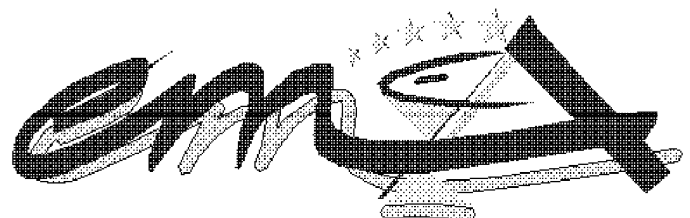


THE EUROPEAN AGENCY
FOR THE EVALUATION OF
MEDICINAL PRODUCTS



WORK
PROGRAMME

1998-99



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

1998-99

Adopted by the Management Board on 19 February 1998

Work programme for the European Agency for the Evaluation of Medicinal Products 1998-99

by **Fernand Sauer, Executive Director**

Based on earlier internal rolling work programmes, the work programme for 1997-98 was adopted by the Management Board on 5 February 1997 and subsequently published by the Office for Official Publications of the European Communities (ISBN 92-9155-006-X).

The experience gained since 1995 inspired this second public work programme, valid for 1998 and 1999 and prepared in accordance with the approved 1998 budget, the preliminary 1999 budget and the expected fee reform.

Strengthening the European approval system and exploring new directions

With considerable support from the European expertise provided by the national regulatory agencies, the new European drug approval system is working well. The EMEA, in particular its scientific committees, have established a worldwide reputation for the quality of their evaluations and opinions.

Besides its main focus on central applications, the EMEA must be prepared for an increase of arbitrations and referrals of national decisions. The continuation of technical harmonisation activities by EMEA scientific committees and their working parties will benefit both the mutual recognition process and the internationalisation of testing requirements.

The EMEA will aim at reinforcing further the partnership already established with national agencies and Commission services. It has sometimes been difficult to use existing formal and informal structures to discuss many of the practical challenges linked to the rapid development of the European approval system, covering EMEA as well as national agencies' activities.

These challenges include, for example, a common understanding of the costing of evaluation work and supervisory functions, or the joint management of expanding communication and informatic facilities.

Progressive introduction of management by objectives

This programme sets out specific goals for each unit and sector of the EMEA, performance indicators and steps to improve transparency, implementation of a quality management system and optimisation of human and logistical resources.

The work programme reflects the first steps towards management by objectives and resource allocation, taking into account the model developed by the European Commission. In this time of rapid evolution and change for the EMEA, the introduction of management by objectives should not lead to the creation of a rigid framework but should serve to enhance transparency and flexibility. The need for flexibility is particularly important given the diversity of tasks carried out by the EMEA.

Attempts have been made to introduce a more objectives-based work programme for each unit. This initiative has been carried out within each unit based on discussions with Heads of Unit and Sector, an approach reflected in the differing presentation of each unit's contribution. In this initial phase, the Veterinary Medicines Unit has been used as a pilot study with specific and measurable management targets.

The proper management of resources is an essential element of planning and an integrated series of measures will be put in place during 1998 to permit this:

- the introduction of the 'SI2' financial accounting system will permit systematic financial reporting;
- the identification and monitoring of cost centres within the EMEA will be facilitated through the application of analytical accounting methods; and
- the implementation of the 'ActiTrak' time management system should allow a more accurate identification of the time taken by EMEA staff for different tasks.

One element of ensuring flexibility is constant review of objectives and resources. An increase in workload of the EMEA is still expected in 1998-99. The management of resources will be particularly important to meet needs arising from the growing surveillance and maintenance of products which have already been authorised, as well as new tasks.

Existing resources and tasks will be reviewed and possibly re-allocated at least twice a year, in particular taking into account any budgetary adjustments adopted at the June and October meetings of the Management Board.

Fee reform and new challenges

The reform of fees payable to the EMEA should be completed in 1998. It is hoped that Council and Parliament will be able to complete the necessary legislative procedures as rapidly as possible. As a consequence revenue increase from fees would only improve the EMEA budgetary situation during the second half of the year. It is therefore important that the EU institutions deal with the new Regulation as a matter of urgency in order to prevent additional budgetary constraints for the EMEA in 1998 and 1999.

The survey begun in 1996 of the costs associated with rapporteur, co-rapporteur and inspection services for the centralised evaluation of medicinal products will continue in 1998-99. The data collected from the survey will be used to help match resources to activities, in particular taking into account the source of revenues for each activity.

A number of new challenges will also need to be addressed in the medium-term period 1998-2002. These include the putting in place of an international benchmarking mechanism. This is particularly important in the context of the harmonised global application dossier ('common technical dossier' - CTD) being developed under the EU-US-Japan International Conference on Harmonisation.

The EMEA will also have to actively prepare for new tasks resulting from future European Union legislation, particularly in the field of orphan medicines, clinical trials and starting materials.

Iceland and Norway will commence direct participation in the work of the EMEA in 1998. The EMEA will also play an increasing role in the direct management of pharmaceutical aspects of mutual recognition agreements negotiated between the European Union and third countries. In addition, the EMEA will be called on to offer technical assistance to central and eastern European countries as they prepare for closer association and possible accession to the European Union.

The Executive Director, in consultation with the Management Board, will anticipate during 1998-99 the review of Council Regulation (EEC) No 2309/93 and of the EMEA's role within the European approval system. In particular this will provide the Council of Ministers, European Parliament and Commission with concrete and practical information upon which to base their work.

EMA 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, particularly through a pharmacovigilance network and the establishment of safe limits for residues in food-producing animals.

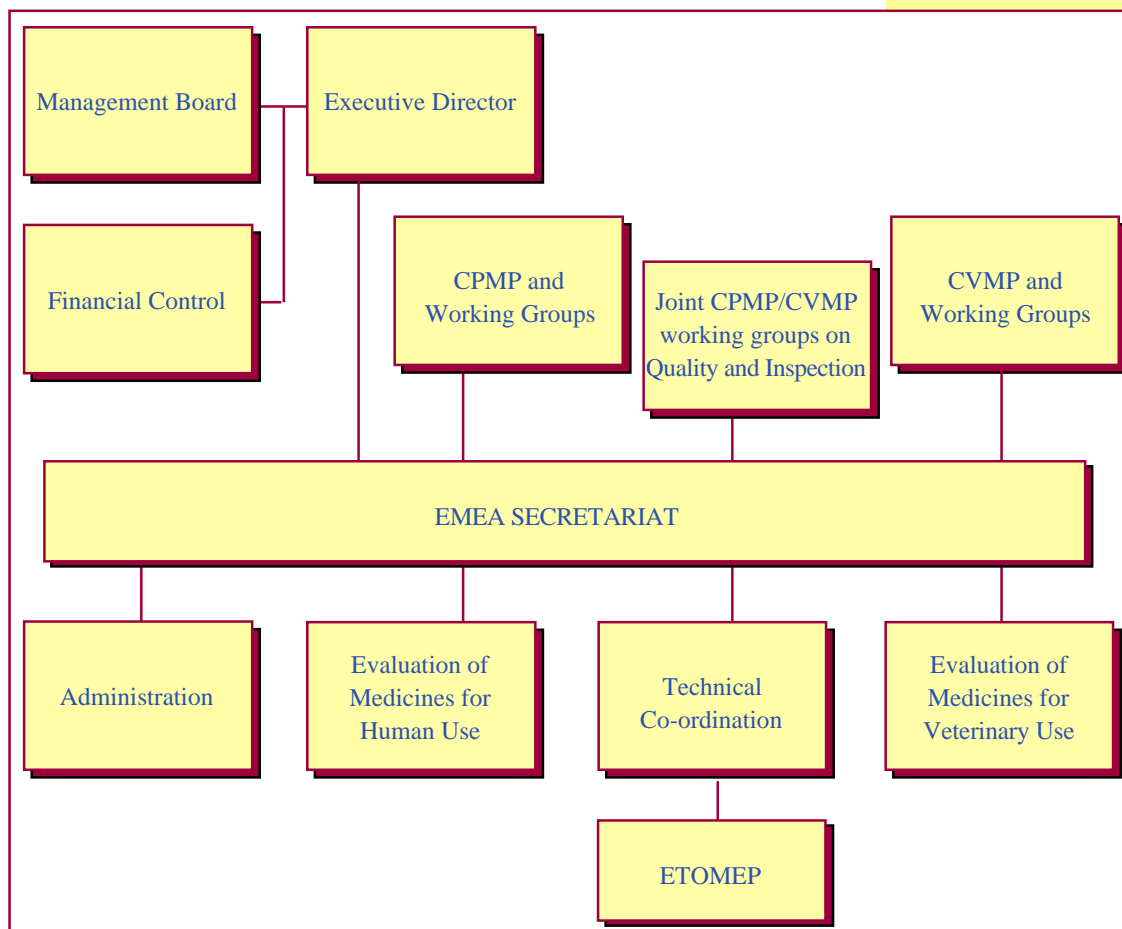
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1. Organisation and priority tasks for the EMEA

Organigram of the EMEA



Organisation of the EMEA

The European Agency for the Evaluation of Medicinal Products comprises an administrative and technical secretariat, under the authority of the Executive Director, with a Management Board, two scientific committees and several working parties.

The Management Board is the supervisory body of the EMEA. It consists of two representatives from each Member State, from the Commission and from the European Parliament. The Board appoints the Executive Director and adopts the financial regulation. It approves the programme of work and the budget as presented by the Executive Director on a yearly basis and gives him discharge for its implementation.

