



The European Agency for the Evaluation of Medicinal Products

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WORK PROGRAMME

FOR THE

EUROPEAN AGENCY FOR THE EVALUATION

OF MEDICINAL PRODUCTS

IN 1997 - 1998

Adopted by the Management Board on 5 February 1997

Work Programme for the European Agency for the Evaluation of Medicinal Products 1997 - 1998

Setting out coherent work programmes for the two first years of the Agency's operations proved a daunting task given the uncertainties about the workload and the way in which the different procedures would evolve. Regular consultations were held with national competent authorities, the scientific committees of the EMEA and the Commission, and rolling programmes were reviewed every six months by the Management Board.

The experience gained served as a starting point for this first public formal work programme for 1997 and 1998. The programme for the next two years is guided by precise objectives and action priorities, and will inspire future EMEA's activities in accordance with the budget approved for 1997 and the preliminary budget for 1998.

In less than two years, and with considerable support from many European experts, the European drug registration system, comprising a number of national agencies, the EMEA and the European Commission, has become a success. The EMEA and in particular its main committees (CPMP/CVMP) have gained a world-wide reputation for the speed and quality of their scientific evaluations. These efforts must be continued and consolidated.

Beyond its legal obligations and its necessary focus on the evaluation and follow-up of central applications, the EMEA must also be ready to cope with a possible increase in the number of referrals under the mutual recognition system. During this period, the Agency may also have to face new challenges in relation to the quality, safety and efficacy of medicinal products for human or veterinary use in the European Union and must help achieve international harmonisation of testing requirements.

Thanks to a more stable management structure, each Unit and each Sector of the EMEA has been able to participate actively in the definition of this work plan before its submission to the Management Board for adoption. Besides the more specific goals to be achieved by each Unit and Sector, the Agency will aim at reinforcing the partnership with national agencies and the Commission, adhering to its new performance indicators, increasing the transparency of its operations and optimising its human and financial resources with the introduction of a quality management system.

Fernand Sauer
Executive Director

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Work Programme for the European Agency for the Evaluation of Medicinal Products 1997 - 1998

1. Introduction and priority tasks for the EMEA

This work programme for 1997 and 1998, presented by the Executive Director in accordance with Article 55(3) of Council Regulation (EEC) No 2309/93, was adopted by the Management Board on 5 February 1997.

Previous activities of the European Agency for the Evaluation of Medicinal Products (EMEA) are described in the 1995 and 1996 Annual Reports (see Reference Documents, p.37).

1.1 EMEA objectives

Council Regulation (EEC) No 2309/93 sets out the main objectives for the EMEA as follows:

to protect public health by mobilising the best scientific resources existing within the European Union (see Articles 49 and 51(a))

to promote health care through the effective regulation of new pharmaceuticals and better information for users and health professionals (see Article 51(i))

to facilitate the free circulation of pharmaceuticals within the European single market (see Article 51, first paragraph)

to support the European pharmaceutical research and development industry by developing efficient, effective and responsive operating procedures (see Article 51, first paragraph)

to support efforts in international co-operation (see Articles 51(f))

1.2 EMEA overall priorities

The Management Board has determined the following overall priorities for 1997-1998:

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

A number of these (priorities 1 to 7) are explicitly mentioned in legislation, of which the first four represent legal obligations and responsibilities for the EMEA with regard to applicants and marketing authorisation holders.

During 1997 the EMEA will seek to improve support for the mutual recognition of national authorisations in addition to which the accompanying harmonisation work may have to be increased (priority 8). This support might be particularly important in 1998 when the mutual recognition procedure becomes systematic for the majority of conventional medicinal products. However, the level of support required will be re-assessed at the beginning of 1998 in the light of experience gained.

Priority number 9 remains difficult principally because of the limited available resources and has been the subject of a number of discussions at Management Board. The European Commission and European Parliament representatives have made it clear that the EMEA should be prepared to actively support other European policies as and when requested. For example, the EMEA is committed to supporting so-called orphan drugs and their veterinary counterparts and Agency's role is expected to increase after the adoption of a Council Regulation on an EU orphan drugs policy. Furthermore, at the request of the European Commission, the EMEA will organise three ad hoc meetings in 1997 to examine the necessity to review existing monographs on herbal remedies.

1.3 *Adjusting the internal structure of the EMEA*

The overall structure of the EMEA, particularly its Scientific Committees and their working parties, was completed during the first year of operations (see organigram, p.36). The structure of the EMEA Secretariat became more stable by the end of 1996 and it is anticipated that it will remain largely unchanged during 1997 and 1998.

The Executive Director, Fernand Sauer, is assisted by a small team made up of two Legal Administrators, a personal assistant and two secretaries covering the general management and functioning of the EMEA, legal affairs, external relations and also liaison with the Management Board.

The EMEA now has four operational Units, each of which has developed several Sectors:

Unit for the Evaluation of Medicinal Products for Human Use	Rolf Bass
Sector for Biotechnology and biologicals	John Purves
Sector for New chemical substances	Josep Torrent Farnell
Sector for Regulatory affairs and pharmacovigilance	Noël Wathion
Unit for the Evaluation of Medicinal Products for Veterinary Use	Peter Jones
Sector for CVMP and veterinary procedures	<i>post vacant</i>
Sector for Maximum residue limits and pharmacovigilance	Kornelia Grein
Technical Co-ordination Unit	Karel de Neef
Sector for Inspections	Stephen Fairchild
Sector for Document management and publishing	Beatrice Fayl
Sector for Conference services	<i>post vacant</i>
Sector for Information technology	<i>post vacant</i>
Administration Unit	Marino Riva
Sector for Personnel and support services	Frances Nuttall
Sector for Accounting	Gerard O'Malley

Now that most key line management positions have been filled, mechanisms for internal co-ordination will be systematically improved during 1997; these include monthly meetings of Heads of Unit and Sector, and weekly meetings of Heads of Unit.

A task force may have to be created in 1997 to respond to urgent matters arising from an increased use of the mutual recognition procedure. If necessary, a dedicated Sector would have to be created in 1998 to deal with arbitrations.

The Secretariat of the Management Board is provided by staff from the Directorate. The Management Board is expected to continue to meet four times a year during 1997 and 1998:

1997 : 5 February, 4 June, 1 October and 3 December

1998 : 19 February, 3 June, 30 September and 2 December

The Financial Controller of the Agency, Birgit Snoeren, reports directly to the Management Board and counsels the Executive Director. During 1997 and 1998 the Financial Controller, together with the assistant financial controller, will focus on the consolidation of financial procedures and structures. Regular periodic production of control results will help to serve as a measure of achieved quality in financial management.

