

The European Agency for the Evaluation of Medicinal Products

Work Programme 2003

Adopted by the Management Board on 19 December 2002



The Work Programme for 2003 is presented by the Executive Director to the Management Board in accordance with Article 57(3) of Council Regulation (EEC) No 2309/93. It is forwarded to the European Parliament, Council, Commission and Member States. It is available on request in all official EU languages.

The European system offers two routes for authorisation of medicinal products. The EMEA plays a role in both procedures:

- The centralised procedure is compulsory for medicinal products derived from biotechnology, and available at the request of companies for other innovative new products. Applications are submitted directly to the EMEA. At the conclusion of the scientific evaluation undertaken in 210 days within the Agency, the opinion of the scientific committee is transmitted to the European Commission to be transformed into a single market authorisation applying to the whole European Union.
- The decentralised procedure (or mutual recognition procedure) applies to the majority of conventional medicinal products and is based upon the principle of mutual recognition of national authorisations. It provides for the extension of marketing authorisations granted by one Member State to one or more other Member States identified by the applicant. Where the original national authorisation cannot be recognised, the points in dispute are submitted to the EMEA for arbitration. The opinion of the scientific committee is transmitted to the European Commission.

The European Commission adopts its decision with the assistance of a standing committee composed of representatives of the Member States.

The European Agency for the Evaluation of Medicinal Products
7 Westferry Circus, Canary Wharf, London E14 4HB, United Kingdom
Tel: (44-20) 74 18 84 00
Fax: (44-20) 74 18 84 16
E-mail: mail@emea.eu.int
Internet: <http://www.emea.eu.int>

A great deal of additional information on the European Union is available on the Internet.
It can be accessed through the Europa server (<http://europa.eu.int>)

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Contents

Introduction by the Executive Director	2		
CHAPTER 1 EMEA IN THE EUROPEAN SYSTEM	3	CHAPTER 4 INSPECTIONS	21
1.1 Management Board	3	4.1 Inspections	21
1.2 National competent authorities	3	4.2 Mutual recognition agreements	22
1.3 Transparency	3	4.3 Sampling and testing	22
1.4 Preparation for EU enlargement	4	4.4 Certificates	22
1.5 Preparation for the review of the European system	4	4.5 Implementation of the clinical trials directive	23
1.6 Revision of EMEA fees	4		
1.7 International partners	5	CHAPTER 5 COMMUNICATIONS AND NETWORKING	24
1.8 European Directorate for the Quality of Medicines	5	5.1 Implementation of the EU telematics strategy	24
1.9 Integrated quality management and financial control	5	5.2 IT and project management at the EMEA	26
1.10 EMEA internal organisation	5	5.3 Meeting management and conferences	26
		5.4 Document management and publishing	27
CHAPTER 2 MEDICINES FOR HUMAN USE	6		
2.1 Initial evaluation	6	CHAPTER 6 ADMINISTRATION	28
2.2 Post-authorisation activities	8	6.1 Personnel and budget	28
2.3 Pharmacovigilance and maintenance activities	9	6.2 Infrastructure services	28
2.4 Scientific advice and protocol assistance	10	6.3 Accounting	29
2.5 Arbitration and Community referrals	11		
2.6 Parallel distribution	11	ANNEXES	30
2.7 International activities	12	Annex 1 EMEA establishment plan 2001 – 2003	31
2.8 Orphan medicinal products	12	Annex 2 EMEA budget summaries 2001 – 2003	32
2.9 Working parties and ad hoc groups	14	Annex 3 EMEA guidance documents for 2003	33
2.10 Mutual recognition facilitation group	15	Annex 4 EMEA contact points	36
		Annex 5 Profiles of EMEA personalities	37
CHAPTER 3 VETERINARY MEDICINES	16		
3.1 Initial evaluation	16		
3.2 Establishment of maximum residue limits for old substances	17		
3.3 Post-authorisation activities	18		
3.4 Pharmacovigilance and maintenance activities	18		
3.5 Scientific advice	19		
3.6 Arbitration and Community referrals	19		
3.7 Interested parties	19		
3.8 International activities	19		
3.9 Working parties and ad hoc groups	19		
3.10 Veterinary mutual recognition facilitation group	20		

Introduction by the Executive Director

Thomas Lönngren

A period of preparation for change and enlargement...

The work programme for 2003 covers a period when the EMEA and the European Union as a whole will be preparing for significant change. The Agency and its partners in the national authorities will be facing the double test of changes in the European system for the authorisation and supervision of medicines, together with meeting the challenges of welcoming a number of new Member States into the European Union.

...while managing a changing workload...

At the same time the EMEA will need to keep its focus on management of its core business of the evaluation of new applications and the supervision of an increasing stock of authorised medicines. At the end of 2002 there were some 269 centrally authorised medicines for both human and veterinary use, to which must be added the 38 applications for human medicines and 10 applications for veterinary medicines expected in 2003.

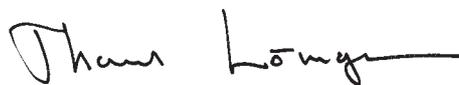
...and fulfilling new public health tasks

Civil and political society is increasingly looking to the European Community to take a bigger role in the protection and promotion of public and animal health. As the Community body responsible for the evaluation and supervision of medicines, the EMEA has a clear role to play in this and has seen a number of new tasks added to its existing responsibilities by the EU institutions and Member States.

The Agency has been requested to implement the Community telematic strategy for pharmaceuticals regulation. This will cover a range of activities and operations to assist regulatory bodies and the pharmaceutical industry directly, but also includes initiatives to give patients and health professionals access to information on medicines throughout the whole of the European Union.

New therapies and advances in medical science will make demands on the Agency and its committees. We will have to improve the capacity of the EMEA to deliver scientific advice to companies as they undertake research and develop new medicines. The Agency must similarly then be able to monitor and risk manage these medicines once they are in use.

The EMEA made an essential contribution to the successful creation of a European orphan drug policy. The Agency will work closely with EU institutions and all interested parties to support the development of a paediatric medicines policy, in addition to completion of preparations for the entry into force of the clinical trials directive.



Chapter 1

EMEA in the European system

1.1 Management Board

The Management Board will meet 4 times in 2003, each meeting lasting 1 day.

The Board will begin a new mandate at the beginning of 2003 and will elect a new chairman and vice-chairman at its February meeting.

Observers from candidate accession countries will be invited to attend the June meeting of the Management Board, together with heads of national agencies who are not members of the Board.

Management Board meetings in 2002

20 February

5 June

2 October

18 December

The Board has responsibility for ensuring appropriate standards of corporate governance, agreeing and monitoring implementation of the Agency's work programme and monitoring standards of performance. Specific priorities for 2003 continue to be to advise the Executive Director on:

- Revision of the European marketing authorisation system
- Accession of new Member States to the European Union
- Development of a long-term funding model for the Agency

1.2 National competent authorities

Useful 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>

There will be increased coordination between the EMEA and national competent authorities in the planning of resources for the operation of the European system for the authorisation and supervision of medicines as a whole. The EMEA will continue to participate as a member in the meetings of heads of agencies for human and veterinary medicines.

The 1997 Statement of principles governing the partnership between the national competent authorities and the EMEA will be revised in 2003. This will include a revised standard contract for the performance of scientific and inspection services on behalf of the EMEA.

1.3 Transparency

It is anticipated that the Agency's founding legislation will be amended in early 2003 to include the EMEA within the scope of Regulation (EC) No 1049/2001 on public access to documents (OJ L 145, 31.5.2001, p. 43). Similar changes will be introduced for all EU agencies. These provisions will replace the Decision of the Executive Director of 3 December 1997 on rules on access to EMEA documents. It is not anticipated that the Regulation will have a significant resource impact on the Agency and the application of the Regulation will be monitored during the year.

In addition to this legislative change, the European Parliament and Council will continue their consideration of a number of proposals to improve EMEA transparency as part of the review of EU pharmaceutical legislation.

Pending the outcome of these political discussions, the EMEA will propose limited initiatives in 2003. These will focus on providing better information on action taken by the Agency on medicines once they are already in use by patients and in animals. In particular this will include publication of summaries of opinions where new indications are approved or information on major safety concerns. Other initiatives relate to a regular updating of EPARs to include information on post-authorisation activities. The EMEA will consult interested parties prior to the introduction of these initiatives.

The principal communication tool remains the EMEA web site – <http://www.emea.eu.int> – and efforts will be made to ensure appropriate development and maintenance of the site.

1.4 Preparation for EU enlargement

Useful web sites:

Pan-European Regulatory Forum

<http://perf.eudra.org>

European Commission Directorate-General for Enlargement

<http://europa.eu.int/comm>

Accession countries' national competent authorities for medicines for human use

<http://www.cadreac.org>

Accession countries' national competent authorities for medicines for veterinary use

<http://www.cavdri.info>

The Council of the European Union has set the date of the proposed enlargement of the European Union as 1 May 2004. This will take the number of Member States participating in the work of the EMA from 15 to 25 (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia), in addition to the EEA-EFTA states Iceland, Liechtenstein and Norway.

There will be considerable preparation required prior to enlargement. The necessary arrangements will have to be made to allow the phasing-in of candidate countries in the Agency's activities, including participation as observers in meetings of EMA scientific committees and working parties in 2003.

Given budgetary constraints it has not been possible to allocate additional resources for the EMA for work related to enlargement in 2003.

The Agency remains committed to working with its partners in the accession candidate countries and the third phase of the Pan-European Regulatory Forum on pharmaceuticals (PERF III) will be carried out in 2003. PERF is funded by the European Commission PHARE programme and has a total budget of €1 430 000. Activities under PERF III include 6 priority action areas:

- Pharmacovigilance
- Good manufacturing practice
- Dossier assessment
- Veterinary topics
- Implementation of Community legislation
- Telematics

Each priority action area involves a programme of practical workshops with the involvement of experts from the competent authorities of the EU and accession candidate countries. A benchmarking exercise aimed at establishing good regulatory practices will also be carried out as part of the 4 technical priority action areas.

Three public conferences will be held as part of PERF III, focusing on the pharmaceutical industry (February 2003), veterinary medicines (July 2003) and patients and health professionals (October 2003).

1.5 Preparation for the review of the European system

Useful web site:

European Commission Directorate-General for Enterprise/ Pharmaceuticals Unit

<http://pharmacos.eudra.org/f2>

The work programme and budget for 2003 are prepared on the basis that the European Commission proposals for the review of the European system for the authorisation and supervision of medicinal products will not enter into force before 2005 (OJ C 75 E, 26.3.2002, p. 189 *et seq.*).

The EMA will contribute as required to the work of the EU institutions as they continue their examination of the proposals. The Agency will also carefully monitor the potential resource and operational implications of the proposals.

1.6 Revision of EMA fees

It is intended to increase the level of fees paid to the EMA by applicants and marketing authorisation holders at the beginning of 2003. This will be introduced by a Regulation adopted by the European Commission. The overall level of increase requested by the EMA is 16.6 % to take into account inflation since the last revision in 1998 and the need to secure an appropriate level of revenue to allow the EMA to operate.

A parallel exercise will be conducted in 2003 to revise the structure of the current fee system to take into account the impact of the revision of the European pharmaceutical legislation and enlargement.

1.7 International partners

Useful web sites:

International Conference on Harmonisation

<http://www.ich.org>

Veterinary International Conference on Harmonisation

<http://vich.eudra.org>

World Health Organization

<http://www.who.int>

European Commission Directorate-General for Research

<http://europa.eu.int/comm>

In addition to the Agency's activities relating to the future EU enlargement, cooperation between the EMEA and other international regulatory authorities will increase in 2003.

The Agency will continue its commitment to the International Conferences on Harmonisation processes for human and veterinary medicines (ICH and VICH) and will in particular contribute to the sixth ICH Conference to be held in Osaka, Japan in 2003.

Cooperation with health authorities such as the US Food and Drug Administration (FDA) will be strengthened. The Visiting Experts Programmes will continue in 2003 with the EMEA welcoming experts from the Canadian and Japanese authorities in 2003. There will be closer cooperation with the World Health Organization, especially in the field of pharmacovigilance.

The Agency will also provide support to activities under the European Union sixth framework programme for research and technological development concerning the development of medicines for the third world.

1.8 European Directorate for the Quality of Medicines

Useful web site:

European Directorate for the Quality of Medicines/

European Pharmacopoeia

<http://www.pheur.org>

The programme for sampling and testing of centrally authorised medicinal products in 2003 will be implemented through the EDQM network of Official Medicines Control Laboratories in the EU and EEA-EFTA states. The 2003 programme will be the most

extensive to date with a 20% increase in the products being sampled and tested as compared with 2002.

The Agency will continue its cooperation with the work of the European Pharmacopoeia Commission. Representatives of the EDQM will also participate in a number of EMEA working parties.

1.9 Integrated quality management and financial control

The focus will be on implementation of the integrated management systems with continual improvement of EMEA processes and the development of an operational risk register as objectives, underpinned by internal audits and competence development.

The good regulatory practices benchmarking exercise with partners from EU, EEA-EFTA and candidate country authorities, together with European institutions, will continue.

The financial control and audit function at the EMEA will be brought in line with the new European Commission framework for resource management and internal auditing. This will take into account existing internal audit arrangements and the view of the Management Board on a number of options to ensure the continuity of financial control and audit within the Agency in the framework of EMEA corporate governance.

1.10 EMEA internal organisation

A stable internal structure has now been reached within the Agency, with 5 Units performing the scientific and support functions of the Agency. It is intended to introduce a reinforced management support function in 2003 to respond to the growing range of EMEA activities and the need to ensure internal coordination within the Agency.

This function will in particular focus on providing support to the internal management team of the Executive Director and Heads of Unit and also play a role in the coordination of the Agency's international, scientific and communication activities.