The two scientific committees are responsible for formulating the Agency's opinion on any question relating to the evaluation of human or veterinary medicinal products. Each committee consists of two members appointed by each competent national authority. The CPMP (Committee for Proprietary Medicinal Products) and the CVMP (Committee for Veterinary Medicinal Products) provide objective scientific opinions to the European institutions and ensure that there is appropriate co-ordination between the tasks of the EMEA and the work of national agencies. They are required to act independently.

Members of each committee may arrange to be accompanied by experts chosen from a European list of more than 2 000 experts with proven experience in the assessment of medicinal products and also ready to serve on EMEA working parties. The financial or other interests of committee members and European experts are to be publicly declared. The Committees appoint their members to act as rapporteur or co-rapporteur for the evaluation tasks, with the assistance of assessors drawn from the European experts list. The provision of services by rapporteurs or experts is governed by a written contract between the EMEA and the national agencies concerned.

Structure of the EMEA Secretariat:

Executive Director	Fernand Sauer
• Financial controller (a.i.)	Claus Christiansen
Administration Unit	Marino Riva
• Sector for personnel and support services	Frances Nuttall
• Sector for accounting	Gerard O'Malley
Unit for the Evaluation of Medicines for Human Use	Rolf Bass
• Sector for regulatory affairs and pharmacovigilance	Noël Wathion
• Sector for biotechnology and biologicals	John Purves
• Sector for new chemical substances	Josep Torrent Farnell
Unit for the Evaluation of Medicines for Veterinary Use	Peter Jones
• Sector for CVMP and veterinary procedures	Jill Ashley-Smith
• Sector for safety of residues (MRLs)	Kornelia Grein
Technical Co-ordination Unit	Karel de Neef
• Sector for inspections	Stephen Fairchild
• Sector for document management and publishing	Beatrice Fayl
• Sector for conference services	Sylvie Bénédicte
• Sector for information technology	Michael Zouridakis

Objectives and priority tasks of the EMEA

The individual priorities of each Unit are set out in the following chapters. Nevertheless there are five main objectives and nine general priorities for the EMEA set by the Management Board for 1998-99:



EMEA objectives:

- To protect public health by mobilising the best scientific resources existing within the European Union (see Articles 49 and 51(a))
- To promote health care through the effective regulation of new pharmaceuticals and better information for users and health professionals (see Article 51(i))
- To facilitate the free circulation of pharmaceuticals within the European single market (see Article 51, first paragraph)
- To support the European pharmaceutical research and development industry by developing efficient, effective and responsive operating procedures (see Article 51, first paragraph)
- To support efforts in international co-operation (see Article 51(f))

EMEA priority tasks:

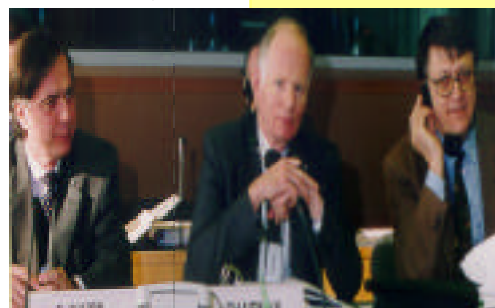
1. centralised applications for marketing authorisations for medicinal products (Council Regulation (EEC) No 2309/93, Article 4)
2. maintenance and pharmacovigilance activities (Council Regulation (EEC) No 2309/93, Articles 15-25, Articles 37-47)
3. establishment of maximum residue limits for substances in veterinary medicinal products (Council Regulation (EEC) No 2309/93, Article 51)
4. arbitrations and other Community referral procedures (Council Directive 75/319/EEC as amended, Articles 10, 11 & 12, and Council Directive 81/851/EEC as amended, Articles 18, 19 & 20)
5. scientific advice to future applicants and the EU institutions (Council Regulation (EEC) No 2309/93, Article 51)
6. information to health care professionals and public (Council Regulation (EEC) No 2309/93, Article 51)
7. technical support to international harmonisation initiatives (ICH, VICH, etc.) (Council Regulation (EEC) No 2309/93, Article 51)
8. support for the mutual recognition national authorisations, as requested
9. support for certain European policies at the request of the Commission or European Parliament

2. Management Board and Directorate

The Management Board is expected to continue to meet four times a year in 1998 and 1999, with the June meeting each year given over for 'brain-storming' on topical issues.

Management Board meetings in 1998	Management Board meetings in 1999
February 19	February 10
June 3	June 2
September 30	September 29
December 2	December 1

On the initiative of its chairman, the Management Board will continue to review in 1998 how it carries out its business. Although a pattern of meetings and practical arrangements has been established to ensure that most business items are dealt with in the time available, the Board will in particular look again at how best additional items raised by members could better be handled.



The Board will explore a proposal from its chairman to collect and publish information about the safety and effectiveness of medicinal products in accordance with Article 51(c) and (i) of Council Regulation (EEC) No 2309/93. This could be achieved by identifying centres of excellence throughout Europe to form a network which would bring together, validate and publish data from existing sources and, exceptionally, encourage new research where sufficient data is not available.



The secretariat of the Management Board is provided by staff of the Directorate. The Executive Director is assisted by a small team made up of two legal administrators, a personal assistant and two secretaries covering the general management and functioning of the EMEA, legal affairs, external relations and also liaison with the Management Board.

The Directorate assumes the preparation of the work programme, together with the preparation and execution of the budget in liaison with Heads of Unit and Sector.

Management tasks were better defined during 1997. Better lines of communication across management has in particular been assured through systematic weekly meetings of the Executive Director with Heads of Unit, who are joined once a month by Heads of Sector. Ad hoc meetings are held with relevant management and staff members to deal with specific issues.

Depending on the evolution of tasks, the Directorate, together with Heads of Unit, will consider the need to adapt the organisation or resources of each sector, and also the need to create new sectors. The current human resource projections of each Unit are as follows:

	Allocation 1998	Allocation 1999
Directorate (including Financial control)	7	7
Administration Unit		
Head of Unit	2	2
Personnel & support	19	19
Accounts	6	6
<i>Total</i>	27	27
Unit for the Evaluation of Medicines for Human Use		
Head of Unit	5	5
Regulatory affairs & pharmacovigilance	24	25
Biotechnology & biologicals	19	21
New chemical substances	27	30
Internal reserve	3	6
<i>Total</i>	78	87
Unit for the Evaluation of Medicines for Veterinary Use		
Head of Unit	4	4
CVMP & veterinary procedures	6	7
Safety of residues (MRLs)	7	7
<i>Total</i>	17	18
Technical Co-ordination Unit		
Head of Unit	4	4
Inspections	11	12
Document management & publishing	12	12
Conference services	8	9
Information technology	17	19
<i>Total</i>	52	56
Additional posts in reserve	3	8
Total number of posts	184	203

During 1998 and 1999 the Directorate will in particular seek to give particular impetus to 3 core projects of general relevance for the EMEA: openness and transparency, performance and dialogue with interested parties, and implementation of a quality management system.

Openness and transparency

The publication of provisional rules on access to documents was welcomed at the workshop on transparency held at the EMEA on 30 October 1997, in particular by the European Ombudsman. These rules were endorsed by the Management Board at its meeting of 3 December 1997, together with a report on the results of the workshop. The Executive Director will in 1998-99 continue to explore with the CPMP and CVMP, further initiatives towards greater transparency in the operations of the EMEA.

The use of the Internet by the EMEA is an important means of allowing access by a wide public to EMEA documents. The regular and timely publication of European public assessment reports (EPARs) will be continued, particularly through the Internet. Building on the experience gained to date, a workshop will be held in early 1998 with concerned interested parties on how EPARs could be further improved.

Following the workshop on transparency and access to documents of the EMEA held on 30 October 1997, contributions from interested parties will be published in early 1998, together with details of EMEA actions. The need to hold a similar meeting at the end of 1998 to measure progress will also be considered.

Performance and dialogue with interested parties

The joint EMEA-EFPIA (European Federation of Pharmaceutical Industries' Associations) performance review questionnaire of the European registration system will be continued in 1998-99. A similar exercise is planned for 1998 in the field of veterinary medicines together with FEDESA (Fédération Européenne de la Santé Animale).

Regular quarterly meetings between interested parties and scientific committees have been held since the creation of the EMEA in 1995 and these will be continued. Other ways of involving interested parties in the work of the EMEA will be also considered, including greater use of info-days. Current initiatives by CPMP and CVMP to explore how they can make themselves more open to the wider scientific community and European and international learned societies will be continued. Better provision of information to patients, users and health professionals will be a major objective in 1998-99.

The Human and Veterinary Medicines Evaluation Units will continue to produce at least two newsletters per year, in four languages.

Quality management system

EMEA has embarked on an ambitious process of structuring its own environment in a transparent, efficient and measurable way. Most notably the effects of the quality management system and an industry standard IT architecture will start to benefit the organisation.

During 1998 key initiatives will be completed in the areas of strategic business planning, information management, provision of scientific opinions, product information quality, EMEA quality manual and internal audits, scorecards, European partnerships, implementation of management actions, and training and appraisals.

Continuous improvement is the key to success of the quality management system of the EMEA. Changes identified and agreed will be systematically implemented. The effects of these changes will be closely monitored and analysed by EMEA managers, with feedback provided to the Management Board and scientific committees.

EMEA financial control

An item to be dealt with in the short term by the Management Board is the re-organisation of financial control at the EMEA. On the basis of a proposal from the European Commission (OJ C 335, 6.11.1997, p. 15), the financial control responsibilities of all newly created EU decentralised bodies is expected to pass to the Commission in 1998.

