The European Agency for the Evaluation of Medicinal Products

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Work programme for the European Agency for the Evaluation of Medicinal Products 2004

Adopted by the Management Board on 18 December 2003

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Introduction by the Executive Director

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Executive Director

The EMEA faces a changing environment in 2004. The legislative framework within which the Agency operates is preparing itself for fundamental change. Individuals and healthcare professionals rightly want more transparency and information about the medicines they use and how they are authorised. New therapies are being developed and regulators must be ready to deal with these when they arrive for authorisation.

The impact of these changes will be felt over many years; 2004 is only the first step towards preparing the Agency and the European medicines system to face these challenges.

With the rising number of centrally authorised medicines, the overall workload of the Agency continues to increase. The core business of the EMEA is the evaluation of new medicines and, after the shortfall in 2002 and, to a lesser extent in 2003, the number of applications is expected to rise in 2004, although not to levels seen in previous years.

In addition to the core business the Agency has set itself seven priorities in 2004.

1. EU enlargement

The first of these priorities is enlargement, which will extend the European medicines system to twenty-eight countries within the European Economic Area. The coordinating role of the Agency within the European network will become more complex and intensive.

- The main objective will be to ensure a smooth transition as we welcome the new members into our activities. This will of course also mean more meetings and more delegates coming to the EMEA

2. Medicines for human use

The Agency's structures and procedures for medicines for human use need to be of the highest calibre.

- Independently of any future legislative changes, the objective is to put in place a programme of improvements for the Committee for Proprietary Medicinal Products
- Improving the provision of scientific advice continues to be an important objective and the Agency will focus here on the scientific expertise needed for this and the process by which it is done
- Surveillance of the safety of medicines is another critical activity for the Agency, particularly with regard to progressing the implementation and upgrading of the EudraVigilance system
- The CPMP must be in a position to give the best possible scientific opinions with regard to medicines for human use. Greater use of external expertise will be made to help the CPMP in its tasks, in particular therapeutic advisory groups established in 2003. In addition, specialised experts will be involved in the scientific evaluation process, both pre- and post-authorisation, in order to allow for a more proactive conduct of pharmacovigilance

3. Medicines for veterinary use

The Agency's structures and procedures for veterinary medicines also need to be of the highest calibre.

- Antimicrobial resistance continues as a critical issue for both animal and human health. Determining the Agency's contribution to facing this challenge this will be an objective in 2004
- The availability of veterinary medicines, especially for minor uses and minor species, will continue as a major objective for the Committee for Veterinary Medicinal Products in 2004
- The surveillance of veterinary medicines is also an important activity for the Agency, particularly with regard to progressing the implementation of the EudraVigilance system in the veterinary sector

4. International

The regulation of pharmaceuticals has become increasingly international in response to the globalisation of the pharmaceutical industry. It is important that regulators share their experience and best practices as part of meeting the international challenge.

- The Agency will continue to play a role with its scientific contribution to the European Union presence in a number of international forums, in particular the trilateral EU-Japan-US ICH and VICH international harmonisation conferences, and to the mutual recognition agreements with third countries
- Implementation of the confidentiality agreement with the US Food and Drug Administration will also be an objective in 2004, together with the conclusion of a similar agreement with the US Department of Agriculture for veterinary biological medicinal products

5. Networks

The European medicines system rests firmly on the network of the national competent authorities of the Member States. The operation and maintenance of that network is of prime importance to the EMEA.

- The main objective here will be to fulfil the Agency's responsibilities for the implementation of the EU telematics strategy for the pharmaceuticals sector
- The exchange of information is central to the networks and there are a number of key European databases for which the EMEA has responsibility, including the clinical trials database

6. Strengthening the EMEA

The Agency plays a central role in the European system. It is important that EMEA staff have the highest competence and the organisation and structures allow it to meet future challenges.

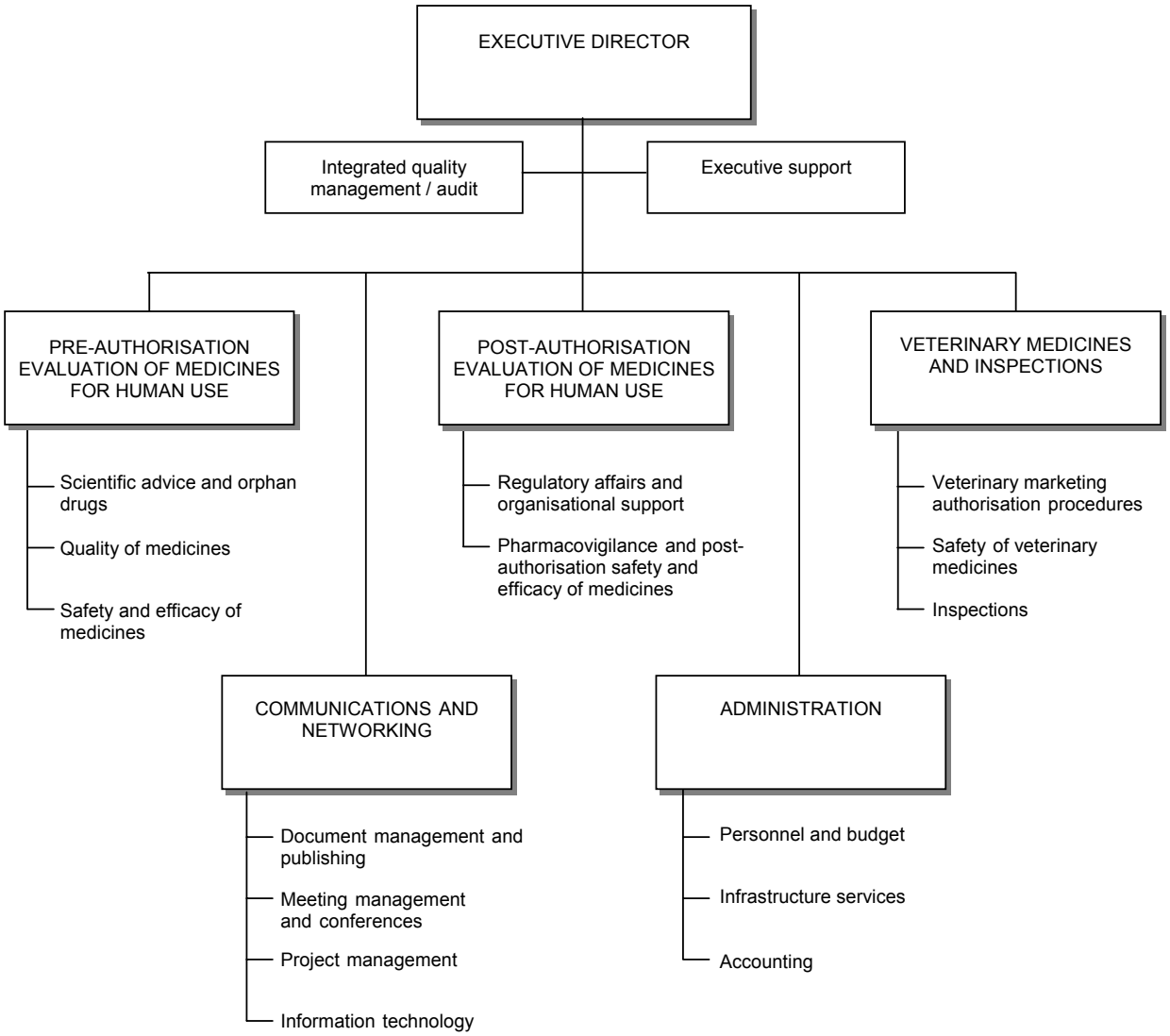
- Significant efforts will be made to improve staff competence, development and training
- A new group will be created in the Agency with responsibility for external communications and internal management support
- It is also an objective to bring the Agency's legal staff together into a new group in order to provide more coordinated legal support to all parts of the EMEA. A head of the legal staff will be appointed

7. Planning for the future

The EMEA and the medicines system are entering a period of significant change. Preparation and planning for the future is a priority activity for the EMEA.

- A high-level strategy document outlining the vision of the Agency for the future will be presented for discussion with all stakeholders.

EMEA organigramme



1. EMEA in the European system

1.1 Management Board

The Executive Director provides support to the work of the Management Board, which will meet 4 times in 2004 each meeting lasting 1 day.

Management Board meetings in 2004	
11 March	10 June
30 September	16 December

The Board will focus its work in 2004 on corporate governance and performance monitoring, but will also include in its specific priorities issues relating to:

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

1.2 National competent authorities

Trends:

- Member State national competent authorities will receive about 28 % of the Agency's total budget in 2004 in return for scientific evaluation and inspection services performed for the EMEA. The total amount in 2004 is expected to reach € 26 783 000
- Ongoing need for close cooperation and joint planning

New issues to be faced in 2004 with workload implications:

- Enlargement of the European Union with 10 new Member States and the participation of their national authorities and experts in the work of the EMEA
- Continue work on the revision of the statement of principles governing the partnership between the national competent authorities and the EMEA, including the standard contract for the performance of scientific and inspection services on behalf of the EMEA
- Ensuring the quality of decisions, including through the conduct of audits of scientific committees and benchmarking exercises involving the EMEA and national competent authorities
- Implementation of the European risk management strategy in close collaboration with heads of national agencies

1.3 EU enlargement

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 EMEA 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.

Trends:

- Having grown from 30 to 34 members at the beginning of 2000 to include members from EEA-EFTA states, the EMEA scientific committees for human and veterinary medicines (CPMP and CVMP) will grow from 34 to 54 members each. The orphan drug committee (COMP) will expand from 21 to 31 members
- While proposals for the review of EU pharmaceutical legislation include reductions in the size of the committees, it is not known whether at least some aspects of the proposals (i.e. Title IV of the new regulation) will come into force at the same time as enlargement

New issues to be faced in 2004 with workload implications:

- The enlarged size of the committees will present operational and practical challenges. This will include increased number of delegates to manage and reimburse for each meeting
- From an operational perspective, the addition of a number of new official EU languages will raise linguistic issues for the approval of information for health care professionals, patients and users of medicines

Objectives:

- To successfully integrate the new Member States into the operation of the European regulatory system and EMEA procedures
- To maintain the rhythm of work with no significant slow down in the centralised procedure

1.4 Transparency and communication

The provisions of Council Regulation (EC) No 1049/2001 on public access to documents were applied to documents held by the EMEA from 1 October 2003 through Council Regulation (EC) No 1647/2003 of 18 June 2003. The Management Board is required to adopt new EMEA implementing rules by 1 April 2004.

The Management Board endorsed a number of actions following a public consultation exercise in 2003. These in particular include improvements to the Agency's web site and the provision of more and better information on medicines that are assessed by EMEA committees. The initiatives also include improvements to general information about the Agency and its activities.

Trends:

- Growing demand from stakeholders and society at large for more information on medicines and the work of the Agency
- Potentially more demand for access to EMEA documents under the new public access rules contained in Council Regulation (EC) No 1049/2001

Objectives:

- To introduce new EMEA rules on access to documents in accordance with the requirements of Council Regulation (EC) No 1647/2003
- To implement the transparency and communication actions endorsed by the Management Board as a result of the 2003 transparency public consultation
- To make the output of the Agency's work more transparent at all stages of the medicines' life cycle, including orphan drug designation, updating of EPARs with new information, availability of information on key maintenance activities, etc.
- To improve the integration of interested parties, particularly patient groups, into EMEA activities

1.5 Preparation for the review of the European system

Trends:

- It is hoped that the European Parliament and Council will be able to conclude their review of the European system in 2004, with implementation of at least some elements of the new proposals in 2004

Objectives:

- To monitor developments within the European Parliament and Council and contribute as requested
- To evaluate the impact of the proposals as part of the Agency's business and resource planning process ahead of the new legislation entering into force

1.6 Revision of EMEA fees

Trends:

- The revision of the European system and EU enlargement will be accompanied by a parallel exercise to revise the system of fees paid to the EMEA

New issues to be faced in 2004 with workload implications:

- The EMEA will follow carefully any proposals from the European Commission on a new fee regulation and contribute as requested
- The EMEA will continue its work on the development of a strategy to ensure long-term funding stability within the European system

1.7 International partners

The Management Board endorsed a strategy for the Agency's international activities in December 2003.

Trends:

- The Agency's work with its traditional partners in the EU-Japan-US trilateral harmonisation of regulatory requirements for human and veterinary medicines (ICH and VICH) will continue. The Agency will also continue to work with the WHO, World Organisation for Animal Health (formerly OIE) and in other international forums
- Interest from around the world in the work of the EMEA and the European system is expected to increase, particularly following enlargement of the system to include 28 EU and EEA-EFTA countries
- Increasing bilateral cooperation with the US Food and Drug Administration following the signature of a confidentiality agreement in September 2003

New issues to be faced in 2004 with workload implications:

- Elaboration and implementation of an action plan for the collaboration between the EMEA and the US Food and Drug Administration under the confidentiality agreement and close monitoring of all actions contained in this plan. The confidentiality agreement covers a wide range of activities, from exchange of information on legislation, regulatory guidance, pre-authorisation phases, evaluation of medicines and post-authorisation surveillance
- A similar agreement will be sought with the US Department of Agriculture, which is responsible for the licensing of veterinary biological medicinal products

1.8 Corporate governance

The Management Board has taken a number of steps to introduce appropriate mechanisms for the corporate governance for the EMEA, including the creation of an Audit Advisory Committee in 2003.

Trends:

- Increasing focus of audit work on the operation of the European system as a whole, rather than just on EMEA as an organisation
- Increasing move towards integrated quality management through integrated audits, looking at operational, financial and other aspects together and conducting a yearly risk analysis
- New EU financial regulation implemented and further formalised

New issues to be faced in 2004 with workload implications:

- Carrying the audit process beyond the immediate operation of the Agency to improve the quality of the European network, to include the committees, rapporteurs, working parties and benchmarking with international partners
- More transparency on the outcomes of the audit process, including the operation of the Audit Advisory Committee
- Increasing legal actions involving the Agency

Objectives:

- To demonstrate the independence of the EMEA and its scientific committees through integrated quality management and system audits. This should also show that the Agency is well managed and independent from the pharmaceutical industry despite receiving funding from fees
- Continual improvement of EMEA processes and networking with regulatory partners

The internal structures of the EMEA will be reorganised in 2004 with the creation of three horizontal services reporting to the Executive Director: an Executive Support Sector, a Legal Affairs Sector and the formalisation of the Internal Audit Function.

The Executive Support Sector will in particular address the need for improved relations with external partners and the provision of support for the Agency's management activities. The Sector will be responsible for developing an EMEA communications strategy. The Head of Executive Support will be appointed in early 2004.

