THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

WORK PROGRAMME

1999-2000

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Contents

Introduction

Annexes

Introduction

by
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Executive Director

The completion of the fee reform in December 1998 ensures that the EMEA has a sound financial basis for the period 1999-2000. The EMEA is now better equipped to face its regulatory responsibilities without the distractions of excessive financial worries. During this period the EMEA and the national competent authorities will be able to analyse their collective experience of the European authorisation system. By 2000 they will be in a position to advise the European Commission on how to adapt the centralised and mutual recognition procedures to the needs of European patients and industry.

EMEA efforts to improve transparency will continue to be aimed at improving information to patients, health care professionals and the general public. It is also important to achieve transparency in the cost of the operation of the European authorisation system. The presentation of EMEA activities in this work programme therefore takes into account the way that they are funded; whether by fees, administrative charges or from the EU general budget.

Transparency is a prerequisite to allowing the European authorisation system to be audited by the European Union institutions and the public at large, as we prepare together for the review of the system in 2001. In particular I welcome the opportunity offered by Commissioner Martin Bangemann to initiate the audit process at a meeting to be held at the EMEA in March 1999.

As part of the quality management initiative launched in 1997, internal audits will begin in 1999 involving volunteers from Agency personnel to look at best practices identified in a number of standard operating procedures developed at the EMEA. By 2000 it is hoped to be able to share our results and some of quality management projects with partner national authorities.

Internationally, the EMEA faces a number of important developments in 1999 and 2000. Iceland and Norway will begin formal participation in the work of the EMEA in 1999 turning the Agency into a European Economic Area body. Support to central and eastern European countries will I hope considerably increase, in particular now that a collaboration agreement (CADREAC) has been finalised between the EMEA and the concerned countries. A great deal of effort will also be invested in the practical implementation of mutual recognition agreements signed between the European Union and a growing number of main international trading partners. In addition, the EMEA will continue to be actively involved with Japan, US and relevant international organisations towards the development of internationally recognised testing guidelines and ultimately a common application dossier (ICH, VICH).

In essence, 1999-2000 will be a period of evolution, not revolution. It will be a period in which the EMEA and its partners in the European system will seek to adapt themselves to the challenges of the millennium and beyond. Better protection of public and animal health and support for European pharmaceutical research remain our key objectives.

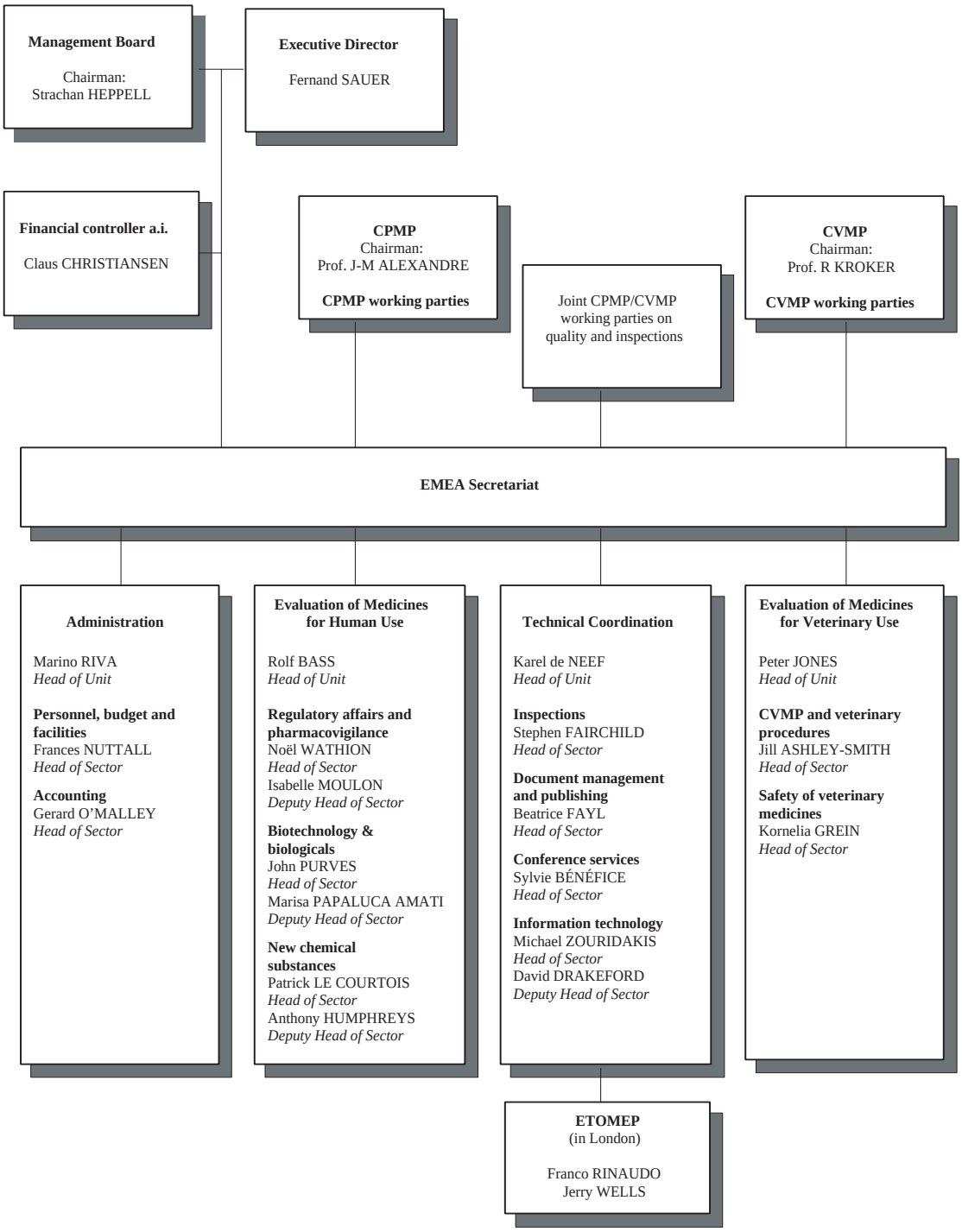
EMEA mission statement

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

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

EMEA main activities (fee and non-fee related)	Budgetary resource or classification
Initial evaluation applications for human and veterinary medicines and initial inspections	Basic fee and inspection fee
Type I and II variations, extensions, transfers and follow-up inspections	Variation fees, etc
Post-authorisation maintenance, including pharmacovigilance, crisis handling, harmonisation of inspections procedures, mutual recognition agreements and testing and sampling	Annual fee
Scientific advice: initial and follow-up	Corresponding fees
Arbitrations and Community referrals	Corresponding fees
Special services: e.g. certificates of medicinal products, subscriptions, parallel distribution	Corresponding administrative charges
General harmonisation activities, in particular CPMP/CVMP working parties	EU general contribution
Specific activities at request of EU institutions and Member States: e.g. support to mutual recognition, old MRLs, herbal remedies, orphan medicinal products, ICH/VICH, CADREAC	EU general contribution or other special budgets to be determined

Organisation of the EMEA



Overview of the European authorisation system

Human and animal health

The European system for the authorisation of medicinal products for human and veterinary use has been in place since 1995. It is designed to promote both public health and the free circulation of pharmaceuticals. Access to the European market is facilitated for new and better medicines – benefiting users and European pharmaceutical research.

In the case of veterinary medicinal products, consumer and animal health is protected through the fixing of maximum residue limits in food-producing animals.

EMEA – a network agency

The new European system is based on co-operation between the national competent authorities of the Member States and the EMEA. The EMEA acts as the focal point of the new system, co-ordinating the scientific resources made available by Member State national authorities, including a network of some 2 200 European experts.

The EMEA is designed to co-ordinate the existing scientific resources of the Member States, acting as an interface between the national competent authorities rather than as a highly centralised organisation. The partnership between the EMEA, national authorities and the European Union institutions is central to the successful functioning of the European authorisation procedure.

The European procedures

The new European system offers two routes for authorisation of medicinal products:

- *Centralised procedure:* Applications are made directly to the EMEA, leading to the granting of a European marketing authorisation. Use of this procedure is compulsory for products derived from biotechnology, and optional for other innovative medicinal products
- *Decentralised procedure:* Applicable to the majority of conventional medicinal products. Applications are made to the Member States selected by the applicant and the procedure operates by mutual recognition of national marketing authorisations. Where this is not possible, the EMEA is called on to arbitrate

Opinions adopted by the EMEA scientific committees in either the centralised procedure or following arbitrations lead to binding decisions adopted by the European Commission.