The Management Board will wish to ensure that suitable arrangements are put in place to ensure a smooth transition and that financial control functions carried out by the Commission are properly reported to the Board.

Pending the re-organisation of EMEA financial control, the interim financial controller will continue to assist the Administration Unit in ensuring a smooth transition in 1998 of responsibilities to the European Commission.

The principal tasks for financial control in 1998-99 will include:

- *a priori* control of all expenditure and income transactions in accordance with the financial regulation; document controls and monitor error rates on a regular, monthly basis;
- delivery of opinion on financial systems and procedures in all areas of income and expenditure; in particular, advise in the setting-up of the EMEA's accounting and reporting system;
- targeted controls on specific areas of the Agency's expenditure/income, with a view to assessing adequacy of procedures and recommend modifications, and assessing cost-effectiveness and performance indicator requirements; and
- follow up of financial statements, discharge procedure and audits of the European Court of Auditors.

3. Key objectives for medicines for human use

	1996	1997	1998 (estimate)	1999 (estimate)
Workload				
New centralised applications: medicinal products	35	60	63	66
New centralised applications: active substances	24	46*	48	50
Type I variations	27	109	135	170
Type II variations	16	47	65	80
Pre-submission regulatory advice	25	80	100	120
Scientific advice	20	23	25	25
ICH-derived CPMP guidelines	9	15	5	2
Other CPMP guidelines	19	20	15	15
Non-EU ADR reports	652	1 812	2 600	3 500
Arbitration opinions	3	1	15	22
Other Community referral opinions	2	4	5	8
Meeting days	141	210	257	277
Resources				
Head of Unit and secretariat	5	5	5	5
Sector for regulatory affairs and pharmacovigilance	17	18	24	25
Sector for biotechnology and biologicals	13	17	19	21
Sector for new chemical substances	13	22	27	30
Internal reserve	—	—	3	6
Total	48	62	78	87

* including two new combinations

3.1 Workload and goals of the Unit



Head of Unit: Prof. Rolf BASS

In 1998 and 1999, the main activity of the Human Medicines Unit will be to support the activities of the CPMP, its working parties and expert groups. This support will focus on the initial review and maintenance of marketing authorisations through the centralised procedure. The Unit will also look at the continuing improvement of related operational procedures.

The number of new applications submitted during 1995-1997 rose substantially. A slower increase in the number of new applications is expected, with a plateau towards the year 2000. The amount of work will however increase considerably due to the change in pattern of the following:

- number of extension applications;
- number of ongoing procedures;
- increase in post-authorisation and pharmacovigilance activities;
- number of arbitrations and referrals;
- advice activities on regulatory and scientific issues.

New activities will also have a significant impact, such as:

- extension of monitoring of performance indicators to maintenance and supervision of marketing authorisations activities;
- support to new topics, such as the 'common technical document', within the International Conference in Harmonisation (ICH);
- implementation of a quality management system;
- development of new tasks in liaison with requests or legislative initiatives of the European Commission (e.g. orphan drugs, herbal remedies, 'new synthetic drugs').

The staffing of the Unit has been carried out carefully to match its major goals as well as the increasing workload.

Due to the overall increase and change in workload, particularly the anticipated increase use of the mutual recognition procedure (and possible increase in arbitrations), together with any new tasks arising in 1998-99, the need to create a new sector within the Unit will be considered.

Key goals for 1998-99 for the Unit are:

Centralised applications:

- to continue to achieve compliance with regulatory targets and deadlines for scientific opinions for marketing authorisation applications under the centralised system;
- to continue to provide a high standard of technical and organisational support to the CPMP;
- to ensure consistency of decisions and scientific documentation;
- to implement the application tracking system (ATS) for an efficient management of procedures under the centralised system;
- to further refine regulatory and procedural guidance for the EMEA, including the CPMP and its working parties, as well as for industry;
- to refine the performance measurement parameters already in place based on developments in IT support and quality systems during 1998.

Maintenance and pharmacovigilance activities:

- to continue to achieve compliance with regulatory targets and deadlines for post-authorisation issues under the centralised system;
- to set up and implement systems for the handling of incoming safety information related to centrally-authorized medicinal products;
- to extend ATS and the performance monitoring to variations and maintenance activities.

Scientific advice:

- to further develop the provision of scientific advice and to continue to provide a high standard of technical and organisational support to this activity;
- to optimise the resources for scientific advice of the CPMP and its working parties by identifying areas of specific expertise of members and arranging working sessions accordingly ;
- to support the multidisciplinary approach for the discussion of emergent therapeutic strategies (e.g. gene therapy) and reinforce dialogue with concerned parties (industry, health care professions, patient associations and academia).

Information to health professionals and public:

- to provide a high level of control for user package leaflets, specimens of packaging and mock-ups;
- to provide assistance in the generation of high quality product information in all official Community languages and to give support to the product information quality (PIQ) and quality review of documents (QRD) groups;
- to review and improve the content and dissemination of European public assessment reports (EPARs) and make them available on the day following the electronic transmission by the European Commission granting the marketing authorisation.

Harmonisation:

- to provide the necessary supports and input to international activities on harmonisation with particular emphasis on the new ICH topic the 'common technical document';
- to promote EU harmonisation through guidance prepared by appropriate working parties to prevent arbitrations and other referrals;
- to support the activities of the mutual recognition of national authorisation as requested.

3.2 Sector for regulatory affairs and pharmacovigilance

Head of Sector: Pharm. Noël WATHION

This sector is in charge of the secretariat of the CPMP, all regulatory issues in relation to medicinal products for human use dealt with by the EMEA, pharmacovigilance activities and scientific advice.



CPMP meetings

Starting in 1998, CPMP meetings have been scheduled on a monthly, four days basis. Nevertheless the need for organising exceptional meetings (e.g. for pharmacovigilance issues) cannot be excluded. In 1997 the trend was to concentrate the plenary meetings on three days. This trend may be confirmed in 1998. In such a case the number of breakout meetings and working groups will increase and readjustments will have to be operated.

In addition the anticipated involvement of EEA countries at CPMP level has to be taken into account. Moreover, the overall task for preparation and follow up of meetings for CPMP is directly linked to the growth of activities for maintenance of authorised products. However, a large part of the secretarial activities for breakout sessions and working parties are shared with the other sectors of the Unit.

For the two coming years at least a 25 percent increase in workload is anticipated for the staff in charge of the secretariat of the CPMP.

	1996	1997	1998 (estimate)	1999 (estimate)
Number of meeting days				
CPMP meetings	48*	33	48	50
Break-out meetings	7	35	53	55
(Co-)Rapporteur meetings	22	40	50	60
Working party meetings	59	70	80	82
Ad hoc working party meetings	5	15	26	30
Total	141	193	257	277

* including special pharmacovigilance & operational meetings of the CPMP

The meeting dates of the CPMP for 1998 and 1999 are as follows:

Regulatory affairs

CPMP meetings in 1998	CPMP meetings in 1999
January 26-29	January 25-28
February 23-26	February 22-25
March 23-26	March 22-25
April 20-23	April 19-22
May 25-28	May 17-20
June 22-25	June 21-24
July 20-23	July 26-29
August 17-20	August 23-26
September 14-17	September 20-23
October 19-22	October 18-21
November 16-19	November 15-18
December 14-17	December 13-16

The sector provides support to the CPMP, its working parties and the other sectors within the Human Medicines Unit. Legal staff members are involved in the development of the necessary regulatory and procedural guidance by preparing standard operating procedures and other documentation as appropriate. Pre-submission advice will be further developed and extended to maintenance activities, which will result in an increase of activity of more than 25 percent. The gain, from the resulting benefits of improved dossiers, will be more efficient procedures.

Pharmacovigilance activities

The Pharmacovigilance Working Party (PhVWP) will

- dedicate an increasing amount of time to discussions on safety issues in relation to centrally-authorized products and products authorized through the mutual recognition procedure;
- remain involved in the discussion of nationally authorized products and organisational matters;
- meet up to 11 times in 1998 and on a monthly basis in 1999, since a considerable increase in the number of products related issues is expected.

Taking into account the number of meetings as well as the growing number of issues for each session, a 30 percent increase in workload of the PhVWP is anticipated.

Other pharmacovigilance activities

As a consequence of the adoption in 1997 by the CPMP of a position paper regarding the "Conduct of pharmacovigilance for centrally authorised products" (CPMP/183/97), monitoring will be a major tool for all partners

involved in this field. One of the major activities of the sector within the EMEA for 1998-99 will consist of the handling of incoming safety information relating to centrally-authorised products. Since the EudraWatch database is expected to be fully operational in 1998, the entering of adverse drug reaction reports into the database will facilitate this task.

The number of case reports received or forecast by the EMEA is given below:

The yearly number of non-EU ADR and EU case reports is anticipated to increase respectively by more than 90 percent and 50 percent within two years because of the increasing stock of centrally-authorised products reaching the

	1996	1997	1998 (estimate)	1999 (estimate)
Non-EU case reports				
Serious unexpected adverse drug reactions	652	1 812	2 600	3 500
EU case reports				
Serious expected and unexpected adverse drug reactions	—	2 400	3 000	3 600

market in the EU and beyond.

Management of periodic safety update reports (PSURs) for centrally authorised products is shared with the other sectors. In relation to the continuously growing number of decisions for centralised products, a forecast of more than 200 PSURs to be treated in 1999 is anticipated, representing a 140 percent growth in workload for project managers.

