THE EUROPEAN AGENCY FOR THE EVALUATION OF MEDICINAL PRODUCTS

SIXTH GENERAL REPORT

2000

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Sixth General Report on the Activities of the European Agency for the Evaluation of Medicinal Products

2000

Adopted by the Management Board on 20 December 2000

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**

The 2000 Annual Report is presented to the Management Board by the Executive Director in accordance with Article 55(3) of Council Regulation (EEC) No 2309/93. It is forwarded to the European Parliament, Council, Commission and Member States. It is available on request in all official EU languages.

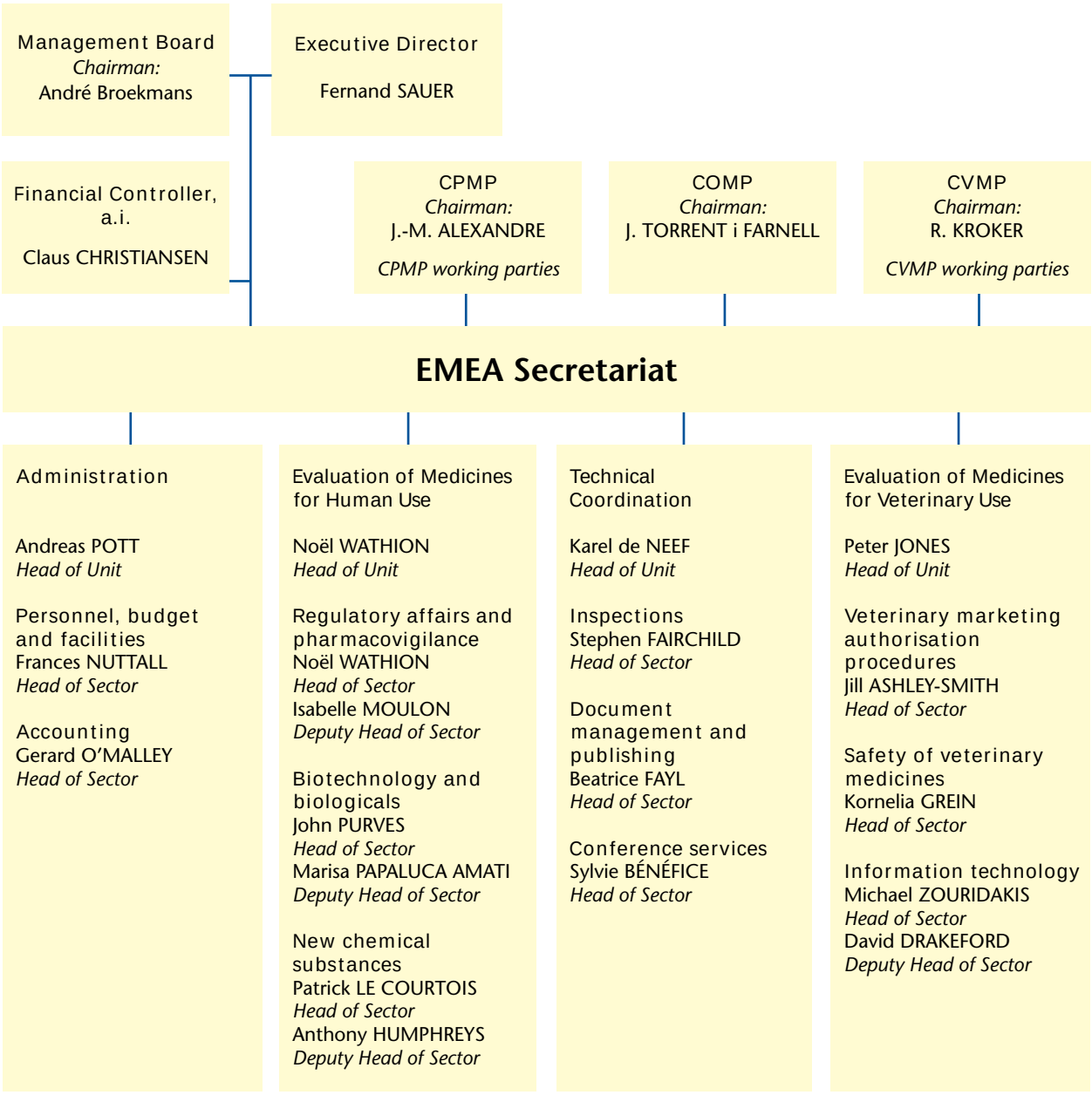
Previous annual reports and other reference documents are available from the EMEA web site at **http://www.emea.eu.int** and further details are set out in Annex 1.

This report covers activities of the EMEA in 2000. Chapter 1 sets out the activities of the Management Board and the Agency's administration. It also covers the Agency's partnership with national competent authorities and European institutions, and other general aspects of the EMEA, including transparency and international activities.

The operational and technical work of the EMEA in 2000 are reported in Chapter 2 on human medicines, Chapter 3 on veterinary medicines and Chapter 4 on technical coordination activities. Administrative and accounting matters are described in Chapter 5.

The Report, in accordance with Article 15c(1) of Council Directive 75/319/EEC, as amended, and Article 23c(1) of Council Directive 81/851/EEC, as amended, also summarises the operation of the decentralised (mutual recognition) procedure during 2000.

Structure of the EMEA



Plans for the restructuring of the EMEA secretariat were discussed during 2000. As announced in the EMEA Work Programme 2000-2001, the Unit for the Evaluation of Medicines for Human Use will be split into 2 operational units. The details of this are given in Chapter 2.

Further details of the restructuring plan will be given in the Work Programme 2001-2002.

Contents

Foreword by the Chairman of the Management Board

André Broekmans

The EMEA with its network of national regulatory authorities is an excellent example how we operate and collaborate within the European Union.

This Annual Report demonstrates this. Although we celebrated the fifth anniversary of the EMEA this year, the European Union has a long tradition of collaboration in the regulatory field. Already in 1975 the first scientific body was created, the 'old CPMP'. Since that time national authorities learned to work together and shared resources and expertise. It was a just a next step that the EMEA was set up and with it the establishment of the centralised procedure. Of course, the legislative framework enabled the EMEA and the national authorities to arrive at this stage but without the commitment of the national authorities the EMEA would not have arrived at this stage.

At its fifth anniversary in January the EMEA received compliments from its stakeholders for its accomplishments. The staff and the executive director, Fernand Sauer, deserved these compliments. The people make the organisation!

The EMEA enters a new era. It faces several new challenges. The outcome of the revision of the current regulatory framework will impact on the tasks and functions of the EMEA. And this will also be influenced by developments in other fields. Incidents in the food sector like the BSE crisis will also effect the actual regulation of human and veterinary medicines. I personally foresee a strengthening of the EMEA, especially in the coordination of pharmacovigilance and inspection.

The European regulatory system offers the unique opportunity of two different procedures for medicines to enter the market. In my opinion we should maintain this principle as it has a positive influence on the quality of performance of the EMEA and the national regulatory authorities. Both procedures need some adjustment, in particular there is a need to apply the resources in an efficient way both for European and national obligations. There are many ways to solve this issue, however to balance the total regulatory system an executive body overlooking the whole system could be a major step forward.

Last but not least, we have to absorb the accession of new members of the European Union. In this the EMEA is also in the lead. The Pan-European Regulatory Forum serves as an excellent vehicle of sharing knowledge and experience. I am glad that is project will be continued next year.

In the meantime the EMEA continues its usual business. From the beginning Fernand Sauer and my predecessor, Strachan Heppell, invested in making the operation and the decisions of the EMEA and its scientific bodies more transparent. The EMEA owes that to the public and it will enhance the credibility of the regulator. In itself it also an important management tool for the Agency itself. It challenges the talents of the EMEA staff and will contribute to the quality of the performance of the EMEA. Quality is not only an absolute standard but should also be perceived in comparison with others. The EMEA wants to learn and share experience and announced a benchmarking exercise at the end of 2000 with its international partners.

This year we said goodbye to the Executive Director, Fernand Sauer. It is not easy to mention the contributions of Fernand to the birth and development of the EMEA. The best way to phrase is that the EMEA reached maturity in 5 years! Not many fathers can say that.

In 2001 we start with the new executive director, Thomas Lönngren. He has proved himself as an excellent manager as Deputy Director-General of the Medical Product Agency in Sweden. He is the right person in the right time, because he couples managerial skills with a sound vision how we should collaborate in a network environment supported by high level information and communication technology.

Introduction by the Executive Director

Fernand Sauer

As I leave to return to the European Commission to deal with public health policy, I am confident that the Agency will be in good hands with Thomas Lönngren when he takes over as Executive Director from the beginning of 2001. Together with André Broekmans, the newly elected chairman of the Management Board, he will guide the EMEA into its next phase of development.

There were a number of other important changes in 2000. Strachan Heppell stepped down in February as chairman of the Management Board after having completed two terms of office. It is also the last year for Jean-Michel Alexandre and Reinhard Kroker who have each served two terms of office as chairmen of the Committee for Proprietary Medicinal Products and of the Committee for Veterinary Medicinal Products. The success of the Agency and of the European system as a whole owes a great deal to their personal commitment as well as that of the committee members and European experts.

Behind the work of the Management Board and the scientific committees are the enthusiasm and skills of the EMEA staff. They have created a world-class regulatory system that has delivered hundreds of decisions based on the best science in the interests of all citizens and users of human and veterinary medicines in the European Union. I take this opportunity to thank all past and current staff members.

One of the most significant developments in terms of public health is the introduction of the European policy for encouraging medicines for rare diseases ('orphan medicinal products'). With the support of the European Parliament and Commission, the EMEA established the Committee for Orphan Medicinal Products early in 2000. With its unique membership of national competent authorities and patients, the Committee has already made remarkable progress in a short period of time under the chairmanship of Josep Torrent i Farnell.

EMEA also made progress in improving transparency with the early publication of information on opinions adopted by our scientific committees. The confirmation of this policy at the end of 2000 was done with the support of our interested parties.

The international harmonisation activities with our partners in Japan and US reached an important stage in November 2000 when agreement was reached during the ICH5 conference in San Diego that paves the way to better dialogue between regulators in the future on the basis of common technical documentation.

Our work with the national authorities of central and eastern European countries continued in 2000 through the Pan-European Regulatory Forum. Funded by the Commission and run by the EMEA, the programme proved an enormous success in allowing all colleagues involved to share their experience.

As we look ahead to the revision of the European marketing authorisation system, I send my warmest regards to the staff and all those associated with the EMEA and wish them continued success in the future.

Chapter 1

The EMEA in 2000

The Management Board and EMEA Directorate

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

A small team assists the Executive Director in the general management and functioning of the European Agency for the Evaluation of Medicinal Products, legal affairs, external relations and liaison with the European Union institutions and Member States. The Directorate also provides the secretariat of the Management Board.

1.1 The Management Board

The Management Board met four times:

- 22 February 2000
- 7 June 2000
- 23 October 2000
- 20 December 2000

The composition of the Board changed a number of times during the year, in particular with the election in February of André Broekmans as the new chairman and Gerhard Kothmann as vice-chairman. This is the third mandate of the Board and members are appointed until the end of 2002.

Details of membership can be found in Annex 3.

Heads of national authorities from EU and central and eastern European countries joined members of the Board on 7 June for an informal discussion on the impact of EU enlargement on the EMEA. Items of particular concern include the composition and operation of the Management Board and the scientific committees, and the conduct of pharmacovigilance. These points will be considered as part of the review of the European marketing authorisation system currently being undertaken by the European Commission.

Appointment of new Executive Director

On the basis of a shortlist presented by the European Commission, the Management Board appointed Thomas Lönngren as Executive Director of the EMEA at its meeting of 23 October 2000. The appointment is with effect from January 2001.

Budgetary and financial decisions

The initial budget for 2000 of €49 559 000 comprised of €34 775 000 in fee revenue and a general contribution from the EU general budget of €13 200 000. Miscellaneous revenue amounted to €1 584 000.

Two supplementary and amending budgets were necessary in 2000, the first adopted at the October meeting and the second in December. These were in particular needed to take into account the creation of a special reserve for activities relating to orphan medicinal products, the continuation of the Pan-European Regulatory Forum on pharmaceuticals (PERF) and higher than expected levels of fee-earning activities. The final budget for 2000 totalled €55 287 220.

The budget statement for 2000, including final appropriations for 1999 and outturn for 1998, is published in OJ L 184, 24.7.2000, p. 1. A summary of the budgets for 1999 to 2001 can be found in Annex 2.

The Management Board granted discharge at its 9 June meeting to the Executive Director and to the EMEA accounting officer for the execution of the 1999 budget following a report by the European Court of Auditors (OJ C 373, 27.12.2000, p. 14).

The 2001 budget, amounting to €61 934 000, was adopted by the Board at its meeting on 20 December, including forecast fee revenue of €42 610 000 and miscellaneous revenue of €1 584 000. The general contribution from the EU general budget is €15 300 000, including a special contribution of €600 000 for activities relating to orphan medicinal products, and €2 440 000 for activities relating to the continuation of the second PERF programme.

Costing exercise

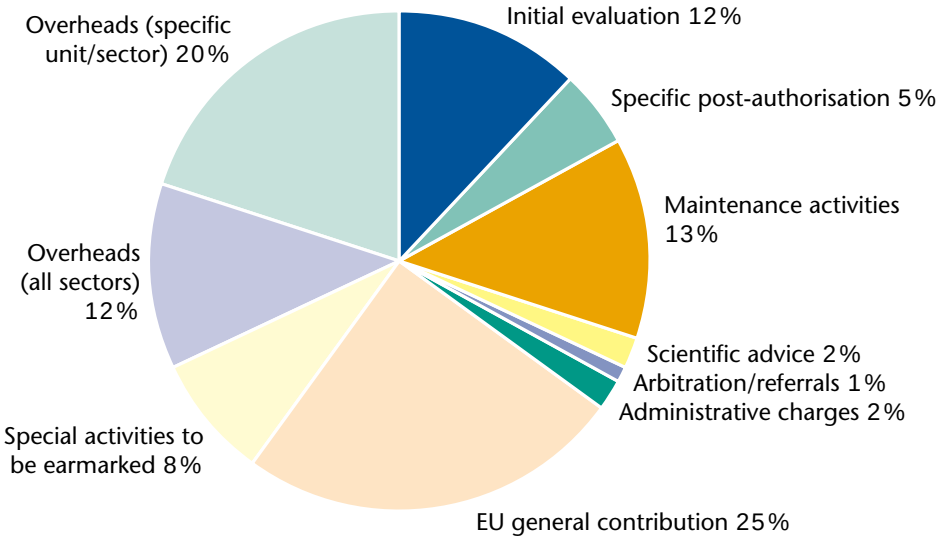
As set out in the 2000-2001 Work Programme, the costing exercise continued during 2000 with particular emphasis on the costs of evaluation, surveillance and inspection services provided by national competent authorities at the request of the EMEA.

The Management Board adopted a revised model cost questionnaires at its 7 June meeting, with the aim of systematically collecting time and cost data from rapporteurs, co-rapporteurs and national inspection services.

Data from ActiTrak (the EMEA activity and time tracking system) for the Agency as a whole and for different areas of activity in 2000 are presented in the relevant chapters of this annual report. A number of national competent authorities expressed an interest in applying the costing methodology to their own operations and in some cases also using the ActiTrak software.

The costing exercise is carried out at the request of the European Parliament and of the European Court of Auditors. The EMEA presented the ActiTrak system and costing methodology to other EU decentralised bodies who are also carrying out similar exercises.

ActiTrak data for all EMEA in 2000



The Management Board agreed at its 20 December meeting to continue with the existing mechanism for payment by the EMEA to national competent authorities for the provision of services (the 'scale of fees') in 2001(EMEA/MB/051/00). Under the mechanism half of most types of fees are redistributed to national competent authorities, with a special distribution for annual fee revenue. This redistribution of fees accounts for approximately one-third of total expenditure in the EMEA budget.

Annual fee revenue distribution:

- 30 % to cover EMEA staff costs
- 30 % is paid to the rapporteur and co-rapporteur for the medicinal product concerned for the production of annual safety reports and other supervisory tasks
- 30 % attributed to special activities and projects agreed by the Management Board, in consultation with the scientific committees (i.e. pharmacovigilance meetings, availability of veterinary medicines, crisis management and other post-marketing projects)
- up to 10 % for sampling and testing costs for centrally authorised medicines under an agreement with the Council of Europe's European Department for the Quality of Medicines and the network of Official Medicines Control Laboratories

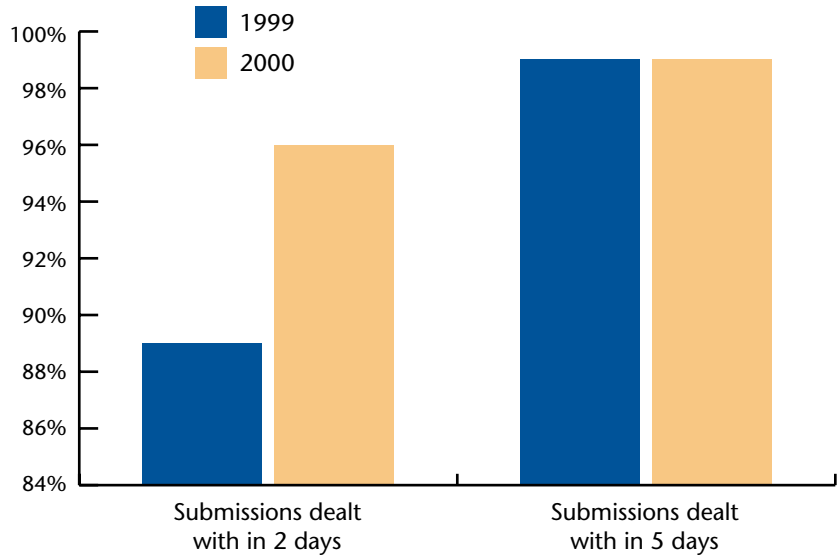
Financial control

The working relationship between the European Commission Directorate-General for Financial control and each of the EU decentralised bodies was reconsidered in 2000 in light of the introduction of internal audit functions within the individual Directorates-General of the Commission. The proposal is for financial control to be replaced by an internal audit function within each of the EU decentralised bodies, including the EMEA.

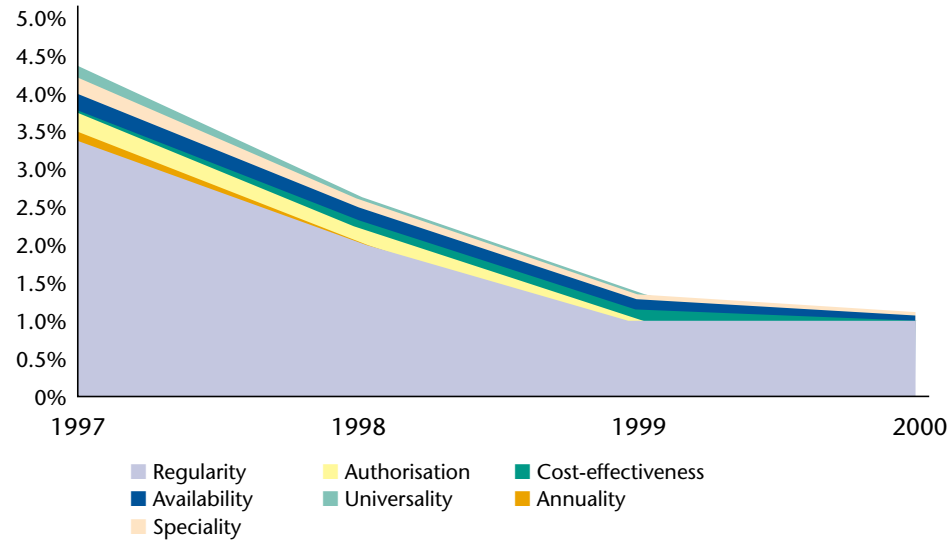
Once adopted by the Commission, this proposal will require a revision of the EMEA financial regulation. It is estimated that this process could take two to three years.

During 2000 the financial control function at the EMEA continued to be ensured by an interim financial controller together with an assistant. The targets set in the 2000-2001 Work Programme for the time taken to deal with submissions to financial control were exceeded in 2000. There was also a continued level of improvement in the quality of financial transactions submitted in 2000, with an average of 1.05 % of submissions requiring revision (1.37 % in 1999).

Turnaround time for submissions to financial control 1999-2000



Reasons for rejection of financial transactions 1997-2000



Explanatory note:

'Formal irregularities'

- Universality (Arts. 3, 4 and 23 of the Financial Regulation): i.e. booking on incorrect year, of part of the amount
- Speciality (Art. 22 of the Financial Regulation): i.e. use of inappropriate budget line
- Availability (Arts. 4, 29 and 31of the Financial Regulation): i.e. shortfall on commitment or of appropriations
- Cost-effectiveness (Art. 2 of the Financial Regulation): i.e. unacceptable contractual clauses, inadequate type of commitment
- Authorisation (Art. 18 of the Financial Regulation): i.e. disrespect for rules of delegation
- Annuality (Arts. 1 and 5 of the Financial Regulation): i.e. disrespect for the annual character of budget

Minor irregularities'

- Regularity: Issues concerning i.e. documentation, calculation, beneficiary, etc.

1.2 The EMEA and its partners

European Union institutions

Within the European Commission the EMEA worked closely with the Pharmaceutical and cosmetics Unit of the Directorate-General for Enterprise, together with the services and scientific committees of the Directorate-General for Health and consumer protection.

The services of the Commission continued to be represented at the EMEA through both the European Technical Office for Medicinal Products (ETOMEP) of the Joint Research Centre and the Anglo-Irish Desk of the Joint Interpretation and Conference Service.

European Technical Office for Medicinal Products (ETOMEP)

ETOMEP is part of the European Commission Joint Research Centre's Institute for Health and Consumer Protection. Based at the EMEA in London, the group supports the IT network that connects all national competent authorities, the European Commission and the EMEA itself.

Iceland and Norway were fully integrated within EudraNet system in 2000. Secure exchange of documents through the Internet, via EudraSafe, was enhanced both for the transmission of individual case safety reports in the framework of the European pharmacovigilance pilot project (**http://icsr.eudra.org**) and for general use between national authorities and industry. Cooperation tools (e.g. EudraRoom) have been put in place to facilitate the operational activities of the various working groups; access is restricted to authorised users.

The tracking system for the mutual recognition procedure was progressed in 2000 and version 5.2.10 of EudraTrack is currently in use by Member States. A prototype of EudraDoc has been included within the tracking system for a simplified document transfer system. Desktop videoconference services were tested between EMEA and some national authorities, with the aim of becoming fully operational in the near future.

ETOMEP continuously updated both the EMEA and European Commission Pharmaceutical Unit web sites during 2000, with a new EMEA web site launched at the end of 2000.

Joint Interpreting and Conference Service (JICS)

The Joint Interpreting and Conference Service of the European Commission is the largest in the world with some 500 staff interpreters and over 1 600 freelance interpreters. It serves the institutions of the European Union, as well as the decentralised agencies and bodies located in the EU Member States.

A representative JICS is based at the EMEA as part of the cooperation between EU institutions and agencies. During 2000, the representative has had the task of coordinating conference and interpreting needs at multilingual meetings, organising briefings for interpreters at EMEA meetings. The JICS representative also advised and lectured on multilingualism, interpreting and communication at Universities in Ireland and the UK.

