format including the organisation of an annual meeting on a public health theme. Themes under consideration include medicines information.

The newly launched EMEA web site will continue to be developed, in particular to improve access to information and news. Once a stable environment has been created, multi-lingual navigation of the web site will be introduced.

1.4 Revision of EMEA fees

The European Commission is required to present a report on the structure and level of EMEA fees to the European Parliament and Council of Ministers by December 2001. The Management Board will be consulted during the preparation of this report on the Agency's experience of the current fee system.

As part of this the Management will continue its costing exercise to determine the costs of the centralised procedure and in particular the costs of services provided by national authorities for inspections and rapporteurships.

Data from the EMEA activity tracking system – ActiTrak – will continue to be kept under review by the Management Board.

1.5 Review of the European marketing authorisation system

Useful web sites:

European Commission Unit for Pharmaceuticals:
regulatory framework and market authorisations

<http://pharmacos.eudra.org>

The Commission is expected to bring forward a report to the European Parliament and Council of Ministers in 2001 reviewing the operation of the European marketing authorisation system. The report is expected to be accompanied by legislative proposals. The EMEA and Management Board will continue to follow the preparations by the Commission and cooperate as necessary.

The Board will in particular be concerned to understand the resource implications of any measures proposed by the Commission and to ensure that the structures of the EMEA are able to meet the future challenges of science and the enlargement of the European Union.

1.6 Quality management

Internal audits, part of the EMEA quality management system will be continued in 2001-2002. Approximately 15 internal audits will be scheduled focusing on key and core tasks, processes and on the quality management system itself, which is supported by the quality manual.

In 2001-2002 an internal EMEA management tool, looking at key EMEA performance indicators, including scientific output, personnel, finance and strategic business planning, will be further developed. Improvement teams will continue to work in the area of the Agency's partnerships with stakeholders and support the product information management project.

Benchmarking the quality management systems of the European competent authorities to assure the quality of the tasks of the competent authorities will result in the harmonisation of the best regulatory practices.

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>

The second Pan-European Regulatory Forum on pharmaceuticals (PERF II) will begin in 2001. The forum is funded by the European Commission under the PHARE programme and a total of approximately €2 658 000 will be available in 2001.

Involving the national competent authorities of the EU associated countries (Bulgaria, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Romania, Slovenia and Slovak Republic), the purpose of PERF II is help candidate countries prepare their regulatory systems before accession to the EU.

The forum will concentrate on the following priority action areas:

- Implementation of Community pharmaceutical legislation and policy ('acquis communautaire')
- Good manufacturing practices
- Pharmacovigilance
- Inter-agency training
- Veterinary issues

The priority action area for veterinary medicines will include specific issues relating to quality, safety (including pharmacovigilance) and efficacy issues for veterinary medicines.

The report of the first Pan-European Regulatory Forum conference is now available. "*Pan-European Regulatory Forum Report*" can be obtained from the PERF web site (<http://perf.eudra.org>), by e-mail (perf@emea.eudra.org) or by writing to the PERF Secretariat at the EMEA address.

The Agency's participation in the EU team in the International Conferences on Harmonisation for medicines for human and veterinary use (ICH and VICH) will continue in 2001-2002. ICH activities will in particular focus on maintenance, new therapies, pharmacovigilance and implementation of the electronic Common Technical Document (eCTD).

The EMEA will continue to cooperate with the World Health Organisation, in particular towards the completion in 2001 of the joint EMEA-WHO application tracking system – SIAMED. Once the system has been fully tested it is intended to make the upgraded product available to partner authorities within the European Economic Area, central and eastern European countries and other European countries. This should facilitate harmonisation of regulatory authority tracking systems within Europe, with consequent benefits in terms of transparency and effectiveness of drug registration processes.

1.8 European Department for the Quality of Medicines

Useful web sites:

European Department for the Quality of Medicines/
European Pharmacopoeia
<http://www.pheur.org>

The EMEA will maintain its collaboration with the European Pharmacopoeia on matters relating to product quality by:

- participation in the work of the European Pharmacopoeia Commission as part of the European Commission delegation
- by inviting representatives of the European Pharmacopoeia Secretariat to attend meetings of the Joint CPMP/CVMP Quality Working Party and the ad hoc Good Manufacturing Practice Inspectors' meetings

The contractual agreement and collaboration between the European Department for the Quality of Medicines and the EMEA for the sampling and testing of centrally authorised products will continue in 2001 and 2002. Products will be included in each of these annual programmes when they reach the third anniversary of receiving the Community marketing authorisation or where there is a specific need as agreed by the EMEA scientific committees. Testing will be carried out on a work sharing basis by the Official Medicines Testing Laboratories of the European Union and EEA-EFTA Member States.

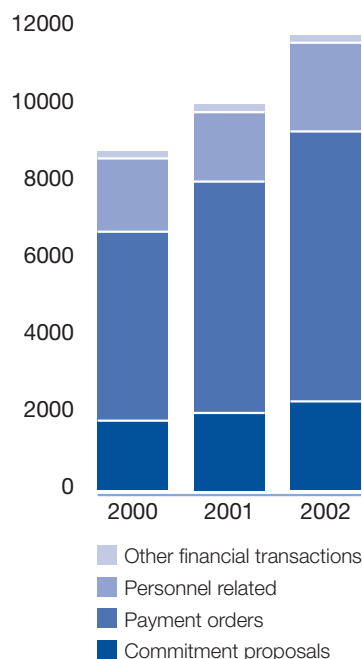
1.9 Financial control

EMEA Financial controller, a.i.
Claus CHRISTIANSEN

In line with other European Union institutions, the EMEA will replace the function of financial control with an internal audit function. This process is expected to take 2-3 years due to the need to consult and coordinate with the European Commission and other EU bodies on the recasting of the financial regulation.

Whereas it is still difficult to outline the future set-up, the Agency's interim financial controller will continue to ensure the application of the financial regulation and prepare and commence the transition to a system of internal audit.

A priori control of budgetary transactions 2000-2002



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 in with the EMEA accounting system, SI2.

Chapter 2

Medicines for human use

Overview

The Units for the evaluation of medicines for human use are responsible for:

- management and follow-up of marketing authorisation applications under the centralised procedure
- post-authorisation maintenance and pharmacovigilance of centrally authorised medicinal products
- management of and follow-up of designation for orphan medicinal products
- provision of support to scientific advice and protocol assistance to sponsors
- management of Community referrals and arbitrations arising from the mutual recognition procedure
- provision of support to European and international harmonisation activities of the CPMP and working parties and of the COMP in relation to orphan medicinal products.

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

Head of Unit

Patrick LE COURTOIS

Head of Sector, Scientific advice and orphan drugs

Patrick LE COURTOIS (acting)

Head of Sector, Quality of medicines

John PURVES

Head of Sector, Safety and efficacy of medicines

Isabelle MOULON

Deputy Head of Sector, 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, Regulatory affairs and organisational support

Tony HUMPHREYS

Head of Sector, Pharmacovigilance and post-authorisation safety and efficacy of medicines

Post vacant

Deputy Head of Sector, 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-Hughes TROUVIN

Efficacy Working Party

Barbara VAN ZWEITEN-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

Re-organisation of the Unit for the Evaluation of Medicinal Products for Human Use

The Unit for the Evaluation of Medicinal Products for Human Use was re-organised at the beginning of 2001 as a result of changes in the profile and volume of work of the Unit. Two new units have been created, dealing with pre- and with post-authorisation activities.

These changes are intended to facilitate the efficient handling of tasks, while maintaining support to the Committee for Proprietary Medicinal Products (CPMP), its working parties and to the Committee for Orphan Medicinal Products (COMP). The new structures will also improve the consistency in the operation of the centralised procedure (both from a procedural and a scientific point of view).

In addition, there will be a better use of the professional qualifications and experience of staff members.

One of the primary goals for the new units and sectors will be to implement the changes in operational activities that result from the restructuring of the Unit for the Evaluation of Medicinal Products for Human Use.

The implementation will be helped by the quality management system that has already been put in place within the Agency and in particular the use of standard operating procedures to assist the consistent handling of the various activities associated with the centralised procedure. Further developments and implementation of the quality management system will be pursued to increase the robustness of the centralised procedure in relation to the review process.

Priorities for medicines for human use in 2001-2002:

In the post-authorisation field:

To improve the management of a significant increase in maintenance activities as a consequence of the growing number of centrally authorised products. To measure performance through a survey of post-authorisation activities, especially in relation to variation and line extension applications.

To implement the electronic transmission and management of individual case safety reports in 2002 through the EudraVigilance project that allows for the establishment of a pharmacovigilance database and the use of a data-processing network.

In the scientific advice field:

To increase the quality of the provision of scientific advice through strengthened interactions with companies and involvement of complimentary expertise. To foresee in an adequate follow-up through continuous dialogue with the companies allowing to further improve the monitoring of the impact of the provision of scientific advice on the marketing authorisation procedure for medicinal products using the central route.