The sector is also involved in the management of all referrals dealing with safety concerns in relation with Articles 12 and 15a of Council Directive 75/319/EEC. These referrals are expected to rise with the same frequency in 1998-99.

Scientific advice to future applicants

The provision of scientific advice will represent a major investment for the EMEA in 1998-99. As agreed at CPMP level, the provision of scientific advice will be further developed by:

- revising current procedures
- ensuring the link with the work carried out by the working parties (e.g. development and update of guidelines), and
- developing a wider network of specialised experts.

Furthermore a survey will be carried out on the impact of scientific advice provided by the CPMP on subsequent evaluation of the application submitted through the centralised procedure (e.g. overall time needed for the assessment of the application, scientific questions to be addressed by the applicant, response time needed by the applicant, etc).

Due to the likely introduction of a fee for scientific advice and the continuous development of guidelines, it is expected that the number of advice given will

remain steady throughout the period 1998-99. Nevertheless high quality secretarial support and project management for the co-ordination and follow-up of scientific advice will be ensured.

3.3 Sector for biotechnology and biologicals

Head of Sector: Dr John PURVES

This sector is in charge of all medicinal products derived from biotechnology or which contain an active substance of biological origin. This sector has responsibility for the Biotechnology Working Party (BWP), a major working party of the CPMP, and several working groups including, for example, those on transmissible spongiform encephalopathies (TSE), Creutzfeld-Jacob Disease (sporadic new-variant CJD), blood products and influenza vaccines.

Centralised applications

New centralised applications within this sector constitute approximately one-third of all centralised applications for products for human use. As for chemical entities, an additional 10 percent in the number of application is anticipated over the two coming years in addition to the ongoing procedures from the previous year.

Moreover, application received in this sector are mostly more complex in relation with the innovative characteristics of the products or its new field of treatment. As a consequence additional ad hoc or expert groups are more often requested for the adequate assessment of such products. This will be adequately proceeded in the coming years as, for example, for gene therapy products.

In 1998-99 one of the main changes in the pattern of activities for this sector will be the increased workload in relation to maintenance activities for products already authorised. One third of the variations and maintenance activities anticipated for 1998-99 will be managed by the sector representing here again more than 20 percent of increase workload each year.

Working Parties

The BWP will continue to provide scientific expertise for biological products and the rapidly advancing and complex area of biotechnology, particularly regarding safety in relation to quality. It will develop the scientific requirements for DNA vaccines and gene therapy and review extensively the scientific developments in the field of combined vaccines, new methodology for viral testing for plasma-derived products and in TSE.

The Working Party will meet at least 10 times a year and a 20 percent increase in resources dedicated by the sector to the activities of the BWP and its related working groups is forecast for the two coming years.

Moreover, it should be noted that the BWP, with the support of the sector, has already contributed to the mutual recognition system since the MRFG has requested its assistance on certain general issues and some product specific issues. It is anticipated that such contributions will continue in 1998-99.

3.4 Sector for new chemical substances

Head of Sector: Prof. Josep TORRENT FARNELL

This sector is in charge of all medicinal products considered by the CPMP as innovative or containing a new chemical substance. As a part of its evolving activities and responsibilities in the management of centralised applications, this sector provides the technical and secretariat support to both the Efficacy and Safety CPMP Working Parties as well as providing a large part of the support of the Unit allocated to the mutual recognition of nationally-authorised products.

Centralised procedures

New centralised applications processed through the sector constitute approximately two-thirds of all centralised applications submitted for human medicinal products. After a significant increase in the number of applications received over 1995-1997 this number is expected to stabilise over the coming two years. Considering the legal time frame for the review of an application together with the time needed for applicants to provide the EMEA with the appropriate additional data, a number of ongoing procedures will overlap with new procedures, representing an increasing of about 30 percent in the stock of files to be managed by staff members.

An increase in the number of pre-submission meetings is anticipated to tackle regulatory and administrative questions aspects. Moreover, maintenance-related activities such as monitoring the fulfilment of specific obligations, follow up measures, periodic safety update reports and variation applications will increase. For example, up to 200 and 250 variation applications are expected for 1998 and 1999 respectively representing an increase of 20 percent in this activity for which the sector is expected to manage up to two-thirds of these procedures.

Working parties

The sector is in charge of the secretariat of the Efficacy and Safety CPMP Working Parties. These working parties will continue to prepare guidelines and provide, on request of the CPMP, scientific advice on specific clinical and pre-clinical issues respectively. In order to achieve their tasks both working parties will increase the number of regular meetings in 1998 and 1999.

When needed, they will invite experts on an ad hoc basis to deal with specific matters. Six Efficacy and three Safety Working Party plenary meetings are foreseen in 1998.

The sector also contributes to the joint CPMP/CVMP Quality Working Party, which deals with discussions on chemical and pharmaceutical aspects of medicinal products.

As a result of these expected increases in activities (an additional 50 percent of meetings and related activities for the EWP and 30 percent for the SWP) a corresponding increase in resources will be required to maintain current standards of support.

3.5 Common and new tasks

A number of activities are common to the operational sectors in charge of centralised applications or are shared with the Sector for Regulatory affairs

and pharmacovigilance.

Arbitrations and other Community referrals

So far only a limited number of referrals in accordance with Articles 10 and 11 of Council Directive 75/319/EEC have been initiated. It is however likely that from 1998 on, after the end of the transitional period, the number of arbitrations could increase significantly. As a result it can be expected that up to 20 referrals and arbitrations in 1998 and 30 in 1999 will be made, compared to the total of 12 in the 3 year transitional period. The change in this pattern would have a clear impact on the workload of the Unit.

Support to mutual recognition

The Sector for New chemical substances, in conjunction with the regulatory affairs sector, is responsible for providing the secretariat support to the Mutual Recognition Facilitation Group (MRFG). Considering the expected increase in the use of the mutual recognition procedure after the beginning of 1998, it is anticipated that meetings of the MRFG will continue to take place at the EMEA on a monthly basis during 1998-99. The number of break-out sessions, involving discussions with the reference Member State, concerned Member States and applicant, will also increase.

The MRFG meeting and its break-out sessions are organised in parallel with the CPMP meeting, frequently running over one day. The EMEA is willing to allocate the resources that may be needed to underpin the activities of the MRFG if requested by the Member States. This, however, will have to take into account the resource implications, which are estimated to amount to a 20 percent yearly increase for allocated staff and other EMEA resources.

Further guidance and assessment criteria have been requested by the European Commission in the framework of the EMEA ad hoc group on herbal remedies.

Transparency and information to health care professionals and the public

The operational sectors participate actively to the overall activities of the Human Medicines Unit with respect to transparency and information to interested parties particularly health care professional and the public.

Particular emphasis will be given to improving the quality of summary of product characteristics, user package leaflets and EPARs together with the accuracy of their translation into the 11 official Community languages. The procedure for checking mock-ups and specimens within the EMEA will also be optimised.

The transparency of the Centralised system has been highly appreciated by all interested parties. One of the major tools in this respect is the continued availability of European public assessment reports (EPARs) with a contribution from all sectors.

Quality management system and performance indicators

Experience gained on the processing of applications will continue to be

consolidated utilising standard operating procedures, which will constitute an integral part of the quality management system (QMS), being developed within the EMEA. The sectors are also involved in all the EMEA initiatives in relation with improvement of quality and make a substantial contribution to the quality review of documents (QRD) and the product information quality (PIQ) activities.

As part of the introduction of performance indicators throughout the Agency the application tracking system (ATS) is considered an essential IT tool to support the compliance with regulatory targets for the initial review of applications for marketing authorisations. In 1998-99 the sectors will direct a major effort to the extension and implementation of performance measurement parameters already in place and the extension of ATS to cover post-marketing authorisation activities.

International Conference on Harmonisation

International Conference on Harmonisation (ICH) activities for 1998-99 will be dedicated to the finalisation of seven on-going guidelines, to the implementation of nine adopted guidelines and the updating of existing approved documents. Moreover, further development of the Electronic Standards for the Transfer of Regulatory Information and Data (ESTRI) and the Medical Dictionary for Drug Regulatory Affairs (MEDDRA) topics will continue, and a major new ICH topic, the 'common technical document' will be prepared.

The Unit is prepared to provide the necessary technical and secretariat support to the European Commission, EU topic leaders, CPMP and working parties for these various phases of ICH.

New tasks

In 1998-99 the Unit will contribute to the development of new tasks. A number of other new activities generally linked to legislative initiatives may have an important impact on the operation of the Human Medicines Unit. These activities will require technical support and secretarial management, in particular relating to:

- the proposal for a European Parliament and Council directive relating to the implementation of good clinical practice (COM(97) 369 final, 3.9.1997) requiring the preparation of further guidelines;
- the proposal for a European Parliament and Council regulation on orphan medicinal products, for which designation-related activities, protocol assistance, and specific guidelines and dedicated database can be anticipated;
- the integration of the EMEA in the Joint Action, adopted by the Council, on new synthetic drugs (OJ L 167, 25.6.1997, p. 1) together with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol networks as requested by Council; and
- the development of additional methodologies for assessing and preventing emerging public health hazards and minimising identified risks (i.e. TSE).