JICS provided know-how and advice in the refurbishment of the Agency's new meeting rooms and for a new meeting management system. A glossary of specialised and technical EMEA terms was also produced by JICS interpreters in 2000 to assist understanding and communication at the Agency's meetings.

The European Department for the Quality of Medicines (EDQM)

http://www.pheur.org

European Pharmacopoeia
The European Pharmacopoeia is part of the Council of Europe and comprises 27 Member States, the European Union and 17 other European and non-European observer countries. The EMEA participates in the work of the European Pharmacopoeia Commission as part of the EU delegation. The Pharmacopoeia secretariat and experts participate in a number of EMEA working groups and undertook several tasks at the request of the EMEA in 2000.

The European Pharmacopoeia maintains an up-to-date list of standard terms used in product information for health professionals and patients. A recently revised version is available in 21 languages, including all 11 official EU languages, on the Pharmacopoeia web site.

European Network of Official Medicines Control Laboratories (OMCL)
Set up as a joint project between the EU and Council of Europe, the network allows the coordination of laboratory controls between EU and other European countries (e.g. central and eastern European countries, Switzerland, EFTA states). A contract between EMEA and the EDQM was extended in 2000 to organise sampling and testing of centrally authorised medicinal products by the OMCL network.

Good relations with the European Parliament are very important for the EMEA. The Agency was therefore pleased to welcome a delegation from the Committee on the Environment, public health and consumer protection led by Caroline Jackson in March, as well as a visit by Members of the European Parliament for the London region in June. The Agency also attended a number of meetings of the Committee on the Environment, public health and consumer protection and of the Committee on Budgets for discussion with the Committees.

Cooperation with other EU agencies included activities with the European Monitoring Centre for Drugs and Drug Addiction. The EMEA participated in a number of meetings in 2000 relating to evaluation of risks associated with new synthetic drugs and the abuse of medicinal products.

Cooperation with national competent authorities

Refurbishment of the third floor of the EMEA offices began at the end of 2000 with the purpose of providing a number of additional meeting rooms. This will in particular improve the facilities available for meetings of the mutual recognition facilitation groups for human and veterinary medicines and the EMEA scientific committees.

The EMEA participated in a number of meetings of the heads of national authorities for human and veterinary medicines organised under the Portuguese and French EU presidencies.

Details of the activities of the mutual recognition facilitation groups are given in Chapters 2 and 3. Contact details for the national competent authorities of EU Member States and EEA-EFTA states can be found in Annex 7.

Heads of agencies' web sites

Heads of agencies for medicines for human use	**http://heads.medagencies.org**
Heads of agencies for medicines for veterinary use	**http://www.hevra.org**

1.3 Transparency and good regulatory practices

Transparency at the EMEA is based on:
- Dialogue with interested parties
- Access to documents
- Good regulatory practices
- Code of conduct for European experts and EMEA staff members

Interested parties

Having established a good working relationship over the past years, the format of dialogue between the EMEA and CPMP with interested parties was reformed following discussion at the March 2000 meeting. Instead of the regular quarterly meetings, the following was agreed:

- one annual meeting, with a single theme related to a public health issue. Proposed topics include orphan medicinal products and the democratisation of health information
- two six-monthly meetings bringing together EMEA, CPMP and interested parties focusing on past and future issues arising from the activities of the CPMP
- ad hoc meetings and workshops as necessary on technical or specific topics. Issues already identified include transparency issues, including post-marketing and pharmacovigilance communication, and readability of patient leaflets

The creation of the Committee for Orphan Medicinal Products at the beginning of 2000 was an important evolution in the EMEA relationship with interested parties. Not only is the legislation the result of cooperation between the regulatory authorities, pharmaceutical industry and patient groups, but for the first time patient representatives are full members of an EMEA committee.

Access to documents

Access to EMEA documents was facilitated with the launch of a public document catalogue in December 2000. The catalogue is available on the on the Agency's web site and allows the public to search documents produced by the EMEA. In addition to all documents classified as 'public' the catalogue also covers those classified as 'restricted' and 'confidential', although in some cases the full title may not be given in order to respect the Agency's obligations of confidentiality.

The publication by the EMEA of a catalogue is a positive action by the EMEA towards better access to documents and transparency, in line with Declaration No 17 of the Amsterdam Treaty on European Union.

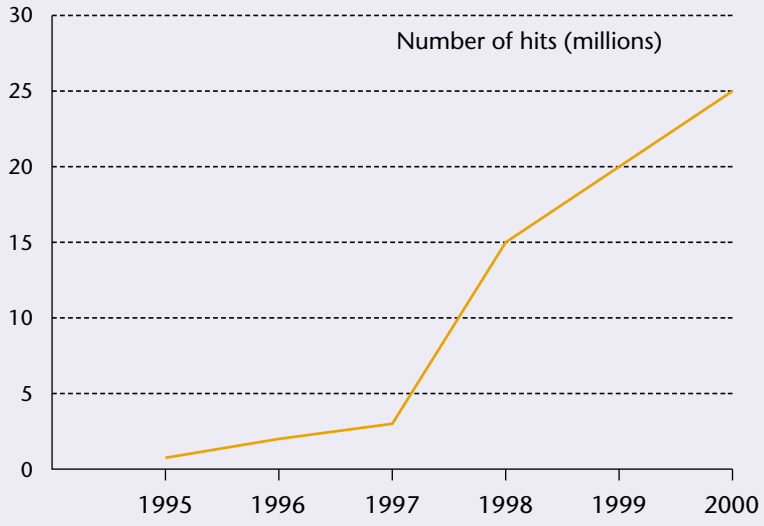
The 1997 Decision on rules on access to documents of the EMEA provides for the classification of and access to documents and is available on the web site in all official EU languages.

New EMEA web site

http://www.emea.eu.int

A new EMEA web site was launched in December 2000, together with a new address. The new site is designed to give improved access to the increasing number of documents available. There are currently over 5 000 documents on the site.

The site will also be able cope with the increased number of visitors – there were more than 25 million 'hits' on the site in 2000.



Good regulatory practices

An important initiative in 2000 to improve regulatory transparency was the publication of summaries of opinions on the granting of marketing authorisations, both positive and negative, 15 days after their adoption by the EMEA scientific committees. After public consultation and initial discussions with interested parties, summaries of opinion were introduced in July 2000 for CPMP opinions only.

Further improvements to pre- and post-authorisation transparency and communication were the main themes of a workshop held with interested parties on 23 November 2000. The recommendations from the workshop were presented to the Management Board at its 20 December meeting.

A new format for the presentation of European public assessment reports (EPARs) on the Agency's web site was introduced in 2000. The new modular presentation is intended to facilitate access to the different parts of the assessment report, in particular to the information for health professionals, patients and users of medicines that is available in all 11 EU official languages.

Ensuring the consistency of EMEA internal procedures is an important aspect of regulatory transparency. Within the framework of the quality management system (QMS), five groups looked at performance measurement, Agency's partnership with interested parties, product information management, staff performance evaluation issues and the development of an electronic 'quality manual'.

Eighteen internal audits were conducted, including in the areas of pharmacovigilance, pre-submission guidance and scientific advice, leading to valuable improvements in EMEA performance.

As announced in the EMEA Work Programme 2000-2001, a benchmarking project for the harmonisation of best regulatory practices was presented to the Management Board in October 2000. The project will initially involve 22 authorities from European Union, EFTA and central and eastern European countries. The purpose of the project is the exchange of experience in the implementation of a quality system ('Good Regulatory Practices') to ensure consistency in methodology and criteria for the implementation of EU legislation and guidelines.

Code of conduct

The EMEA Code of conduct entered into force on 1 January 2000 and is available in all official EU languages on the EMEA web site. The Code applies to all European experts and EMEA members of staff.

In line with the Agency's commitment to greater transparency, a list of the names and addresses of European experts was published on the EMEA web site for the first time in February 2000 and was regularly updated throughout the year.

The full list of experts, together with their curriculum vitae and declarations of interests, continues to be available for public consultation by prior written request at the EMEA offices. Declarations of interest for staff members are also available for public inspection on prior request at EMEA. Contact points for requests are given in Annex 1.

1.4 International aspects

European Economic Area

Iceland and Norway completed their first year as members of the CPMP and CVMP. The EMEA was pleased to note that a member of the CPMP from Norway was appointed to act as co-rapporteur for a centralised procedure in 2000.

A guidance document for industry on the extension of the centralised procedure to Iceland and Norway was made available on the EMEA web site in March 2000. The document addresses the practical arrangements of the processing of applications for centrally authorised products and their subsequent harmonisation with respect to Iceland and Norway.

Liechtenstein completed preparations for the creation of independent national structures and began its participation in EMEA activities at the end 2000.

Central and eastern European countries

Following the success of the first Pan-European Regulatory Forum (PERF) programme, the European Commission agreed funding for a second programme for the period 2000-2001 of €2 440 000. The PERF II programme focuses on implementation and practical issues to assisting associated countries as part of their preparations for accession to the European Union.

Topics covered by PERF I

- pharmacovigilance
- EU pharmaceutical legislation
- dossier assessment (quality, safety and efficacy)
- responsibilities and mandate of competent authorities
- good manufacturing practices
- information technology issues
- establishment of maximum residue limits for veterinary medicines

Topics to be covered by PERF II

- pharmacovigilance
- implementing EU pharmaceutical legislation
- dossier assessment (quality, safety and efficacy)
- good manufacturing practices
- specific aspects relating to veterinary medicines
- implementation of quality systems
- information technology issues, in particular relating to EudraNet implementation

PERF web site: **http://perf.eudra.org**

A number of national experts from the Czech Republic, Estonia, Poland, Slovak Republic and Slovenia were on secondment to the EMEA in 2000 for training

Other international activities

The joint EMEA-World Health Organisation project for the co-development of an application tracking system (SIAMED 2000) came near to completion in 2000. Discussions began on how best to make this model application tracking system freely available to regulatory authorities not only in the European region and throughout the world.

The exchange between the EMEA and authorities of third countries continued in 2000, with national experts from both Japan and US spending extended periods of time at the Agency. The EMEA was pleased to welcome delegations from China, Kuwait, Malta, Russia Taiwan and US during the year.

Details of activities within the International Conferences on Harmonisation for human and veterinary medicines (the ICH and VICH initiatives) can be found in Chapters 2 and 3 of the report.

Chapter 2

Medicines for human use

Overview of the Unit for the Evaluation of Medicines for Human Use in 2000

Head of Unit	**Noël WATHION**
Head of Sector for regulatory affairs and pharmacovigilance	**Noël WATHION**
Deputy Head of Sector	**Isabelle MOULON**
Head of Sector for biotechnology and biologicals	**John PURVES**
Deputy Head of Sector	**Marisa PAPALUCA AMATI**
Head of Sector for new chemical substances	**Patrick LE COURTOIS**
Deputy Head of Sector	**Anthony HUMPHREYS**

During 2000 the Unit for the Evaluation of Medicines for Human Use:

- management and follow-up of marketing authorisation applications under the centralised procedure
- provided scientific advice
- provided support to the Committee for Proprietary Medicinal Products, Committee on Orphan Medicinal Products and to protocol assistance
- continued supporting pharmacovigilance and post-marketing maintenance of authorised medicinal products
- managed Community referrals and arbitrations arising from the mutual recognition procedure
- provided support to European and international harmonisation activities of the CPMP and its working parties
- provision of support to the Mutual Recognition Facilitation Group

Developments in the workload of the Unit, in particular relating to orphan medicinal products and post-marketing activities, lead to discussions in 2000 concerning the restructuring of the Unit. The proposed new structure of two Units is intended to facilitate the handling of an increasing workload and to further enhance support for the CPMP and its working parties. The following nominations for the posts in the two new Units were announced at the end of 2000:

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

[To be announced]
Head of Unit

Sector for scientific advice and orphan drugs
Patrick LE COURTOIS
Head of Sector

Sector for quality of medicines
John PURVES
Head of Sector

Sector for safety and efficacy of medicines
Isabelle MOULON — *Head of Sector*
Marisa PAPALUCA AMATI — *Deputy Head of Sector*

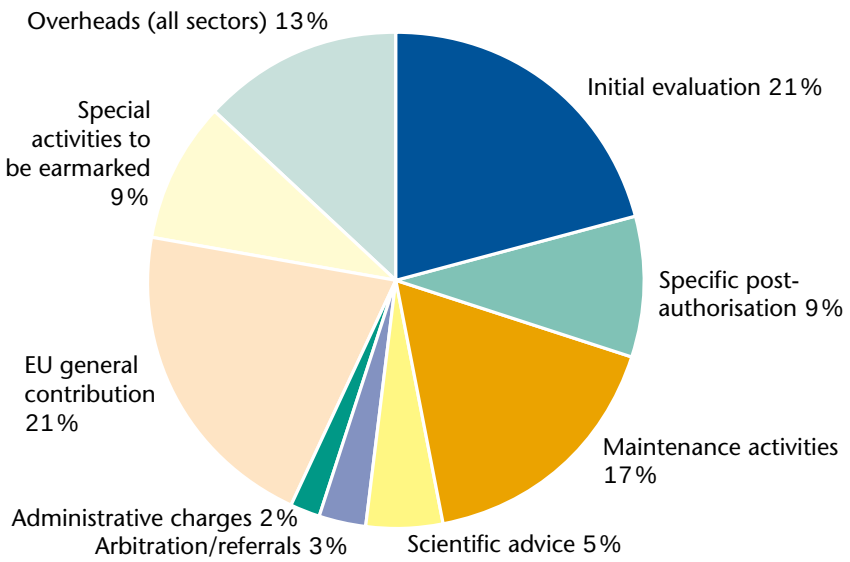
Unit for the Post-authorisation evaluation of medicines for human use

Noël WATHION
Head of Unit

Sector for regulatory affairs and organisational support
Anthony HUMPHREYS
Head of Sector

Sector for pharmacovigilance and post-authorisation safety and efficacy of medicines
[Post vacant] — *Head of Sector*
Sabine BROSCH — *Deputy Head of Sector*

ActiTrak data for human medicines evaluation in 2000



2.1 Operation of the Committee for Proprietary Medicinal Products

Chairman of the CPMP **Jean-Michel ALEXANDRE**
Vice-chairman of the CPMP **Mary TEELING** *(January-September 2000)*
Hans van BRONSWIJK *(September-December 2000)*

Details of membership of the Committee can be found in Annex 4.

Centralised procedures	1998	1999	2000	Total 1995-2000
Applications received				
Part A	12	19	17	278
Part B	33	32	37	
Withdrawals				
Part A	8	1	0	49
Part B	12	7	11	
Opinions adopted by product				
Part A	11	9	20	176*
Part B	30	17	30	
Opinions adopted by substance				
Part A	11	8	15	134*
Part B	19	15	14	
Type I variations				
Part A	50	68	106	816
Part B	108	207	205	
Type II variations				
Part A	26	48	69	384*
Part B	40	61	95	
Extension & abridged applications				
Part A	11	6	2	84
Part B	4	13	5	

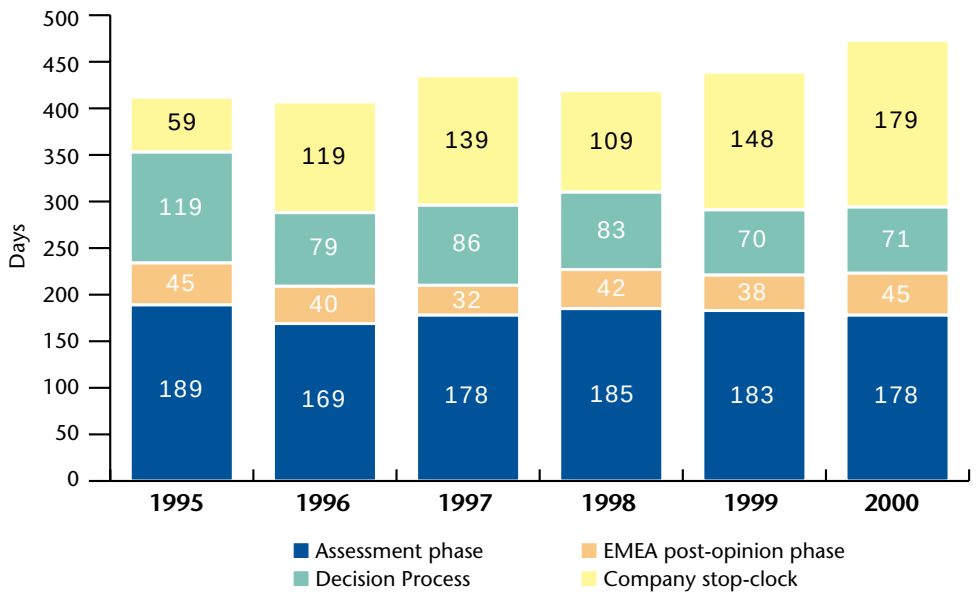
** These figures include negative opinions given for 6 products (representing 4 substances), and for 2 variations.*

Performance indicators

The results of the joint EMEA-European Federation of Pharmaceutical Industries and Associations (EFPIA) performance survey were presented at the EMEA-EFPIA Info-day on 20 October 2000. The level of satisfaction of both CPMP members and applicants with most aspects of the centralised procedure was acknowledged to have reached a consistently high level. It was decided to revise the focus of the annual performance survey in 2001.

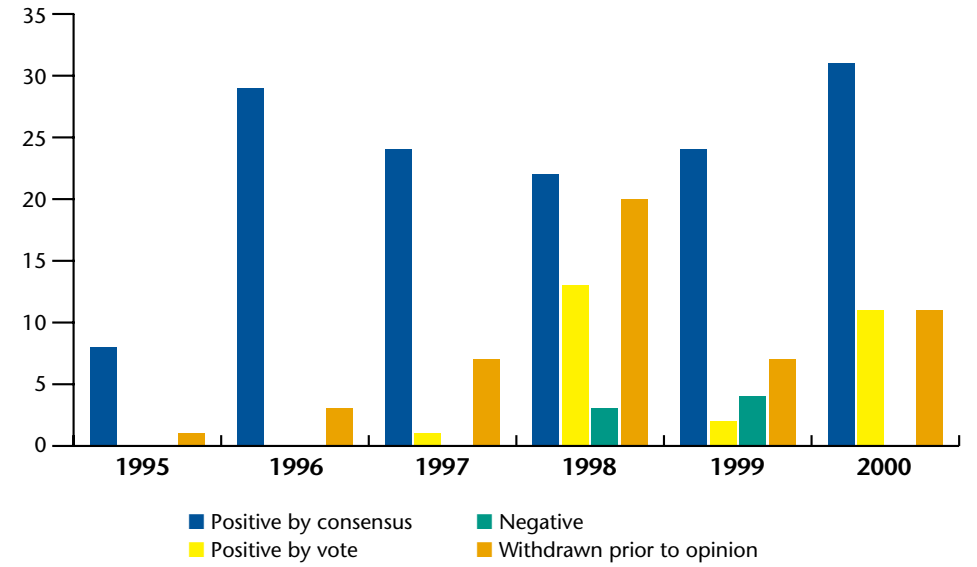
The EMEA continued to meet its performance target of adopting all opinions on the evaluation of medicinal products within the 210-day time frame.

Average number of days for centralised procedures 1995-2000



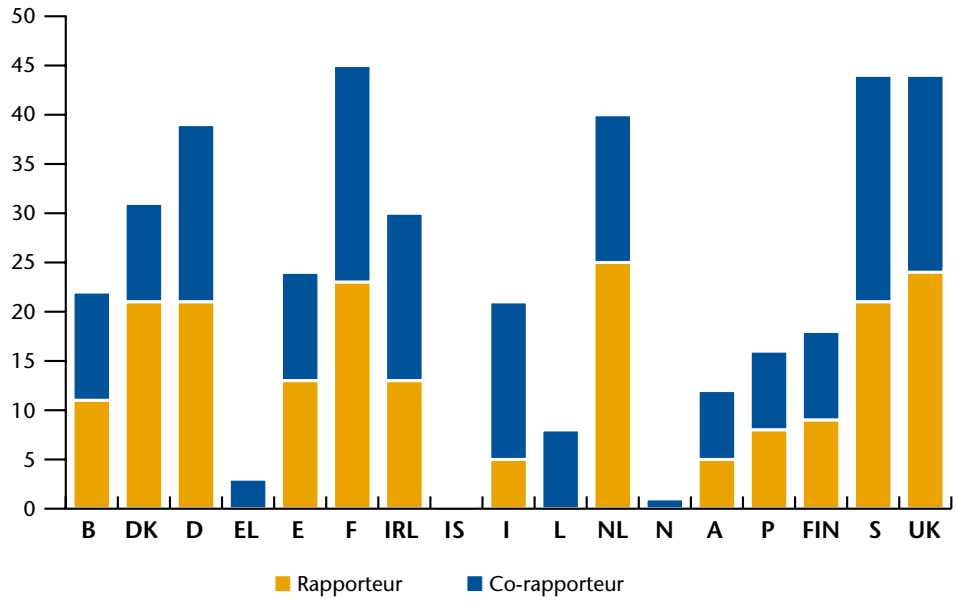
Centralised procedures

CPMP opinions on initial applications in the centralised procedure 1995-2000



The CPMP adopted a larger number of positive opinions by vote in 2000 compared to 1999, leading to more positive opinions overall. This increase in voting matches a fall in the number of negative opinions and of withdrawals from the centralised procedure.

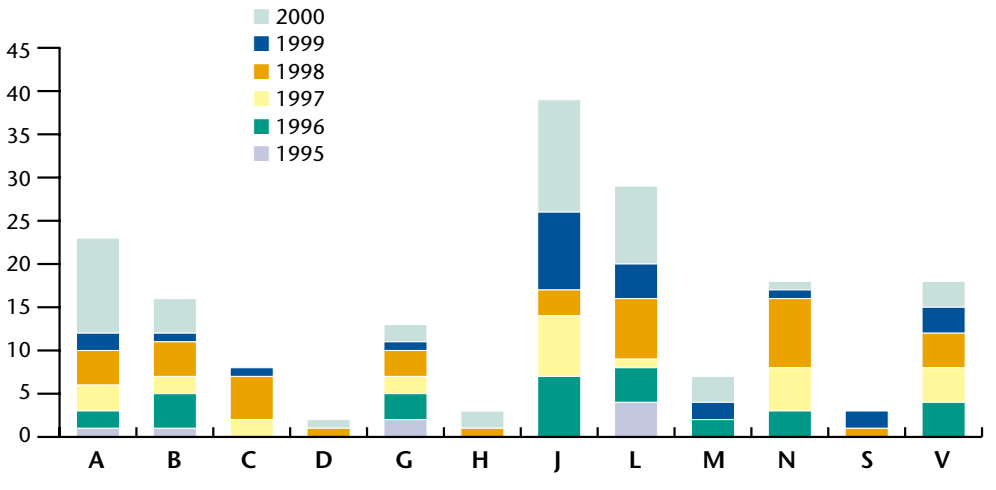
Distribution of rapporteurships by national delegations 1995-2000



There has been a significant increase in the number of opinions in 2000 for medicinal products falling in the metabolism (class A) and antineoplastic – immuno-modulating (class L) anatomical therapeutic chemical (ATC) classification codes.

