THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

WORK PROGRAMME

2000–2001

The European Agency for the Evaluation of Medicinal Products
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Work Programme for the European Agency for the Evaluation of Medicinal Products

2000-2001

Adopted by the Management Board on 22 February 2000

Contents

The Work Programme for 2000-2001 is presented to the Management Board by the Executive Director 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.

Previous work programmes and other reference documents are available from the EMEA web site at http://www.eudra.org/emea.html and further details are set out in annex 3.

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

Some useful web sites

• European Commission Pharmaceuticals and Cosmetics Unit	http://pharmacos.eudra.org
• EMEA	http://www.eudra.org/emea.org
• Heads of agencies for human medicines	http://heads.medagencies.org
• Heads of agencies for veterinary medicines	http://www.hevra.org
• 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
• European Pharmacopoeia	http://www.pheur.org

Introduction by the Executive Director

Fernand Sauer

The EMEA celebrated the fifth anniversary of its inauguration on 26 and 27 January 2000, an important event at which our many partners recognised the Agency as a mature and a well-established regulatory authority both in Europe and internationally.

Many people have played a part in the Agency's development, but I would like to pay special tribute to Strachan Heppell. He was first appointed chairman of the Management Board at the April 1994 and stepped down in February 2000 after having served two terms of office. Recognition must also be given to the considerable work of the two EMEA scientific committees, the CPMP and CVMP, under the leadership of Professors Jean-Michel Alexandre and Reinhard Kroker.

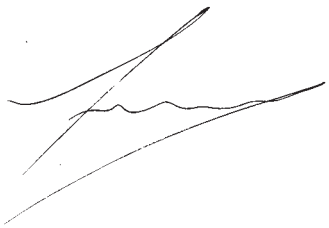
Together with the newly elected chairman of the Board, André Broekmans, I look forward to preparing for future challenges of the EMEA, including the changes that will come out of the review of the European marketing authorisation system in 2001. Until the review is over the EMEA will of course have to continue to operate within the current regulatory framework. There is still much to do within the current structures that can provide valuable lessons for the review process. The continuing dialogue with heads of national competent authorities for human and veterinary medicines and the European Commission will be essential during this process.

The entry into force of the Regulation on orphan medicinal products at the beginning of 2000 is a major step forward in making visible a coherent public health policy at EU level, bringing with it positive and tangible benefits for patients suffering from rare diseases. The EMEA hopes to add many more to the six orphan medicines that the Agency has already helped make available for patients even before the Regulation came into force – on its own resources.

The Pan-European Regulatory Forum for pharmaceuticals (PERF) between partners in the European Union and in central and eastern European countries has proved a success – as shown by the conference held 2-4 February 2000 in Budapest. I very much hope that that the European Commission PHARE or TAIEX programmes will be able continue funding for these efforts. This will allow for a more focused approach as we introduce our colleagues from central and eastern Europe into the EU scientific network, as we did for Iceland and Norway over the past 5 years.

Harmonisation initiatives with our main international partners continues in 2000-2001, culminating with the fifth International Conference on Harmonisation in San Diego in November 2000. Some 40 trilateral international guidelines will have been adopted by the close of this fifth conference. Completion of the harmonisation work with Japan and the US should help bring us closer to the goal of a worldwide application dossier and the possibility of joint evaluation in the coming years. Building on the success of the first public meeting of the veterinary VICH process held in Brussels in November 1999, some 10 trilateral international guidelines should be adopted over the next two years.

Within the EMEA, we have always been eager to pursue opportunities for improvement in the interests of human and animal health. Together with the pharmaceutical industry, an ongoing cycle of questionnaires is organised to assess the performance of the Agency and the centralised procedure. An approach based on the link between resources and objectives ('management by objectives and activity-based budgeting') has been attempted by the EMEA. A time management system – called ActiTrak –allows the EMEA to measure the resources used for each of the priorities set out in this work programme. The implementation of the new EMEA code of conduct will further increase the transparency and accountability of the EU medicines evaluation system.



Chapter 1

EMEA in 2000 and 2001

Overview of the Management Board and Executive Director

Chairman of the Management Board	André BROEKMANS
Vice-chairman	Gerhard KOTHMANN
Executive Director	Fernand SAUER
Financial controller, a.i.	Claus CHRISTIANSEN

1.1 Management Board

The Management Board began a new mandate in 2000, electing André Broekmans as its new chairman and Gerhard Kothmann as vice-chairman. This is the third mandate of the Board and members are appointed until the end of 2002. Representatives from Iceland and Norway now officially participate in meetings of the Board as observers.

Management Board meetings in 2000	Management Board meetings in 2001
• 22 February	• 21 February
• 7 June	• 6 June
• 27 September	• 3 October
• 20 December	• 19 December

As in previous years, those heads of national authorities that are not members of the Board will be invited to attend the June 'brainstorming' meetings of the Board.

The Management Board will in 2000 focus on:

- preparation of the Agency for changes that will arise from the review of the European marketing authorisation system by the European Union institutions
- collection of costing data for rapporteur activities and monitoring of the results of the ActiTrak system for EMEA secretariat activities
- preparation for the challenges of enlargement of the European Union

Review of the European marketing authorisation system

A review of the European marketing authorisation system is required by Council Regulation (EEC) No 2309/93 (OJ L 214, 24.8.1993, p. 1). The European Commission is expected to present a report and legislative proposals to the European Parliament and Council of the European Union at the beginning of 2001 on the operation of the centralised and mutual recognition procedures, as well as on the EMEA itself.

The Management Board will follow closely preparations by the European Commission in 2000 and the proposals and discussions of the European Parliament and Council in 2001. The EMEA will be ready to provide factual information on an ongoing basis as required by the EU institutions.

Costing exercise

Review of the fee regulation in 2002

Article 12 of Council Regulation (EC) No 297/95, as amended

"Within three years of the entry into force of this Regulation [21 December 1998], the Commission will present a report on its implementation, after consultation of the Agency's Management Board.

Future reviews of fees shall be based on a comprehensive evaluation of the Agency's costs, including expenditure relating to Member States' rapporteurs."

The Management Board will be concerned in 2000 and 2001 to build on progress in achieving a better understanding by EMEA and national competent authorities of the costs associated with the centralised procedure.

A comprehensive methodology for determining the costs of the EMEA secretariat was approved by the Management Board in 1999 and the Board will continue to monitor data generated by the model. Particular attention will be paid in 2000-2001 to looking at national authorities' costs for the provision of evaluation and inspection services. A further cost survey will be carried out on the basis of a questionnaire to be finalised by the Management Board in 2000.

Scale of fees payable by the EMEA to national competent authorities

The EMEA outsources the performance of scientific evaluation, surveillance and inspection services to national competent authorities. This represents about one-quarter of the EMEA budget that is used for European experts and peer review meetings.

Fees received from applicants and marketing authorisation holders are distributed between the EMEA and national authorities according to a scale of fees adopted by the Management Board. The Management Board decided the scale of fees applicable for 2000 at its 1 December 1999 meeting, under which half of most fees are paid to national authorities. About one-third of the EMEA budget is paid to national authorities each year for the provision of scientific services via appropriate contractual arrangements.

In addition to deciding the scale of fees for 2001, the Board will look at the basis for distribution of the annual fee paid by each marketing authorisation holder. The distribution of the new annual fee in 2000 is as follows: 30 % to cover EMEA staff costs, 30 % paid to rapporteur and co-rapporteur, 30 % attributed to special activities, and up to 10 % for sampling and testing of centrally authorised products. The Board will in particular review the scope of the special activities and projects for 2001.

Cooperation with national competent authorities

The EMEA relies on a network of 2,300 European experts nominated by national authorities for the performance of scientific tasks of the Agency. Following the launch of the electronic database in 1999, the list of experts available to the EMEA was published on the EMEA website in early 2000. The full list, together with the curriculum vitae and declarations of interests of all experts, remains available for public consultation by prior written request at the EMEA offices.

The programmes of the EMEA scientific committees for the development of guidelines and notes for guidance are set out elsewhere in this document and are also available on the EMEA website (http://www.eudra.org/emea.html). This harmonisation work – benefiting both the centralised and mutual recognition procedures – continues to be an important part of the activities of the EMEA.

The increase in the number of mutual recognition procedures is expected to continue in 2000-2001. Support from the EMEA will in particular include the availability in early 2000 of better facilities for break-out sessions and videoconferencing on the third floor. The Executive Director and the Management Board, together with heads of national authorities, will continue to explore initiatives to increase support to the mutual recognition procedure.

Further information on the work of the national competent authorities for human and veterinary medicines can be found on the following Internet sites: http://heads.medagencies.org and http://www.hevra.org.

Transparency and relations with interested parties

The first EMEA Internet web site was launched in September 1995. Since that time the number of documents available has increased dramatically and the number of requests for information – or 'hits' – has risen to over 2 million per month. An improved web site will be introduced during 2000 with greatly improved multi-lingual content, increased availability of 'modular' European public assessment reports (EPARs) and additional features.

A key part of the Agency's transparency initiatives are the joint reviews with industry trade associations of the performance not only of the Agency but also of the evaluation procedures themselves. The joint EMEA-EFPIA performance survey will continue in 2000-2001 and will be complemented by the results of the first EMEA-FEDESA survey expected in early 2000.