4. Key objectives for medicines for veterinary use

	1996	1997	1998 (estimate)	1999 (estimate)
Workload				
New centralised applications	9	2	9	11
Extensions to centralised applications	—	2	4	6
Variations	—	5	10	11
New MRL applications	20	6	6	8
Modification/extension of new MRLs	10	13	10	12
Establishment of old MRLs - opinions	52	60	100	170
Old MRLs – list of questions	45	71	20	0
CVMP and VICH guidelines adopted	4	8	10	12
Community referrals	—	—	5	6
Scientific advice	6	3	5	6
Meeting days	54	67	80	80
Resources				
Head of Unit and secretariat	4	4	4	4
Sector for CVMP and veterinary procedures	4	5	6	7
Sector for safety of residues (MRLs)	4	6	7	7
Total	12	15	17	18

4.1 Workload and goals of the Unit

Head of Unit: Dr Peter JONES



The staff structure of the Veterinary Medicines Unit has been assembled taking account of the likely workload forecasted in both MRL and CVMP/Procedures sectors. In the latter staff numbers of one sector head and 3 project managers has adequately met the demands presented by the workload to date. However, the demands on the MRL sector, which includes one sector head, 2 scientific administrators and one national expert, to process the assessment of applications to set MRLs particularly for old substances remain very onerous. In the case of old substances, it must be noted that no income is forthcoming in respect of application fees for this work.

In short the total of eight technical staff reflect the cautious and measured approach undertaken in setting up the staff of the Veterinary Medicines Unit since the opening of the EMEA in January 1995.

Looking ahead, it is estimated that 9 new centralised applications will be made in 1998 and 11 in 1999. The number of applications for new MRLs and extensions/modifications remains approximately the same.

The actual income of the Unit from applications for the centralised procedure and new MRL applications in 1997 was ECU 438 000. The projected income forecasted for 1998 based on anticipated number of applications in both sectors approximates to ECU 900 000 – an increase of approximately ECU 500 000 in the income of the Veterinary Medicines Unit. It is therefore with this in mind that the staffing of the Unit be adjusted as described below.

Sector for safety of residues (MRLs)

Head of Sector: Dr Kornelia GREIN

While the deadline to establish the MRLs for old substances has now been extended to 1 January 2000, the efforts to complete the task on time will continue unabated. The steps in place to pursue this goal and the anticipated progress during the coming year are presented below and the current resources within the MRL sector are considered barely adequate for the year ahead. Consequently it is planned to recruit one additional scientific officer in early 1998 as well as one national expert on secondment to support the sector in this work.

Goals for 1998

- To complete all validations for new MRL applications within 14 days (by 1st quarter 1998);
- to complete the processing of all applications for new MRLs within the legal time frame (throughout 1998);
- to continue the assessment for the remaining old substances including homeopathics and herbal remedies leading to 100 opinions being recommended by CVMP (throughout 1998);
- to prepare a paper expanding the risk assessment concept for establishment of MRLs (by 3rd quarter 1998);

- to redraft Notice to Applicants in Volume VI of the *Rules Governing Medicinal Products in the European Community* once the amendment of Council Regulation (EEC) No 2377/90 has been adopted (by 3rd quarter 1998);
- to ensure consistency of all status and MRL summary reports is maintained fully according to quality control standards established previously (by 4th quarter 1998); and
- to finalise revision of guidelines on injection site residues once issues are resolved at Codex Alimentarius (by 4th quarter 1998).

New goals for 1999

- to implement QMS standards agreed in the EMEA programme (by 1st quarter 1999);
- to finalise the assessment of all defended old substances and agree opinions to establish MRLs for all substances where the required data have been provided, including homeopathic substances and herbal remedies (by 3rd quarter 1999); and
- to prepare and implement plan for revision of safety guidelines where necessary for veterinary medicines (by 2nd quarter 1999).

Sector for CVMP and veterinary procedures

Head of Sector: Dr Jill ASHLEY-SMITH

Given the projected forecast for centralised applications and associated tasks, the staffing resources in this sector are considered adequate for 1998 with 3 project managers each being responsible for approximately 5 procedures. It is planned to recruit one additional secretary in early 1998 and an additional scientific administrator in 1999 if the continuing trend towards an increase in number of applications is confirmed towards the end of 1998 when future forecasts are prepared.

Goals for 1998

- To improve industry confidence in the centralised system, to encourage companies to apply under the new system (by 2nd quarter 1998);
- to continue to achieve 100 percent compliance with regulatory deadlines for completion of marketing authorisation applications and variations under the centralised system (throughout 1998);
- to complete standardisation of summary of product characteristics, label and package leaflet for centralised opinions to ensure consistency of presentation (by 1st quarter 1998);
- to ensure consistency of all CVMP assessment reports and EPARs is maintained fully according to established quality control standards (by 4th quarter 1998);
- to review contents of CVMP assessments and EPARs, to monitor quality standards (by 2nd quarter 1998);
- to initiate a programme of workshops on pre-evaluation, evaluation and procedural phases of centralised procedures to streamline the process (by 2nd quarter 1998);

- to provide full and efficient co-ordination of EU regulatory input into VICH initiatives to complete phase I topics and progress phase II topics (by 3rd quarter 1998);
- to examine further ways of fostering a culture of openness and transparency in the sector's work (throughout 1998); and
- to define and implement a crisis management plan for veterinary medicines (by 2nd quarter 1998).

New goals for 1999

- To implement the system of electronic submissions for veterinary medicinal products (by 2nd quarter 1999);
- to participate in organisation of the first public conference of VICH (by 2nd quarter 1999); and
- to implement QMS standards agreed in the EMEA programme (by 2nd quarter 1999).

4.2 Committee for Veterinary Medicinal Products

Meeting dates for the CVMP have been fixed for 1998 and 1999 to allow for planning for both the EMEA/CVMP and applicants to optimise the timing and progress of submissions.

CVMP meetings in 1998	CVMP meetings in 1999
January 13–15	January 12–14
February 10–12	February 16–18
March 10–12	March 16–18
April 7–8	April 13–15
May 5–7	May 11–13
June 9–11	June 15–17
July 7–9	July 13–15
	(August 17–19)
September 8–10	September 14–16
October 13–15	October 12–14
November 10–12	November 9–11
December 8–10	December 7–9

New applications under the centralised system and scientific advice

To some extent, the number of applications through the centralised procedure is dependent on the change to Part B of the Annex to Council Regulation (EEC) No 2309/93 being completed soon so that new molecules for companion animals may be considered eligible for a Community authorisation.

If the change to the Annex proceeds as planned in a timely manner, then the number of applications in 1998 for a Community authorisation, based on the forecast carried out in association with FEDESA, the European veterinary medicines industry association, approximates to 9. These new applications would be in addition to the ongoing evaluations which would carry over from 1997 and reach the opinion stage during the year. The number of applications predicted reflects the situation which currently prevails in the animal health industry in the EU.



A major goal will be to maintain the record so far of completing opinions for all applications within the 210 day timeframe laid down in the Regulation. With the likelihood of several new centrally-authorized products coming to the market place the number of variations is expected to increase and this is reflected in the numbers forecast for 1998 and 1999.

4.3 Applications for establishment of maximum residue limits (MRLs)

MRLs for old substances

Further to the extension of the deadline of 1 January 1997 for defended old substances to 1 January 2000, and the identification by the EMEA of those falling under this provision, the Secretariat together with the Safety of Residues Working Party (SRWP) will continue in their efforts to advance the assessments of the remaining substances in order to meet the new deadline. The recently created sub-group of experts will continue to process the evaluation of applications relating to herbal remedies and advise the CVMP accordingly.

The SRWP will continue to review its *modus operandi* to seek areas for greater efficiency to ensure progress in this regard. The number of meetings of the SRWP will remain the same in 1998 (8 meetings) and the duration of the meetings will continue to be 3 days. Consideration has been given to increasing the frequency of the Working Party meetings. However this was considered counterproductive, since the shorter time frame would not allow sufficient time for the efficient preparation of assessment reports and the necessary participation of experts at intervening plenary meetings of the CVMP.

MRLs for new substances

The number of applications for the establishment of MRLs for new substances in 1998 is not expected to differ significantly from the previous year and in consultation with the industry association is forecast at approximately 6, with 10 applications for extensions or modifications.

Nonetheless as stated in the 1998 objectives compliance with the deadlines laid down in the Regulations remains the major objective. The work undertaken by the CVMP in 1997 to clarify its position through guidelines on a number of critical issues relating to establishment of MRLs is expected to pay dividends in facilitating the review process for new applications in the year ahead.

4.4 CVMP working parties and guidelines

Pharmacovigilance

With the introduction of several centrally-authorized products into the market place, we may anticipate the reporting of some serious adverse reactions reports in the coming year, which will present the Pharmacovigilance Working Party with the first cases in which its advice and recommendations may be sought.

Whilst good progress has been made in defining a dictionary of defined terms, further work needs to be done to bring this task to a conclusion during 1998.

The Working Party will complete the preparation of a guideline on post-marketing surveillance, and reporting requirements for authorities, and will further review and update the measures in force for rapid alert reporting in the veterinary sector.

Immunological veterinary medicinal products

The Immunologicals Working Party is scheduled to meet four times in 1998 and will continue to examine the following issues on behalf of the CVMP:

- Elaboration of new guidelines:
 - production and quality control of veterinary medicinal products derived by recombinant DNA technology;
 - duration of protection and vaccination schemes; and
 - policy on the use of adjuvants in veterinary medicines
- Ongoing review of existing guidelines including guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via veterinary medicinal products
- Product advice or scientific advice, if requested
- Contribution to the international harmonisation of technical requirements for immunologicals

As the number of centralised applications in the veterinary sector favours medicinal products developed by means of biotechnological processes, the role of this working party is increasing in importance in the provision of scientific advice and ad hoc groups may also be convened to address specialist topics.