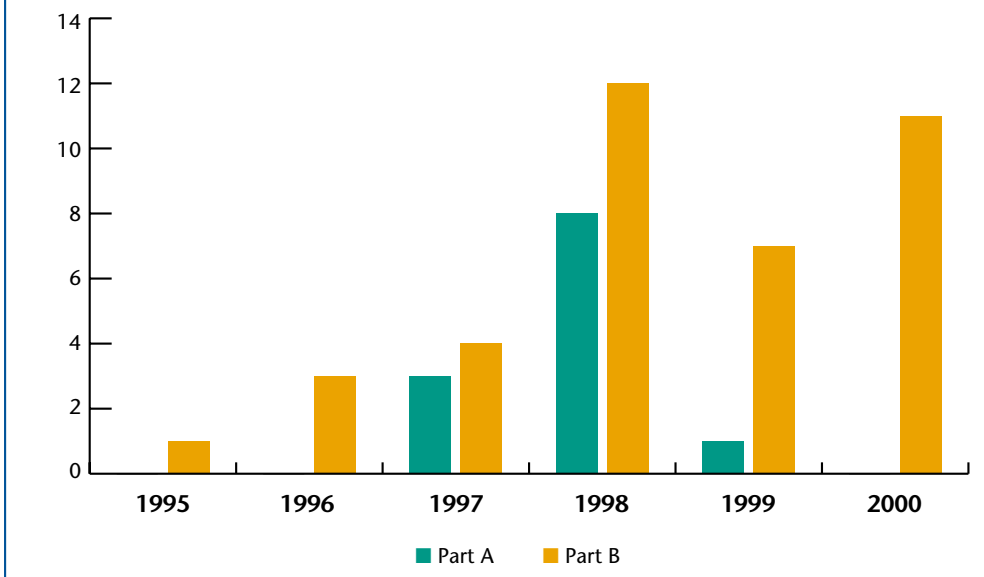
The highest number of withdrawals from the centralised procedure continue to fall within the ATC categories of blood (class B), neurology (class N) and oncology (class L).

CPMP opinions by therapeutic class 1995-2000



A: Metabolism
B: Blood
C: Cardiovascular
D: Dermatologicals
G: Genito-Urinary, sex hormones
H: Endocrinology
J: Antiinfective
L: Antineoplastic – immuno-modulating
M: Musculo Skeletal
N: Nervous system
S: Sensory organs
V: Diagnostic agents

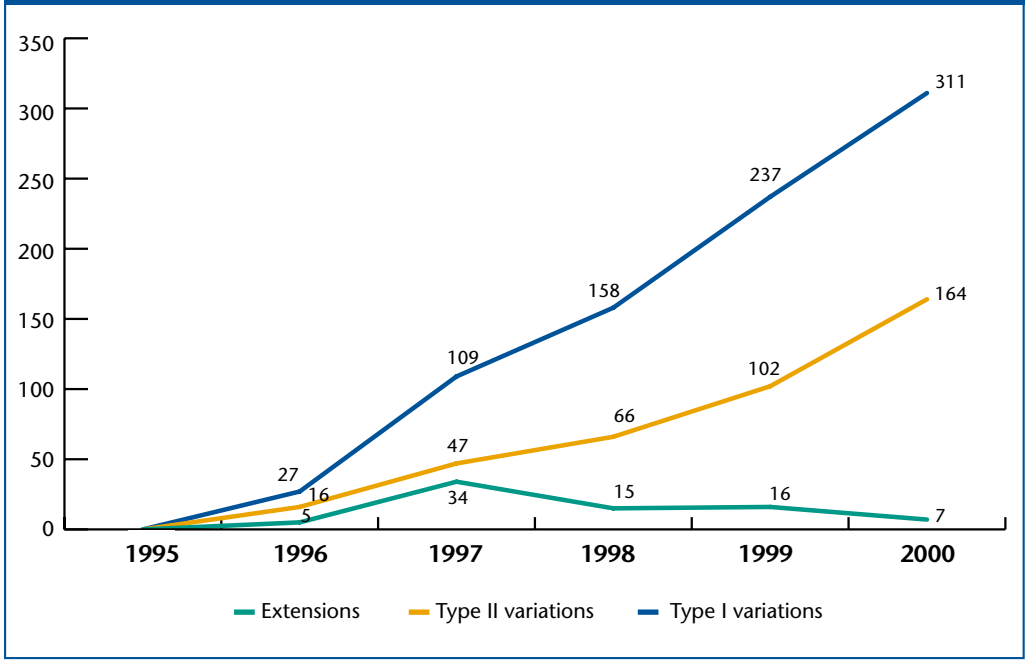
Withdrawal of applications in the centralised procedure 1995-2000



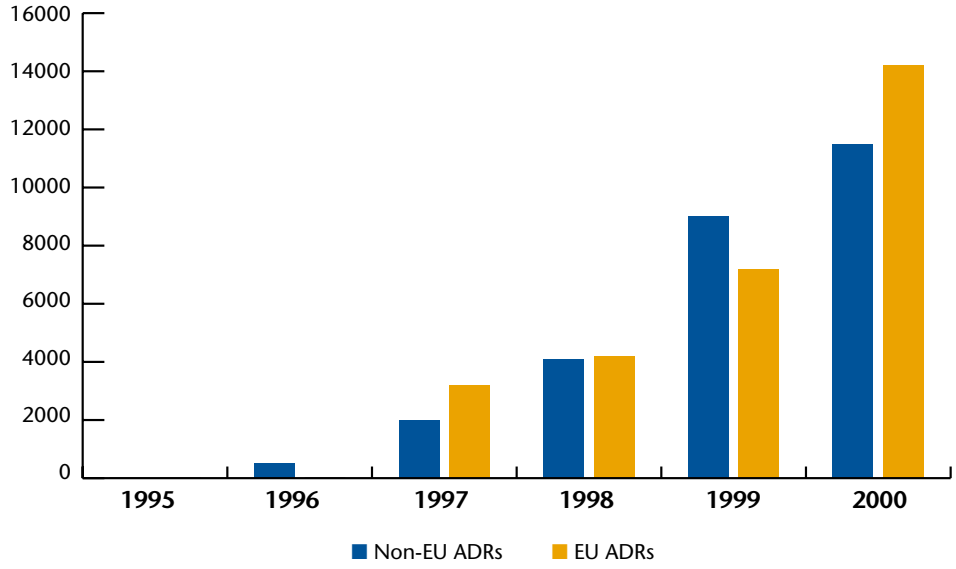
2.2 Post-authorisation activities

The increase in the workload for post-authorisation activities, particularly for variations and in pharmacovigilance, in 2000 reflects the increased cumulative number of centrally authorised medicinal products. In particular the number of suspected series adverse drug reactions (ADRs) and periodic safety update reports (PSURs) handled by the EMEA continued to grow in 2000.

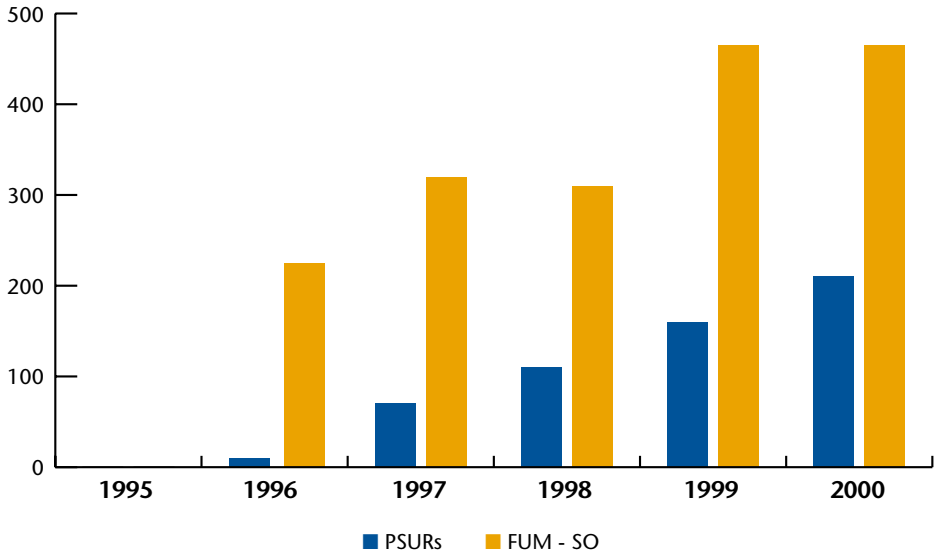
Opinions on variations and extensions for centrally authorised products 1995-2000



EU and non-EU adverse drug reports 1995-2000



Period safety update reports, follow-up measures and specific obligations 1995-2000



Work continued on the development of EudraVigilance, the electronic Community pharmacovigilance system for transmission and management of adverse drug reactions. A joint pilot for the implementation of the electronic transmission of individual case safety reports was initiated and five meetings were held at the EMEA with participants from 7 national competent authorities and 17 pharmaceutical companies.

The new EudraVigilance Technical Implementation Group was established in 2000, under the aegis of the European Commission Telematic Steering Committee, comprising representatives of the Commission, Member States and EMEA. The Group is chaired by the EMEA and met twice in 2000.

Regulatory affairs

Tradenames

An ad hoc Tradename review group was set up in 2000 at the request of the CPMP as a forum for the discussion of tradename-related issues arising from centralised applications. The group is chaired by an EMEA representative and is composed of Member States representatives, the European Commission and EMEA representatives.

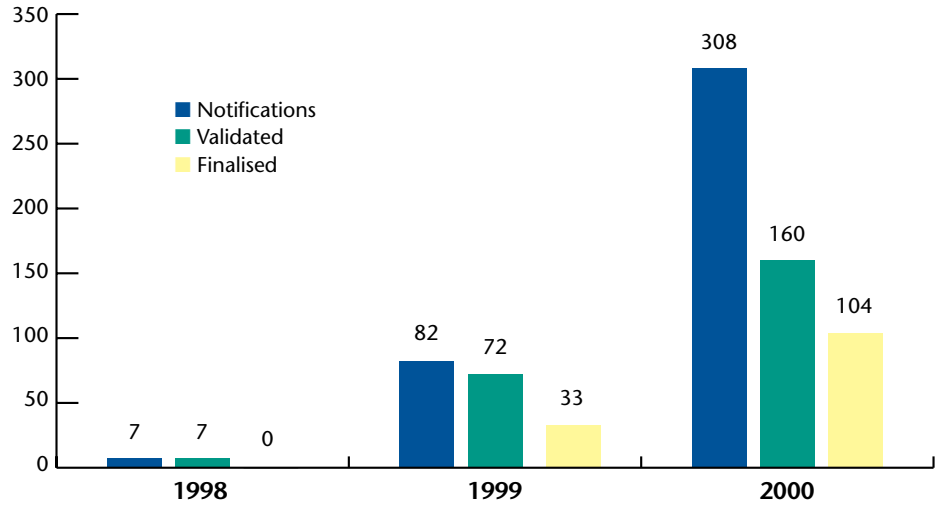
The group meets every month on the Monday prior to the CPMP plenary meetings for the review of objections and comments made by Member States, Iceland and Norway, with a view to making recommendations to the CPMP.

Parallel distribution

The workload for parallel distribution notifications increased significantly in 2000, greatly in excess of the level foreseen in the Work Programme 1999-2000.

The main destination for products being primarily Germany and the UK, whilst the main Member States of origin were Spain, France, Italy and Austria.

Parallel distribution notifications 1998-2000



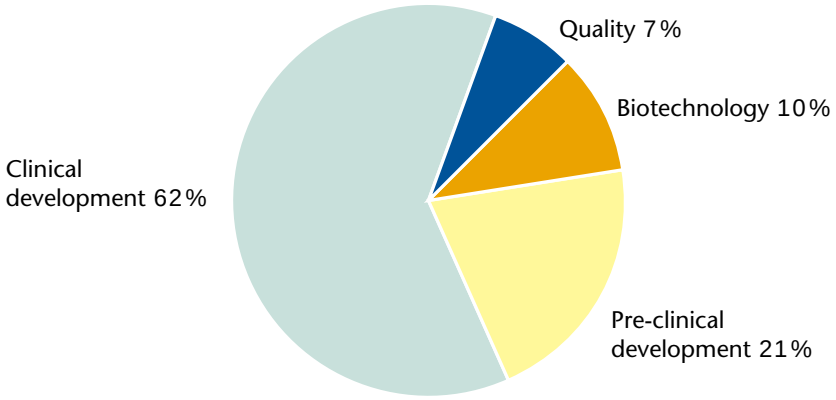
2.3 Scientific advice

Scientific advice	1997	1998	1999	2000	Total 1995-2000
Scientific advice given	20	35	60	58	196
Follow-up to scientific advice	3	8	4	9	26

Additional guidance for companies seeking scientific advice was developed in 2000 and made available on the EMEA web site. The process also benefited from an increase in the time available for interaction between applicants and the experts involved in the procedures during CPMP week.

Of the 36 positive opinions adopted by CPMP in 2000, 5 had previously benefited from scientific advice. Of the 7 negative opinions/withdrawn applications, 1 had received scientific advice prior to the application.

Distribution of scientific advice requests in 2000



2.4 Operation of the Committee on Orphan Medicinal Products

The COMP in 2000

Chairman of the COMP	**Josep TORRENT i FARNELL**
Vice-chairman of the COMP	**Yann LE CAM**

Details of membership of the Committee can be found in Annex 6.

In April 2000 the EMEA began an important new role in stimulating the development of medicinal products for rare diseases – 'orphan medicines'. This followed the entry into force in 2000 of the legislative framework for orphan medicinal products in the European Union (Regulation (EC) No 141/2000 (OJ L 18, 22.1.2000, p. 1) and Commission Regulation (EC) No 847/2000 of 27 April 2000 (OJ L 103, 28.4.2000, p. 5)).

Designation as an orphan medicinal product is the mechanism by which sponsors have access to various incentives designed to encourage the development of such medicines and their availability to patients. Incentives include a 10-year period of market exclusivity, protocol assistance from the EMEA and the possibility of fee reductions for all activities relating to the centralised marketing authorisation procedure.

The new Committee for Orphan Medicinal Products (COMP) was established for the designation of orphan medicinal products and met for the first time in April 2000. The Committee met eight times in 2000 to review applications for designation and the development of guidance documents.

The COMP is the first institutional committee of the European Union to have patient organisation representatives as full members. Josep Torrent i Farnell and Yann Le Cam were elected chairman and vice-chairman respectively, for a term of three years renewable once.

Applications for orphan designation

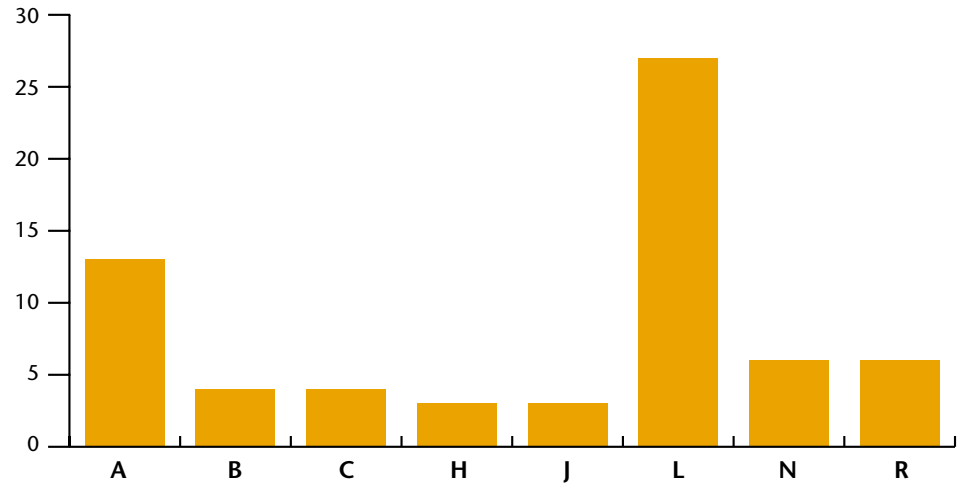
The first applications for orphan medicinal product designation were submitted to the EMEA in April 2000. The EMEA held 25 pre-submission meetings to assist sponsors.

Year	Intent to file notified	Applications submitted	Applications withdrawn	Positive COMP opinions	Negative COMP opinions	Designations granted by the Commission
2000	29	71	3	26	-	8

A coordinator from the EMEA and from the COMP is appointed for each application for designation. They are assisted by experts on rare diseases drawn from a list nominated by the Committee. The list had 66 experts at the end of 2000.

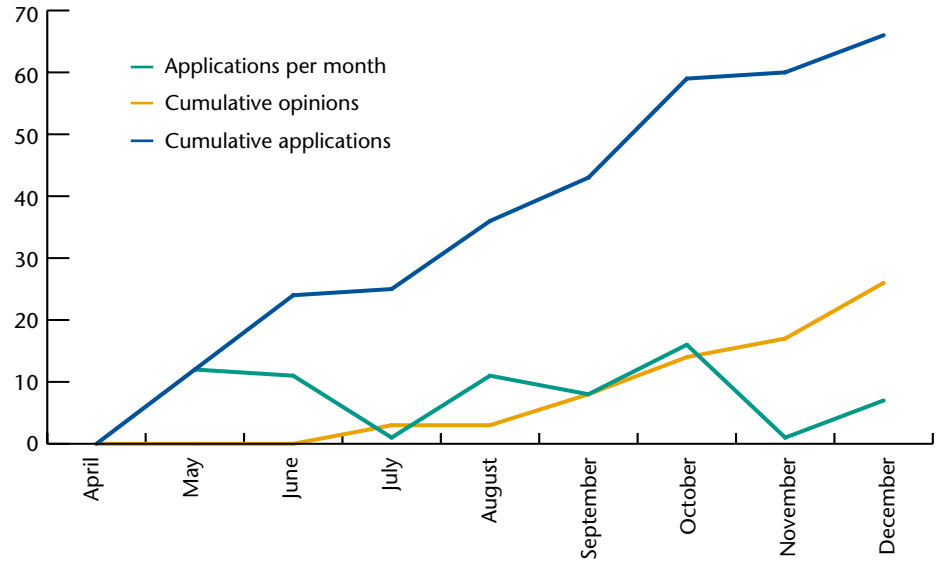
The highest number of applications for orphan medicinal product designation by therapeutic class in 2000 was in the antineoplastic and immuno-modulating area (class L).

Applications for orphan medicinal product designation by therapeutic class 2000



A: Metabolism
B: Blood
C: Cardiovascular
H: Endocrinology
J: Antiinfective
L: Antineoplastic – immuno-modulating
N: Nervous System
R: Respiratory

Applications and opinions for orphan medicine designation 2000



Positive opinions were adopted by the Committee in an average timeframe of 63 days. Details are given in Annex 10. The first orphan medicinal products were officially designated by the European Commission in August 2000 and have been published in the Community register of orphan medicinal products. The register is available through the European Commission Pharmaceutical Unit web site.

2.5 Working party activities

The CPMP working parties and the Joint CPMP/CVMP Quality Working Party (see Chapter 4) met regularly in 2000. Details of notes for guidance, points to consider documents and position papers prepared by the working parties for the CPMP are given in Annex 11.

Working Party	Chairperson	Meetings in 2000	Guidelines and points to consider documents approved in 2000
Pharmacovigilance working party (PhVWP)	Patrick WALLER	8	5
Biotechnology working party (BWP)	Giuseppe VICARI, then Jean-Hughes TROUVIN	9	5
Scientific advice review group (SARG)	Mary TEELING, then Markku TOIVONEN	11	0
Blood and plasma working group (BPWG)	Manfred HAASE	4	4
Safety working party (SWP)	Beatriz SILVA LIMA*	3	1
Efficacy working party (EWP)	Alfred HILDEBRANDT, then Barbara VAN ZWIETEN-BOOT*	5	11

* Acting Chairperson

2.6 Cooperation with competent authorities

Referrals and arbitrations

There were 9 referral procedures in 2000, of which 5 were finalised. Information on finalised procedures are published on the EMEA web site.

Type of referral	Date of CPMP final opinion	International non-proprietary name (INN)
Article 7(5) Commission Regulation EC 541/95	27.07.2000	Zofenopril
	Procedure ongoing	Cerazette
Article 10 Council Directive 75/319/EEC	29.06.2000	Ketoprofen Retard Scand Pharm
	Procedure ongoing	Capthydro
Article 11 Council Directive 75/319/EEC	19.10.2000	Glucophage
Article 12, Council Directive 75/319/EEC	16.11.2000	Sibutramin
	Procedure ongoing	Calcitonins
	Procedure ongoing	Cisapride
Article 15, Council Directive 75/319/EEC	19.10.2000	Sertindole

International Conference on Harmonisation

International Conference on Harmonisation (ICH)

Final guidelines

- Choice of control group in clinical trials (CPMP/ICH/364/96), ICH E10
- Clinical investigation of medicinal products in children (CPMP/ICH/2711/99), ICH E11
- Safety pharmacology studies for human pharmaceuticals (CPMP/ICH/539/00), ICH S7A
- Stability testing guidelines: stability testing of new active substances and medicinal products (CPMP/ICH/2736/99 rev. of CPMP/ICH/380/95), ICH Q1AR
- Non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals (CPMP/ICH/286/95, modification), ICH M3 modification
- Reproductive toxicology: toxicity to male fertility (CPMP/ICH/136/95 modification), ICH S5B modification
- Data elements for transmission of individual case safety reports (CPMP/ICH/287/95 modification), ICH E2B
- Recommendations on electronic transmission of individual case safety reports message specification (CPMP/ICH/285/95), ICH M2
- Good Manufacturing practice guide for active pharmaceutical ingredients (CPMP/ICH/4106/00), ICH Q7A
- Common Technical Document (CTD), (CPMP/ICH/2887/99), ICH M4

Guidelines released for consultation

- Bracketing and matrixing designs for stability testing of drug substances and drug products (CPMP/ICH/4104/00), ICH Q1D
- Maintenance of the guideline on impurities: residual solvents: permissible daily exposure (PDE) for Tetrahydrofuran and N.Methylpyrrolidine (CPMP/ICH/283/95), ICH Q3C(M)

Details of these and other CVMP guidelines are given in Annex 11.

Working Party on Herbal Medicinal Products

The Working Party on Herbal Medicinal Products met at the EMEA on 3 occasions in 2000, chaired by Konstantin Keller.

The working party was involved in the review of the risks associated with the use of herbal medicinal products containing Aristolochia. A position paper was prepared in collaboration with CPMP pharmacovigilance and safety working parties and published in November 2000.

Details of notes for guidance and position papers from the group are given in Annex 11.

A meeting with European interested associations was held in October 2000. Topics discussed included the scope of dialogue and proposals for improved transparency in the communication from the working party to the public on herbal related matters.

2.7 Activities of the mutual recognition facilitation group

The mutual recognition facilitation group (MRFG) is intended to coordinate and facilitate the operation of the mutual recognition procedure. The 11 meetings of the group were chaired by António Melo Gouveia during the Portuguese Presidency in the first half of 2000 and Jean-Michel Alexandre during the French Presidency in the second half.

Two informal meetings of the MRFG were organised under the presidencies to discuss issues related to the mutual recognition procedure such as transparency, quality of assessments and the 2001 review were discussed.