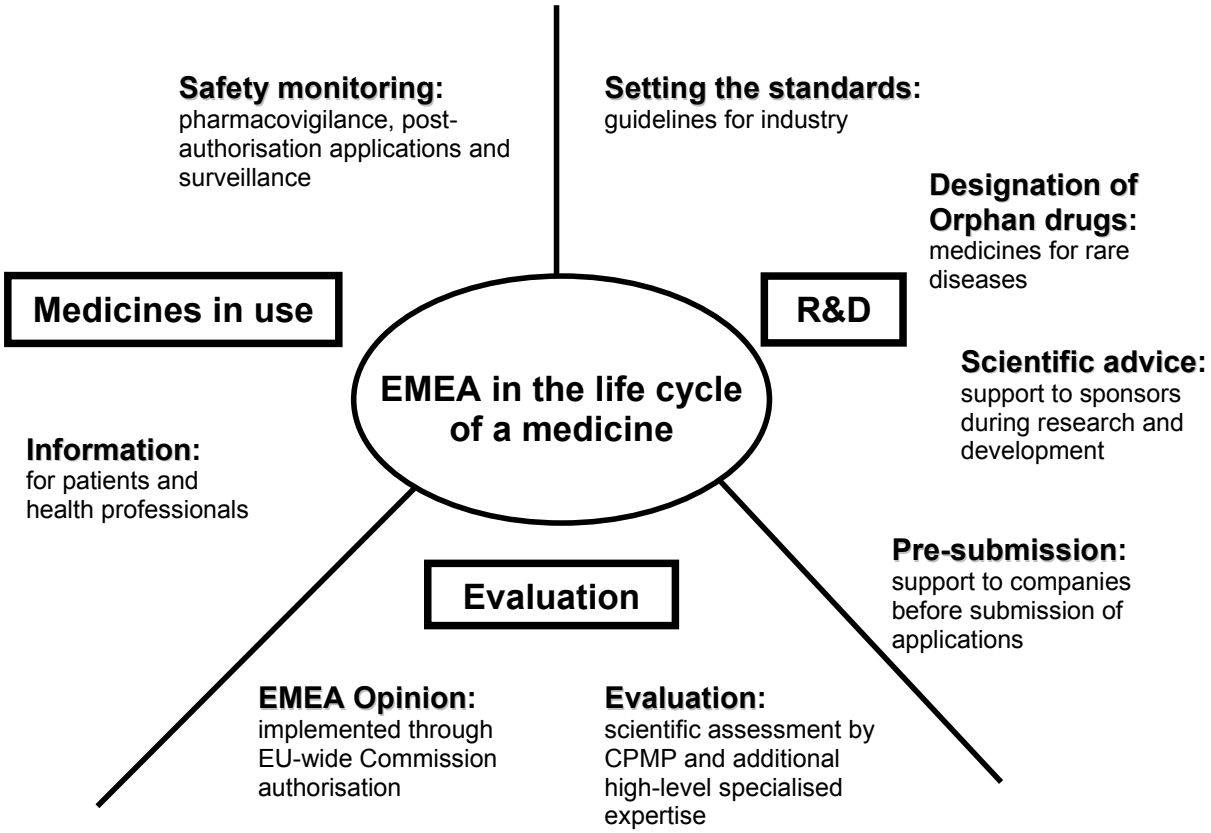
The Legal Affairs Sector will bring together the legal resources of the Agency into one specialised group in response to the increasing demand for legal services and the need for more rational organisation of legal competence. A competition will be organised in 2004 with a view to recruiting a head of sector.

The internal audit function will have an advisory function for integrated quality management at the Agency and the secretariat to the Audit Advisory Committee. The audit function will also ensure the Agency's risk management and serve as liaison for the European Commission's Internal Audit Service.

2. Medicines for human use

Priorities for medicines for human use in 2004:

- Ensure the successful integration of the accession countries in the Agency's processes and activities related to medicines for human use
- Manage the workload and adhere to regulatory timelines for pre- and post-authorisation activities, including scientific advice, protocol assistance and activities related to orphan medicinal products designation, initial evaluation, post-authorisation activities and pharmacovigilance
- Implement the short-term improvements stemming from the EMEA action plan on the improvement of the Agency's processes in relation to human medicines, which should result in an increased regulatory and scientific consistency of the outcome of the scientific evaluation
- Encourage the systematic use of the scientific advice and protocol assistance procedure with an increased use of external expertise and develop a procedure for proactive advice in particular for rare diseases
- Focus on the concept of life-cycle management of medicines by introducing the concept of risk management throughout the life-cycle, as part of the implementation of the EMEA risk management strategy
- Facilitate and improve the electronic exchange of individual case safety reports (ICSRs) through the implemented EudraVigilance database and data-processing network
- Continue to develop the regulatory and scientific environment for emerging and new technologies and therapies
- Implement procedures for new legislative requirements for plasma master files (PMFs) and vaccine antigen master files (VAMFs)
- Contribute to the EU public health strategies on marketing authorisation aspects such as the influenza pandemic and tissue engineered products



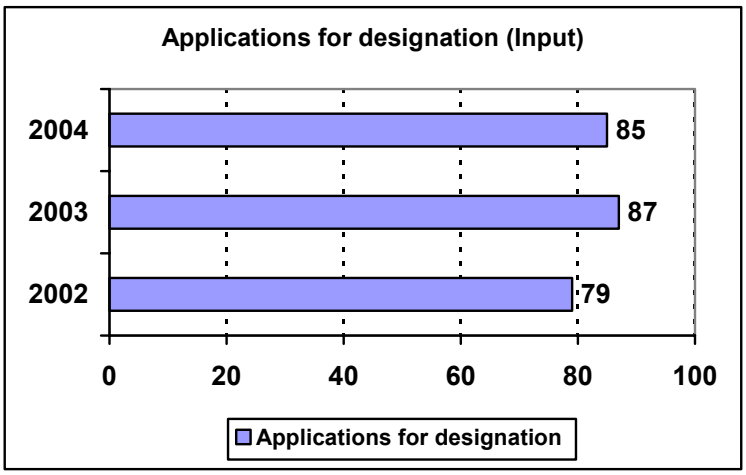
2.1 Orphan medicinal products

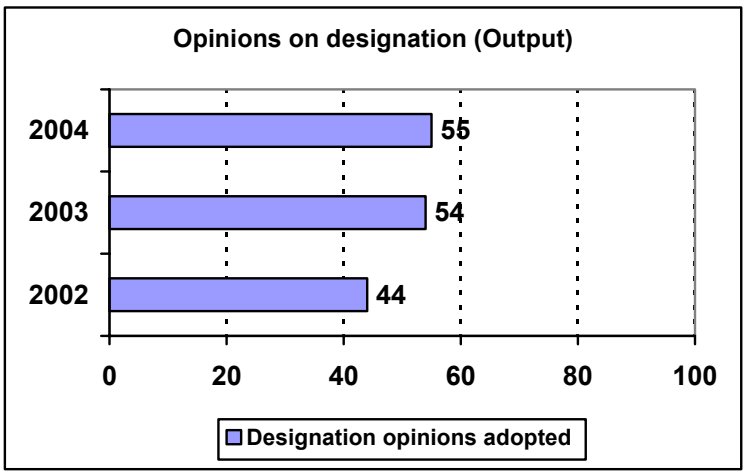
Orphan medicinal products are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10 000 persons in the European Community, or where for economic reasons such medicines would not be developed without incentives.

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 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') is intended to support additional new applications, protocol assistance, as well as 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 2004 is expected to amount to € 3 500 000.

The level of reductions in 2004 will take into account the expectations from sponsors and patient organisations and the level of the orphan drug fund made available.





Trends:

- After the initial high level of applications for orphan drug designation observed after the introduction of the EU orphan drug policy, numbers have decreased but are now expected to be similar to 2003 with 85 applications

New issues to be faced in 2004 with workload implications:

- With the number of designated products expected to reach close to a total of 180, the post-designation workload will dramatically increase in 2004 in relation to regulatory advice, assessment and reporting of annual reports (more than 125 are expected), and follow up of designation criteria at marketing authorisation phase
- More complex applications in relation with emerging therapies such as gene therapy and cell therapy
- Extension to new EU member states of transparency initiatives and communication with third parties in particular patient associations, health care professionals and learned societies in relation with rare diseases
- Increase co-operation with international regulatory partners and the EU 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

- Continuous support to sponsors seeking orphan status for their products, in particular small and medium sized companies through pre-submission meetings
- Increased involvement of expertise at all stages of procedures relating to orphan medicines

Management and organisation of the COMP

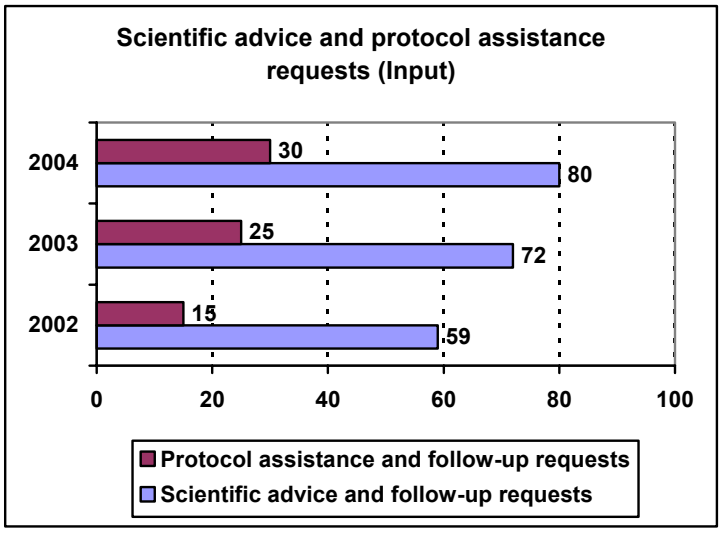
COMP meetings in 2004	
12-14 January	21-23 July
4-6 February	No meeting in August
16-18 March	8-9 September
14-16 April	6-8 October
13-14 May	9-11 November
15-17 June	7-9 December

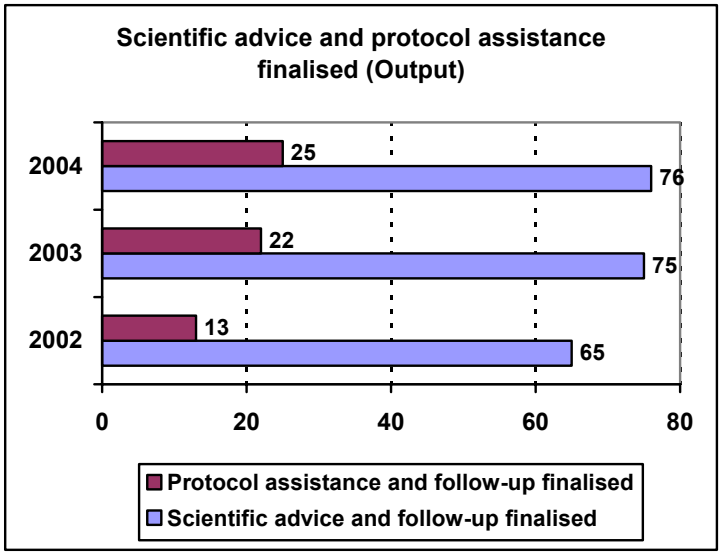
The Committee for Orphan Medicinal Products (COMP) will meet 11 times in 2004, meeting for 2 to 3 days each month.

Following enlargement, the Committee for Orphan Medicinal Products will incorporate one member per new EU Member State and as a consequence workload will increase in relation to the additional complexity of coordination and secretarial activities, as well as the need for additional languages for the COMP opinions.

2.2 Scientific advice and protocol assistance

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





Trends:

- Steady increase in number of requests for scientific advice as a result of the new mandate of the Scientific Advice Working Group and for follow up requests
- Increase in the number of requests for protocol assistance as a consequence of the number of medicinal products designated as orphan
- Significant increase in the number of pre-submission meetings with sponsors with a view to improve the quality of the requests

New issues to be faced in 2004 with workload implications:

- The provision of scientific advice and protocol assistance remains a priority area for the EMEA in 2004
- Increased number of face to face meetings with sponsors, involving more additional experts for common and rare diseases
- Possible increase of request from companies to have EMEA scientific advice in parallel with advice given by regulatory authorities from third countries
- Continuous monitoring of impact of scientific advice and protocol assistance for applications for marketing authorisation
- Extension to new Member States of continuing communication and interactions with interested parties

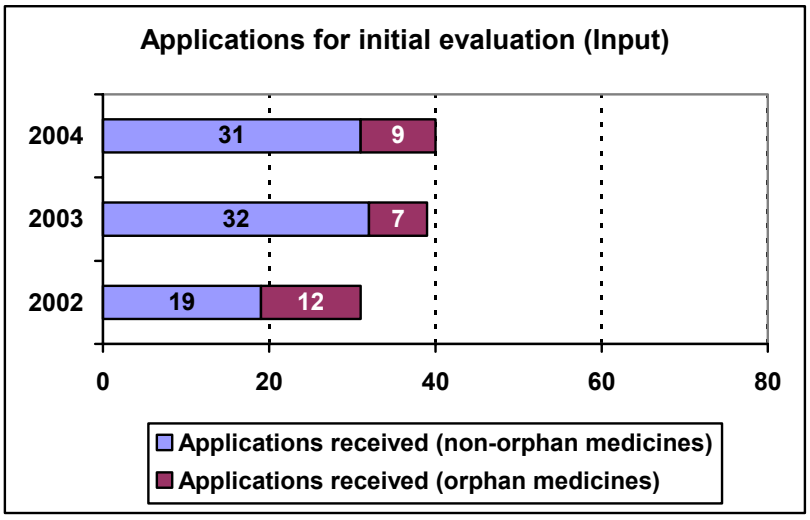
Objectives

- Monitor the implementation of the scientific advice 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 at the time of marketing authorisation applications
- Encourage the systematic use of the CPMP scientific advice procedure for any new compound to be authorised in EU and for all designated orphan medicinal products
- Offer the possibility for face-to-face meetings to all sponsors applying for scientific advice or protocol assistance allowing for more dialogue on development plans
- Provide regular involvement of external expertise particularly for clinical aspects for rare diseases and for more common ones
- Provide scientific support to the Scientific Advice Working Group
- Develop a procedure allowing on a voluntary basis the simultaneous consultation of the SAWG group and of regulatory authorities from third countries

- Develop a procedure allowing for proactive advice in particular for rare diseases, and for minor requests or follow up
- Monitor the impact of the procedure on research and development of medicines and impact on outcome at the time of marketing authorisation applications

2.3 Initial evaluation

This covers the phase of EMEA activities from pre-submission discussion with future applicants, through the evaluation by the CPMP and the granting of marketing authorisation by the European Commission. These activities culminate in the production of the European public assessment report (EPARs).