1.4 Specific tasks for the EMEA

Consolidating the achievements of 1996 will be crucial over the next two years. In addition to continuing the spirit of partnership between the national competent authorities and the EMEA, a sound financial basis for future EMEA operations must be found.

During 1997 the EMEA will also concern itself with focusing on its own technical role within the framework of international activities conducted under the auspices of the European Commission. This includes the ICH and the new VICH initiatives, and also the closer association of Iceland and Norway to the work of the EMEA.

The individual priorities of each Unit are set out in the following chapters. Nevertheless there are three main goals for the EMEA Secretariat:

a. Consolidating partnership with national competent authorities and Commission

The adoption in December 1996 of the Statement of principles governing the partnership between national competent authorities and the EMEA was a means of reinforcing the existing substantial partnership.

The putting at the Agency's disposal of European experts by national authorities will continue to be an essential contribution to the work of the EMEA; there were about 2 000 European experts on the EMEA lists at the beginning of 1997. It will be important to update these lists in 1997 and 1998 to ensure that a full range of expertise is available to the EMEA.

In addition, starting in March 1997, the standard contract (annex II of the Statement of principles) will be implemented between national authorities and the EMEA. This will clarify the responsibilities and position of parties involved in the evaluation of medicinal products.

Consultation has and will continue to take place with the European Commission on the stream-lining of the decision-taking procedure. In particular the transmission of opinions must take place efficiently to allow Commission Decisions to be taken in all languages as quickly as possible.

b. Respect of performance indicators

Following adoption of performance indicators by the Board, these will be implemented in 1997 and 1998.

During 1997, the Agency will focus on its standards of service, efficiency and costs and improving the quality of its output. Tables showing the Agency's activities will be regularly published, together with European Public Assessment Reports detailing the scientific review carried out by the EMEA. A questionnaire jointly developed with EFPIA will be implemented to assess performance of the Agency in individual procedures.

Review panels will be set up comprising representatives of the Scientific Committees and interested parties to ensure that the performance of the EMEA in the centralised procedure meets the standards set by the Management Board.

Streamlining of EMEA activities will continue in particular through the progressive introduction in 1997 of the Application Tracking System (ATS) and the work of the ad hoc Working Group on the Quality Review of Documents.

The CPMP, CVMP and the Mutual Recognition Facilitation Groups will be consulted on the possible extension in 1998 of performance indicators to their activities.

The increasing international context of the pharmaceutical sector will inevitably result in the performance of the EMEA and the European registration systems in general being compared to that of the US Food and Drug Administration and the new Japanese Drug Agency. Work on international benchmarking will be explored in 1997 for possible implementation in 1998.

c. Increasing transparency

The making public of the European Public Assessment Report (EPAR) is already well established and has become a main attraction of the EMEA Internet homepage, which also gives a range of additional information.

The policy of holding public 'info-days' with the principal partners of the EMEA will be refined and dialogue with pharmaceutical companies will be continued, both with meetings at the EMEA or meetings at the London satellite offices of the European trade associations.

Along with the higher profile of the Agency has come an increased demand for information from the press and other sources, and a new communications policy will be explored in 1997.

Following contact with the European Ombudsman, the release of a larger number of EMEA documents will be explored, where such action would not raise questions of confidentiality. During 1997 the distribution of EPARs and other key EMEA documents will be re-examined to enhance their availability, including increased active distribution through the creation of a subscription service for all documents and better use of dissemination points. This should also aid in receiving feed-back from users.

2. Key objectives for medicinal products for human use 1997-1998

2.1 Workload and goals of the Unit

The structure of the Unit for the Evaluation of Medicinal Products for Human Use, introduced in September 1996, comprises three operational sectors:

- Biotechnology ('Part A') and biologicals
- New chemical substances and other 'Part B' products
- Regulatory affairs & pharmacovigilance

Depending on the development of the workload in the Unit, re-structuring may have to be addressed in 1997 and 1998. In particular this will depend on the development of the mutual recognition procedure and the need for a task force in 1997 to deal with arbitrations and the necessity of creating a dedicated Sector for arbitrations.

	1995	1996	1997 (estimate)	1998 (estimate)
Workload				
Centralised applications	16	24	24	25
Variations	1	24	100	125
Pre-submission regulatory advice	10	25	35	45
Scientific advice	16	20	20	20
ICH-derived CPMP guidelines adopted	7	9	15	5
Other CPMP guidelines adopted	7	19	16	15
Non-EU AD reports	0	652	1200	2300
Referrals	-	4	14	20
Meeting days	62	141	210	256
Resources				
- Head of Unit & secretariat	21	5	5	5
- Centralised procedures : Part A		13	17	19
- Centralised procedures : Part B		13	23	27
- Regulatory affairs & pharmacovigilance		17	20	24
Total human resources		48	65	75

Improving support to the CPMP and its working parties

Support to CPMP activities will increase in 1997 and 1998, including

handling the large number of parallel break-out meetings and (Co-)Rapporteur meetings during CPMP plenary week

creating the necessary templates for opinions, follow-up measures, obligations, variations, extensions, renewals

revise consistency of texts within and across products, for EPARs, SPCs, package leaflets and labelling, and between language versions

development of standard operating procedures (SOPs)

2.2 Committee for Proprietary Medicinal Products

CPMP Meetings

It is expected that meetings of the CPMP will continue to be held on a monthly basis in 1997 and 1998. Whereas regular meetings are expected to occupy one week per month, exceptional meetings (e.g. for pharmacovigilance) may have to be foreseen and would last 1-2 days each. It is foreseen that the organisation of meetings will be reviewed in order to optimise the presence of Committee members and experts.

Meeting dates of the CPMP have been fixed for 1997 and 1998 to allow for planning for both the EMEA and to guide applicants for optimisation of time of submission of applications:

<u>CPMP meetings in 1997</u>		<u>CPMP meetings in 1998</u>	
January	20, 21, 22 / 23	January	26, 27, 28 / 29
February	17, 18, 19 / 20	February	23, 24, 25 / 26
March	17, 18, 19 / 20	March	23, 24, 25 / 26
April	14, 15, 16 / 17	April	20, 21, 22 / 23
May	12, 13, 14 / 15	May	25, 26, 27 / 28
June	16, 17, 18 / 19	June	22, 23, 24 / 25
July	21, 22, 23 / 24	July	20, 21, 22 / 23
August	<i>to be determined</i>	August	17, 18, 19 / 20
September	22, 23, 24 / 25	September	14, 15, 16 / 17
October	20, 21, 22 / 23	October	19, 20, 21 / 22
November	17, 18, 19 / 20	November	16, 17, 18 / 19
December	15, 16, 17 / 18	December	14, 15, 16 / 17

	1995	1996	1997 (estimate)	1998 (estimate)
Number of meeting days				
CPMP Meetings	62	48	50	55
Break-out Meetings		7	35	45
(Co-)Rapporteur Meetings		22	40	50
Working Party Meetings		59	70	80
Ad-Hoc Working Party Meetings		5	15	26
Total	62	141	210	256

CPMP Working Parties

It is foreseen that the permanent CPMP Working Parties (QWP, SWP, EWP) will meet 4 times a year in 1997-1998, which should allow on-going work especially on the development of guidelines needed for mutual recognition and other work to be accomplished. The Biotechnology Working Party (BWP) will meet 8 or 9 times a year, in order to allow it to support the preparation of opinions for the CPMP regarding biotechnology products. The Pharmacovigilance Working Party (PhVWP) is expected to meet up to 12 times in 1998. Ad-hoc groups will be formed for short-term tasks as needed at numbers and frequencies exceeding those introduced now considerably.