Chapter 2

Medicines for human use

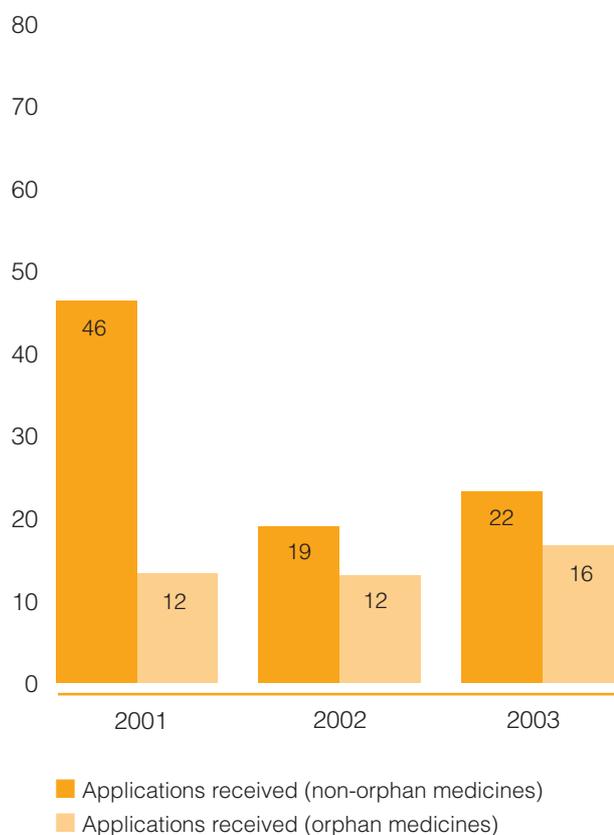
Priorities for medicines for human use in 2003:

- Manage the workload and adhere to regulatory timelines both for pre- and post- authorisation activities
- Facilitate and improve the electronic exchange of individual case safety reports (ICSRs) through the implemented EudraVigilance database
- Finalise and implement the EMEA risk management strategy and collaborate with heads of national authorities on the development of a European risk management strategy
- Manage the workload, adhere to timelines and improve the procedure for scientific advice and protocol assistance
- Focus on the concept of life-cycle management of medicines by improving operations and procedures (scientific advice, CPMP opinions and risk management) and regulatory memory
- Improve the Agency's transparency policy by refining current communication tools
- Manage the workload and adhere to timelines for activities related to orphan medicinal products designation and its follow-up

2.1 Initial evaluation

This covers the phase of EMEA activities from pre-submission discussion with future applicants, through the evaluation by the CPMP, the product's authorisation and the production of the European public assessment report (EPAR).

Applications for initial evaluation (Input)



Trends:

- Same level of initial applications for marketing authorisations, continuing the trend experienced in 2002, with an expected 38 applications and very few multiple applications
- Slight increase in initial applications for designated orphan drugs

New issues to be faced in 2003 with workload implications:

- Implementation of therapeutic advisory groups at CPMP level to provide specialised advice to rapporteurs, co-rapporteurs and CPMP on specific applications and development of guidelines. Increased involvement of EMA staff to support the therapeutic groups as coordinators. The initial pilot phase will see the creation of therapeutic advisory groups in three areas: anti-infectives, oncology and diagnostic agents
- Rise in number of applications from designated orphan drugs – about 40 % of total applications in 2003 – will impact on working practices. These applications tend to involve considerable complexities, requiring additional resources compared to non-orphan medicines
- Elaboration of an EMA risk management strategy and development of a European strategy in collaboration with national authorities
- The first challenges to orphan drug 10-year marketing exclusivity can be expected
- Applications using the common technical document (CTD) format will be mandatory as of mid-2003 and more applications are expected later in the year using the electronic CTD format. The electronic CTD format was approved in 2002 through the trilateral EU-Japan-US International Conference on Harmonisation (ICH). This will require training and familiarisation for both EMA staff and experts
- The CPMP will initiate its collaborative activities with patient organisations with 4 meetings planned in 2003

Objectives:

- Adhere to regulatory timelines for active review time by the CPMP
- Publish summaries of opinion at the time of adoption by the CPMP
- Rapid publication of EPARs after the European Commission decision granting marketing authorisation
- Follow-up of the implementation by the CPMP of the therapeutic advisory groups and active support from the Agency secretariat
- Continuous efforts to support the increasing activities of the CPMP in terms of workload, new scientific and public health challenges, orphan drugs and new therapies

Management and organisation of the CPMP

Provision is made for the Committee for Proprietary Medicinal Products (CPMP) to meet 11 times. In addition provision has been made for 1 extraordinary CPMP meeting in case of need.

The CPMP will keep its working practices under review in order to introduce any necessary changes to improve the functioning and operation of the Committee and of the centralised procedure, including the development of new quality assurance tools and the follow-up to previously implemented tools, the activities of its satellite groups (Invented Names Review Group, Organisational Matters Group, Meeting of the chairmen of the CPMP and working parties).

The CPMP will continue discussions on the implementation of the EMA risk management strategy. This will in particular focus on the nature and extent of the organisational changes to be introduced in order to provide for a more adequate system capable of handling safety concerns in an efficient and timely manner both before and after authorisation, leading to scientifically robust decision-making.

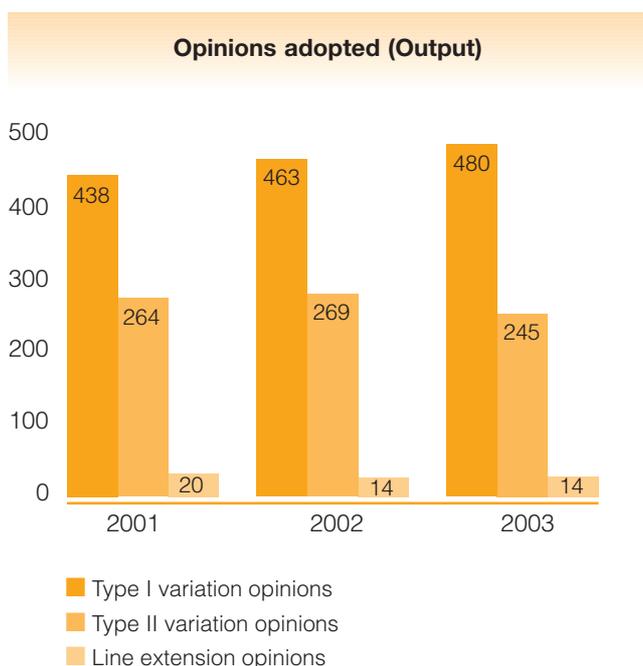
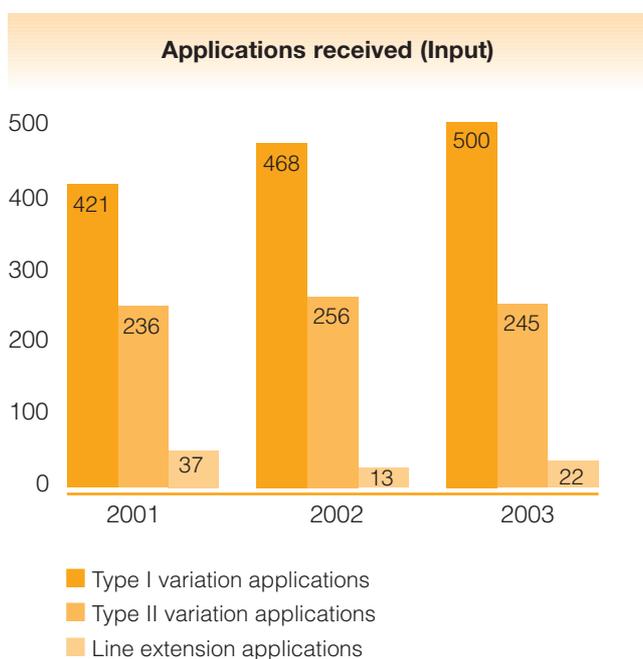
CPMP meetings in 2003

- 21-23 January
- 18-20 February
- 18-20 March
- 23-25 April
- 20-22 May
- 24-26 June
- 22-24 July
- No meeting in August
- 23-25 September
- 21-23 October
- 18-20 November
- 16-18 December

Rapporteurs and co-rapporteurs will be appointed at each meeting

2.2 Post-authorisation activities

This includes activities relating to variations, line extensions and transfers of marketing authorisation. Changes to marketing authorisations are known as variations, which can be either minor (type I) or major (type II) changes. This classification of these changes is set out in EU legislation.



Trends:

- Stable or small increase in applications for, respectively, type II and type I variations is forecast on the basis of current legislation
- The same trend is expected for line extension applications

New issues to be faced in 2003 with workload implications:

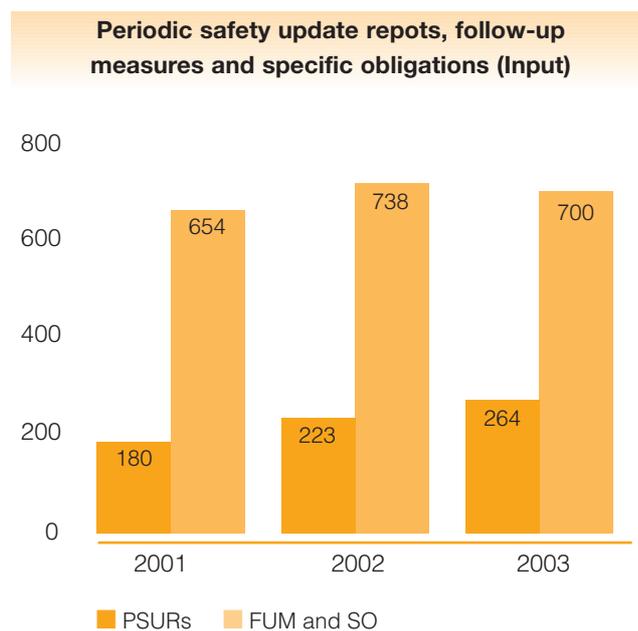
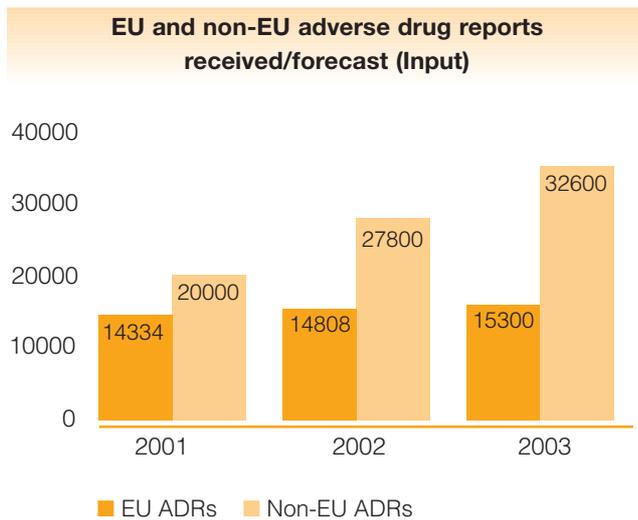
- The implementation of the new EU regulation on variations may impact on the number and type of applications for both type I and type II applications in 2003 and will be kept under close review
- The new regulation proposes the introduction of a new type of variation for which EMEA will take full responsibility, without involvement of rapporteur and co-rapporteur
- The concept of annual meetings with marketing authorisation holders to plan post-authorisation strategy for each product, which started as a pilot project in 2002, will be implemented in 2003
- Further improvement of EMEA transparency policy will include regular procedural and scientific updating of European public assessment reports (EPARs) for all centrally authorised medicinal products (for about 250 products in 2003), as well as publication of summaries of opinion for certain post-authorisation activities

Objectives:

- Adhere to regulatory timelines for active review time by the CPMP
- Publish summaries of opinion at the time of adoption by the CPMP for certain post-authorisation activities which have an important impact on the use of the medicinal product
- Regularly update of EPARs in the post-authorisation phase for both procedural and scientific aspects

2.3 Pharmacovigilance and maintenance activities

This includes activities related to pharmacovigilance information (adverse drug reaction reports (ADRs) and periodic safety update reports (PSURs)), follow-up measures, specific obligations, annual reassessments and renewal applications.



Trends:

- Continued increase in maintenance activities compared to 2002

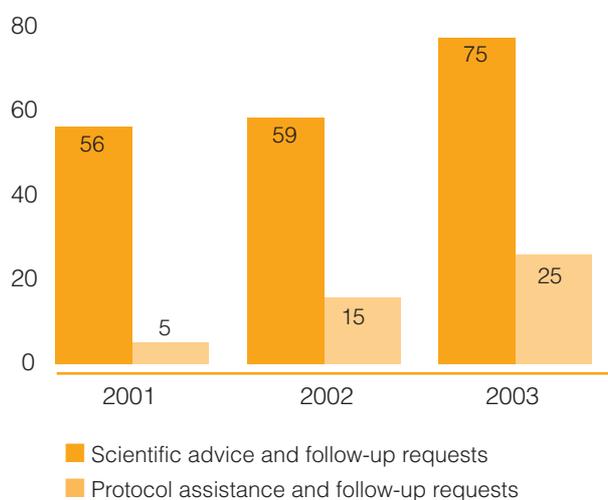
New issues to be faced in 2003 with workload implications:

- Maintain, update and further improve the EudraVigilance database and data processing network. Envisaged activities relate to a careful monitoring of the further implementation of the handling of ICSRs including quality assurance, the management of the backlog of these reports, the preparation and coordination of a training programme for pharmaceutical industry and the further development of the system including the availability of electronic reporting tools for small and medium size companies
- Manage, as part of the implementation of the EMEA risk management strategy, a substantial increase in Pharmacovigilance Working Party meetings as well as the introduction of specialised expertise both in the pre- and post-authorisation phase
- Contribute, together with the heads of national agencies, to the establishment of a European risk management strategy, by providing the necessary input in the elaboration of the different aspects of such a strategy

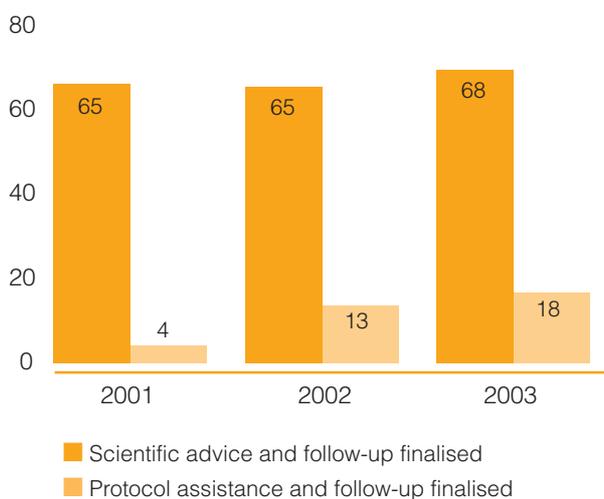
2.4 Scientific advice and protocol assistance

This relates to the provision of scientific advice and protocol assistance to sponsors during the research and development of medicinal products. Scientific advice is a priority area for the EMEA and is provided on any aspect of research and development relating to quality, safety or efficacy of medicinal products. In addition the Agency provides advice to sponsors of designated orphan medicines. This advice is provided in the form of protocol assistance that can also include advice on the significant benefit of their product.