Purely national authorisations remain available for medicinal products to be marketed in one Member State.

1. EMEA policies

The work of the Management Board in 1999-2000 will in particular focus on the Agency's contribution to the review of the European authorisation system for medicinal products. This review, to be conducted by the European Commission, will cover both the centralised and mutual recognition procedures. As part of this, Commissioner Martin Bangemann, Member of the European Commission with responsibility for the pharmaceutical industry, will hold his third audit meeting at the EMEA on 19 March 1999.

In order to optimise functioning of the global European authorisation system, the heads of national authorities and agencies that are not members of the Management Board will be invited to participate in the regular brainstorming meeting held in June each year. Similarly, the EMEA Executive Director is also invited to meetings of the Heads of Agencies groups (human and veterinary medicines). This will allow for discussion and coordination of matters of common interest to both the centralised and mutual recognition procedures.

The cycle of four Management Board meetings per year will continue in 1999 and 2000. Meeting dates for 1999 and 2000 are given below:

Management Board meetings in 1999	Management Board meetings in 2000
10 February	23 February
2 June	7 June
29 September	27 September
1 December	20 December

The office of the Executive Director provides the secretariat of the Management Board. A small team made up of two legal administrators, a personal assistant and two secretaries assists the Executive Director in the general management and functioning of the EMEA, legal affairs, external relations and liaison with the European Union institutions and Members State national competent authorities.

With an increasing number of centrally authorised human and veterinary medicinal products reaching the market, pharmacovigilance mechanisms in the European Union will be need to be continuously reinforced. Improvements to handling of crises and alerts (including product defect alerts) will also be needed, including also for products subject to national authorisations. Better communication must be established between the EMEA, its scientific committees, national competent authorities and the services of the European Commission. The EMEA will also seek to work with marketing authorisation holders concerning communication of safety matters, including communication to health care professionals.

The EMEA already provides support to the two Mutual Recognition Facilitation Groups for human and veterinary medicines. Work will take place in 1999-2000 on fitting out of an additional floor at the EMEA headquarters to provide in particular more meeting space for the EMEA and mutual recognition. Preventative harmonisation work benefiting both the centralised and mutual recognition procedures constitutes the major part of the work of the CPMP

and CVMP working parties in the form of guidelines. The Executive Director will continue discussion with the Management Board and the Heads of Agency groups to explore other initiatives to increase support to the mutual recognition procedure.

The Board will also consider in 1999 continuation of the work of the EMEA working party on herbal medicinal products on the basis of a report and work programme to be presented by the group.

Improvements in the transparency of the Agency's activities will remain a key theme in 1999-2000. Improvements in the structure and content of the European public assessment report (EPAR) will be made, in particular through dialogue with patient and health professional organisations. A priority in 1999 will also be the publication of the list of European experts, which is currently available at the EMEA. Other initiatives to be undertaken include a code of conduct concerning good administrative behaviour.

Dialogue with all interested parties is an essential part of the functioning of the EMEA. The extension of the established quarterly meetings between the scientific committees and interested parties to European learned societies will be explored in 1999.

The joint EMEA-EFPIA (European Federation of Pharmaceutical Industries' Associations) survey of the centralised evaluation of medicines is now well established. In addition, a survey will be conducted of the experience of companies once they have obtained a centralised Community authorisation. Similar initiatives in the veterinary medicines sector will be explored with FEDESA (Fédération européenne de la santé animale). The AESGP (Association européen des spécialités pharmaceutique grand public) has also shown interest in preliminary discussion on non-prescription medicines and their treatment in the different fields of activities of the EMEA.

Drawing on the achievements made with the EMEA quality management system, a quality manual of internal quality management processes will be compiled by summer 1999. The Executive Director will share this with interested national authorities later in 1999 as part of an initiative to share experience of quality management within the European authorisation system.

One such initiative already supported by the Management Board is the Quality review of documents working group. The group will continue its work in 1999-2000 on the improvement and consistency of patient and health care professional information, making increased used of electronic means of communication. The group is supported by an internal EMEA volunteer panel of scientific administrators that reviews texts in all official European Union languages to ensure the quality of product information.

Once adopted by the European Parliament and Council, the Board will consider the practical implementation at the EMEA of changes in the budgetary and financial control arrangements of all EU decentralised bodies.[1]

A pilot project with the European Commission Joint Research Centre for the medicinal information network for Europe (MINE) initiative will take the form of the electronic publication of the summary of product characteristics of products authorised after evaluation by the EMEA and the mutual recognition procedure. Other products will also be included at the request of the marketing authorisation holder. Proposals on how to take forward the MINE initiative will be presented by the Chairman to the Board during 1999.

(1) COM(1997) 489 final, OJ C 335, 6.11.1997, p. 15

2. Management of EMEA resources

The sound management of human, technical and other resources remains a key objective for the EMEA as a whole. The EMEA is increasingly dependent on fee revenue as a proportion of total revenue (65 per cent in 1999, 69 per cent in 2000 and up to 75 per cent by 2002).

The Agency will continue to collect data on the actual cost of the centralised system and referrals, including precise activities of the EMEA secretariat and the provision of rapporteur, co-rapporteur and inspection services by national competent authorities. The collection of this data is required under the new fee regulation[2] and has also been requested by the European Parliament before the next review of fees in 2002.

The scale of fees payable to national competent authorities in 1999[3] was finalised by the Management Board at its meeting on 10 February 1999. This will be reviewed before the end of 1999 for future years.

Within the secretariat, given the increasing workload of the EMEA and additional tasks performed at the request of the EU institutions, the Directorate will continue to closely monitor the resources and expenditure of each unit and sectors. Recruitment was postponed in previous years due to budgetary constraints and it is anticipated that the much needed staff will be recruited in 1999 (maximum of 203), rising to 210 by the end of 2000. The establishment plans for 1999-2000 are given in annex 1 of this work programme.

A stable structure of Units and sectors has now been developed. This will be kept under review to ensure that it is adapted to the workload and activities of the Agency. A small number of posts have been reserved to allow a degree of limited flexibility to meet unexpected needs and to allow the EMEA to perform new tasks which may present themselves in the future (4 posts in reserve).

(2) Article 12(4) of Council Regulation (EC) No 297/95 (OJ L 35, 15.2.1995, p. 1), as amended by Regulation (EC) No 2743/98 (OJ L 345, 19.12.1998, p. 3)

(3) EMEA/MB/035/98-Rev.1

The current distribution of posts between Units and sectors is given below:

	Allocation in 1999	Allocation in 2000
Directorate and financial control	8	8
Administration Unit		
Head of Unit team	2	2
Personnel, budget and facilities sector	21	21
Accounting sector	6	6
Unit total	29	29
Unit for the Evaluation of Medicines for Human Use		
Head of Unit team	5	5
Regulatory affairs and pharmacovigilance sector	27	27
Biotechnology and biologicals sector	23	23
New chemical substances sector	33	35
Internal reserve	--	2
Unit total	88	92
Unit for the Evaluation of Medicines for Veterinary Use		
Head of Unit team	4	4
CVMP and veterinary procedures sector	7	8
Safety of veterinary medicines sector	7	7
Unit total	*18*	*19*
Technical Coordination Unit		
Head of Unit team	4	4
Inspections sector	12	14
Document management and publishing sector	12	12
Conference services sector	10	10
Information technology sector	18	18
Unit total	*56*	*58*
Additional posts in general reserve	4	4
Total number of posts	203	210

Financial control

Financial controller, a.i.: Claus Christiansen

The transfer to the European Commission of financial control responsibilities is now expected towards the end of 1999. In the meantime, financial control activities will continue under the responsibility of the interim financial controller who will endeavour to ensure a smooth transition to Directorate-General for Financial control (DG XX).

Additional activities will include the giving opinions on financial systems and procedures, the development of a specific tool for financial control that links in with the EMEA accounting system (SI2) and ad hoc targeted controls on specific areas.