In 1997 the workload for guidelines derived from ICH will represent one third of guidelines and approximately one half of the actual workload. While this will reduce in 1998, updating ICH-derived and purely European CPMP guidelines will remain a considerable task. The programmes for the Working Parties will continue to be updated twice a year for adoption by the CPMP.

The Biotech Working Party as an expert body will remain involved in scientific advice and co-reviewing certain parts of the Quality section of 'Part A' centralised applications. Together with the Safety Working Party it is expected to continue with the development of guidance for viral safety issues, DNA vaccines and gene therapy.

The Pharmacovigilance Working Party, partially in parallel with the Secretariat and the Commission Services, will address issues for handling pharmacovigilance for centralised products. It will also be involved in the further development and introduction of the Crisis Management, evaluation of adverse drug reaction (ADR) reports (EudraWatch).

2.3 Centralised applications for marketing authorisations

In the two Sectors handling centralised applications project managers are grouped in teams. They are responsible for following applications from pre-submission to post-opinion. Initially a senior scientific administrator with a team of junior scientific administrators was able to deal with 7 major projects. Efficiency gains should allow this number to rise to 10 for 1997 and perhaps up to 15 in 1998. A prerequisite for this steep increase will be the implementation of the necessary support systems: the Application Tracking System (ATS) and document management system. These estimates relate to work on new centralised applications, fulfilment of specific obligations and other follow-up measures.

During 1997, the electronic Application Tracking System, as developed by ETOMEP and made available for the first time for core centralised applications. Procedural steps for any post-marketing situations will have to be incorporated into the software (follow-up measures/specific obligations, variations, extensions, pharmacovigilance). This is expected for the second half of 1997 and will facilitate such activities in 1998.

The Unit will continue to support the completion of reviews of centralised applications within the 210 days limit for all applications. Systematic recourse to pre-submission meetings should minimise potential problems and speed-up the review process.

The introduction in 1997 of contractual arrangements between national competent agencies and the EMEA will promote a standardised approach to the preparation of rapporteurs' and co-rapporteurs' assessment reports. An audit trail for the creation and release of EPARs will be implemented in 1997.

In 1997 the preparation of opinions in all 11 languages will have to be streamlined. The Secretariat will have to assure a high standard of translations and the development of acceptable and understandable package leaflets. The impact from the development of EMEA opinion templates is expected to be felt in the second half of 1997, permitting project teams to manage a larger number of projects. The timing of additional language versions of scientific opinions and annexes will have to be checked with the Commission.

2.4 Maintenance, variations and pharmacovigilance activities

Applications for variations to marketing authorisations granted under the centralised procedure essentially began in the latter half of 1996. A significant growth in the number of variations received is expected as more Community marketing authorisations are granted and products are placed on the market. With the increasing workload it will be necessary to review the processing of variation applications in 1997.

A pharmacovigilance action plan will be finalised in 1997, covering the main aspects of the EMEA's role in pharmacovigilance, such as:

- adverse drug reaction case reports for centralised medicinal products
- periodic safety update reports for centralised medicinal products
- Article 12 procedures (Council Directive 75/319/EEC as amended)
- CPMP Pharmacovigilance Working Party and external communication

Together with the CPMP Pharmacovigilance Working Party and CPMP, a crisis management system will shortly be developed. Public health concerns require the establishment of efficient communication lines with the European Commission and the competent authorities of the Member States. The setting-up of an internal system for the handling of incoming adverse drug reaction case reports will be facilitated by the implementation of the EudraWatch database.

On past experience, approximately 5 major pharmacovigilance referrals are expected per year. In order to prevent delays in future it would be better that class actions concerning more than one substance are avoided.

	1995	1996	1997 (estimate)	1998 (estimate)
Non-EU case reports received/expected by the EMEA				
Serious suspected unexpected adverse drug reactions	--	652	1 200	2 300
Serious suspected unexpected adverse events	--	--	2 400	4 600

2.5 *Arbitration and other Community referral procedures* **(Art. 10 and 11 of Directive 75/319/EEC)**

With the expected growth in use of the mutual recognition procedure in 1997 and 1998, an increase in the number of arbitrations at the EMEA is also foreseen. The limited experience of the mutual recognition procedure does not make it possible to give valid estimates for the number of arbitrations which will arise once the procedure becomes systematic in 1998. The impact of the systematic use of mutual recognition will probably be felt in the second half of 1998.

In addition, the development of Article 11 referrals (harmonisation of existing national authorisations) also remains unclear, with perhaps 4 referrals being initiated in 1997 and 5 in 1998.

Whilst the procedures necessary for the CPMP and the Secretariat to handle referrals are in place, they have so far been handled on an ad hoc basis by personnel from the different Sectors of the Unit. The possible creation of a task force for arbitrations in 1997 and perhaps a dedicated Sector for Arbitration procedures in 1998 could take on this task.

2.6 *Scientific advice to future applicants*

'Scientific advice' should promote dialogue between the EMEA and companies during the course of a research and development programme; sometimes many years prior to submission of an application for a marketing authorisation. It represents an important investment on the part of both the company and the EMEA, and minimises the evaluation time when the application for marketing authorisation is finally submitted.

On the basis of interest already expressed by potential applicants it is expected that the number of requests for such advice will remain steady throughout the period 1997 and 1998.

The procedure does require time and human resources on the part of both the EMEA Secretariat and the members of the CPMP and experts. Consequently it is expected that a fee will be introduced in the forthcoming fee reform.

The CPMP will consider in 1997 how better to organise hearings held with applicant companies and also the expertise required. Where appropriate the EMEA will assure any necessary liaison with the European Commission's biomedical R&D programme and the European network of experts maintained by Directorate-General XII.

2.7 *Information to health care professionals and public*

A system has been put in place to disseminate European Public Assessment Reports (EPARs) (including summary of product characteristics in all languages). For 1997 an upgrading of this dissemination system will be implemented to assure public availability of the EPAR on the day following publication of the positive decision in the Official Journal of the European Communities.