Scientific advice and protocol assistance requests (Input)



Scientific advice and protocol assistance requests (Input)



Trends:

- Steady increase in number of requests for scientific advice and follow-up requests
- Significant increase in number of requests for protocol assistance
- Overall workload increase of 20 %

New issues to be faced in 2003 with workload implications:

- The provision of scientific advice and protocol assistance is a priority area for the EMEA. Scientific advice will be provided in 2003 through the Scientific Advice Working Group
- The status of the group has changed to become a full working party of the CPMP. The group will meet 11 times in 2003, with meetings running for 2 full days each month separately from the CPMP allowing more time for proper discussion between the group and companies requesting advice and better preparation of scientific advice conclusions ahead of CPMP meetings, allowing for faster provision of advice and assistance to sponsors
- Greater involvement of external experts for both common and rare diseases
- The impact of scientific advice on outcomes for applications for marketing authorisations will be monitored and analysed as part of the scientific memory and scientific advice databases
- Increased communication and interactions with interested parties, including learned societies

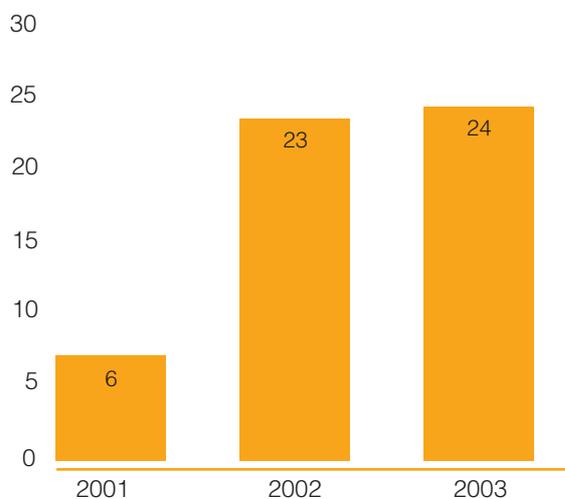
Objectives:

- Monitor the implementation of the new procedure in terms of timing, face-to-face meetings with sponsors and involvement of supplementary expertise
- Continue monitoring of the impact of scientific advice and protocol assistance procedures on future marketing authorisation applications

2.5 Arbitration and Community referrals

- Arbitration procedures (either under Article 29 of Directive 2001/83/EC or Article 7(5) of Commission Regulation (EC) No 542/95) are initiated because of disagreement between Member States in the framework of the mutual recognition procedure
- Article 30 referrals are mainly initiated in order to obtain harmonisation within the Community of the conditions of authorisation for products already authorised by the Member States
- Article 31 and 36 referral procedures are mainly initiated in case of Community interest and for safety related issues

Arbitration and Community referrals made to EMEA (Input)



Trends:

- Total of 24 arbitration and Community referrals are expected in 2003
- The number of referrals related to pharmacovigilance concerns is expected to remain at the same high level compared with 2002

New issues to be faced in 2003 with workload implications:

- Workload from harmonisation referrals will increase depending on the first experiences of the European exercise to harmonise summaries of product characteristics of selected medicines in major therapeutic areas
- Workload arising from referrals is higher than that required for marketing authorisation applications. Referrals usually involve

a large number of marketing authorisations and marketing authorisation holders

- Transparency of arbitration and Community referrals will be improved through the timely publication of information, providing details on the rationale for the CPMP recommendations, the conditions and, where relevant, amended product information

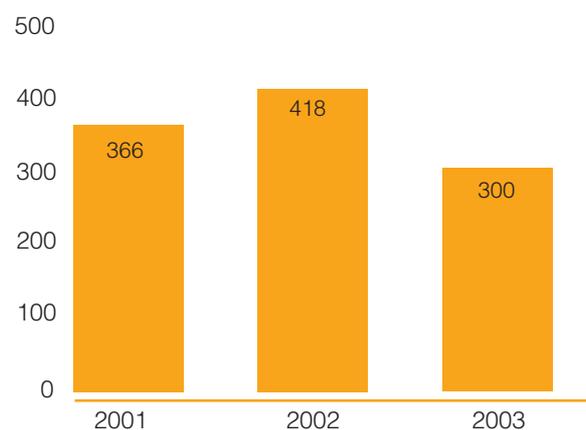
Objectives:

- Management of the workload related to referrals and arbitrations
- Adherence to regulatory timeframes for arbitration and Community referrals
- Timely publication of public information on referral and arbitration procedures

2.6 Parallel distribution

A Community marketing authorisation is valid throughout the EU and a centrally authorised medicinal product is by definition identical in all Member States. Products placed on the market in one Member State can be marketed in any other part of the Community by a distributor ('parallel distributor') independent of the marketing authorisation holder. Typically this is done to benefit from price differentials. The EMEA checks compliance of such products distributed in parallel with the appropriate terms of the Community marketing authorisation.

Notifications received (Input)



Trends:

- The number of valid initial parallel distribution notifications is expected to remain relatively stable in 2003, while the number of notifications of changes are expected to continue rising due to labelling updates

New issues to be faced in 2003 with workload implications:

- There will be increased pressure to maintain or improve processing times, which will necessitate substantial process revision in the face of existing resource availability

Objectives:

- To streamline the current procedure taking into account experience thus far in particular by identifying a pragmatic solution to the timely availability of product labelling updates

2.7 International activities

Trends:

- Level of international activities is expected to remain strong, both in terms of the Agency's commitments to international partners and interest in the work of the Agency from non-EU regulatory authorities

New issues to be faced in 2003 with workload implications:

- Significant involvement in PERF III for both the Pre- and Post-authorisation evaluation of medicines for human use units in 2003
- Support to observers from accession candidate countries as they begin participation in the work of the Agency's scientific committees and working parties
- Interaction with US FDA to further develop cooperation, e.g. in the fields of orphan drugs, scientific advice requests, new applications and pharmacovigilance, and with the exchange of trainees
- Interactions with Canada and Japan will continue through the EMEA Visiting Experts programme
- ICH activities will increase particularly with regard to the preparation of the ICH 6 conference in Autumn 2003 in Japan
- Interactions and participation to scientific meetings and trainings with or at the request of WHO

- Contribution to the activities of the EMCDDA in Lisbon through contribution to EU Joint Actions and the Trend project
- Contribution to the activities initiated by European Commission Directorate-General for Research related to medicinal products for developing countries

2.8 Orphan medicinal products

Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10 000 persons in the European Community, or where for economic reasons such medicines would not be developed without incentives.

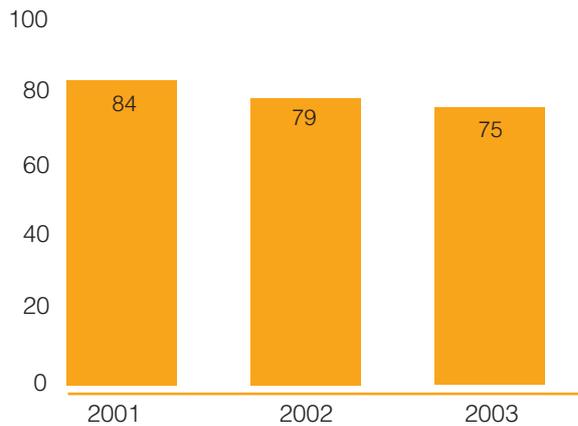
The Committee for Orphan Medicinal Products (COMP) is responsible for making recommendations to the European Commission for the designation of orphan medicinal products for rare diseases. The COMP is also responsible for advising the European Commission on the development of an orphan drug policy and for providing assistance in liaison with international partners and patient organisations in this respect.

The special Community fund ('orphan drug fund') should support additional new applications and protocol assistance, in addition to post-authorisation activities due to the increasing number of orphan medicinal products with Community marketing authorisations. The orphan drug fund allocated by the European Union budgetary authority in 2003 is expected to amount to €3 300 000.

In order to meet expectations from sponsors and patient organisations and taking into account the level in 2003 of the orphan drug fund, it is proposed that the level of fee reductions should cover:

- 100 % of fees for protocol assistance and 50 % for initial applications and related inspections
- 50 % fee reductions for post-authorisation applications, with a priority for orphan medicines in their first year of authorisation

Applications for designation (Input)

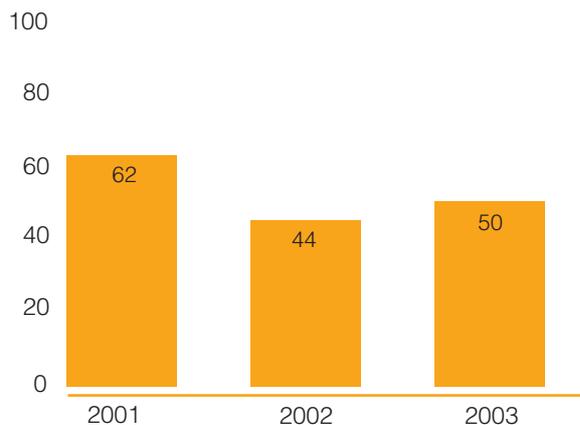


- Management and follow-up of approximately 100 annual reports to be submitted in 2003 for designated orphan drugs
- Increased follow-up and assessment of designation criteria at the time of marketing authorisation as more orphan drugs apply for authorisations
- Applications for designation are expected to include more complex emerging therapies
- New initiatives to increase transparency of the orphan designation procedure
- Increase cooperation with international regulatory partners and the European Union institutions

Objectives:

- Adherence to regulatory timelines for applications for designation of orphan medicines
- Publication of summaries of opinion at the time of the European Commission decision on designation

Opinions on designation (Output)



Management and organisation of the COMP

The COMP will meet 11 times in 2003, meeting for 2 days each month. The mandate of the current Committee finishes in 2003 and a new Committee will be nominated in April 2003. The new Committee will also elect its chairman and vice-chairman at the April meeting.

COMP meetings in 2003

- 9-10 January
- 6-7 February
- 18-19 March
- 14-15 April
- 7-8 May
- 12-13 June
- 29-30 July
- No meeting in August
- 9-10 September
- 9-10 October
- 6-7 November
- 4-5 December

Trends:

- After the initial high level of applications for orphan drug designation experienced after the introduction of the EU orphan drug policy, numbers are expected to remain stable compared to 2002 with 75 applications

New issues to be faced in 2003 with workload implications:

- With 134 designated orphan drugs at the end of 2002, the post-designation workload is expected to increase by 30 % in 2003

2.9 Working parties and ad hoc groups

The working parties of the EMEA scientific committees responsible for medicinal products for human use are involved in the development and revision of guidelines, the provision of recommendations and advice on medicinal products for which applications are made for orphan drug designation, scientific advice, protocol assistance, marketing authorisation or post-authorisation activities, according to the specific area of responsibility of each group. This includes advice and recommendations on general public health issues related to medicinal products.

This activity also supports the work of the national competent authorities in the functioning of the mutual recognition procedure.

Many of the guidelines adopted by the CPMP derive from the Agency's work as part of the trilateral EU-Japan-US International Conference on Harmonisation (ICH). The ICH process involves regulatory authorities and the pharmaceutical industry in the development of guidelines. This process makes a significant contribution to harmonisation of technical and regulatory requirements for the research and development of medicines.

Trends:

- 60 CPMP draft or final guidelines are scheduled to be adopted or released for consultation
- 5 ICH-CPMP guidelines are scheduled to be adopted or released for consultation

New issues to be faced in 2003 with workload implications:

- CPMP working parties and ad hoc groups will streamline their processes and outcomes with regard to transparency and effectiveness
- Ad hoc groups on new emerging therapies, new technologies and comparability of biotechnology medicines will continue to meet in 2003. This will be important as the Agency prepares to receive such applications in the future and also contributes to the international regulatory developments within the ICH process
- Work in 2003 in anticipation of EU legislation on paediatric medicines, expected in 2004, will include support to the European Commission in developing its proposals. The Paediatric Expert Group will meet with individual companies to discuss the development of paediatric formulations and work on the availability of information on medicines for use in children
- New activities are also expected in relation to plasma master files, vaccine antigen master files and medical devices containing biotechnology and blood-derived medicinal products
- Work and expertise required to help the CPMP provide guidance to the European Commission on chemical terrorism in 2003 and to follow-up on work begun in 2002 on bioterrorism threats
- The COMP ad hoc Biotechnology Group will meet as necessary to support the designation process for emerging therapies, and the COMP group with interested parties will continue to meet every quarter
- Support will be provided to workshops organised at the initiative of the COMP and CPMP in relation to new scientific and methodological aspects, as well as to the activities related to the training of national assessors as agreed with the EMEA scientific committees and EU national competent authorities

The resource implications of development of new and revision of existing guidelines will be carefully monitored by the CPMP and working parties when planning their activities. New tools for

resource measurement will be developed in collaboration with national competent authorities in order to streamline and improve the current process.

CPMP working parties and ad hoc groups in 2003	Number of meetings	New guidelines	Ongoing guidelines
Pharmacovigilance Working Party	11	9	17
Biotechnology Working Party	9	6	13
Joint CPMP/CVMP Quality Working Party	4	7	9
Blood Products Working Group	3	4	12
Efficacy Working Party	4	2	28
Safety Working Party	3	3	10
Herbal Medicinal Products Working Party	3	18	28
Paediatric Expert Group	4	–	–
Vaccine Expert Group	4	3	4

Details of the guidance documents expected to be released for consultation or finalised in 2003 are given in Annex 3.

2.10 Mutual recognition facilitation group

Useful web site:

Heads of agencies for medicines for human medicines

<http://heads.medagencies.org>

EMEA/MRFG secretariat (e-mail)

email: mrp@emea.eu.int

European product index

<http://mri.medagencies.com/prodidx>

The operation of the Mutual Recognition Facilitation Group (MRFG) will continue to be supported by the EMEA at its monthly meetings held on the day preceding the start of CPMP meetings.