The EMEA code of conduct, adopted at the end of 1999 by the Management Board, will be fully implemented in 2000 and in particular the systematic annual renewal of declarations of interest by members of the Management Board, scientific committees, European experts and EMEA staff members. The independence of EMEA scientific expertise is vital to maintaining the Agency's credibility and particular attention will be paid to monitoring potential conflicts of interests of European experts. As part of this the list of experts is now available on the EMEA web site.

Following on from the workshop held in December 1999, the first open meeting on the Medicines Information Network for Europe (MINE) initiative will be held in June 2000. Representatives of national competent authorities and interested parties, in particular industry representatives, will be invited to the presentation of the MINE1 project and define future directions for the initiative.

1.2 EMEA management challenges

A number of changes will be progressively introduced to the EMEA management structure in 2000 and 2001. The most important will concern the structure of the Unit for the Evaluation of Medicines for Human Use and its possible division into two operational Units to cover additional tasks, in particular with regard to protocol assistance for orphan medicinal products. A small team will also be established to focus on the scientific expertise available to the EMEA, including the interface between national authorities and the EMEA, and the integration of the scientific expertise of central and eastern European national competent authorities into the EU network.

The former Unit for the Evaluation of Medicinal Products for Veterinary Use has been expanded to include responsibility for information technology and the responsibilities of the two existing Sectors have been modified to reflect changing priorities for veterinary medicines.

In the context of preparations for the review of the European system, the Directorate will play an increased role in ensuring liaison with the EU institutions. The quality management system (QMS) initiative has now become a key tool in the EMEA management. A programme of 10-12 internal audits of key functions will be conducted in 2000 and in 2001. This initiative might be extended to other EU and non-EU authorities as part of a wider benchmarking exercise. Teams made up of staff volunteers will focus on performance measurement and strategic business planning, European partnerships and also on training and implementation of management decisions.

A number of budgetary matters will need to be addressed again. Firstly, the EMEA will continue to discuss with the EU institutions the need for appropriate funding for orphan medicinal products. Without this financial support, it will not be possible for the EMEA to grant fee waivers as foreseen in European Parliament and Council Regulation (EC) No 141/2000 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1). It is hoped that the European Parliament will be able to provide for this reserve in a supplementary and amending budget to the EU general budget in 2000 and also in the initial 2001 budget.

Secondly, the relevant European institutions will need to be persuaded of the need to allow the Agency to create a limited pluri-annual reserve. Predicting the exact number of applications is difficult leading either to a budgetary deficit or excess towards the end of each year. As an agency that is increasingly reliant on fee revenue, this clearly hampers the operational activities of the EMEA in November and December. In addition the EMEA is subject to currency fluctuations between the euro and Pound Sterling because while it receives its income in euro, the majority of its expenditure is in Pound Sterling.

Currency fluctuations

In accordance with EU budgetary practices, the EMEA budget for 2000 was drawn up based on the euro exchange rate of February 1999 (1 euro = UKL 0.6928). By the time this Work Programme was adopted by the Management Board in February 2000, the exchange rate had fallen to 1 euro = UKL 0.6051, creating a budget shortfall of nearly 14 %.

Allocation of EMEA posts		
	Allocation in 2000	Allocation in 2001
Directorate and financial control	11	11
Administration unit		
Head of Unit team	2	2
Personnel, budget and facilities sector	21	22
Accounting sector	6	6
Unit total	*29*	*30*
Unit for the Evaluation of Medicines for Human Use		
Head of Unit team	5	6
Regulatory affairs and pharmacovigilance sector	30	30
Biotechnology and biologicals sector	23	23
New chemical substances sector	36	36
Reserve for new activities, including for orphan medicinal products	0	5
Unit total	*94*	*100*
Unit for Veterinary Medicines and Information Technology		
Head of Unit team	3	3
Veterinary marketing authorisation procedures sector	8	9
Safety of veterinary medicines sector	7	7
Information technology sector	17	17
Unit total	*35*	*36*
Technical Coordination Unit		
Head of Unit team	4	4
Inspections sector	14	14
Document management and publishing sector	13	13
Conference services sector	10	11
Unit total	*41*	*42*
Additional posts in general reserve	0	1
Total number of posts	210	220

1.3 Financial control

Financial controller, a.i.: Claus Christiansen

	1998	1999	2000 (estimate)	2001 (estimate)
a priori control of budgetary transactions				
Commitment proposals	1 126	1 326	1 500	1 650
Payment orders	3 350	4 010	4 600	5 500
Other financial transactions	513	1 037	1 200	1 300
Personnel related	316	291	300	300
Turnaround time in financial control				
Within 2 days	68 %	90 %	90 %	90 %
3-5 days	21 %	10 %	10 %	10 %
Over 5 days	11 %	—	—	—

The expected transfer to the European Commission of financial control responsibilities is now dependent on the re-organisation of the Commission services. The replacement of the European Commission's financial control by a decentralised structure based on internal audits within the individual Directorates-General has been publicly announced. As a consequence the links between the European Commission Directorate-General for Financial control and each of the EU decentralised bodies will have to be reconsidered during 2000.

Pending the results of this review, the Agency's financial control will continue to ensure compliance with the financial regulation and further consolidate internal procedures and structures in order to maintain and improve their quality.

Chapter 2

Key objectives for administration

Overview of the Administration Unit

Head of Unit	Andreas POTT*
Head of Sector for personnel, budget and facilities	Frances NUTTALL
Head of Sector for accounting	Gerard O'MALLEY

The Administration Unit is responsible for carrying out administrative and financial functions to ensure that the EMEA Secretariat and staff are able to perform their statutory tasks under satisfactory conditions.

(* From May 2000)

2.1 Sector for personnel, budget and facilities

- recruit suitable staff for the needs of the Agency promptly through selection procedures
- administer staff entitlements in accordance with the Staff Regulations
- provide information and assistance to new staff and to organise and co-ordinate training programmes for all staff
- deal with individual staff needs, liase with other units and the Staff Committee
- implement the current budget in 2000 in accordance with the financial regulations, report to management regularly thereon
- prepare the 2001 budget and follow up on the approval process for the European Community contribution
- provide a suitable office environment to support and facilitate the work of the Agency e.g. security, switchboard and reception services, office environment, equipment and supplies, restaurant and health and safety,
- complete the fitting out of the new floor 7 offices and the modification of existing floor 3 facilities

Personnel

Administration of entitlements for existing, new and departing staff covers the major part of the work. An important workload is related to the selection and the recruitment of new staff, as well as replacement of staff who leave. An internal competition will be conducted in 2000 to integrate the Agency's secretarial and clerical staff within the Regulations and rules applicable to officials and other servants of the European Communities.

The size of the Agency now requires a computerised personnel system to be implemented in 2000-2001.

As the Agency has grown in size, the role of the Staff Committee has become increasingly important. The Executive Director has four meetings a year with the Staff Committee and liaison is assured by the Sector.

Budget

The Sector is responsible for the overall management of the budget, in particular for all staff expenditure and premises-related expenditure. It carries out the functions of income and budget monitoring and the preparation of analytical accounts. Timely reports will be presented to management to ensure effective and efficient use of financial resources. The analytical accounts are facilitated by the ActiTrak system that records time spent by staff of the Agency on their different responsibilities. The Sector is also responsible for assisting the Executive Director in the process to obtain the approval of the budgetary authority for the EU contribution.

Close relations will be maintained with the Commission services responsible for personnel and budgetary matters, the European Parliament Committees on Budgets and Budgetary Control of the European Parliament, the Council of Ministers' Budgetary Committee and also the European Court of Auditors.

Facilities

The Sector also deals with security, switchboard, reception, fitting out of floors 3 and 7, building and equipment maintenance, cleaning, office supplies and equipment, and restaurant services. They also have responsibilities for health and safety. A computerised inventory system was introduced in 1999 and the process of converting the records will be completed in 2000.

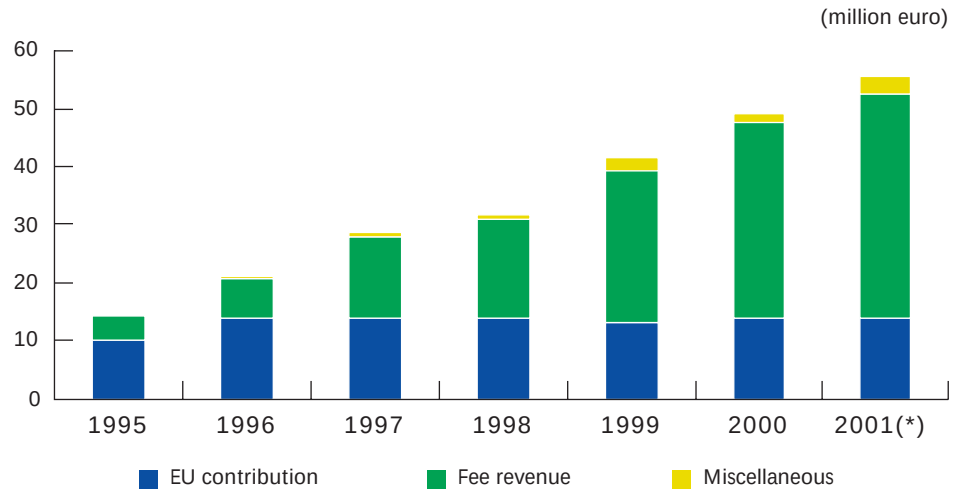
2.2 Sector for accounting

The Accounting Sector is responsible for the collection of revenue, the payment of expenditure, the preparation of budgetary accounts and the management of the Agency's cash resources. The budgetary accounts are kept up to date each day so that, at any time, the exact situation on any given budget line is available. The sector actively contributes to the documentation and streamlining of financial procedures to ensure that system specifications are in line with user requirements.