Safety of residues

The Safety of Residues Working Party will continue to process MRLs for old substances as outlined above.

The CVMP and its Safety of Residues Working Party will also actively monitor developments at the international level respectively within Codex Alimentarius and the Joint Committee for Food Additives (JECFA) in relation to the establishment of global MRLs and will provide scientific input to such bodies when requested.

The CVMP will complete its review on the subject of injection site residues, taking account of recommendations of Codex Alimentarius which are anticipated to be finalised in 1998, and will address the subject of reporting publicly how the concept of risk assessment is dealt with in the process of establishing MRLs in the EU.

The input from the Secretariat to the redrafting of the 'Notice to Applicants' in Volume VI of the *Rules Governing Medicinal Products in the European Union* will be finalised once the amendment of Council Regulation (EEC) No 2377/90 under discussion has been adopted.

Efficacy of veterinary medicines

The CVMP Efficacy Working Party is scheduled to meet four times in 1998. In relation to existing guidelines that have been identified by the CVMP as needing revision, the following should be dealt with in 1998-99:

- Conduct of pharmacokinetic studies in animals (*Rules Governing Medicinal Products in the European Union, Volume VII, p. 31*)
- Conduct of bioequivalence studies in animals (*ditto, p. 37*)
- Veterinary medicinal products administered via the teat duct to lactating cows for the treatment of clinical mastitis (*ditto, p. 129*)
- Veterinary medicinal products administered via the teat duct to lactating cows for the treatment of subclinical mastitis (*ditto, p. 133*)
- Veterinary medicinal products administered via the teat duct to cows at drying off for the treatment of subclinical mastitis and prevention of new infections (*ditto, p. 137*)

In relation to the elaboration of new guidelines, the following two guidance notes will be developed in priority order:

- biostatistical methodology in veterinary clinical trials
- demonstration of efficacy of anti-inflammatory drugs

International harmonisation

Good progress in the VICH initiative in 1997 bodes well for further progress in 1998. Whilst a number of priority topics in phase I have reached step 4 in the harmonisation process, with the adoption of draft recommendations for guidelines being released for consultation, further work is planned for the remaining ones in 1998. In particular, outstanding issues remain to be addressed on anthelmintic guidelines, environmental risk assessment phase II and reproduction toxicity.

Two new priority topics have been agreed by the Steering Committee for action in 1998 and these are pharmacovigilance and testing for extraneous agents in biologicals. In the pharmacovigilance group, the European Union is topic leader for veterinary pharmacovigilance framework and terminology, with US Animal Health Institute (AHI) as topic leader for electronic standards for the transfer of information.

The biologicals group has three sub-topics. The US Food and Drug Administration is topic leader for mycoplasma testing, AHI is topic leader for formaldehyde and moisture testing, with FEDESA acting as topic leader for extraneous agents.

The EMEA will continue to promote and publicise the VICH initiative through participation at meetings and through publications.

4.5 Mutual recognition of veterinary medicines

The number of applications being processed using the mutual recognition procedure is increasing and this trend is expected to continue, principally because from 1 January 1998 parallel applications for a product authorised in another Member State will have to be processed using mutual recognition, in accordance with the legislation.

To date there have been no referrals for arbitration to the EMEA (with advice from the CVMP), but it can be expected that this situation will not continue indefinitely. Arbitration referrals may be expected to be received by the EMEA during the next 12 months.

Since April 1997 the Veterinary Mutual Recognition Facilitation (VMRF) Group has met immediately prior to the meetings of the CVMP. The remit of the VMRF Group is to discuss and resolve the various issues raised during assessment procedures, along with organisational and procedural problems. Administrative support to the group is provided by the EMEA Secretariat and national competent authorities are appreciative of this assistance. One of the most important issues for national competent authorities outside of individual procedure issues, relates to communication and the exchange of information. The VMRF Group has, in principle, accepted a share of the management responsibility for the EudraTrack system (an EU IT intranet system). It is intended that transfer of responsibility from the European Commission will take place during 1998.

It is understood that during 1998 Member States have the following aims and objectives:

- to process all applications submitted under the mutual recognition procedure according to the published best practice guide and in line with time requirements of the legislation;
- to address all issues which arise as a result of mutual recognition procedures.

5. Key objectives for technical co-ordination

	1996	1997	1998 (estimate)	1999 (estimate)
Workload				
Inspections				
• <i>GMP inspections</i>	19	29	50	60
• <i>GCP inspections</i>	—	3	15	35
• <i>Export certificates</i>	1 700*	3 364	5 000	6 000
Document management and publishing				
• <i>Document dissemination</i>				
Subscriptions	—	159*	350	450
Requests for information	N/A	1 160*	3 040	3 400
• <i>Internal services</i>				
Mail in	27 218	36 419	50 000	60 000
Mail out	13 323	36 330	50 000	60 000
Number of pages translated	10 100	5 770	7 000	7 500
Conference services				
• <i>Meeting days</i>	270	320	405	440
• <i>Interpretation days</i>	427	474	540	540
Resources				
Head of Unit and secretariat	2	4	4	4
Sector for inspections	4	8	11	12
Sector for document management and publishing	6	9	12	12
Sector for conference services	5	8	8	9
Sector for information technology	5	14	17	19
Total	22	43	52	56

* half-year activity

5.1 Workload and goals of the Unit

Head of Unit: Dr Karel de NEEF



By the end of 1997, a number of key positions in the Unit had been filled and the Unit is now fully operational. One example is the design and implementation of the new information technology platform which was successfully completed without interruption of the EMEA's operations and also the transfer of the information stored on the old platform which was re-arranged into a new folder structure. This will lead to improvement in the speed of operation of the IT platform, maintenance of appropriate security and the introduction of systematic document identification.

Similar progress has been achieved by the other sectors of the Unit, for example concerning document dissemination, export certificates and conference services, which are described below.

The global objective for 1998-99 is to build on the solid base now created. The Unit will become able to fully develop its support to the EMEA while fulfilling a similar support role common to all EU pharmaceutical regulators. Objectives to be achieved in pursuit of this goal include:

- assisting in the further implementation of management decision-making processes focusing on cost, benefit and efficiency based on data made available by newly introduced management information tools.
- helping to improve the efficiency of the Agency through the provision of better tools for internal communication, diary synchronisation, scheduling of meetings etc;
- expanding the EMEA's capacity to communicate electronically with its partners through on the Eudra projects.

5.2 Sector for inspections

Head of Sector: Mr Stephen FAIRCHILD

The co-ordination of both pre- and post-authorisation good manufacturing practice (GMP) and good clinical practice (GCP) inspections will continue to increase over the period 1998-99, and the volume of requests for 'export certificates' is also expected to increase. Work on the harmonisation of inspection procedures and practices within the Community (GMP and GCP) and mutual recognition agreements will become major activities.

The efficiency and level of control of the systems for co-ordinating inspections and producing 'export certificates' should improve significantly following the introduction of the Agency's application tracking system (ATS) and quality management system (QMS). The work already underway on strict monitoring of time and cost for these activities will be continued. Improvements will be made which reduce the time required for producing 'export certificates' and co-ordinating inspections.

The sector will continue to help in setting up and operating the Agency's quality management system, being responsible for the quality manual and internal quality system audits.

The sector has an ongoing role in responding to requests to participate in formulating proposals for European policies and legislation, and will be contributing to several such projects, e.g. future legislation on inspection arrangements for starting materials manufacturers and good clinical practice.

Mutual recognition agreements with third countries

The period 1998-99 will be one of intense activity in respect of the EMEA's role in the co-ordination of implementation of mutual recognition agreements (MRAs) covering GMP inspections. This task is carried out by the EMEA at the request of the European Commission.

The texts of MRAs with Canada and the USA were initialled in June 1997. Considerable resources will be required to manage and monitor the proposed confidence building phases of these agreements in order to ensure successful implementation. Agreements with Australia and New Zealand are also due for implementation in 1998 and a number of others are likely to be progressed during 1998-99.

Harmonisation and joint CPMP/CVMP Quality Working Party

Work will intensify to harmonise GCP and GMP inspections in the Community through regular meetings of inspectors. During 1999 this will take a much higher priority (in light of pending Community Directives), involving increased effort and resources. The authorisation of medicinal products by national competent authorities within the Community will thus be supported, as will the implementation of MRAs and international harmonisation.

The sector will continue to support and guide the work of the joint CPMP/CVMP Quality Working Party in developing new work and maintaining existing Community guidelines on quality topics.

5.3 Sector for document management and publishing

Head of Sector: Ms Beatrice FAYL

During the previous year, the activity level of the sector increased considerably and this trend is expected to continue through 1998-99. The responsibility for co-ordinating translation services was transferred from conference services to this sector.

Document dissemination

The Agency's publishing activities will continue to require considerable resources. Document dissemination activities are expected to further increase in 1998-99 in respect of both the subscription service and the provision of information on an *ad hoc* basis. At the end of 1997, the majority of retrievals (80 percent) related to electronic documents.

In light of the popularity of the prototype CD-ROM (containing all documents issued by the EMEA to date), a new release will be issued during the first half of 1998. Improvements to the presentation of and access to information on

the CD-ROM will be made. In addition, a new style EMEA web-site with increased functionality will be available in 1998, with extended multi-lingual access.