Consultation will be undertaken in 1997 and 1998 with consumers' and patients' organisations to improve the text of the package leaflets and to audit results.

2.8 *Technical support to international harmonisation initiatives (ICH)*

The EMEA has already provided substantial technical support to the European Commission. The strengthening of the links between EU topic leaders, the CPMP Working Parties and the CPMP itself will be assured by the Secretariat. The Unit will continue to provide such support to the Commission and the CPMP Chairman in their role of ICH Steering Committee members with the help of the Technical Secretaries of each CPMP Working Party and the project manager for each therapeutic area.

Nineteen remaining topics are currently being examined by the CPMP Working Parties in preparation for the ICH4 meeting in July 1997 in Brussels. Some ICH guidelines will have to be consolidated with pre-existing CPMP guidelines.

2.9 *Support for mutual recognition of national authorisations, as requested*

Following the creation of the Mutual Recognition Facilitation Group (MRFG), regular meetings of national authorities have provided a forum for the discussion and resolution of many problems at the EMEA. The MRFG has requested assistance from the EMEA Secretariat to support the work of the Group. The Secretariat remains prepared to upgrade this service when requested by national authorities.

A database and tracking system for the decentralised procedure is currently being developed between national agencies and the European Commission. The EMEA is ready to participate as requested, depending on the human and financial resource implications.

3. Key objectives for medicinal products for veterinary use 1997-1998

3.1 Workload and goals of the Unit

The Unit for the Evaluation of Medicinal Products for Veterinary Use comprises two operational sectors:

- CVMP & veterinary procedures
- Maximum residue limits & pharmacovigilance

The staffing of the unit has been judiciously undertaken in line with the workload estimates for 1997-1998. A Head of Sector for CVMP & veterinary procedures will shortly be recruited. The option is available to recruit additional scientific administrators and one administrator (non-scientific) if a considerable increase in applications should be forthcoming.

	1995	1996	1997 (estimate)	1998 (estimate)
Workload				
New centralised applications	2	9	10	10
Variations	--	--	20	27
Establishment of MRLs for new products	3	20	30	40
Establishment of old MRLs	190	52	50	50
CVMP and VICH guidelines adopted	2	4	14	15
Referrals	--	--	2	5
Scientific advice	1	6	6	5
Meeting days	30	54	75	86
Resources				
- Head of Unit & secretariat		4	5	5
- CVMP & veterinary procedures	6	4	5	6
- MRLs & pharmacovigilance		4	6	6
Total human resources	6	12	16	17

Sector for CVMP and veterinary procedures

- Goals for 1997

to continue to achieve 100% compliance with regulatory deadlines for completion of MA applications and variations under the centralised system

to complete the provision of scientific advice to applicants within 3 months

to guarantee quality standards in scientific assessments, product literature and EPARs

to achieve full industry confidence in the centralised system so that companies are encouraged to submit for eligible products through the new system and to build on current relationships with industry to advance their confidence in the work of the agency

to maximise the proactive dialogue with applicants in the pre-evaluation phase to ensure full efficiency of the centralised procedures - once initiated

to monitor decentralised procedures and to provide efficient technical support in those cases referred for arbitration to CVMP

to provide efficient co-ordination and support on behalf of the EU delegation into VICH

to complete drafting of the following guidelines on immunological veterinary medicinal products: Diminution of Animal Experimentation; Potency Testing of Veterinary Vaccines; Use of Adjuvants in Veterinary Vaccines

to ensure quality reporting of CVMP proceedings with release of Press Release within 24 hours of each meeting, and the record of proceedings within one week maximum

- New goals for 1998

to implement fully the recommendations made for the unit following progress made in establishing a Quality Standard Programme in 1997

to deliver fully on all key performance targets agreed for the Veterinary Unit by the Management Board

to foster a culture of openness and transparency in the conduct of veterinary regulatory affairs within EMEA

Sector for MRLs and pharmacovigilance

- Goals for 1997

to complete 75% of validations for new MRL applications within 14 days

to complete the processing of all (100%) applications for new MRLs within the legislative time frame

to complete the assessment of MRL applications for old products for at least 100 substances, of which 50% will result in final opinions recommended to CVMP and the remaining 50% maybe status reports with a list of questions to the applicant

to ensure a full Quality Control system for MRL Summary of Status reports to ensure accuracy and consistency of format and presentation

to draft new pharmacovigilance guidelines on post-marketing surveillance

to finalise guidelines on withdrawal periods in milk, requirements for minor species and selection of marker tissue for MRLs

to progress the re-evaluation of guidelines on injection site residues and to reach consensus within CVMP

- New goals for 1998

to complete 100% of validations for new MRL applications within 15 days

to advance the establishment of MRLs for old substances consistent with time available under the revised deadline

to deliver fully on all key performance targets agreed for the MRL sector by the Management Board

to participate actively in representing EMEA in international fora on subject of drug residue safety, e.g. Codex

to co-ordinate with maximum efficiency the Adverse Drug Reaction scheme for centrally approved products established in the Community

to maintain need for additional safety guidelines in conjunction with VICH initiative and to co-ordinate further progress through SRWP

3.2 *Committee for Veterinary Medicinal Products*

Meeting dates for the CVMP have been fixed for 1997 and 1998 to allow for planning for both the EMEA and applicants for optimisation of time of submission of applications:

<u>CVMP meetings in 1997</u>		<u>CVMP meetings in 1998</u>	
January	14 - 15 - 16	January	13 - 14 - 15
February	11 - 12 - 13	February	10 - 11 - 12
March	11 - 12 - 13	March	10 - 11 - 12
April	8 - 9 - 10	April	7 - 8 - 9
May	6 - 7	May	5 - 6 - 7
June	10 - 11 - 12	June	9 - 10 - 11
July	15 - 16 - 17	July	7 - 8 - 9
September	9 - 10 - 11	September	8 - 9 - 10
October	14 - 15 - 16	October	13 - 14 - 15
November	11 - 12 - 13	November	10 - 11 - 12
December	9 - 10 - 11	December	8 - 9 - 10

New applications under the centralised system and scientific advice

Prediction for new applications in 1997-98 is difficult because there still appears a reluctance on industry's part to submit applications through the centralised procedure. In addition, the small size of the industry tends to limit the number of new entities discovered and developed through to submission, and the number of innovative products that emerge from basic research.

Whilst industry is co-operating to forecast the workload for 1997, their figures are not yet available, so currently the Secretariat can only estimate that approximately 10 applications will be forthcoming in 1997 and that this figure is likely to be similar in 1998.