In the orphan drugs field:

To further strengthen the provision of advice given to sponsors applying for orphan drugs designation in order to improve the quality of the applications and to reduce the time for validation.

To implement a procedure for the annual follow-up of designated products and to identify experts on rare diseases for the benefit of the Agency processes from designation to marketing authorisation.

To implement the protocol assistance policy for orphan medicinal products for scientific and regulatory aspects in a framework allowing the interaction and communication expected by sponsors. To develop a follow-up of the protocol assistance procedure up to the marketing authorisation phase and to monitor the impact of the protocol assistance on such marketing authorisation procedure for medicinal products using the central route.

In the pre-authorisation field:

To continue the quality assurance exercise through continuous monitoring of the centralised marketing authorisation procedure by means of the EMEA-European Federation of Pharmaceutical Industries and Associations (EFPIA) survey. To increase the EMEA contribution in such quality improvement through a strengthened involvement of the EMEA scientific expertise through its specialised groups.

In the field of support to the CPMP:

To identify the areas for improvement in the functioning of the Committee, with a view of developing an action plan in order to allow the CPMP to cope with its increasing workload and to

prepare for future challenges (such as gene therapy, cell therapy and medicinal products derived from transgenic animals and transgenic plants) as a result of the EU 2001 review of the marketing authorisation procedures.

In the field of transparency:

To further improve the transparency of the Agency's activities, with special emphasis on the operation of the centralised procedure. To increase the interaction and discussions with all stakeholders in order to implement changes in the Agency's transparency policy, especially in the post-authorisation field.

In the field of international collaboration:

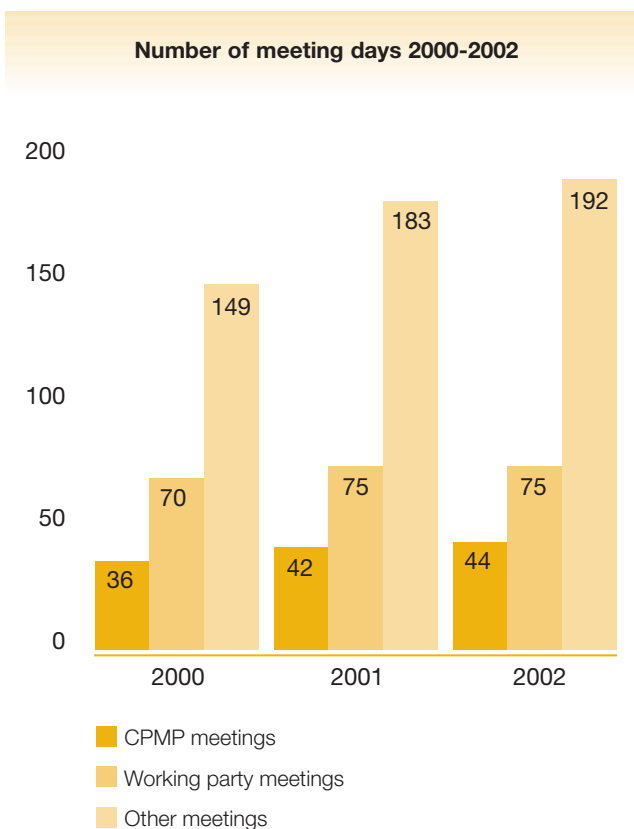
To further strengthen the collaboration with the national competent authorities of central and eastern European countries (CEEC) in the framework of the PERF programme, as well as through a continuation of the training facilities provided at EMEA level to CEEC visiting experts. Such increased collaboration will significantly facilitate the future accession of such countries.

To continue the benchmarking exercise with other regulatory authorities, in particular the US Food and Drug Administration and the Japanese Ministry of Health, Labour and Welfare.

In the field of harmonisation:

To further promote the implementation of a single EU market for medicinal products via harmonisation activities with focus on the product information for nationally authorised products and on the technical requirements in the field of quality, safety and efficacy through the development and updating of CPMP guidance documents. The extent of such harmonisation activities will have to be adjusted according to the funding made available by the EU.

The workload arising from these priorities can be seen in the increase in meeting days forecast for 2001 and 2002.

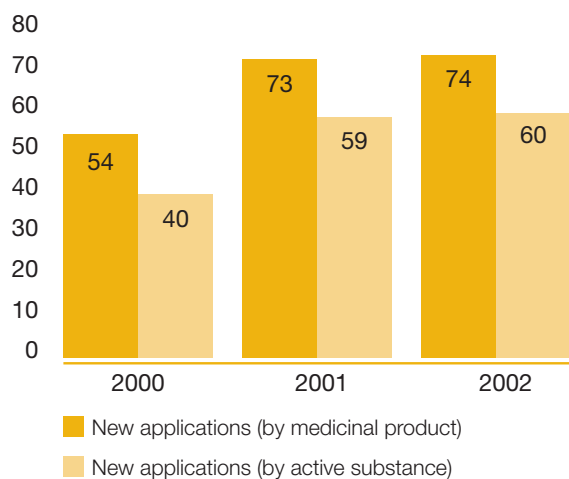


2.1 Initial evaluation

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 2001 and 2002. A large number of these applications will be for authorisation of medicines designated under new orphan drug legislation in 2000 and 2001. Once designated as an orphan medicinal product, an application for marketing authorisation can be submitted. Fee reductions for this are granted from a special contribution to the EMEA budget from the EU general budget.

- Increase in initial evaluation work of 40% in 2001 and 42% in 2002
- Improve quality and consistency of CPMP assessment reports and EPARs
- Improve quality, consistency and readability of information given to health care professionals and patients

Initial evaluation applications 2000-2002



The Committee for Proprietary Medicinal Products began a new three-year mandate in January 2001. Discussions on the future organisation of CPMP meetings will be initiated in 2001 in order to allow the elaboration of proposals with a view of preparing the Committee for the expected significant increase in workload as well as the future challenges it will face.

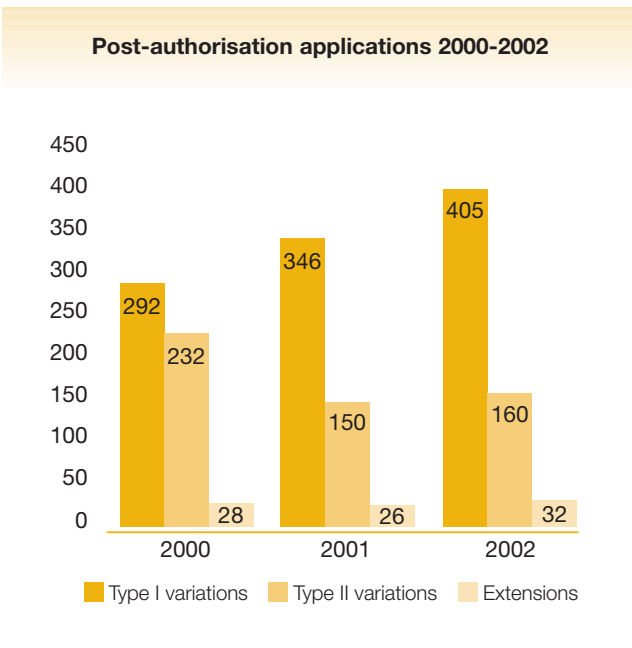
The CPMP will continue to meet in 2001 and 2002 on a monthly basis.

CPMP meetings in 2001	CPMP meetings in 2002 <i>(to be confirmed)</i>
3-25 January ¹	15-17 January ¹
27 February – 1 March	19-21 February
27-29 March ¹	19-21 March ¹
24-26 April	23-25 April
29-31 May ¹	28-30 May ¹
26-28 June	25-27 June
24-26 July ¹	23-25 July ¹
21-23 August ²	20-22 August ²
18-20 September ¹	17-19 September ¹
16-18 October	15-17 October
13-15 November ¹	19-21 November ¹
11-13 December	17-19 December
<i>1 Rapporteurs to be appointed</i>	<i>2 Only if required</i>

2.2 Post-authorisation activities

This includes activities relating to variations, extensions, transfers of marketing authorisation and follow-up inspections. There was a high number of type II variations submitted towards the end of 2000 as marketing authorisation holders sought to comply with their obligations for transmissible spongiform encephalopathy certification (TSE) under Community law. As this process nears completion it is expected that the number of type II variations in 2001 will drop by comparison. This expected decrease also reflects a relatively high number of class-related labelling changes submitted in 2000.