As one of the established European procedures for the authorisation and supervision of medicines in the European Union, the number of mutual recognition procedures increased in 2000 requiring a solid support from the EMEA and an increase in the number of subgroup meetings and break-out sessions.

A total of 52 breakout sessions were organised by reference Member States (referring to 46 new applications and 6 variations). In relation to the number of new applications, the number is higher than in 1999.

Mutual recognition procedure	Total submitted in 2000*	Under evaluation in 2000*	Ended positively in 2000*	Referrals started in 2000
New applications	373	78	309	2
Type I variations	953	124	934	--
Type II variations	323	135	312	2

*The numbers includes multiple procedures and as stated as at 15 December 2000.

The total number of both submitted and completed applications increased. The number of arbitrations increased from the previous years and as an indirect consequence of the mutual recognition procedures, the number of referrals under Article 11 of Directive 75/319/EEC increased notably.

The frequency of withdrawals of applications – 30.5 % – (at least one withdrawal per procedure) from individual Member States in the mutual recognition procedure continued to be an issue of concern in 2000. It should be noted, however, that out of 3 107 applications in the concerned Member States, 236 were withdrawn (7.6 %).

An in-depth analysis of withdrawals endorsed by the Heads of Agencies was started in September 1998 and the Member States were encouraged to prepare the reports highlighting the reasons behind each withdrawal. As a result of this analysis, it has been concluded that the main reasons for withdrawals are related to issues arising from the summary of product characteristics (57 %), problems linked to the dossier assessment (38%) or other reasons (5 %).

There are still some Member States who have not acted as reference Member State. The distribution between Member States remains uneven, with a few Member States continuing to play a dominant role.

Considerable effort was dedicated to improving the quality of data in the EudraTrack database. A new classification of procedures was agreed in order to more clearly identify the nature of the procedure and legal basis as well as to improve the quality of the information released relating to mutual recognition procedure.

Applications ended positively in 2000 (1st and 2nd level of classification)				
	Initial applications	Multiple (copy) applications	Repeat use applications	Additional strength or form applications
Abridged	119	33	17	4
Known active substance	44	4	10	-
New active substance	27	14	7	-
Line extension	13	2	2	7
Not classified by reference Member State	6	-	-	-

Applications ended positively in 2000 (3rd level of classification)						
Full dossier	Informed consent	Bibliographic	Generic	Fixed combination	Different use, route or dose	Not classified by reference Member State
97	8	24	122	18	35	5

Applications ended positively in 2000 (4th level of classification)					
Chemical substance	Biological: blood product	Biological: vaccine	Biological: other	Herbal	Not classified by reference Member State
287	4	7	6	1	4

Applications ended positively in 2000 (5th level of classification)		
Prescription only	Non-prescription (including OTC)	Not classified by reference Member State
275	30	4

A number of guidance documents were published in 2000 to assist applicants and marketing authorisation holders in the use of the mutual recognition procedure. These include a proposal for a harmonised summary of product characteristics for influenza vaccines, a standard operating procedure on urgent safety restrictions and a best practice guide for reference Member States in the mutual recognition procedure.

The MRFG advanced its work on a number of ongoing projects, including one for promoting the preparation of harmonised summary of product characteristics for mutually recognised medicinal products and another for the production of updated assessment reports.

Norway and Iceland began participation as full members in the mutual recognition procedure and in meetings of the MRFG from the beginning of 2000. In addition two observers from central and eastern European countries also attended MRFG meetings during 2000. Representatives of the European Commission also regularly participated in meetings of the group.

Contacts with interested parties consisted of liaison meetings between the MRFG and trade associations as well as MRFG members' participation in conferences and seminars in the pharmaceutical field.

Chapter 3

Medicinal products for veterinary use and information technology

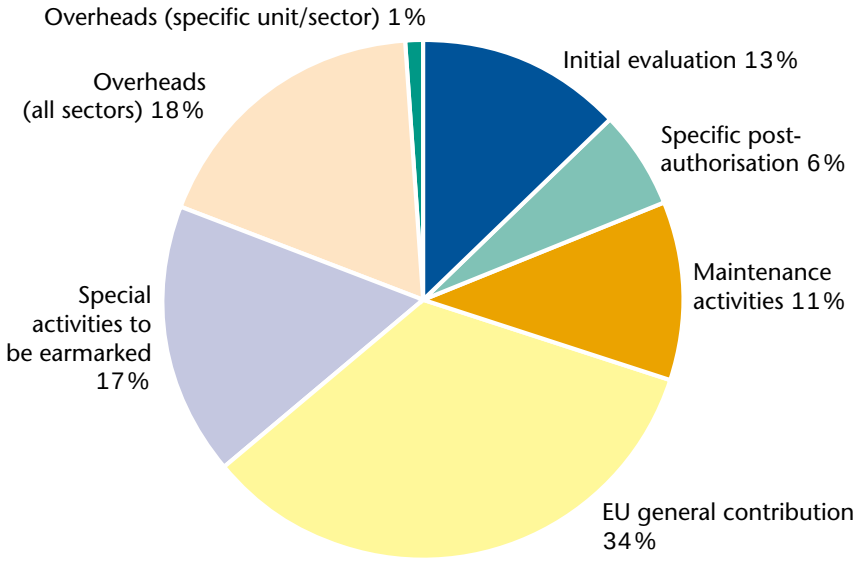
Overview of the Unit for Veterinary Medicines and Information Technology in 2000

Head of Unit	**Peter JONES**
Head of Sector for veterinary marketing authorisation procedures	**Jill ASHLEY-SMITH**
Head of Sector for safety of veterinary medicines	**Kornelia GREIN**
Head of Sector for information technology	**Michael ZOURIDAKIS**
Deputy Head of Sector for information technology	**David DRAKEFORD**

The Unit for the Veterinary Medicines and Information Technology is responsible for:

- management and follow-up of marketing authorisation applications under the centralised procedure
- management of applications for the establishment of maximum limits (MRLs) for residues of veterinary medicinal products that may be permitted in foodstuffs of animal origin
- post-marketing maintenance of authorised medicinal products
- provision of information technology support to the EMEA
- management of Community referrals and arbitrations arising from the mutual recognition procedure
- provision of support to European and international harmonisation activities of the CVMP and its working parties
- provision of support to the Veterinary Mutual Recognition Facilitation Group

ActiTrack data for veterinary medicines evaluation in 2000



During 2000 fee-earning activities have increased in line with the rise in the number of centralised applications forecasted, requiring greater focus on initial evaluation work, whilst new MRL applications have decreased slightly.

3.1 Operation of the CVMP

Chairman of the CVMP **Reinhard KROKER**
Vice-chairman of the CVMP **J. Gabriel BEECHINOR**

Details of membership of the Committee can be found in Annex 5.

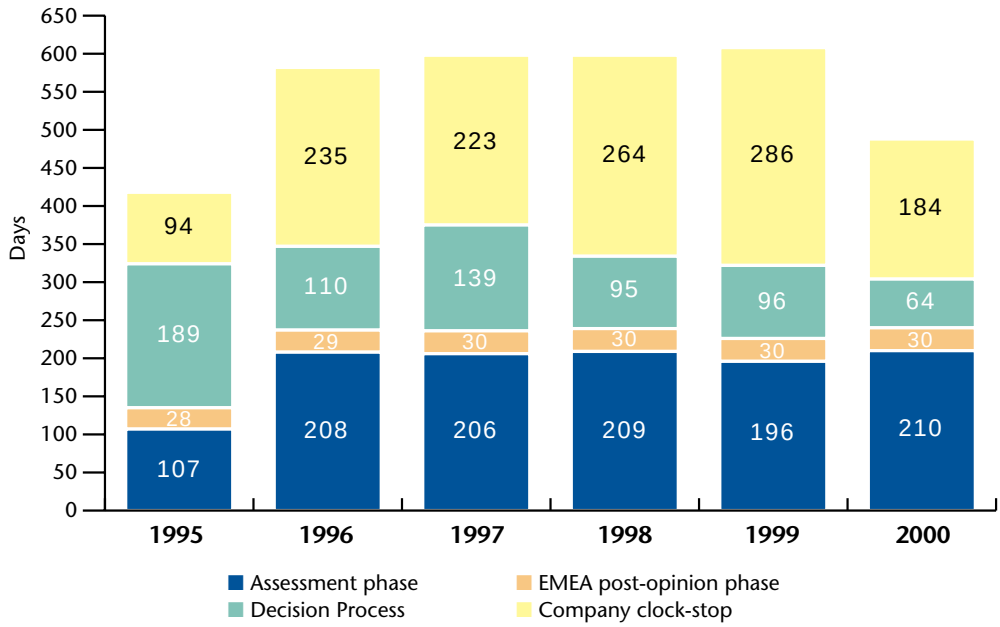
Centralised procedures	1998	1999	2000	Total 1995-2000
Applications received	14	4	6	38
Withdrawals	1	0	1	4
Opinions adopted by product	3	9	8	28
Type I variations	7	16	31	59
Type II variations	0	3	4	7
Extension & abridged applications	7	6	1	16
Maximum residue limit (MRL) procedures				
Establishment of MRLs for old substances	114	157	20	593
Applications for new MRLs	4	3	2	40
Withdrawal of applications for new MRLs	1	0	0	4
Applications for modifications and extensions	10	12	13	62
Withdrawal of applications for modifications and extensions	1	0	0	3
Opinions on new MRLs	27	32	20	99

Performance indicators

The goals and objectives of the veterinary sectors in this reporting period have mostly been met satisfactorily with 100 % compliance with regulatory deadlines for centralised applications and maximum residue limit (MRL) applications and extensions/ modifications. The average time for clock-stop for applicants to respond to questions was

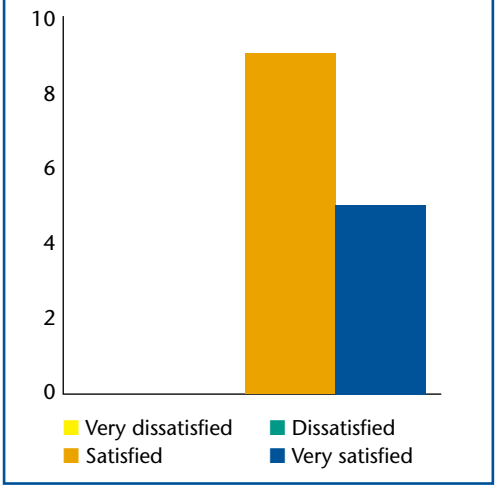
considerably reduced in 2000, reflecting a better standard of dossier in the original application. An improvement in the time taken for the decision process at the Commission was also seen in 2000.

Average number of days for centralised procedures 1995-2000

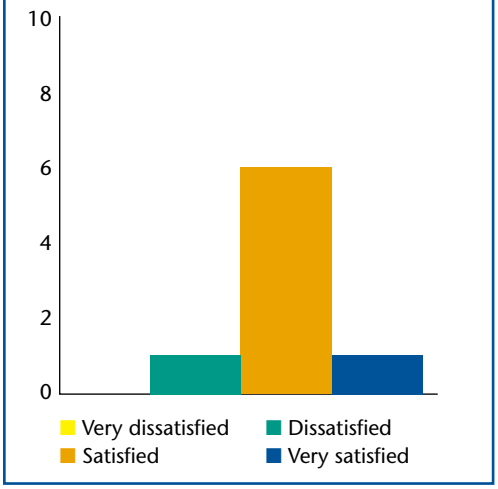


The results of the first joint EMEA-European Federation of Animal Health (FEDESA) performance survey on the centralised procedure were published in May 2000. The survey showed that there is a high level of satisfaction with the operation and results of the centralised procedure from all sides.

Satisfaction with the centralised procedure – EMEA/CVMP survey



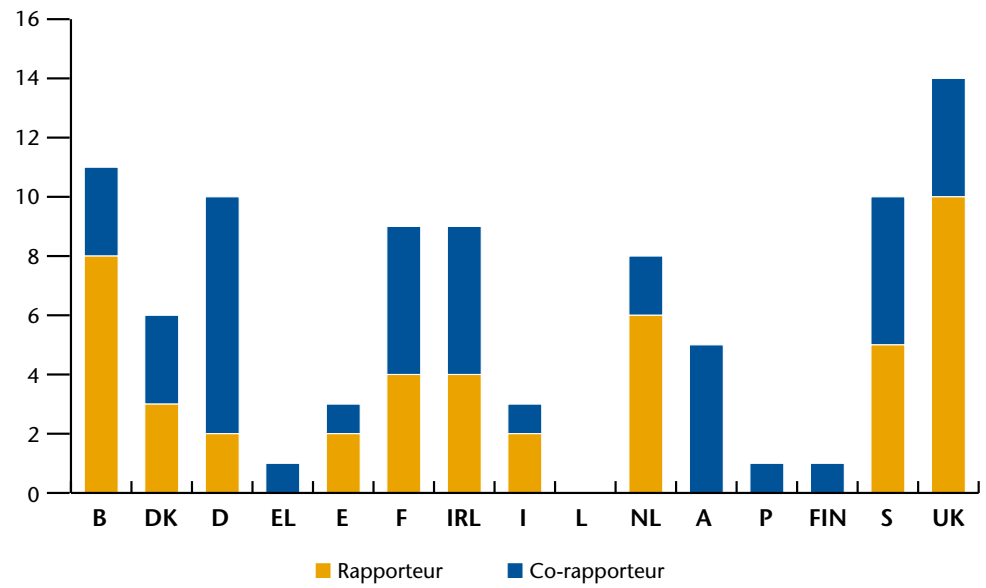
Satisfaction with the centralised procedure – FEDESA survey



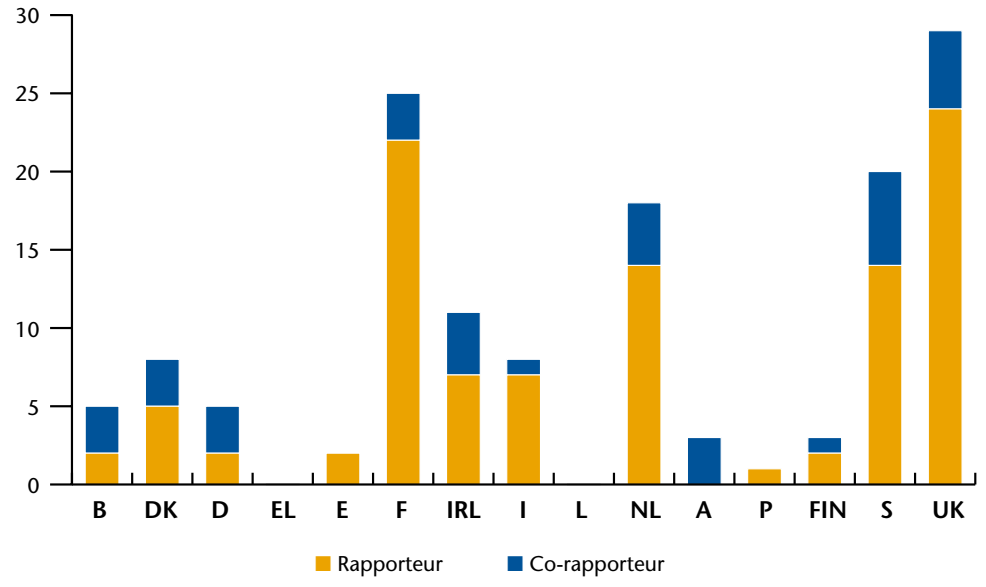
Rapporteurships

Distribution of rapporteurships for centralised and new MRL applications followed a similar pattern in 2000 to previous years with members coming from the larger national authorities accepting responsibility for most of the applications.

Distribution of rapporteurships by national delegations 1995-2000



Distribution of rapporteurships for new maximum residue limits by national delegation 1995-2000



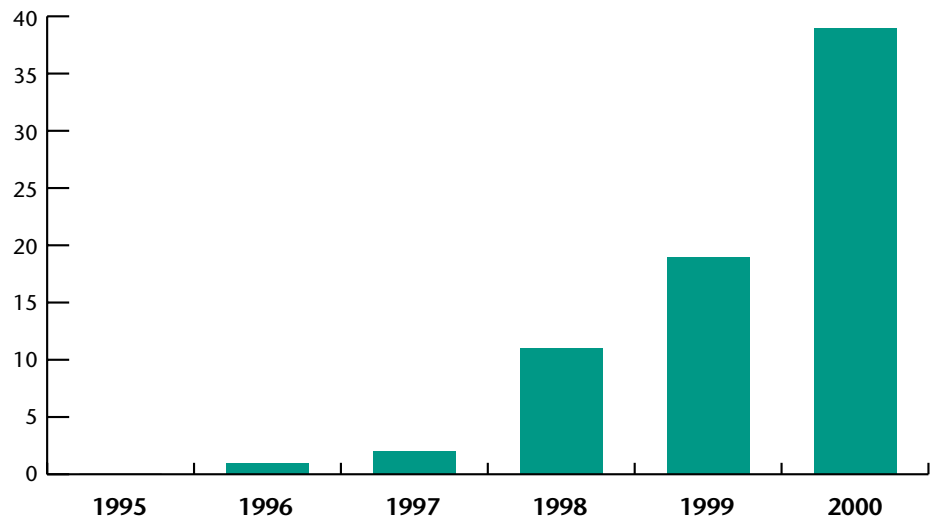
3.2 Post-authorisation activities

The significant expansion in 2000 of specific post-authorisation activities reflects the increase in the number of applications for variations to centralised procedures and extensions/modifications to MRLs as compared to previous years.

With the granting of opinions for centralised authorisations growing in number, maintenance support is requiring considerably more attention, particular for pharmacovigilance and the requirements for periodic safety update reports (PSURs).

The number of PSURs submitted doubled in 2000 compared to 1999. However some applicants are still uncertain of their obligations in this respect and pharmacovigilance reporting was a key subject on the agenda of the second joint EMEA-FEDESA Info-day held in December 2000 at the EMEA.

Periodic safety update reports 1995-2000



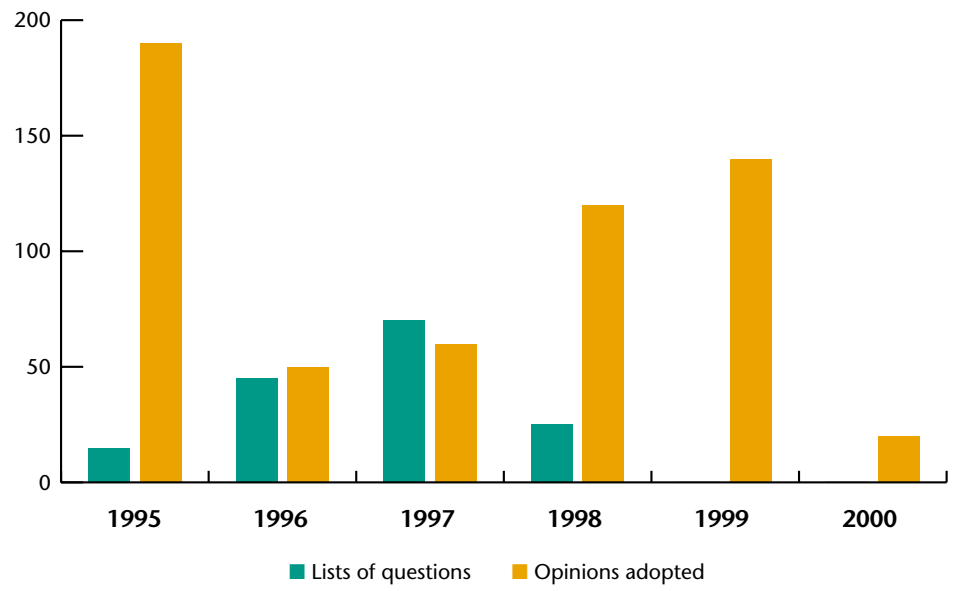
The CVMP adopted its first opinion recommending the suspension of the marketing authorisation for a centralised product in the EU in 2000. The product concerned was Econor, an antimicrobial in-feed medication for treatment of enzootic pneumonia and swine dysentery, and was subject to a product recall.

The CVMP also considered its first referral in respect of a product, Bayovac IBR & Rhinobovin Marker Live, authorised under the mutual recognition procedure, and agreed a variation to the marketing authorisation to include additional quality control tests to avoid viral contamination of the final product.

3.3 MRLs for old substances

The completion of assessment of applications to set MRLs for old substances was met before the 1 January 2000 deadline. However work continued in 2000 to set definitive MRLs for those substances currently in Annex III of Council Regulation (EEC) No 2377/90 and allocated provisional status pending provision of additional data, mainly relating to validation of analytical methods for surveillance purposes.

Opinions and lists of questions adopted for old substances 1995-2000



Other key events in 2000 in brief

- Workshop on analytical methods for residue surveillance to monitor completed MRLs held at EMEA in January 2000
- Availability of medicines task force continued to propose initiatives to the Commission – to be considered as part of the 2001 review of the European marketing authorisation system
- EMEA recommendations for a veterinary orphan drug policy submitted to Commission in June 2000
- CVMP risk management strategic plan on antimicrobial resistance in implementation phase in 2000 by CVMP Safety and Efficacy Working Parties
- Ongoing commitment to international harmonisation with active participation in WHO, Codex Alimentarius and Veterinary International Conference on Harmonisation (VICH). Four VICH guidelines adopted for final release in 2000, with a further five were released for consultation by CVMP.

Veterinary International Conference on Harmonisation (VICH)

Final guidelines

- Good Clinical Practices CVMP/VICH/595/98)
- Stability Testing of Biotechnological/Biological VMPs (CVMP/VICH/501/99)
- Impurities: Residual Solvents (CVMP/VICH/502/99)
- Environmental Impact Assessment (EIAs) for VMPs (CVMP/VICH/592/98)

Guidelines released for consultation

- Management of adverse event reports (CVMP/VICH/547/00)
- Efficacy of anthelmintics: Specific recommendations for poultry (CVMP/VICH/546/00)
- Efficacy of anthelmintics: Specific recommendations for feline (CVMP/VICH/545/00
- Environmental impact assessment (EIAS) for VMPs - Phase I (CVMP/VICH/592/98)
- Safety studies for veterinary drug residues in human food: Genotoxicity studies (CVMP/VICH/526/00)

Details of these and other CVMP guidelines are given in Annex 11.

EMEA/CVMP transparency and dialogue in 2000

January	Celebration of 5th anniversary of EMEA inauguration
February	Bilateral meeting with FEDESA
March	Joint EMEA/TAIEX meeting for central and eastern European countries
	CVMP/interested parties meeting
May	EMEA-FEDESA Info-day
July	Bilateral meeting with FEDESA
October	CVMP/interested parties meeting
November	Bilateral meeting with FEDESA
December	EMEA-FEDESA Info-day

3.4 Working party activities

The CVMP working parties and the Joint CPMP/CVMP Quality Working Party (see Chapter 4) met regularly in 2000. Details of notes for guidance prepared by the working parties for the CVMP are given in Annex 11.

Working Party	Chairperson	Meetings in 2000	Guidelines and points to consider documents approved in 2000
Pharmacovigilance working party (PhVWP)	Gabriella CONTI, then Cornelia IBRAHIM*	4	2
Immunologicals working party (IWP)	Paul-Pierre PASTORET	4	5
Efficacy working party (EWP)	Liisa KAARTINEN	4	6
Safety working party (SWP)	Michelle DAGORN	4	6
Antimicrobial resistance working group (ARWG)	Margarita ARBOIX	3	0

* Acting Chairperson

3.5 Activities of the veterinary mutual recognition facilitation group

The veterinary mutual recognition facilitation group (VMRF) met each month in 2000 except August at the EMEA, chaired by the Portuguese and then the French presidency. The EMEA provided full secretariat and administrative support to the group.