Workload estimates for principal activities:

	1997	1998	1999	2000
a priori control of budgetary transactions				
Commitment proposals	881	1 126	1 400	1 600
Payment orders	2 793	3 350	3 600	3 800
Other financial transactions	501	513	700	800
Personnel related	365	316	400	400
Turnaround time in financial control				
Within 2 days	75%	68%	90%	90%
3-5 days	17%	21%	10%	10%
Above 5 days	8%	11%	--	--

3. Key objectives for administration

Head of Unit: Mr Marino Riva

	1997	1998	1999 (estimate)	2000 (estimate)
Resources				
Head of Unit and secretariat	2	2	2	2
Sector for personnel, budget and facilities	14	19	21	21
Sector for accounting	6	6	6	6
Total staff	22	27	29	29

The staffing of the Unit has been undertaken in line with the workload estimates for 1999-2000. Particular objectives for the Unit include:

- facilitating the smooth introduction of the euro within the context of the Agency's work
- completing recruitment delayed from 1998 due to financial constraints

Sector for personnel, budget and facilities

Head of Sector: Ms Frances Nuttall

With an increasing number of staff, a growing budget and a soon to be enlarged headquarters premises, the workload of the sector will increase considerably in 1999-2000.

Specific objectives over this period include:

- Completion of recruitment procedures currently in progress and the organisation of an internal competition to integrate the Agency's secretarial and clerical staff within the statute governing officials and other servants of the European Communities
- Organisation of the traineeship programme for new graduates and start of a new cooperation programme for visiting scientists

- Completion in 1999 of selection procedures for provision of training services and for a computerised personnel system
- Production of analytical accounts on the basis of data on the time spent by EMEA staff on different tasks (ActiTrak)
- Ensure close liaison with Commission Directorate-General for Financial control (DG XX) in preparation for the take over of financial control responsibilities by the Commission
- Completion of the fitting out of the seventh floor in 1999 to provide additional meeting rooms and office space for the Unit for the Evaluation of Medicines for Human Use
- Completion of the rent review process before 2000

Sector for accounting

Head of Sector: Mr Gerard O'Malley

The principal responsibility of the sector is to maintain the accounting records in accordance with the Agency's financial regulation. In particular this involves the collection of revenue, the payment of expenditure, the management of the Agency's cash flow and the preparation of monthly and annual financial and budgetary accounts.

In addition to carrying out its regular responsibilities the Sector has the following goals for 1999-2000:

- Integration of the SI2 budgetary accounting system (introduced in 1998) with other financial systems of the Agency
- Coordination with other sectors to develop reporting systems in order to provide management with sound financial information related to the alignment of objectives, activities and the related resources
- Ensure coordination with other sectors the successful implementation of the revenue accounting module in SI2 including the incorporation of the provisions of the new fee regulation
- Absorb forecasted growth in the volume of the transactions without increasing the staff numbers

4. Key objectives for medicines for human use

	1997	1998	1999 (estimate)	2000 (estimate)
Workload				
Scientific advice given	23	43	30	35
Pre-submission meetings	80	70	80	90
New procedures				
Number of medicinal products	60	45	56	60
Number of active substances	48	40	50	54
Type I variation applications	109	158	170	190
Type II variation applications	47	66	70	75
Extension applications	34	15	22	26
Specific obligations, follow-up measures	277	379	494	580
Non-EU ADR reports (unexpected)	1 812	4 417	7 000	10 000
Periodic safety update reports	61	108	160	243
Guidelines				
CPMP guidelines	11	12	18	22
ICH-derived CPMP guidelines	13	3	4	8
Arbitrations and other Community referrals				
Arbitration opinions	3	5	10	14
Other Community referrals (opinions)	2	1	15	15
Meeting Days				
CPMP	33	34	36	38
Working parties (permanent)	54	47	53	58
Other meetings	123	109	101	125
Total meeting days	210	190	190	221
Resources				
Head of Unit and operational support	5	5	5	5
Sector for regulatory affairs & pharmacovigilance	18	21	27	27
Sector for biotechnology and biologicals	14	16	23	23
Sector for new chemical substances	19	23	33	35
Reserve	--	--	--	2
Total staff	62	65	88	92

4.1 Workload and goals of the Unit

Head of Unit: Prof. Rolf Bass

The core activity of the Human Medicines Evaluation Unit is to support the Committee for Proprietary Medicinal Products (CPMP), the working parties and expert working groups. The volume and workload of meetings of these committees has been calculated in terms of meeting days per year, the estimates for 1999 and 2000 include a reserve for crisis (e.g. CPMP and pharmacovigilance).

In order to handle the increasing workload derived from both new procedures and the maintenance of marketing authorisations, the focus will be on tools to measure productivity and improve efficiency. Work will be carried out according to predetermined objectives and each sector will undergo internal auditing.

Whereas the number of new applications has risen substantially since 1995, a slower increase is expected in 1999, with a plateau towards the year 2000. However, the workload is expected to increase further and become more complex in the following areas:

- advice on regulatory and scientific issues
- scientific complexity of new centralised procedures
- many more variations, extensions, annual re-assessments and renewals
- increased maintenance including pharmacovigilance activities
- more arbitration and other Community referrals
- extension of performance indicators to maintenance and supervision activities
- implementation of quality improvements and auditing systems

In addition new activities may arise from European Union legislative initiatives that will also have a significant impact on the workload:

- establishment of working relationship with the national authorities of central and eastern European countries in the framework of CADREAC agreement
- handling of parallel distribution notifications
- integration of the EMEA in the Joint Action on new synthetic drugs together with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol networks as requested by Council of Ministers[4]
- proposal for a European Parliament and Council regulation on orphan medicinal products[5]
- proposal for a European Parliament and Council directive relating to the implementation of good clinical practice[6]

(4) OJ L 167, 25.6.1997, p. 1

(5) COM(1998) 450 final, OJ C 276, 4.9.1998, p. 7

(6) COM(1997) 369 final, OJ C 306, 8.10.1997, p. 9

CPMP meeting dates for 1999 and 2000 are given below. Deadlines for the submission of applications to the EMEA have been identified in order to avoid any delay in their validation and evaluation. In addition, CPMP meetings at which rapporteurs and co-rapporteurs will be appointed have also been fixed.

1999			2000		
CPMP meeting	**Rapporteurs appointed**	**Submission deadline**	**CPMP meeting**	**Rapporteurs appointed**	**Submission deadline**
26-28 January	Yes	12 January	18-20 January	Yes	4 January
23-25 February	No	9 February	15-17 February	No	1 February
23-24 March	Yes	9 March	14-16 March	Yes	29 February
20-22 April	No	6 April	25-27 April	No	11 April
18-20 May	Yes	30 April	30 May - 1 June	Yes	16 May
22-24 June	No	8 June	27-29 June	No	13 June
27-29 July	Yes	13 July	25-27 July	Yes	11 July
24-26 August	No	10 August	22-24 August	No	8 August
21-23 September	Yes	7 September	19-21 September	Yes	5 September
19-21 October	No	5 October	17-19 October	No	3 October
16-18 November	Yes	29 October	14-16 November	Yes	31 October
14-16 December	No	30 November	12-14 December	No	28 November

4.2 General work objectives

The first six general work objectives are related to activities for which fees or administrative charges are payable and which have to be performed within binding timeframes. The monitoring of and adherence to these timeframes was the first performance indicator introduced at the EMEA. Work objectives 7 and 8 address European Community activities not covered by fees.