Of the nine applications received in 1996 it is expected that eight of these will be the subject of CVMP opinions in 1997, all of which should be processed within the 210 day limit laid down in Council Regulation (EEC) No 2309/93.

The number of applications for scientific advice is expected to also remain constant in 1997 and 1998. An average of 5 months was required in 1996 for the opinions given and it is intended to reduce this to provide scientific advice within 3 months to applicants. The recently adopted standard operating procedure (SOP) on scientific advice will be implemented in 1997.

With 8 opinions on centralised applications anticipated in 1997, the number of variations to Community marketing authorisations is expected to increase significantly to 20. Applications for variations will be processed within the legislative time frame. The number of variations processed in 1998 is expected to increase to 27.

3.3 *Applications for establishment of maximum residue limits (MRLs)*

MRLs for old substances

The European Commission is undertaking the necessary steps to extend the present deadline of 1 January 1997 under Council Regulation (EEC) No 2377/90 by which all the MRLs for old substances have to be established.

The Secretariat has considered in detail, ways of advancing the assessment and review time, recognising that rapporteurs have left the most difficult substances until last and many of these substances have dossiers of poor quality, necessitating additional data to be requested from the applicants. Provision of such data on these old substances takes considerable time and, once received, requires further review time by the Safety of Residues Working Party (SRWP).

The number of meetings of the SRWP will remain the same in 1997 but the duration of the meetings will be extended from 2 to 3 days. This extension of the meeting times acknowledges additional workload in the months to come, when responses to questions sent to applicants on Annex III substances, - provisional MRLs, are submitted to the SRWP, necessitating further review. Delegates to the SRWP are now being asked to commit actual review plans for each substance assigned to them and will be expected to work within this time frame. The Secretariat is also re-allocating substances from those rapporteurs who are overburdened with too many dossiers to those with fewer applications to review.

Notwithstanding all the steps being taken as outlined above, this task is unlikely to be completed unless the deadline to establish MRLs for these old substances is extended.

Very recently however it has become apparent that a number of applications for groups of substances comprising herbal remedies and homeopathics have been acknowledged by the European Commission. Many of these are likely to be candidates for Annex II of Council Regulation (EEC) No 2377/90, but there remains approximately 100 additional substances yet to be evaluated which will necessitate additional work by the CVMP and its Safety of Residues Working Party.

MRLs for new substances

Many of the additional applications for so-called new substances, which led to a doubling of the applications forecast at the beginning of 1996, were for existing substances which had not been defended prior to the deadline for these submissions set by the Commission originally, and subsequently revised by EMEA.

Companies are now deciding to defend these substances under the procedure laid down in Article 6 of Council Regulation (EEC) No 2377/90 for new substances and for which a fee is levied. Whilst these

applications are dealt with directly by the CVMP and not the SRWP, the same experts who are members of the SRWP are called upon to conduct the assessment, so these applications place additional burdens on these same experts assigned to the old substances.

Notwithstanding the above, it is expected that applications for new molecules will increase in 1997 so the total number of new applications is placed at 30, contingent on the industry survey currently underway and expected to be completed early in 1997. Extensions/modifications are expected to number 20. In 1998 these applications are expected to rise by a similar margin resulting in 40 applications for MRLs for new substances and 29 for extensions/modifications.

3.4 CVMP Working Parties and guidelines

Pharmacovigilance

The Pharmacovigilance Working Party, having successfully completed all its objectives in 1996, is now embarking on defining a veterinary dictionary of defined terms (Veterinary Dictionary for Drug Regulatory Authorities - VEDDRA) in anticipation of the full EudraWatch programme being implemented in 1997. This is being co-ordinated by an ad hoc group of experts under the chairmanship of Professor G. Keck from the University of Lyon.

The Working Party will also work in 1997 to develop guidelines on post marketing surveillance and the Secretariat will draft standard operating procedures for internal administration of pharmacovigilance within the Veterinary Unit. In 1998, as the number of authorisations via the centralised procedure increases, pharmacovigilance reporting is also expected to advance for these substances so that the Working Party will meet more frequently than has previously been the case, with six meetings predicted.

Immunological Veterinary Medicinal Products

The Immunological Veterinary Medicines Working Party will meet four times in 1997 and will continue the ongoing development of guidelines on:

- potency testing of biologicals
- reduction in the number of animals - safety testing
- use of adjuvants in veterinary biologicals
- production and quality control of veterinary medicinal products derived by recombinant DNA technology.
- revision of guidelines on duration of protection and vaccination schemes.

As the number of centralised applications in the Veterinary sector favours IVMPs, the role of this working party increases in importance in the provision of scientific advice. As greater technological advances are made in the biotechnology field, additional guidelines on critical topics will be required. The working party is expected to meet 6 times in 1998. Ad-hoc groups may also be convened to address specialist topics.

Safety of Residues

The Safety of Residues Working Party will continue to progress MRLs for old substances and will complete the guidelines on standardisation of withdrawal periods in milk in early 1997, as well as revising those requirements for MRLs for substances for use in minor species and redefining the target tissues for which MRLs should be established generally. The CVMP will continue its efforts to revise its position on injection site residues, taking account of recent progress made on the subject at Codex Alimentarius and will address the subject of reporting publicly how the concept of risk assessment is dealt with in the process of establishing MRLs in the European Union.

Once the new Council Regulation addressing proposed changes on establishment of MRLs and the extension of the deadline is published, the Veterinary Unit Secretariat will provide input for the process of redrafting the Notice to Applicants in Volume VI of Rules Governing Medicinal Products in the European Community.

International Harmonisation

At the January 1997 meeting of the CVMP, consideration will be given to whether further guidelines on safety and efficiency should be drafted or any revision to existing guidelines on these topics, taking account of technical advances.

1997 will signal the start of significant progress being made on the International Conference for the Harmonisation of Technical Requirements for the Registration of Medicinal Products for Veterinary Use (VICH) initiative following the first VICH Steering Committee Meeting held in Paris in April 1996 at which priority topics for 1997 and 1998 were agreed upon.

In preparation for the series of expert working group meetings scheduled to begin in early 1997, the CVMP will adopt position papers on the following topics:-

ICH Quality Guidelines related to stability, analytical validation and impurities: EU expert - Dr J-L Robert, Luxembourg

ICH Safety Guidelines related to genotoxicity - EU expert Dr Derek Renshaw, UK

ICH Safety Guidelines on reproduction toxicity - EU expert Dr Susan Barlow, UK

Good Clinical Practice: EU expert Dr Satu Pyörälü, Finland

Environmental Risk Assessment - EU expert Dr Carol Aldridge, UK

Efficiency Requirements for Anthelmintics Efficacy - EU Expert Prof. Jozef Vercruysse, Belgium

Later in 1997 the CVMP will consider position papers on pharmacovigilance, target animal safety and testing methods for veterinary biologicals.