Quality of documentation

Enhancement of the quality of user information in the official Community languages is a continuing priority for the EMEA. Internal systems for monitoring and ensuring the high quality of product information documentation will be refined in 1998 and systems to ensure their standardisation will be implemented. The development of standard templates will also be continued. Once these systems have been fully established they will be continually monitored and improved.

The Management Board has approved a mandate for the Agency's Working Group on the Quality Review of Documents, allowing continuation of this programme during 1998.

Document management



In the field of document management, the focus will be the establishment of an effective management system and document repository, allowing business data to be easily accessed irrespective of format or media it is stored on. Building on work done during 1997, the concept of 'document life cycle' will be introduced and version control systems implemented.

Electronic access to application dossiers and their maintenance is a key priority and the ATS will facilitate this aspect of effective document management. In general, attention will be paid to changing the emphasis from the use of paper copies to electronic handling and forwarding of documents. Specific procedures will be developed for identified business sub-processes in the context of the QMS project.

A procedure for the systematic management of versions of multiple-language documents will be introduced and interaction with the Translation Centre in Luxembourg will be improved to further reduce turnaround time and enhance quality of translations.

The library will continue to be expanded and improved (e.g. introduction of electronic dictionary systems and new on-line facilities). Measures will be taken to ensure that the anticipated increase in the volume of mail can be handled.

5.4 Sector for conference services

Head of Sector: Dr Sylvie BÉNÉFICE

The number of meetings hosted by conference services has increased over the past two years and this trend is expected to continue in 1998-99. Conference services will focus on improving the quality of services provided to delegates and increasing efficiency through the adoption of integrated computer systems.

Delegate support

The sector will focus on active consultation with delegates with respect to their working needs, with a view to improved facilities, technology and support from EMEA personnel. Improvements will also be made to the information made available to delegates relating to new developments at the EMEA as well its immediate environment, Canary Wharf.

The travel and accommodation options available to delegates will be increased through a revision of the terms on which the EMEA purchases from its suppliers. A second objective of this change is an improvement in the value for money obtained by the EMEA from its external sources. Delegate reimbursement procedures will also be improved, leading to a reduction in the average time taken to process transactions from 17 to 10 days.



Meeting organisation

Steps will be taken to optimise the use of EMEA facilities through better communication with the organisers of meetings. In addition to more pro-active scheduling, this will include analysis and implementation of a consistent policy in respect of interpretation facilities. Video-conferencing facilities will be upgraded, with the aim of increasing use.

Following analysis of the existing conference management systems, new computerised processes will be introduced, leading to the streamlining of procedures to minimise administrative tasks. Financial and operating data will be reviewed monthly in order to control costs and improve budgeting procedures.



Reprographics

Revised working practices will be introduced in reprographics to take into account the wide fluctuations in workload over each month. Existing reprographic equipment will be replaced with higher capacity machines better suited to the increased workloads being experienced by the EMEA.

5.5 Sector for information technology

Head of Sector: Mr Michael ZOURIDAKIS

During 1997, the strategy for providing appropriate information technology facilities for the EMEA was formally defined and adopted. This provides for a functional and organisational division between the administration and support of existing facilities on the one hand and development and implementation of new or improved systems on the other. Investment in both personnel and equipment will continue to be necessary in order to achieve EMEA medium term objectives.

The 'millennium bug' will not pose a problem for the EMEA as a result of the introduction of the new hardware platform in 1997. It will be necessary to ensure that the Agency's partners in the European pharmaceutical approval system are in a similar position.

In 1998 emphasis will be on the consolidation and improvement of in-house facilities and the opening up of external communications, whilst maintaining all necessary security. At the same time, the organisational structure adopted by the sector will lead to greater transparency in the way that expenditure and activity in the IT sector is driven by the business requirements of the EMEA as a whole.

New features

During 1998 users will benefit from the introduction of 'SI2' (an EU-specific budgetary accounting package), a CD-ROM tower, access to the system from remote locations and mobile computing. Projects of a more technical nature relating to security, integrity of data and optimisation of the system will be undertaken. An example is the installation and fine-tuning of Oracle to run SI2, ATS and ActiTrak (an activity tracking system) efficiently.

Communication

The focus on external communication will be maintained through increasing involvement in the Eudra applications, particularly EudraWatch and EudraNet. At the same time, and following discussions with the European Commission Joint Research Centre, the relationship with the European Technical Office for Medicinal Products (ETOMEPE) group will change in nature. Some production work such as the management of communications systems and web site maintenance will be transferred to the EMEA IT sector from ETOMEPE, liberating the latter's resources for new development work. In parallel, participation in the European Commission's fifth research and development framework programme will be sought.

Meeting user needs

Dialogue with the IT departments of Member States' regulatory authorities initiated during 1997 will be encouraged. Within the EMEA, the IT sector's plans will be the subject of wider and more informed discussion through briefing sessions, direct representation from all the Units, greater use of the IT user group and increased training. In addition, the level of service expected of the IT sector will be agreed internally.

6. Key objectives for administration

	1996	1997	1998 (estimate)	1999 (estimate)
Resources				
Head of Unit and secretariat	2	2	2	2
Personnel and support services	13	14	19	19
Accounting	4	6	6	6
Total	19	22	27	27

6.1 Workload and goals of the Unit

Head of Unit: Mr Marino RIVA



The Administration Unit comprises two operational sectors:

- Accounting
- Personnel and support services

The staffing of the Unit has been undertaken in line with the workload estimates for 1998-99. Given the support role of the Unit, its own workload is dependent on that of the Human Medicines, Veterinary Medicines and Technical Co-ordination Units.

The Unit will undertake the necessary preparations for the introduction of the Euro ahead of economic and monetary union.

The EMEA is increasingly dependent on revenue from fees as a proportion of total income. Recruitment of personnel will therefore continue to be undertaken on a prudent basis. Within the total number of posts authorised for 1998 and requested for 1999, a small number of posts have been reserved to allow a degree of flexibility for each Unit to meet unforeseen needs. Similarly a limited number of posts have been reserved to allow the EMEA to meet unexpected needs or perform new tasks which may present themselves in the near future (3 posts in reserve in 1998 and 8 posts in reserve in 1999).

6.2 Sector for personnel and support services

Head of Sector: Ms Frances NUTTALL

Goals for 1998 and 1999

- To implement the current budget in 1998 and 1999 in accordance with the financial regulations and report to management regularly thereon;
- to recruit suitable staff for the needs of the Agency promptly through selection procedures;
- to ensure that salaries are paid correctly on time each month, refund mission expenses promptly and administer personnel entitlements in line with the Staff Rules and Regulations;
- to provide information and assistance to new staff and organise and co-ordinate training programmes for all staff;
- to provide a suitable office environment to support and facilitate the work of the Agency, e.g. switchboard service, reception of visitors, office equipment, furniture, and supplies, restaurant, security, health and safety;
- to deal with individual staff needs or problems, liaise with other units and the Staff Committee;
- to prepare the 1999 budget and follow up and act on the approval process for the European Community contribution; and
- to implement rules adapted for performance evaluation of staff and support the first promotion round in 1998.

Personnel

Apart from its responsibility for everyday staff matters, the personnel function will continue to experience in 1998 an intense workload related to new staff covering the cycle from competitions through interviews, recruitment, contracts, welcome partner scheme, introductory training and probation.

The personnel function will also be introducing a performance evaluation system and will be directly involved in the first round of internal promotions.

Support services

Support services work programme covers a wide range of activities crucial to the effective and efficient functioning of the Agency. Their activities cover such key areas as security, switchboard/reception, restaurant, building and equipment, maintenance, and cleaning and office supplies.

The Support service is also responsible for the physical and accounting control of the Agency's inventory of equipment.

Finance

The sector is responsible for the overall management of the budget and in particular for all staff expenditure and premises-related expenditure including purchase and maintenance of office equipment and furniture. The sector also will carry out the important function of budget monitoring and the preparation of analytical accounts. Timely reports will be presented to management to ensure effective and efficient use of financial resources.

Close relations will be maintained with the Commission services responsible for overseeing the financial activities of the EMEA (Directorates-General for Personnel and Administration, DG IX; and for Budgets, DG XIX), with the Committees on Budgets and Budgetary Control of the European Parliament, with the Council of Ministers' Budgetary Committee and also the European Court of Auditors.

Training

During 1997 management training courses were attended by the Executive Director, Heads of Unit and Heads of sector. This type of training will be extended in 1998 and 1999. Since staff at the EMEA come from a wide range of backgrounds this training will contribute to the development of a common management approach. Group training or where appropriate individual training will be provided for all staff in 1998 and 1999.

6.3 Sector for accounting

Head of Sector: Mr Gerard O'MALLEY

Goals for 1998 and 1999

- To contribute to the successful implementation of the budgetary accounting system (SI2) and to move to the integration of budgetary, analytical, costing and financial accounting systems;
- to consolidate the electronic banking software introduced in 1997;
- to streamline a cash management system which will need to be responsive to continually increasing dependence on fees revenue vis-à-vis subsidy;
- to execute payments within 15 days of receipt of approved payment orders;
- to actively contribute to development of the Quality Management System;
- and to maintain the Agency's accounting records, make payments, collect receipts and manage the cash resources in accordance with the requirements of the Financial Regulation and the corresponding implementing rules.

Accounting

The Accounting sector is responsible for the collection of revenue, the payment of expenditure, the preparation of budgetary and financial accounts and the management of the EMEA 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.

Budgetary accounting system

The Financial Controller of the Commission expects all Agencies to use the same software for their budgetary and financial needs. The EMEA, in conjunction with other EU bodies and the Commission, is testing the SI2 budgetary system with a target production date of 1 April 1998.