Initial evaluation applications and initial inspections (basic fee and inspection fee)	Expected to increase by 10 per cent, levelling off after 2000 with fewer multiple applications. In addition: · improvements to patient and healthcare professionals - increased participation in internal product information quality initiatives and the Quality review of documents working group · checking of mock-ups and specimens to be improved
Type I and II variations, extensions, transfers and follow-up inspections (variation fee, etc)	These will increase steadily in 1999-2000 in line with the number of centrally authorised medicinal products. The first renewals are expected in 2000.
Post-authorisation maintenance and pharmacovigilance (annual fee)	Workload is expected to increase by 30 per cent per year as more centrally authorised products reach and remain on the market. The special and innovative character or many centrally authorised products requires close monitoring, especially when used in life-threatening conditions. Resulting in: · increase in reporting of EU and non-EU adverse drug reactions · increase in number of periodic safety update reports and more frequent safety reporting · improvements in tools for handling pharmacovigilancecrisis situations
Scientific advice (corresponding fees)	Increase in both initial and follow-up scientific advice of 10 per cent per year is expected, depending on the impact of the introduction of a fee. Companies may also involve the EMEA at a much earlier stage of their research and development programmes.
Arbitration and Community referrals (corresponding fees)	The number of arbitration and other referral procedures arising cannot be predicted with certainty. The number of referral opinions forecast for 1999 includes 11 referral procedures initiated in 1998, with a larger number expected in 2000.
Special services (corresponding administrative charges)	· handling of parallel distribution notifications · support for the preparation of certificates for medicinal products · preparation of documents for the EMEA subscription service · validations with a negative outcome
General harmonisation activities (EU general contribution)	The main general harmonisation activities – which benefit both the centralised and mutual recognition procedures – are developed through the CPMP working parties and ad hoc working groups in the form of guidelines. This work will increase in 1999-2000 and other workload increases include contributions to the following internal initiatives: · improve the management and quality of the centralised procedure · surveys of applicant companies and marketing authorisation holders · dialogue with wider spectrum of interested parties
Specific activities at request of EU institutions and Member States (EU general contribution or special budget to be determined)	The pronounced increase in mutual recognition procedures in 1998 requires strong support from the Unit to facilitate the smooth running of the Mutual Recognition Facilitation Group (MRFG) and this continues as a key objective. Workload arising from other specific activities includes: · participation of Iceland and Norway in the EMEA, and support to central and eastern European countries · continued active participation in and support to the International Conference on Harmonisation (ICH) · support to evaluation of herbal medicinal products, in particular to prevent routine arbitrations in the mutual recognition procedure · EU legislative initiatives give EMEA responsibilities in the field of risk assessment of new synthetic drugs and also will give new responsibilities in areas including orphan medicines and good clinical practice inspections

4.3 Sector for regulatory affairs and pharmacovigilance

Head of Sector: Pharm. Noël Wathion

The main responsibilities of the sector are the provision of support in relation to the development, evaluation and surveillance of medicinal products for human use submitted through the centralised procedure and in relation to referrals and other safety issues, which have been raised for nationally authorised medicinal products.

Such support includes technical, regulatory and administrative input to the CPMP, its working parties and other sectors in the Unit. In addition, regulatory and scientific guidance is provided to industry and interested parties. The sector also acts as coordinator for the EU pharmacovigilance system. Furthermore, support is provided in relation to harmonisation activities, for example the EMEA Working Party on Herbal Medicinal Products.

Key goals of the sector

CPMP meetings

- To continue to provide a high standard of technical and organisational support to CPMP meetings in its new 3-day plenary meeting structure
- To investigate the development of new means of communication, i.e. electronic links between CPMP members, the European Commission and the EMEA, in order to reduce the paper flow, using the experience to be gained by the Commission services in 1999

Regulatory affairs

- To continue to provide legal, regulatory and procedural guidance to all involved parties with a view of contributing to cross-EMEA compliance with measures relating to the protection and promotion of public health
- To coordinate the handling of parallel distribution notifications within a timeframe of 30 days
- To coordinate the collaboration with central and eastern European countries (CEECs) in the framework of recognition by CEECs of centrally authorised medicinal products and the variation and renewal of such marketing authorisations

Scientific advice

- To improve the provision of high quality scientific advice in collaboration with the CPMP within reasonable timeframes, to ensure consistency in the provision of such advice and to provide high quality guidance to industry
- To reorganise the procedure for the provision of scientific advice by the CPMP, and to further develop the network of specialised experts in order to guarantee the availability and input of best expertise in the different scientific fields
- To investigate the impact of scientific advice provided on subsequent evaluation of the application submitted through the centralised procedure

Pharmacovigilance activities

- To optimise the management and monitoring of an increasing amount of safety information relating to centrally authorised medicinal products (adverse drug reaction reports, periodic safety update reports) through a continued close collaboration with CPMP and Member States
- To further streamline the management of referrals dealing with safety concerns for non-centrally authorised products and to achieve 100 per cent compliance with regulatory deadlines for the completion of such referral procedures
- To continue the development of an EU database of adverse drug reactions (EudraWatch) and to subsequently optimise data management and administration and to provide technical information to marketing authorisation holders in order to assist in the development of appropriate electronic links and software

4.4 Sector for biotechnology and biologicals

Head of Sector: Dr John Purves

The sector is in charge of providing support to the CPMP and its working parties for the evaluation of medicinal products derived from biotechnology or those that contain an active substance of biological origin. Innovative and rapidly evolving new types of medicinal products like borderline products combined with medical devices, gene transfer, cell therapy products as well as the comparability of biotechnology derived proteins are new scientific challenges for the coming years.

Procedures for coordinating the evaluation of medicinal products containing genetically modified organisms will be further developed and streamlined. In addition to the Biotechnology Working Party (BWP), the sector has responsibility for a number of ad hoc working groups. These include the ad hoc working group on blood products (BPWG), the working party on influenza vaccines and a number of specialised working groups (e.g. on transmissible spongiform encephalopathies (TSE), including Creuztfeld-Jacob's Disease (CJD), on quality of plasma derived medicinal products, on gene transfer products).

Key goals of the sector

- To achieve 100 per cent compliance with regulatory deadlines for completion of marketing authorisation applications and post-authorisation activities for products falling under part A of the annex to Council Regulation (EEC) No 2309/93 and to optimise management of applications and the scientific/technical output (EPAR)
- To promote better information to the public on the state of art in the area of biotechnology and biological medicinal products
- To closely monitor and contribute to the development of additional methodologies, for assessing and preventing emerging public health hazards and minimise identified risks (e.g. TSE/CJD, nuclear amplification technique testing methodologies)
- To identify new areas of specific expertise needed and arrange expert working sessions accordingly and support the CPMP/BWP scientific advice, reinforcing relationships with specialist working groups and European learned societies. Such areas include TSE/CJD, comparability of biotechnology derived products, medicinal products for the replacement of coagulation factors, new vaccines, gene transfer and cell therapy

4.5 Sector for new chemical substances

Head of Sector: Dr Patrick Le Courtois

The sector is responsible for the support to the CPMP for the evaluation of new chemical and innovative medicinal products. These products cover a larger number of therapeutic areas, as well as new medical fields and also new types of combinations with medical devices.

The sector has responsibility for the Efficacy Working Party (EWP), the Safety Working Party (SWP) and, in liaison with the Technical Coordination Unit, for the Joint CPMP/CVMP Quality Working Party. It also coordinates as necessary several clinical or multidisciplinary ad hoc CPMP working parties such as AIDS or oncology. The sector is in charge of the secretarial support to the Mutual Recognition Facilitation Group and to its related activities.

Key goals for the sector

- To continue to achieve 100 per cent compliance with regulatory deadlines for completion of marketing authorisation applications and post-authorisation activities for new chemical substances and innovative products
- To optimise the management of the applications by teams coordinated by therapeutic class
- To coordinate the standardisation and the consistency of CPMP assessment reports and EPARs through the development of quality control activities
- To continuously improve the technical and secretarial support to the Harmonisation activities particularly for the Efficacy Working Party, Safety Working Party and Quality Working Party and for the ICH related activities. To support the increased production of guidance documents their dissemination and related transparency activities
- To continuously improve the support to the MRFG and its anticipated expanded activities

5. Key objectives for medicines for veterinary use

	1997	1998	1999 (estimate)	2000 (estimate)
Workload				
New centralised applications	2	14	14	15
Extensions to centralised applications	2	7	4	5
Arbitrations and other Community referrals	--	--	7	8
Type I variations	5	7	10	15
Type II variations	--	--	2	4
Transfer of marketing authorisation	--	--	3	4
Scientific advice	3	3	3	3
New MRL applications	6	4	5	6
Modification/extension of new MRLs	13	10	16	18
Opinions on establishment of old MRLs	60	114	81	15
CVMP and VICH guidelines adopted	8	6	12	12
Meeting days	67	59	65	71
Resources				
Head of Unit and secretariat	4	4	4	4
Sector for CVMP and veterinary procedures	5	6	7	8
Sector for safety of veterinary medicines	5	6	7	7
Total staff	15	16	18	19

5.1 Workload and goals of the Unit

Head of Unit: Dr Peter Jones

The period 1999-2000 will see a period of consolidation and growth in the Unit. Given the significant increase in the number of centralised applications over those forecasted in 1998, a prediction of 14 new applications now appears to be justified in 1999. The majority of these can be expected to be companion animal products or biologicals, both of which fall outside the scope of Council Regulation (EEC) No 2377/90 since the number of applications to establish maximum residue limits (MRLs) for new substances appears to remain fairly static at 5. It is also anticipated that work on the establishment of MRLs for all remaining old substances will be completed before the deadline of 1 January 2000, although a number of provisional MRLs of old substances will expire after this date.