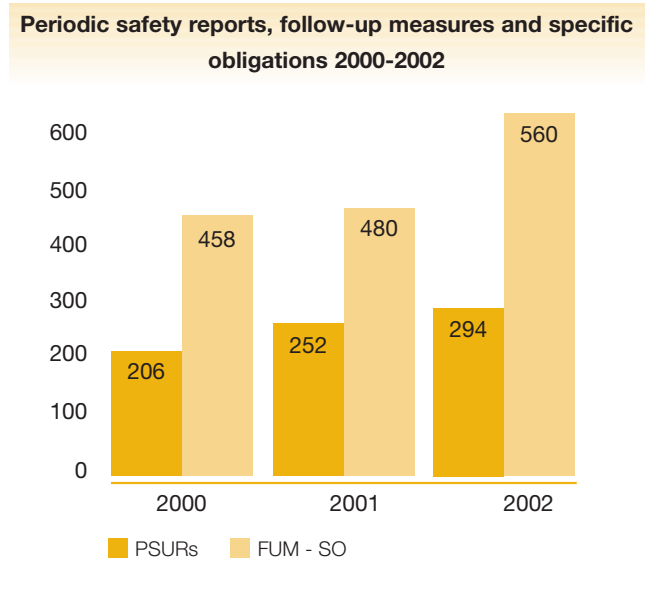
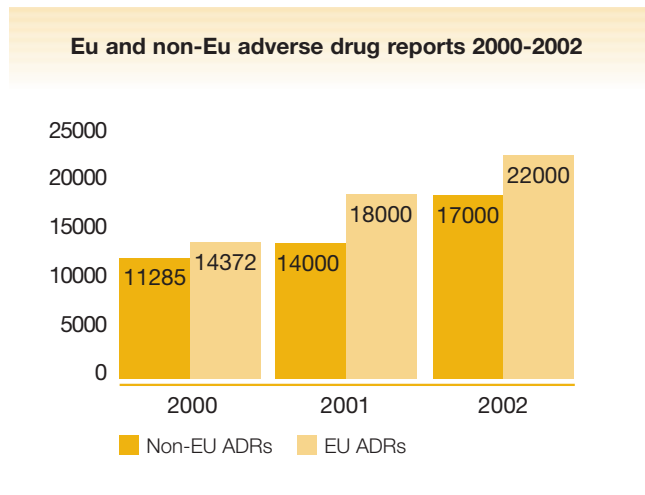
- An overall increase in the level of activities related to post-authorisation applications is expected
- Develop and implement performance indicators in 2001-2002



2.3 Maintenance activities

This includes follow-up measures, specific obligations, annual reassessments, renewals of marketing authorisations, pharmacovigilance (expedited reporting of adverse drug reports (ADRs) and management of periodic safety update reports (PSURs).

- Increase in applications for renewal of marketing authorisations to 24 in 2001 and 22 in 2002
- Increase in EU and non-EU ADRs and PSURs as the stock of centrally authorised products on the market increases



Other maintenance-related activities in 2001-2002 will include:

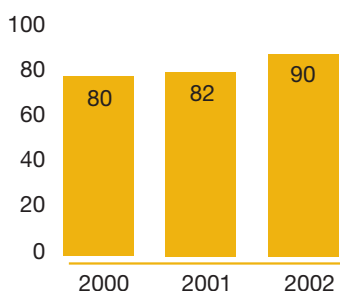
- Testing and implementation of the electronic exchange of individual case safety reports in the frame of the joint pharmacovigilance pilot programme in collaboration with national competent authorities and the European pharmaceutical industry represented by EFPIA
- Management of the EudraVigilance project and implementation and testing of the human and veterinary EudraVigilance database
- Implementation of the Medical Dictionary for Regulatory Activities (MedDRA) to support European pharmacovigilance activities
- Chair and organise the EudraVigilance Telematics Implementation Group and subgroup meetings

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.

- Increase in the number of initial and follow-up scientific advice procedures of 2.5 % in 2001 and 12.5 % in 2002

Scientific advice submissions (including follow-up advice) 2000-2002



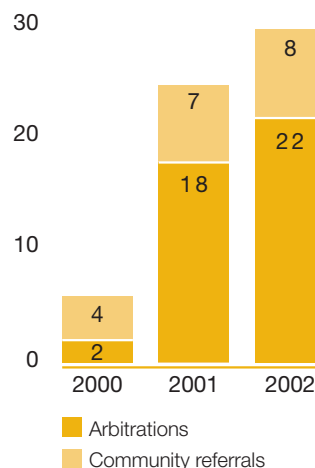
Scientific advice procedures will be streamlined in 2001 for greater efficiency, including the operation of the Scientific Advice Review Group. As part of the EMEA commitment to scientific advice, the procedure will be one of the first areas of activity to benefit from the electronic document management system to be implemented in 2001-2002.

2.5 Arbitration and Community referrals

The number of arbitration referrals from the mutual recognition procedure is expected to rise as experience and use of the procedure progresses. A proposal to create a joint group CPMP-Mutual Recognition Facilitation Group will be discussed by the EMEA and Heads of Agencies. This group would be asked to select candidates for harmonisation among European brand leaders in major therapeutic classes. The number of Community harmonisation referrals is therefore expected to increase.

- Increase in the number of arbitration procedures (Articles 10 and 11 of Council Directive 75/319/EEC) from 2 in 2000 to 18 in 2001 and 22 in 2002
- Increase in the number of Community referrals (Articles 7(5), 12 and 15 of Council Directive 75/319/EEC) from 4 in 2000 to 7 in 2001 and 8 in 2002

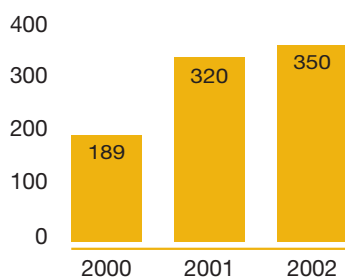
Arbitration and Community referrals 2000-2002



2.6 Special services

- Parallel distribution notifications are expected to increase from 169 in 2000 to 320 in 2001 and 350 in 2002

Parallel distribution notifications 2000-2002

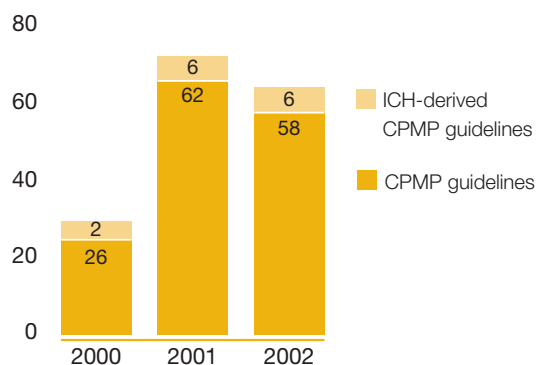


2.7 Guideline development

The development and continuous revision of CPMP guidelines is an important contribution to ensuring harmonisation of scientific evaluation criteria within the European marketing authorisation system. The Units will continue to support the work of the CPMP working parties, subject to the availability of funding from the European Union.

- Increase in CPMP guidelines from 26 in 2000 to 62 in 2001 and 58 in 2002
- Increase in ICH-derived CPMP guidelines from 2 in 2000 to 6 in 2001 and 2002

CPMP guidelines 2000-2002



2.8 Orphan medicinal products

The EMEA role in orphan medicinal products began in 2000 and the Committee for Orphan Medicinal Products (COMP) was established in April 2000. The new Sector for scientific advice and orphan drugs will provide the support to the work of the COMP and the provision of protocol assistance.

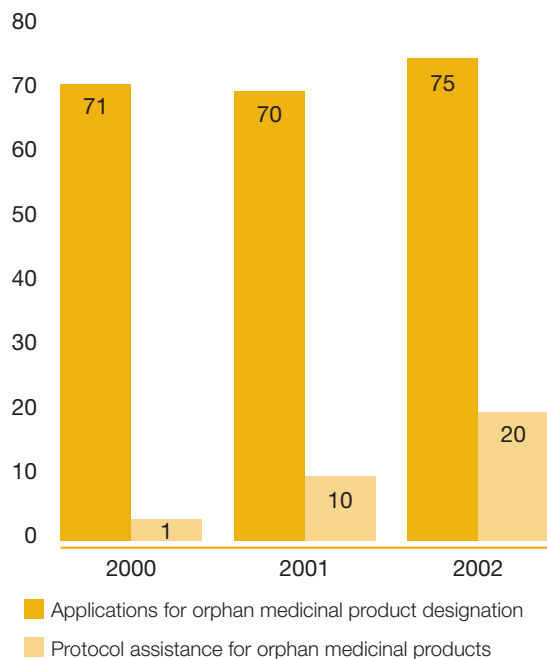
The Committee for Orphan Medicinal Products will meet in 2001 and 2002 on a monthly basis.