Trends:

- A similar level of initial applications for marketing authorisation is expected in 2004 (40) continuing the trend experienced in recent years (with the exception of 2002). The percentage of marketing authorisation applications for orphan drugs will remain stable

New issues to be faced in 2004 with workload implications:

- Strengthen the operation of the core business through further development of the integrated quality management system (IQMS), in relationship to the core business and the secretariat support required to achieve this objective
- Adaptation of all processes in relationship to enlargement, in particular additional workload in relation to coordination of procedures, additional comments and contribution on documents (up 66 %), and nine additional languages (up 90 %) for summaries of product characteristics (SPC) and patient leaflets (PL)
- Based on the first positive experience with the therapeutic advisory groups implemented in 2003 the pilot phase will continue in 2004 with anticipated extension to additional therapeutic areas and in line with future legislation
- Implementation of the new procedures for the processing of plasma master files (PMFs) and vaccine antigen master files (VAMFs)
- Challenges to the exclusivity of orphan drugs, which will require multi-disciplinary effort within the Units to address the parameters around the 'similarity' of products

- Development of a procedure for the adoption of CPMP opinion at the request of international organisations in anticipation of changes to the Agency's founding regulation
- Development of adapted processes in relationship to an increasing number of electronic submissions of applications for marketing authorisations

Objectives:

- Strengthen the quality assurance system in relation to the management of the Agency's core procedures and CPMP activities
- Adhere to regulatory timelines for active review time by the CPMP
- Integrate the consequences of enlargement in the processes for marketing authorisation applications without disruption or delay in the procedure
- Implement the arrangements in the pre-authorisation phase arising from the newly established procedure for the handling of safety concerns for centrally processed applications
- Publish summaries of opinion at the time of adoption by the CPMP
- Timely publication of EPARs after the European Commission decision granting marketing authorisation with 9 additional languages
- Active support from the Agency secretariat and follow-up of the implementation by the CPMP of the therapeutic advisory groups (TAGs) and creation of additional ones
- Further develop and refine the activities of the CPMP working parties and experts groups contributing to the initial evaluation phase
- 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
- Reinforcement of the Unit activities related to new therapies and new technologies in order to prepare for the first applications

Management and organisation of the CPMP

CPMP meetings in 2004	
20-22 January	27-29 July
24-26 February	No meeting in August
23-25 March	14-16 September
20-22 April	19-21 October
25-27 May	16-18 November
22-24 June	14-16 December

The mandate of the Committee for Proprietary Medicinal Products (CPMP) will be renewed in January 2004.

Provision is made for the CPMP to meet 11 times. Two additional extraordinary meetings are provided for in case of need, either to deal with urgent product related issues or to investigate the need for further organisational changes as a result of the new mandate of the Committee.

As of May 2004, the CPMP will incorporate two members per new Member State as a consequence of EU enlargement leading to a large increase in workload in terms of the support to be provided to the Committee.

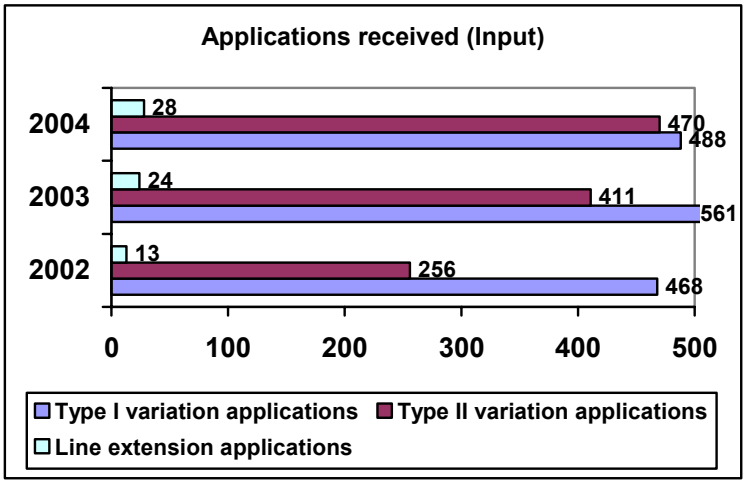
In response to the CPMP audit performed in July 2003, the Agency will introduce further improvements to the centralised procedure and to the working practices for the Committee, its working parties and ad-hoc groups. This should allow the EMEA to further contribute to the successful elaboration of the concept of lifecycle management of medicines. The introduction as of the beginning of 2004 of the newly established procedure for the handling of safety concerns, both pre- and post-authorisation for centrally authorised products, will be an important step in achieving such objective.

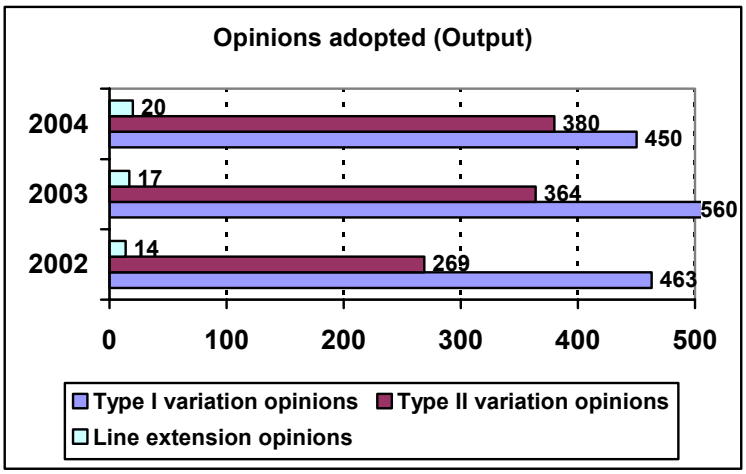
Furthermore, the Committee will continue its collaborative activities with interested parties. In 2004, emphasis will be put on a strengthening of the Committee's interaction with patients' organisations, health care professionals associations and learned societies. The interaction with patients associations, started in 2003 through discussions at the level of the EMEA/CPMP Working group with patients organisations, should lead in 2004 to the development of an EMEA strategy on interaction with patients.

In accordance with the Agency's revised transparency policy, efforts will be made in order to further increase the transparency of the activities of the CPMP, its working parties and satellite groups.

2.4 Post-authorisation activities

This includes activities relating to variations, line extensions and transfers of marketing authorisation. Further to a revision of the EU legislation on variations in October 2003, variations are now classified as either minor (type IA or IB) or major (type II) changes.





Trends:

- Further increase in type II variation applications is expected for 2004 in line with the natural increase in the number of marketing authorisations granted
- In addition, the implementation of the new Community legislation on variations will result in a change in the balance between type I and type II variation applications

New issues to be faced in 2004 with workload implications:

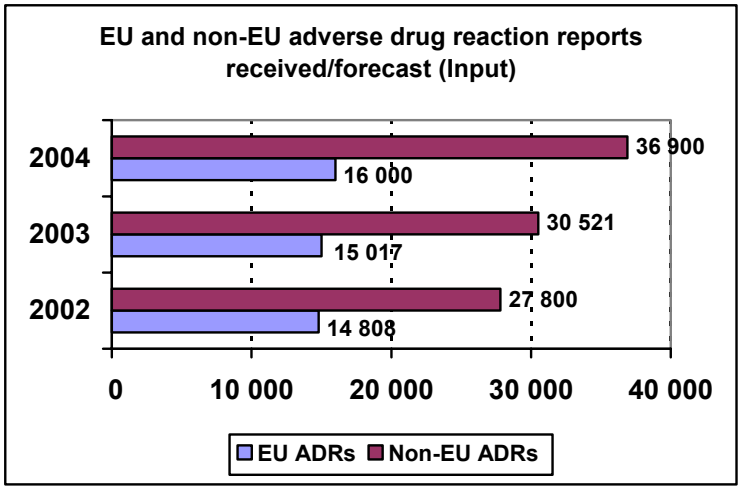
- The implementation of the new EU legislation on variations will impact on the number and type of applications for both type I and type II variations. The new regulation has introduced a new type of variation (type IA), for which EMEA will take full responsibility. The impact of these changes on the Agency's workload will be monitored throughout 2004.
- EU enlargement will heavily impact on post-authorisation activities, since the product information will need to be handled in 9 additional languages for all post-authorisation applications which require an updating of the product information
- Interaction with marketing authorisation holders for centrally authorised products will be strengthened through familiarisation meetings once the marketing authorisation has been granted

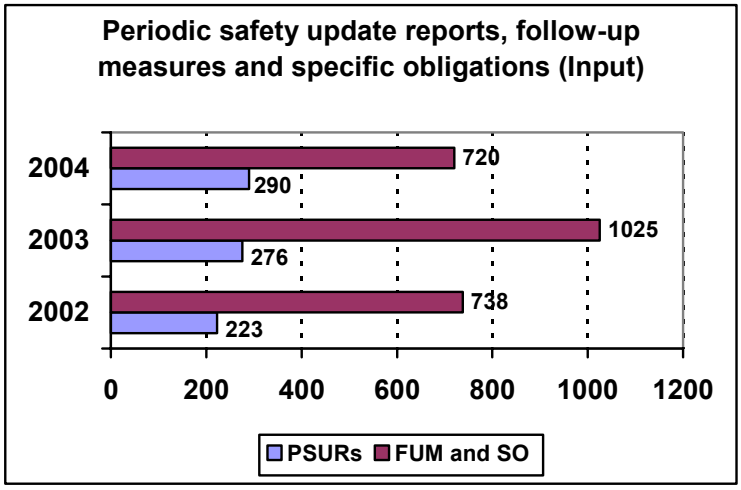
Objectives:

- Adhere to regulatory timelines for active review time by the CPMP and the Agency
- Strengthen the quality assurance system in relation to the management of post-authorisation activities
- 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
- Regular updating of EPARs in the post-authorisation phase for both procedural and scientific aspects
- Organise annual meetings with marketing authorisation holders to better plan the post-authorisation strategy for each product

2.5 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 re-assessments and renewal applications. It should be noted that pharmacovigilance is a priority area for the Agency and that, as a consequence, the EMEA will continue and further strengthen its efforts in order to ensure the safe use of products licensed in accordance with the centralised procedure.





Trends:

- Further increase in all maintenance activities compared to 2003
- Further elaboration and implementation of the EMEA risk management strategy
- Increased reporting of individual case safety reports through EudraVigilance

New issues to be faced in 2004 with workload implications:

- The EudraVigilance project will in 2004 mainly focus on the further implementation, maintenance and upgrading of the database and data processing network. Other issues to be addressed in 2004 include the expansion to accession countries' health authorities and pharmaceutical companies, the implementation of the clinical trials directive, as well as the provision of training to the Agency's business partners

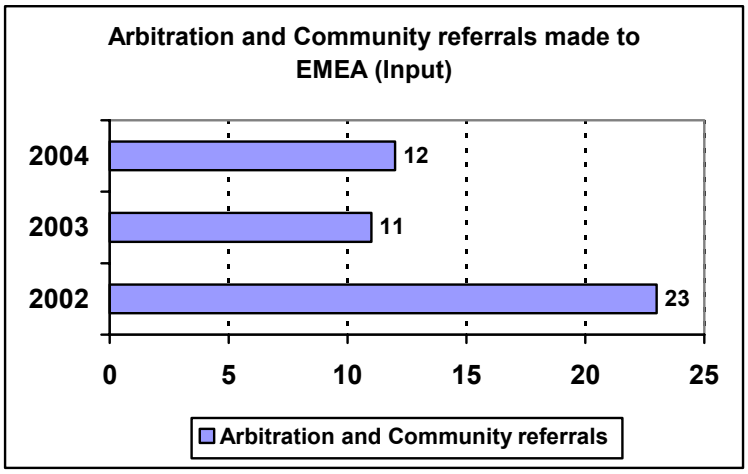
- Further work will be undertaken in 2004 on the implementation of the EMEA risk management strategy, in close collaboration with heads of national competent authorities. Particular emphasis will be put on the implementation of the newly established procedure for the handling of safety concerns for centrally processed applications, both pre- and post-authorisation, which should allow for a proactive conduct of pharmacovigilance. Emphasis will also be put on improvements to be introduced to risk management methodologies

Objectives:

- Adhere to the Agency's legal obligations as defined in Community legislation.
- Further implement and maintain the EudraVigilance database and data-processing network and develop new system functionality
- Involve accession countries' national competent authorities and pharmaceutical industry in the EudraVigilance project
- Further implement the EMEA risk management strategy in collaboration with national competent authorities

2.6 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, 36 and 37 referral procedures are mainly initiated in case of Community interest and for safety related issues



Trends:

- Total of 12 arbitration and Community referral procedures are expected in 2004

New issues to be faced in 2004 with workload implications:

- Consequences of enlargement on the mutual recognition procedure, resulting in possible additional arbitration procedures, will need to be closely monitored
- Workload in relation to referrals will increase taking into account EU enlargement with a considerable increase in the number of marketing authorisation holders and marketing authorisations, as well as the handling of product information in 9 additional languages

Objectives:

- Adherence to legal timeframes for arbitration and Community referrals
- Management of the workload related to referrals and arbitrations which will further increase as a result of EU enlargement
- Timely publication of public information on referral and arbitration procedures

2.7 Regulatory activities

EU institutions and regulatory authorities

Trends:

- The level of involvement of the Agency in activities developed at European level for medicines for human use will continue to increase in 2004, both in terms of commitment to European institutions and national authorities
- Increased support to accession countries during the months before enlargement of the EU in order to facilitate their participation in the work of the Agency's scientific committees and working parties and continuous monitoring of the integration in the Agency's activities after the date of accession. Other candidate countries will continue their participation in working parties
- Contribution to the activities of the EMCDDA in Lisbon through active participation to EU Joint Actions and the implementation of the early information function as a consequence of the 'Trend' project
- Contribution to the international activities initiated by the European Commission Directorate-General for Enterprise, Directorate-General for Research and the Directorate-General for Health and consumer protection, such as influenza pandemic, bio-terrorism or development of medicinal products for developing countries

Regulatory and procedural guidance

Regulatory and procedural advice is provided to pharmaceutical industry during the lifecycle of medicinal products, starting from pre-submission meetings with applicants up to annual meetings with marketing authorisation holders. Guidance documents focussing on the key steps of the centralised procedure are continuously developed and updated by the EMEA. In addition regulatory and procedural guidance is provided to the CPMP and COMP and their related working parties and ad-hoc groups.