Continued effort will be made in advancing two important projects. The first will be the compilation and release of the report by the Committee for Veterinary Medicinal Products (CVMP) ad hoc group on antimicrobial resistance into its risk assessment of whether any resistance in animals emerging after veterinary use of these products is likely to transfer to man. Secondly, the CVMP will maintain its focus on the important issues surrounding the topic of availability of medicines, helping to identify accurately those therapeutic gaps that are occurring, whilst at the same time attempting to find solutions to resolve matters in the short and medium term.

The increase in centralised applications is expected to continue throughout 1999 at a similar pace to that of 1998. This requires an additional post to be considered in 2000 for the Sector for CVMP and veterinary procedures. The likelihood of arbitrations arising from the mutual recognition procedure, pharmacovigilance referrals and other possible new initiatives that arise may require a reallocation of staff resources to be undertaken.

The CVMP working parties have a busy programme ahead with a number of new guidelines either planned for release for consultation or final adoption. The Committee will also continue to hold meetings with interested parties at regular intervals and to capitalise on the success of earlier info days with industry to review and debate topics of current regulatory interest. Much remains to be done in the field of harmonisation with the EU maintaining its commitment to the VICH initiative and to participate in the activities of International Technical Consultation on Veterinary Medicinal Products.

Meeting dates have been set for CVMP plenary for 1999 and 2000 as given below.

CVMP meetings in 1999	CVMP meetings in 2000
12-14 January	11-13 January
16-18 February	8-10 February
16-18 March	7-9 April
13-15 April	18-19 April
11-12 May	16-18 May
15-17 June	20-22 June
13-15 July	18-20 July
(17-19 August)	(16-17 August)
14-16 September	12-14 September
12-14 October	10-12 October
9-11 November	7-9 November
7-9 December	5-7 December

The provision of a meeting in August 1999 is foreseen to progress remaining old MRL opinions if the need arises. Meetings will continue to be held over a 3 day period preceded by a half day period for rapporteur meetings on centralised applications which have been shown to facilitate review and discussion of key issues relating to the assessment process in plenary meetings. As the increase in centralised applications evolves and the pressure increases to complete the outstanding opinions for old MRLs, the CVMP workload can be expected to increase substantially in 1999-2000.

The focus on advising potential applicants of their obligations in the pre-submission phase of an evaluation will continue with the launch of a veterinary pre-submission guidance document. This will contribute significantly to achieving full compliance with regulatory deadlines laid down in Community law, which to date has been complied with.

The Secretariat will continue to provide full administrative and secretarial support to the Veterinary Mutual Recognition Facilitation Group (VMRFG) and seek to find ways of improving its support. The Unit will be prepared for the efficient coordination of any arbitrations which may be submitted to the CVMP during 1999-2000. The CVMP and its working parties will continue to provide scientific counsel on any matter that the VMRFG may refer to it.

5.2 Sector for CVMP and veterinary procedures

Head of Sector: Dr Jill Ashley-Smith

The sector is responsible for all centralised applications considered by the CVMP. It also provides full technical secretariat support to the Committee and its working parties on immunologicals, efficacy, pharmacovigilance and the joint CPMP/CVMP Quality Working Party. As more centrally approved products are authorised it is anticipated that the workload relating to variations, extensions and pharmacovigilance activities will be seen as these products enter onto the market.

Sector goals for 1999-2000

- To continue to achieve 100 per cent compliance with regulatory deadlines, for completion of marketing authorisation applications
- To maximise the proactive dialogue with applicants in the pre-evaluation phase to ensure full efficiency of the centralised procedure and to maximise industry confidence in the system to encourage applications for products considered eligible under Council Regulation (EEC) No 2309/93 (ongoing)
- To have achieved consistency and satisfactory quality standards in scientific assessments and EPARs by collaboration with Rapporteurs and experts (2nd quarter of 1999)
- To have optimised high quality product documentation in all official languages of the European Union (2nd quarter of 1999)
- To continue to achieve 100 per cent compliance with regulatory deadlines for completion of extensions and variations under the centralised system (ongoing)
- To have systems in place to ensure compliance with regulatory targets and deadlines for post-authorisation maintenance activities under the centralised system including the monitoring of compliance for packaging and advertising copy (3rd quarter of 1999)
- To implement the systems in place for the handling of incoming safety information related to medicinal products authorised through the centralised and mutual recognition procedure, in compliance with pharmacovigilance requirements (ongoing)
- To complete the provision of scientific advice of the highest and consistent quality to applicants within 3 months in compliance with the relevant standard operating procedure (ongoing)
- To achieve 100 per cent compliance with regulatory deadlines for processing any arbitrations/referrals to CVMP from mutual recognition procedures (ongoing)
- To support the working parties in drafting guidelines on immunological working products, pharmacovigilance, efficacy requirements and quality issues relating to veterinary medicinal products, as mandated by CVMP which in term will be the basis of EU input into VICH
- To report on performance measures in preparation for the review of the European system in 2001
- To reappraise communication and working relationships with interested parties

Efficacy working party

The Efficacy Working Party will continue its work on reviewing existing guidelines. The guideline for conduct of pharmacokinetic studies is nearly completed. The progress on the guideline on the conduct of bioequivalence studies will continue and the new combined guideline for intramammary products for use in cattle, which replaces three previous guidelines, is likely to be reviewed by mid-1999.

With regard to completely new guidelines, the first draft biostatistical guideline will be developed. Two ectoparasiticide guidelines, one for small and one for large animals will be created. Finally, a guideline for non-steroidal anti-inflammatory drugs will be elaborated, on the basis of preliminary work.

Immunologicals working party

The Immunologicals Working Party is scheduled to meet four times a year and will continue to examine several important issues on behalf of the CVMP including the elaboration of new guidelines as agreed by the Committee. The topics for these guidance notes will include:

- requirements for combined veterinary vaccines
- duration of protection achieved by veterinary vaccines
- efficacy of veterinary vaccines under field conditions
- the need for strain replacement in swine influenza vaccines
- gene therapy in veterinary medicine

The Working Party intends to continue its ongoing review of existing guidelines where technical advances deem this to be necessary, and will again play a key role on the provision of scientific advice, and possibly product specific advice if and when requested. In addition the working party handles other enquiries which may arise in relation to veterinary biologicals. With progress now underway in VICH on the topic of biologicals quality monitoring, the input of the working party on such issues will also be sought.

Pharmacovigilance working party

Cancellation of two meetings of the Pharmacovigilance Working Party as a result of the 1998 contingency plan has resulted in a number of objectives being carried over to 1999. These include a revision of the Guidance note on rapid alert reporting and the release for consultation of a Guidance note on post-marketing surveillance and the final adoption of a Guidance note on reporting of adverse reactions for competent authorities. The Working Party is scheduled to meet 4 times yearly.

The completion of the VEDDRA initiative last year has allowed the provision of all remote information for completion of the final version of EudraWatch. The entry of safety report data into the database will also now be undertaken.

As more centrally authorised products enter the marketplace it can be anticipated that an increasing amount of time will be devoted to reviewing safety reports on such products and other related issues.

5.3 Sector for safety of veterinary medicines

Head of Sector: Dr Kornelia Grein

The main focus of this sector since 1995 was directed at the establishment of MRLs for old and new substances. However, the need to address wider safety issues is growing – particularly in the context of human safety – and it seems appropriate to rename this sector to accommodate certain increased responsibilities. These include risk assessment, antimicrobial resistance and issues relating to safety guidelines in the context of global harmonisation.

In order to meet the 1 January 2000 deadline, the CVMP must have agreed its opinion on all remaining old substances by 31 August 1999 to allow sufficient time for the requisite inter-service consultation process at the Commission and to ensure satisfactory progress through Standing Committee in the remaining timeframe.