Notwithstanding the expected further growth of the Agency increases in the volume of transactions will be met as far, as is possible from the allocated staffing. Through the electronic banking payment and consultation system approved payments are executed within a maximum of 10 days.

A general ledger system has been selected and will be implemented in 2000.

Evolution of the EMEA budget 1995-2001



(*) Preliminary draft budget for 2001 adopted by the Management Board 22 February 2000.

Chapter 3

Key objectives for medicines for human use

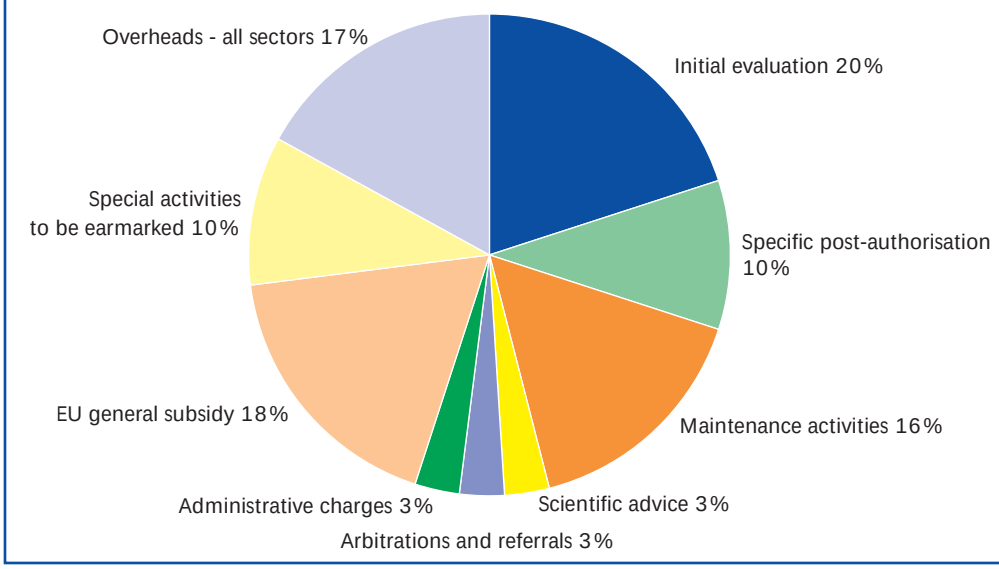
Overview of the CPMP and the Unit for the Evaluation of Medicinal Products for Human Use

Chairman of the CPMP	Jean-Michel ALEXANDRE
Vice-chairman of the CPMP	Mary TEELING
Head of Unit	Rolf BASS
Head of Sector for regulatory affairs and pharmacovigilance	Noël WATHION
Deputy Head of Sector	Isabelle MOULON
Head of Sector for biotechnology and biologicals	John PURVES
Deputy Head of Sector	Marisa PAPALUCA-AMATI
Head of Sector for new chemical substances	Patrick LE COURTOIS
Deputy Head of Sector	Tony HUMPHREYS

The Unit for the Evaluation of Medicines for Human Use is responsible for:

- management and follow-up of marketing authorisation applications under the centralised procedure
- post-marketing maintenance and pharmacovigilance of centrally 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 CPMP and its working parties

Activity forecasts for 2001



	1998	1999	2000 (estimate)	2001 (estimate)
Workload – fee related activities				
Scientific advice adopted (including follow-up advice)	43	64	65	68
Applications for new medicinal products	45	47	55	58
New medicinal substances	40	38	45	48
Type I variation applications	158	275	334	386
Type II variation applications	66	102	108	123
Extension applications	15	19	29	29
Renewals	—	—	5	25
Parallel distribution notifications	—	67	160	130
Arbitration referral opinions	5	4	10	11
Other Community referral opinions	1	5	5	5
Workload – non-fee related activities				
Pre-submission meetings	70	54	80	86
Specific obligations and follow-up measures	379	369	510	561
Non-EU ADR reports (unexpected)	4 417	8 878	12 000	15 000
Periodic safety update reports	108	133	243	277
CPMP guidelines	12	33	52	69
ICH-derived CPMP guidelines	3	7	6	7
Meeting days				
CPMP	34	33	36	36
Working parties (permanent)	47	56	70	72
Other meetings	109	67	91	94
Meetings on orphan medicinal products (designation and protocol assistance)	—	—	8	15
Total meeting days	190	192	205	217

3.1 Goals and objectives of the Unit for the Evaluation of Medicines for Human Use

The core responsibility activity of the Unit is support to the Committee for Proprietary Medicinal Products (CPMP), its working parties and the expert working groups.

An increase in the number of new centralised applications is expected in 2000 and 2001. This is mainly due to applications for orphan medicinal products following the entry into force of the European Parliament and Council Regulation on orphan medicinal products. Workload relating to variations (2000, 21 %; 2001, 15 %) and non-EU ADR reports (2000, 35 %; 2001, 25 %) will also increase. Additional workload will arise from annual re-assessments, specific obligations, follow-up measures and periodic safety reports.

The Unit intends to contribute to the Agency's objective of improving transparency, both for the general public and for patient, consumer, health care professionals, learned societies and pharmaceutical representative groups. In particular this will include:

- harmonisation of the content and standardisation of the presentation of medicinal product information documents. A key part of this will be the implementation of the readability guideline on package leaflets and the feedback from interested parties
- increased use of 'modular' European public assessment reports (EPAR), permitting access to the most up to date medicinal product information in all 11 official EU languages and increased standardisation of the scientific content and presentation
- ongoing analysis of positive opinions and withdrawals to better understand negative outcomes and analysis of authorisations under exceptional circumstances, including fulfilment of obligations and exploration of whether new information led to a changed benefit/risk ratio

Benchmarking and development of performance indicators

The Unit will:

- continue to monitor all phases of the centralised procedure. Performance measures for variation and line extension applications will be developed and introduced
- continue the joint EMEA-EFPIA survey to measure the level of satisfaction with the centralised procedure and the management of marketing authorisation applications
- develop and implement benchmarking with other regulatory authorities, e.g. Japanese Ministry of Health and Welfare and the US Food and Drug Administration
- monitor the number of new applications for the centralised procedure compared to the number of new active substances launched in 2000 and 2001 by the pharmaceutical industry within EU and worldwide
- continue to contribute to the internal quality management system (QMS), including to the EMEA QMS manual and support to internal auditing

To cope with the increased workload and the high number of procedures, it will be necessary to reorganise the Unit to increase efficiency, whilst maintaining the support required for CPMP and its working parties. This will require changes in the management structure and organisation of the sectors.

New activities and EU initiatives with significant impact on the workload include:

- entry into force of the European Parliament and Council regulation on orphan medicinal products. A cross-Unit team will be set up in 2000 to prepare for and initiate associated implementing legislation and in 2001, with the requested staff increase, it may be possible create a dedicated Sector responsible for the Committee on Orphan Medicinal Products and the provision of protocol assistance
- provision of operational information to Iceland and Norway, to facilitate their integration into the European procedures
- development of working relationships with the national authorities of central and eastern European countries in the framework of the Collaboration Agreement of Drug Regulation Authorities of European Union Associated Countries (CADREAC) and continuation of the PERF exercise

To deal with these activities, the number of working party and other meetings is expected to increase by approximately 30 % in 2000 and 2001. The number of guidance documents is expected to increase by one-half in 2000 and one-third in 2001.

The CPMP will continue to meet monthly under the chairmanship of Jean-Michel Alexandre and vice-chair Mary Teeling. In January 2001 the Committee's mandate will change in accordance with its three-year cycle and new members will meet and elect a new chairman and vice-chair.

CPMP meetings in 2000	CPMP meetings in 2001 (to be confirmed)
• 18-20 January*	• 23-25 January
• 15-17 February	• 27 February – 1 March
• 14-16 March*	• 27-29 March
• 11-13 April	• 24-26 April
• 23-25 May*	• 29-31 May
• 27-29 June	• 26-28 June
• 25-27 July*	• 24-26 July
• 22-24 August	• 21-23 August
• 19-21 September*	• 18-20 September
• 17-19 October	• 16-18 October
• 14-16 November*	• 13-15 November
• 12-14 December	• 11-13 December
** Rapporteurs to be appointed*	

3.2 General areas of activity

The first six areas of work are related to activities for which fees or administrative charges are payable and which have to be performed within binding timeframes. Objectives 7 and 8 address harmonisation and specific activities not covered currently by fees.