3.5 Decentralised procedures (mutual recognition)

Contrary to the forecast of expected referrals for arbitration for the mutual recognition procedure in 1996, none were actually received, although the number of decentralised procedures increased dramatically in 1996.

Mindful of the need to progress these procedures efficiently and within the prescribed time frame within Member States, the CVMP at its October 1996 meeting endorsed the establishment of a Veterinary Mutual Recognition Facilitation Group by the Member States. The group will meet on an ad hoc basis scheduled around the CVMP meetings and will be chaired by a member coming from the Member State holding the Presidency of the Council of Ministers. Administrative support will be provided by the Secretariat of the Veterinary Medicines Evaluation Unit.

With the disappearance of multiple national authorisations after 31 December 1997, a significant increase in decentralised procedures is anticipated in 1998, with an accompanying increase in number of arbitrations. The limited experience of the mutual recognition procedure does not make it possible to give valid estimates for the number of arbitrations which will arise once the procedure becomes systematic in 1998.

4. Key objectives for technical co-ordination 1997-1998

4.1 Workload and goals of the Unit

The Technical Co-ordination Unit comprises four operational sectors:

- Sector for Inspections
- Sector for Document management & publishing
- Sector for Conference services
- Sector for Information technology

The Heads of sector posts for Conference services and Information technology are expected to be filled in 1997. Other posts are also expected to be filled following recent recruitment competition procedures held in 1996.

	1995	1996	1997 (estimate)	1998 (estimate)
Workload				
Inspections (requests)	14	19	35	50
Export certificates	--	1 700	5 000	7 000
Mail in	7 350	26 000	40 000	50 000
Mail out	--	8 500	12 000	18 000
Meeting days	180	270	300	360
Interpretation days ¹	400	427	474	500
Resources				
- Head of Unit and secretariat	--	2	3	3
- Inspections	1	4	8	10
- Document management & publishing	4	6	10	13
- Conference services	6	5	6	6
- Information technology ²	4	5	13	16
Total human resources	15	22	40	48

¹ The number of person-days of interpretation needed for active spoken languages.

² Not including additional external support personnel and ETOMEPA team support

For 1997 the focus will be on:

- maintaining and improving production activities specific to each of the four sectors
- implementation of a robust industry-standard IT platform supporting all relevant EMEA functions
- contributing to the development of formal work processes and document management, computer assisted wherever possible

An overall goal will be the active contribution to the successful implementation of a Quality Management System which will enable the EMEA as a whole to qualify and quantify itself against objective standards of performance.

A business model for the EMEA is to be developed using information from the financial package (SI2), time management package (ActiTrak) and the application tracking system (ATS) (all three currently still under development) to provide insight into the costs of individual activities of the Agency. This model will also allow for budget and cost projections to be more easily prepared.

In 1998 the focus will shift from basic support to active implementation of workflow and document management systems. Dependent on the full implementation of the ATS, the focus in 1998 will be on:

- maintaining production activities of each of the four sectors, with emphasis on personal performance indicators based on continuous training and improvement
- implementing a workflow and document management system
- realising a harmonised system for performance and evaluation of inspections in the EEA

4.2 Inspections

Inspection activities are expected to further increase in 1997-1998 in relation to the new applications for Human and Veterinary medicines.

Acceptance of a common approach to Good Manufacturing Practice (GMP) inspections is important. Preparatory work will begin in 1997, with initiatives for implementation to be proposed in 1998. Continued and intensified interaction with the relevant working parties will in particular be important; the Joint CPMP/CVMP Quality Working Party, the ad hoc EEA Inspectors Group and the relevant groups for Good Clinical Practice and Good Laboratory Practice activities.

For the management of inspections, a computerised system will be specified and installed, either as part of ATS or as a stand-alone function.

The production of export certificates is also expected to increase in parallel with the increasing number of medicinal products that have been authorised via the centralised procedure. Provided that demand continues to increase, a reliable production process will be put in place during the first half 1997 to produce a pre-defined number of certificates within a time limit of 5 days.

4.3 Document management & publishing

The increasing activity of this sector, now focusing more on publishing, will also be reflected by the ever increasing volume of documents to handle, both by mail, fax and e-mail.

A document dissemination service will be brought into operation in early 1997. Since there will be a parallel offering of documents in electronic and paper format, it is expected that the majority of the retrievals will relate to electronic documents, especially when the electronic subscription service will provide automatic distribution of relevant material.

The specification of a fully-integrated document management facility, covering the full document life cycle, has the highest priority in order to provide support and relief to staff involved with management of many large and complex documents.

The application should cover the best support work processes and also document archiving in order to allow for cost effective access to any document at any time. Document transfer to key EMEA partners like the Commission, national authorities and the Luxembourg Translation Centre would also need to be included.

It is expected that the basic technological choices will have been made and dedicated prototypes successfully completed by the end of 1997.

4.4 Conference services

For 1997 a total of 161 meetings is expected over some 300 meeting days. Also up to 474 days of interpretation are expected to be needed. In 1998, this is expected to rise to approximately 200 meetings with a total of 360 meeting days requiring up to 500 days of interpretation. This number of days of interpretation is calculated on the basis of number of man-days required to provide interpretation from spoken languages into the interpreted languages. The usual language regime for most meetings permits 6 passive and 2 active languages.

Further improvement to the services provided to the delegates will be the most important priority for this sector. This will take the form of better technical support in the offices as well as further improvement to audio-visual facilities during conferences, including the use of video conferencing as well as personal assistance during the stay at the EMEA.

On the business side, negotiations to obtain the best possible service from both hotels and travel organisations will have a high priority as these costs form a large share of EMEA's budget.

An effective meeting management system, including all reimbursement aspects, will be developed. This system will have to be integrated with general EMEA information systems, especially the financial package and electronic payment system.

With the successful introduction of assistance from hostesses in 1996, flexibility is available to manage both very large conferences and smaller conferences equally well and with a relatively small number of staff. It is foreseen that a Head of Sector will be appointed in early 1997.

4.5 Information technology

During 1996 the use of existing information technology systems was consolidated and optimised for best possible operation. During the year it gradually became clear that the set up might not be able to cope with increasing staff and data volumes. Compatibility with both external as well as internal software under development might be difficult to maintain.

In order to obtain an objective view a study was commissioned and external experts were invited to review the current set up and provide advice for future development. As a result of the study, it has been decided to implement an industry-standard hardware architecture for the EMEA.

This is especially challenging as none of the key EMEA processes, such as support to the scientific committees or presentation of opinions to the Commission, can be interrupted. Detailed planning will ensure a correct installation followed by extensive training of staff in order to optimise the effects of the change for day-to-day work.