At the same time the EMEA is actively seeking, in liaison with the Financial Controller of the Commission and the other EU Agencies, a software solution for general ledger, analytical and cost accounting which satisfies both the needs of the EMEA and at the same time is acceptable to Financial Control. The cost implications of the various proposed solutions are being examined and also their operational practicalities.

Electronic banking software

During the year a number of electronic banking software products have been installed. This system provides to the Agency a highly secure, two way electronic link through which information can be received and transactions executed.

During 1998, once the budgetary accounting (SI2) system is in production and the new information system architecture is established, the Agency will explore the possibility of moving to a financial electronic data interchange link between the EMEA's bank, suppliers and other business partners.

Annexes

1. EMEA establishment plan 1997-99
2. EMEA budget summaries 1997-99
3. Reference documents
4. Profiles of EMEA personalities

Annex 1
EMEA establishment plan

Category and Grade	Occupied as per 31.12.1996	Occupied as per 31.12.1997	Authorised for 1997	Authorised for 1998	Requested for 1999
A1	—	—	—	—	—
A2	1	1	1	1	1
A3	4	4	4	4	4
A4	—	12	18	18	25
A5	13	15	15	19	23
A6	—	17	19	25	25
A7	14	21	21	23	23
A8	13	—	—	—	—
TOTAL A	45	70	78	90	101
B1	1	1	2	2	3
B2	—	2	6	8	10
B3	6	7	8	12	13
B4	—	5	9	9	9
B5	9	6	6	5	5
TOTAL B	16	21	31	36	40
C1	1	5	5	5	8
C2	—	3	10	12	12
C3	2	32	32	37	37
C4	—	—	—	—	—
C5	3	—	—	—	—
TOTAL C	6	40	47	54	57
D1	—	—	—	—	1
D2	—	4	4	4	4
D3	1	—	—	—	—
D4	—	—	—	—	—
TOTAL D	1	4	4	4	5
TOTAL POSTS	68	135	160	184	203

Annex 2
EMEA budget summaries 1997 - 1999

Annex 3

Reference documents

a) *EU official publications*

- Council Regulation (EEC) No 2309/93 of 22 July 1993 (OJ L 214, 24.8.1993, p. 1)
- Council Regulation (EEC) No 2377/90 of 26 June 1990 as amended (OJ L 224, 18.8.1990, p. 1)
- Council Directive 75/319/EEC as amended (OJ L 147, 9.6.1975, p. 13)
- Council Directive 81/851/EEC as amended (OJ L 317, 6.11.1981, p. 1)

The texts of these and other provisions may be also be found in the series *Rules governing medicinal products in the European Community*, volumes I to VII. These publications, along with copies of the Official Journal, are available from:

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

The texts will also be available in 1998 on the EudraLex Internet site at <http://dg3.eudra.org>

b) *EMEA documents*

- First General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1995 (ISBN 92-827-7491-0)
- Second General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1996 (EMEA/MB/055/96)
- Statement of principles governing the partnership between the national competent authorities and the EMEA (EMEA/MB/013/96)
- Report on performance goals and indicators for the EMEA (EMEA/MB/062/96)
- EMEA contribution to the preparation of a Commission proposal for a definitive Council Regulation on fees payable to the EMEA (EMEA/MB/057/96)

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

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

Strachan Heppell, Chairman of the Management Board, b. 15 August 1935, n. British



Education: Graduate of Oxford University.

Career to date: Mr Heppell has worked in a number of Government Departments in the United Kingdom and for the Government of Hong Kong. Most recently, he was Deputy Secretary in the UK Department of Health. He was elected the first Chairman of the EMEA Management Board in 1994 and re-elected in 1997. He is also a member of the UK Broadcasting Standards Commission; Chairman of the Family Fund Trust; and Visiting Fellow of the London School of Economics.

Romano Marabelli, Vice-Chairman of the Management Board, b. 03 May 1954, n. Italian

Education: Veterinary medicine degree from the University of Milan. Various post-graduate diplomas in food hygiene and technology, veterinary legislation and veterinary public health.

Career to date: From 1980 to 1984, Dr Marabelli was veterinary officer at the Italian Ministry of Health, then counsellor for health issues at the Italian Delegation to the European Community in Brussels until 1990. He returned to the Ministry of Health as Director-General of Veterinary Services in 1991. In 1994 he was elected Vice-Chairman of the EMEA Management Board, and Vice-Chairman of the Commission for Europe of the OIE in Paris. Appointed Director-General of the Department for Food, Nutrition and Veterinary Public Health of the Health Ministry in December 1995, in 1997 he was elected Vice-Chairman of the Management Board of the EMEA and of OIE.



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. First Executive Director of the EMEA, starting in September 1994.

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 Agence du Médicament in 1993 and, in the same year, elected as Chairman of the former Committee for Proprietary Medicinal Products (CPMP) 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. 03 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 veterinarian 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.

Cyril M. O'Sullivan, Vice-Chairman of the CVMP, b. 09 February 1945, n. Irish

Education: Qualified as a veterinary surgeon at the Veterinary College of Ireland, University College Dublin. MVB, admitted to membership of the Royal College of Veterinary Surgeons. MRCVS, studied for MSc at the Veterinary School of the University of Edinburgh.

Career to date: Dr O'Sullivan was in general veterinary practice in the UK and Ireland from 1972 to 1976, then in service as Veterinary Officer with Overseas Development in Botswana and North Yemen until 1982. From 1982 to 1986 he was employed in the pharmaceutical industry as technical adviser for a major multinational company, and has been Veterinary Director of the Irish Medicines Board in Dublin since 1986. He was elected Vice-Chairman of the CVMP in 1995 and re-elected in 1998.



Marino Riva, Head of Unit, Administration, b. 06 March 1937, n. Italian



Education: Degree in law from the University of Genoa.

Career to date: From 1965 to 1976, Mr Riva was an official of the Italian Institute for Foreign Trade, serving at headquarters in Rome and at the Berlin office, which he headed from 1972 to 1976. He then joined the European Centre for the Development of Vocational Training as Head of Administration, a position he held until April 1995 when he joined the EMEA.

Frances Nuttall, Head of Sector, Personnel and support services, b. 11 November 1958, n. Irish

Education: BSc in Public Administration and an MSc in Economics from Trinity College Dublin.

Career to date: Variety of 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 for five years before joining the EMEA in May 1995.



Gerard O'Malley, Head of Sector, Accounting, b. 04 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 with Stokes Kennedy Crowley. 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 including risk benefit and risk assessment. He joined the EMEA in April 1995.

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.



Josep Torrent Farnell, Head of Sector, New chemical substances, b. 02 May 1954, n. Spanish



Education: Qualified pharmacist and Degree in medicine and surgery from the University of Barcelona, as well as Diploma in Pharmacology and Toxicology. Specialist in internal medicine and clinical pharmacology. Doctorate in clinical pharmacology from the Autonomous University of Barcelona (UAB).

Career to date: From 1977 to 1990, Prof. Torrent Farnell worked in internal medicine and clinical pharmacology in Spain and was Assistant Professor of Pharmacology at UAB. From 1990 to 1994, he was Technical Counsellor in Clinical Evaluation at the Spanish Ministry of Health, Member of the CPMP/EWP and involved in the Efficacy Group of the ICH. In 1992, he became Professor of Clinical Pharmacology and Therapeutics and Director of the Master/Diploma on European Registration of Medicinal Products (UAB). He joined the EMEA in February 1996.

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 the CPMP (Committee for Proprietary Medicinal Products) and CVMP (Committee for Veterinary Medicinal Products). He joined the EMEA in August 1996.



Peter G.H. Jones, Head of Unit, Evaluation of Medicines for Veterinary Use, b. 09 August 1947, n. British



Education: Graduate of the Faculty of Veterinary Science at Liverpool University.

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.

Jill Ashley-Smith, Head of Sector, CVMP and veterinary 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 residues (MRLs), 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 1993, she returned to Germany to the Ministry for Environment in 1995. She has been involved in the EU classification and labelling scheme and in the harmonisation of risk assessment approaches and data requirements for human health and environment of chemical substances both within the European Commission and OECD. She joined the EMEA in April 1996.

Karel de Neef, Head of Unit, Technical Co-ordination, b. 21 December 1946, n. Dutch



Education: PhD in developmental cardiology at Leiden University. Medical physiology qualification, post-graduate work in cardiology and epidemiology at Erasmus University, Rotterdam. Post-graduate courses 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. In 1976 he joined Organon International in the Netherlands, holding posts in research and clinical information management. In 1992 he became International Director of Clinical Data Management with Hoffmann-La Roche in the USA. With experience in clinical drug development, including international integration, process optimisation and implementation of information systems, 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 multinational pharmaceutical companies monitoring and setting up quality assurance systems in a number of different countries before joining the EMEA in August 1995.

Beatrice Fayl, Head of Sector, Document management and publishing, b. 09 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 at 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: Doctor of Sciences in physical sciences and qualification in management of research, PhD and MSc in physical organic chemistry, Degree in Biochemistry, from the University of Montpellier.

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 as *Chargé de Recherche 1st Class* and was nominated Officer for European Affairs in 1991. From 1993 to 1997, as Scientific Secretary for COST Chemistry Actions at the European Commission in Brussels, she was involved in co-ordination of research networks in Europe and organisation of conferences. She joined the EMEA in September 1997.



Michael Zouridakis, Head of Sector, Information technology b. 08 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.