1. Initial evaluation work New applications (Part A/B) from pre-submission to EPAR	An increase of 17 % in 2000 and 5 % in 2001. In addition: • improvement of information to patients and healthcare professionals dedicated documents–participation in internal product information quality initiatives and the Quality review of documents working group • checking of mock-ups and specimens to be accelerated
2. Post-authorisation activities Variations type I/II, extensions, transfers, follow-up inspections	An increase in variations of 21 % for 2000, and of 15 % for 2001, in line with the increasing number of centrally authorised products. In addition: • development and implementation of improved performance indicators
3. Maintenance activities Follow-up measures, specific obligations, annual re-assessments, renewals, pharmacovigilance, reinforced dialogue with interested parties	Workload is expected to increase by 35 % in 2000 for non-EU ADR reports (unexpected) and by another 25 % in 2001, as more centrally authorised products reach the market. The special and innovative character of many of these authorised products requires close monitoring, resulting in • increases in reporting of EU and non-EU adverse drug reactions • increases in the number of periodic safety update reports and more frequent safety reporting • improvements in tools for handling pharmacovigilance crisis situations • dialogue with wider spectrum of interested parties and learned societies In addition, the first renewals are due in 2000. Also, there are now more than 10 products for which marketing authorisations have been granted under ‘exceptional circumstances’, that require annual re-assessment.
4. Scientific advice	A slight increase in the number of both initial, and follow-up scientific advice is expected in 2000, with a further increase in 2001 (5 %).
5. Arbitration and Community referrals	The number of arbitration procedures is expected to rise in 2000 as a consequence of arbitration on variation applications to the initial authorisation where individual concerned Member State withdrawals are not an option. It is difficult to predict the number of pharmacovigilance referral opinions expected in 2000 as such referrals typically relate to unexpected and serious safety issues for nationally or mutually recognised products. Therefore a similar level of activity to 1999 is proposed.

6. Special services	• handling of parallel distribution notifications • support for the preparation of certificates for medicinal products • preparation of documents for the EMEA subscription service • validations with a negative outcome Since the introduction of the EMEA procedure on handling of parallel distribution notifications, applicants have been familiarised with the procedure and the bulk of applications are expected to be finalised in 2000, whereas submissions are expected to level off to a constant level in 2001.
7. Harmonisation tasks Support to CPMP and Working Parties	The main harmonisation activities – which benefit both the centralised and mutual recognition procedures – are developed through the CPMP working parties and ad hoc working groups as guidelines. This work will increase in 2000-2001 and other workload increases include contributions to the following internal initiatives: • improve the management and quality of the centralised procedure • surveys of applicant companies and marketing authorisation holders • collaboration and communication with other regulatory authorities, especially those in central and eastern European countries, Japan and USA
8. Specific activities at request of EU institutions and Member States Collaboration with central and eastern European countries, support to the Mutual Recognition Facilitation Group, EMCDDA/Europe networks	The pronounced increase in mutual recognition procedures requires support to facilitate the smooth running of the Mutual Recognition Facilitation Group (MRFG) and to support to the evaluation of herbal medicinal products, in particular to prevent routine arbitrations in the mutual recognition procedure. Other specific activities includes: • participation of Iceland and Norway in EMEA activities • continued active participation in and support to ICH with finalisation of the 'common technical document' in 2000 and implementation in 2001 • development of new activities in favour of orphan medicinal products • continued collaboration with central and eastern European countries in the framework of the simplified procedure for the recognition of centrally authorised products (CADREAC agreement) and the PERF initiative • collaboration with the European Monitoring Centre for Drugs and Drug Addiction in the field of risk assessment for new synthetic drugs will continue to increase

3.3 Key functions for the evaluation of medicines for human use

Provision of CPMP secretariat, regulatory affairs, relations with national competent authorities and EU institutions

- contribute to the protection and promotion of public health, including new activities like orphan medicinal products
- provide a high standard of technical and organisational support to CPMP meetings
- provide legal, regulatory and procedural guidance to all involved parties
- provide support to the Commission decision-taking process
- coordinate the handling of parallel distribution notifications within 30 days
- coordinate practical arrangements for inclusion of Iceland and Norway in EMEA activities
- further strengthen the collaboration with central and eastern European countries in the framework of recognition of centrally authorised medicinal products including maintenance and provision of pharmacovigilance information
- support the Mutual Recognition Facilitation Group (MRFG) and its expanding activities
- provide technical and organisational support to EMEA Herbal Medicinal Products Working Party
- support participation of the EMEA in the Joint Action on new synthetic drugs together with the European Monitoring Centre for Drugs and Drug Addiction and Europol

Provision of secretariat for the Committee for Orphan Medicinal Products

- provide technical and organisational support for the new Committee
- provide administrative and scientific management of orphan designation
- coordinate with the European Commission activities arising from the implementation of the European Parliament and Council Regulation on orphan medicinal products

CPMP working parties and ad hoc groups

- improve the technical and secretarial support to the harmonisation activities particularly for the Efficacy, Safety, Quality and Biotechnology Working Parties and for ICH-related activities
- support the quality, consistency and production of guidance documents and their dissemination
- establish contacts with specialist working groups and European learned societies to further improve dialogue with the scientific community
- develop the principle of a multidisciplinary approach to address new issues related to the use of transgenic animals, transgenic plants and cells for the production of medicinal products
- support the ad hoc working group on blood products, the working group on influenza vaccines and a number of specialised working groups e.g. on transmissible spongiform encephalopathies (TSE), including Creutzfeld-Jacob's Disease (CJD), on the quality of plasma derived medicinal products and on gene transfer products
- coordinate as required several clinical or multidisciplinary ad hoc CPMP working groups, e.g. on AIDS or oncology

Provision of scientific advice and protocol assistance

- provide better guidance to industry through the availability of a scientific advice pre-submission guidance document to facilitate the submission of scientific advice requests
- provide high quality scientific advice to industry within targeted timeframes, and to ensure consistency in the provision of such advice
- investigate the impact of scientific advice provided on outcomes of subsequent applications submitted through the centralised procedure
- provide protocol assistance for the development of orphan medicinal products
- develop a scientific advice database, open to scientific committee members and EMEA, to ensure consistency in scientific documents

Management of centralised procedures

- achieve total compliance with regulatory deadlines for completion of marketing authorisation applications
- coordinate the standardisation and consistency of CPMP assessment reports and EPARs through the development of quality control activities
- provide better information to the public on the state of art in the area of biotechnology and biological products
- contribute to the development of additional methodologies for assessing and minimising identified risks, e.g. TSE/CJD, nuclear amplification technique testing methodologies
- further develop the procedures for the evaluation of medicinal products containing genetically modified organisms and ancillary medical devices

Management of pharmacovigilance and relevant post-authorisation procedures

- achieve total compliance with regulatory deadlines for completion of relevant procedures and applications and updating of the scientific output (e.g. product information and the EPAR)
- optimise the management and monitoring of an increasing amount of safety information relating to centrally authorised medicinal products through close collaboration with CPMP, Member States and European pharmacovigilance experts
- further streamline the management of referrals dealing with safety concerns for nationally authorised products and respect deadlines for the completion of such referral procedures
- further strengthen collaboration and communication with non-EU regulatory authorities, especially the US FDA, on pharmacovigilance related matters
- further develop and implement the electronic transmission and management of pharmacovigilance information

Chapter 4

Key objectives for veterinary medicines and information technology

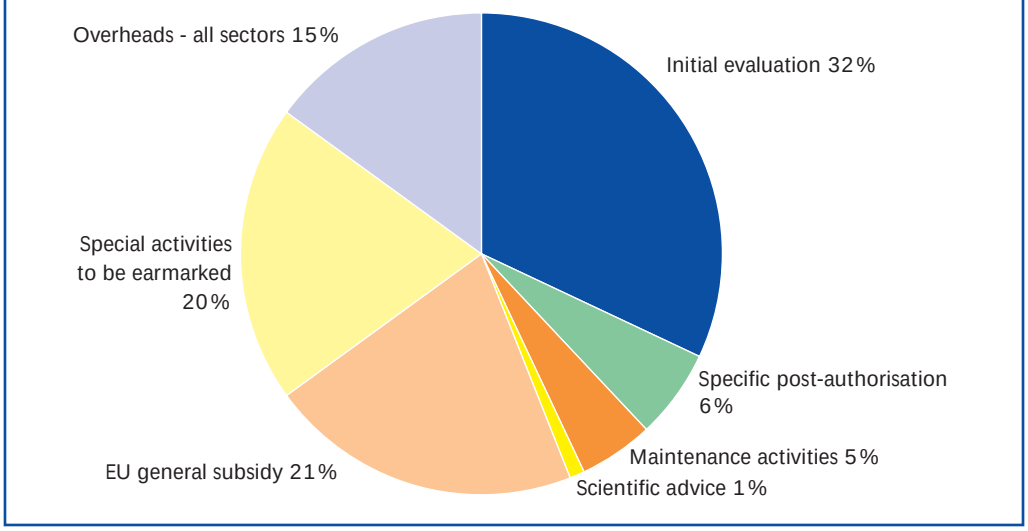
Overview of the CVMP and the Unit for Veterinary Medicines and Information Technology

Chairman of the CVMP	Reinhard KROKER
Vice-chairman of the CVMP	Gabriel BEECHINOR
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 Unit is responsible for:

- management and follow-up of marketing authorisation applications under the centralised procedure
- management of applications for the establishment of maximum limits of residues 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
- provision of information technology support to the EMEA

Activity forecasts for 2001



	1998	1999	2000 (estimate)	2001 (estimate)
Workload				
New centralised applications	14	4	8	10
Extensions to centralised applications	7	6	8	12
Abridged applications	0	1	1	2
Arbitrations/referrals	—	1	1	1
Variations type I	7	16	15	20
Variations type II	—	3	5	6
Transfers	—	0	0	1
Scientific advice	3	2	2	2
New MRL applications	4	3	4	6
Modification/extensions of new MRLs	10	12	16	18
Opinions on establishment of old MRLs	114	157	15*	10**
CVMP and VICH guidelines adopted	6	17	12	12
Meeting days	59	61	67	63

** Provisional MRLs expiring after January 2000*
*** Provisional MRLs expiring after January 2001*

4.1 Goals and objectives for veterinary medicines

Within the restructuring plans for the Agency, responsibility for the management of the Sector for information technology transferred to the Unit for Veterinary Medicines and Information Technology at the beginning of 2000. Activity forecasts for information technology are therefore included in this chapter.