The development and publication of a work programme for the completion of MRLs for old substances has greatly facilitated the efforts being directed at this assignment and will continue to do so in 1999-2000. Companies defending substances, and in the process of replying to questions on outstanding issues relating to their substances, have been made aware of the deadlines they must meet to enable the assessment of their substance or substances to be completed within the agreed time frame. However it should be noted that if data is inadequate or is delayed, then no MRL would be established by the deadline.

Good progress is anticipated in the finalisation of opinions for herbal remedies and homeopathic medicines with their evaluation and opinion completed by the end of the second quarter of 1999.

The number of applications for establishing MRLs for new substances remains fairly constant at 5 in 1999. However, the expansion of product use to new species and new indications is illustrated by the significant increase in growth from 10 to 22 in the number of applications to extend and/or modify existing MRLs.

The sector has relied heavily in the past on the support of national experts on secondment for this work. Whilst their contribution has proved invaluable, by definition such an arrangement is a temporary one and the recruitment of a new scientific administrator is foreseen early in 1999 to assist both in the MRL work and in additional assignments in relation to safety issues.

Sector goals for 1999-2000

- To continue to achieve 100 per cent compliance with regulatory deadlines for processing of applications for new MRLs (including extensions and modifications) (ongoing)
- To finalise the assessment for the remaining old substances and those with provisional MRLs, including homeopathic substances and herbal remedies by CVMP and its Safety of Residues Working Party before the legal deadlines, where response to list of questions has been submitted in time (old substances – August 1999)
- To ensure that consistency of all MRL status and summary reports for new applications and old substances is maintained fully according to quality control standards established previously (ongoing)

- To process requests for scientific advice in relation to MRL applications issues within 2-3 months
- To provide full logistical support for the Veterinary Mutual Recognition Facilitation Group (throughout 1999)
- To prepare a paper expanding the risk assessment concept for establishment of MRLs (by 2nd quarter of 1999)
- To conduct a workshop on analytical methods for surveillance of MRLs (3rd quarter of 1999) within the Community
- To provide support for European policies at the request of the European Commission and to contribute proposals for redrafting of Council Regulation (EEC) No 2377/90
- To coordinate and support EU regulatory input on issues relating to safety for European participation at international fora, e.g. Codex Alimentarius Commission and VICH
- To support activity in relation to CVMP initiative on availability of veterinary medicines.
- To further expand risk assessment concept and provide for full revision of volume VI of the *Rules governing medicinal products in the European Union* (see annex 3 for publication details)
- To provide support to the European Commission and Member States regarding the provision of routine analytical methods
- Finalise remaining work on old substances
- To continue the risk analysis programme in respect of antimicrobial resistance

Safety of residues working party

The Safety of Residues Working Party will continue its task of finalising opinions to establish MRLs for old substances. The Working Party will also continue to monitor developments in international fora, e.g. Codex Alimentarius Commission and JECFA. It will also advise the CVMP on how to attain consistency in setting MRLs with the said organisations.

The Working Party will monitor contributions from EU experts to the VICH Expert Working Groups on consumer safety of veterinary medicines and review draft guidelines, as they become available.

Availability of medicines

Continued efforts will be directed at identifying those veterinary medicines and subsequently the accompanying indications, particularly in minor species, that are being lost as a result of the failure to set MRLs for old substances or possibly an inadequate approach to the principles of risk analysis.

The CVMP with the support of the European Commission will continue to work on a strategy to address this problem in consultation with many of the interested parties concerned, keeping in mind at all times the need to guarantee consumer safety. The first phase of such a strategy will be to identify those substances likely to be lost after 1 January 2000 because of inadequacy of data submitted by applicants in support of their products. Where such substances are contained in products for indications and or species for which no other medicinal product will be available after the year 2000, the Committee will examine options for a further assessment of their safety and residue profile. Such an assessment will examine all possible sources of additional data, and in consultation with CVMP the option to create a new ad hoc group of experts to undertake the task.

Ad hoc working group on antimicrobial resistance

Another major issue relating to safety of veterinary medicines in the context of safety to man is that of antimicrobial resistance. The CVMP ad hoc working party set up in 1997 to conduct a risk assessment on the extent of such resistance in animals and its potential transfer to man is expected to complete its report by May 1999. This report will assess the incidence in the EU of resistance development in certain classes of antimicrobials in certain zoonotic bacteria and will provide a qualitative risk assessment of the situation as it currently prevails in well-defined classes of antimicrobials. Depending on the outcome of this first report, further quantitative risk assessment may be undertaken.

6. Key objectives for technical coordination

	1997	1998	1999 (estimate)	2000 (estimate)
Workload				
Inspections				
GMP inspections	29	61	60	65
GCP inspections	1	--	4	10
Certificates of a medicinal product	3 364	9 300	5 200	5 500
MRA implementation	--	2	5	6
Document management and publishing				
Subscriptions	159	229	136	121
Requests for documents	1 160	2 122	3 400	3 600
Mail in	36 419	40 897	42 500	45 000
Mail out	36 330	18 083	21 000	25 000
Number of pages translated	5 770	4 071	4 000	5 000
Conference service				
Total meeting days at EMEA	329	324	333	377
Interpretation man/days	422	412	416	420
Information technology				
Minimum system availability	n/a	99 %	98 %	98 %
IT helpdesk requests/user	24	22	20	20
Resources				
Head of Unit and secretariat	4	4	4	4
Sector for inspections	8	8	12	14
Sector for document management and publishing	10	10	12	12
Sector for conference services	8	8	10	10
Sector for information technology	15	16	18	18
Total staff	45	46	56	58

6.1 Workload and goals of the Unit

Head of Unit: Dr Karel de Neef

The Unit provides technical support common to human and veterinary evaluation activities as well as generic services to the EMEA, especially in the areas of conferences, document management & publishing and information technology. This support is provided applying quality principles and predetermined objectives. Responsibility for the coordination of the Agency's quality management programme also lies within the Unit.

In addition to the workload determined by the evolution of the Agency as a whole, the Unit has specific responsibilities:

- The inspections sector acts as the European coordinator for the assurance of equivalent standards in the manufacture and distribution of pharmaceutical products in Europe and third countries where the two parties have signed a mutual recognition agreement.
- The information technology sector provides specific technical support to the implementation of costing systems within the Agency and to the selection and implementation across the EMEA of an appropriate electronic document management system.

The Unit will seek to achieve the following general goals during 1999 and 2000:

- Improve the use of management tools already in place
- Operate the EMEA quality management system in a practical manner including participation in the development and implementation of a internal performance indicator reporting system
- Gradually assume responsibility for developing and maintaining the application tracking system (ATS) which is already serving across various functions within the Agency
- Define, together with all interested parties, a common electronic format for dossiers to be submitted for regulatory approval

6.2 Sector for inspections

Head of Sector: Mr Stephen Fairchild

The sector supports the evaluation of medicinal products within the European Community by coordinating the work of inspectors, expert groups and the implementation of mutual recognition agreements with third countries, harmonising inspection procedures and pharmaceutical quality as well as monitoring products that have been authorised within the Community.

Coordination of the work of good manufacturing practice (GMP) inspectors is expected to increase in 1999-2000. Good clinical practice (GCP) inspection activity will commence.

Mutual recognition agreements (MRAs)

The coordination of the implementation of the mutual recognition agreements with Australia, Canada, Japan, New Zealand and the USA represents a major new undertaking by the EMEA at the specific request of the Commission. In 2000, the scope of work on MRAs will increase due to the implementation of the agreement with Switzerland. The transitional phase for the Canadian MRA will be completed and the evaluation phase of the agreement with the USA will begin.

Inspection procedures

An EU programme to ensure the introduction of standardised GMP inspection procedures in support of MRAs and new Community legislation will begin. The initiation of GCP inspections will further stimulate the standardisation of GCP inspection procedures and documentation as well as operating practices.

Internal procedures

Existing systems and procedures will be further consolidated and expanded. This work will include the use of the EMEA application tracking system for the production of certificates of a medicinal product and the extension of other databases containing information about manufacturers, clinical trial sites and GCP and GMP inspections.