COMP meetings in 2001 **COMP meetings in 2002 (to be confirmed)**

15-16 January	22-23 January
8-9 February	26-27 February
20-21 March	25-26 March
9-10 April	29-30 April
22-23 May	22-23 May
11-12 June	19-20 June
17-18 July	17-18 July
6-7 September	11-12 September
25-26 October	8-9 October
20-21 November	14-15 November
17-18 December	12-13 December

- Stable number of applications for orphan medicinal products designation in 2001 (70) and increase in 2002 (75)
- Increase in protocol assistance for designated orphan medicinal products from 1 in 2000 to 10 in 2001 and 20 in 2002
- Increase in meeting days of the Committee for Orphan Medicinal Products 11 days in 2000 to 31 in 2001 and 2002

Orphan medicinal procedures 2000-2002



2.9 Working parties and ad hoc groups

• Biotechnology Working Party

- Review the quality aspects of marketing authorisation applications for biological and biotechnological medicinal products
 - To provide scientific advice on the quality aspects for requests for scientific advice for biological and biotechnological medicinal products
 - To provide advice and recommendations to CPMP on public health issues related to medicinal products, such as:
 - *Transmissible spongiform encephalopathy (TSE)*
 - *Issues related to blood products, including Creutzfeldt-Jakob's Disease (CJD), viral safety, plasma derivatives used as excipients in medicinal products*
 - *Development of workshops on the above issues, if necessary*
- To provide advice and recommendations to CPMP on specific procedures being developed by the Commission such as demonstration of compliance with the TSE guideline, facilitation of the processing of data in support of variations to vaccines and blood products, Common Technical Document (CTD)
 - Expert Working Group on Influenza Vaccines on the annual selection of virus strains for the influenza vaccine campaign
 - To review current guidelines and to develop guidelines, points to consider documents and concept papers to facilitate the evaluation of future applications for marketing authorisations, such as:
 - *Note for guidance on minimising the risk of transmitting TSE via medicinal products*
 - *Note for guidance on plasma-derived medicinal products*
 - *Note for guidance on the use of transgenic animals in the manufacture of biological medicinal products for human use*
 - *Note for guidance on the use of transgenic plants in the manufacture of medicinal products*
 - *Annex to CPMP Note for guidance on influenza vaccines: Cell-derived influenza vaccines*
 - *Note for guidance on the quality, pre-clinical and clinical aspects of gene transfer medicinal products (jointly with Efficacy and Safety Working Parties)*
 - *Points to consider on live-attenuated influenza vaccines*
 - *Points to consider on cumulative stability requirements for vaccines*
 - *Concept paper on requirements for evaluation of new immunological 'adjuvants' in vaccines*
 - *Note for guidance on comparability r-DNA-derived medicinal products (joint with Efficacy and Safety Working Parties)*
 - *Note for guidance on immune sera of animal origin*
 - *Points to consider on human somatic cell therapy products (jointly with Efficacy and Safety Working Parties)*
 - *Note for guidance on xenogenic cell therapy products (jointly with Efficacy and Safety Working Parties)*
 - *Note for guidance on requirements and controls of bovine serum used during the manufacture of medicinal products*
 - New activities relating to the implementation of European Parliament and Council Directive 2000/70/EC on medical devices incorporating stable derivatives of human blood or human plasma (OJ L 313, 13.12.2000, p. 22)

• Efficacy Working Party

- Revision of the following existing guidelines:
 - *Anti-depressive agents*
 - *Peripheral arterial occlusive disease**
 - *Osteoporosis in women*
 - *Rheumatoid arthritis (revision to be considered)*
 - *Schizophrenia, development of an appendix on depot formulations developed for the treatment of schizophrenia*
- Development of new guidelines:
 - *Bipolar disorders,* multiple sclerosis,* acute stroke,* Crohn's disease,* diagnostic agents,* diabetes mellitus, irritable bowel syndrome, asthma, pain, urinary incontinence*
 - *Clinical documentation for metered dose inhalers*
 - *Biostatistical/methodological guidelines (adjustment for multiplicity and related topics, missing data,* choice of delta, validity and interpretation of meta-analyses and one pivotal trial,* adjustment for baseline covariates)*
 - *Antimicrobial resistance*
 - *Thrombolytic treatment of acute myocardial infarction*
- Development of guidelines through multidisciplinary groups:
 - *Comparability of medicinal products containing biotechnology-derived proteins*
 - *Use of medicinal products in pregnancy*
 - *Xenogenic cell therapy*
- Other tasks:
 - *New modified formulations of acetyl salicylic acid in the secondary prevention of cardiovascular events: Requirements for the marketing authorisation to be discussed*
 - *Harmonisation of the summary of product characteristics for authorised antibiotics*

* Documents have previously been released for consultation.

• Pharmacovigilance Working Party

- Evaluation of product-related safety issues at the request of the CPMP and national competent authorities
- Revision of pharmacovigilance-related guidelines in the light of experience and following Commission Directive 2000/38/EC amending Chapter Va of Council Directive 75/319/EEC
- Development of Good Pharmacovigilance Practice
- Contribution to multidisciplinary guidelines with regard to medicinal products used for xenogeneic cellular therapy and for treatment of pregnant women
- Collaboration and communication with non-EU regulatory authorities, in particular by providing support to the ICH initiative and to the PERF initiative, and by strengthening communication with the US Food and Drug Administration by means of regular videoconferences and mechanisms of urgent information exchange

• Safety Working Party

- Revision and development of draft ICH safety-related guidelines on behalf of CPMP.
- Revision of existing CPMP safety notes for guidance:
 - *Update of Note for guidance on non-clinical local tolerance testing of medicinal products*
 - *Update of Note for guidance on carcinogenic potential*
 - *Update of Draft Note for guidance on non-clinical testing of substances with long-term marketing experience ('old substances')*
- Development of new CPMP safety guidelines, points to consider documents and discussion papers:
 - *Note for guidance on photosafety testing*
 - *Points to consider document on the non-clinical assessment of the carcinogenic potential of insulin analogues*
 - *Points to consider document on the need for reproduction studies in the development of human insulin analogues*
 - *Discussion paper on environmental risk assessments for pharmaceuticals*

- Review of Scientific Advice sought by the industry related to pre-clinical safety testing
- Joint revision and development of multidisciplinary guidelines and points to consider documents with other Working Parties:
 - *Note for guidance on gene transfer medicinal products (with Biotechnology Working Party)*
 - *Points to consider document on xenogeneic cell therapy (with Biotechnology Working Party)*
 - *Note for guidance on specification limits for residues of heavy metal catalysts in active substances and in medicinal products (with Joint Quality Working Party)*
 - *Revision of Note for guidance on radiopharmaceuticals (with Joint Quality Working Party)*
 - *Note for guidance on risk assessment of use of medicinal products during pregnancy and lactation (multidisciplinary)*
 - *Update Points to consider on the assessment of the potential for QT interval prolongation by non-cardiovascular medicinal products (multidisciplinary)*

• Scientific Advice Review Group

- Continue to support the CPMP through provision of scientific advice by carrying out scientific reviews of the requests for advice from companies, providing a guarantee of proper and adequate expertise
- Strengthen the level of interaction with companies, particularly through a wide use of oral explanation and by promotion of the use of the follow-up procedure
- Provide appropriate scientific expertise for the implementation of the protocol assistance procedure within the framework of European Community orphan drugs policy

• *ad hoc* Working Group on Blood Products

- Input to CPMP on scientific advice requests for blood products (plasma derived and recombinant) and advice to CPMP and MRFG on general and product specific matters related to efficacy and safety of blood products
- Development of the following new notes for guidance and core summaries of product characteristics:
 - *Antithrombin (plasma derived)*
 - *Human normal immunoglobulin for intramuscular and subcutaneous use*
 - *Fibrin sealants*
 - *Von Willebrand factor*
 - *Alpha₁ antitrypsin*

- Development of the following new core summaries of product characteristics:
 - *C₁ esterase inhibitor*
 - *Human hepatitis B immunoglobulin*
- Revision of the following core summaries of product characteristics:
 - *Specific immunoglobulins*
 - *Factor VII (plasma derived)*
 - *IV immunoglobulin (treatment of parvovirus B19 infection)*

2.10 Herbal medicinal products

Support to the Herbal Medicinal Products Working Party will continue in 2001-2002, with the working party expected to meet 3 times a year in 2001 and 2002.

The group's work programme will be developed in line with the future European Commission proposal on herbal and traditional medicines.

2.11 Mutual recognition facilitation group

Useful web sites:

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. Improvements to EMEA facilities are expected to be of particular benefit to the operation of the MRFG, in particular the additional meeting and videoconferencing rooms on the third floor of the Agency's offices.

Chapter 3

Veterinary medicines

Overview of the CVMP and the Unit for Veterinary Medicines and Information Technology

The Unit is responsible for:

- management and follow-up of marketing authorisation applications under the centralised procedure
- management of applications for the establishment of maximum residue limits of veterinary medicinal products that may be permitted in foodstuffs of animal origin
- post-marketing maintenance of authorised medicinal products
- management of Community referrals and arbitrations arising from the mutual recognition procedure
- provision of support to European and international harmonisation activities of the CVMP and its working parties

Unit for the veterinary medicines and information technology

Head of Unit

Peter JONES

Head of Sector for veterinary marketing authorisation procedures

Jill ASHLEY-SMITH

Head of Sector for safety of veterinary medicines

Kornelia GREIN

Head of Sector for information technology

Michael ZOURIDAKIS

Deputy Head of Sector for information technology

David DRAKEFORD

The work programme for information technology can be found in Chapter 5.