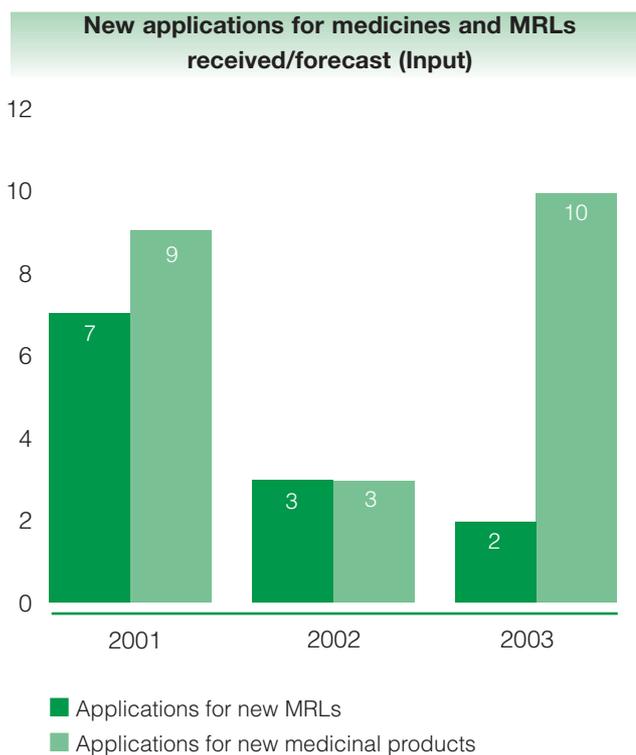
Chapter 3

Veterinary medicines

Priorities for veterinary medicines in 2003:

- To advance work on the definition of EU standards for electronic reporting in order to implement the delayed EudraVigilance programme in the veterinary sector during 2003. This follows lack of progress with VICH in finalising the guideline on data elements for electronic transmission of suspected adverse reactions to veterinary medicines
- In accordance with its guideline on extrapolation of MRLs to other species, the CVMP will continue to explore means to generate the requisite data for such extrapolation through further initiatives to facilitate the wider availability of medicines to minor species
- Based on the conclusions of the joint EMEA/FEDESA/FVE workshop on veterinary pharmacovigilance in May 2002, the EMEA will strive to implement some agreed recommendations of the workshop to promote a greater acceptance of, and efficiency in, adverse event reporting for veterinary medicines throughout the EU
- Continuing on the success of the results achieved in PERF II in the veterinary sector, the EMEA supported by CVMP and its experts will continue to address outstanding regulatory issues in the context of continued assistance to the candidate countries to prepare for their accession to the European Union through a series of workshops and a mini-conference under the PERF III programme
- CVMP will prepare a guideline for consultation on operator safety for veterinary medicinal products in the European Union
- The CVMP will agree a protocol on actions necessary following the detection of contamination of veterinary medicinal products with bovine viral diarrhoea (BVD) virus particles by means of PCR, and develop a guideline on the need for target animal safety batch testing for immunological veterinary medicinal products with the aim of reducing animal testing
- Following the growth in requests for scientific advice to the CVMP in 2002, the Agency will continue to encourage potential applicants to seek such advice and to implement fully the new operating procedure and guidance now available from the Agency

3.1 Initial evaluation



Trends:

- Increase in the number of applications for initial evaluation of veterinary medicines is expected following delays in submission of applications in 2002
- Continuing decline in the number of applications to establish maximum residue limits (MRLs) for new substances reflects the fact that few new molecules are currently being developed for veterinary medicines for food producing animals

Objectives:

- Ensure the processing of all applications for centralised procedures and MRLs within regulatory timeframes
- Review further opportunities for increased transparency in communicating the business of the Committee for Veterinary Medicinal Products (CVMP) and its working parties to interested parties and stakeholders
- Publish EPARs within five days of notification of the European Commission decision granting marketing authorisation
- Publish full CVMP assessment reports for new MRL applications

Management and organisation of the CVMP

The CVMP will meet 11 times in 2003.

The strategic planning group will meet 4 times, chaired by the CVMP vice-chairman. Ad hoc expert groups will be convened on availability of medicines, extrapolation of MRLs, preparation for Codex Alimentarius and finalisation of EU input into VICH on environmental toxicity testing of veterinary medicines.

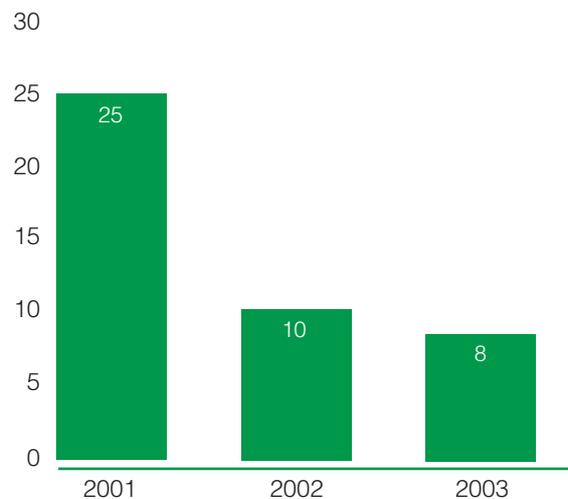
CVMP meetings in 2002
14-16 January
11-13 February
11-13 March
8-10 April
13-15 May
17-19 June
22-24 July
19-21 August*
16-18 September
14-16 October
11-13 November
9-11 December
<i>*The CVMP will meet in August only if required</i>

3.2 Establishment of maximum residue limits for old substances

The last remaining 8 substances with provisional MRLs in Annex III of Council Regulation (EEC) No 2377/90 will be progressed. The substances are:

- Alpha-cypermethrin
- Altrenogest
- Cypermethrin
- Deltamethin
- Flugestone acetate
- Kanamycin
- Metamizole
- Morantel

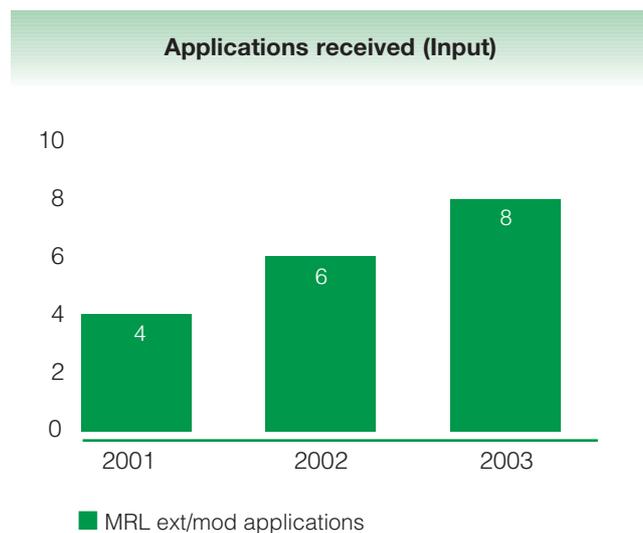
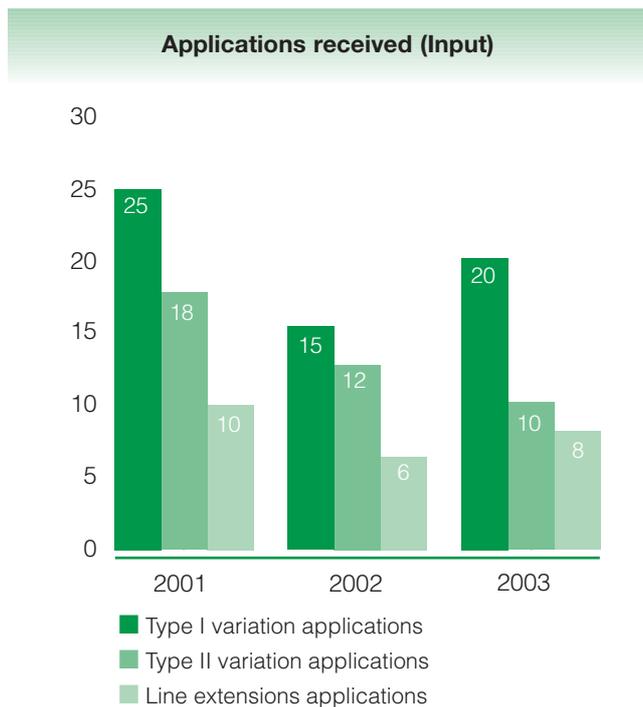
Opinions for maximum residue limits for old substances (Output)



Trend:

- The workload will decrease as definitive MRLs are set for the remaining old substances in Annex III

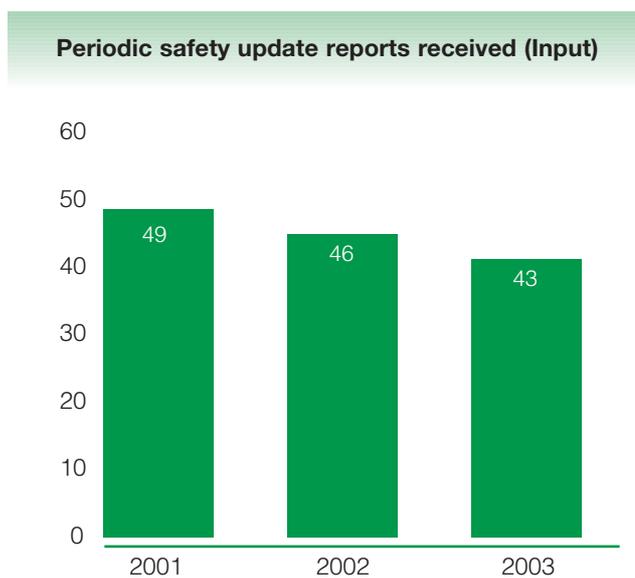
3.3 Post-authorisation activities



Trends:

- Steady increase in post-authorisation activities is expected to continue as the number of centrally authorised medicines increases
- Increased number of applications to extend and modify MRLs is expected to continue in 2003. This is in part a response to CVMP initiatives to encourage extrapolation of MRLs to minor species

3.4 Pharmacovigilance and maintenance activities



Trends:

- Annual reports to be carried out for 27 products
- 4 applications for renewal of marketing authorisations are expected
- 43 periodic safety update reports to be evaluated by CVMP

New issues to be faced in 2003 with workload implications:

- Efforts will continue within the Veterinary International Conference on Harmonisation (VICH) towards finalising guidelines on the scope of pharmacovigilance and the definition of standards for electronic reporting taking into account European requirements
- The CVMP will meanwhile develop EU standards for electronic reporting of adverse reactions as part of the implementation of the EudraVigilance pharmacovigilance reporting system for veterinary medicines
- Recommendations agreed to by CVMP from the joint EMEA/FEDESA/FVE seminar on pharmacovigilance in 2002 will result in the following activities in 2003:
 - Pharmacovigilance bulletin on centrally approved products published annually by EMEA
 - Harmonisation of a common pharmacovigilance reporting form throughout the Community

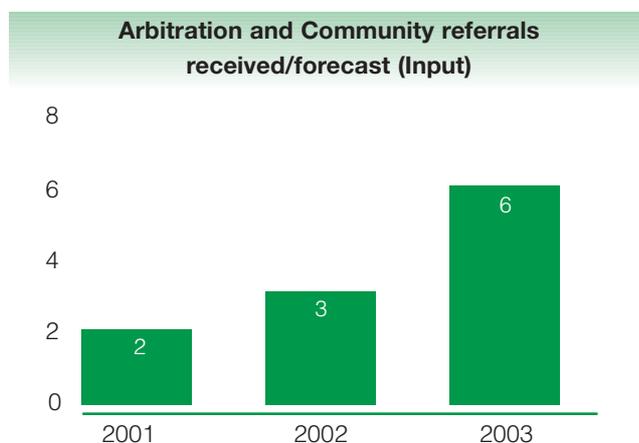
- Provision for promoting good pharmacovigilance practice in educational establishments for veterinarians and animal owners

3.5 Scientific advice

Trends:

- The number of applications for scientific advice is expected to show a steady increase over previous year, with 5 requests forecast. Applicants are becoming more aware of the procedure and the benefits it can offer in preparing the submission of the marketing authorisation application

3.6 Arbitration and Community referrals



Trends:

- The work in this area is expected to increase significantly in 2003
- 3 referrals as a result of safety issues relating to veterinary medicines are forecast
- 3 arbitration referrals are expected to be submitted to CVMP

3.7 Interested parties

Building on the excellent relationships established in the past, efforts will continue to further opportunities with the key interested parties e.g. Federation of Veterinarians in Europe, FEDESA, Federation of Veterinarians in Industry and consumer groups.

A number of bilateral meetings with FEDESA, a series of Info-days and the new concept of focus groups developed in 2001 will continue, especially to better communicate in advance the programmes for the CVMP working parties.

3.8 International activities

As in the past, the EMEA and CVMP will contribute activity to a number of international activities.

- Full coordination of EU contribution to VICH and participation in expert working groups and two Steering Committees, and possibly antibiotic resistance working groups
- Scientific expertise at Codex Alimentarius and WHO meetings
- Activities with the European institutions, e.g. European Commission Veterinary Pharmaceutical and Standing Committees, as well as heads of national agencies for veterinary medicines (HEVRA)
- PERF III will continue to require technical, logistical and scientific support to complete the programme prior to accession of candidate countries

3.9 Working parties and ad hoc groups

Trends:

- It is expected that the CVMP will refer a number of important topics and issues to the working parties for advice and recommendations in 2003. The number of meetings is therefore anticipated to increase
- Increased level of pharmacovigilance activities will require 6 meetings per year of the CVMP Pharmacovigilance Working Party

CVMP working parties and ad hoc groups in 2003	Number of meetings	New guidelines	Ongoing guidelines
Immunologicals Working Party	4	5	4
Efficacy Working Party	2	2	2
Pharmacovigilance Working Party	6	1	3
Safety Working Party	4	1	2
Joint CPMP/CVMP Quality Working Party	4	5	4
ad hoc Group on Environmental Risk Assessment	2	3	–
ad hoc Group on Antimicrobial Resistance	3	–	–

Details of the guidance documents expected to be released for consultation or finalised in 2003 are given in Annex 3.

3.10 Veterinary mutual recognition facilitation group

Useful web site:

Heads of agencies for medicines for veterinary use
<http://www.hevra.org>

The Agency will continue to provide support to the increasing workload of the VMRFG in 2003, together with a national expert on secondment from the Irish Medicines Board.