Pharmaceutical quality and product monitoring

The sector operates a crisis management system for quality problems and defects in centrally authorised medicinal products. Routine monitoring of centrally authorised products will be initiated in collaboration with the European Pharmacopoeia and its European Directorate for the Quality of Medicines and the network of Official Medicines Control Laboratories. The arrangements within the Community for monitoring distribution of medicinal products and detecting counterfeits will be reviewed and proposals made for better communication between interested parties as well as standardisation of procedures.

Cooperation with the European Pharmacopoeia/European Directorate for the Quality of Medicines and the network of Official Medicines Control Laboratories (OMCL)

Harmonisation of pharmacopoeial standards, in particular

- international harmonisation between the European, US and Japanese pharmacopoeias in the context of ICH, e.g. general methods, dissolution tests, sterility tests and pyrogens
- preparation of new European monographs at the request of the Joint CPMP/CVMP Quality Working Party, e.g. in particular relating to multi-sourcing for generics of medicinal products coming out patent protection
- revision of existing European Pharmacopoeia monographs at the request of the EMEA, e.g. in the domains of biotechnology, herbal medicines, veterinary immunological products, etc
- promotion of the mutual recognition of c. 400 national pharmacopoeial monographs

OMCL network: continuation of the pilot phase in close cooperation with CPMP and CVMP

- support to the centralised European authorisation system, especially through development and practical implementation of annual surveillance programmes
- extension of OMCL network: initially to Iceland and Norway; to central and eastern European countries within the context of CADREAC cooperation agreement; and to Australia and New Zealand
- development of future joint programmes for quality assurance, proficiency studies, joint auditing, etc

6.3 Sector for document management and publishing

Head of Sector: Ms Beatrice Fayl

The sector manages operations supporting the EMEA's functioning in the areas of document management and publishing.

The sector's routine tasks comprise controlling product information quality, translations and the coherence of regulatory documents, document management including control of publication, cataloguing and electronic storage, the furnishing of relevant documentation in response to requests from third parties, running the library, archiving and mailroom services.

Quality of information

During 1999, Quality review of document working group functions will be undertaken primarily by means of electronic working methods and the resulting reduction in meetings to one every two months will be formalised. This has been made possible in part by the successful standardisation work undertaken during 1998. The possibility of consulting with consumer and patient groups to improve the quality of product information is to be initiated during 1999.

Document management

Now that the business-driven folder structure and specific file naming convention for ease of access are in place, the principal new task of the sector will be the introduction of a fully computerised document management and workflow system. Electronic document management systems in place in other institutions of the European Union will be assessed and the Agency's

approach defined and implemented in 2000. Transparent access to EMEA documents will continue to be the guiding principle behind cataloguing and electronic storage by the Agency. The sector will also implement off-site archiving.

Library services will be improved in two ways. A new electronic catalogue will enable the location of information not only more rapidly, but also more accurately. The library will also become more proactive by alerting staff when articles and other works are published on topics known to be within their areas of interest.

Document dissemination

During 1999 and 2000 the Agency's requirement to provide information to third parties, especially in response to ad hoc requests, is expected to increase. The majority of this information is provided electronically and in order to speed up response times from the enquirer's perspective, the EMEA plans to make its website more interactive.

6.4 Sector for conference services

Head of Sector: Dr Sylvie Bénéfice

The sector supports meetings at the EMEA by assisting delegates, providing the best possible facilities and services and constantly improving the resources available.

Routine tasks comprise the organisation of meetings, including making travel arrangements and the reimbursement of delegates, as well as the provision of centralised copying services to the EMEA as a whole.

The sector is expecting further increases in the volume of transactions. A call for tender to select a provider or providers of travel agency services, to be based at the EMEA, is underway to better meet the requirements of both the delegates and EMEA staff.

New facilities

A computerised meeting management system will be set up to facilitate and optimise the whole meetings process. The meeting organisation process, reimbursement of delegates and financial reporting of conference activity will also be streamlined.

The extension of the EMEA to an additional floor of its current building will allow for additional meeting facilities. A review of the entire technical equipment set-up including audiovisual system and video conferencing facilities is underway to ensure that the technical and logistical requirements of the (enlarged) European Union are taken into account. This may also result in improvements to the technical facilities in the existing meeting rooms.

6.5 Sector for information technology

Head of Sector: Mr Michael Zouridakis

The sector's mission is to provide reliable and robust information technology (IT) services to EMEA staff and delegates together with appropriate levels of operational support while introducing new services and improvements to the infrastructure.

The routine activities of the sector are the maintenance of the systems and the provision of support to users. The minimum system availability target aims at ensuring that the complete range of IT services is available at least 98 per cent of the time that the EMEA is open for business. As regards new features, efforts are being made to balance requests of users with available resources. During 1999 the sector's human resource profile will be adjusted and strengthened.

Consolidation

Work will continue on the addition of new features to SI2 (an EU-specific budgetary accounting package) as well as the fine-tuning of ActiTrak (an activity tracking system). Technical work on cabling, the EMEA's Intranet and antivirus software will be carried out. Participation in European communication projects will be maintained aimed at improving functionality of pharmaceutical-related projects, e.g. EudraNet, EudraWatch, EudraTrack and EudraMat.

IT services will be made available to the new floor of the existing building that will be taken over by the EMEA.

New features

Remote access to the Agency's network and IT facilities via secure telecommunications links will be made available for use by the Agency's regulatory partners and others. This project was deferred from 1998 as a result of the contingency plan implementation during the second half of that year.

Assistance will be provided to the document management and publishing sector in the selection and implementation of a fully computerised document management system. Conference services will be assisted in the design and implementation of the computerised meetings system as well as the analysis and implementation of desktop electronic terminals and communication packages in conference rooms. This last project aims to enable delegates to carry out their work without the need to resort to paper copies of documents during meetings.

Development activities relating to ATS will be gradually transferred to the sector from the European Commission Joint Research Centre.

The sector will design, build, test and install a centralised database of experts that will be accessible throughout the Agency and will also be capable of being updated remotely by Member States national competent authorities when required.

A trial installation of a desktop video conferencing package will be set up and tested. New software packages for accounting and personnel functions will be put in place following testing.

Annexes

1. EMEA establishment plan 1997-2000
2. EMEA budget summaries 1998-2000
3. EMEA reference documents
4. Profiles of EMEA personalities

1. EMEA establishment plan 1997-2000

Category and Grade	Occupied as per 31.12.97	Authorised for 1998	Authorised for 1999	Requested for 2000
A1	--	--	--	--
A2	1	1	1	1
A3	4	4	4	4
A4	--	18	25	29
A5	26	19	23	23
A6	--	25	25	25
A7	37	23	23	23
A8	2	--	--	--
TOTAL A	**70**	**90**	**101**	**105**
B1	1	2	3	3
B2	--	8	8	8
B3	9	12	8	8
B4	--	9	6	6
B5	11	5	5	5
TOTAL B	**21**	**36**	**30**	**30**
C1	6	5	10	13
C2	--	12	14	14
C3	7	37	43	43
C4	--	--	--	--
C5	27	--	--	--
TOTAL C	**40**	**54**	**67**	**70**
D1	--	--	1	1
D2	--	4	4	4
D3	4	--	--	--
D4	--	--	--	--
TOTAL D	**4**	**4**	**5**	**5**
TOTAL POSTS	**135**	**184**	**203**	**210**

2. EMEA budget summaries 1998-2000

The summarised comparative budget statements for 1998 to 2000 are as follows: (amounts expressed in euro)