Dossier assessment

The number of mutual recognition procedures completed increased from 39 in 1999 to 47 in 2000. There was also a steady increase in the number of variation procedures. Seven Member States acted as reference member state in the procedures.

In order to improve the procedure, Member States committed to decrease the number of questions asked to applicants and a follow-up of reasons for withdrawal was performed with a view to solve problems for future applications.

Improvement in transparency

The VMRF-FEDESA liaison group met regularly during 2000. The 1999 joint VMRF-FEDESA survey of the mutual recognition procedure was completed and results were published, this survey was continued in 2000.

An index of products authorised through the mutual recognition procedure was published in April 2000 on the heads of veterinary agencies (HEVRA) web site: **http://www.hevra.org**. The index gives access to core information for each product, together with the English-language version of the summary of product characteristics.

Organisational issues

A number of organisational issues were discussed and solved. The best practice guide was modified to detail Member States' work and to allow more time to applicants to answer questions raised by concerned Member States.

Companies were given the possibility of asking questions directly to the VMRF through the HEVRA web site and the VMRF answered 8 questions related to the mutual recognition procedure in 2000.

3.6 Information technology

Preparations for ensuring compliance with year 2000 requirements were found to have been justified and well founded when the Agency opened for business on 2 January 2000 with no associated problems encountered.

The Agency's expansion to floor 7 in 2000 required a significant commitment to provide the necessary infrastructure and support to service the needs of staff in their new office accommodation.

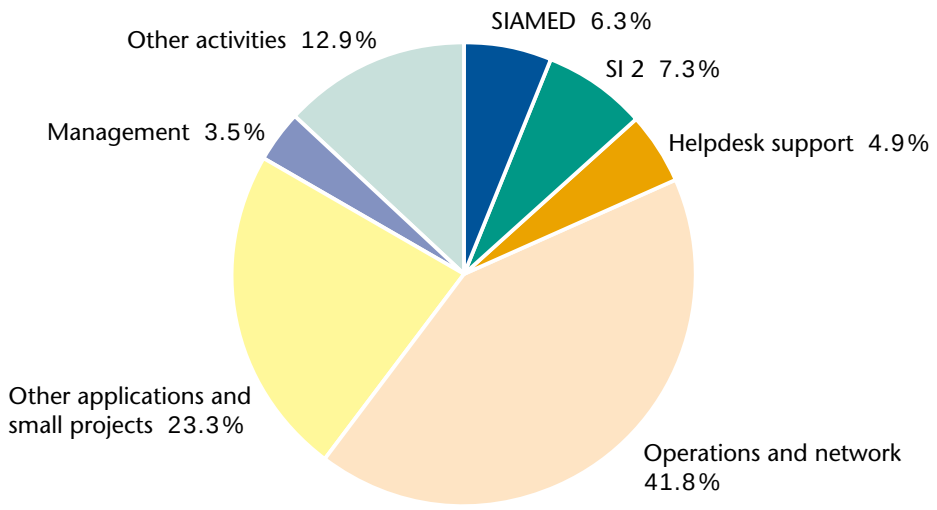
As part of the sector's commitment to performance, the target of minimum system availability was exceeded in 2000, with almost 100 % availability of the complete range of information technology services.

During 2000, the sector developed and implemented a desktop videoconferencing system (using Internet protocol and ISDN). After successful operation within the EMEA, testing with a number of partners began in 2000.

In addition to its support function, the sector undertook the development and implementation of a number of new mainstream projects, including an EMEA internal web-based news and alert channel called Ticker.

The majority of resources in the sector are assigned to operations and network support functions, with a significant proportion also assigned to the development of applications and other small projects.

Resource allocation for information technology



Chapter 4

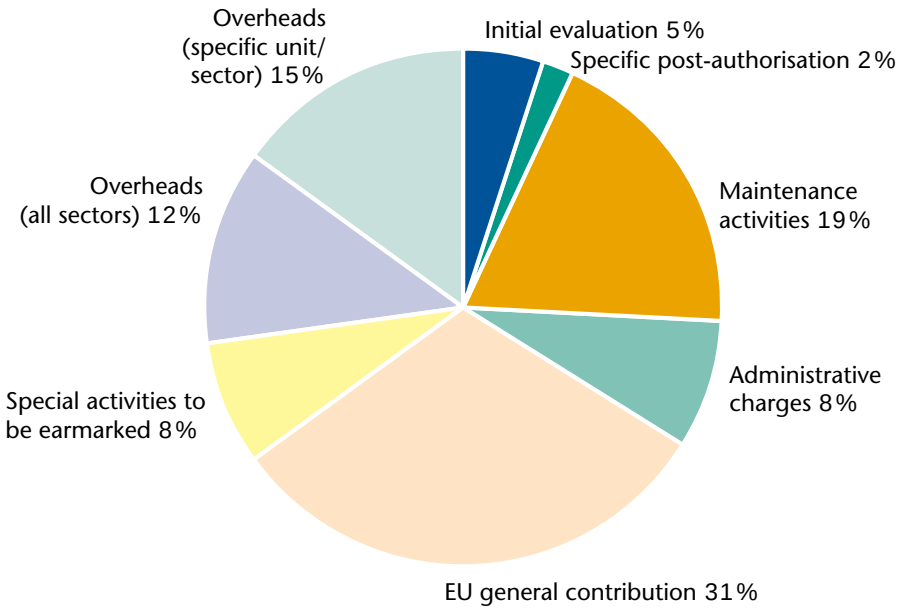
Technical coordination activities

Overview of the Technical Coordination Unit

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

The Technical Coordination Unit provides logistical support to human and veterinary medicines evaluation activities regarding inspections and medicinal products certificates, as well as a number of general services to EMEA, including document management and conference services.

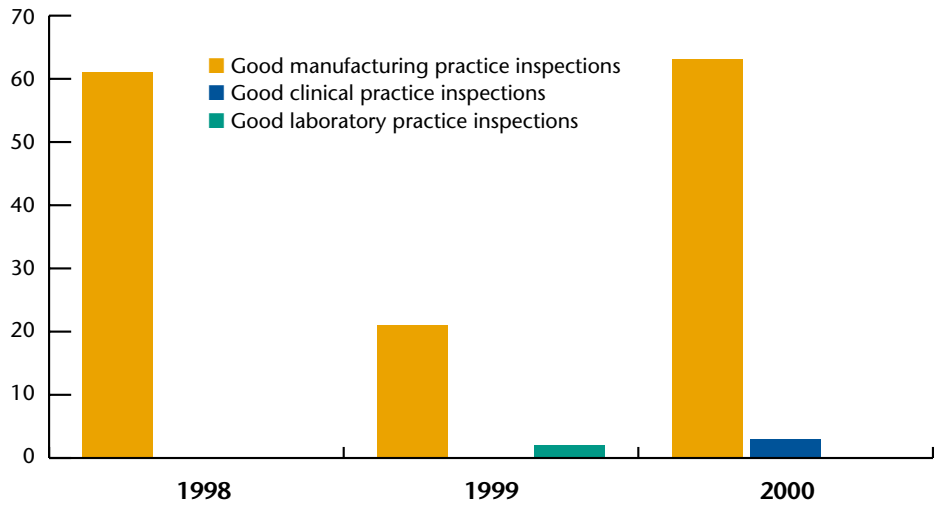
ActiTrak data for technical coordination activities in 2000



4.1 Inspections

Coordination of inspections for centralised procedures

Inspections carried-out for centralised procedures 1998-2000



The number of good manufacturing practice (GMP) inspections performed in 2000 was higher than expected due to a carry-over of 16 inspection requests from 1999 and a significant increase in requests in 2000.

A database of GMP inspections was completed in 2000 in order to provide management reports and information for coordinating inspections and to provide a direct input of data into the SIAMED application tracking system.

There was a marked increase in the number of good clinical practice (GCP) inspections performed for centralised procedures in 2000, involving sponsor, investigator and laboratory sites. This included a significant number of inspections performed outside of the EU.

Sampling and testing

Monitoring of centrally authorised medicinal products is performed by the Network of Official Medicines Control Laboratories. The activities of the network are coordinated by the European Department for the Quality of Medicines (Council of Europe) and the EMEA. The 1999-2000 testing programme was implemented for 35 centrally authorised products. No major problems were identified during the testing programme.

A testing programme for 2001 was agreed in 2000.

A total of 5 reports on quality problems concerning centrally authorised products were received and monitored by the EMEA, leading to 2 product recalls.

Mutual recognition agreements

On-going discussions or MRAs in transition period	
EC – Canada MRA	The equivalence assessment between EC and Canada of GMP compliance systems was completed in 2000. Also documentation, procedures and monitoring arrangements for the programme were agreed and are ready to be put into operation. However, the transition period was extended related to some outstanding issues that need to be resolved.
EC – US MRA	The evaluation of the EC and US legislation and GMP guidelines and compliance systems continued in 2000. The EU finalised its plans for the first evaluation visits to the US in March 2001. Current projections by the US indicate that the assessments of the EU would not be finished by the November 2001 end of the transition period.
EC – Switzerland MRA	The text of the agreement and explanatory notes were agreed and ratified in May 2000. The date of entry into force is expected to be summer 2001.
EC – Australia MRA and EC – New Zealand MRA (veterinary medicinal products)	Activities continued in 2000 to evaluate equivalence of these agreements.
MRAs in force	
EC – Australia MRA and EC – New Zealand MRA (human medicinal products)	Activities in 2000 included the development of a maintenance programme and other documents to facilitate the operation. Alert systems and certification schemes have been agreed in principle.

Certification of medicinal products

New arrangements for requesting certificates of a medicinal product were introduced in 2000 and posted on the EMEA web site. The efficiency of certificate production was improved by generating certificates directly from a database, resulting in an improved service in terms of time to issue of an average 4.9 days for 2000. An internal audit of procedures was conducted in 2000, leading to improved internal communication of pharmacovigilance rapid alerts and arrangements for defective product reporting.

The number of certificates requested fell from 9 652 in 1999 to 8 357 in 2000.

Joint CPMP/CVMP Quality working party

The Joint CPMP/CVMP Quality working party met on three occasions in 2000. The group finalised 7 guidelines for consultation and a further 8 guidelines for adoption. The group also liaised with the safety and efficacy working parties in the development of guidelines of common interest. A meeting with interested parties took place in October 2000.

4.2 Document management and publishing

Product information

A joint project on product information management between EMEA and the European Federation of Pharmaceutical Industries and Associations was launched in 2000. About 150 delegates from national competent authorities, pharmaceutical industry and software companies attended a workshop in September 2000 and welcomed the initiative.

The purpose of the product information management (PIM) project is to reduce the workload for industry and regulators for the maintenance of product information documents (summary of product characteristics, patient information and labelling). An average of 400 to 500 documents usually have to be revised for each product per change in product information.

The product information templates on the EMEA web site were reviewed in 2000 and the template for summary of product characteristics, labelling and package leaflet (template 1a) was revised in all 11 official EU languages following the adoption of the December 1999 Guideline on summary of product characteristics and is available on the EMEA web site.

Electronic submission

Electronic submission will facilitate data exchange between applicants and marketing authorisation holders with the EMEA. There are activities on product information management, marketing authorisation applications, maximum residue limits and the Xdossier Internet draft. The EMEA actively contributed in 2000 to discussions concerning the electronic common technical dossier (eCTD) and demonstrated a template for the eCTD at the ICH5 meeting in San Diego.

An electronic submission development web site was established in 2000 to provide information on work in progress: **http://esubmission.eudra.org**

Document management

A public tender procedure was conducted in 2000 for the selection of an electronic document management system. A feasibility study was begun at the end of 2000 prior to the final selection of the system provider. The system will focus in the initial stages on document control for the scientific advice and modular EPAR processes.

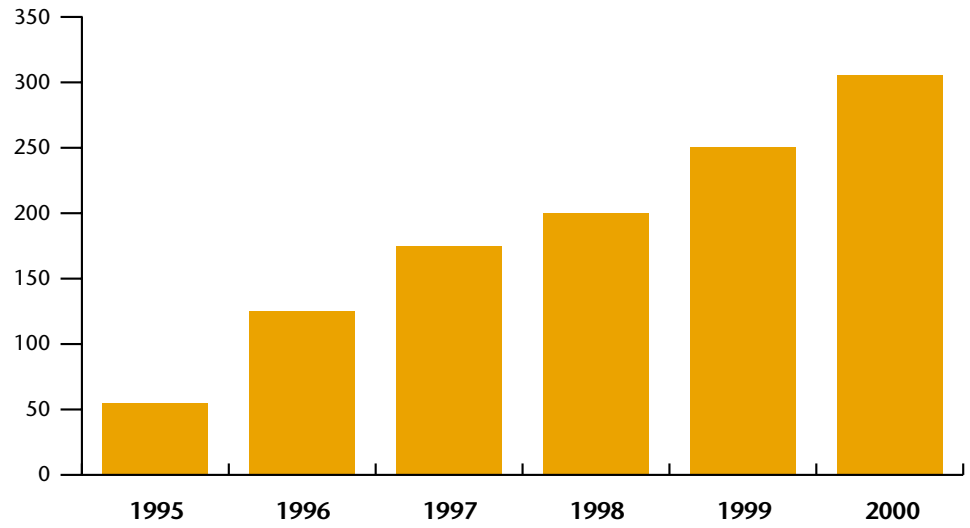
The sector coordinated the compilation of the EMEA catalogue of documents, which was published for the first time in November 2000. The number of subscribers for EMEA documents fell in 2000, with users increasingly using the web site to access information directly.

4.3 Conference services

EMEA meetings

Activities relating to the organisation of meetings at the EMEA increased by over 37 % in 2000.

Meetings at the EMEA 1995-2000



A call for tender for the provision of travel agency services was completed in 2000 and a service provider appointed The user requirements for improving the meeting management system were defined. A survey in 2000 to measure the level of satisfaction of the delegates showed a high level of satisfaction with the level of service provided by the EMEA.

Meeting facilities and technical equipment in the meeting rooms themselves were improved in 2000. Progress was made in planning the new conference rooms on floor 3.

Pan-European Regulatory Forum

The contract for the conduct of the first phase of the Pan-European Regulatory Forum on Pharmaceuticals (PERF I) was completed in 2000. A total of 119 delegates involved in the programme was handled by the sector and some 37 meetings. In addition a conference was organised in Hungary in February 2000 attended by over 350 delegates.

Chapter 5

Administration

Overview of the Administration Unit

Overview of the Administration Unit

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

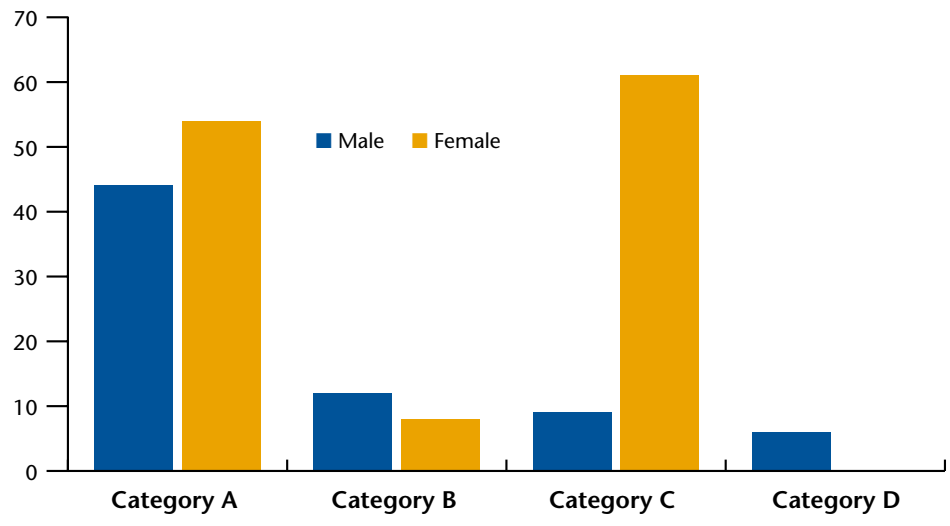
The Administration Unit is responsible for personnel, budget, accounting and facilities. In addition, a number of projects set out in the Work Programme have been completed:

- Euro consolidated into the financial and budgetary proceedings of the Agency
- recruitment targets achieved
- budget monitored and adjusted, particularly in response to increased revenues and the financing of new tasks such as orphan medicinal products and PERF II
- preparation of organisational restructuring of the Unit for the Evaluation of Medicines for Human Use
- restructuring and refurbishment of EMEA offices as part of building policy

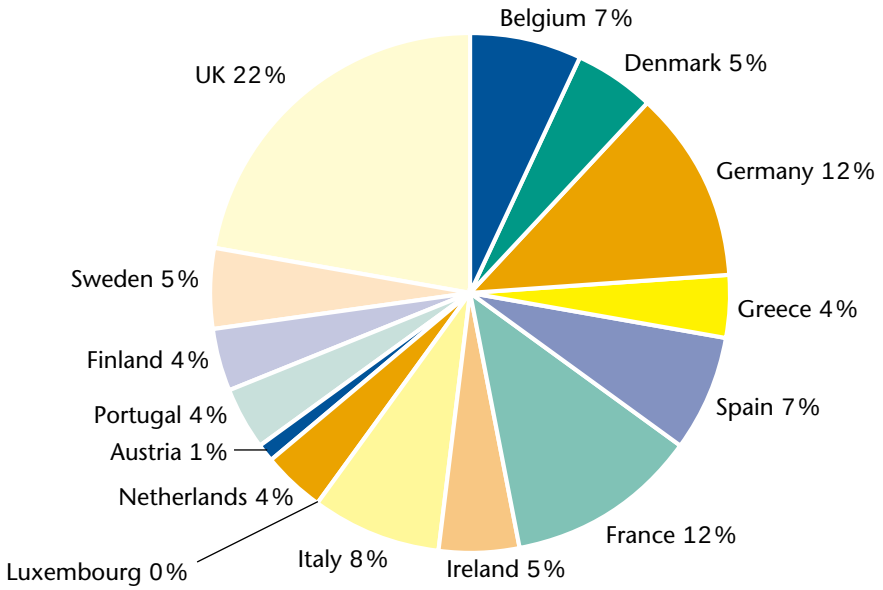
Personnel, budget and facilities

A personnel database was selected in 2000 that will facilitate personnel administration, in particular leave records, evaluation reports and other personnel details.

EMEA staff members by category and sex



EMEA staff members by nationality



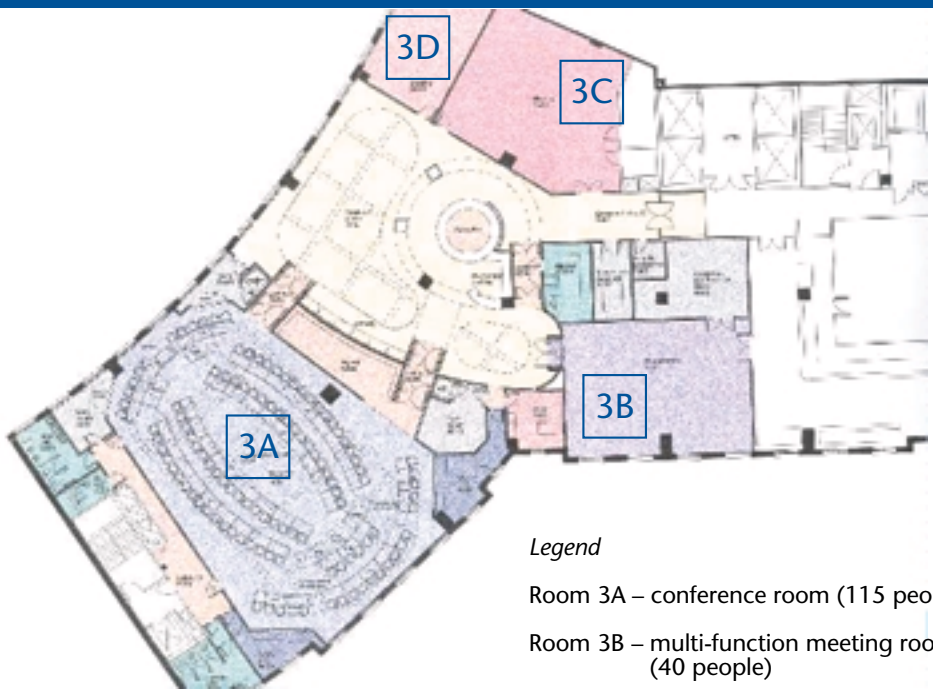
By constant budget monitoring and cost control the budget team successfully coordinated the execution of the budget and strove to achieve cost efficiencies.

A detailed review of training needs and the provision of training was undertaken during the year to improve the opportunities available to staff members.

Additional office space of 1 460 m^2 on the seventh floor of 7 Westferry Circus was occupied in 2000 to complement the existing three floors. The staff of the Unit for the Evaluation of Medicines for Human Use, about 100 in total, were able to move to the new office space in March 2000.

Facilities personnel also planned and began another major fitting out project in 2000 of the third floor for additional meeting rooms and delegate facilities. The work will be concluded in early 2001.

Refurbishment plans for the third floor, EMEA offices



Legend

Room 3A – conference room (115 people)

Room 3B – multi-function meeting room (40 people)

Room 3C – meeting room and video-conference suite (35 people)

Room 3D – meeting room (18 people)

Open area/reception

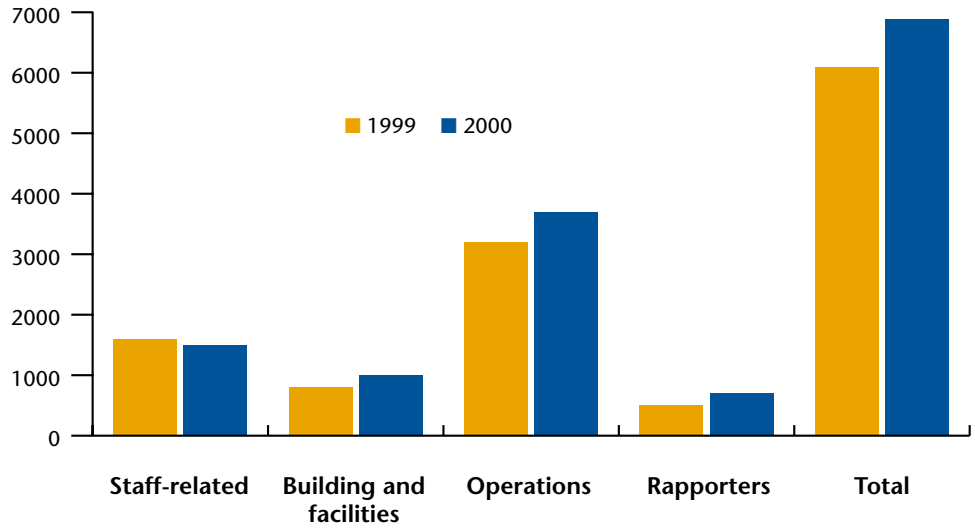
Accounts

Further productivity gains were seen in 2000 as increases in the volume of transactions processed were absorbed without increasing staff numbers. Following on from its implementation in 1999, further development of the SI2 budgetary accounting system and the implementation of the Sage general ledger system also contributed to increases in productivity.