Trends:

- Pre-submission meetings with applicants will continue to be encouraged in 2004 since they facilitate the running of the procedures and more emphasis will be put on annual meetings with marketing authorisation holders in order to discuss the planning strategy in the post-authorisation phase
- Guidance documents on how to further improve the centralised procedure and the functioning of the CPMP, its working parties and ad-hoc groups will be developed in the framework of the follow-up to the EMEA action plan on the improvement of the Agency's processes for human medicines

New issues to be faced in 2004 with workload implications:

- Implementation of the EMEA action plan on the improvement of the Agency's processes for human medicines through the development of guidance documents and standard operating procedures

- Further elaboration of the EMEA post-authorisation guidance document in order to include regulatory and procedural guidance on all post-authorisation activities
- Continued support to the European Commission in the updating and further development of the 'Notice to applicants' and the 'Notice to marketing authorisation holders'

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.

Trends:

- CPMP and ICH-CPMP guidelines will continue to be finalised or released for consultation in 2004 as a result of continuous scientific developments and European and International harmonisation efforts

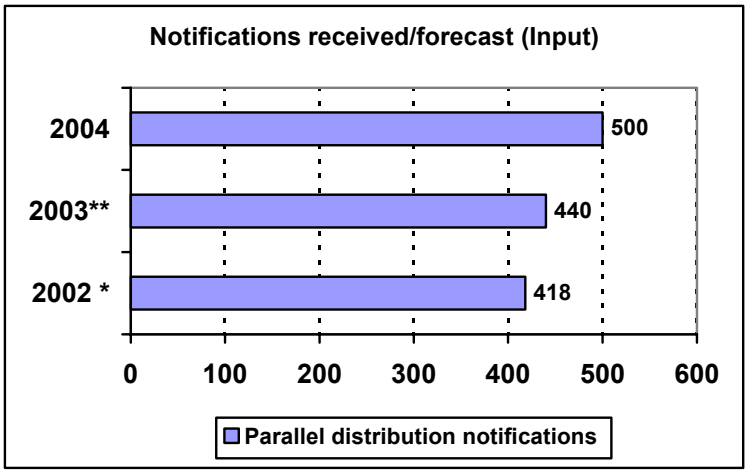
New issues to be faced in 2004 with workload implications:

- Composition and working processes of the working groups and ad hoc groups of the CPMP and COMP will have to be adapted in order to further develop their efficiency especially taking into account the participation by the future Member States in their activities as well as the transparency of their outcomes
- Ad hoc groups on new emerging therapies and new technologies (e.g. pharmacogenetics, gene therapy, cell therapy) will meet in 2004 as well as the ad-hoc group on comparability of biotechnology medicines. This will be important as the Agency prepares to receive applications in relation to emerging therapies and also contributes to the international regulatory developments within the ICH process
- Work in 2004 in anticipation of EU legislation on paediatric medicines, will include support to the European Commission in developing its proposals. The Paediatric Expert Group will work with individual companies to discuss the development of paediatric formulations and work on the availability of information on medicines for use in children
- Depending on the outcome of the discussions at European Parliament and Council level, preparation for the establishment of a new Committee on Herbal Medicinal Products, likely to be operational as of 2005, will have to be initiated
- Activities will continue on anti-bioresistance, in particular with an update from the CPMP note for guidance, consultation of the anti-infectives TAG and interested parties in relation with CVMP activities
- Activities are also expected in relationship to plasma master files, vaccine antigen master files and medical devices containing biotechnology and blood-derived medicinal products
- EMEA work and expertise required to provide scientific guidance to the European Commission on legislative and public health issues, including those on influenza pandemic, similarity to orphan products or tissue engineered products
- The COMP ad hoc Biotechnology Working Group will meet as necessary to support the designation process for emerging therapies, and the COMP group with interested parties will continue to meet on a regular basis
- 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

Main CPMP working parties and ad hoc groups in 2004	Number of meetings
Pharmacovigilance Working Party	11
Biotechnology Working Party	11
Joint CPMP/CVMP Quality Working Party	4
Blood Products Working Group	3
Efficacy Working Party (plenary)	4
Safety Working Party (plenary)	4
Scientific Advice Working Group	11
Herbal Medicinal Products Working Party	5
Paediatric Expert Group	4
Vaccine Expert Group	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 may 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.



* 294 out of 418 notifications received were valid
** 389 out of 440 notifications received were valid

Trends:

- Taking into account the current policy in relation to parallel distribution, the number of valid initial parallel distribution notifications is expected to remain at the same high level compared to 2003, while the number of notifications of changes should continue to rise due to labelling updates

Objectives:

- To adhere to the timeframes for processing of parallel distribution notifications
- To further improve the procedure, taking into account experience gathered
- To publish regulatory and procedural guidance for parallel distributors

2.8 International activities

Trends:

- Level of international activities will remain high during 2004, both in terms of the Agency's commitments to international partners and interest in the work of the Agency from non-EU regulatory authorities
- International activities will concentrate during 2004 on the implementation of the EU enlargement and the implementation of the EU – US Food and Drug Administration confidentiality agreement

New issues to be faced in 2004 with workload implications:

- Strengthening of the interaction with the FDA through the implementation of the action plan elaborated in the framework of the EU-FDA confidentiality agreement
- Interactions with Canada and Japan and other regulatory authorities will continue through the EMEA Visiting Experts Programme
- Contribution to ICH activities will continue in 2004 following the ICH 6 conference held in November 2003 in Japan
- Interactions and participation to scientific meetings and trainings with or at the request of WHO

2.9 Mutual recognition facilitation group

Useful web site:

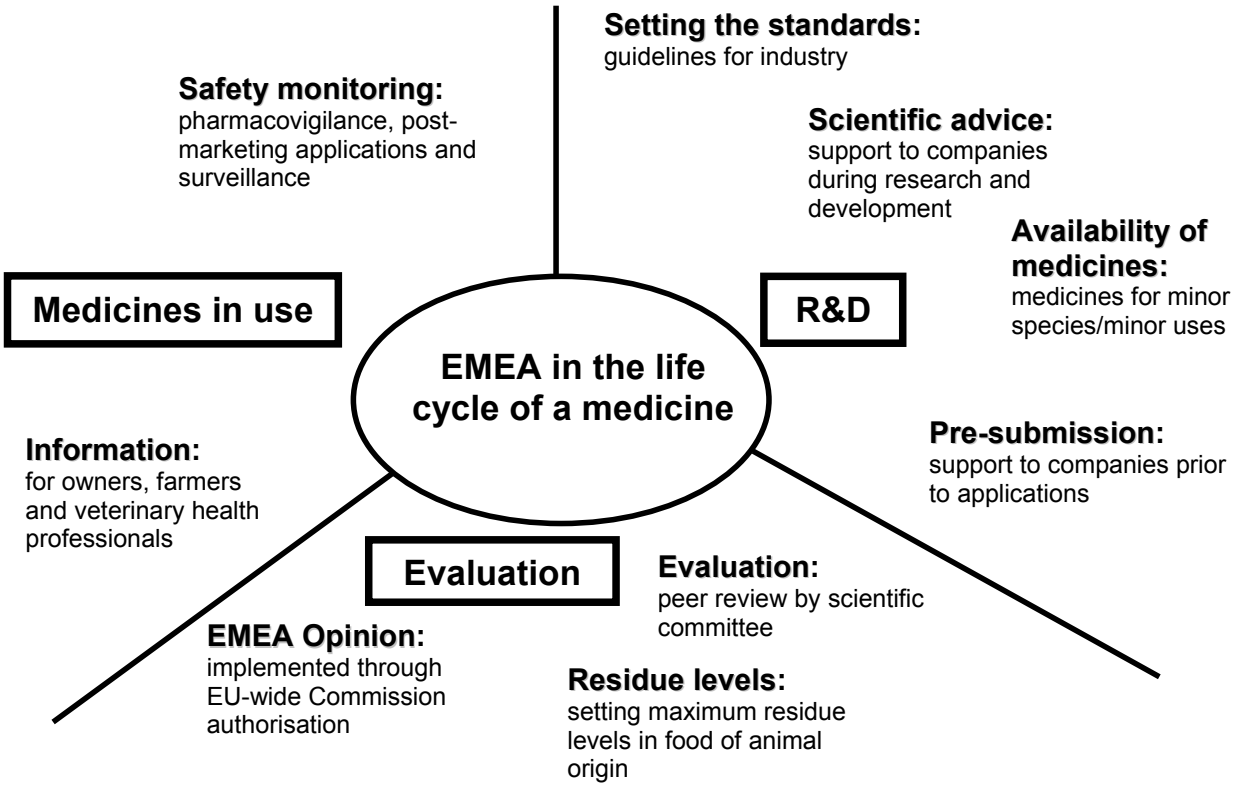
Heads of agencies for medicines for human medicines	*http://heads.medagencies.org*
European product index	*http://mri.medagencies.com/prodidx*

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.

3. Veterinary medicines

Priorities for veterinary medicines in 2004:

- To continue the leading role of EMEA and CVMP in cooperation with interested parties, Member States and the European Commission in developing an overall strategy for a minor uses minor species policy, addressing aspects for data requirements, scientific assessment, procedural and regulatory issues for scientific advice and marketing authorisations for minor uses and minor species products; to include finalisation of the CVMP position paper for minor uses and minor species following the period of consultation in 2003.
- To progress EudraVigilance in the veterinary sector from the testing phase into full operational phase in 2004, whilst at the same time working to achieve harmonisation for electronic reporting in the VICH programme
- Enlargement of the European Union on 1 May 2004 will result in considerable challenges for the CVMP and its working parties, which the Unit will adequately prepare for in terms of effective organisation and planning to ensure a smooth transition, as well as phasing in for centrally authorised products
- The adoption within VICH of the second phase of environmental safety testing guidelines for veterinary medicines will signal the beginning of a programme of activities by the veterinary sectors to draw attention to these latest requirements including the coordination of training of European assessors in liaison with the CVMP and its Interested Parties
- To create a scientific advisory group of experts to advise the CVMP on its continuing strategy on minimising antimicrobial resistance in veterinary medicines
- To ensure adherence to regulatory timelines for pre- and post-authorisation activities for veterinary applications including generic applications, the first of which are expected in 2004 and those in respect of MRLs
- To continue the initiative begun in 2003 to monitor and, where necessary improve, the quality and consistency of CVMP assessments for centrally authorised products, with the aim of ensuring the that the scientific assessments are of the highest standard
- To conduct an audit of CVMP, its processes, records and its working practices to ensure compliance with the regulations of ISO standards



3.1 Scientific advice

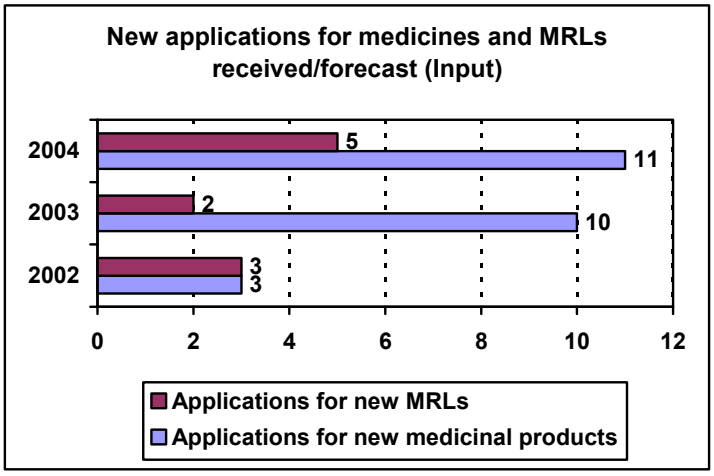
Trends:

- Contrary to earlier expectations, there appears to be little interest to date by potential applicants to seek scientific advice from the CVMP in the pre-development phase for new products. The secretariat will initiate discussions with industry with the aim of improving scientific advice procedures for potential applicants
- Endorsement by the Management Board of CVMP proposals to provide free scientific advice to applicants who are planning to develop products for minor uses and minor species is expected to result in a few more additional applications

Objectives:

- The decision of the Management Board to agree to the CVMP request to grant free advice for products intended for minor uses and minor species signals a likely increase in number of applications over last year; five are forecast in total

3.2 Initial evaluation



Trends:

- The growth in applications seen in 2003 is expected to continue gradually in 2004, where predications from the joint EMEA – IFAH-Europe survey indicate 11 applications will be received
- The low number of applications for new MRLs in past years continued in 2003. However, as firm intents for new applications have been received, an increase to 5 applications is predicted for 2004. This interest acts as a pointer to new substances for food producing animals emerging through development

Objectives:

- To meet all regulatory deadlines for the CVMP to reach its opinions and for transmission of such opinions to the European Commission in a timely and accurate manner
- To publish summaries of opinions at time of adoption by CVMP and continued publication of EPARs within 5 days of notification of the European Commission marketing authorisation decision
- To ensure the quality, integrity and consistency of the CVMP assessment reports and EPARs at the highest level
- To agree standard operating procedures in anticipation of generic applications for those products which, although approved for food animals after 1 January 1995, were originally authorised for companion animals pre-1995 at the Member State level; the data protection period for some of these initial national authorisations now having expired
- To continue publication of MRL summary reports and provision of analytical methods to the relevant competent authorities following the publication of Commission regulations on inclusion of MRLs in the annexes of Council Regulation (EEC) No 2377/90

CVMP meetings in 2004	
13-15 January	13-15 July
10-12 February	No meeting in August
16-18 March	7-9 September
14-16 April	12-14 October
11-13 May	9-11 November
15-17 June	7-9 December

The Committee for Veterinary Medicinal Products (CVMP) will meet 11 times, but with an enlarged membership following the accession of 10 new Member States to the Union on 1 May 2004. The possibility of a Committee with 25 members and alternates plus additional co-opted members will place new demands on the secretariat to maintain the efficiency of organisational support, which has become the expected norm since 1995.

Processing of applications through the authorisation process with the administrative burdens of dealing with the additional languages for 10 new Member States in relation to the annexes and opinions will require additional administrative and scientific support within the unit. Extensive assessor training for experts from new countries building on the success achieved in the PERF programme will be undertaken.

The Strategic Planning Group, which has consolidated its role as an advisory support body to the CVMP, will continue to meet quarterly to assist in defining the strategy and organisation aspects of the Committee and particularly to prepare for enlargement.

The CVMP will create a new scientific advisory group to advise the Committee on its continuing strategy for minimising antimicrobial resistance and all issues related to this subject.