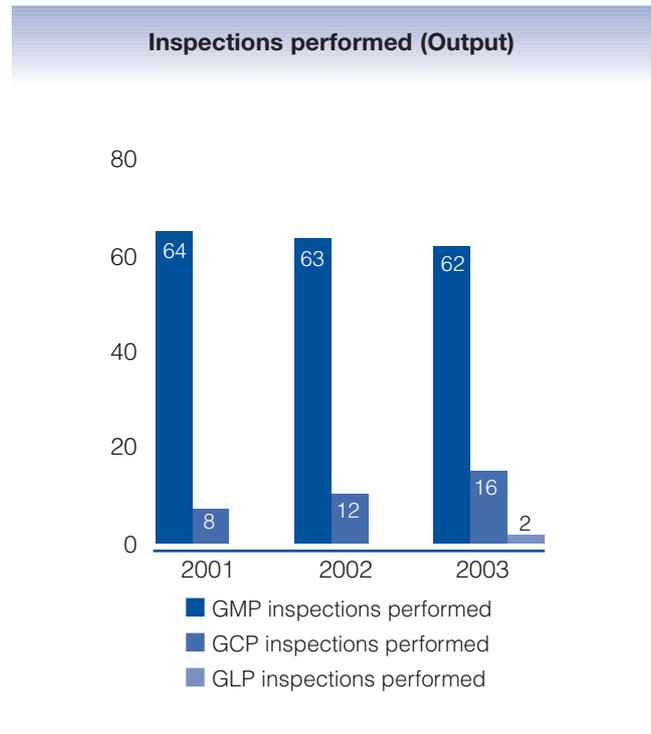
Chapter 4

Inspections

Priorities for inspections in 2003:

- To bring the preparatory phase of the mutual recognition agreement (MRA) with Japan to a successful conclusion and to finalise the entry into force of the EU agreement with Canada. Monitoring of other operational agreements will continue throughout 2003
- Active involvement in the activities required under the clinical trial directive for human medicines and in particular the finalisation of associated guidelines and creation of the clinical trials-related databases
- Successful contribution of support to the candidate countries preparing for accession to the EU through PERF III with the organisation of observed inspections and two technical GMP workshops
- To coordinate and manage effectively the requests for GMP, GCP and GLP inspections relating to applications for products through the centralised procedure within the timeframe laid down in Community law and to the standards required in the Agency's quality management system
- Operate the crisis management system for quality problems and defects in centrally authorised products and coordinate with Member States to ensure effective recalls as necessary
- Successful operation of the new 5-year covenant with the EDQM in respect of the sampling and testing procedures established previously, to ensure effective and adequate surveillance of the quality of centrally approved medicinal products marketed in the EU
- Concerted efforts to harmonise GMP and GCP inspection activities, in particular with accession countries in readiness for 2004

4.1 Inspections



Good clinical practice (GCP) inspections are anticipated to increase in 2003 as the awareness of GCP-related matters increases with Member States preparing for the implementation of the clinical trials directive. Inspections of pharmacovigilance compliance activities are also expected to increase. Good manufacturing practice (GMP) inspection requests for 2003 will not increase significantly as many of the sites specified in new applications have already been inspected in relation to previous products. In addition, the mutual recognition agreement (MRA) with Switzerland, which came into effect in June 2002 will mean that inspection of Swiss manufacturing sites will not be required. Although there were no good laboratory practice (GLP) inspection requests in 2002, provision is also made for a small number of GLP inspections to be carried out.

The ad hoc group of GMP inspection services will meet on four occasions in 2003. The focus of its work will be on the continued harmonisation of inspection procedures including the development of a common approach to quality systems implementation and coordination of follow-up actions to GMP inspections as well as providing support for ongoing MRA activities. One of these meetings will include a liaison meeting with the Joint CPMP/CVMP Quality Working Party.

The ad hoc meeting of GCP inspection services will meet five times in 2003. In addition to harmonisation work, focus will be on the development and consolidation of guidelines and procedures in preparation for the implementation of clinical trials directive in 2004.

Trends:

- Requests for GMP inspections are expected to remain stable in 2003 as many of the manufacturing sites cited in new applications have already been recently inspected for already authorised medicines and the impact of the MRAs with Switzerland and Canada are seen. This will be balanced by an increasing need for re-inspections of authorised sites
- Requests for GMP inspections for manufacturing sites for orphan medicinal products are expected to form a high proportion of GMP requests in 2003
- The workload in dealing with product defects is expected to grow as more new products are authorised
- Ad hoc groups of inspectors for GMP and GCP will continue to meet 4 and 5 times respectively as they continue with EU harmonisation activities

New issues to be faced in 2003 with workload implications:

- Additional work will need to be undertaken with inspection services of candidate countries prior to accession. A programme of 8 observed inspections in accession countries and 2 workshops are planned as part of the GMP activities of the PERF III programme
- Preparation for implementation of the clinical trials directive

4.2 Mutual recognition agreements

Trends:

- EC-Swiss MRA: 2003 will be the first full year of the operational phase of this MRA
- EC-Canada MRA: expected to come into effect early in 2003
- EC-Japan MRA: efforts will be made towards concluding the preparatory phase of this MRA through a series of visits and associated meetings with EU representatives

4.3 Sampling and testing

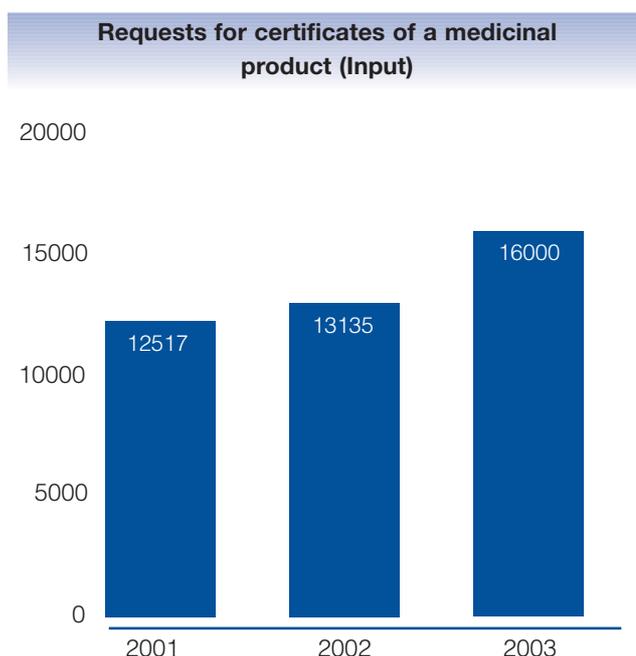
Trends:

- Programme of sampling and testing of centrally authorised products will continue in 2003
- A new agreement with the European Directorate for the Quality of Medicines (EDQM) will come into operation from the beginning of 2003

New issues to be faced in 2003 with workload implications:

- Observers from the accession candidate countries will participate in the sampling and testing programme for the first time
- A pilot procedure for the follow-up of testing results will be initiated
- A seminar for assessors, inspectors and representatives from the network of Official Medicines Control Laboratories to monitor and review the programme will be organised in 2003

4.4 Certificates



Trends:

- Increase of 20 % is forecast due to the larger number of authorised products

New issues to be faced in 2003 with workload implications:

- Maintenance and streamlining of procedures will continue
- Increase in demand will impact on available resource and may require the fee structure for this service to be reviewed

4.5 Implementation of the clinical trials directive

The deadline for coming into force of Council Directive 2001/20/EC on the conduct of clinical trials on medicinal products for human use is 1 May 2004 (OJ L 121, 1.5.2001, p. 34). The EMEA is taking the lead role in the development of a number of guidance documents required for the implementation of the Directive.

New issues to be faced in 2003 with workload implications:

- Significant effort will be devoted to the design, building and rollout of the clinical trials database and the database for unexpected suspected adverse reaction reporting in clinical trials

Chapter 5

Communications and networking

The Agency's communications and information technology networks are central to maintaining the relationship between itself and the 27 different competent authorities in the EU and EEA-EFTA Member States, the European Commission and the public. The Unit for Communications and networks assures the operation and maintenance of these networks.

5.1 Implementation of the EU telematics strategy

Trends:

- Increasing use of electronic communication and storage tools within the pharmaceutical industry
- Increasing demand for authoritative information on products from stakeholders
- Requirement for more reliable and focused signal detection in pharmacovigilance on a pan-European basis
- Requirement for more efficient evaluation procedures

New issues to be faced in 2003 with workload implications:

- Transfer of responsibilities for IT pharmaceutical sector projects within the 'Eudra' family (not including the Member

States' tracking system EudraTrack) from the European Commission Joint Research Centre (JRC) to the EMA. This transfer is made in full consultation between the European Commission and the Member State authorities

The EMA expects the implementation of the complete telematics strategy to take place over a period of 4 years, with an estimated budget of approximately €39 million. The EU budgetary authority has provided funding of €7 million in 2003 for the initial phase.

The telematics strategy aims to:

- support and facilitate the operation of the procedures as established in the legislation
- create and enhance transparency
- provide effective tools to disseminate information
- increase efficiency and make the best use of available resources

Implementation is based around five core projects. The core projects are built on a common infrastructure, which will be put in place at the same time.

Initiative	Activities
EudraNet	<p>The EudraNet has been established in order to provide a secure communications network between regulators together with related services, including a secure means of communicating files with internal & external partners. The principal objectives for 2003 are:</p> <ul style="list-style-type: none"> • EMA takes over responsibility from the European Commission Joint Research Centre on 1 January 2003 • Launch of EudraSafe II in January 2003 • Increased bandwidth implemented • Launch of EudraWorkSpace in June 2003 • PKI infrastructure implemented by December 2003 • IP/VPN infrastructure implemented by December 2003
EuroPharm database	<p>The EuroPharm is intended to be a European database of information relating to all medicinal products on the market in the European Union. The review has resulted in an increase in the scope of information to be collected and maintained by the Agency, which will impact on the development of this database. In establishing this database, the principal objectives for 2003 are:</p> <ul style="list-style-type: none"> • Pan-European agreement on reference data model by April 2003 • Intra-agency exchange standard for the submission of data agreed by July 2003

EudraVigilance	<ul style="list-style-type: none"> • Functional specifications for the first pilot available by September 2003 • Tender procedure for selection of contractor for first pilot complete <p>EudraVigilance is a database of safety information relating to all products on the market in the EU that is updated electronically, and whose information is available for analysis to all EU regulators. The principal objectives for 2003 are:</p> <ul style="list-style-type: none"> • Procure and install additional infrastructure by February 2003 • Implement data warehousing and business intelligence by end 2003
Electronic submission	<p>The purpose of this project is to establish exchange standards and to implement applications to enable data for the evaluation of medicinal products to be submitted to the EMEA and to be processed electronically. Two sub-projects are being progressed, namely the implementation of the electronic common technical document (eCTD – a defined structure and set of formats for the submission of information by applicants to the competent authorities in support of a marketing authorisation application), and the product information management project (PIM – a defined structure for the exchange of Summary of Product Characteristics, patient information leaflet and labelling/packaging information between applicant and competent authority). The principal objectives for 2003 are:</p> <p>eCTD:</p> <ul style="list-style-type: none"> • Process for receiving, storing and making available eCTD submissions using the centralised procedure agreed by April 2003 • Basic European Review System (EURES) in place June 2003 • Review of requirements based on experience of eCTD submissions received in December 2003 <p>PIM:</p> <ul style="list-style-type: none"> • Funding model decided by February 2003 • Report on proof of concept and associated documentation available in March 2003 • Requirements for Agencies' system drafted by June 2003
Clinical trials database	<p>This project has been set up in order to establish a European database to register all clinical trials requested in the EU, and to record all suspected unexpected serious adverse reactions occurring during these trials. The principal objectives for 2003 are:</p> <ul style="list-style-type: none"> • Prepare requirements specifications (by March 2003) • Call-for-tender for system development and subsequent contract (by June 2003)
Infrastructure	<p>The Eudra information technology projects require a common, architecturally sound infrastructure rooted in well-defined business processes and supported by an appropriately qualified complement of staff. This is set up in parallel with the execution of the individual projects described above. The principal objectives for 2003 are:</p> <ul style="list-style-type: none"> • Put in place appropriate system and project management software • Accompany the individual projects with appropriate hardware, software and system administration • Upgrade technical support arrangements

5.2 IT and project management at the EMEA

The smooth operation of EMEA internal information technology systems is critical to the Agency's ability to perform its tasks. The aim is to provide reliable and robust IT services to EMEA staff and delegates, together with appropriate levels of operational support while introducing new services and improvements to the infrastructure as required from the business and the users.

The support of the Agency's corporate information technology requires systems to be maintained and upgraded, as far as possible without the users of these systems being aware of the work being undertaken in the background.

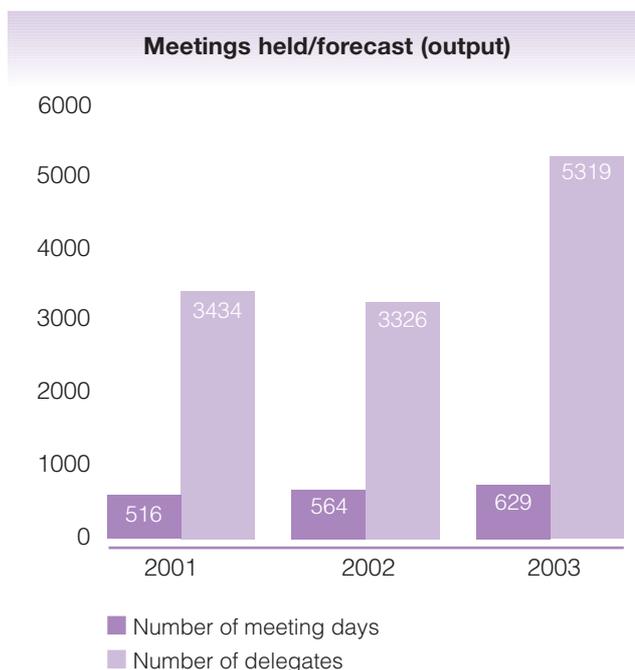
Specific operational objectives for 2003 include:

- Operate 20+ servers
- Operate, support and maintain all existing hardware and software of the Agency
- Maintain help desk service levels at greater than 95 % problem resolution within target
- Initiate new ways of information storage, access and retrieval
- Implement IT requirements requested by the Agency
- Ensure a minimum system availability of 99.5 % of IT services during EMEA working hours
- Ensure that the IT environment is correctly sized to EMEA needs

As the workload of the Agency evolves, new or revised requirements for information technology support are developed and implemented. These are defined through a standard operating procedure, and put into place, either as enhancements to existing systems or as new systems. During 2003, the objectives in this domain are:

- Develop EMEA core applications (SIAMED, SI2, ActiTrak, and the personnel database)
- Implement videostreaming
- Extend desktop videoconferencing facilities
- Continue implementation of the electronic document management system in conjunction with the Sector for Document management and publishing

5.3 Meeting management and conferences



The Sector is responsible for ensuring efficient support for EMEA meetings by providing the best possible facilities and services and constantly improving the resources available, as well as assisting delegates with logistics and practical arrangements. This includes the organisation of meetings, travel and hotel arrangements for delegates and hosts, reception of visitors, as well as the organisation of travel reimbursements (in cooperation with the Accounting Sector) and the preparation and follow-up of meeting room arrangements.