	1998 (3.12.1997)		1999 (2.12.1998)		2000 (10.2.1999)	
Expenditure						
Staff						
salaries	12 743 000	*39.95%*	16 987 000	*41.08%*	17 903 000	*35.55%*
interim and other support persons	620 000	*1.94%*	1 180 000	*2.85%*	1 007 000	*2.00%*
other staff-related expenditure	1 010 000	*3.17%*	978 000	*2.37%*	1 118 000	*2.22%*
total title 1	*14 373 000*	*45.06%*	*19 145 000*	*46.30%*	*20 028 000*	*39.77%*
Building/equipment						
rent/charges	2 080 000	*6.52%*	2 574 000	*6.22%*	4 600 000	*9.13%*
expenditure on data processing	954 000	*2.99%*	893 000	*2.16%*	1 239 000	*2.46%*
other capital expenditure	165 000	*0.52%*	745 000	*1.80%*	516 000	*1.02%*
postage and communications	410 000	*1.29%*	417 000	*1.01%*	505 000	*1.00%*
other administrative expenditure	922 000	*2.89%*	1 276 000	*3.09%*	1 443 500	*2.87%*
total title 2	*4 531 000*	*14.20%*	*5 905 000*	*14.28%*	*8 303 500*	*16.49%*
Operational expenditure						
meetings	2 487 000	*7.80%*	2 715 000	*6.57%*	3 505 000	*6.96%*
evaluations	9 800 000	*30.72%*	13 000 000	*31.44%*	17 432 500	*34.62%*
translation	584 000	*1.83%*	350 000	*0.85%*	700 000	*1.39%*
studies and consultants	105 000	*0.33%*	175 000	*0.42%*	310 000	*0.62%*
publications	20 000	*0.06%*	60 000	*0.15%*	80 000	*0.16%*
total title 3	*12 996 000*	*40.74%*	*16 300 000*	*39.42%*	*22 027 500*	*43.74%*
TOTAL EXPENDITURE	**31 900 000**	***100.00%***	**41 350 000**	***100.00%***	**50 359 000**	***100.00%***
Revenue						
fees	17 030 000	*53.39%*	27 150 000	*65.66%*	34 765 000	*69.03%*
EU contribution	14 000 000	*43.89%*	13 000 000	*31.44%*	14 000 000	*27.80%*
other	870 000	*2.72%*	1 200 000	*2.90%*	1 594 000	*3.17%*
TOTAL REVENUE	**31 900 000**	***100.00%***	**41 350 000**	***100.00%***	**50 359 000**	***100.00%***

3. EMEA reference documents

a) EU official publications

- Council Regulation (EEC) No 2309/93 as amended (OJ L 214, 24.8.1993, p. 1)
- Council Regulation (EEC) No 2377/90 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)
- Council Regulation (EC) No 2743/98 (OJ L 345, 19.12.1998, p. 3)
- EMEA budget statement for the financial year 1998 (OJ L 57, 26.2.1998, 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*. These publications, along with copies of the Official Journal, are available from:

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

The texts are also available on the EudraLex Internet site at *http://dg3.eudra.org/eudralex/index.htm*

b) EMEA documents

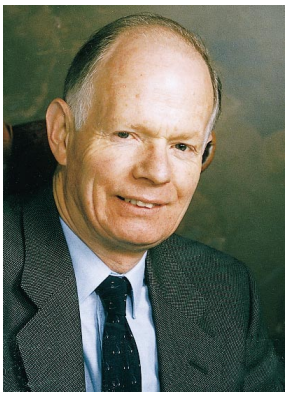
- First General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1995 (ISBN 92-827-7491-0, Office for Official Publications of the EU)
- Second General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1996 (ISBN 92-9155-002-7, Office for Official Publications of the EU)
- Third General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1997 (ISBN 92-9155-010-8, Office for Official Publications of the EU)
- Fourth General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1998 (ISBN 92-9155-018-3, Office for Official Publications of the EU)
- Work programme for the European Agency for the Evaluation of Medicinal Products 1997-1998 (ISBN 92-9155-006-X, Office for Official Publications of the EU)
- Work programme for the European Agency for the Evaluation of Medicinal Products 1998-1999 (ISBN 92-9155-014-0, Office for Official Publications of the EU)
- Statement of principles governing the partnership between the national competent authorities and the EMEA (EMEA/MB/013/97)
- Financial regulation applicable to the budget of the EMEA (EMEA/MB/011/97)
- Decision of the Executive Director of 3 December 1997 on rules on access to documents of the EMEA

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

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

4. Profiles of EMEA personalities

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 UK Family Fund Trust; and Visiting Fellow of the London School of Economics.

Romano Marabelli, Vice-Chairman of the Management Board, b. 3 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. He was elected chairman of the UN Food and Agricultural Organisation's European Commission for the Control of Foot-and-Mouth Disease in 1997. 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 the Pharmaceuticals Unit, 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, Japan and US. Appointed the first Executive Director of the EMEA 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 Department for the Evaluation of Medicinal Products at 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. 3 May 1955, n. Irish

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

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

Education: Qualified 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. 9 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. 6 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, budget and facilities, b. 11 November 1958, n. Irish

Education: BSc in public administration and 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. 4 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 of drug toxicology including risk assessment and risk/benefit evaluation. He is a former chairman of the CPMP Safety Working Party. He joined the EMEA in April 1995.

Noël Wathion, Head of Sector, Regulatory affairs and pharmacovigilance, b. 11 September 1956, n. Belgian

Education: Qualified Pharmacist from the Free University of Brussels.
Career to date: Mr Wathion first worked as pharmacist in a retail pharmacy. He was later appointed to the Pharmaceutical Inspectorate (Ministry of Social Affairs and Public Health) in Brussels as a Chief Inspector, acting as the Secretary of the Belgian Medicines Commission. He is a former Belgian Member of the CPMP (Committee for Proprietary Medicinal Products) and CVMP (Committee for Veterinary Medicinal Products). He joined the EMEA in August 1996.

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

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

Patrick Le Courtois, Head of Sector, New chemical substances, b. 9 August 1950, n. French

Education: Qualified medical doctor from the University of Paris. PhD in public health from the University of Bordeaux. Post-graduate degrees in tropical medicine, clinical research and epidemiology.
Career to date: From 1977 to 1986, Dr Le Courtois worked as a general practitioner and as director of a medical centre in Paris. In 1986 he joined the University of Bordeaux and was involved in research areas in public health including epidemiology, clinical research, pharmacovigilance, tropical and infectious diseases, health economy and education. In 1990, he joined the Directorate of Pharmacy at the French Ministry of Health and in 1993 the French Medicines Agency as CPMP rapporteur, Head of Unit of European Procedures and from January 1995 as a French CPMP member. He joined the EMEA in September 1997 and was appointed Head of Sector for new chemical substances in June 1998.

Isabelle Moulon, Deputy Head of Sector, Regulatory affairs and pharmacovigilance, b. 9 March 1958, n. French

Education: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology. Post-graduate studies in statistics, methodology and nutrition.
Career to date: Worked as a clinical endocrinologist in a French hospital until 1987 and then joined the Directorate of Pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the EMEA in July 1995.

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

Education: Degree in medicine and surgery from the University of Rome. Specialist in internal medicine. Diploma in reumatology, clinical endocrinology and clinical electrocardiography.
Career to date: From 1978 to 1983 Dr Papaluca worked in the Third Internal Medicine Department of the University of Rome in charge of research projects in the area of Clinical Immunology and cellular immunology. From 1984 to 1994 she was medical officer of the Pharmaceutical Department of the Italian Ministry of Health. She was an Italian member of the former Committee for Proprietary Medicinal Products. She was rapporteur for an ICH efficacy topic and a member of the International CIOMS Working Groups I and II on pharmacovigilance. She joined the EMEA in October 1994.

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

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

Peter G.H. Jones, Head of Unit, Evaluation of Medicines for Veterinary Use, b. 9 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 Unit for the Evaluation of Medicines for Veterinary Use 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 veterinary medicines, b. 24 July 1952, n. German

Education: Qualified chemist and pharmacist from the Free University of Berlin. PhD in organic chemistry from the Free University of Berlin.
Career to date: From 1976 to 1987, Dr Grein held positions in Germany as scientific assistant at the Free University of Berlin and as pharmacist. In 1987 she joined the German Environmental Agency as scientific administrator. Seconded to the European Commission in 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 Coordination, b. 21 December 1946, n. Dutch

Education: Qualified medical doctor from the Medical School at Leiden University, the Netherlands. PhD in developmental cardiology at Leiden University. 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 in international quality assurance before joining the EMEA in August 1995.

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

Education: Languages and linguistics at the University of East Anglia and post-graduate degree in librarianship and information science at University of Wales.
Career to date: Various positions as a documentalist in several European countries, the latest from 1988 to 1995 setting up and running the documentation service in the European Commission Delegation in Norway. Ms Fayl joined the EMEA in April 1995.

Sylvie Bénéfice, Head of Sector, Conference services, b. 28 December 1954, n. French

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

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

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

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

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

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