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

Availability of Medicines Task Force

Peter JONES

Priorities for veterinary medicines in 2001-2002:

- Finalise and adopt a Note for guidance on risk assessment in establishing maximum residue limits (MRL) to facilitate extrapolation of MRLs from major species' to minor species in support of the availability of medicines initiative
- Following the installation and the testing phase of the EudraVigilance database, to fully implement the effective and consistent electronic reporting of adverse reactions to veterinary medicines
- Meet key targets identified in the Committee for Veterinary Medicinal Products (CVMP) risk management strategic plan on antimicrobial resistance adopted and released by the Committee in January 2000
- Continue to seek advances in the initiatives identified by the EMEA Task Force to facilitate the availability of veterinary medicines
- Work with market authorisation holders to ensure conformity with the legal framework and deadlines, requiring companies to demonstrate compliance with the Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products
- Achieve improved satisfaction of all parties in the benchmarking study, on the basis of the joint EMEA-European Animal Health Federation (FEDESA) questionnaire on the centralised system

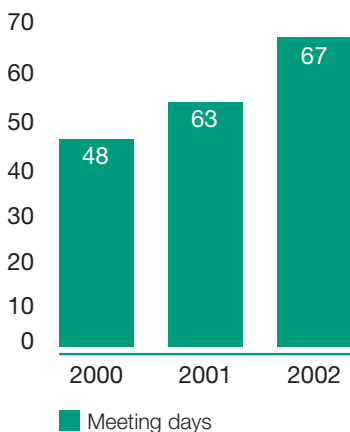
- Continue to work with FEDESA to reach agreement on improving transparency in the regulatory process through publication of CVMP opinions on dates to be agreed by all parties
- Optimise the efficiency of the centralised system, thereby encouraging industry to choose this route for the authorisation of medicines as its preferred option

The increase in number of meeting days for the CVMP, working parties and ad hoc groups reflects the increased workload for veterinary medicines in 2001-2002.

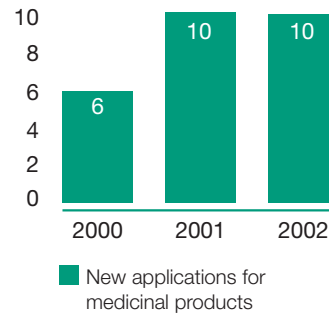
3.1 Initial evaluation

- Based on preliminary forecasts received from industry, an increase in applications for centralised authorisations is foreseen from 6 in 2000 to 10 in 2001 and 2002 and those for new MRL applications is expected to approximately double in number

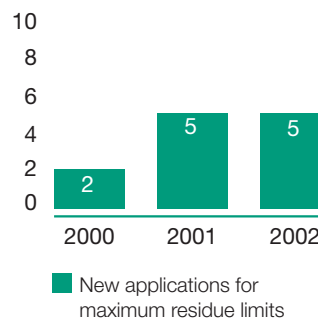
Number of meeting days 2000-2002



New centralised applications 2000-2002



New applications for maximum residue limits 2000-2002



The Committee for Veterinary Medicinal Products began a new three-year mandate in January 2001.

The new Committee will create a strategic planning group to be chaired by Gérard Moulin, with the participation of the CVMP chairman and chairpersons of the working parties together with the secretariat to give guidance to the CVMP on strategic issues and organisational efficiency.

The CVMP will continue to meet in 2001 and 2002 on a monthly basis, with 4 meetings per year with interested parties.

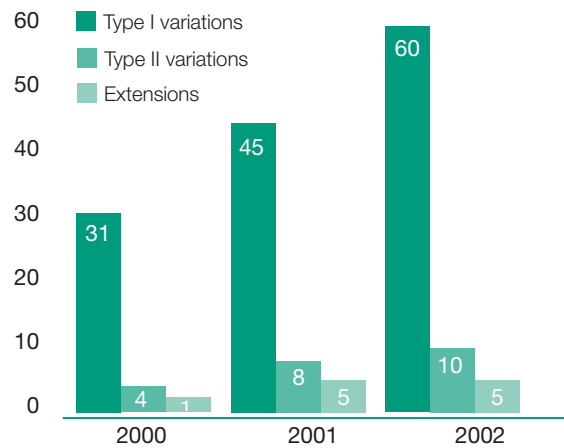
CVMP meetings in 2001	CVMP meetings in 2002 (to be confirmed)
9-11 January	8-10 January
13-15 February	12-14 February
13-15 March	12-14 March
18-19 April	16-18 April
15-17 May	14-16 May
12-14 June	11-13 June
10-12 July	9-11 July
7-9 August ¹	13-15 August ¹
11-13 September	10-12 September
9-11 October	8-10 October
6-8 November	12-14 November
4-6 December	10-12 December

¹ Only if required

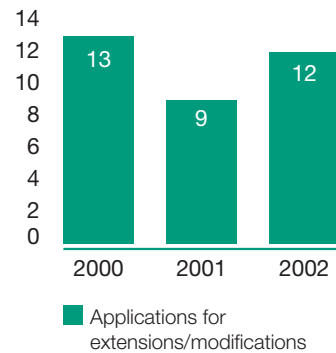
3.2 Post-authorisation activities

- Steady increase in post-authorisation activities is anticipated in line with the increased number of products authorised through the centralised procedure
- A significant number of the expected variations are anticipated to ensure compliance with the TSE guideline

Post-authorisation applications for central authorised medicinal products 2000-2002



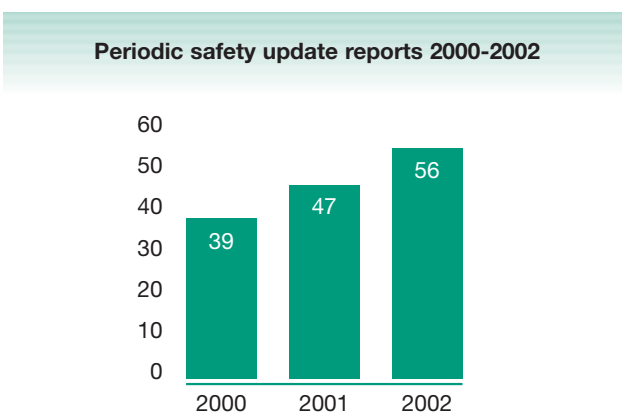
Applications for extensions/modification of maximum residue limits 2000-2002



3.3 Maintenance activities

The continued rise in the number of centrally authorised veterinary medicines has led to an increase in adverse event reporting. The level of pharmacovigilance activities will intensify in 2001 and 2002, especially with the increased number of submissions of periodic safety update reports and their assessment by the CVMP, which are expected to rise significantly in 2001 and again in 2002.

- Increase in number of meetings of the CVMP Pharmacovigilance Working Party by 25%
- Increase in applications for renewal of marketing authorisations with 1 application in 2001 to 3 in 2002



3.4 Scientific advice

Scientific advice is not often sought by industry in the veterinary sector and activity expected to remain constant with 1 application in 2001 and in 2002.

3.5 Arbitration and Community referrals

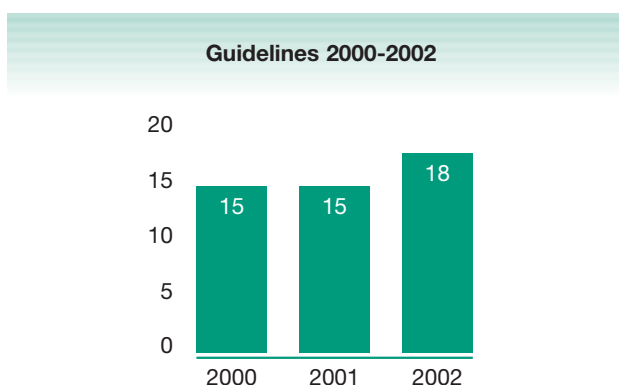
One arbitration/Community referral is expected in both 2001 and 2002.

3.6 Interested parties

The secretariat commits to continued liaison and co-operation with the Interested Parties to CVMP to underpin the spirit of transparency to ensure regular meetings on a quarterly basis with the Committee, as well as Info-days twice a year on topics of key interest, capitalising on the success of these meetings in the past.

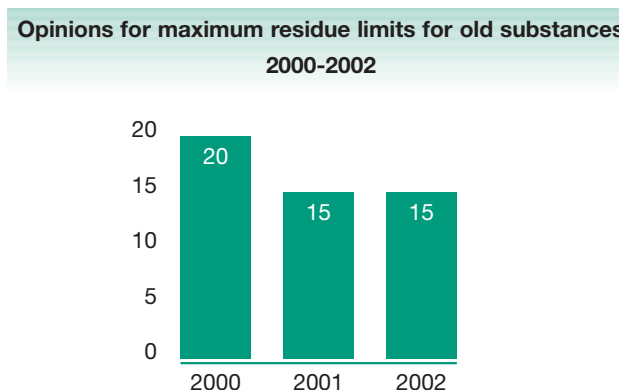
3.7 Guideline development

The EMEA will continue to co-ordinate the activities and participation of the EU in the Veterinary International Conference on Harmonisation (VICH) process to develop guidelines to assist and support the regulatory process. A range of new guidelines embracing safety, biologicals quality monitoring, pharmacovigilance and others are anticipated in the two years ahead.