Contingent on further new topics being agreed to in the VICH programme, or dependent on the need on other emerging issues ad hoc groups of experts may be convened to advise CVMP in certain specialist areas.

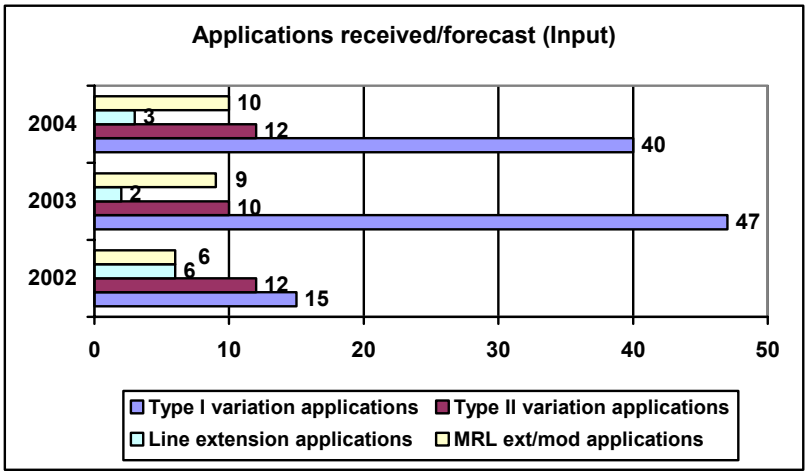
3.3 Establishment of maximum residue limits for old substances

Of the last eight old substances with provisional MRLs in Annex III of Council Regulation (EEC) No 2377/90 only one remains, namely altrenogest, which will be finalised in 2004. In addition, two substances proposed for Annex II entry by CVMP, namely flugesterone and norgestomet, were recently placed in Annex III of Council Regulation (EEC) No 2377/90 with an expiry of 2008 and their assessment will proceed in 2006/2007.

Trends:

- Even with the two additional substances, the workload continues to decline

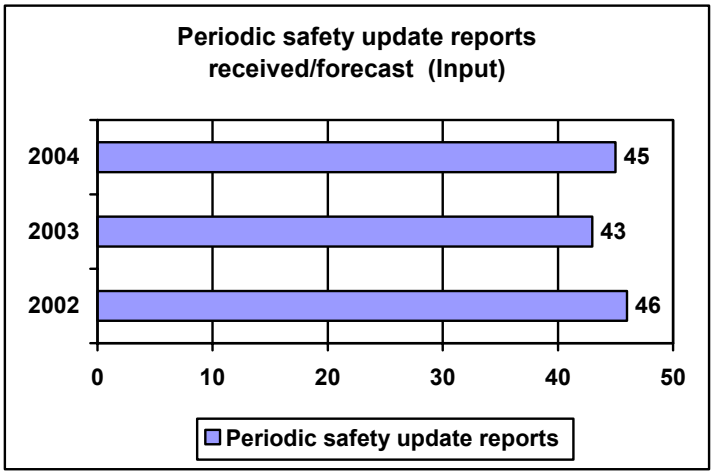
3.4 Post-authorisation activities



Trends:

- A total of 40 type I variations are anticipated, which as a result of the new variation regulations that came into force on 1 October 2003, will probably be represented by 28 type IA and 12 type IB variations
- Extensions to original authorisations continue at a steady pace but rather lower than anticipated
- Slight increase in applications for extensions or modifications of MRLs is anticipated as applicants seek to extend authorised products into new food animal species
- In accordance with the initiatives being undertaken to facilitate greater availability of medicines, CVMP will continue its efforts to extrapolate MRLs considered essential in certain minor species

3.5 Pharmacovigilance and maintenance activities



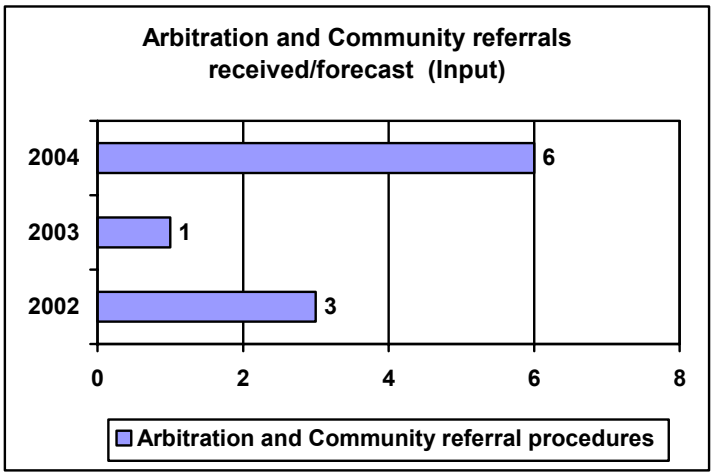
Trends:

- Annual reports to be carried out for 32 products, each of which is prepared in cooperation with rapporteur and co-rapporteur and adopted by CVMP
- 7 applications for renewal of market authorisations issued in 1999 are anticipated
- 45 periodic safety update reports will be evaluated by CVMP

Key issues to be faced in 2004 with workload implications:

- A greater number of issues relating to safety of nationally approved products are being referred to the Pharmacovigilance Working Party
- The CVMP and its working party will continue to support initiatives promoting pharmacovigilance in the EU with particular focus on providing support to the new Member States
- The EMEA/CVMP will liase with the heads of national veterinary agencies in implementing the European surveillance strategy intended to foster collaboration and support between Member States in the conduct of good pharmacovigilance practice
- Continue to implement CVMP recommendations to promote more effective and adequate reporting of ADRs to veterinary medicines in the EU following on from progress achieved in 2003
- Move the pilot scheme for veterinary EudraVigilance into full operational mode in collaboration with Member States and industry and prepare the new Member States for EudraVigilance installation

3.6 Arbitration and Community referrals



Trends:

- Member States and the EMEA recognise the usefulness of Community referrals to the CVMP to adequately address safety concerns for veterinary medicinal products post-authorisation and some additional referrals on safety can be expected in 2004
- With 10 new Member States in the Community, some additional referrals to CVMP for arbitration in the mutual recognition procedure can be anticipated
- Work in this area is expected to increase with 6 arbitrations and referrals being submitted

3.7 Regulatory activities

EU institutions and regulatory authorities

- To coordinate activities with the European institutions, in particular with the European Commission, and to develop and strengthen relations with new European Food Safety Authority. The EMEA will also continue to participate in and support the work of heads of national veterinary regulatory agencies (HEVRA)

Interested parties

Relationships with interested parties continue to flourish. Provisional plans are already in place for a continuation of the themes in previous years with Infodays and focus groups on topics of current interest being planned. Further efforts will be made to encourage those interested parties unable to attend such meetings in the previous years to actively participate in 2004 e.g. consumers and livestock producers.

Proposals adopted by CVMP to precede development of new guidelines/position papers with a concept paper, which is circulated to all interested parties as the basis of an impact analysis, will be pursued in 2004.

Working parties and ad hoc groups

The CVMP and its working parties will continue to maintain business efficiency and to meet objectives given the challenge of increase membership of the various working parties after enlargement in May 2004, necessitating a growth of membership of the working parties from 15 to 25.

The CVMP will create a new scientific advisory group to advise the Committee on its future strategy in reducing antimicrobial resistance including the various initiatives to be undertaken in support of the strategy.

As recommended in the CVMP position paper on minor use and minor species policy, the working parties will consider whether flexibility in requirements for quality, safety and efficacy data in accordance with European legislation may be possible in respect of minimising the regulatory burden for authorisation of products intended for minor uses minor species. In particular the Immunologicals Working Party will consider in some depth the application of minor use and minor species policy for veterinary immunologicals and the specific needs for this class of compounds.

CVMP working parties and ad hoc groups in 2004	Number of meetings
Immunologicals Working Party	4
Efficacy Working Party	2
Pharmacovigilance Working Party	6
Safety Working Party	4
Joint CPMP/CVMP Quality Working Party	4
Ad hoc group on environmental risk assessment	3
Scientific advisory group on antimicrobials	3

Details of the guidance documents expected to be released for consultation or finalised in 2004 are given in Annex 3.

3.8 International activities

- Continued coordination and organisation of EU participation in VICH at Steering Committee and Working Party level
- Scientific expertise at Codex Alimentarius, World Health Organisation, Food and Agriculture Organisation and Office International des Epizooties meetings
- The Veterinary medicines unit and CVMP will continue to provide support to the two remaining accession candidate countries (CAVDRI), Bulgaria and Romania, as they prepare to join the EU in 2007
- As in the past, the EMEA and CVMP will, contingent on adequate budgetary provisions, contribute activity to a number of other international activities

3.9 Veterinary mutual recognition facilitation group

The Agency will continue to provide support to the increasing workload of the VMRFG in 2004, together with a national expert on secondment from INFARMED, the Portuguese national agency.

4. Inspections

Priorities for inspections in 2004:

- To bring the mutual recognition agreement (MRA) with Japan to a successful conclusion, in light of the extension of the preparatory phase of the agreement and taking into account the impact of EU enlargement. Coordination of work with new Member States, in view of expected internal and external evaluations in the context of the MRA with Canada. Monitoring of other operational agreements will continue throughout 2004

- To support the planned activities required under the clinical trials directive for human medicines and in particular the implementation of the EudraCT database

- To coordinate and manage effectively the requests for GMP, GCP (including pharmacovigilance) 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

- To review the sampling and testing programmes for centrally authorised products in cooperation with EDQM to take into account the issues raised during the joint EMEA/EDQM seminar on this topic in September 2003 in order to ensure effective and adequate surveillance of the quality of centrally approved medicinal products marketed in the EEA throughout their shelf-life

- Support to the European contribution to international discussions on GMP/quality systems in cooperation with FDA and within the ICH framework

- To facilitate increased transparency and quality of published guidance documents in particular through consolidation of adopted CPMP/CVMP quality guidelines with the objective of providing a single and transparent source of quality guidance in the EU and revision of the compilation of Community inspection procedures, in combination with improvements to the EMEA web site

- To provide support to the new Member States after enlargement to optimise compliance with Community requirements in relation to GMP and GCP

4.1 Inspections

The coordination work of the inspections sector will be underpinned by an increasing focus on assessor and inspector cooperation in all good practice areas.

Good clinical practice (GCP) inspections are anticipated to decrease in 2004 as Member States focus their resources on national inspections, on additional duties relating to the review of applications to conduct clinical trials and on implementing the clinical trials directive. Inspections of pharmacovigilance compliance activities are however expected to increase.

Good manufacturing practice (GMP) inspection requests for 2004 are expected to remain stable relative to 2002 and 2003.

The ad hoc group of GMP inspection services will meet on five occasions in 2004. The focus of its work will be on the continued harmonisation of inspection procedures and GMP interpretation, as well as GMP implications of the new Community blood and GCP directives. This harmonisation work will include the development of GMP guidelines on investigational medicinal products used as gene and cell therapies. The emphasis on quality systems implementation at Member State level will be further supported by the development of a coordinated joint audit programme of each others' systems.

A separate meeting will take the form of a liaison meeting with the Joint CPMP/CVMP Quality Working Party.

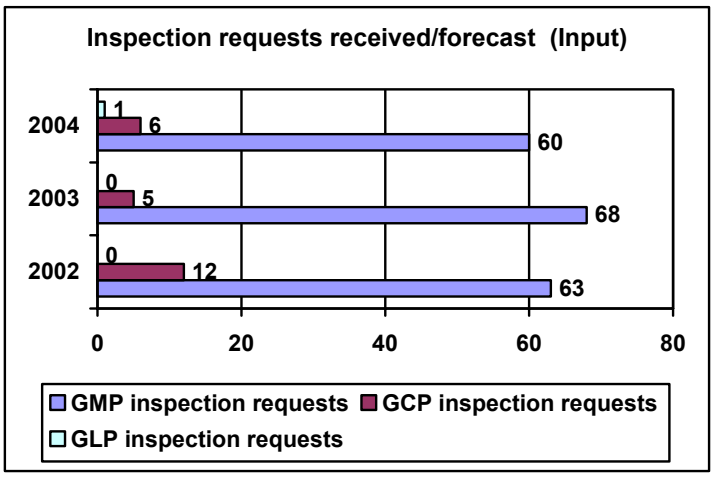
The ad hoc meeting of GCP inspection services will meet five times in 2004. In addition to general harmonisation work on approaches to GCP inspection, focus will be on the development of guidelines on bioequivalence studies and on consolidation of procedures to support the implementation of the clinical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

Trends:

- Requests for GMP inspections are expected to remain stable in 2004
- Requests for GMP re-inspections for manufacturing sites are expected to form a high proportion of GMP requests in 2004
- The workload in dealing with product defects and deviations is expected to continue to grow
- 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
- Joint CPMP/CVMP Quality Working Party will also meet 4 times in 2004 as they continue with the development of EU quality guidelines

New issues to be faced in 2004 with workload implications:

- Support for implementation of the clinical trials directive
- Implementation of confidentiality arrangements with FDA in inspection-related activities
- Responsibility for review and update of the Community compilation of inspection procedures
- Impact of the new legislative provisions for plasma master files and vaccine master files
- Cooperation on the ICH/FDA initiative on quality systems/GMP is expected to build on the need for interaction between GMP inspectors and quality assessors
- Support for the integration of new Member States in the good practice work of the Agency
- Resource availability for the conduct of GCP and pharmacovigilance inspections



4.2 Mutual recognition agreements

Trends:

- 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
- Increasing focus on the monitoring of operational agreements and cross-harmonisation of the operational aspects of the respective agreements

New issues to be faced in 2004 with workload implications:

- EC-Canada MRA: focus will be on extending the current agreement to include new Member State authorities

4.3 Sampling and testing

Trends:

- Programme of sampling and testing of centrally authorised products will continue in 2004, with 42 products to be tested, representing an increase of 12 % over 2003

New issues to be faced in 2004 with workload implications:

- New Member States will participate in the testing part of the programme from May 2004 and in the sampling and testing programme for 2005
- The pilot procedure for the follow-up of testing results will be reviewed
- Increased transparency of the programmes and consolidation of supporting documentation to ensure better understanding and clarity of responsibilities
- Post-September 2003 seminar review of the programmes will be undertaken with a view towards improving the existing arrangements and better communication between all stakeholders