Trends:

- Meetings and delegates will increase over 2002 levels. This is partly as a result of activities related to meetings postponed from 2002 to 2003, and partly due to EudraVigilance-related meetings and the implementation of the EU telematics strategy

New issues to be faced in 2003 with workload implications:

- Implementation of the electronic meeting management system
- Participation of observers from accession candidate countries in meetings at the EMEA
- Introduction of a pilot project for live web broadcasting of meetings. This is aimed at improving the involvement of external experts in meetings of the CPMP
- Setting up of a visitors' centre on the EMEA web site
- Participation in the implementation of PERF III
- Increase in number of video conferences to approximately 40 in 2003

5.4 Document management and publishing

The Sector is responsible for publishing, cataloguing, distributing and conserving EMEA documents. These activities include quality management (particularly in the areas of translations, product information and the control of quality and coherence of regulatory documents) and logistics. Further, it comprises the running and management of the EMEA library as well as electronic archiving.

Trends:

- Increase number of documents published on web site, including multilingual publications
- Increase number of requests for information

New issues to be faced in 2003 with workload implications:

- Further development and implementation of the electronic document management system (EDMS)
- Continuous development of the EMEA web site and web management organisation, including the implementation of a number of new services in line with the Agency's commitment to increased transparency and communication
- Continuous review of product literature and opinion templates, including readability of patient leaflets

Chapter 6

Administration

The Administration Unit consists of three sectors responsible for managing the Agency's revenue, expenditure and accounts according to existing rules and regulations, for recruiting, managing and administering staff and seconded personnel, as well as for providing and running the necessary infrastructure services for an effective functioning of the Agency.

6.1 Personnel and budget

The principal objectives of the Sector for Personnel and budget are the development and timely and accurate management of the Agency's human and financial resources.

Trends:

- Recruitment will remain at a conservative level, but personnel and staff administration activities will increase proportionately more as a result of staff turnover, internal mobility and training

New issues to be faced in 2003 with workload implications:

- Continuation of the overhaul of human resource management at the EMEA, including rules regarding part-time working, revision of the performance evaluation system and the rules regarding internal transfer of staff
- Finalisation of the implementation of the computer-based personnel data and management system
- Implementation of an advanced training policy for continuing competence development
- Preparation for implementation of future new EU Staff Regulations and adaptation of internal implementing rules
- Implementation of new EU and EMEA financial regulations

6.2 Infrastructure services

The general technical development and diversification of EMEA activities require the accomplishment of a number of projects in order to ensure the accommodation of the Agency's staff and also in order to provide an adequate working environment and appropriate facilities for staff and visitors.

New issues to be faced in 2003 with workload implications:

- Development and maintenance of a business continuity plan for the EMEA
- Continuous training of the technical support team for meeting rooms and offices
- Maintenance of the office and public areas
- Review of the accommodation strategy for the EMEA. This will include office, meeting and technical equipment space needs, particularly with regard to future EU enlargement
- Evaluation of health and safety implementation as well as fire and emergency plans
- Expansion in scope of EMEA activities and enlargement will require further increase in office space, including provision of new delegation offices and meeting rooms
- Provision of improved offsite archiving facilities for the increasing number of files held by the EMEA, together with improved records management system

6.3 Accounting



New issues to be faced in 2003 with workload implications:

- Revision of EMEA financial regulation and implementing rules following reform of the EU financial regulation
- Implementation of improved systems to facilitate reimbursement of meeting expenses and follow-up of fee payment issues with applicants and marketing authorisation holders
- Upgrading of the SI2 accounting system
- Continuous upgrading of the ActiTrak system and improvement of the activity costing schemes (including rapporteur costs)
- Participation in the development of a review of the EMEA fees system

Trends:

- Overall workload for the Accounting Sector is expected to grow by 21 % in 2003 over 2001 levels
- Productivity gains achieved will not be sufficient to offset further increases
- Trends in the number of centralised applications will have only limited impact on workload of the Sector
- Increased number of delegates and meetings in 2003 will result in increased number of transactions to be executed

Annexes

1. EMA establishment plan 2001– 2003
2. EMA budget summaries 2001 – 2003
3. EMA guidance documents in 2003
4. EMA contact points and reference documents
5. Profiles of EMA personalities



Annex 1

EMEA establishment plan 2001 – 2003

Category and Grade	2001	2002		2003
	Occupied as at 31.12.2001	Authorised for 2002	Occupied as at 31.12.2002	Authorised for 2003
A1	--	--	--	--
A2	1	1	1	1
A3	4	5	5	5
A4	26	29	28	32
A5	24	28	26	32
A6	24	29	24	34
A7	24	30	30	32
A8	--	--	--	--
TOTAL A	103	122	114	136
B1	4	4	2	6
B2	8	9	8	10
B3	9	11	10	12
B4	5	9	8	12
B5	5	8	6	9
TOTAL B	31	41	34	49
C1	14	15	15	19
C2	13	19	19	23
C3	42	44	43	47
C4	--	4	4	6
C5	--	--	--	--
TOTAL C	69	82	81	95
D1	1	1	1	2
D2	4	5	5	5
D3	--	--	--	--
D4	--	--	--	--
TOTAL D	5	6	6	7
TOTAL POSTS	208	251	235	287

Annex 2

EMEA budget summaries 2001 – 2003

The summarised comparative budget statements for 2001 to 2003 are as follows:
(Amounts expressed in euro)

	2001 ⁽¹⁾ (31.12.2001)		2002 ⁽²⁾ (31.12.2002)		2003 ⁽³⁾ (19.12.2002)	
Revenue						
Fees	45 771 000	69.49%	39 000 000	63.58%	48 142 000	61.66%
General EU contribution	14 700 000	22.32%	17 135 000	27.95%	15 500 000	19.85%
Special EU contribution for IT telematics strategy	--	--	--	--	7 000 000	8.97%
Special EU contribution for orphan medicinal products	600 000	0.91%	2 750 000	4.49%	3 300 000	4.23%
Contribution from EEA	287 640	0.44%	366 000	0.60%	558 000	0.71%
Contribution from EU programmes (PERF)	2 314 360	3.51%	231 000	0.38%	1 430 000	1.83%
Other	2 193 000	3.33%	1 840 000	3.00%	2 151 000	2.75%
TOTAL REVENUE	65 866 000	100.00%	61 304 000	100.00%	78 081 000	100.00%
Expenditure						
Staff						
Salaries	20 615 000	31.30%	24 850 000	40.54%	29 130 000	37.31%
Interim and other support persons	1 414 000	2.15%	1 760 000	2.87%	1 845 000	2.36%
Other staff-related expenditure	1 683 640	2.56%	1 502 000	2.45%	2 213 000	2.83%
Total title 1	23 712 640	36.00%	28 112 000	45.86%	33 188 000	42.50%
Building/equipment						
Rent/charges	5 149 000	7.82%	5 572 000	9.09%	6 275 000	8.04%
Expenditure on data processing	4 293 000	6.52%	2 570 000	4.19%	6 250 000	8.00%
Other capital expenditure	1 658 000	2.52%	381 000	0.62%	627 000	0.80%
Postage and communications	617 000	0.94%	264 000	0.43%	418 000	0.54%
Other administrative expenditure	1 829 000	2.78%	2 107 000	3.44%	2 083 000	2.67%
Total title 2	13 546 000	20.57%	10 894 000	17.77%	15 653 000	20.05%
Operational expenditure						
Meetings	4 110 000	6.24%	3 535 000	5.77%	4 920 000	6.30%
Evaluations	21 308 000	32.35%	17 855 500	29.13%	21 941 000	28.10%
Translation	428 000	0.65%	477 000	0.78%	451 000	0.58%
Studies and consultants	225 000	0.34%	98 500	0.16%	350 000	0.45%
Publications	190 000	0.29%	119 000	0.19%	148 000	0.19%
EU programmes	2 346 360	3.56%	213 000	0.34%	1 430 000	1.83%
Total title 3	28 607 360	43.43%	22 298 000	36.37%	29 240 000	37.45%
TOTAL EXPENDITURE	65 866 000	100.00%	61 304 000	100.00%	78 081 000	100.00%

Notes (1) Final appropriations for the 2001 budget.

(2) Final appropriations for the 2002 budget.

(3) Budget for 2003 adopted by the Management Board on 19.12.2002.

Annex 3

EMEA guidelines for 2003

The following documents are intended to be finalised or released for consultation in 2003:

CPMP Biotechnology Working Party

Document title

Note for Guidance on the Use of Bovine Serum in the manufacture of Human Biological Medicinal Products

Points to Consider on Quality Aspects of Medicinal Products containing Active Substances Produced by Stable Transgene Expression in Higher Plants

Revision of Note for guidance on minimising the risks of TSE transmission via medicinal products

Points to Consider on the Development of Live Attenuated Influenza Vaccines

CPMP Blood Product Working Party

Document title

Note for Guidance on the Clinical investigation of plasma derived fibrin sealants

Note for guidance on the Clinical investigation of von Willebrand factor

Warning on transmissible agents for patient leaflets and SPCs

Core SPC for Plasma derived fibrin sealants

CPMP Efficacy Working Party

Document title

Points to consider on the clinical development of fibrinolytic medicinal products in the treatment of patients with ST segment elevation acute myocardial infarction (STEMI)

Note for Guidance on the clinical development of medicinal products for the treatment of HIV infection

Note for Guidance on clinical investigation of medicinal products for the treatment of migraine

Note for Guidance on evaluation of anticancer medicinal products in man (CPMP/EWP/205/95 rev. 2) – Addendum on paediatric oncology

Points to consider on the evaluation of new anti-fungal agents for invasive fungal infections

Points to consider on clinical investigation of medicinal products for treatment of rheumatoid arthritis

Points to consider on the evaluation of medicinal products for the treatment of irritable bowel syndrome

Appendix to the Note for Guidance on the Clinical investigation of medicinal products in the treatment of schizophrenia (CPMP/EWP/559/95) – methodology of clinical trials concerning the development of depot preparations of approved medicinal products in schizophrenia

Points to consider on the requirements for clinical documentation for metered dose inhalers (MDI)

Addendum on neuropathic pain to the Note for Guidance on clinical investigation of medicinal products for nociceptive Pain treatment

Note for Guidance on Clinical Investigation of Medical Products in the Treatment of Generalised Anxiety Disorder

Note for Guidance on Clinical Investigation of Medical Products in the Treatment of Panic Disorder

Note for Guidance on Clinical Investigation of Medical Products in the Treatment of Obsessive-compulsive Disorder

Addendum on acute cardiac failure to the CPMP Note for Guidance on clinical investigation of medicinal products in the treatment of acute cardiac failure

Note for guidance on the evaluation of medicinal products for the treatment of dyslipoproteinaemia

Note for Guidance on Clinical investigation of steroid contraceptives in women

Revision of Note for Guidance on evaluation of new anti-bacterial medicinal products (CPMP/EWP/558/95) and Note for Guidance on the pharmacodynamic section of the summary of product characteristics for antibacterial medicinal products

Points to consider on Biostatistical/methodological issues arising from CPMP discussion on licensing applications: Choice of Non-inferiority margin

Points to consider on Biostatistical/methodological issues arising from CPMP discussion on licensing applications: Adjustment for baseline covariates

Points to consider on the use of statistical methods for flexible design and analysis of confirmatory clinical trials

Points to consider on clinical pharmacokinetic investigation of the pharmacokinetics of peptides and proteins

Note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function

Points to consider on the evaluation of the pharmacokinetics of medicinal products in the paediatric population

Note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with hepatic impairment

Note for guidance on clinical investigation of medicinal products for the treatment of psoriasis

Points to consider on allergic rhino-conjunctivitis

Addendum to the Note For Guidance on Modified Release Oral and Transdermal Dosage Forms: Section II (Pharmacokinetic and Clinical Evaluation) on the clinical requirements of modified release products submitted as a line-extension of an existing marketing authorisation

Points to consider on Xenogenic Cell Therapy

Note for Guidance on Comparability of Medicinal Products containing biotechnology- derived proteins as active substance

Note for Guidance on the use of medicinal products during pregnancy

Note for Guidance on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling

CPMP Safety Working Party

Document title

Position Paper on the Non-clinical safety studies to support clinical trials with a single low dose of a compound

Note for Guidance on specification limits for residues of metal catalysts

Note for Guidance on Comparability of Medicinal Products Containing Biotechnology-derived Proteins as Drug Substance: Annex on Non-Clinical and Clinical Considerations

Note for Guidance on the Non-Clinical Documentation of Medicinal Products with Well-Established Use

Position Paper on the limits of genotoxic impurities

Note for Guidance on the Need for Pre-clinical Testing of Human Pharmaceuticals in Juvenile Animals

Note for Guidance on Environmental Risk Assessments for Pharmaceuticals

CPMP Pharmacovigilance Working Party

Document title

Note for Guidance on Criteria for Recall and Repackaging Following Urgent Safety Restriction and Variation Procedures

CPMP Points-to-Consider Document on Xenogeneic Cell Therapy (CPMP/1199/02)

ICH-V1: Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs – Addendum to ICH-E2C (CPMP/ICH/4679/02)

ICH-V2: Post-Approval Safety Management: Definitions and Standards for Expedited Reporting and Good Case Management Practices