In addition, the remits of the two existing Sectors within the Unit were redefined from 1 January 2000 now that the task of setting maximum residue limits (MRLs) for old substances, coordinated by the former Sector for MRLs, has been completed. The names of the Unit and two veterinary Sectors have been changed to reflect these developments.

Sector for veterinary marketing authorisation procedures

- manage procedures for centralised applications
- coordinate procedures for variations and extensions, and post-authorisations activities
- provide logistical and scientific support to the Immunologicals, Efficacy and Quality Working Parties
- provide secretariat support to the VMRFG

Sector for safety of veterinary medicines

- supervise and coordinate pharmacovigilance
- manage procedures for new MRL applications
- provide logistical and scientific support to CVMP and the Safety and Pharmacovigilance Working Parties
- coordinate mainstream topics relating to consumer safety

The major impact of changes to the two Sectors dealing with veterinary medicines is expected to be an increase in 2000-2001 of the allocation of time to fee-related activities.

Fee-related activities will grow as the number of centralised applications increases in 2000-2001. Support for activities funded from the EU general subsidy will decline due to the reduction in demands on the CVMP Safety Working Party to work on MRLs in future. While the level of support to experts assigned to MRL-related work will decline, this will be compensated for by the ongoing commitment to the availability of medicines programme and the increased activities in support of central and eastern European countries.

The CVMP will continue to meet monthly under the chairmanship of Reinhard Kroker and vice-chair Gabriel Beechinor. In January 2001 the Committee's mandate will change in accordance with its three-year cycle and new members will meet and elect a new chairman and vice-chair.

CVMP meetings in 2000	CVMP meetings in 2001 *(to be confirmed)*
• 11-13 January	• 9-11 January
• 8-10 February	• 13-15 February
• 7-9 March	• 13-15 March
• 18-19 April	• 17-19 April
• 16-18 May	• 15-17 May
• 20-22 June	• 12-14 June
• 18-20 July	• 10-12 July
• 16-17 August*	• 7-9 August*
• 12-14 September	• 11-13 September
• 10-12 October	• 9-11 October
• 7-9 November	• 6-8 November
• 5-7 December	• 4-6 December

** These meetings will be held if urgent matters need attending to.*

In the years 2000 and 2001 the Unit will strive to progress a number of very important initiatives which commenced in previous years.

Major topic	Key activity
• antimicrobial resistance	• risk management strategic plan
• availability of veterinary medicines	• pursue European task force objectives
• international harmonisation	• VICH guidelines and CADREAC agreements
• pre-submission guidance	• optimise efficiency in the centralised procedure

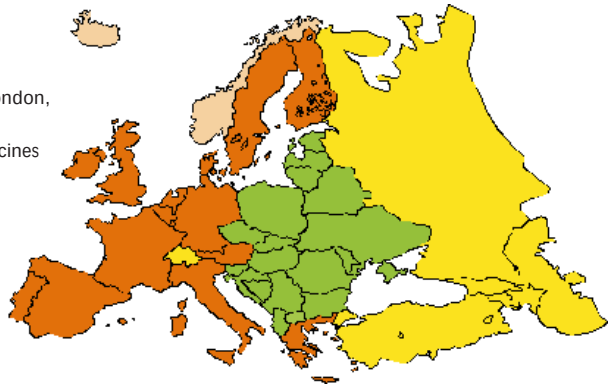
International Harmonisation 2000-2001

Guidelines Scheduled for Release	Step
1. Environmental Impact Assessment Phase 1	7
2. Good Clinical Practice	7
3. Efficacy of Anthelmintics Swine, Equines, Canines	5
4. Stability Testing of Biotechnology/ Biological Veterinary Medicines	7
5. Impurities Residual Solvents	7
6. Testing of Extraneous Agents in Biologicals	3
7. Pharmacovigilance Guidelines	3

Projects to be undertaken

- Joint EMEA/TAIEX meetings for CADREAC Countries
  - Immunological Veterinary Medicines London, 20-21 March
- CADREAC Agreement on Veterinary Medicines
- Veterinary Topics in PERF

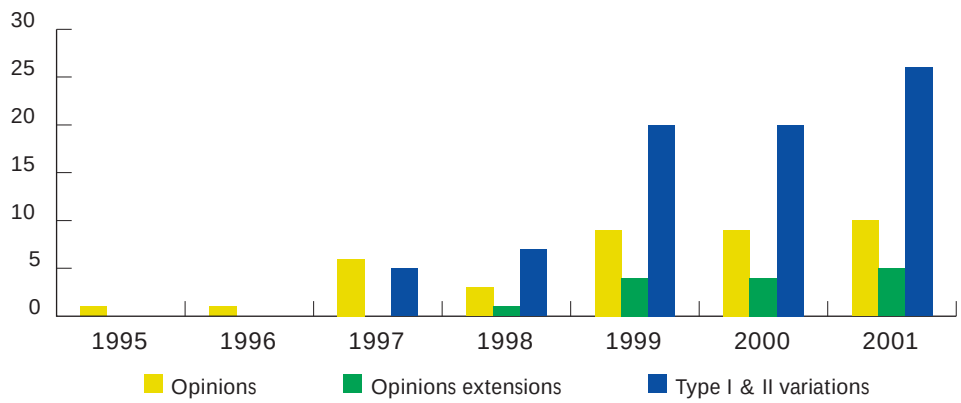
Details will be posted on EMEA web page



4.2 Veterinary marketing authorisation procedures

The forecast of 8 centralised applications for 2000 is made based on the letters of intent received in the final quarter of last year and enquiries about eligibility of products in development. A total of 21 opinions are expected to be finalised during 2000-2001 and as a consequence the number of variations and extensions is expected to significantly increase. The outcome of these developments is expected to result in increased efforts in specific post-authorisation activities in the Sector for veterinary marketing authorisation procedures.

Forecast opinions and post-authorisation activities



The level of support required for scientific advice and Community referrals is likely to remain stable in 2000-2001.

Further emphasis will be given to consolidating the risk assessment and conclusions in the assessment reports of the CVMP for centralised opinions to better reflect discussions of the Committee in reaching its opinions.

Working party priorities

The Sector provides Secretariat support to the following working parties of the CVMP, the chairpersons of which have agreed with the members, the following priorities for the work programme in 2000:

Immunologicals Working Party

- To draft guidelines on a number of new topics, including
  - batch consistency of vaccines
  - vectored vaccines
- In addition the Working Party will conclude its work on
  - DNA vaccines for veterinary use
  - field efficacy testing of veterinary vaccines
  - requirements for combined veterinary vaccines
  - duration of protection achieved by veterinary vaccines

Efficacy Working Party

- To finalise a draft guidance note to be released for consultation on a range of topics to include:
  - bioequivalence studies
  - ectoparasiticide testing requirements for tick and flea infestations in dogs and cats
  - ectoparasiticide testing requirements for sheep
  - biostatistical requirements
  - efficacy guidelines for non-steroidal anti-inflammatory drugs (NSAIDs)
- Elaborate guidelines for the definition of:
  - glossary of therapeutic claims
  - efficacy requirements for minor requirements and minor species
  - standard phrases for summaries of product characteristics

Joint CPMP/CVMP Quality Working Party

- The Working Party will continue to develop guidance notes and particular focus will be given to the following veterinary topics:
  - consideration of the guidance for requirements for active substances
  - guideline on the stability of non-biological established active ingredients and finished products
- The Working Party will monitor developments in ICH with a view to making similar recommendations for VICH guidelines

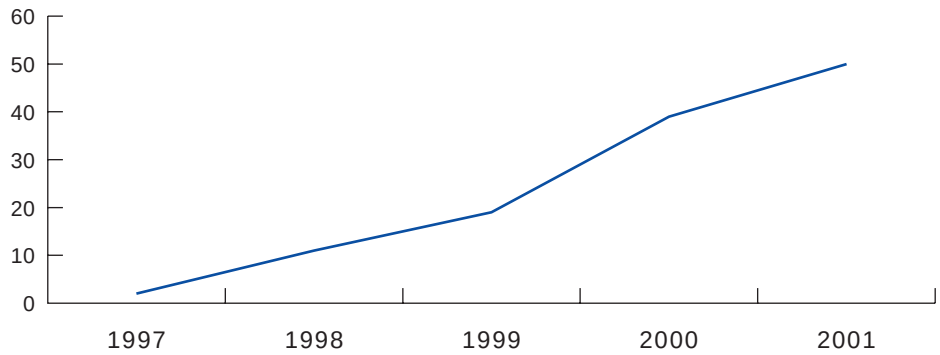
4.3 Safety of veterinary medicines

A major distribution of activities in terms of fee earning capacity is expected for the Sector for the safety of veterinary medicines in 2000.