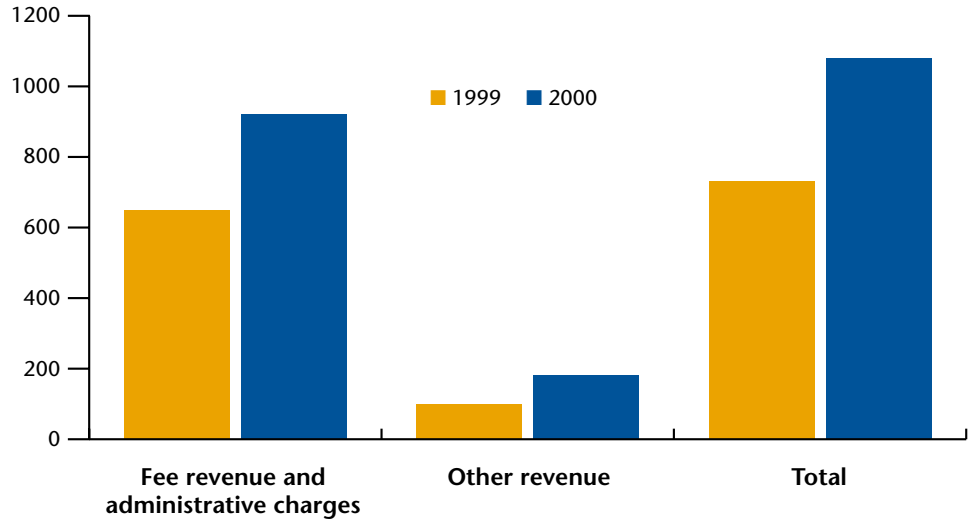
A forward exchange facility was negotiated with the Agency's banks to reduce to a minimum the effects of a weak Euro on the Agency's finances.

In 2000, 6 761 payments were made and 1 084 receipts processed, which is an increase of 11 % and 45 % respectively over 1999.

Volume of payments made in 1999 and 2000



Volume of income operations in 1999 and 2000



Annexes

Annexes

Annex 1: EMEA contact points and reference documents

EMEA contact points

Pharmacovigilance and product defect reporting
The constant monitoring of the safety of medicines after authorisation ('pharmacovigilance') is an important part of the work of the national competent authorities and EMEA. The EMEA receives safety reports from within the EU and outside concerning centrally authorised medicinal products and coordinates action relating to the safety and quality of medicinal products.

For matters relating to pharmacovigilance for medicinal products for human use	*Contact point* **Noël WATHION** Direct telephone (44-20) 74 18 85 92 E-mail: noel.wathion@emea.eudra.org
For matters relating to pharmacovigilance for medicinal products for veterinary use	*Contact point* **Barbara FREISCHEM** Direct telephone (44-20) 74 18 85 81 E-mail: barbara.freischem@emea.eudra.org
For product defect and other quality-related matters	*Contact point* **Stephen FAIRCHILD** Fax number for defective product rapid alerts (44-20) 74 18 85 90 E-mail: stephen.fairchild@emea.eudra.org

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

For enquiries concerning certificates for centrally authorised medicines for human or veterinary use	*Contact points* **Jonna SUNELL-HUET** Direct telephone (44-20) 74 18 84 65 E-mail: certificate@emea.eudra.org

Documentation services
A wide range of documents has now been published by the EMEA, including press releases, general information documents, annual reports and work programmes. These and other documents are available either on the Internet at **http://www.emea.eu.int** or by writing to:

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

A subscription service is available for all EMEA public documents, distributing documents electronically or in paper form.

Further information can be obtained from the above address or from

Contact point
Iro MAVROPOULOS
Direct telephone (44-20) 74 18 85 82
E-mail: subscriptions@emea.eudra.org

Requests for general information packs should be sent to

Contact point
Amanda BOSWORTH
Direct telephone (44-20) 74 18 84 08
E-mail: amanda.bosworth@emea.eudra.org

Requests for inspection of European experts lists
The list of European experts is available for inspection on request at the EMEA offices. Requests may be made either in writing to the EMEA or sent to the following e-mail addresses:

Human medicines' experts list	*human_experts@emea.eudra.org*
Veterinary medicines' experts list	*vet_experts@emea.eudra.org*
Inspectors experts list	*inspectors_experts@emea.eudra.org*

Media and press contacts
Representatives of the media should contact the following people for information:

For matters concerning medicinal products for human use

Contact point
Noël WATHION
Direct telephone (44-20) 74 18 85 92
E-mail: noel.wathion@emea.eudra.org

For matters concerning medicinal products for veterinary use

Contact point
Peter JONES
Direct telephone (44-20) 74 18 84 13
E-mail: peter.jones@emea.eudra.org

For general information on any other matter

Contact points
Martin HARVEY
Direct telephone (44-20) 74 18 84 27
E-mail: martin.harvey@emea.eudra.org

Antoine CUVILLIER
Direct telephone (44-20) 74 18 84 28
E-mail: antoine.cuvillier@emea.eudra.org

EU official publications

- Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, as amended (OJ L 214, 24.8.1993, p. 1)
- Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin, as amended (OJ L 224, 18.8.1990, p. 1)

- Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products, as amended (OJ L 147, 9.6.1975, p. 13)
- Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of Member States relating to veterinary medicinal products, as amended (OJ L 317, 6.11.1981, p. 1)
- Council Regulation (EC) No 2743/98 of 14 December 1998 amending Council Regulation (EC) No 297/95 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 345, 19.12.1998, p. 3)
- European Parliament and Council Regulation (EC) No 141/2000 of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1)
- EMEA budget statement for the financial year 2000, including final appropriations for 1999 and outturn for 1998 (OJ L 184, 24.7.2000, p. 1)

The texts of these and other provisions are available in the series *Rules governing medicinal products in the European Community*. These publications, along with copies of the Official Journal, are available from: Office for Official Publications of the European Communities, 2, rue de Mercier, L - 2985 Luxembourg, and also on the EudraLex Internet site at **http://pharmacos.eudra.org/eudralex/index.htm**

EMEA documents

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

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

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

Annex 2: EMEA budgets for 1999 to 2001

The summarised comparative budget statements in euro for 1999 to 2001 are given below.

	1999[1] (31.12.1999)		2000[2] (as at 31.12.2000)		2001[3] (as at 20.12.2000)	
Expenditure						
Staff						
salaries	15 074 905	*36.61%*	18 493 000	*33.45%*	21 772 000	*35.15%*
interim and other support persons	955 456	*2.32%*	1 058 000	*1.91%*	1 379 000	*2.23%*
other staff-related expenditure	1 191 570	2.89%	1 350 000	*2.44%*	1 501 000	*2.42%*
total title 1	**17 221 931**	**41.82%**	**20 901 000**	**37.80%**	**24 652 000**	**39.80%**
Building/equipment						
rent/charges	2 136 038	*5.19%*	5 212 220	*9.43%*	5 685 000	*9.18%*
expenditure on data processing	1 034 357	*2.51%*	2 423 500	*4.38%*	1 400 000	*2.26%*
other capital expenditure	1 824 960	*4.43%*	2 353 000	*4.26%*	824 500	*1.33%*
postage and communications	370 754	*0.90%*	480 000	*0.87%*	537 000	*0.87%*
other administrative expenditure	1 194 962	*2.90%*	1 593 000	*2.88%*	1 784 500	*2.88%*
total title 2	**6 561 071**	**15.93%**	**12 061 720**	**21.82%**	**10 231 000**	**16.52%**
Operational expenditure						
meetings	3 274 441	*7.95%*	3 487 000	*6.31%*	6 565 000	*10.60%*
evaluations	13 894 457	*33.74%*	18 682 500	*33.79%*	19 658 000	*31.74%*
translation	-	*0.00%*	p.m.	*0.00%*	428 000	*0.69%*
studies and consultants	93 650	*0.23%*	5 000	*0.01%*	180 000	*0.29%*
publications	137 130	*0.33%*	150 000	*0.27%*	220 000	*0.36%*
total title 3	**17 399 678**	**42.25%**	**22 324 500**	**40.38%**	**27 051 000**	**43.68%**
TOTAL EXPENDITURE	**41 182 680**	**100.00%**	**55 287 220**	**100.00%**	**61 934 000**	**100.00%**
Revenue						
fees	28 952 500	*70.31%*	39 154 000	*70.82%*	42 610 000	*68.81%*
general EU contribution	10 481 649	*25.45%*	13 200 000	*23.88%*	14 700 000	*23.73%*
special EU orphan medicinal product contribution	--	*0.00%*	1 000 000	*1.81%*	600 000	*0.97%*
contribution from EEA	--	*0.00%*	245 220	*0.44%*	250 000	*0.40%*
contribution from EU programmes (PERF)	800 000	*1.94%*	217 000	*0.39%*	2 440 000	*3.94%*
other	948 531	*2.30%*	1 471 000	*2.66%*	1 334 000	*2.15%*
TOTAL REVENUE	**41 182 680**	**100.00%**	**55 287 220**	**100.00%**	**61 934 000**	**100.00%**

Notes
(1) 1999 budget: outturn figures.
(2) 2000 budget: final appropriations.
(3) 2001 budget: draft appropriations.

Annex 3: Members of the Management Board

Chairman André BROEKMANS [1]

Members

European Parliament	Gianmartino BENZI, José-Luis VALVERDE LÓPEZ [2] *Alternates:* Dietrich HENSCHLER, Jean-Pierre REYNIER
European Commission	Fabio COLASANTI [3], Bertrand CARSIN [4] *Alternates:* Paul WEISSENBERG
Belgique/België	André PAUWELS, Frans GOSSELINCKX
Danmark	Ib VALSBORG, Jytte LYNGVIG [5]
Deutschland	Hermann Josef PABEL, Gerhard Josef KOTHMANN, *(Vice-chairman)*
Ελλάδα/Greece	Marios MARSELOS [6], Elias MOSSIALOS [7]
España	María Victoria de la CUESTA GARCIA [8], Ramón PALOP BAIXAULI [9]
France	Philippe DUNETON, Martin HIRSCH [10]
Ireland	Tom MOONEY, Colm GAYNOR [11]
Italia	Nello MARTINI, Romano MARABELLI
Luxembourg	Mariette BACKES-LIES
Nederlands	John LISMAN [12], Frits PLUIMERS
Österreich	Alexander JENTZSCH, Ernst LUSZCZAK
Portugal	Miguel ANDRADE [13], Rógerio GASPAR [14]
Suomi/Finland	Pekka JÄRVINEN [15], Hannes WAHLROOS
Sverige	Birgitta BRATTHALL, Anders BROSTRÖM
United Kingdom	Keith JONES, Michael RUTTER

Observers

Ísland	Rannveig GUNNARSDÓTTIR, Ingolf PETERSEN
Liechtenstein	Brigitte BATLINER, Peter MALIN
Norge/Noreg	Andreas DISEN, Gro Ramsten WESENBERG

1 Resigned at the 20 December 2000 meeting.
2 Replaced Dietrich HENSCHLER as of the 22 February 2000 meeting.
3 Replaced Jörn KECK as of the 22 February 2000 meeting.
4 Replaced Joachim HEINE as of the 22 February 2000 meeting.
5 Replaced Ib Bo LUMHOLTZ as of the 23 October 2000 meeting.
6 Replaced Haralampos MOUTSOPOULOS as of the 20 December 2000 meeting.
7 Replaced John PSOMAS as of the 20 December 2000 meeting.
8 Replaced María Theresa PAGÉS JIMÉNEZ as of the 20 December 2000 meeting.
9 Replaced Mariano BITRIÁN CALVO as of the 20 December 2000 meeting.
10 Replaced Jacques BOISSEAU as of the 22 February 2000 meeting.
11 Replaced John COSTELLOE as of the 22 February 2000 meeting.
12 Replaced André BROEKMANS as of the 7 June 2000 meeting.
13 Replaced José António ARANDA da SILVA as of the 22 February 2000 meeting.
14 Replaced Maria Armanda MIRANDA as of the 22 February 2000 meeting.
15 Replaced Kimmo LEPPO as of the 22 February 2000 meeting.

Annex 4: Members of the Committee for Proprietary Medicinal Products[1]

- · Jean-Michel ALEXANDRE (France), *Chairman*

- · Eric ABADIE (France)
- · Mark AINSWORTH (Danmark) [2]
- · Fernando de ANDRES-TRELLES (España)
- · Cristina AVENDAÑO (España)
- · Michalis AVGERINOS (Ελλάδα/Greece)
- · Rolf BASS (Deutschland) [3]
- · Daniel BRASSEUR (Belgique/België)
- · Hans van BRONSWIJK (Nederlands), *Vice-chairman* [4]
- · Geert DE GREEF (Belgique/België)
- · Jens ERSBØLL (Danmark)
- · Silvio GARATTINI (Italia)
- · Jacqueline GENOUX-HAMES (Luxembourg)
- · Willem van der GIESEN (Nederlands)
- · Lars GRAMSTAD (Norge/Noreg)
- · Manfred HAASE (Deutschland)
- · Magnús JÓHANNSSON (Ísland)
- · Tove KARLSUD (Norge/Noreg)
- · Pekka KURKI (Suomi/Finland) [5]
- · David LYONS (Ireland)
- · Jose Guimarães MORAIS (Portugal) [6]
- · Per NILSSON (Sverige)
- · Jean-Louis ROBERT (Luxembourg)
- · Frances ROTBLAT (United Kingdom) [7]
- · Patrick SALMON (Ireland) [8]
- · Tomas SALMONSON (Sverige)
- · Cristina SAMPAIO (Portugal)
- · Sigurdur THORSTEINSSON (Ísland)
- · Markku TOIVONEN (Suomi/Finland)
- · Jean-Hugues TROUVIN (France)
- · Guiseppe VICARI (Italia)
- · Patrick WALLER (United Kingdom)
- · Hans WINKLER (Österreich)
- · Christa WIRTHUMER-HOCHE (Österreich)
- · Julia YOTAKI (Ελλάδα/Greece)

1 The country of the nominating Member State is given for information purposes only.
2 Replaced Gorm JENSEN as of the January 2000 meeting.
3 Replaced Alfred HILDEBRANDT as of the September 2000 meeting.
4 Replaced Mary TEELING as Vice-chairman as of the September 2000 meeting.
5 Replaced Eva ALHAVA as of the March 2000 meeting.
6 Replaced Rogério GASPAR as of the January 2000 meeting.
7 Replaced David JEFFERYS as of the March 2000 meeting.
8 Replaced Mary TEELING as of the September 2000 meeting.

Annex 5: Members of the Committee for Veterinary Medicinal Products[1]

- Reinhard KROKER (Deutschland), *Chairman*

- Margarita ARBOIX (España)
- J. Gabriel BEECHINOR (Ireland), *Vice-chairman*
- Hanne BERGENDAHL (Norge/Noreg)
- Rory BREATHNACH (Ireland)
- Gabriella CONTI (Italia)
- Luis CORBALAN (España)
- Steve DEAN (United Kingdom)
- Johannes DICHTL (Österreich)
- Sabine EGLIT (Deutschland)
- Françoise FALIZE (Belgique/België)
- Christian FRIIS (Danmark)
- Helle HARTMANN FRIES (Danmark)
- Johannes HOOGLAND (Nederlands)
- Tonje HØY (Norge/Noreg)
- Albert HUBERTY (Luxembourg)
- Eva FABIANSON-JOHNSSON (Sverige)[2]
- Liisa KAARTINEN (Suomi/Finland)
- Herman LENSING (Nederlands)
- Jan LUTHMAN (Sverige)
- Agostino MACRI (Italia)
- Ioannis MALEMIS (Ελλάδα/Greece)
- Maria Leonor MEISEL (Portugal)[3]
- Manfred MOOS (Deutschland)
- Gérard MOULIN (France)
- John O'BRIEN (United Kingdom)
- Eugen OBERMAYR (Österreich)
- Sigurdur ÖRN HANSSON (Ísland)
- Orestis PAPADOPOULOS (Ελλάδα/Greece)[4]
- Paul-Pierre PASTORET (Belgique/België)
- Margarida PRATAS (Portugal)
- Halldór RUNÓLFSSON (Ísland)
- Jean-Claude ROUBY (France)
- Liisa SIHVONEN (Suomi/Finland)
- Marc WIRTOR (Luxembourg)

1 The country of the nominating Member State is given for information purposes only.
2 Replaced Annika WENNBERG as of the October 2000 meeting.
3 Replaced Carlos SINOGAS as of the July 2000 meeting.
4 Replaced Christos HIMONAS as of the April 2000 meeting.

Annex 6: Members of the Committee for Orphan Medicinal Products

Chairman (España)	Josep TORRENT i FARNELL

Members

Belgique/België	André LHOIR
Danmark	Jan RENNEBERG
Deutschland	Rembert ELBERS [1]
Ελλάδα/Greece	George STRATHOPOULOS [2]
France	François MEYER
Ireland	Brendan BUCKLEY
Italia	Domenica TARUSCIO
Luxembourg	Henri METZ [3]
Nederlands	Harrie SEEVERENS
Österreich	Hans Georg EICHLER
Portugal	José Manuel Gião TOSCANO RICO
Suomi/Finland	Kalle HOPPU
Sverige	Kerstin WESTERMARK
United Kingdom	Rashmi SHAH
Patient organisation representatives	Moisés ABASCAL ALONSO [5] Yann LE CAM, [5] *Vice-chairman* Alastair KENT [6]
EMEA representatives	Jean-Michel ALEXANDRE [7] Gianmartino BENZI Mary TEELING [8]

Observers

Ísland	Sigurdur THORSTEINSSON
Norge/Noreg	Randi NORDAL

1 Replaced Tilman OTT as of the September 2000 meeting.
2 Replaced Thrassyvoulos KEPHALAS as of the October 2000 meeting.
3 Replaced Mariette BACKES LIES as of the November 2000 meeting.
4 Replaced Alexander NICHOLSON as of the June 2000 meeting.
5 Representing the European Association for Orphan Diseases (Eurodis).
6 Representing the European Alliance of Genetic Support Groups (EAGS).
7 Resigned as of the December 2000 meeting.
8 Resigned as of the September 2000 meeting.

Annex 7: National competent authority partners

Further information on the national competent authorities is also available on the national authorities' Internet sites: **http://heads.medagencies.org** and **http://www.hevra.org**

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Annex 8: CPMP opinions in 2000 on medicinal products for human use

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - ATC - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CPMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
- Orgalutran - ganirelix - B	- N.V. Organon - NL	- H01CC01 - Prevention of premature luteinising hormone surges in conteolled ovarian hyperstimulation	- Solution for injection - 0.5 mg/ml - 2 presentations	- 29.01.1999 - 19.01.2000 - 162 days - 189 days	- 22.02.2000 - 17.05.2000 - 22.05.2000 - OJ C 183, 30.06.2000, p. 3
- Pegintron - peginterferon alfa-2b - A	- SP Europe - US	- L03AB10 - Treatment of chronic hepatitis C	- Powder and solvent for solution for injection - 50 µg/0.5 ml, 80 µg/0.5 ml, 100 µg/0.5 ml 120 µg/0.5 ml, 150µg/0.5 ml - 25 presentations	- 26.03.1999 - 17.02.2000 - 189 days - 139 days	- 27.03.2000 - 25.05.2000 - 05.06.2000 - OJ C 183, 30.06.2000, p. 3
- Viraferon PEG - peginterferon alfa-2b - A	- SP Europe - US	- L03AB10 - Treatment of chronic hepatitis C	- Powder and solvent for solution for injection - 50 µg/0.5 ml, 80 µg/0.5 ml, 100 µg/0.5 ml 120 µg/0.5 ml, 150µg/0.5 ml - 25 presentations	- 03.01.2000 - 17.02.2000 - 43 days - 0 days	- 27.03.2000 - 25.05.2000 - 05.06.2000 - OJ C 183, 30.06.2000, p. 3
- Lantus - insulin glargine - A	- Aventis Pharma Deutschland GmbH - D	- A10AE - Diabetes mellitus	- Solution for injection - 100 IU/ml - 7 presentations	- 23.04.1999 - 17.02.2000 - 215 days - 83 days	- 23.03.2000 - 06.06.2000 - 14.06.2000 - OJ C 183, 30.06.2000, p. 3
- Optisulin - insulin glargine - A	- Aventis Pharma Deutschland GmbH - D	- A10AE - Diabetes mellitus	- Solution for injection - 100 IU/ml - 7 presentations	- 24.09.1999 - 17.02.2000 - 116 days - 28 days	- 23.03.2000 - 27.06.2000 - 28.06.2000 - OJ C 216, 28.07.2000, p. 4
- Nyracta - rosiglitazone - B	- SmithKline Beecham Pharmaceuticals - UK	- A10BG02 - Combination treatment of Type II diabetes mellitus	- Film coated tablet - 1 mg, 2 mg, 4 mg, 8 mg - 12 presentations	- 18.12.1998 - 21.10.1999 - 186 days - 119 days	- 17.04.2000 - 11.07.2000 - 26.07.2000 - OJ C 244, 25.08.2000, p. 2
- Avandia - rosiglitazone - B	- SmithKline Beecham Pharmaceuticals - UK	- A10BG02 - Combination treatment of Type II diabetes mellitus	- Film coated tablet - 1 mg, 2 mg, 4 mg, 8 mg - 12 presentations	- 18.12.1998 - 21.10.1999 - 186 days - 119 days	- 17.04.2000 - 11.07.2000 - 28.06.2000 - OJ C 216, 28.07.2000, p. 4
- Venvia - rosiglitazone - B	- SmithKline Beecham Pharmaceuticals - UK	- A10BG02 - Combination treatment of Type II diabetes mellitusus	- Film coated tablet - 1 mg, 2 mg, 4 mg, 8 mg - 12 presentations	- 18.12.1998 - 21.10.1999 - 186 days - 119 days	- 17.04.2000 - 11.07.2000 - 26.07.2000 - OJ C 244, 25.08.2000, p. 2
- Myocet - doxorubicin - B	- The Liposome Company - US	- L01DB - Treatment of metastatic breast cancer	- Powder and pre-admixtures for concentrate for, liposomal dispersion for infusion - 50 mg - 1 presentation	- 30.07.1999 - 12.04.2000 - 167 days - 91 days	- 17.05.2000 - 13.07.2000 - 26.07.2000 - OJ C 244, 25.08.2000, p. 2
- Datscan - ioflupane - B	- Nycomed Amersham - UK	- V09AB03 - Diagnosis of Parkinson disease	- Solution for injection - 74 MBq/ml - 1 presentation	- 18.12.1998 - 16.03.2000 - 178 days - 272 days	- 05.05.2000 - 27.07.2000 - 02.08.2000 - OJ C 244, 25.08.2000, p. 10