3.8 Establishment of maximum residue limits for old substances

Work related to the establishment of MRLs for old substances will continue in 2001 and 2002 for those substances whose provisional MRLs expire.



3.9 Availability of medicines

Following the publication of the Commission Communication to the Council and the European Parliament on availability of veterinary medicines (COM(2000) 806 final, 5.12.2000), the CVMP and EMEA secretariat will continue to support all initiatives and proposals being considered to facilitate the availability of veterinary medicines to minor species.

3.10 Working parties and ad hoc groups

• Efficacy Working Party

- Revision of existing guidelines:
 - *Ectoparasiticide guideline for sheep, cattle and goats*
 - *Antimicrobials for general veterinary use*
 - *Guidance on the evaluation of fluid therapy in case of diarrhoea*
- Development of new guidelines:
 - *Biostatistical guideline*
 - *Guideline for the conduct of efficacy studies for non-steroidal anti-inflammatory drugs*
- Development of position papers and policy papers
 - *Advice to the CVMP regarding the risk management strategic plan on antimicrobial resistance to include:*
 - *Pharmacodynamic/pharmacokinetic modelling of antimicrobials*
 - *Standard phrases for product literature for antimicrobials*
 - *Guidelines for antimicrobial prophylaxis, combination therapies, in-feed and water mass medication*
 - *Minor indications and minor species guidance document*
 - *Standard phrases for summary of product characteristics*
 - *Glossary of terms for therapeutic claims*
- Other tasks:
 - *Two informative meetings with non-EU regulatory authorities from the enlargement countries as foreseen within the PERF II initiative*

• Immunologicals Working Party

- Development of guidelines and position papers:
 - *Harmonisation of requirements for low (efficacy) and high (safety) potency and batch consistency of vaccines*
 - *Gene therapy*
 - *Vectored vaccines (when the vector is part of the vaccine)*
 - *Revision of CVMP guidance with regard to compliance with the European Pharmacopoeia*
 - *Review of equine influenza guidelines*
 - *Note for guidance on DNA vaccines combined with cytokines and cytokines used for therapeutic purposes*
 - *Immunological veterinary medicinal products used for treatment in accordance with Article 1(3) of Council Directive 90/677/EEC*

• Pharmacovigilance Working Party

- Finalisation of the Veterinary Medicinal Dictionary for Drug Regulatory Authorities (VEDDRA) list of clinical terms
- Finalise and implement the electronic transmission and management of pharmacovigilance information and data following implementation of EudraVigilance
- Revise current guidelines in the light of changes of the relevant legislation (amendment of Council Directive 81/851/EEC by Commission Directive 2000/37/EC)
- Further optimisation of a drug monitor scheme in order to provide a summary of all key and relevant pharmacovigilance information, enhance traceability of issues under investigation, and to provide a general overview on post-marketing surveillance studies
- Participation in PERF II activities through workshops

- **Safety Working Party**

- Review on behalf of CVMP draft safety guideline from VICH
- Revise guideline on safety evaluation of effects of antimicrobial residues in food from food animals on human gut flora for the establishment of MRLs
- Finalise requirement for routine analytical methods in establishment of MRLs
- Guidance note on determination of withdrawal periods in eggs
- Consider need for operator safety guidelines
- Assessment of risk in relation to intake of residues from veterinary medicinal products in milk for children

- **ad hoc Group on Antimicrobial Resistance**

- Note for guidance on pre-authorisation studies to assess the potential impact of veterinary medicinal products to antimicrobial resistance
- Providing advice to the CVMP on specific issues relating to antimicrobial resistance

3.11 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 full secretariat support to the Veterinary Mutual Recognition Facilitation Group (VMRFG) which meets at the EMEA on a monthly basis to coordinate the decentralised procedure and which is made up of key regulatory officials from all EU Member States.

In addition to extensive preparation of meetings and follow-up activities, including preparation of agenda, tables of decision and press releases, other support activities include coordination of meetings with interested parties as well as giving advice to applicants on procedural issues. The Secretariat also provides assistance in the compilation of documents for publication on the web site of the Heads of Veterinary Regulatory Agencies (HEVRA) and for transmission to the CVMP.

The chair of the group rotates every six months with the EU presidency and the support to the chairman by the EMEA secretariat is acknowledged and appreciated by the Group.

Chapter 4

Inspections

The Sector for inspections is part of the Technical Coordination Unit

Head of Sector

Stephen FAIRCHILD (until 15th April 2001)

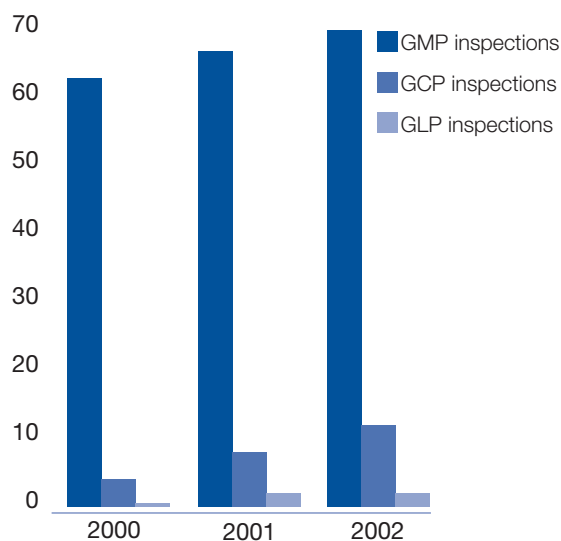
Joint CPMP/CVMP Quality Working Party

Jean-Louis ROBERT

Operational procedures will be reviewed to improve the level of service provided, in particular focusing on activities related to the Joint CPMP/CVMP Quality Working Party and the ad hoc Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP) Inspectors' Groups.

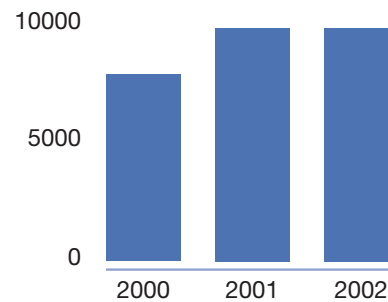
- Increase in GMP inspections performed from 63 in 2000 to 67 in 2001 and 70 in 2002, reflecting the increase in applications for initial authorisation and variations in the centralised procedure, and also relating to orphan medicinal products
- Increase in GCP inspections performed from 4 in 2000 to 8 in 2001 and 12 in 2002. Good Laboratory Practice (GLP) inspection requests are also expected to increase

Inspections performed 2000-2002



- Work on 5 mutual recognition agreements (MRA) will continue with Switzerland, Canada, New Zealand, Australia and Japan
- Resource allocation is made for work on the MRA with the USA, despite uncertainties about the rate of implementation
- Requests for certificates of medicinal products are expected to increase from 8 357 in 2000 to 10 000 in 2001 and in 2002

Certificates of a medicinal product 2000-2002



Preparations for the implementation of Council Directive 2001/20/EC on clinical trials (OJ L 121, 1.5.2001, p. 34) will be made in 2001 and 2002. Initial work plans will focus on the development of a number of guidance documents specified in the Directive, in particular with the ad hoc groups of GMP and GCP inspectors, together with work already in progress. In addition there will be participation in the development of guidance on serious adverse reaction reporting.

Future work will concern the implementation of the responsibilities given to the EMEA in the Directive in relation to GCP and GMP inspections and serious adverse reaction reporting. Preparation will also be made for EMEA joint management, with the Commission and national competent authorities, of databases for the exchange of information on clinical trials and adverse reaction reporting.

Chapter 5

Administration and support activities

Administration Unit	Technical Coordination Unit
Head of Unit <i>Andreas POTT</i>	Head of Unit <i>Karel de NEEF (until 14th March 2001)</i>
Head of Sector for personnel, budget and facilities <i>Frances NUTTALL</i>	Head of Sector for inspections <i>Stephen FAIRCHILD (until 15th April 2001)</i>
Head of Sector for accounting <i>Gerard O'MALLEY</i>	Head of Sector for document management and publishing <i>Beatrice FAYL</i>
	Head of Sector for conference services <i>Sylvie BÉNÉFICE</i>

5.1 Administration

The Administration Unit staff level reflects the demand-driven workload of the Agency in 2001-2002 and the operational activities arising from the growth in the units for human and veterinary medicines, the expanded office space and associated facilities.

The principal objectives of the Administration Unit remain unchanged for the years 2001 and 2002, and include

- sound management of human, budgetary and technical resources
- further development of efficient management and organisational structures
- adaptation of administrative structures and procedures to a growing Agency as well as to new developments in the area of human resource management and information and office technologies

An improved budget planning process will be developed in 2001 to make a closer link between budget activities and the work planning process.

Personnel, budget and facilities

Personnel will continue to experience an important workload due to selection and the recruitment of new staff and the replacement of staff who resign as well as the continuing administration of entitlements for existing, new and leaving staff.

The number of posts requested by the Agency is 220 in 2001 and 251 for 2002. Eight selection procedures will take place in

2001 to put in place reserve lists for suitably qualified staff to cover needs up to the end of 2002.