An important reduction in the time spent in processing old MRLs is anticipated as this work draws to a close, while the number of applications for new MRLs, their extensions and modifications is expected to remain stable. Considerable effort will be given to supporting the ongoing initiatives on Availability of Medicines with the continued work of the European task force established by the Agency in collaboration with the Commission, Member States and interested parties. Attention will focus once again, in consultation with the CPMP, on antimicrobial resistance with the development and implementation of the CVMP risk management strategic plan following the publication of the CVMP report on this topic in July 1999.

The increase in the number of authorised veterinary medicines will result in a considerable increase in pharmacovigilance activities, which now falls within the responsibility of this Sector.

Projected increases in periodic safety update reports



Working party priorities

The Safety Sector provides Secretariat support to the Safety and Pharmacovigilance Working Parties. Their work programme priorities have been agreed with the chairpersons and members and are presented here:

Safety Working Party

- guidelines on the determination of withdrawal periods in milk
- assessment of antimicrobial substances on dairy starter culture
- development of a risk management strategy plan for controlling antimicrobial resistance
- coordinate EU input into guidelines in the VICH process
- proposal of opinions for substances currently placed in Annex III of Council Regulation (EEC) No 2377/90

Pharmacovigilance Working Party

- Development of a drug monitor in order to
  - provide a summary of all key and relevant pharmacovigilance information
  - enhance traceability
  - provide a general overview on post-marketing surveillance studies
- Finalisation of the VEDDRA (Veterinary Medical Dictionary for Drug Regulatory Authorities) list of clinical terms
- Finalisation of a guideline on post-marketing surveillance studies

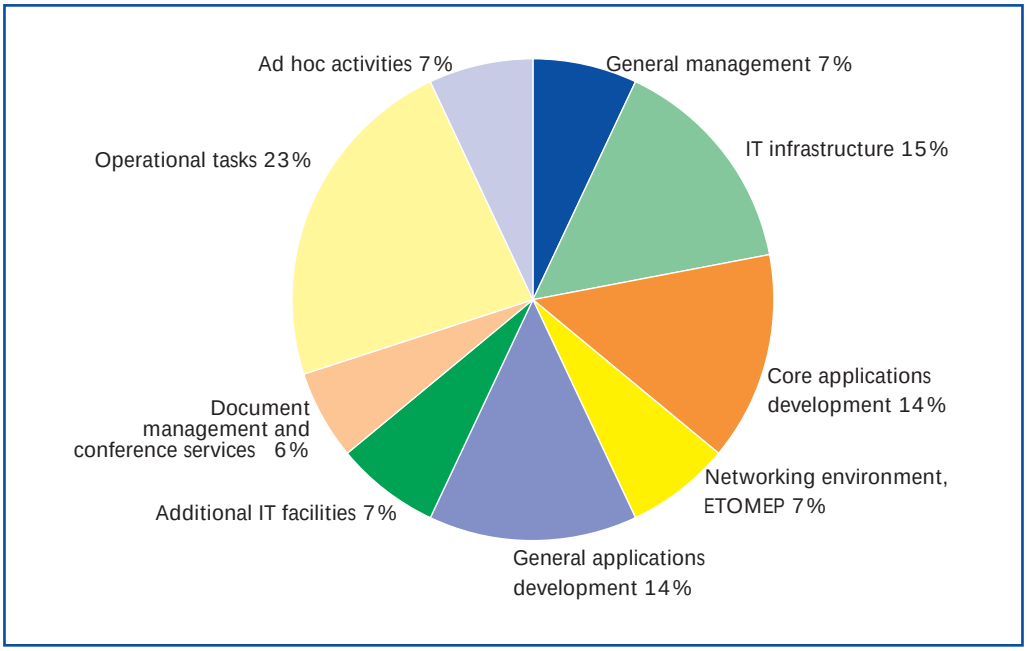
4.4 Information technology

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.

A minimum system availability target of 98 % aims at ensuring that all IT services are available when the EMEA is open. Continued emphasis will be made to balance IT user requests with available resources while the Sector's human resource profile will be consolidated.

Key Sector responsibilities include:

Topic	Activities
• IT Infrastructure	• increase in availability and fault tolerance, rationalisation of architecture, videoconference
• core application development • network environment	• ActiTrak, SI2, SIAMED, EudraWatch • EudraNet, intranet, internet, secure document transmission
• general application development	• databases for experts, contacts, personnel, payments, recruitment
• additional IT facilities • document management & conferences	• upgrades, new devices and technology • implement document management system, automatic catalogue, meeting system
• operational tasks	• systems and network administration, Helpdesk, application support



Coordination of European activities

At a strategic level the EMEA will participate in the newly formed Telematics Steering Committee 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 the Member State partners via EudraNet and universally via the Internet.

The implementation of an effective videoconference system is seen as an important step towards facilitating meetings between the EMEA, Commission and national authorities. The Sector will implement a trial system and will collaborate with the European Commission Joint Research Centre in the development of a videoconference system as part of the 5th framework programme.

Chapter 5

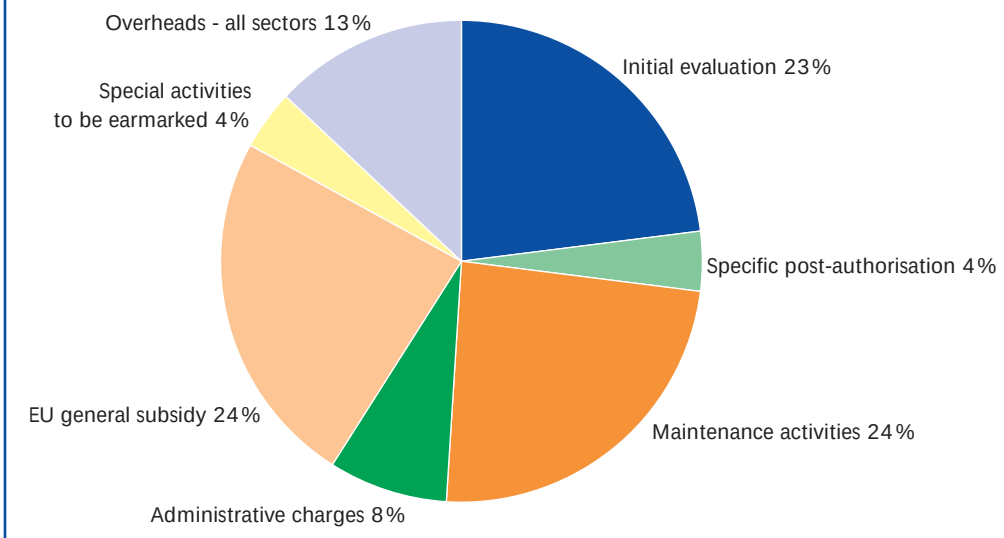
Key objectives for technical coordination

Overview of the Technical Coordination Unit

Head of Unit	Karel DE NEEF
Head of Sector for inspections	Stephen FAIRCHILD
Head of Sector for document management and publishing	Beatrice FAYL
Head of Sector for conference services	Sylvie BÉNÉFICE

The Unit is responsible for providing logistical support to both human and veterinary medicines evaluation activities as well as a number of general services to the EMEA.

Activity forecasts for 2001



	1998	1999	2000 (estimate)	2001 (estimate)
Workload				
Inspections				
GMP inspections	61	21	60	55
GCP inspections	0	0	5	8
GLP inspections	0	2	3	4
Certificates of a medicinal product	9 300	9 652	12 000	16 000
MRA implementation	2	5	6	6
Document management and publishing				
Subscriptions	229	180	250	270
Requests for documents	2 122	2 000	3 600	3 800
Mail in	40 897	18 613	25 000	30 000
Mail out	18 083	23 500	30 000	35 000
Number of pages translated	4 071	4 993	5 000	5 500
Conference services				
Total meeting days at the EMEA	324	430	459	421
Interpretation man/days	412	351	357	357

5.1 Workload and goals of the Technical Coordination Unit

The Unit provides logistical and technical support to the evaluation activities relating to human and veterinary medicinal products. The primary areas of responsibility are inspection activities, document management and publishing, and conference services.

The focus in 2000-2001 will be on improving efficiency, e.g. production of certificates for medicinal products and document dissemination. Increases in workload are to a large extent to be absorbed through improved facilities and working practices.