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - ATC - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CPMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
- Visudyne - verteporfin - B	- Ciba Vision - CH	- L01XX - Treatment of age-related macular degeneration	- Powder for solution for infusion - 15 mg - 1 presentation	- 27.08.1999 - 12.04.2000 - 138 days - 63 days	- 15.05.2000 - 27.07.2000 - 31.07.2000 - OJ C 244, 25.08.2000, p. 10
- NovoMix 30 - insulin aspart - A	- Novo Nordisk - DK	- A10AD - Diabetes mellitus	- Suspension for injection - 100 IU/ml - 8 presentations	- 24.09.1999 - 12.04.2000 - 144 days - 55 days	- 17.05.2000 - 01.08.2000 - 01.08.2000 - OJ C 244, 25.08.2000, p. 10
- Kogenate Bayer - octocog alfa - A	- Bayer AG - D	- B02BD02 - Treatment and prophylaxis of bleeding in haemophilia A	- Powder and solvent for solution for injection - 250 IU, 500 IU, 1000 IU - 3 presentations	- 26.02.1999 - 16.03.2000 - 182 days - 201 days	- 05.06.2000 - 04.08.2000 - 07.08.2000 - OJ C 244, 25.08.2000, p. 10
- Helixate NexGen - octocog alfa - A	- Bayer AG - D	- B02BD02 - Treatment and prophylaxis of bleeding in haemophilia A	- Powder and solvent for solution for infusion - 250 IU, 500 IU, 1000 IU - 3 presentations	- 26.02.1999 - 16.03.2000 - 182 days - 201 days	- 05.06.2000 - 04.08.2000 - 07.08.2000 - OJ C 244, 25.08.2000, p. 10
- Hepacare - triple antigen hepatitis B vaccine - A	- Medeva Pharma Ltd - UK	- J07BC - Immunisation against hepatitis B virus in adults	- Suspension for injection - Monodose preparation of 1 ml contains Hepatitis B surface antigen S, pre-S1 and pre S2 20 µg - 2 presentations	- 23.10.1998 - 16.03.2000 - 210 days - 293 days	- 16.05.2000 - 04.08.2000 - 07.08.2000 - OJ C 244, 25.08.2000, p. 10
- Herceptin - trastuzumab - A	- Roche Registration Ltd - CH	- L01XC03 - Treatment of patients with metastatic breast cancer whose tumour overexpress HER2	- Powder for concentrate for solution for infusion - 150 mg - 1 presentation	- 26.02.1999 - 25.05.2000 - 147 days - 305 days	- 03.07.2000 - 28.08.2000 - 04.09.2000 - OJ C 277, 29.09.2000, p. 14
- Keppra - levetiracetam - B	- UCB S.A. - US	- N03A - Adjunctive therapy in the partial onset seizures in epilepsy	- Film coated tablet - 250 mg, 500 mg, 750 mg, 1000 mg - 26 presentations	- 26.02.1999 - 29.06.2000 - 187 days - 300 days	- 31.07.2000 - 29.09.2000 - 11.10.2000 - OJ C 308, 27.10.2000, p. 12
- Panretin - alitretinoin - B	- Ligand Pharmaceuticals Ltd - US	- L01XX22 - Ttopical treatment of cutaneous lesions in AIDS related Kaposi's sarcoma	- Gel - 0.1 %w/w - 1 presentation	- 26.02.1999 - 29.06.2000 - 174 days - 313 days	- 31.07.2000 - 11.10.2000 - 18.10.2000 - OJ C 337, 28.11.2000. p. 2
- Glustin - pioglitazone - B	- Takeda Europe - JP	- A10BG03 - Combination treatment of Type II Diabetes mellitus	- Tablet - 15 mg, 30 mg - 6 presentations	- 23.04.1999 - 29.06.2000 - 178 days - 251 days	- 31.07.2000 - 11.10.2000 - 17.10.2000 - OJ C 337, 28.11.2000. p. 2
- Actos - pioglitazone - B	- Takeda Europe - JP	- A10BG03 - Combination treatment of Type II Diabetes mellitus	- Tablet - 15 mg, 30 mg - 6 presentations	- 23.04.1999 - 29.06.2000 - 178 days - 251 days	- 31.07.2000 - 13.10.2000 - 19.10.2000 - OJ C 337, 28.11/00. p. 2
- Agenerase - amprenavir - B	- Glaxo Group - UK	- J05AE05 - Treatment of HIV infected adults and children	- Capsule, soft, Oral solution - 50 mg, 150 mg, 15 mg/ml - 4 presentations	- 20.11.1998 - 29.06.2000 - 219 days - 324 days	- 09.08.2000 - 20.10.2000 - 25.10.2000 - OJ C 337, 28.11.2000. p. 2

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - ATC - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CPMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
- Infanrix hexa - Hep B-IPV HIB vaccine - A	- SmithKline Beecham Biologicals S.A. - B	- JO7CA - Immunisation against Haemophilus influenza, Diphtheria, Pertussis, Tetanus, HepB and Poliomyelitis	- Powder and suspension for suspension for injection - Diphtheria toxoid, adsorbed ≥. 30IU Tetanus toxoid, adsorbed ≥ 40IUPertussis toxoid, adsorbed 25 µg Filamentous haemagglutinin, adsorbed 25 µg Pertactin, adsorbed 8 µg Recombinant Hepatitis B surface Antigen (S protein), adsorbed 10 µg Inactivated type 1 Poliovirus 40 DU Inactivated type 2 Poliovirus 8 DU Inactivated type 3 Poliovirus 32 DU Conjugate of Haemophilus influenzae type b capsular polysaccharide (PRP) 10 µg and Tetanus toxoid (T), adsorbed (PRP-T) 20-40 µg - 16 presentations	- 30.07.1999 - 29.06.2000 - 201 days - 132 days	- 09.08.2000 - 23.10.2000 - 26.10.2000 - OJ C 337, 28.11.2000. p. 2
- Infanrix penta - Hep B-IPV vaccine - A	- SmithKline Beecham Biologicals S.A. - B	- JO7CA - Primary and booster immunisation of infants against Diphtheria, Tetanus, Pertussis, Hepatitis B and Poliomyelitis	- Suspension for injection - Diphtheria toxoid, adsorbed ≥ 30IU Tetanus toxoid, adsorbed ≥ 40IU Pertussis toxoid, adsorbed 25 µg Filamentous haemagglutinin, adsorbed 25 µg, Pertactin, adsorbed 8 µg Recombinant Hepatitis B surface antigen (S protein), adsorbed 10 µg Inactivated type 1 Poliovirus 40 DU Inactivated type 2 Poliovirus 8 DU Inactivated type 3 Poliovirus 32 DU - 8 presentations	- 30.07.1999 - 29.06.2000 - 201 days - 132 days	- 09.08.2000 - 23.10.2000 - 26.10.2000 - OJ C 337, 28.11.2000. p. 2
- Hexavac - Comb vaccine - A	- Pasteur Merieux MSD - F	- JO7CA - Immunisation Diphtheria, pertussis, Tetanus, HepB, Poliomyelitis, Haemophilus influenza	- Suspension for injection - Purified diphtheria toxoid, adsorbed ≥ 20 IU, Purified tetanus toxoid, adsorbed ≥ 40 IU Purified pertussis toxoid, adsorbed 25 µg Purified pertussis filamentous haemagglutinin adsorbed 25 µg Recombinant hepatitis B surface antigen 5.0 µg Inactivated poliomyelitis virus: type 1 40 D units type 2 8 D units type 3 32 D units Haemophilus influenzae polysaccharide type b 12 µg conjugated to tetanus toxoid (24 µg) - 8 presentations	- 30.07.1999 - 26.06.2000 - 180 days - 153 days	- 10.08.2000 - 23.10.2000 - 26.10.2000 - OJ C 337, 28.11.2000. p. 2
- Luveris - lutropin alfa - A	- Ares Serono (Europe) Ltd - CH	- G03G - Stimulation of follicular development in women with servere Leng HEng and FSH deficiency	- Powder and solvent for solution for injection - 75 IU - 6 presentations	- 25.06.1999 - 27.07.2000 - 192 days - 200 days	- 07.09.2000 - 29.11.2000 - 30.11.2000 - OJ C 2, 05.01.2001, p. 3

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - ATC - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CPMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
- NeoSpect - depreotide - B	- Nycomed Imaging A/S - NO	- V09IA05 - Scintigraphic imaging of suspected malignant tumours in the lung	- Kit for radiopaharmaceutical preparation - 47 µg - 2 presentations	- 20.11.1998 - 27.07.2000 - 204 days - 404 days	- 28.08.2000 - 29.11.2000 - 04.12.2000 - OJ C 2, 05.01.2001, p. 3
- Trizivir - lamivudine zidovudine abacavir - B	- Glaxo Group - UK	- J05AF30 - Treatment of HIV-1 infected patients	- Film coated tablet - 150/300/300 mg - 3 presentations	- 21.01.2000 - 29.06.2000 - 158 days - 0 days	- 13.10.2000 - 08.12.2000 - -
- Nutropin AQ - somatropin - A	- Schwarz Pharma AG - D	- H01AC01 - Treatment of growth failure	- Solution for injection - 5 mg/ml - 2 presentations	- 21.10.1999 - 21.09.2000 - 174 days - 186 days	- 05.12.2000 - - -
- Neurobloc - botulinum toxin type B - B	- Elan Pharma International Ltd - UK	- M03AX01 - Treatment of cervical cancer	- Solution for injection - 5000 IU/ml - 3 presentations	- 27.08.1999 - 21.09.2000 - 187 days - 229 days	- 21.11.2000 - - -
- Tenecteplase - tenecteplase - A	- Boehringer Ingelheim International GmbH - D	- B01AD - Treatment of suspected myocardial infarction	- Powder and solvent for solution for injection - 6000 IU, 8000 IU, 10000 IU - 3 presentations	- 24.09.1999 - 21.09.2000 - 176 days - 215 days	- 27.11.2000 - - -
- Metalyse - tenecteplase - A	- Boehringer Ingelheim International GmbH - D	- B01AD - Treatment of suspected myocardial infarction	- Powder and solvent for solution for injection - 6000 IU, 8000 IU, 10000 IU - 3 presentations	- 24.09.1999 - 21.09.2000 - 176 days - 215 days	- 27.11.2000 - - -
- Azomyr - desloratadine - B	- SP Europe - US	- R06AX27 - Relief of symptoms associated with seasonal allergic rhinitis	- Film coated tablet - 5 mg - 13 presentations	- 24.09.1999 - 21.09.2000 - 201 days - 159 days	- 06.11.2000 - - -
- Opulis - desloratadine - B	- SP Europe - US	- R06AX27 - Relief of symptoms associated with seasonal allergic rhinitis	- Film coated tablet - 5 mg - 13 presentations	- 24.09.1999 - 21.09.2000 - 201 days - 159 days	- 06.11.2000 - - -
- Allex - desloratadine - B	- SP Europe - US	- R06AX27 - Relief of symptoms associated with seasonal allergic rhinitis	- Film coated tablet - 5 mg - 13 presentations	- 24.09.1999 - 21.09.2000 - 201 days - 159 days	- 06.11.2000 - - -
- Aerius - desloratadine - B	- SP Europe - US	- R06AX27 - Relief of symptoms associated with seasonal allergic rhinitis	- Film coated tablet - 5 mg - 13 presentations	- 24.09.1999 - 21.09.2000 - 201 days - 159 days	- 06.11.2000 - - -
- Neoclarityn - desloratadine - B	- SP Europe - US	- R06AX27 - Relief of symptoms associated with seasonal allergic rhinitis	- Film coated tablet - 5 mg - 13 presentations	- 24.09.1999 - 21.09.2000 - 201 days - 159 days	- 06.11.2000 - - -
- Xeloda - capecitabine - B	- Roche Registration Ltd - CH	- L01BC - treatment of metastatic colorectal cancer	- Film coated tablet - 150 mg, 500 mg - 2 presentations	- 21.10.1999 - 21.09.2000 - 201 days - 159 days	- 20.11.2000 - - -
- Ovidrelle - chorio-gonadotropin alfa - A	- Ares Serono (Europe) Ltd - CH	- G03GA01 - Assisted reproductive techniques sus as in vitro fertilisation (IVF)	- Powder and solvent for solution for injection - 250 µg - 6 presentations	- 21.10.1999 - 21.09.2000 - 174 days - 186 days	- 23.11.2000 - - -

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - ATC - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CPMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
- Prevenar - Prevenarp-neumococcal conjugate vaccine - A	- Wyeth-Lederle Vaccines S.A. - US	- J07AL - Active immunisation of infants and children against invasive disease, pneumonia and otitis media caused by Streptococcus pneumoniae	- Suspension for injection - A monodose preparation of 0.5 ml contains *Streptococcus pneumoniae*: saccharide suspension of Serotype 4 2 (gSerotype 9V 2 µg Serotype 14 2 µg Serotype 18C 2 µg Serotype 19F 2 µg Serotype 23F 2 µg Serotype 6B 4 µg Conjugated to CRM197 carrier protein - 20 µg - 2 presentations	- 19.11.1999 - 21.09.2000 - 205 days - 125 days	- 21.11.2000 - - -
- Prandin - replaglinide - B	- Novo Nordisk - DK	- A10BX02 - Treatment of Type II diabetes mellitus	- Tablet - 0.5 mg, 1.0 mg, 2.0 mg, - 18 presentations	- 30.06.2000 - 21.09.2000 - 91 days - 0 days	- 26.10.2000 - - -
- Rapamune - sirolimus - B	- Wyeth Europe Ltd - US	- L04AA10 - rophylaxis of organ rejection in patient receiving renal transplants	- Oral solution - 1 mg/ml - 5 presentations	- 29.01.1999 - 16.11.2000 - 214 days - 393 days	- 08.01.2001 - - -
- Targretin - bexarotene - B	- Ligand Pharmaceuticals Ltd - US	- L01XX25 - Treatment of skin manifestations of advanced stage of cutaneous T-cell Lymphoma	- Capsule, soft - 75 mg - 1 presentation	- 17.12.1999 - 16.11.2000 - 197 days - 159 days	- - - -
- Fasturtec - rasburicase - A	- Sanofi - F	- V03AF07 - Treatment of tumor induced hpreuricemia	- Powder and solvent for solution for infusion - 1.5 mg/ml - 1 presentation	- 21.01.2000 - 16.11.2000 - 177 days - 118 days	- - - -
- Trazec - nateglinide - B	- Novartis Europharm Ltd - CH	- A10B03 - Combination treatment of diabetes mellitus Type II	- Film coated tablet - 60 mg, 120 mg, 180 mg - 21 presentations	- 31.10.2000 - 14.12.2000 - 58 days - 0 days	- - - -
- Vaniqa - eflornithine - B	- Bristol Myers Squibb Pharma EEIG - US	- D11AX - Treatment of facial hirsutism	- Cream - 11.5 % - 3 presentations	- 03.01.2000 - 14.12.2000 - 182 days - 157 days	- - - -
- Starlix - nateglinide - B	- Novartis Europharm Ltd - CH	- A10BX03 - Combination treatment of diabetes mellitus Type II	- Film coated tablet - 60 mg, 120 mg, 180 mg - 21 presentations	- 21.01.2000 - 14.12.2000 - 179 days - 144 days	- - - -
- Zometa - zoledronic acid - B	- Novartis Europharm Ltd - CH	- M05BA08 - Treatment of tumour induced hypercalcaemia	- Powder and solvent for solution for infusion - 4 mg - 3 presentations	- 21.01.2000 - 14.12.2000 - 177 days - 146 days	- - - -
- Kaletra - lopinavir/ritonavir - B	- Abbott Laboratories - US	- J05A - Combination treatment in combination of HIV-1 infected patients	- Capsule, soft, Oral solution - 133.3/33.3 mg, 80/20 mg/ml - 3 presentations	- 18.07.2000 - 14.12.2000 - 145 days - 0 days	- - - -
- SonoVue - sulphur hexafluoride - B	- Bracco S.P.A. - I - V08DA	- Ultrasound agent to enhance the echogenicity of the blood	- Powder for injection - 8 µl/ml - 2 presentations	- 27.08.1999 - 14.12.2000 - 194 days - 276 days	- - - -
- Osteogenis Protein 1 Howmedia International - Osteogenic Protein-1 BMP-7 - A	- Stryker-Biotech - US	- M09AX - Treatment of non-union of tibia of at least 9 month duration	- Powder for suspension for implantation - 3.5 mg - 1 presentation	- 30.07.1999 - 14.12.2000 - 201 days - 297 days	- - - -

Annex 9: CVMP opinions in 2000 on medicinal products for veterinary use

Centralised applications

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - Target species - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CVMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
Ibraxion Inactivated vaccine Part A	Merial F	Cattle Vaccine against IBR (QJ57DA)	Emulsion for injection 2 ml 1	- 17.11.1998 - 10.11.1999 - 210 days - 176 days	- 10.12.1999 - 09.03. 00 - 10.03. 00 - OJ C 95, 04.04.2000
Metacam Meloxicam Part B extension	Boehringer Ingelheim D	Dogs Initiation therapy for alleviation of pain and inflammation (QM01AC06)	Solution for injection 5 mg/ml 1	- 12.01.1999 - 10.11.1999 - 210 days - 92 days	- 10.12.1999 - 24.03.2000 - 27.03.2000 - OJ C 120, 28.04.2000
Incurin Oestriol Part B	Intervet International NL	Dogs Hormone-dependent urinary incontinence (QG03CA04)	Scored tablets 1 mg 1	- 14.07.1998 - 08.12.1999 - 210 days - 302 days	- 07.01.2000 - 24.03.2000 - 29.03.2000 - OJ C 120, 28.04.2000
Rabigen SAG2 Live vaccine Part A	Virbac F	Foxes Vaccine against rabies (QJ57HA)	Liquid within a blister pack embedded in a bait 8 log 10 CCID50 2	- 23.03.1998 - 08.12.1999 - 196 days - 428 days	- 07.01.2000 - 06.04.2000 - 10.04.2000 - OJ C 120, 28.04.2000
Eurifel FeLV Live vaccine Part A	Merial F	Cats Vaccine against feline leukaemis (QJ57BA04)	Pellet plus diluent 1 ml 3	- 12.01.1999 - 08.12.1999 - 183 days - 120 days	- 12.11.1999 - 09.06.2000 - 14.06.2000 - OJ C 183, 30.06.2000
Ibaflin Ibafloxacin Part B	Intervet International NL	Dogs Pyoderma (QG51AC)	Tablet 150 & 300mg 1	- 12.01.1999 - 09.02.2000 - 210 days - 184 days	- 10.03.2000 - 13.06.2000 - 15.06.2000 - OJ C 183, 30.06.2000
Metacam Meloxicam Part B (extension)	Boehringer Ingelheim D	Dogs Post-operative pain (QM01AC06)	Solution for injection 5mg/ml 1	- 02.01.2000 - 19.04.2000 - 101 days - 7 days	- 28.04.2000 - 15.09.2000 - 18.09.2000 - OJ C 277, 29.09.2000
Econor Valnemulin Part B (extension)	Novartis A	Pigs Prevention & treatment of dysentery (QJ01XX94)	0.5% premix various 2	- 10.08.1999 - 19.04.2000 - 210 days - 43 days	- 19.05.2000 - 15.09.2000 - 20.09.2000 - OJ C 308, 27.10.2000
Econor Valnemulin Part B extension	Novartis A	Pigs Prevention /treatment of dysentery and treatment/control of enzootic pneumonia (QJ01XX94)	10%/50% premix various 2	- 12.10.1999 - 08.03.2000 - 148 days - 0	- 07.04.2000 - 15.09.2000 - 20.09.2000 - OJ No. 308, 27.10.2000
Econor Valnemulin Part B (extension)	Novartis A	Pigs Prevention /treatment of dysentery and treatment/control of enzootic pneumonia (QJ01XX94)	10%/50% premix various 2	- 12.10.1999 - 08.03.2000 - 148 days - 0	- 07.04.2000 - 15.09.2000 - 22.09.2000 - OJ C 308, 27.10.2000

Product - Brandname - INN - Part A/B	Company - Name - Origin	Therapeutic area - Target species - Indication	Presentation - Form - Dosage - Number of presentations	EMEA/CVMP - Validation - Opinion - Active time - Clock stop	Commission - Opinion received - Date of Decision - Notification - Official Journal
Dicural Difloxacin Part B (extension)	Fort Dodge Animal Health NL	Cattle & pigs Antibacterial for systemic use (QJ01MA)	Solution for injection 50 mg/ml 3	- 16.12.1998 - 21.06.2000 - 203 days - 351 days	- 21.07.2000 - 24.10.2000 - 25.10.2000 - OJ C 337, 28.11.2000
Poulflox Difloxacin Part B	Virbac S.A. F	Poultry Antibacterial for systemic use (QJ01MA94)	Oral solution 100 mg/ml 3	- 09.12.1999 - 21.06.2000 - 152 days - 43 days	- 21.07.2000 - 16.11.2000 - OJ C 2, 05.01.2001
Bayovac CSF Marker Live vaccine Part A	Bayer D	Pigs Marker vaccine against Classical Swine Fever (QJ57EA)	Emulsion for injection E2 glycoprotein of Classical Swine Fever virus 4	- 16.12.1998 - 19.07.2000 - 210 days - 309 days	- 07.08.2000
Porcilis AR-T-DF Inactivated vaccine Part A	Intervet International NL	Pigs Vaccine against atrophic rhinitis (QJ57EA)	Suspension for injection 2 ml 2	- 12.01.1999 - 19.07.2000 - 204 days - 336 days	- 18.08.2000 - 16.11.2000 - OJ C 2, 05.01.2001
Pruban Rescortol butyrate Part B	Intervet International NL	Dogs Anti-inflammatory for cutaneous inflammatory disorders (QD07AC90)	Cream 1 mg/g 1	- 15.09.1998 - 19.07.2000 - 196 days - 477 days	- 18.08.2000 - 16.11.2000 - OJ C 2, 05.01.2001
Pirsue Pirlimycin Part B	Pharmacia Upjohn B	Dairy cattle Clinical & sub-clinical mastitis (QJ51FF90)	Sterile solution for intramammary use 5 mg/ml 4	- 12.01.1999 - 11.10.2000 - 210 days - 428 days	- 10.11.2000
Zubrin Tepoxalin Part B	Schering-Plough UK	Dogs Treatment of pain & inflammation	Oral lyophilisate 30,50,100 & 200 mg/ml 39	- 18.05.1999 - 08.11.2000 - 210 days - 330 days	- 08.12.2000
Eurican herpes 205 Inactivated vaccine Part B	Merial F	Dogs Vaccine against canine herpes	Powder plus solvent for emulsion for injection 1 ml 2	- 13.07.1999 - 08.11.2000 - 209 days - 274 days	- 08.12.2000