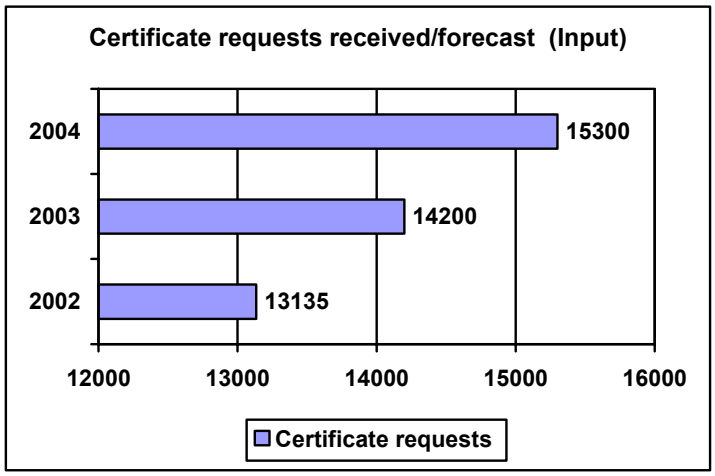
4.4 Certificates

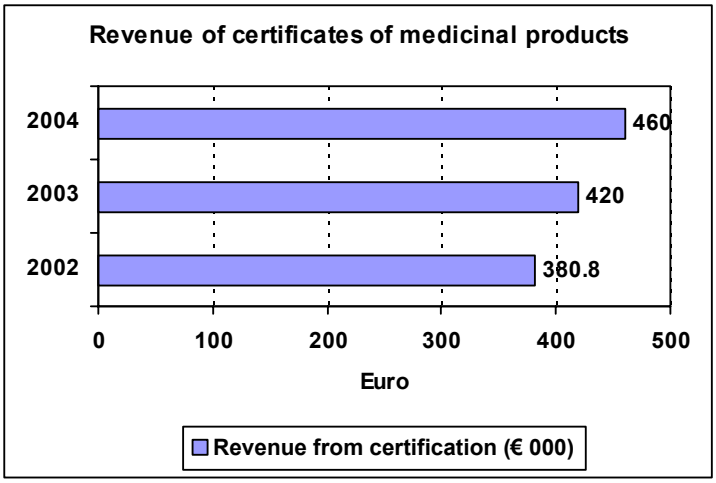
Trends:

- As in previous years, an increase of 10 % in revenue is forecast due to the larger number of authorised products and related variations. However, the low number of new applications for marketing authorisation in 2002 may mean that there is a slowdown in the rate of increase in revenues

New issues to be faced in 2004 with workload implications:

- Maintenance and streamlining of procedures will continue, in particular to build on the direct data export from the EMEA application tracking database (SIAMED) onto the issued certificates that was begun in 2003
- Revisiting the fee structure for this service





4.5 Implementation of the clinical trials directive

The deadline for entry into force of Council Directive No 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). EMEA will actively contribute to the rollout of the Commission databases foreseen in the Directive. Implementation of the Directive at EU level will also require continued support to the development of harmonised procedures within the ad hoc GCP inspection services.

New issues to be faced in 2004 with workload implications:

- Continued contribution of support to the design and rollout of the clinical trial database EudraCT and assistance to the development of the SUSAR module of the EudraVigilance database

5. EU telematics strategy

The European Union telematics strategy for pharmaceuticals is agreed between Member States, the EMEA and the European Commission. In order to implement European pharmaceutical policy and legislation, the various initiatives aim to increase efficiency, enhance transparency, and support and facilitate the operation of procedures established by legislation.

The implementation strategy concentrates on a small number of projects with high European added value. These projects have been agreed as being EudraNet, EudraVigilance, the EuroPharm database, electronic submissions, implementation of the clinical trials directive, and the central tracking system (formerly known as EudraTrack).

The work programme covering European telematics is based on a detailed study carried out by external consultants between November 2001 and February 2002. The programme was modified to take into account the budget reductions imposed by the European Commission for 2003 and 2004, and the agreement reached between the Heads of Agencies, the EMEA and the European Commission during a series of meetings at Verona on 8-9 July 2003. The effect was to change the implementation strategy from a sequential approach involving beginning and completing a small number of projects before embarking upon a second wave, to a slower implementation across the whole spectrum of projects.

The overall objectives in this area are to:

- Provide a high quality service in EU telematics to the EMEA's partners on an ongoing basis
- Structure and take forward the EU telematics projects in a consistent manner
- Put into place the modifications to systems and services necessary to successfully integrate 10 new Member States

The plans for the telematics projects for 2004 are as follows:

Initiatives	Targets
EudraNet	EudraNet II in operation by May 2004. All new member states connected by 1 April 2004. EudraWorkspace in operation by May 2004, subject to successful pilot.
EuroPharm	Resolve any outstanding compatibility issues. Build and deploy first production version by December 2004. Fully develop user requirements for extended database in line with additional requirements resulting from the review, G10 recommendations and Council conclusions.
EudraVigilance	Implement data warehousing and business intelligence. Add sophisticated statistical analysis. Build interface to other databases.
Electronic submission	Basic European Review System (EURS) in test use by January 2004 Product Information Management: Find appropriate funding and following a call-for-tender, place a contract for building the system; Integrate with eCTD.
Clinical trials databases	Build, test and deploy phase 1 registration system (by 1 May 2004). Build, test and deploy EudraVigilance Clinical Trials Module (by 1 May 2004).

The Management Board adopted a separate more detailed implementation plan on 18 December 2003.

6. Support activities

6.1 Administration

The Administration Unit consists of three sectors for personnel and budget, for accounting and for infrastructure services.

Particular challenges in the year 2004 will be:

- Implementation of the new Financial Regulation with revision of procedures
- Implementation of the new staff regulation
- Implementation of an improved activity based budgeting database and budgetary planning
- Refurbishment of parts of the EMEA offices to accommodate new staff, the telematics projects and delegates and experts from the new Member States
- Integration of delegates from the new Member States
- Implementation of new and modified accounting practices in line with the reform of the Commission

Personnel and budget

In addition to the general objectives for Administrative, specific objectives for 2004 include:

- Implementation of the new Financial Regulation with revision of procedures and staff training
- Implementation of the new staff regulation
- Development and implementation of a system of activity based budgeting
- Professional training management directed towards a continuous system of competence development
- Productivity review of recruitment procedures

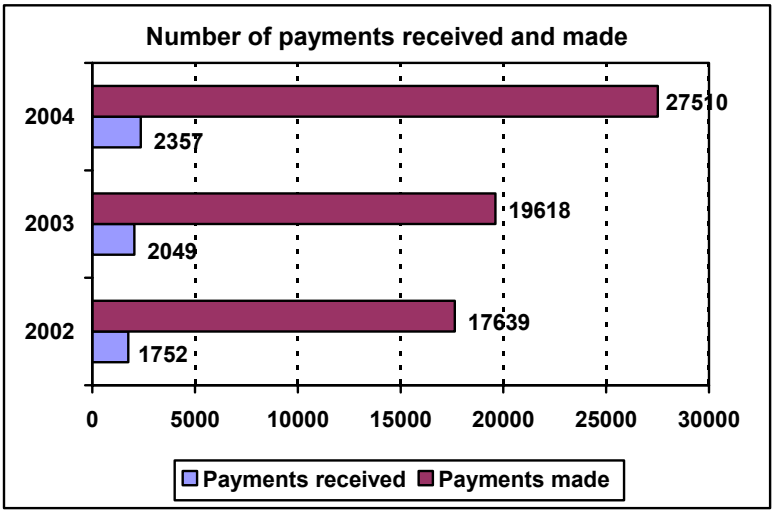
	2002 Final	**2003 Estimated**	**2004 Projected**
Workload			
Total staff	251	287	341
EMEA budget	€ 61 304 000	€ 84 179 000	€ 96 500 000
Selection procedures (including internal ones)	20	21	22
Mission claims	665	950	1140
Salaries	2 782	3 300	3 700
Staff movements	65	80	96

Accounts

In addition to the general objectives for Administrative, specific objectives for 2004 include:

- Implementation of inventory accounting system in coordination with the Infrastructure Services and IT Sectors
- Management of third parties database including update for IBAN and delegates from accession countries
- Requirement to produce financial accounts based on generally accepted accounting principles by 2005

- Impact of enlargement in the accounts sector will be the increased number of meeting reimbursements estimated to be 13 000

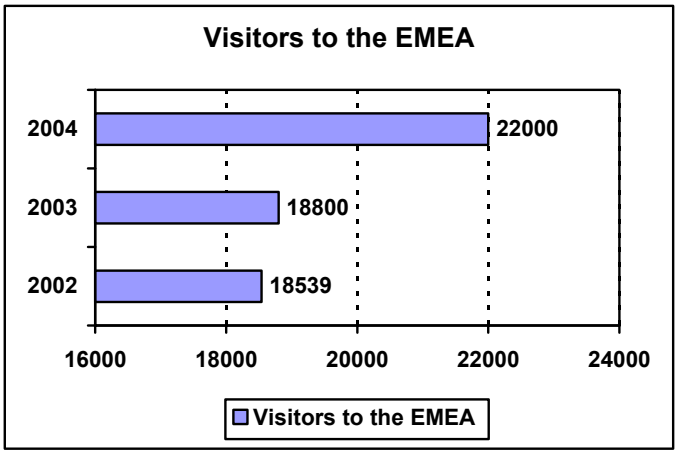


The biggest impact on future workload estimated for 2004 will be an increase in meeting reimbursements by 54 % due to EU enlargement, which will mean a similarly large increase in the recording of new third parties.

Infrastructure services

In addition to the general objectives for Administrative, the specific objectives for 2004 include:

- Business continuity plan – the exercising and testing of the plan will be carried out and the updating of the plan is a continuous process
- Disaster recovery – detailed plans to be prepared for the implementation of telecommunications back up arrangements
- Fitting out of the 8th floor
- Refurbishment of the 4th and 5th floors
- Preparation for the review of the rent and rates due in 2005
- Scheduling of tenders for the EMEA
- Centralised management of EMEA contracts
- Review of the office space available and future accommodation strategy



6.2 Information technology at the EMEA

The smooth operation of EMEA internal and EU telematics 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, and to all users of pan-European systems 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.

Trends for IT:

- The lowering of costs for high-speed communications and the need to ensure transmissions are both secure and authenticated brings these two areas to the forefront of technology
- Electronic communication is moving away from pure text to more sophisticated visual and audio systems. This requires increasingly capable networks and administration
- Stakeholders' increasing appetite for better quality information
- Requirement for efficiency gains through technology implementation to counter the geographical and linguistic expansions taking place through the enlargement
- Economic and logistical pressure to make more and more use of electronic means for all business related activities within the Pharmaceutical Sector
- Increasing usage with ever-greater volumes of information within telematics communications

New issues to be faced by IT in 2004 with workload implications:

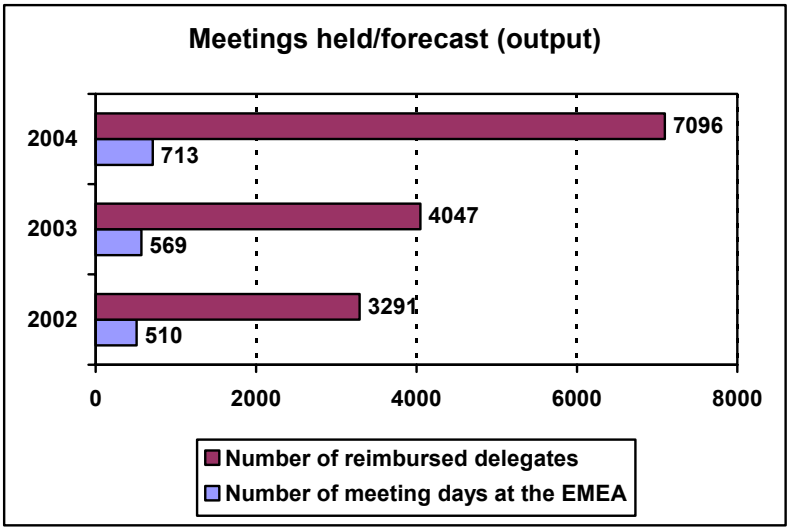
- To achieve 99.5 % availability for all IT services supporting the corporate activities of the EMEA
- To provide ongoing help and support between the hours of 08h30 and 18h00, five days a week
- To promote internal awareness of and training on EMEA specific IT systems amongst EMEA staff and delegates
- To ensure the timely back up and archiving of the EMEA data, including off-site disaster recovery scenarios
- To maintain the highest levels of security and confidentiality for all EMEA corporate data
- To achieve 98 % availability for all IT services supporting the Eudra activities of the European regulators for pharmaceuticals
- To incorporate the requirements of users of the systems that are not competent authorities

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 2004, the objectives in this domain are:

- To ensure that the Agency's processing and storage capabilities are aligned to its workload
- To ensure that the help and support available to EMEA staff , delegates and users of EU telematic system is in line with the Agency's operating requirements
- That security systems and corporate procedures ensure the highest levels of security and confidentiality for all held on systems at the EMEA data

6.3 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 meeting expenses reimbursements, payments of suppliers and the preparation and follow up of meeting room arrangements.



Trends:

- The enlargement of the European Union to ten new Member States from 1 May 2004, as well as the participation of representatives of Bulgaria and Romania in meetings as active observers, will have an impact on the Meeting Management & Conference sector activities, as the number of delegates invited to attend meetings will increase by 33 %
- Sector workload will have an impact on the meetings organisation area, as well as the financial support area since travel and hotel services are expected to rise, and meetings reimbursements to increase
- The provision of interpretation will be reviewed and tailored to real needs, in light of enlargement
- Videoconferences and web streaming activities will be developed in order to reduce meeting costs due to an increase in the number of meeting days and number of experts attending meetings

New issues to be faced in 2004 with workload implications:

- Developing and setting up the necessary videoconferencing and web streaming facilities
- Implementing the Meeting Management System in order to streamline the meetings organisation and the reimbursement of delegates' expenses processes
- Setting up the right resources to be faced with the increased number of meetings and the increased number of participants in meetings due to the enlargement of the European Union with up to 10 new Member States
- Investigations will be carried out on further development of on-line booking facilities directly on the web sites of the EMEA travel agency and hotel booking agency

6.4 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:

- Increasing use of electronic documents and dissemination through the Internet
- Move from classical paper-based document management to enterprise information management
- Increasing access to public documents

Documentum, the electronic document management system selected for implementation at the Agency, will be rolled out in a phased approach during the course of 2004.

New issues to be faced in 2004 with workload implications:

- Enlargement and the addition of 9 new target languages
- Increase in translation costs
- Increase in QRD volume
- Increased demands on staff handling requests for information

The introduction of nine new languages will almost double the workload for the quality review of documents (QRD) process. This includes completion of quality checks of translations of product information for those products already authorised through the centralised procedure. In addition, concerns about the quality and readability of product information destined for patients will be addressed.