Project work will include the continuation of the Pan-European Regulatory Forum on pharmaceuticals (PERF) into 2000. The Agency has organised this forum since July 1999 and the current programme will conclude during the second quarter of 2000. The PERF has been realised with significant contribution from experts from both national competent authorities and the EMEA.

It is hoped that, following an evaluation of the PERF programme and its achievements, budgetary facilities will be made available to

continue harmonisation of regulatory practices between candidate countries and the European Union. In the event of extension of such activities, programme activities will be spread more evenly over a longer time period, continuing until accession.

Work on the definition of a common electronic format for dossiers to be submitted for regulatory approval will continue. The first step, electronic management of product information throughout the product life cycle will become operational.

5.2 Inspections

The Sector for inspections coordinates the work of inspectors and expert groups in support of the evaluation of medicinal products and general inspection activities. The Sector also plays an active role in monitoring products authorised within the Community.

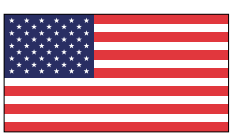
The EMEA organises meetings of the inspection services of the Community Member States that have responsibility for good clinical practice (GCP) and good manufacturing practice (GMP) inspections. These two groups meet at the EMEA on a regular basis to develop procedures and guidelines for the harmonisation of GCP and GMP inspections carried out by the Community and for the inspections that are required to complete the evaluation of applications under the Centralised System. The GMP group is also actively involved in supporting the implementation of mutual recognition agreements (on GMP inspections) with third parties.

Initial evaluation and specific post-marketing activities

The workload for the Sector in connection with the initial evaluation of applications will increase slightly during 2000 and 2001 in line with the upward trend in the number of new applications and variations under the centralised system. This will consist mainly of Good Manufacturing Practice (GMP) inspections to which will be added a number of Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) inspections.

A small increase in the post-marketing inspections (for GMP, GCP and possibly GLP) is expected for centrally authorised products. Additional work will also be involved in monitoring and, where necessary, coordinating routine inspections of manufacturers of centrally authorised products.

Maintenance activities and mutual recognition agreements



Maintenance activities will include the operation of systems to deal with defective products and crisis management, mutual recognition agreements (MRAs) between the European Community and third countries and the programme for monitoring the quality of centrally authorised products. These activities will also increase in 2000 and 2001 in line with the number of authorised products.

Product monitoring is performed by the network of Official Medicines Control Laboratories coordinated by the European Department for Quality of Medicines and the EMEA. The program will involve the sampling and testing of centrally authorised

products three years after authorisation; 16 products will be tested in 2000 and 28 products in 2001.

The level of work arising from MRAs is expected to rise by around 20 %. In 2000 the increase will be due to completion of the transitional phase of the EC-Canada MRA, the start of full operation of the EC-Australia and EC-New Zealand agreements and the evaluation of equivalence under the EC-USA MRA. In 2001 it is expected that work on the EC-USA MRA will increase and that the EC-Switzerland MRA will come into full operation.

Certification of medicinal products

The number of certificates issued for centrally authorised medicinal products is expected to increase by approximately 20 % in 2000 and 30 % in 2001. No increased in the size of the team dealing with requests is foreseen due to improvements to the production system recently introduced.

5.3 Document management and publishing

The Sector is responsible for product information quality, translations and the coherence of regulatory documents. It is also responsible for the publication, cataloguing and electronic storage of the EMEA documentation. The provision of information to third parties, the EMEA library, archiving and mailroom services fall within the Sector's area of operation.

Quality of information

The workload of the Quality Review of Documents Working Group (QRD) will increase gradually, reflecting the trend in applications received. The successful implementation of distributed document review through the network of national competent authorities will be extended to Iceland and Norway in 2000. This successful functioning of this network will permit the resolution of complex issues and cover the new summary of product characteristics guidance and legibility testing for patient information.

Document management and dissemination

The Agency has put in place a robust structure for creating and maintaining electronic documents. During 2000-2001 the Agency will review its future needs in the context of information being increasingly available in electronic format and the benefits of this not only to simplify work processes, but also to improve public access to documents. The Sector will also participate in the development of a harmonised approach to electronic submission of application dossiers.

Attention will be given to improving electronic access to and archiving of documents by the scientific committees and EMEA staff in order to simplify document workflow, in particular in relation to meetings.

5.4 Conference services

The Sector is responsible for EMEA conference facilities and organisation of meetings. Specific responsibilities include assisting delegates by making travel arrangements, reimbursement of expenses and the provision of photocopying facilities for the EMEA.

An increase of 5 % in the number of meetings is expected in 2000. With the start of preparations for the mutual recognition agreement with Canada and the PERF programme the Sector is also involved with meeting organisation outside the EMEA. These activities are expected to increase and require new arrangements for meeting organisation as well as reimbursement of delegates.

Completion of the modifications to floor 3 facilities will increase the capacity for EMEA meetings and support for mutual recognition procedures. This will be accompanied by a review of the technical equipment set-up including audio-visual system and videoconferencing facilities to ensure that the technical and logistical requirements are being met.

The use of paper versions of documents for mailings and meetings will be reviewed in 2000-2001 with the aim of reducing the volumes of paper photocopied and distributed. Wherever possible, the use of electronic versions will be encouraged, reducing not only the volumes required of the centralised reprographics facility, but also mailing volumes and the number of physical documents transported by delegates attending meetings.

The activities of the Sector also include the provision of proceedings documents and technical reports on workshops organised at the EMEA. The Sector also cooperates with the Ireland and UK liaison office of the European Commission Joint Interpretation and Conference Service located within the EMEA.

Annexes

1. EMEA establishment plan 1998 – 2001
2. EMEA budget summaries 1998 – 2001
3. EMEA contact points and reference documents
4. Profiles of EMEA personalities

Annex 1: EMEA establishment plan 1998 – 2001

Category and Grade	Occupied as per 31.12.1998	Occupied as per 31.12.1999	Authorised for 2000	Requested for 2001
A1	—	—	—	—
A2	1	1	1	1
A3	4	4	4	5
A4	13	15	29	29
A5	15	22	23	27
A6	17	25	25	25
A7	37	23	23	24
A8	0	—	—	—
TOTAL A	73	90	105	111
B1	1	1	3	4
B2	3	3	8	8
B3	6	6	8	9
B4	7	5	6	6
B5	5	4	5	5
TOTAL B	22	19	30	32
C1	5	9	13	14
C2	3	12	14	14
C3	36	43	43	44
C4	—	—	—	—
C5	—	—	—	—
TOTAL C	44	63	70	72
D1	—	—	1	1
D2	—	4	4	4
D3	4	—	—	—
D4	—	—	—	—
TOTAL D	4	4	5	5
TOTAL POSTS	143	176	210	220

Annex 2: EMEA budget summaries 1999 – 2001

The summarised comparative budget statements for 1999 to 2001 are as follows:
(Amounts expressed in euro)

	1999 (1.12.1999)		2000 (1.12.1999)		2001 (22.2.2000)	
Expenditure						
Staff						
salaries	16 172 000	*37.92%*	18 693 000	*37.72%*	21 544 000	*37.62%*
interim and other support persons	1 183 000	*2.77%*	1 048 000	*2.11%*	1 376 000	*2.40%*
other staff-related expenditure	1 161 000	*2.72%*	1 130 000	*2.28%*	1 402 000	*2.45%*
total title 1	18 516 000	43.41%	20 871 000	42.11%	24 322 000	42.47%
Building/equipment						
rent/charges	2 167 450	*5.08%*	5 200 000	*10.49%*	5 200 000	*9.08%*
expenditure on data processing	883 000	*2.07%*	1 434 000	*2.89%*	635 000	*1.11%*
other capital expenditure	2 008 280	*4.71%*	308 000	*0.62%*	50 000	*0.09%*
postage and communications	378 000	*0.89%*	460 000	*0.93%*	555 000	*0.97%*
other administrative expenditure	1 214 270	*2.85%*	1 553 000	*3.14%*	1 642 000	*2.86%*
total title 2	6 651 000	15.60%	8 955 000	18.07%	8 082 000	14.11%
Operational expenditure						
meetings	3 284 000	*7.70%*	3 875 000	*7.82%*	5 411 000	*9.45%*
evaluations	13 894 000	*32.58%*	15 458 000	*31.19%*	18 600 000	*32.48%*
translation	—	*0.00%*	p.m.	*0.00%*	530 000	*0.93%*
studies and consultants	95 000	*0.22%*	210 000	*0.43%*	200 000	*0.35%*
publications	210 000	*0.49%*	190 000	*0.38%*	120 000	*0.21%*
total title 3	17 483 000	40.99%	19 733 000	39.82%	24 861 000	43.42%
TOTAL EXPENDITURE	42 650 000	100%	49 559 000	100%	57 265 000	100%
Revenue						
fees	27 550 000	*64.60%*	34 775 000	*69.03%*	38 580 000	*67.37%*
EU contributions	13 000 000	*30.48%*	13 200 000	*27.80%*	16 010 000	*27.96%*
other	2 100 000	*4.92%*	1 584 000	*3.17%*	2 675 000	*4.67%*
TOTAL REVENUE	42 650 000	100%	49 559 000	100%	57 265 000	100%

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.eudra.org
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.eudra.org
For product defect and other quality-related matters	*Contact point* Stephen FAIRCHILD Fax number for defective product rapid alerts (44-20) 74 18 85 90 E-mail: stephen.fairchild@emea.eudra.org

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 point* Jonna SUNELL-HUET Direct telephone (44-20) 74 18 84 65 E-mail: certificate@emea.eudra.org

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.eudra.org/emea.html or by writing to:

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

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.eudra.org

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.eudra.org

Media and press contacts

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

For matters concerning medicinal products for human use

Contact points
Rolf BASS
Direct telephone (44-20) 74 18 84 11
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For matters concerning medicinal products for veterinary use

Contact point
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For general information on any other matter

Contact points
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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 1999, including final appropriations for 1998 and outturn for 1997
  (OJ L 58, 5.3.1999, 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)
- 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 monthly)
- EMEA Code of Conduct (EMEA/D/37674/99)

These and other documents are available either on the Internet at http://www.eudra.org/emea.html or by writing to:

Sector for Document Management and Publishing
European Agency for the Evaluation of Medicinal Products
7 Westferry Circus, Canary Wharf
London E14 4HB – UK

Annex 4: Profiles of EMEA personalities

André Broekmans, Chairman of the Management Board, b. 22 January 1949, n. Dutch

Education: Qualified medical doctor from the University of Leiden and was later granted a PhD from the same University.