A computerised personnel system with an intranet function was selected in 2000 and will be implemented in 2001-2002.

The staff training programme will be reinforced in 2001-2002 and a strategy for professional training will be developed with the aim to set up a comprehensive and coherent scheme assuring both a continuous adaptation to a changing work environment and the improvement of professional competencies.

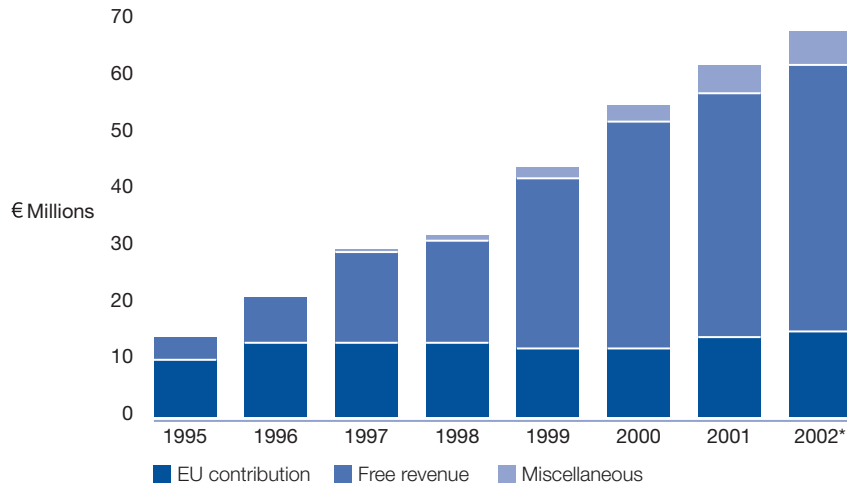
The facilities work programme covers a wide range of activities necessary for the effective and efficient functioning of the Agency. This includes security, telecommunications, reception, fitting out of the 3rd floor in 2001, modifications to the 4th and 5th floors, building and equipment maintenance, cleaning, office supplies/equipment, restaurant services as well as planning for future office space on the 6th floor.

Accounting

Key objectives in 2001-2002 include:

- Absorb the increasing level of operations due to the increased activity levels of the operational units, particularly in the areas of meetings and revenue transactions
- Further develop analytical and activity costing information as part of the costing exercise
- Further develop internal management information mechanisms

Evolution of the EMEA budget 1995-2002



* Preliminary draft budget for 2002 adopted by the Management Board 21-22 February 2001.

- Progress the electronic transfer of data between accounting systems and explore and implement electronic commerce data exchange with third parties, such as suppliers and customers, thereby gaining in productivity
- Develop trained accounting personnel who provide efficient and friendly service to delegates, national competent authorities, customers, suppliers, banks, staff and other EMEA partners

5.2 Document management and publishing

The sector is responsible for publishing, cataloguing, distributing and conserving EMEA documentation. 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, and internal mail services)

Priorities in 2001-2002 are:

- Continue the product information management project (PIM) in 2001 with a view to reducing workload for industry and regulators for the maintenance of product information documents. PIM is a joint EMEA-EFPIA initiative.
On a trial basis, the EMEA will accept more electronic submissions of product information relating to both full applications and variations using the PIM approach in parallel to assess the feasibility of electronic submissions in this area.

The project plans to develop a prototype information system linked to an underlying database and then to test the electronic exchange of information between applicants and the EMEA, consolidating this approach over time to include the whole process for product information.

- Implement an electronic document management system over 2001-2002. The electronic document handling system should also improve the handling of incoming and outgoing documents, in particular allowing central registration, storage and access. The system will first be implemented in 2001 in the activities relating to scientific advice and the preparation of European public assessment reports (EPARs) for human and veterinary medicines. It will be extended in 2002 to the activities of the CPMP and its working parties. The EMEA expects to receive between 10 000 and 12 000 pieces of mail a year in 2001 and 2002 and send out about 20 000 pieces of mail.
- Increase in documents handled by the sector for publication on EMEA web site in 2001 and 2002. This is expected to coincide with a only a small increase in number of subscriptions to the EMEA documentation service as more users obtain documents directly from the web site
- New publication strategy to ensure faster publication of key documents, including local printing of key documents such as annual reports and work programmes
- The off-site archiving strategy will be reviewed and a call for tender issued in 2001

5.3 Conference services

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 administratively.

- EMEA meeting facilities will substantially improve in 2001, with the completion of the new conference and meeting rooms on the third floor
- Increase in workload of 17 % in 2001 is expected, particularly due to more meetings relating to human medicines and PERF activities
- A computerised meetings management system will be implemented in 2001. Procedures will also be reviewed to assist with the expected 32 % increase in 2001 in delegate reimbursement transactions
- Seek to increase the use of electronic versions of documents circulated to members of committees and working parties. This should reduce the volumes of documents photocopied and also the number of documents transported by delegates to and from meetings
- Videoconferencing capacities will be developed in 2001-2002 in order to improve and maximise the participation by experts in the work of the scientific committees, working parties and mutual recognition facilitation groups

5.4 Information technology

The sector's mission is to provide reliable and robust IT services to EMEA staff and delegates, together with appropriate levels of operational support while introducing new services and improvements to the infrastructure as required from the business and the users.

- Ensure a minimum system availability of 98% of IT services during EMEA working hours
- Ensure successful installation and implementation of the EudraVigilance electronic data reporting system for adverse reactions in the human and veterinary sectors
- Provide support to the installation of a document management system at EMEA

In addition, the following priorities will be progressed.

Topic	Activities
IT infrastructure	<i>High availability server installation, operating system change, open source software initiative, videoconference phase 3, upgrade of internet security</i>
Core application development	<i>ActiTrak, SI2, SIAMED, EudraVigilance, personnel management, meetings administration</i>
Network environment	<i>EudraNet, intranet, internet secure document transmission, firewall, automatic catalogue</i>
General application development	<i>Databases for European experts, scientific advice, scientific memory, orphan drugs, etc</i>
Additional IT facilities	<i>Several upgrades, new devices and technology</i>
Operational tasks	<i>Systems and network administration and support, Helpdesk, application support</i>

European initiatives and activities

At a strategic level the EMEA will participate fully in the Telematics Steering and Management Committees to coordinate activities between the EMEA, national competent authorities and the European Commission. The Agency's network will provide secure communications internally as well as with Member State partners via EudraNet and universally via the internet.

The question of whether EMEA should increase IT activities in the European marketing authorisation system will be addressed in 2001 in the context of the European Commission pharmaceutical IT strategy review.

Desktop videoconferencing services will be extended in 2001 to facilitate conferences between the EMEA, European Commission and national competent authorities.

The joint EMEA-World Health Organisation development of the SIAMED application tracking system will be completed during 2001.

Annexes

1. EMEA establishment plan 1999 – 2002
2. EMEA budget summaries 2000 – 2002
3. EMEA contact points and reference documents
4. Profiles of EMEA personalities



Annex 1

EMEA establishment plan 1999–2002

Category and Grade	Occupied as per 31.12.1999	Occupied as per 31.12.2000	Authorised for 2001	Requested for 2002
A1	--	--	--	--
A2	1	--	1	1
A3	4	4	5	5
A4	15	24	29	29
A5	22	22	27	28
A6	25	25	25	29
A7	23	23	24	30
A8	--	--	--	--
Total A	90	98	111	122
B1	1	3	4	4
B2	3	4	8	9
B3	6	6	9	11
B4	5	5	6	9
B5	4	5	5	8
Total B	19	23	32	41
C1	9	13	14	15
C2	12	13	14	19
C3	42	37	44	44
C4	--	--	--	4
C5	--	--	--	--
Total C	63	63	72	82
D1	--	1	1	1
D2	4	4	4	5
D3	--	--	--	--
D4	--	--	--	--
Total D	4	5	5	6
TOTAL POSTS	176	189	220	251

Allocation of posts		
	Allocation in 2001	Allocation in 2002
Directorate and financial control	11	11
Administration Unit		
Head of Unit team	2	2
Sector for Personnel, budget and facilities	22	23
Sector for Accounting	6	6
Reserve posts	2	2
Unit total	32	33
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	13
Sector for Quality of medicines	19	21
Sector for Safety and efficacy of medicines	16	21
Reserve posts	--	--
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	32
Reserve posts	--	4
Unit total	51	62
Unit for Veterinary Medicines and Information Technology		
Head of Unit team	3	3
Sector for Veterinary marketing authorisation procedures	9	10
Sector for Safety of veterinary medicines	7	8
Sector for Information technology	17	20
Reserve posts	--	1
Unit total	36	42
Technical Coordination Unit		
Head of Unit team	4	4
Sector for Inspections	15	16
Sector for document management and publishing	12	13
Sector for Conference services	10	12
Reserve posts	--	--
Unit total	41	45
Additional posts in general reserve	--	1
TOTAL NUMBER OF POSTS	220	251