Annexes

1. **EMEA establishment plan 2001– 2004**
2. **EMEA budget summaries 2002 – 2004**
3. **Guidelines and working documents in 2004**
4. **EMEA contact points**
5. **Profiles of EMEA personalities**

Annex 1
EMEA establishment plan 2001 – 2004

Category and Grade (up to 30.04.2004)	Grades (from 01.05.2004)	TEMPORARY POSTS						
		Occupied as per 31.12.01	Occupied as per 31.12.02	Authorised for 2003	Original - Request for 2004	Change + / -		Updated - Request for 2004
A1	20							
	19							
	18							
	17							
	16							
A2	15				1	0		1
		1	1	1	1	0		1
A3	14				5	0		5
	13							
		4	5	5	5	0		5
A4	12				32	+2		34
		26	28	32	32	+2		34
A5	11				37	+3		40
		24	26	32	37	+3		40
	10				45	+3		48
	9							
A6		24	24	34	39	+3		42
B1		4	2	6	6	0		6
	8				42	+5		47
A7		24	30	32	32	+5		37
B2		8	8	10	10	0		10
	7				15		-1	14
A8								-
B3		9	10	12	15		-1	14
	6				34		-3	31
B4		5	8	12	15		-3	12
C1		14	15	19	19	0		19
	5				36		-3	33
B5		5	6	9	9	0		9
C2		13	19	23	27		-3	24
	4				53		-3	50
C3		42	43	47	51		-3	48
D1		1	1	2	2	0		2
	3				14		-3	11
C4			4	6	9		-3	6
D2		4	5	5	5	0		5
	2							
C5								
D3								
D4	1							
TOTAL POSTS		**208**	**235**	**287**	**314**	**+13**	**-13**	**314**

Annex 2
EMEA budget summaries 2002 – 2004

The summarised comparative budget statements for 2002 to 2004 are as follows:
(Amounts expressed in euro)

	2002[1] (31.12.2002)		2003[2] (2.10.2002)		2004[3] (20.02.2003)	
Revenue						
Fees	39 000 000	*63.62 %*	56 742 000	*67.41 %*	64 800 000	*67.07 %*
General EU contribution	17 135 000	*27.94 %*	12 300 000	*14.61 %*	17 500 000	*18.11 %*
Special EU contribution for IT telematics strategy	--	--	7 000 000	*8.32 %*	7 500 000	*7.76 %*
Special EU contribution for orphan medicinal products	2 750 000	*4.49 %*	3 100 000	*3.68 %*	3 500 0000	*3.62 %*
Contribution from EEA	366 000	*0.60 %*	558 000	*0.66 %*	573 000	*0.59 %*
Contribution from EU programmes (PERF)	213 000	*0.35 %*	1 530 000	*1.82 %*	p.m.	*0.00 %*
Other	1 840 000	*3.00 %*	2 949 000	*3.50 %*	2 746 000	*2.84 %*
TOTAL REVENUE	**61 304 000**	*100.00 %*	**84 179 000**	*100.00 %*	**96 619 000**	*100.00 %*
Expenditure						
Staff						
Salaries	24 337 000	*39.70 %*	27 352 000	*32.49 %*	32 596 000	*33.74 %*
Interim and other support persons	1 760 000	*2.87 %*	1 845 000	*2.19 %*	2 046 000	*2.12 %*
Other staff-related expenditure	1 502 000	*2.45 %*	2 355 000	*2.80 %*	2 493 000	*2.58 %*
Total title 1	*27 599 000*	*45.02 %*	*31 553 000*	*37.48 %*	*37 135 000*	*38.43 %*
Building/equipment						
Rent/charges	5 526 000	*9.01 %*	5 686 000	*6.75 %*	5 670 000	*5.87 %*
Expenditure on data processing	3 083 000	*5.03 %*	9 517 000	*11.31 %*	8 209 000	*8.50 %*
Other capital expenditure	491 000	*0.80 %*	1 959 000	*2.33 %*	1 737 000	*1.80 %*
Postage and communications	264 000	*0.43 %*	418 000	*0.50 %*	505 000	*0.52 %*
Other administrative expenditure	2 043 000	*3.33 %*	2 075 000	*2.46 %*	2 780 000	*2.88 %*
Total title 2	*11 407 000*	*18.60 %*	*19 655 000*	*23.35 %*	*18 901 000*	*19.56 %*
Operational expenditure						
Meetings	3 535 000	*5.77 %*	3 924 000	*4.66 %*	8 835 000	*9.14 %*
Evaluations	17 855 500	*29.13 %*	21 941 000	*31.85 %*	30 075 000	*31.13 %*
Translation	477 000	*0.78 %*	701 000	*0.83 %*	1 375 000	*1.42 %*
Studies and consultants	98 500	*0.16 %*	27 000	*0.03 %*	50 000	*0.05 %*
Publications	119 000	*0.19 %*	78 000	*0.09 %*	248 000	*0.26 %*
EU programmes	213 000	*0.35 %*	1 430 000	*1.70 %*	p.m.	*0.00 %*
Total title 3	*22 298 000*	*36.38 %*	*32 971 000*	*39.17 %*	*40 583 000*	*42.00 %*
TOTAL EXPENDITURE	**61 304 000**	*100.00 %*	**84 179 000**	*100.00 %*	**96 619 000**	*100.00 %*

Notes
(1) 2002 budget: final appropriations
(2) 2003 budget: supplementary budget adopted by the Management Board on 2.10.2003
(3) 2004 budget: adopted by the Management Board on 18.12.2003. Note that the EU Budgetary Authority has placed € 2.9 million of the EU general contribution in reserve pending approval of the EU budget for the enlarged European Union.

Annex 3
Guidelines and working documents in 2004

CPMP Biotechnology Working Party (BWP)

Reference number	Document title	Status
EMEA/410/01 rev. 2	Revision of note for guidance on minimising the risks of TSE transmission via medicinal products	Maintenance of guideline
CPMP/BWP/269/95 rev. 3	Note for guidance on plasma-derived medicinal products	Update of viral safety aspects in 2004
CPMP/BWP/5180/03	Note for guidance on assessing the risk for virus transmission - new chapter 6 of the note for guidance on plasma-derived medicinal products (CPMP/BWP/269/95)	To be finalised in 2004
CPMP/BWP/3794/03	Note for guidance on the scientific data requirements for a plasma master file (PMF)	Finalisation of scientific data requirements (excluding epidemiology) first half of 2004 joint working group with industry in 2004
CPMP/BPWG/561/03	Warning on transmissible agents for SPCs and patient leaflets	To provide guidance during 2004-2005 as needed to support use of the revised warning statements for SPCs and patient leaflets. Discussions in 2004 on the question of whether to develop statements for where albumin is used as excipient
EMEA/CPMP/BWP/2879/02	CPMP position statement on CJD and plasma derived and urine derived medicinal products	Finalise report of June 2002 Workshop in 2004
CPMP/BWP/5136/03	Discussion paper on the investigation of manufacturing processes for plasma-derived medicinal products with regard to vCJD risk	Workshop in 2004
CPMP/BWP/3752/03	West Nile Virus	Update and maintenance of position statement.
CPMP/BWP/3207/00	Note for guidance on comparability of medicinal products containing biotechnology-derived proteins as drug substance	Maintenance of and input into ICH activity
III/3612/93	Note for guidance on the use of transgenic animals in the manufacture of biological medicinal products for human use	Revision of guideline
CPMP/BWP/764/02	Points to consider on the use of transgenic plants in the manufacture of biological medicinal products for human use	Development and finalisation of points to consider document
	Description of strength of insulin analogues	Development of concept paper and development of recommendations
	Manufacture and control of recombinant allergens	Development of concept paper for preparation of guideline

Reference number	Document title	Status
	Commission guideline on similarity of orphan medicinal products	Scientific input for biological medicinal products in 2004
CPMP/BWP/2517/00	Points to consider on the reduction, elimination or substitution of thiomersal in vaccines	Update, maintenance of position statements and contribution to assessment of dossiers
	Position paper on cumulative stability requirements for vaccines	Development of position paper
CPMP/17/03	Guideline on requirements for evaluation of new immunological 'adjuvants' in vaccines	Input into development of guideline; preparation/ contribution to the quality section
EMEA/CPMP/VEG/4717/03	Note for guidance on dossier structure and content for pandemic influenza vaccine marketing authorisation application	Contribution to finalisation of document in 2004
EMEA/CPMP/VEG/4986/03	Guideline on submission of marketing authorisation applications for pandemic influenza vaccine through the centralised procedure	Contribution to finalisation of document in 2004
CPMP/BWP/1700/01	Points to consider on xenogeneic cell therapy products	Maintenance/revision of points to consider document in the light of new scientific developments
CPMP/BWP/41450/98	The manufacture and quality control of human somatic cell therapy medicinal products	Development of note for guidance in the light of new scientific developments
	Concept paper on development of assays for neutralising antibodies for biotech medicinal products	Development of concept paper
CPMP/BWP/3088/99 rev. 1	Note for guidance on the quality, pre-clinical and clinical aspects of gene transfer medicinal products	Contribution to ICH, contribution to meetings of the ad hoc gene therapy group
CPMP/BWP/2458/03	Position paper on design and manufacture of lentiviral vectors	Finalisation of position paper and contribution to ICH
	Procedure for handling marketing authorisation applications in centralised procedure for human medicines consisting of or containing GMOs	Contribution to development of the procedure
EMEA/CVMP/134/02-CPMP/QWP/227/02	European drug master file	Development of an annex to the note for guidance on the European drug master file procedure on content of restricted part and applicants part for plasma-derived medicinal products
	EU recommendations for the influenza vaccine composition for the season 2004/2005	To be finalised and published on EMEA website in 2004
EMEA/CPMP/BWP/1793/02	Note for guidance on the use of bovine serum in the manufacture of human biological medicinal products	Workshop in 2004

Reference number	Document title	Status
CPMP/4548/03	Note for guidance on requirement for vaccine antigen master file (VAMF) certification	To be finalised in 2004
EMEA/CPMP/BWP/4663/03/1	Note for guidance on requirement for plasma master file (PMF) certification	To be finalised in 2004
EMEA/CPMP/BWP/3734/03	Note for guidance on scientific data requirements for a vaccine antigen master file (VAMF)	To be finalised and released on EMEA website in 2004
EMEA/CPMP/BWP/3794/03	Note for guidance on scientific data requirements for plasma master file (PMF)	To be finalised and released on EMEA website in 2004
EMEA/CPMP/BWP/1571/02	Update position statement on the quality of water used in the production of vaccines for parenteral use	To be finalised and released on EMEA website in 2004
EMEA/CPMP/BWP/2758/02	Note for guidance on pharmaceutical aspects of the product information for human vaccines	To be finalised and release on EMEA website in 2004

CPMP Ad Hoc Working Group on Blood Products (BPWG)

Reference number	Document title	Status
CPMP/BPWG/1089/00	Note for guidance on the clinical investigation of plasma derived fibrin sealants	To be finalised in 2004
CPMP/BPWG/153/00	Core SPC for plasma derived fibrin sealants	Released for further consultation in March 2003 and to be finalised in 2004
CPMP/BPWG/220/02	Note for guidance on the clinical investigation of von Willebrand factor	Released for 6 months consultation in July 2003 and to be finalised in 2004
CPMP/BPWG/278/02	Core SPC for von Willebrand factor	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/388/95 rev. 1	Note for guidance on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)	If revision of the guideline is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/859/95 rev. 1	Core SPC for human normal immunoglobulin for intravenous administration (IVIg)	If revision of the core SPC is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/1561/99	Note for guidance on the clinical investigation of recombinant factor VIII and IX products	If revision of the guidelines is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/198/95 rev. 1	Note for guidance on the clinical investigation of human plasma derived Factor VIII and IX products	If revision of the guidelines is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/1619/99	Core SPC for human plasma derived and recombinant coagulation factor VIII products	If revision of the core SPC is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/1625/99	Core SPC for human plasma derived and recombinant coagulation factor IX products	If revision of the core SPC is needed, revision expected to be released for consultation in 2004 and finalised in 2005

Reference number	Document title	Status
CPMP/BPWG/575/99	Note for guidance on the clinical investigation of human anti-D immunoglobulin for intravenous and/or intramuscular use	If revision of the guideline is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/574/99	Core SPC for human anti-D immunoglobulin for intravenous and/or intramuscular use	If revision of the core SPC is needed, revision expected to be released for consultation in 2004 and finalised in 2005
CPMP/BPWG/3726/02	Core SPCs for human varicella immunoglobulin i.v.	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/3728/02	Core SPCs for human rabies immunoglobulin i.m	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/3730/02	Core SPCs for human tetanus immunoglobulin i.m.	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/3732/02	Core SPCs for human tick-borne encephalitis immunoglobulin i.m.	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/2048/01	Core SPC for human plasma derived Factor VII products	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/4222/02	Core SPC for human plasma derived Hepatitis B immunoglobulin for intramuscular use	Core SPCs released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/4027/02	Core SPC for human plasma derived Hepatitis B immunoglobulin for intravenous use	Released for 6 months consultation in 2003 and to be finalised in 2004
CPMP/BPWG/3735/02	Core SPC for human plasma prothrombin complex	Released for 6 months consultation in 2003 and to be finalised in 2004
	Core SPC for human plasma fibrinogen concentrate	Core SPC to be prepared in 2004 for release for consultation
CPMP/BPWG/BWP/561/03	Warning on transmissible agents for SPCs and patient leaflets	To provide guidance during 2004-2005 as needed to support use of the revised warning statements for SPCs and patient leaflets. Discussions in 2004 on the question of whether to develop statements for where albumin is used as excipient
CPMP/BWP/3207/00 CPMP/3097/02	Note for guidance on comparability of medicinal products containing biotechnology-derived proteins as drug substances (As part of CPMP guidance on comparability of biological medicinal products) Annex on non-clinical and clinical considerations	Comments to the CPMP ad hoc group on comparability as needed in relation to the maintenance of the guideline, development of specific guidance, and ICH activity

CPMP ad hoc Vaccine Expert Group (VEG)

Reference number	Document title	Status
CPMP/1100/02	Note for guidance on the development of vaccinia based vaccines against smallpox	The guideline will be updated as further experience is gained in the development and manufacture of second-generation smallpox vaccines
CPMP/BWP/2289/01	Points to consider on the development of live attenuated influenza vaccines	Revision of points to consider document to include guidance also for a pandemic scenario