As mentioned above, development of EMEA-specific software applications is necessary and initial analysis has shown that, depending on requirements and available resources, it will take between 2 - 3 years to make these available. Although the policy is to buy industrial standard software where possible, the unique position of the EMEA requires specific development in several areas such as tracking of applications, finance monitoring, tracking of business processes, etc.

In order to embark on this ambitious set of tasks, it will be critical to during 1997 recruit highly qualified staff with senior level technical and project management skills and experience. Operational technical staff would be recruited thereafter. As both the implementation of a new IT architecture plus the development of several EMEA specific applications must be carried out over the next three years, the IT human resources over this period will be relatively high and may temporarily reach high levels. However, careful balancing of the hiring of internal staff against obtaining external support will be the key to delivering a smooth working organisation during this time.

5. Key objectives for administrative support 1997-1998

5.1 Administration Unit

	1995	1996	1997 (estimate)	1998 (estimate)
Administration Unit staffing				
- Personnel & support services	8	13	15	15
- Accounting	3	4	5	5
Total Administration Unit staffing	12	19	21	21

The Administration Unit carries out important administrative and financial functions ensuring that the Secretariat and its staff are able to perform their statutory tasks under satisfactory conditions. The Unit has two Sectors:

Sector for Personnel & support services

Sector for Accounting

5.2 Personnel and support services

In conjunction with a number of other new European Agencies, the EMEA participated in 1996 in a call for tenders for the delivery of a dedicated computerised budget and financial control package. However, the response from commercial suppliers was disappointing and expensive and did not meet the Agency's needs in complying with the financial regulations.

The Agency worked in conjunction with the European Commission on the development of a Budget and Accounting system. The system, which is designed to meet general and specific needs of each Agency should be fully implemented in the latter half of 1997. This system will provide a clear overview and understanding of the EMEA's financial operations and the different stages involved in the processing of these operations.

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

The Secretariat staff is primarily responsible for providing logistical support to the Management Board, Scientific Committees and their Working Parties. The Agency has no permanent officials and staff recruited through competitions are offered contracts of five years in accordance with the rules and practices of the EU institutions. Once selected by an independent jury, candidates are placed on a reserve list from which they may be recruited for a post.

External recruitment procedures will be undertaken to recruit staff in line with the Agencies needs. Internal competitions will be conducted to integrate the Agency's secretarial and clerical staff within the Regulation and Rules applicable to officials and other servants of the European Communities. A training programme has been developed to cover introductory training, training on the history and main policy of the European Union, management training, and relevant professional training courses.

The sector seeks to reduce costs and to attain increased efficiency through greater co-operation with the Commission and other EU Agencies in such areas as staff pensions, sickness benefit and the provision of other different services.

As the Agency has grown in size, the social and cultural role of the Staff Committee has become increasingly important.

5.3 Accounting

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

Notwithstanding the expected further growth of the Agency increases in the volume of transactions will be met as far as is possible from the allocated staffing. An electronic banking payment and consultation system will be installed in 1997 which is expected to facilitate the work of the sector. It aims to execute approved payments within a maximum of five days within the UK and within 10 days for other Member States.

5.4 Budgetary perspectives

The 1997 budget, as last amended by Management Board, totals ECU 28.2 million, made up of a subsidy of ECU 14 million from the EU general budget, expected fee revenue of ECU 14 million and ECU 200 000 from bank interest. The European Commission will bring forward a proposal in 1997 for a new Council Fee Regulation. Uncertainties over the level and structure of fees makes financial planning for 1998 difficult. Estimates for 1998 are also made uncertain because of questions relating to the real impact of arbitration once the decentralised system becomes systematic

Budgetary perspectives for 1997

The budget total for 1997 is less than the amount initially requested by the Management Board. As a result, planned expenditure has been cut in several parts of the budget. These cuts will in particular again lead to recruitment being delayed in 1997.

It is clear, given the budgetary constraints on the EU budget and the subsidy, that the EMEA will continue to rely heavily in 1997 and 1998 on the resources placed at its disposal by national competent authorities, in particular those for which no compensation is given. For 1997 this has been estimated at 5 full-time equivalent people per national competent authority in the human medicines sector, and 2.75 full-time equivalent people per authority in the veterinary medicines sector.

To assist in future financial planning the Executive Director will explore in 1997, in liaison with the European Court of Auditors and relevant services of the European Commission, the creation of pluri-annual reserves in the budget.

Budgetary perspectives for 1998

The preliminary draft budget for 1998 adopted by the Management Board on 5 February 1997 totals ECU 33.9 million, comprising a requested subsidy from the EU budget unchanged from 1997, i.e. ECU 14 million, and fees from industry amounting to ECU 19.6 million, representing a 40 percent increase on fee revenue compared to 1997.

The 1998 draft budget for 1998 proposes total staff-related expenditure (title 1) of approximately ECU 15 million. An increase in 1998 of ECU 326 000 is proposed for title 2 expenditure relating to building, equipment and other costs, totalling ECU 4.727 million. Operational expenditure for 1998 amounts to ECU 14.19 million, an increase of ECU 3.18 million over 1997, mainly because of the rise in number of meetings expected in 1998 and increase in the evaluation services provided by rapporteurs and co-rapporteurs.

The level of fee revenue in 1998 is based on the assumption that the modifications to current fee levels will be adopted by the Council of Ministers, in consultation with the European Parliament, before the end of 1997.

If the fee reform is not completed in time, additional revenue will have to be sought by the Commission by a temporary increase in fees through the Regulatory Committee procedure provided for under Article 10(2) of Council Regulation (EC) No 297/95, pending the entry into force of the new Fees Regulation.

5.5 Evolution of staff

At the end of 1996, a total of 100 EMEA staff members were in place, in addition to 3 national experts on secondment to the Agency (from France, Italy and Finland) and 10 external interim staff. A delay in recruitment of between 8 and 10 months, recurrent since 1995, meant that a large number of staff will still have to be recruited in 1997.

The continuous flow of new applications and the maintenance of associated post-authorisation work (pharmacovigilance, variations, etc.) will require adequate human resources to meet the legal obligations of the EMEA.

Category and grade	Posts authorised for 1995	Posts authorised for 1996	Posts authorised for 1997	Posts authorised for 1998
Human resources (authorised temporary posts) 1995-1998				
- A2	1	1	1	1
- A3	4	4	4	4
- A4 and A5	16	22	33	37
- A6, A7 and A8	29	25	40	48
Total A	50	52	78	90
Total B	12	20	31	37
Total C	5	31	47	54
Total D	--	4	4	4
Total posts authorised	67	107	160	185

The age break-down of EMEA staff reveals that about 25% of staff are below the age of 30 years and that 70% are less than 40 years old. Training is therefore important to compensate for the relative lack of experience.