Career to date: From 1974 to 1987, Prof. Broekmans held a number of medical posts with the Leiden University Hospital and Leiden Thrombosis Service. He was Head of Medical Affairs of the Netherlands Heart Foundation from 1987 and moved to the Netherlands Medicines Evaluation Board in 1990 as Head of Department for Clinical Assessment. He was appointed Executive Director in 1992. He was appointed part-time professor of pharmaceutical technology assessment at Utrecht University in 1999. Prof. Broekmans joined the EMEA Management Board in 1995 and was elected chairman in 2000.

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.

Fernand Sauer, Executive Director, b. 14 December 1947, n. French

Education: Qualified pharmacist from the University of Strasbourg. Masters Degree in European and international law from University of Paris II and various post-graduate diplomas in public health, pharmaceutical legislation and European Community Studies.

Career to date: From 1972 to 1979, hospital pharmacist and pharmaceutical inspector at the Ministry of Health in France. In 1979 he joined the European Commission in Brussels and in 1986 became Head of Pharmaceuticals, involved in completion of the European Internal Market and industrial policy in the pharmaceutical sector, as well as trilateral harmonisation of regulatory requirements (ICH) between EC, US and Japan. Mr Sauer was appointed in September 1994 as the first Executive Director of the EMEA.

Jean-Michel Alexandre, Chairman of the CPMP, b. 23 February 1936, n. French

Education: Qualified as a pharmacist, doctor of medicine and hospital biologist.

Career to date: Prof. Alexandre was Head of the Pharmacology Department at the Broussais Hospital and Professor of Pharmacology at UFR Broussais-Hôtel Dieu, Paris. He was also Chairman of the French Medicines Registration Committee from 1985 to 1993 and a member of the national Committees on Transparency and Pharmacovigilance. He was appointed Director of the Department for the Evaluation of Medicinal Products at the Agence Française de Sécurité Sanitaire des Produits de Santé in 1993 and, in the same year, elected as Chairman of the former Committee for Proprietary Medicinal Products attached to the European Commission. In 1995 he was elected as first Chairman of the new CPMP attached to the EMEA and re-elected in 1998.

Mary Teeling, Vice-Chairman of the CPMP, b. 3 May 1955, n. Irish

Education: Qualified medical doctor from the Medical School of the University of Dublin. Admitted as a Member of the Royal College of Physicians in Ireland. Doctorate in clinical pharmacology. Elected Fellow of the Royal College of Physicians in 1995.

Career to date: From 1979 to 1984 Dr Teeling was employed as a hospital doctor in various teaching hospitals in Dublin. From 1984 to 1985 she studied for a BSc (Honours) in pharmacology and from 1985 to 1988 was a Research Fellow in pharmacology/oncology at the Mater Misericordiae Hospital in Dublin. From 1988 to 1995 she was Medical Assessor and Deputy Medical Director of the National Drugs Advisory Board, and has been Medical Director at the Irish Medicines Board since 1996. She was elected Vice-Chairman of the CPMP in 1998.

Reinhard Kroker, Chairman of the CVMP, b. 21 February 1945, n. German

Education: Qualified veterinary surgeon from the University of Giessen. Doctorate in veterinary medicine. Habilitation in pharmacology, toxicology and pharmacy, University of Munich. Degree as Dr.med.vet. habil.. Professor of Pharmacology and Toxicology, Free University of Berlin.

Career to date: From 1971 to 1979, Prof. Dr Kroker held different positions in pharmacological institutes in Giessen and Munich. In 1980 he moved to Berlin and the former Federal Health Institute and is now director of the Animal Drug Registration, Residue Control and Feed Additives Division. In 1995 he was elected as first Chairman of the Committee for Veterinary Medicinal Products (CVMP) and re-elected in 1998.

J. Gabriel Beechinor, Vice-Chairman of the CVMP, b. 25 March 1960, n. Irish

Education: Qualified veterinary surgeon from University College Dublin. Received a Masters degree in veterinary medicine in 1984.

Career to date: From 1982 to 1987, Dr Beechinor was a general veterinary practitioner in several mixed practices in Ireland. From 1987 to 1999 he was Veterinary Assessor at the National Drugs Advisory Board (now the Irish Medicines Board). In 1995, he was appointed Member of the CVMP and elected Chairman of the Working Group on Safety of Residues for the period 1996-1999. In 1999 he was elected Vice-Chairman of CVMP and appointed Veterinary Director of the Irish Medicines Board.

Andreas Pott, Head of Unit, Administration, 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 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. Mr Pott 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 Organisation and Interinstitutional Cooperation Department. 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.

Rolf Bass, Head of Unit, Evaluation of Medicines for Human Use, b. 25 May 1941, n. German

Education: Qualified medical doctor from the Medical School of the Free University of Berlin.

Career to date: After working as a post-doctoral fellow at The Johns Hopkins School of Medicine in Baltimore USA from 1967 to 1969, Prof. Bass was both Head of Drug Toxicology at the Institute for Drugs at the Federal Health Office (BGA) in Berlin and Adjunct Professor of Pharmacology and Toxicology at the Free University of Berlin. He has been involved in research areas including prenatal toxicology and transplacental carcinogenicity and in regulatory areas of drug toxicology including risk assessment and risk/benefit evaluation. He is a former chairman of the CPMP Safety Working Party. He joined the EMEA in April 1995.

Noël Wathion, Head of Sector, Regulatory affairs and pharmacovigilance, 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.

John Purves, Head of Sector, Biotechnology and biologicals, b. 22 April 1945, n. British

Education: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. Doctor of Philosophy, degree 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.

Patrick Le Courtois, Head of Sector, New chemical substances, 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 Directorate of Pharmacy at the French Ministry of Health and in 1993 the French Medicines Agency as CPMP rapporteur, Head of Unit of European Procedures and from January 1995 as French CPMP delegate. He joined the EMEA in September 1997 and was appointed Head of Sector for New Chemical Substances in June 1998.

Isabelle Moulon, Deputy Head of Sector, Regulatory affairs and pharmacovigilance, 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.

Marisa Papaluca Amati, Deputy Head of Sector, Biotechnology and biologicals, b. 12 October 1954, n. Italian

Education: Degree in medicine and surgery from the University of Rome. Specialist in internal medicine.

Career to date: From 1978 to 1983 Dr Papaluca worked in the Third Internal Medicine Department of the University of Rome on research projects in the area of clinical immunology and cellular immunology. From 1984 to 1994, as medical director of the Pharmaceutical Department of the Italian Ministry of Health, she 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.

Tony Humphreys, Deputy Head of Sector, New chemical substances, b. 12 December 1961, n. Irish

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

Career to date: Since qualifying in 1983 Mr Humphreys has worked in the area of development pharmaceutics for a national branded generics manufacturer and an international research and development company. In 1991 he joined the International Regulatory Affairs Division of Glaxo Group Research Limited where he was responsible for the development and submission of a series of international registration applications in a number of therapeutic areas. He joined the EMEA in May 1996.

Peter Jones, Head of Unit, Veterinary Medicines and Information Technology, b. 9 August 1947, n. British

Education: Qualified veterinary surgeon from the Faculty of Veterinary Science at Liverpool University and a Member of the Royal College of Veterinary Surgeons.

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. He acts as EU coordinator in the VICH.

Jill Ashley-Smith, Head of Sector, 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, 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, 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, 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 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.

Karel de Neef, Head of Unit, Technical Coordination, 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.

Stephen Fairchild, Head of Sector, 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.

Beatrice Fayl, Head of Sector, Document management and publishing, b. 9 October 1959, n. Danish

Education: 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: Various positions as a documentalist in several European countries, the latest from 1988 to 1995 setting up and running the documentation service in the European Commission Delegation in Norway. Ms Fayl joined the EMEA in April 1995.

Sylvie Bénéfice, Head of Sector, 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.

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