ICH-V3: Prospective Planning of Pharmacovigilance

Notice to Applicants – Guideline on the Summary of Product Characteristics (EC December 1999 – Revised Version)

CPMP Herbal Medicinal Products Working Party

Document title

Note for guidance on non-clinical testing of herbal drug preparations with long-term marketing experience - guidance to facilitate mutual recognition and use of bibliographic data

Concept paper for a Note for Guidance on the investigation of biopharmaceutical characterisation and bioavailability/ bioequivalence of herbal drugs/preparations

Position paper on the risk associated with the use of herbal products containing estragole

Position paper on the risk associated with the use of herbal products containing methyleugenol

Position paper on the risk associated with the use of herbal products containing α - and β -asarone

Position paper on the use of *Sassafras albidum* as active substance or ingredient in herbal medicinal products

Concept paper on the levels of scientific evidence required for the authorisation of well-established use and traditional herbal medicinal products

Core-data on *Urticae radix*

Core-data on *Lini semen*

Core-data on *Rosmarini folium cum flore*

Core-data on *Primulae Radix*

CVMP Efficacy Working Party

Document title

Antimicrobials for general use in target animal species
 Summary of product characteristics for antimicrobial products
 Efficacy requirements for ectoparasiticides for cattle
 Fluid therapy

CVMP Immunologicals Working Party

Document title

Requirements and controls applied to bovine serum used in the production of immunological veterinary medicinal products
 EU requirements for batches with maximum and minimum titre or batch potency for developmental safety and efficacy studies
 Requirements for live recombinant vectored vaccines
 Requirements for compatibility statements for veterinary vaccines
 Harmonisation of requirements for potency and batch consistency of vaccines
 VICH: Testing for the detection of mycoplasma contamination
 VICH: Biologicals: testing of residual formaldehyde
 VICH: Target animal safety for veterinary biological products
 VICH: Tests on the presence of extraneous viruses in veterinary viral vaccines

CVMP Pharmacovigilance Working Party

Document title

VICH: Pharmacovigilance of veterinary medicinal products: Management of adverse event reports
 VICH: Pharmacovigilance of veterinary medicinal products: Management of periodic summary update reports
 VICH: Pharmacovigilance of veterinary medicinal products: Controlled list of terms
 VICH: Pharmacovigilance of veterinary medicinal products: Electronic standards for transfer of data

CVMP Safety Working Party

Document title

VICH: Pre-approval information for registration of new medicinal products for food producing animals with respect to antimicrobial resistance
 Injection site residues
 User safety
 Estimation of predicted environmental concentrations, including harmonisation of default values and development of a harmonised computer model
 Toxicity of substances to dung fauna
 Degradation of substances in manure

Joint CPMP/CVMP Quality Working Party

Document title

Use of near infrared spectroscopy by the pharmaceutical industry
 Modified release oral and transdermal dosage forms
 Revision: European Drug Master File
 Declaration of storage conditions for pharmaceutical veterinary medicinal products in the product particulars and active substances: Annex: Stability testing of new active substances and medicinal products Annex: Stability testing of existing active substances and related finished products
 Summary of requirements for active substances
 Process validation (update)
 Quality aspects of veterinary medicinal products administered via drinking water

Annex 4

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

Panos TSINTIS

Direct telephone (44-20) 75 23 71 08

E-mail: panos.tsintis@emea.eu.int

For matters relating to pharmacovigilance for medicinal products for veterinary use

Barbara FREISCHEM

Direct telephone (44-20) 74 18 85 81

E-mail: barbara.freischem@emea.eu.int

For product defect and other quality-related matters

E-mail: qualitydefects@emea.eu.int

Fax: (44-20) 74 18 85 90

Out of hours telephone: (44-7880) 55 06 97

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

Jonna SUNELL-HUET

Direct telephone (44-20) 74 18 84 65

E-mail: certificate@emea.eu.int

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:

EMEA Documentation Service

European Agency for the Evaluation of Medicinal Products

7 Westferry Circus

Canary Wharf

UK – London E14 4H

Further information can be obtained from the above address or from

E-mail: emearequests@emea.eu.int

Fax: (44-20) 74 18 86 70

Requests for general information packs should be sent to

Amanda BOSWORTH

Direct telephone (44-20) 74 18 84 08

E-mail: amanda.bosworth@emea.eu.int

European experts list

Approximately 3 000 are used by the EMEA in its scientific evaluation work. The list of these European experts is available for examination on request at the EMEA offices.

Requests should be sent in writing to the EMEA or to

E-mail: europeanexperts@emea.eu.int

Integrated quality management

IQM adviser

Marijke KORTEWEG

Direct telephone (44-20) 74 18 85 56

E-mail: iqmanagement@emea.eu.int

Press office

Press officer

Martin HARVEY ALLCHURCH

Direct telephone (44-20) 74 18 84 27

E-mail: martin.harvey-allchurch@emea.eu.int

Annex 5

Profiles of EMEA personalities



Keith Jones,
Chairman of the
Management Board,
b. 14 October 1937, n. British

Education: Dr Jones is qualified in medicine and has held posts in clinical medicine and research at UK teaching hospitals. He then trained as a toxicologist in the agrochemical industry.

Career to date: Dr Jones went on to spend 22 years in industry as Head of the Medical Department at Fisons Agrochemical Divisions, Head of Safety Assessment and Clinical Pharmacology at Beecham Pharmaceuticals and Executive Director, Medical Affairs at Merck Sharp and Dohme in the USA. In 1991 Dr Jones was appointed Chief Executive of the UK Medicines Control Agency, and is presently the UK delegate to the EU Pharmaceutical and Standing Regulatory Committees, and a member of the EU Scientific Steering Committee within the European Commission Directorate-General for Public health and consumer protection. He is currently visiting Professor of Pharmacology at the School of Pharmacy University of London and has published widely. Dr Jones joined the EMEA Management Board in 1995. He was first elected chairman of the Board in 2001 and re-elected chairman in 2003.



Philippe Duneton,
Vice-chairman of the
Management Board,
b. 15 September 1961, n. French

Education: Dr Duneton qualified as a doctor in medicine from the University of Paris VI, Faculty de Lariboisière Saint Louis. He is a former house doctor and former assistant head of section for Paris Hospitals.

Career to date: From 1992 to 1993, Dr Duneton was technical advisor for public health in the Cabinet of the French Minister responsible for health and humanitarian action. From 1993 to 1995 he was coordinator of the C-Clin Paris-Nord (inter-regional centre for nosocomial infections). He was nominated as head of the AIDS and drug addiction group of Paris public hospitals. He served in the Cabinet of the French Secretary of State for health as public health adviser from 1997 to 1998, before being nominated as Secretary-General of the French Agence du Médicament in 1998. He was appointed Director-General of the new Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) in 1999. He joined the EMEA Management Board in 1999 and was elected vice-chairman of the Board in 2003.



Thomas Lönnngren,
Executive Director,
b. 16 December 1950, n. Swedish

Education: Qualified pharmacist from the University of Uppsala Faculty of Pharmacy. MSc in social and regulatory pharmacy. Post-graduate studies in management and health economics.

Career to date: From 1976 to 1978, lecturer at University of Uppsala. Mr Lönnngren was with the National Board of Health and Welfare, Sweden, from 1978 to 1990 during which time he was responsible for herbal medicines, cosmetics, medical devices, narcotics and contraceptives. He acted as senior pharmaceutical consultant for the Swedish health cooperation programme in Vietnam from 1982 to 1994. He joined the Swedish Medicinal Products Agency in 1990, serving as Director of Operations and later as Deputy Director-General. He is Executive Director of the EMEA since January 2001.

EMA scientific committees



Daniel Brasseur,
Chairman of the CPMP,
b. 7 June 1951, n. Belgian

Education: Qualified medical doctor from the Free University of Brussels. Post-graduate degree in paediatrics and a PhD in nutrition.

Career to date: From 1976 to 1986

Dr Brasseur worked as a paediatrician at the University Sint Pieter Hospital in Brussels. He moved briefly to the pharmaceutical industry from 1986 to 1987, before returning to clinical work at the Queen Fabiola Children's University Hospital in Brussels as head of the nutrition and pharmacodynamics unit, a post he continues to hold today. He joined the Pharmaceutical Inspectorate of the Belgian Ministry of Public Health as head of medical assessors in 1997. He was appointed a member of the CPMP in 1997. Dr Brasseur has held a number of teaching posts and is currently professor of nutrition and related diseases at the Free University of Brussels.



Gérard Moulin,
Chairman of the CVMP,
b. 18 October 1958, n. French

Education: PhD in Microbiology from the University of Lyon.

Career to date: From 1981 to 1984, Dr Moulin worked in the Bovine Pathology Laboratory in Lyon.

In 1984, he joined the Veterinary Medicines Laboratory in Fougères where he was assessor and rapporteur for marketing authorisation dossiers. He was also responsible for a laboratory unit. In 1997 he was appointed as Head of the pharmaceuticals assessment unit of the French veterinary agency (AFSSA-ANMV).



Eric Abadie,
Vice-chairman of the CPMP,
b. 14 July 1950, n. French

Education: Qualified medical doctor from the University of Paris. Post-graduate qualifications in internal medicine, endocrinology, diabetology and cardiology. He also holds an MBA.

Career to date: From 1981 to 1983 Dr Abadie held a number of clinical and laboratory positions, before joining the pharmaceutical industry in 1983. He was director of medical affairs of the French pharmaceutical trade association from 1985 to 1993 and returned to industry until 1994. He joined the French medicines agency in 1994 as director of pharmacotherapeutic evaluation, a post he holds today. Dr Abadie has been a consultant in cardiology and diabetology since 1984.



Johannes Hoogland,
Vice-chairman of the CVMP,
b. 22 February 1956, n. Dutch

Education: Degree in analytical chemistry from the University of Amsterdam 1984, followed by PhD Biochemistry from the University of Amsterdam 1988.

Career to date: Worked for the food industry (1976-1977), biological laboratory of the Free University of Amsterdam (1977-1978). Employed by Ministry of Agriculture, Nature Management and Fisheries since 1988; from 1988 to 1998 by State Institute for Quality Control of Agricultural Products (RIKILT-DLO) as an assessor for veterinary medicinal products and feed additives, research on development of analytical methods and development of quality systems for agricultural production. From 1998 to present by Bureau Registratie Diergeneesmiddelen (BRD). CVMP member since 1998 and chairman of the ad hoc Group for environmental risk assessment of CVMP. Appointed vice-chairman of the CVMP in January 2002.



**Josep Torrent i Farnell,
Chairman of the COMP,
b. 2 May 1954, n. Spanish**

Education: Qualified Pharmacist and Degree in medicine and surgery from the University of Barcelona as well as postgraduate courses in pharmacology and toxicology, public health and

European institutions. Specialist in internal medicine and clinical pharmacology. Doctorate in clinical pharmacology from the Autonomous University of Barcelona (UAB).

Career to date: From 1977-1990, Prof. Torrent i Farnell worked in internal medicine and clinical pharmacology in Spain and was Assistant Professor of Pharmacology at UAB. From 1990 to 1994, he was Technical Counsellor in Clinical Evaluation and Pharmacology at the Spanish Ministry of Health, Member of the CPMP Efficacy Working Party and involved in the Efficacy Group of the ICH. In 1992, he became Professor of Clinical Pharmacology and Therapeutics and Director of the Masters/Diploma course on European Registration of Medicinal Products (UAB). He joined the EMEA in 1995 as Principal Scientific Administrator and from 1996 to 1998 he was Head of Sector for new chemical substances. In 1998 he was coordinator Director for the creation of the Spanish Medicines Agency and Executive Director of the Spanish Medicines Agency from 1999-2000. He was elected Chairperson of the Committee for Orphan Medicinal Products in May 2000. In November 2000, he became Director-General of the Advanced Centre of Services and Training for Health and Life Sciences, Dr. Rober Foundation (UAB).



**Yann Le Cam,
Vice-chairman of the COMP,
b. 15 July 1961, n. French**

Education: He is a graduate in business administration from the Institut Supérieur de Gestion in Paris. He also holds an MBA from the Centre de Perfectionnement aux Affaires, Groupe HEC-CPA, 2000, Jouy-en-Josas, France.

Career to date: Mr Le Cam has 15 years of professional experience and personal commitment in health and medical research non-governmental organisations in France, Europe and the United States in the fields of cancer, AIDS and genetic diseases. He served as Director-General of AIDES Fédération Nationale from 1992 to 1998. He later joined the French Neuromuscular Diseases Association (AFM) as Special Advisor to stimulate public health policy on rare diseases, to create the French Alliance Maladies Rares, a national umbrella organisation of 70 patients associations, and to advise the European Organisation for Rare Disorders (Eurordis), based in Paris. He is also the Vice-Chairman of the International Alliance of Patients Organisations (IAPO) based in London. Mr Le Cam has three daughters, the eldest of whom is affected by cystic fibrosis.

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



Patrick Le Courtois,
Head of Unit,
b. 9 August 1950, n. French

Education: Qualified medical doctor from the University of Paris. PhD in public health from the University of Bordeaux. Post-graduate degrees in tropical medicine, clinical research and epidemiology.

Career to date: From 1977 to 1986, Dr Le Courtois worked as a general practitioner and as director of a medical centre in Paris. In 1986 he joined the University of Bordeaux and was involved in research areas in public health including epidemiology, clinical research, pharmacovigilance, tropical and infectious diseases, health economy and education. In 1990, he joined the Pharmacy Directorate of the French Ministry of Health and in 1993 the French Medicines Agency as CPMP rapporteur, Head of Unit of European Procedures and from January 1995 as a French CPMP delegate. He joined the EMEA in September 1997 and was appointed Head of Sector for new chemical substances in June 1998 and Head of Sector for orphan drugs and scientific advice in January 2001.



John Purves,
Head of Sector for quality of medicines,
b. 22 April 1945, n. British

Education: Qualified as a pharmacist from Heriot-Watt University, Edinburgh. PhD in pharmaceutical microbiology from the University of Strathclyde, Glasgow.