Whilst EMEA personnel may be relatively inexperienced, they are well qualified and half of staff have received a university education. There are 14 pharmacists, 10 with medical degrees, 5 have degrees in veterinary medicine and 7 have other scientific backgrounds (chemistry, biochemistry, pharmacology). In addition there are 6 lawyers, 4 management or finance graduates and 6 staff members with other University degrees (IT, documentation, linguistics).

5.6 *Optimising EMEA resources*

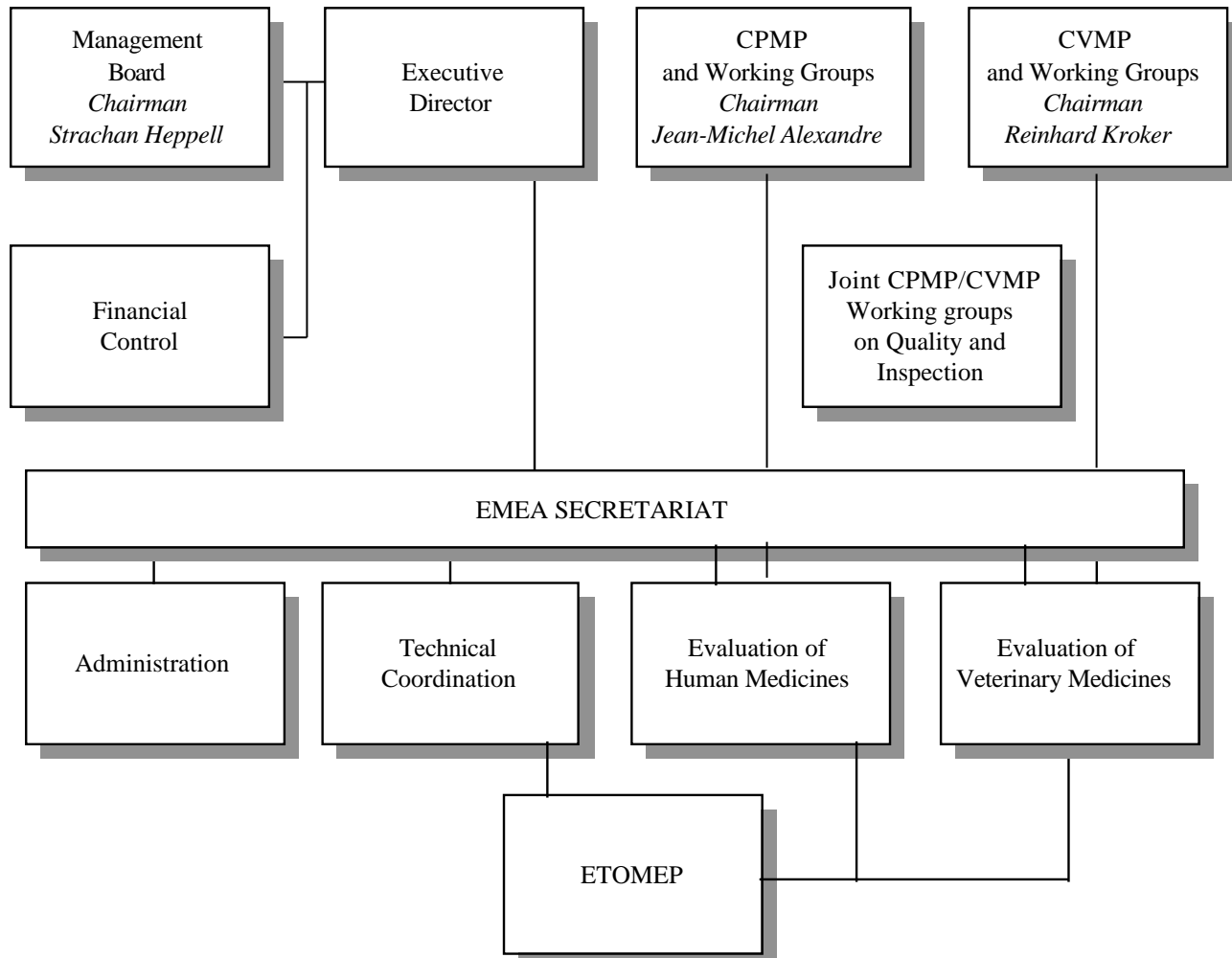
Constraints on the EU general budget mean that the EMEA will be increasingly required to rely on fees for its income. The extension of the European registration system to the whole of European Economic Area (Iceland and Norway) and general depreciation since 1995, place additional demands on the resources of the Agency. Securing an adequate funding basis for the future is therefore a major priority for 1997 and 1998.

Considerable efforts were made in 1996 to investigate the costs of the EMEA Secretariat, rapporteurs and co-rapporteurs, and of the national competent authorities themselves. This costing exercise will continue in 1997 and the results regularly presented to Management Board, with the objective of obtaining a transparent overview of the costs of the EMEA and national authorities.

The exercise permitted a clearer view in preparation of the EMEA contribution to the fee reform proposals. At the Commission's request the EMEA presented its formal contribution to the reform of the current fee system in early 1997, the report seeks to ensure that an appropriate mechanism is in place to provide stable and adequate funding for the EMEA.

At the same time as seeking to optimise EMEA resources - human, scientific and financial - a total quality management system will be progressively put in place to ensure that these resources are properly used. This will start in 1997 with the Units for Evaluation of Human and Veterinary Medicinal Products and be later extended to other operations of the Agency.

Organigram of the European Agency for the Evaluation of Medicinal Products



Reference documents

a) EU Official Publications

Council Regulation (EEC) No 2309/93 of 22 July 1993
(Official Journal No L.214/1 of 24.8.93)

Council Regulation (EEC) No 2377/90 of 26 June 1990 as amended
(Official Journal No L.224/1 of 18.8.90)

Council Directive 75/319/EEC as amended
(Official Journal No L.147/13 of 9.6.75)

Council Directive 81/851/EEC as amended
(Official Journal No L.317/1 of 6.11.81)

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

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

b) EMEA documents

First General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1995 (ISBN 92-827-7491-0)

Second General Report on the Activities of the European Agency for the Evaluation of Medicinal Products 1996 (EMEA/MB/055/96)

Statement of principles governing the partnership between the national competent authorities and the EMEA (EMEA/MB/076/96)

Report on performance goals and indicators for the EMEA (EMEA/MB/062/96)

EMEA contribution to the preparation of a Commission proposal for a definitive Council

Regulation on fees payable to the EMEA (EMEA/MB/057/96)

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

European Agency for the Evaluation of Medicinal Products
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