Establishment of maximum residue limits for new substances

Substance - INN	Therapeutic area - Target species	EMEA/CVMP - Validation - Opinion - Active time - Clockstop	Commission - Sent to Commission - Date of Regulation - Official Journal
Bismuth subnitrate (extension)	Bovine	- 18.06.1999 - 13.10.1999 - 113 days - 0	- 12.11.1999 - 19.06.2000 - OJ L 145, 20.06.2000
Acetyl isovaleryl tylosin tartrate	Porcine	- 18.10.1995 - 13.10.1999 - 195 days - 1260 days	- 12.11.1999 - 19.06.2000 - OJ L 145, 20.06.2000
Methylprednisolone	Bovine	- 13.07.1999 - 13.10.1999 - 92 days - 0	- 12.11.1999 - 19.06.2000 - OJ L 145, 20.06.2000
Deltamethrin (extension)	Fin fish	- 09.12.1999 - 08.03.2000 - 90 days - 0	- 07.04.2000 - 15.09.2000 - OJ L 234, 16.09.2000
Tylosin (extension)	Eggs	- 09.11.1999 - 08.03.2000 - 90 days - 0	- 07.04.2000 - 15.09.2000 - OJ L 234, 16.09.2000
Dicyclanil	Ovine	25.02.1997 - 08.03.2000 - 281 days - 825 days	- 07.04.2000 - 15.09.2000 - OJ L 234, 16.09.2000
Tilmicosin (extension)	Rabbit	- 16.07.1999 - 13.10.1999 - 86 days - 0	- 12.11.1999 - 20.10.2000 - OJ L 269, 21.10.2000
Flumequine (extension)	Bovine milk & turkey	- 27.07.1999 - 10.11.1999 - 89 days - 0	- 09.12.1999 - 20.10.2000 - OJ L 269, 21.10.2000
Tiamulin (extension)	Rabbit	- 14.10.1999 - 12.01.2000 - 90 days - 0	- 11.02.2000 - 20.10.2000 - OJ L 269, 21.10.2000
Dicyclanil (modification)	Sheep fat	- 23.02.2000 - 17.05.2000 - 84 days - 0	- 16.06.2000 - 27.10.2000 - OJ L 276, 28.10.2000
Butafosfan (extension)	Dairy cattle	- 19.01.2000 - 19.04.2000 - 90 days - 0	- 19.05.2000 - 27.10.2000 - OJ L 276, 28.10.2000
Tilmicosin (extension)	Bovine milk	- 22.02.1999 - 19.04.2000 - 203 days - 210 days	- 19.05.2000 - 27.10.2000 - OJ L 276, 28.10.2000
Phoxim (extension)	Ovine	- 19.01.2000 - 19.04.2000 - 90 - 0	- 19.05.2000 - 27.10.2000 - OJ L 276, 28.10.2000

Substance - INN	Therapeutic area - Target species	EMEA/CVMP - Validation - Opinion - Active time - Clockstop	Commission - Sent to Commission - Date of Regulation - Official Journal
Flumethrin (extension)	Ovine	- 19.01.2000 - 19.04.2000 - 90 days - 0	- 19.05.2000 - 27.10.2000 - OJ L 276, 28.10.2000
Flunixin (extension)	Equine	- 23.03.2000 - 21.06.2000 - 90 days - 0	- 21.07.2000 - 29.12.2000 - OJ L 336, 30.12.2000
Toltrazuril (extension)	Porcine	- 16.02.1999 - 21.06.2000 - 206 days - 284 days	- 21.07.2000 - 29.12.2000 - OJ L 336, 30.12.2000
Thiamphenicol (extension)	Porcine, Ovine, Turkey, Fish	- 15.05.1998 - 21.06.2000 - 206 days - 562 days	- 08.11.2000
Difloxacin (extension)	Bovine, Porcine	- 14.07.1998 - 21.06.2000 - 205 days - 503 days	- 21.07.2000 - 29.12.2000 - OJ L 336, 30.12.2000
Halofuginone	Bovine	- 10.12.1996 - 21.06.2000 - 281 days - 1008 days	- 21.07.2000 - 29.12.2000 - OJ L 336, 30.12.2000
Linear dodecyl benzene sulfonic acid	Bovine	- 22.01.1999 - 19.07.2000 - 195 days - 321 days	- 18.08.2000
Phoxim (extension)	Ovine	- 19.01.2000 - 19.07.2000 - 120 days - 0	- 18.08.2000
Acetyl isovaleryl tylosin tartrate	Porcine	- 18.01.1995 - 13.09.2000 - 274 days - 1790 days	- 18.02.2000
Florfenicol (extension)	Fish	- 29.01.1996 - 11.11.2000 - 212 days - 1504 days	- 08.11.2000
Meloxicam (extension)	Porcine	- 07.09.2000 - 06.12.2000 - 90 days - 0 days	- 04.01.2001
Tilmicosin z(extension)	Turkey	- 07.09.2000 - 06.12.2000 - 90 days - 0 days	- 04.01.2001

Annex 10: COMP opinions in 2000 on orphan medicinal products

Product	Sponsor	Indication	EMEA/COMP - Submission - Validation - Opinion - Active time	Commission - Opinion received - Date of Designation
Somatropin	Ares-Serono (Europe) Ltd	AIDS-wasting	- 28.04.2000 - 15.06.2000 - 11.07.2000 - 27 days	- 17.07.2000 - 08.08.2000
Alpha-Galactosidase A	TKT Europe-5S AB	Treatment of Fabry disease	- 03.05.2000 - 15.06.2000 - 11.07.2000 - 27 days	- 17.07.2000 - 08.08.2000
Alpha-Galactosidase A	Genzyme BV	Treatment of Fabry disease	- 12.05.2000 - 15.06.2000 - 11.07.2000 - 27 days	- 17.07.2000 - 08.08.2000
Fluorouracil	Ethypharm S.A.	Treatment of glioblastoma	- 26.05.2000 - 31.07.2000 - 13.09.2000 - 45 days	- 18.09.2000 - 18.10.2000
Gemtuzumab ozogamicin	Wyeth-Ayerst Research	Treament of acute myeloid leukaemia	- 07.06.2000 - 31.07.2000 - 13.09.2000 - 45 days	- 18.09.2000 - 18.10.2000
1,5-(Butylimino)-1,5-dideoxy, D-glucitol	Oxford GlycoSciences Ltd	Treatment of Gaucher disease	- 07.06.2000 - 31.07.2000 - 13.09.2000 - 45 days	- 18.09.2000 - 18.10.2000
N-carbamyl-L-glutamic acid	Orphan Europe Sarl	Treatment of N-acetylglutamate synthetase (NAGS) deficiency	- 02.05.2000 - 31.07.2000 - 13.09.2000 - 45 days	- 18.09.2000 - 18.10.2000
Arsenic trioxide	Voisin Consulting Sarl	Treatment of acute promyelocytic leukaemia	- 08.05.2000 - 15.06.2000 - 13.09.2000 - 90 days	- 18.09.2000 - 18.10.2000
Thalidomide	Laboratoires LAPHAL	Treatment of erythema nodosum leprosum or type II reactions in Hansen's disease	- 01.06.2000 - 25.08.2000 - 27.10.2000 - 64 days	- 6.11.2000 - 29.12.2000
Anagrelide hydrochloride	Shire Pharmaceutical Development Ltd	Treatment of essential thrombocythaemia	- 31.05.2000 - 31.07.2000 - 27.10.2000 - 89 days	- 6.11.2000 - 29.12.2000
Busulfan (intravenous use)	Pierre Fabre Médicament	Intravenous conditioning treatment prior to hematopoietic progenitor cell transplantation	- 09.06.2000 - 31.07.2000 - 27.10.2000 - 89 days	- 6.11.2000 - 29.12.2000
Nitisinone	Swedish Orphan AB	Treatment of tyrosinaemia type 1	- 05.06.2000 - 25.08.2000 - 27.10.2000 - 64 days	- 6.11.2000 - 29.12.2000

Product	Sponsor	Indication	EMEA/COMP - Submission - Validation - Opinion - Active time	Commission - Opinion received - Date of Designation
Ethyl eicosopentaenoate	Laxdale Ltd	Treatment of Huntington's disease	- 05.06.2000 - 31.07.2000 - 27.10.2000 - 89 days	- 6.11.2000 - 29.12.2000
Iloprost	Schering AG	Treatment of primary and of the following forms of secondary pulmonary hypertension: connective tissue disease pulmonary hypertension, drug-induced pulmonary hypertension, portopulmonary hypertension, pulmonary hypertension associated with congenital heart disease and chronic thromboembolic pulmonary hypertension	- 10.05.2000 - 31.07.2000 - 27.10.2000 - 89 days	- 6.11.2000 - 29.12.2000
-	-	Treatment of amyotrophic lateral sclerosis	- 07.08.2000 - 25.08.2000 - 21.11.2000 - 89 days	-
-	-	Treatment of acute promyelocytic leukaemia	- 08.08.2000 - 22.09.2000 - 21.11.2000 - 61 days	-
-	-	Treatment of acute respiratory distress syndrome	- 01.09.2000 - 22.09.2000 - 21.11.2000 - 61 days	-
-	-	Treatment of cystic fibrosis	- 09.08.2000 - 22.09.2000 - 19.12.2000 - 89 days	-
-	-	Treatment of patent ductus arteriosus	- 02.05.2000 - 19.10.2000 - 19.12.2000 - 62 days	-
-	-	Treatment of glycogen storage disease type II (Pompe's disease)	- 10.08.2000 - 19.10.2000 - 19.12.2000 - 62 days	-
-	-	Treatment of acromegaly	- 11.08.2000 - 19.10.2000 - 19.12.2000 - 62 days	-
-	-	Treatment of pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension	- 21.08.2000 - 19.10.2000 - 19.12.2000 - 62 days	-
-	-	Treatment of haemorrhagic fever with renal syndrome	- 07.08.2000 - 25.08.2000 - 21.11.2000 - 89 days	-
-	-	Treatment of mucopolysaccharidosis type I	- 08.09.2000 - 19.10.2000 - 19.12.2000 - 62 days	-
-	-	Treatment of chronic myeloid leukaemia	- 03.10.2000 - 19.10.2000 - 19.12.2000 - 62 days	-
-	-	Mucopolysaccharidosis type VI (Maroteaux-Lamy Syndrome)	- 04.10.2000 - 19.10.2000 - 19.12.2000 - 62 days	-

Annex 11: EMEA guidelines in 2000

CPMP Biotechnology Working Party

Reference number	Guidelines/*Status*
EMEA/CPMP/BWP/840/00	Final EU recommendations for the Influenza vaccine composition for the season 2000/2001 *Adopted April 2000*
EMEA/CPMP/BWP/1244/00	Report of the EMEA Expert Workshop on human TSEs and plasma-derived medicinal products, 15-16 May 2000 *Adopted July 2000*
EMEA/CPMP/BWP/3326/99	Concept paper on the Development of a Points to consider on xenogeneic cell therapy *Adopted November 2000*
EMEA/CPMP/BWP/3354/99 Draft	Note for Guidance on the production and quality control of animal immunoglobulins and immunosera for human use *Released for consultation January 2000*
EMEA/CPMP/BWP/3207/00	Note for Guidance on Comparability of medicinal products containing biotechnology-derived proteins as active substances *Released for consultation May 2000*
EMEA/CPMP/BWP/1143/00	Position statement on the Use of tumorigenic cells of human origin for the production of biological and biotechnological medicinal products *Released for consultation July 2000*
EMEA/CPMP/BWP/269/95rev. 2	Revision of section 3.2.5 of CPMP Note for guidance on Plasma-derived medicinal products *Released for consultation July 2000*
EMEA/CPMP/BWP/2571/00	Points to consider on the Reduction, elimination or substitution of thiomersal in vaccines *Released for consultation November 2000*

CPMP Blood and Plasma Working Group

Reference number	Guidelines/*Status*
EMEA/CPMP/BPWG/575/99	Note for guidance on the Clinical investigation of human anti-D immunoglobulin for intravenous and/or intramuscular use *Adopted June 2000*
EMEA/CPMP/BPWG/388/95 rev. 1	Note for guidance on the Clinical investigation of human normal immunoglobulin for intravenous administration (IVIg) *Adopted June 2000*
EMEA/CPMP/BPWG/574/99	Core SPC for Human and anti-D immunoglobulin for intravenous and/or intramuscular use *Adopted June 2000*
EMEA/CPMP/BPWG/859/95 rev. 1	Core SPC for Human normal immunoglobulin for intravenous administration (IVIg) *Adopted June 2000*
EMEA/CPMP/BPWG/1619/99	Core SPC for Human plasma derived and recombinant coagulation factor VIII products *Adopted June 2000*
EMEA/CPMP/BPWG/1625/99	Core SPC for Human plasma derived and recombinant coagulation factor IX products *Adopted June 2000*
EMEA/CPMP/BPWG/198/95 rev.1	Note for Guidance on the Clinical investigation of human plasma derived factor VIII and IX products *Adopted October 2000*
EMEA/CPMP/BPWG/1561/99	Note for Guidance on the Clinical investigation of recombinant factor VIII and IX products *Adopted October 2000*

EMEA/CPMP/PhvWP/BPWG/ 2231/99	Core SPC for Human albumin *Adopted October 2000*
EMEA/CPMP/BPWG/198/95 rev. 1	Note for guidance on the Clinical investigation of human plasma derived factor VIII and IX products *Released for consultation June 2000*
EMEA/CPMP/BPWG/1561/99	Note for guidance on the Clinical investigation of recombinant factor VIII and IX products *Released for consultation June 2000*
EMEA/CPMP/PhvWP/BPWG/ 2231/99	Core SPC for Human albumin *Released for consultation June 2000*
EMEA/CPMP/BPWG/2220/99	Note for Guidance on the Clinical investigation of plasma derived antithrombin products *Released for consultation December 2000*
EMEA/CPMP/BPWG/3226/99	Core SPC for Human plasma derived antithrombin *Released for consultation December 2000*

CPMP Efficacy Working Party

Reference number	Guidelines/*Status*
EMEA/CPMP/EWP/519/98	Note for Guidance on clinical investigation of steroid contraceptives in woman *Adopted February 2000*
EMEA/CPMP/EWP/197/99	Points to consider concerning Endpoints in clinical studies with haematopoietic growth factors for mobilisation of autologous stem cells *Adopted February 2000*
EMEA/CPMP/EWP/570/98	Points to consider on the clinical investigation of new medicinal products for treatment of acute coronary syndrome (ACS) without persistent ST-segment elevation *Adopted February 2000*
EMEA/CPMP/EWP/2922/99	Concept paper on the development of a CPMP Note for Guidance on the clinical investigation of medicinal products in the treatment of asthma *Adopted February 2000*
EMEA/CPMP/EWP/2863/99	Concept paper on the development of a CPMP Points to Consider on biostatistical/methodological issues arising from CPMP discussions on licensing applications: adjustment for baseline covariates *Adopted February 2000*
EMEA/CPMP/EWP/707/98	Points to consider on Clinical investigation of medicinal products for prophylaxis of intra- and post-operative venous thromboembolic risk *Adopted June 2000*
EMEA/CPMP/EWP/612/00	Concept paper on the Development of a CPMP Note for Guidance on the Clinical investigation of medicinal products in pain management *Adopted June 2000*
EMEA/CPMP/EWP/2655/99	Points to consider on pharmaco-kinetics and pharmacodynamics in the development of anti-bacterial medicinal products *Adopted July 2000*
EMEA/CPMP/EWP/482/99	Points to consider on switching between superiority and non-inferiority *Adopted July 2000*
EMEA/CPMP/EWP/1080/00	Concept paper on the Development of a CPMP Note for Guidance on Clinical investigation of medicinal products in the treatment of diabetes mellitus *Adopted July 2000*
EMEA/CPMP/EWP/565/98	Points to consider on Clinical investigation of medicinal products for treatment of Amyotrophic Lateral Sclerosis (ALS) *Adopted October 2000*
EMEA/CPMP/EWP/785/97	Concept paper on the Evaluation of drugs for the treatment of the irritable bowel syndrome *Adopted November 2000*
EMEA/CPMP/EWP/566/98 rev. 1	Note for Guidance on Clinical investigation of medicinal products in the treatment of epileptic disorders *Adopted in November 2000*
EMEA/CPMP/EWP/2284/99	Points to consider on Clinical investigation of medicinal products for the management of Crohn's disease *Released for consultation July 2000*

EMEA/CPMP/EPW/205/95 rev. 1	Note for Guidance on Evaluation of anticancer medicinal products in man *Released for consultation July 2000 and extended in September 2000 for a further 2 months*
EMEA/CPMP/EWP/560/98	Points to consider on Clinical investigation of medicinal products in the treatment of acute stroke *Released for consultation October 2000*
EMEA/CPMP/EWP/2330/99	Points to consider on Validity and interpretation of meta-analyses, and one pivotal study *Released for consultation October 2000*
EMEA/CPMP/EWP/1119/98	Points to consider on the Evaluation of diagnostic agents *Released for consultation November 2000*
EMEA/CPMP/EWP/714/98	Note for Guidance on Clinical investigation of medicinal products for the treatment of peripheral arterial occlusive disease *Released for consultation November 2000*
EMEA/CPMP/EWP/QWP/1401/98	Note for Guidance on the investigation of bioavailability and bioequivalence *Released for consultation December 2000*
EMEA/CPMP/EWP/2747/00	Note for Guidance on co-ordinating investigator signature of clinical study reports *Released for consultation December 2000*

CPMP Pharmacovigilance Working Party

Reference number	Guidelines/*Status*
EMEA/CPMP/PhVWP/2058/99	Joint Pilot Plan for the implementation of the electronic transmission of individual case safety reports between the EMEA, national competent authorities, and the Pharmaceutical Industry *Released for consultation May 2000*

CPMP Safety Working Party

Reference number	Guidelines/*Status*
EMEA/CPMP/SWP/2775/99	CPMP Position paper on Selective Serotonin Uptake Inhibitors (SSRIs) and dependency/withdrawal reactions *Adopted April 2000*
EMEA/CPMP/SWP/1042/99	Note for Guidance on Repeated dose toxicity *Adopted July 2000*
EMEA/CPMP/SWP/2278/00	Discussion paper on Possible pre-clinical studies to investigate addiction and dependence/withdrawal related to use of SSRIs *Adopted December 2000*
EMEA/CPMP/SWP/4163/00	Concept paper on the Development of a CPMP Points to consider on the need for reproduction toxicity studies in the development of human insulin analogues *Adopted December 2000*
EMEA/CPMP/SWP/2145/00 Draft 4	Note for Guidance on Non-clinical local tolerance testing of medicinal products *Released for consultation September 2000*

EMEA Herbal Medicinal Products Working Party

Reference number	Guidelines/*Status*
EMEA/HMPWP/23/00	Position paper on the Risks associated with the use of Herbal Products containing Aristolochia Species *Adopted by the Working Party in October 2000*
CPMP/QWP/2819/00	Note for guidance on quality of herbal medicinal products *Released for consultation November 2000*
CPMP/QWP/2820/00	Note for guidance on specifications: test procedures and acceptance criteria for herbal drugs, herbal drug preparations and herbal medicinal products *Released for consultation November 2000*

CVMP Efficacy Working Party

Reference number	Guidelines/*Status*
EMEA/CVMP/133/99	Conduct of pharmacokinetic studies in animals *Adopted March 2000*
EMEA/CVMP/344/99	Conduct of efficacy studies for intramammary products for use in cattle *Adopted March 2000*
EMEA/CVMP/005/00	Testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestation in cats and dogs *Adopted November 2000*
EMEA/CVMP/016/00	The conduct of bioequivalence studies for veterinary medicinal products *Released for consultation January 2000*
CVMP/VICH/546/00	Efficacy of anthelmintics: Specific recommendations for poultry *Released for consultation July 2000*
CVMP/VICH/545/00	Efficacy of anthelmintics: Specific recommendations for feline *Released for consultation July 2000*

CVMP Immunologicals Working Party

Reference number	Guidelines/*Status*
CVMP/IWP/52/97	Requirements for combined veterinary vaccines *Adopted March 2000*
CVMP/IWP/07/98	DNA vaccines non-amplifiable in eukaryotic cells for veterinary use *Adopted March 2000*
EMEA/CVMP/682/99	Duration of protection achieved by veterinary vaccines *Adopted October 2000*
EMEA/CVMP/852/99	Field trials with veterinary vaccines *Released for consultation March 2000*
EMEA/CVMP/743/00	Requirements and controls applied to bovine serum (foetal or calf) used in the protection of immunological veterinary medicinal products *Released for consultation October 2000*

CVMP Pharmacovigilance Working Party

Reference number	Guidelines/*Status*
EMEA/CVMP/044/99	Conduct of post-marketing surveillance studies of veterinary medicinal products *Adopted April 2000*
CVMP/VICH/547/00	Management of adverse event reports (AERs) *Released for consultation July 2000*

CVMP Safety Working Party

Reference number	Guidelines/*Status*
EMEA/CVMP/276/99	Assessment of the effect of antimicrobial substances on dairy starter cultures *Adopted March 2000*
EMEA/CVMP/473/98	Determination of withdrawal periods for milk *Adopted March 2000*
CVMP/VICH/592/98	Environmental impact assessment (EIAS) for veterinary medicinal products - Phase 1 *Adopted July 2000*
EMEA/CVMP/187/00	Risk analysis approach for residues of veterinary medicinal products in food of animal origin *Released for consultation May 2000*
CVMP/VICH/526/00	Safety studies for veterinary drug residues in human food: Genotoxicity studies *Released for consultation July 2000*
CVMP/VICH/525/00	Safety studies for veterinary drug residues in human food: Reproduction studies *Released for consultation July 2000*

Joint CPMP/CVMP Quality Working Party

Reference number	Guidelines/*Status*
CPMP/QWP/1676/00	Concept Paper on the Development of a CPMP/CVMP Note for Guidance on Quality of Water for Pharmaceutical Use *Adopted July 2000*
CPMP/QWP/3015/99	Note for Guidance on Parametric Release *Released for consultation March 2000*
CPMP/QWP/1719/00	Note for Guidance on Medicinal Gases – Pharmaceutical Information *Released for consultation July 2000*
CPMP/QWP/2845/00	Note for Guidance on Requirements for Pharmaceutical Documentation for Pressurised Metered Dose Inhalation Products *Released for consultation November 2000*
CPMP/QWP/2820/00 (CVMP/815/00)	Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products *Released for consultation November 2000*
CPMP/QWP/2819/00 (CVMP/814/00)	Note for Guidance on Quality of Herbal Medicinal Products *Released for consultation November 2000*
EMEA/CVMP/065/99	Annex to Guideline: Development pharmaceutics for veterinary medicinal products: Decision trees for the selection of sterilisation methods *Adopted February 2000*
EMEA/CVMP/422/99	Declaration of storage conditions for veterinary medicinal products in the product particulars *Adopted February 2000*
CVMP/VICH/501/99	Stability testing of biotechnological/biological veterinary medicinal products *Adopted June 2000*
CVMP/VICH/502/99	Impurities: residual solvents *Adopted June 2000*
EMEA/CVMP/198/99	Maximum shelf-life for sterile medicinal products after first opening or following reconstitution *Adopted July 2000*
CVMP/VICH/595/98	Good clinical practices *Adopted July 2000*
EMEA/CVMP/846/99	Stability testing of existing active substances and related finished products *Adopted November 2000*
EMEA/CVMP/816/00	Statistical principles for veterinary clinical trials *Released for consultation November 2000*

Ad hoc GMP Inspectors Working Group

Reference number	Guidelines/*Status*
ENTR/III/5717/99	Revised Version of Annex 14 - Manufacture of medicinal products derived from human blood or plasma to the EU Guide to Good Manufacturing Practice *Finalised in February 2000*
ENTR/6266/00	Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects *Finalised in April 2000*
ENTR/6109/00	Draft Annex 6 to EU Guide to Good Manufacturing Practice on Medicinal Gases *Released for consultation March 2000*
ENTR/6270/00	Draft Annex 17 to EU Guide to Good Manufacturing Practice on Parametric Release *Released for consultation April 2000*

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