Career to date: From 1972 to 1974, Dr Purves worked in the pharmaceutical industry. Between 1974 and 1996, he held posts in the UK Medicines Division and the Medicines Control Agency, including inspector of pharmaceutical manufacture, reviewer of dossiers and manager of the Biotechnology and Biological Unit. He was the UK representative at the Biotechnology Working Party, involved in the generation of many guidelines relating to biotechnology and biological products. He joined the EMEA in August 1996 as Head of Sector for biotechnology and biologicals. He was appointed Head of Sector for quality of medicines in January 2001.



Agnès Saint Raymond,
Head of Sector for orphan drugs and scientific advice,
b. 7 September 1956, n. French

Education: Qualified medical doctor from the University of Paris. Post-graduate qualifications in paediatrics and methodology.

Career to date: Dr Saint Raymond held a position as paediatrician in a teaching paediatric hospital in Paris, followed by a number of years working for a number of pharmaceutical companies. In 1995 she joined the French Medicines Agency as Head of Unit for pharmaco-toxico-clinical assessment. She joined the EMEA in January 2000 and was appointed Head of Sector for Scientific Advice and Orphan Drugs in December 2001. She is also in charge of issues relating to medicines used in children.



Isabelle Moulon,
Head of Sector for safety and efficacy of medicines,
b. 9 March 1958, n. French

Education: Qualified medical doctor from the University of Grenoble, France. Specialist in endocrinology. Post-graduate studies in statistics, methodology and nutrition.

Career to date: Worked as a clinical endocrinologist in a French hospital until 1987 and then joined the Directorate of Pharmacy at the French Ministry of Health. She worked for the pharmaceutical industry from 1992 to 1995 before joining the EMEA in July 1995. She was appointed Head of Sector for safety and efficacy of medicines in January 2001.



**Marisa Papaluca Amati,
Deputy Head of Sector for safety
and efficacy of medicines,
b. 12 October 1954, n. Italian**

Education: Degree in medicine and surgery from the University of Rome. Specialist in internal medicine. Post-graduate studies in cardiology and endocrinology.

Career to date: From 1978 to 1983 Dr Papaluca worked as a research fellow in the State University of Rome on projects in the area of clinical immunology, oncology and cellular immunology. From 1984 to 1994, as medical director of the Pharmaceutical Department of the Italian Ministry of Health, she was in charge of the Operative Centre for Community Procedures and was an

Italian member of the former Committee for Proprietary Medicinal Products. Dr Papaluca has acted as EU rapporteur for an ICH efficacy topic and as a member of the International CIOMS Working Groups I and II on pharmacovigilance. She joined the EMEA in October 1994. She was appointed Deputy Head of Sector for safety and efficacy of medicines in January 2001.

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



**Noël Wathion,
Head of Unit,
b. 11 September 1956, n. Belgian**

Education: Qualified pharmacist from the Free University of Brussels.

Career to date: Mr Wathion first worked as pharmacist in a retail pharmacy. He was later appointed to the

Pharmaceutical Inspectorate (Ministry of Social Affairs and Public Health) in Brussels as a Chief Inspector, acting as the Secretary of the Belgian Medicines Commission. He is a former Belgian Member of both the CPMP and CVMP, and representative on the Pharmaceutical Committee, Standing Committee and Notice to Applicants working group. He joined the EMEA in August 1996 as Head of Sector for regulatory affairs and pharmacovigilance and was appointed Head of the Human Medicines Evaluation Unit in September 2000. Further to the restructuring of the Human Medicines Evaluation Unit in 2001, he was appointed Head of Unit for the Post-authorisation evaluation of medicines for human use.



**Tony Humphreys,
Head of Sector for regulatory
affairs and organisational support,
b. 12 December 1961, n. Irish**

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

Career to date: Since qualifying in 1983 Mr Humphreys has worked in the area of development pharmaceuticals for a national branded generics manufacturer and an international research and development company. In 1991 he joined the International Regulatory Affairs Division of Glaxo Group Research Limited where he was responsible for the development and submission of a series of international registration applications in a number of therapeutic areas. He joined the EMEA in May 1996 and was appointed Head of Sector for regulatory affairs and operational support in January 2001.



**Panos Tsintis,
Head of Sector for
pharmacovigilance,
post-authorisation safety and
efficacy of medicines,
b. 18 September 1956, n. British**

Education: Qualified in medicine from Sheffield University in 1983. Post-

graduate qualifications in internal medicine (FRCP) and pharmaceutical medicine (FFPM).

Career to date: Six years of clinical experience in UK hospitals, 5 years as Director of Pharmacovigilance and Regulatory Affairs at Astra Pharmaceuticals in the UK and a total of 7 years at the UK Medicines Control Agency. Prior to his appointment as Unit Manager in Pharmacovigilance, he held a number of positions in both pre- and post-authorisation areas and was also the UK delegate to the CPMP Pharmacovigilance Working Party. Dr Tsintis joined EMEA as Head of Sector, Pharmacovigilance and post-authorisation safety and efficacy of medicines in March 2002.



**Sabine Brosch,
Deputy Head of Sector for
pharmacovigilance, post-
authorisation safety and efficacy
of medicines,
b. 17 August 1963, n. Austrian**

Education: Masters Degree in pharmacy and Doctor of Natural Sciences Degree in

pharmacology from the University of Vienna. Post-graduate studies in pharmacology at the University of Melbourne and Auckland.

Career to date: From 1988 to 1992, Dr Brosch worked as an assistant professor at the Department of Pharmacology and Toxicology at the University of Vienna, where she was specialised in electrophysiology. In 1992 she moved to the Pharmacovigilance Department at the Austrian Ministry of Health and completed a 6-month regulatory traineeship in the Pharmaceuticals Unit of the European Commission in 1995. She joined the EMEA in November 1996 and was appointed Deputy Head of Sector for pharmacovigilance, post-authorisation safety and efficacy of medicines in January 2001.

Unit for Veterinary medicines and inspections



Peter Jones,
Head of Unit,
b. 9 August 1947, n. British

Education: Graduated in veterinary medicine from the Faculty of Veterinary Science at Liverpool University and is a Member of the Royal College of Veterinary Surgeons of the United Kingdom.

Career to date: After several years in general veterinary practice in the United Kingdom and Canada, Dr Jones joined the pharmaceutical industry in the animal health sector. He has held a number of appointments in research and regulatory affairs in multinational companies and, most recently, as Senior Director of International Regulatory Affairs for Animal Health Products for Merck Sharp and Dohme in New Jersey, USA. He joined the EMEA in June 1995, and was appointed Head of the Veterinary Unit in December of the same year and took on responsibility for information technology in January 2000. He is EU coordinator in the VICH.



Melanie Leivers,
Deputy Head of Sector for
veterinary marketing authorisation
procedures,
b. 1 December 1958, n. British

Education: Graduate in biochemistry and pharmacology from Leeds University. Post-graduate diploma in European Community law from King's College, London.

Career to date: Miss Leivers worked for the Milk Marketing Board for England and Wales (MMB) as a Liaison Chemist for 5 years prior to being appointed Assistant Director of the MMB/Federation of Agricultural Cooperatives office in Brussels, representing all sectors of agricultural cooperation to the European institutions. Following this she worked for a short-term contract at the European Commission (DG XI) and then in industry at Pfizer (formerly SmithKline Beecham Animal Health) as a regulatory affairs manager. Miss Leivers joined the EMEA in February 1996 and was appointed Deputy Head of Sector in June 2001.



Jill Ashley-Smith,
Head of Sector for veterinary
marketing authorisation
procedures,
b. 18 December 1962, n. British

Education: Graduated in pharmacology from Kings College, London University. Qualified as a veterinary surgeon from the Royal Veterinary College, London University.

Career to date: From 1987 to 1994, Dr Ashley-Smith was employed in the veterinary pharmaceutical industry, first as a technical adviser and subsequently as a registration manager. In 1994, she joined the UK Veterinary Medicines Directorate as senior veterinary assessor in the pharmaceuticals and feed additives team. She participated as UK CVMP member from 1996 until joining the EMEA in July 1997.



Kornelia Grein,
Head of Sector for safety of
veterinary medicines,
b. 24 July 1952, n. German

Education: Qualified chemist and pharmacist from the Free University of Berlin. PhD in organic chemistry from the Free University of Berlin.

Career to date: From 1976 to 1987, Dr Grein held positions in Germany as scientific assistant at the Free University of Berlin and as pharmacist. In 1987 she joined the German Environmental Agency as scientific administrator. Seconded to the European Commission in 1992, she returned to Germany to the Ministry for Environment in 1995. She was involved in the EU classification and labelling scheme and risk assessment of chemical substances, as well as in the harmonisation activities on these topics both within the EU and OECD. She joined the EMEA in April 1996.



**Emer Cooke,
Head of Sector for inspections,
b. 09 April 1961, n. Irish**

Education: Qualified Pharmacist with Masters degree in Pharmaceutical Chemistry and Masters in Business Administration (MBA) from Trinity College Dublin. Member of the Pharmaceutical Society of Ireland.

Career to date: Ms. Cooke worked in a number of positions within the Irish pharmaceutical industry before joining the Irish Medicines Board as a pharmaceutical assessor in 1988. Following graduation with a MBA degree in 1991, she joined EFPIA, the European pharmaceutical industry association as Manager of Scientific and Regulatory Affairs. Her responsibilities there included coordination of regulatory aspects of European procedures and International Conference on Harmonisation (ICH) activities. After a three-year stay in Prague, Czech Republic,

where she worked as a consultant on European pharmaceutical matters as well as continuing her work with EFPIA, she joined the Pharmaceuticals Unit of the European Commission in September 1998. Her responsibilities there included coordination of ICH activities, relations with the FDA, pharmaceutical aspects of mutual recognition agreements, GMP and inspection-related matters, orphan medicinal products, preparatory work on a regulation on paediatric medicinal product and issues relating to EU enlargement. She joined the EMA as Head of the Inspections Sector in July 2002.

Communications and networking Unit



Hans-Georg Wagner,
Head of Unit,
b. 29 November 1948, n. German

Education: Doctorate in natural sciences (applied physics and materials science) from Saarbruecken University, Diploma in physics from Tuebingen University, Master of Arts (mathematics) from the University of Cambridge, UK.

Career to date: Dr Wagner was a research and teaching assistant at Saarbruecken University from 1976 to 1981. He later taught as a lecturer and senior lecturer at the same university until he joined the European Commission in Luxembourg in January 1986. There he was responsible for a number of groups in the technical support division of the Euratom Safeguards Directorate. Dr Wagner was appointed head of sector for IT in the same service in 1993. He joined the EMEA on 1 May 2002.



Sylvie Bénédice,
Head of Sector for meeting
management and conferences,
b. 28 December 1954, n. French

Education: Doctorate of Science in physical sciences; qualification in research management; PhD in physical organic chemistry; Masters degree in physical organic chemistry; Degree in biochemistry.

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



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

Education: Bachelor of Arts in languages and linguistics at the University of East Anglia and post-graduate degree in librarianship and information science at University of Wales.

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



Tim Buxton, Head of Sector for
project management, b. 27
February 1959, n. British

Education: Bachelor of Laws from the University of Birmingham, qualified as a Member of the Institute of Chartered Accountants in England and Wales.

Career to date: Tim Buxton completed articles with Touche Ross & Co in London in 1987. After a year in merchant banking, he was finance director of a private company from 1988 to 1995. He undertook long term assignments as a management consultant until January 1997, when he joined the EMEA. He was appointed Head of Sector on 1 May 2002.



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

Education: MSc in computer science and BSc in business administration and economics at the University of Gothenburg.

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



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

Education: Honours degree in experimental physics, and MSc in electronic engineering from Trinity College Dublin.

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

Administration Unit



Andreas Pott,
Head of Unit,
b. 14 April 1949, n. German

Education: Masters Degree in political science, history and English from the University of Hamburg. Certificat de Hautes Etudes Européennes (economics) from the College of Europe, Bruges.

Career to date: From 1972 to 1989 Mr Pott held a number of teaching and research posts, including a research fellowship at the Institute of Peace Research and Security Policy, University of Hamburg. He joined the Secretariat of the European Parliament in 1989, serving on the secretariats of the Committee on Research, Technological Development and Energy, of the Committee on Budgets and latterly of the Parliament's Bureau and Conference of Presidents. He moved to the Translation Centre for Bodies of the European Union in 1999 as Head of the Department for Interinstitutional Cooperation. He joined the EMEA in May 2000.



Sara Mendosa,
Head of Sector for
infrastructure services,
b. 23 January 1950, n. British

Education: Business studies and languages at Loughborough Polytechnic.

Career to date: From 1975 to 1990 Mrs Mendosa held a number of posts at

the European Commission in Luxembourg, including the Conference Service, the Office for Official Publications and the Statistical Office. In 1991 Mrs Mendosa was transferred to the London office of the European Commission Representation in the UK. She joined the EMEA in November 1994 and was nominated as head of sector in November 2002.



Frances Nuttall,
Head of Sector for personnel
and budget,
b. 11 November 1958, n. Irish

Education: Master of Science in economics and Bachelor of Science in public administration from Trinity College Dublin.

Career to date: Ms Nuttall held several posts in the Irish Civil Service, serving in the Departments of Health, Finance and the Office of Public Works. Ms Nuttall then served with the Food and Agriculture Organisation of the United Nations from 1990 to 1995. She joined the EMEA in May 1995.



Gerard O'Malley,
Head of Sector for accounting,
b. 14 October 1950, n. Irish

Education: Bachelor of Commerce from University College Dublin. Fellow of the Institute of Chartered Accountants in Ireland. Censor Jurado de Cuentas and Member of the Registro Oficial de Auditores de Cuentas in Spain.

Career to date: From 1971 to 1974, Mr O'Malley completed articles in Dublin. From 1974 to 1985 he was an audit manager in Spain with Ernst and Young and from 1985 to 1995 he was Financial Controller at Johnson Wax Española. He joined the EMEA in April 1995.

Press office



**Martin Harvey Allchurch,
Press officer,
b. 20 October 1966, n. British**

Education: Law degree from the University of Dundee, UK. Masters degree in European and international law from the Vrije Universiteit Brussel, Belgium.

Career to date: After a traineeship with the European Commission 1991-92, Martin Harvey Allchurch worked as a European affairs consultant in Brussels from 1992 to 1995. During this time he also worked as contributing editor for a European affairs publication and as Brussels correspondent for an American pharmaceutical journal. He joined the EMA in September 1995 working in the office of the Executive Director. He was nominated as press officer in September 2001.