Annex 2

EMEA budget summaries 2000-2002

	2000 ⁽¹⁾ (31.12.2000)		2001 ⁽²⁾ (21-22.2.2001)		2002 ⁽³⁾ (21-22.2.2001)	
Revenue						
fees	39 154 000	70.82%	42 610 000	68.56%	46 521 000	66.13%
general EU contribution	13 200 000	23.88%	14 700 000	23.64%	15 500 000	22.04%
special EU orphan medicinal product contribution	1 000 000	1.81%	600 000	0.97%	3 943 000	5.61%
contribution from EEA	245 220	0.44%	250 000	0.40%	250 000	0.36%
contribution from EU programmes (PERF)	217 000	0.39%	2 658 000	4.28%	2 627 000	3.74%
other	1 471 000	2.66%	1 334 000	2.15%	1 491 000	2.12%
TOTAL REVENUE	55 287 220	100.00%	62 152 000	100.00%	70 332 000	100.00%
Expenditure						
Staff						
salaries	18 493 000	33.45%	21 772 000	35.03%	24 842 000	35.32%
interim and other support persons	1 058 000	1.91%	1 379 000	2.22%	1 413 000	2.01%
other staff-related expenditure	1 350 000	2.44%	1 501 000	2.42%	1 622 500	2.31%
Total title 1	20 901 000	39.80%	24 652 000	39.67%	27 877 500	39.64%
Building/equipment						
rent/charges	5 212 220	9.43%	5 685 000	9.15%	5 450 000	7.74%
expenditure on data processing	2 423 500	4.38%	1 400 000	2.25%	1 200 000	1.71%
other capital expenditure	2 353 000	4.26%	824 500	1.33%	1 389 500	1.98%
postage and communications	480 000	0.87%	537 000	0.86%	577 000	0.82%
other administrative expenditure	1 593 000	2.88%	1 784 500	2.87%	1 947 500	2.77%
Total title 2	12 061 720	21.82%	10 231 000	16.46%	10 564 000	15.02%
Operational expenditure						
meetings	3 270 000	5.92%	4 125 000	6.64%	4 363 000	6.20%
evaluations	18 682 500	33.79%	19 658 000	31.63%	24 107 500	34.28%
translation	p.m.	0.00%	428 000	0.69%	467 000	0.66%
studies and consultants	5 000	0.01%	180 000	0.29%	100 000	0.14%
publications	150 000	0.27%	220 000	0.35%	226 000	0.32%
EU programmes	217 000	0.39%	2 658 000	4.27%	2 627 000	3.74%
Total title 3	22 324 500	40.38%	27 051 000	43.87%	31 890 000	45.34%
TOTAL EXPENDITURE	55 287 220	100.00%	62 152 000	100.00%	70 332 000	100.00%

Notes

(1) 2000 budget: final appropriations.

(2) 2001 budget: supplementary and amending budget No 1/2001.

(3) 2002 budget: preliminary draft budget.

Annex 3

EMEA contact points and reference documents

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

Contact point

Noël WATHION

Direct telephone (44-20) 74 18 85 92

E-mail: noel.wathion@emea.europa.eu

For matters relating to pharmacovigilance for medicinal products for veterinary use

Contact point

Barbara FREISCHEM

Direct telephone (44-20) 74 18 85 81

E-mail: barbara.freischem@emea.europa.eu

For product defect and other quality-related matters

Contact point

Francisco PEÑARANDA FERNANDEZ

Fax number for defective product

rapid alerts (44-20) 74 18 85 90

E-mail: francisco.penaranda@emea.europa.eu

Certificates of a medicinal product

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

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

Contact points

Jonna SUNELL-HUET

Direct telephone (44-20) 74 18 84 65

E-mail: certificate@emea.europa.eu

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

Contact point

Iro MAVROPOULOS

Direct telephone (44-20) 74 18 85 82

E-mail: subscriptions@emea.europa.eu

Requests for general information packs should be sent to

Contact point

Amanda BOSWORTH

Direct telephone (44-20) 74 18 84 08

E-mail: amanda.bosworth@emea.europa.eu

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.eudra.org

Veterinary medicines' experts list

vet_experts@emea.eudra.org

Inspectors' experts list

inspectors_experts@emea.eudra.org

Media and press contacts

Representatives of the media should contact the following people for information:

For general information

Contact points

Martin HARVEY

Direct telephone (44-20) 74 18 84 27

E-mail: martin.harvey@emea.eudra.org

Antoine CUVILLIER

Direct telephone (44-20) 74 18 84 28

E-mail: antoine.cuvillier@emea.eudra.org

For matters concerning medicinal products for human use

Contact point

Noël WATHION

Direct telephone (44-20) 74 18 85 92

E-mail: noel.wathion@emea.eudra.org

For matters concerning medicinal products for veterinary use

Contact point

Peter JONES

Direct telephone (44-20) 74 18 84 13

E-mail: peter.jones@emea.eudra.org

EU official publications

- Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, as amended (OJ L 214, 24.8.1993, p. 1)
- Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as amended (OJ L 224, 18.8.1990, p. 1)
- Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, as amended (OJ L 147, 9.6.1975, p. 13)
- Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of Member States relating to veterinary medicinal products, as amended (OJ L 317, 6.11.1981, p. 1)
- Council Regulation (EC) No 2743/98 of 14 December 1998 amending Council Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 345, 19.12.1998, p. 3)
- European Parliament and Council Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1)
- EMEA budget statement for the financial year 2000, including final appropriations for 1999 and outturn for 1998 (OJ L 184, 24.7.2000, p. 1)

The texts of these and other provisions are available in the series *Rules governing medicinal products in the European Community*. These publications, along with copies of the Official Journal, are available from:

Office for Official Publications of the European Communities
2, rue de Mercier
L - 2985 Luxembourg

and also on the EudraLex Internet site at

<http://pharmacos.eudra.org/eudralex/index.htm>

EMEA documents

- First General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1995 (ISBN 92-827-7491-0, Office for Official Publications of the EU)
- Second General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1996 (ISBN 92-9155-002-7, Office for Official Publications of the EU)
- Third General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1997 (ISBN 92-9155-010-8, Office for Official Publications of the EU)
- Fourth General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1998 (ISBN 92-9155-018-3, Office for Official Publications of the EU)
- Fifth General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1999 (ISBN 92-9155-026-4, EMEA)
- Sixth General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 2000 (ISBN 92-9155-034-5, EMEA)
- Statement of principles governing the partnership between the national competent authorities and the EMEA (EMEA/MB/013/97)
- Financial Regulation applicable to the budget of the EMEA (EMEA/MB/011/97)
- Decision of the Executive Director of 3 December 1997 on rules on access to documents of the EMEA (EDIR/016/1997)
- Decision of the Executive Director of 1 June 1999 on cooperation with the European Anti-Fraud Office (OLAF) (EDIR/006/1999)
- Catalogue of EMEA public documents (updated regularly)
- EMEA Code of Conduct (EMEA/D/37674/99)

These and other documents are available either on the Internet at <http://www.emea.eu.int> or by writing to:

Sector for Document management and publishing
European Agency for the Evaluation of Medicinal Products
7 Westferry Circus
Canary Wharf
UK - London E14 4HB

Annex 4

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 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.



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.



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.



G rard 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 Foug res 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. He was appointed Head of Unit March 2001.

Patrick Le Courtois, Acting Head of Sector for orphan drugs and scientific advice



**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.

**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.



**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.



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

Post vacant



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 pharmaceuticals 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 pharmaceuticals 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.

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 Information Technology



**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.



**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.

**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.

Technical Coordination Unit



**Karel de Neef, Head of Unit,
b. 21 December 1946, n. Dutch**

Education: Qualified medical doctor from the Medical School at Leiden University. PhD in developmental cardiology at Leiden University. Post-graduate work in cardiology and epidemiology at Erasmus

University, Rotterdam. Post-graduate training in clinical drug development, information management, biostatistics, pharmacovigilance, regulatory affairs and change management.

Career to date: From 1973, Dr de Neef taught medical physiology at the University of Surinam, South America. In 1976 he joined Organon International in the Netherlands, holding posts in neurophysiology, clinical research and clinical information management. He was also associated professor of medical physiology at the Technical University, Eindhoven. In 1992 he became International Director of clinical data management with Hoffmann-La Roche based the USA. He joined the EMEA in March 1996.



**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.

**Stephen Fairchild, Head of Sector
for inspections,
b. 19 June 1943, n. British**



Education: Qualified as a pharmacist from the University of Manchester in 1965. Member of the Royal Pharmaceutical Society of Great Britain and a Fellow of the Institute of Quality Assurance.

Career to date: From 1965 to 1973, Mr Fairchild worked in a major pharmaceutical company setting up quality assurance systems and in production operations. Between 1973 and 1980 he was employed as a medicines inspector in the UK Department of Health. He rejoined industry working for French and British multi-national pharmaceutical companies in international quality assurance before joining the EMEA in August 1995.

**Sylvie Bénéfice, Head of Sector
for conference services,
b. 28 December 1954, n. French**



Education: DSc 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.

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, Personnel, budget and facilities, 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.

Gerard O'Malley, Head of Sector, 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.