Reference number	Document title	Status
CPMP/BWP/2517/00	Points to consider on the reduction, elimination or substitution of thiomersal in vaccines	Update, maintenance of position statements and contribution to assessment of dossiers
CPMP/17/03	Note for guidance on requirements for evaluation of new immunological adjuvants in vaccines	Release of guideline for consultation in 2004
	Note for guidance/points to consider on requirements for evaluation of therapeutic vaccines	Development of guideline/points to consider
CPMP/EWP/463/97	Note for guidance on clinical evaluation of new vaccines	Maintenance in the light of WHO activities and revision of guideline to include advice on co-administration of vaccines

CPMP Efficacy Working Party (EWP)

Reference number	Document title	Status
CPMP/EWP/252/03	Points to consider on clinical investigation of medicinal products in neuropathic pain management	Concept paper adopted in February 2003. Release for 3-month consultation expected in 2Q 2004
CPMP/EWP/3635/03	Concept paper for the development of note for guidance on clinical investigation of medical products in the treatment of social anxiety disorder (social phobia)	Concept paper adopted in September 2003. Release for consultation of the note for guidance expected in 2/3Q 2004
CPMP/EWP/4284/02	Note for guidance on clinical investigation of medical products in the treatment of generalised anxiety disorder	Released for consultation in September 2003 for comments by March 2004. Finalisation expected in 2/3Q 2004
CPMP/EWP/4280/02	Note for guidance on clinical investigation of medical products in the treatment of panic disorder	Released for consultation in September 2003 for comments by March 2004. Finalisation expected in 2/3Q 2004
CPMP/EWP/4279/03	Note for guidance on clinical investigation of medical products in the treatment of obsessive-compulsive disorder	Released for consultation in September 2003 for comments by March 2004. Finalisation expected in 2/3Q 2004
CPMP/EWP/2986/03	Addendum on acute cardiac failure to the CPMP note for guidance on clinical investigation of medicinal products in the treatment of cardiac failure	Draft addendum released for 6-month consultation in July 2003. Finalisation expected 2/3Q 2004
CPMP/EWP/3020/03	Note for guidance on clinical investigation of medicinal products for the treatment of lipid disorders	Draft note for guidance release for 6-month consultation in June 2003. Finalisation expected in 2/3Q 2004
CPMP/EWP/234/95	Revision of note for guidance on the clinical investigation of antianginal medicinal products in stable angina pectoris	Draft revision document expected to be released in 1/2Q 2004
CPMP/EWP/238/95	Revision of note for guidance on the clinical investigation of medicinal products in the treatment of hypertension	Draft revision document expected to be released in 1/2Q 2004
	Note for guidance on clinical investigation of medicinal products for secondary prevention of cardiovascular events	Concept paper expected to be released in 1/2Q 2004

Reference number	Document title	Status
	Questions and answers document on fixed combination of antihypertensive and lipid lowering agents	Concept paper expected to be released in 1/2Q 2003
CPMP/EWP/519/98	Note for guidance on clinical investigation of steroid contraceptives in women	Draft revision expected to be released for consultation 1/2Q 2004
CPMP/EWP/4891/03	Points to consider on clinical investigation of medicinal products for treatment of ankylosing spondylitis	Concept paper adopted in November 2003. Draft expected to be released for consultation1/2Q 2004
CPMP/EWP/	Points to consider on clinical investigation of medicinal products for treatment of juvenile arthritis	Concept paper expected in 1Q 2004
CPMP/EWP/	Points to consider on clinical investigation of medicinal products for treatment of psoriatic arthritis	Concept Paper expected in 1Q 2004
CPMP/EWP/558/95 rev. 1	Revision of note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections	Draft revision document released for consultation on May 2003. Finalisation expected in 2/3Q 2004
CPMP/EWP/	Concept paper on the development of points to consider on clinical investigation of medicinal products for the treatment of Hepatitis B	Concept Paper expected in 1Q 2004
CPMP/EWP/2158/99	Points to consider on biostatistical/methodological issues arising from CPMP discussion on licensing applications: choice of non-inferiority margin	Release for consultation expected in 1Q 2004
CPMP/EWP/2459/02	Points to consider on the use of statistical methods for flexible design and analysis of confirmatory clinical trials	Release for 3-month consultation expected 3Q 2004
CPMP/EWP/	Concept paper on the development of points to consider on data Management Board	Concept paper expected in 1Q 2004
CPMP/EWP/226/02	Points to consider on clinical pharmacokinetic investigation of the pharmacokinetics of peptides and proteins	Release for 3-month consultation expected 1/2Q 2004
CPMP/EWP/225/02	Note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with impaired renal function	Release for 6-month consultation in March 2003. Finalisation expected in 1Q 2004
CPMP/EWP/968/02	Points to consider on the evaluation of the pharmacokinetics of medicinal products in the paediatric population	Release for consultation expected 1/2Q 2004
CPMP/EWP/2339/02	Note for guidance on the evaluation of the pharmacokinetics of medicinal products in patients with hepatic impairment	Release for consultation expected 1Q 2003

Reference number	Document title	Status
CPMP/EWP/4151/00	Points to consider on the requirements for clinical documentation for metered dose inhalers	Released for 3-month consultation in January 2002 for comments by April 2002. Finalisation expected by 1/2Q 2004
CPMP/EWP/2454/02	Note for guidance on clinical investigation of medicinal products for the treatment of psoriasis	Release for consultation expected in November 2003 for comments by May 2004. Finalisation expected by 3/4Q 2004.
CPMP/EWP/2455/02	Points to consider on allergic rhino-conjuctivitis	Released for 6-month consultation in September 2003.Finalisation expected in 2/3Q 2004
CPMP/EWP/1875/03	Points to consider on the clinical requirements of modified release products submitted as a line-extension of an existing marketing authorisation	Draft document released for 3-months consultation in June 2003. Finalisation expected in 1/2Q 2004
	Points to consider on the clinical investigation of medicinal products for the treatment of sepsis	Released for consultation expected by 1/2Q 2004.
	Points to consider on the clinical investigation of antiemetic medicinal products for use in oncology	Concept paper is expected in 4Q 2003/1Q 2004
CPMP/EWP/3018/03	EWP position paper on quality of life	Document to be published in 2/3Q 2004
	EWP discussion paper on clinical trials in small populations	Document to be prepared in 2004
	Note for guidance on comparability of medicinal products containing biotechnology- derived proteins as active substance. Multidisciplinary guideline: other involved working parties: BWP, SWP, PhVWP	Draft document released for 6-month consultation in July 2002. Finalisation expected in 4Q 2003/1Q 2004
CPMP/EWP/PhVWP/1417/01	Note for guidance on the use of medicinal products during pregnancy: need for post-marketing data Multidisciplinary Guideline: Other involved working parties: PhVWP	Release for consultation expected in 1Q 2004
CPMP/SWP/373/01	Note for guidance on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling. Multidisciplinary Guideline: Other involved working parties: SWP	Concept paper adopted in June 2001. Release for 6-month consultation expected in 2004
CPMP/EWP/239/95	Note for guidance on the clinical requirements for locally applied, locally acting products containing known constituents	Revision to be considered
CPMP/EWP/555/95	Note for guidance on clinical trials with haematopoietic growth factors for the prophylaxis of infection following myelosuppressive or myeloablative therapy	Revision to be considered
CPMP/EWP/240/95	Note for guidance on fixed combination medicinal products	Revision to be considered

Reference number	Document title	Status
	MEDDEV guideline	EWP contribution in consideration
	Clinical guidance on assessing qt prolongation potential	EWP contribution. Step 4 expected for 2Q 2004
	E2E: Pharmacovigilance planning	EWP contribution
	Notice to applicant (CTD – ICH M4)	Follow-up of the implementation of the CTD
	Guideline on SPC multidisciplinary guideline: European Commission, PhWP, SWP, QWP, BWP, QRD group	Contribution to expected revision in 2003/2004
	Eureopean Comission guidelines relating to the implementation of the clinical trial directive	Follow-up of the EWP contribution

CPMP Pharmacovigilance Working Party (PhVWP)

Reference number	Document title	Status
	Good pharmacovigilance practice (GVP)	Consultation of draft and finalisation
EC Volume 9 2001	Procedure for competent authorities on the undertaking of pharmacovigilance activities	Revision to implement the EU risk management strategy
EC Volume 9 2001	CPMP note for guidance on the rapid alert system and non-urgent information system in pharmacovigilance	Revision in order to improve communication between competent authorities and the EMEA and to implement the EU risk management strategy
	Note for guidance for the preparation of assessment reports on periodic safety update reports	Finalisation of draft developed in 2003
EC Volume 9 2001	Note for guidance on the conduct of pharmacovigilance for centrally authorised products	Revision to implement the revised PhVWP mandate, new procedures for handling safety concerns at level of the CPMP and the EU risk management strategy
EC Volume 9 2001	Note for guidance on the conduct of pharmacovigilance for medicinal products authorised through mutual recognition	Revision to implement the revised PhVWP mandate and the EU risk management strategy, including the outcome of the joint working group of the MRFG and the PhVWP
	Note for guidance on the conduct of pharmacovigilance for medicines used by children	Development of draft based on concept paper (CPMP/PhVWP/4838/02) adopted by CPMP in November 2002
	Note for guidance on the conduct of pharmacovigilance for vaccines	Development of draft based on concept paper (CPMP/PhVWP/4838/02) adopted by CPMP in November 2002
	EudraVigilance – definition of pre-defined queries for signal generation and usage of the data warehouse	Further elaboration of proposals provided by the joint subgroup of the EudraVigilance-telematics implementation group and the PhVWP ongoing
	Note for guidance on the conduct of post-authorisation safety studies	Development of concept paper
	Note for guidance on criteria for recall and repackaging following urgent safety restriction and variation procedures	Finalisation of criteria in the light of experience

Reference number	Document title	Status
CPMP/PhVWP/3897/03	Note for guidance on handling direct healthcare professional communication for medicinal products for human use	Finalisation of draft developed in 2003 in the context of overall EMEA communication strategy
	Note for guidance on handling public position statements on matters relating to the safety of medicinal products for human use	Development of draft in the context of overall EMEA communication strategy
	Guidance on risk management tools and risk communication	Guidelines to be developed in order to implement the new pharmaceutical legislation, the EU risk management strategy and the awaited outcome of the EMEA/CPMP working group with patients and consumer organisations
CPMP/PhVWP/135/00	Standard operating procedure for the review of CPMP scientific advice by the CPMP Pharmacovigilance Working Party (PhVWP)	Revision in the light of experience and to implement the revised PhVWP mandate and the EU risk management strategy
	Policy for the transmission of PhVWP recommendations and assessment reports for mutually recognised and purely nationally authorised products to marketing authorisation holders	Development of policy, also in co-operation with the MRFG
EC Volume 9 2001	Notice to marketing authorisation holders	Revision to implement the new pharmaceutical legislation, new ICH guidelines and guidance documents in relation to directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use with regard to reporting of adverse drug reactions from studies
CPMP/PhVWP/1618/01	Position paper on compliance with pharmacovigilance regulatory obligations	Discussion of implementation issues and development of further guidance documents in co-operation with the EMEA ad hoc meeting of GCP inspection services ongoing, in particular in order to implement the new pharmaceutical legislation
	Note for guidance on the exposure to medicinal products during pregnancy: need for post-authorisation data	Discussion of comments from interested parties on the draft to be released for public consultation by the CPMP and finalisation jointly with EWP
	Note for guidance on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling	Commenting on draft to be developed by joint SWP/EWP/PhVWP expert group on the basis of the concept paper adopted by the CPMP in June 2001 (CPMP/SWP/373/01)
	Guidance documents in relation to directive 2001/20/EC on the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use and its implications for reporting of adverse drug reactions and the use of EudraVigilance	Contribution to guidance documents as requested by the EC working group and the EudraVigilance task force

Reference number	Document title	Status
CPMP/BWP/2571/00	Points to consider on the reduction, elimination or substitution of thiomersal in vaccines	Contribution to update by BWP
CPMP/BWP/2289/96	Points to consider on the development of live attenuated influenza vaccines	Contribution to update by BWP
CPMP/BWP/2571/00	Guideline on requirements for evaluation of new immunological 'adjuvants' in vaccines	Contribution to guideline to be developed by QWP
	Note for guidance on quality, pre-clinical and clinical aspects of gene transfer medicines – lentiviral vectors	Contribution to update by BWP
CPMP/BWP/1700/01	Points to consider on xenogeneic cell therapy products	Contribution to revision by BWP in the light of scientific progress
CPMP/BWP/41450/98	Note for guidance on the manufacture and quality control of human somatic cell therapy medicinal products	Contribution to note for guidance to be developed by QWP
	CPMP list of herbal drugs with serious risks (October 1992)	Contribution to update by HMPWP
EC Volume 9 2001	ICH-E2D: Post-approval safety management: definitions and standards for expedited reporting and good case management practices	Implementation into volume 9 (ICH step 4)
EC Volume 9 2001	ICH-E2E: Pharmacovigilance planning	Finalisation of the contribution with regard to comments from interested parties on the draft released for public consultation by the CPMP in 2003 (ICH Step 3)
	ICH-M1: Medical dictionary for drug regulatory activities (MedDRA)	Contribution to maintenance
EC December 1999	Notice to applicants – guideline on the summary of product characteristics	Finalisation of draft contribution to revision provided in 2003 and to consultation of all working parties contributions within multidisciplinary working group
EC Volume 2C June 2001	Notice to applicants – guideline on the processing of renewals in the centralised procedure	Review of the contribution of the PhVWP in the light of experience ongoing
MRFG March 2001	Standard operating procedure on urgent safety restrictions for medicinal products authorised through mutual recognition procedure	Review in the light of experience ongoing for comments to be forwarded to MRFG
	Vaccine identification standards initiative	Scientific input
EMEA/CPMP/PhVWP/5009/03	Principles of urgent exchange of important information between the FDA and the PhVWP	Finalisation on the basis of the EU – US FDA confidentiality agreement concluded in 2003
	Rules and procedures for further cooperation between US FDA and EU	Contribution as requested by European Commission according to action plan to be drafted by European Commission
	Pharmacovigilance in Europe: the way forward – views of the CPMP PhVWP	Updating and editing of discussion paper developed in 2002

Reference number	Document title	Status
	Tracking systems for safety issues and implementation of safety-related regulatory action	Further development ongoing and implementation to be initiated
	Documents on working practices, new document management and communication tools	Drafting of documents in order to make use of technical progress as well as to implement the EU risk management strategy, in particular the revised PhVWP mandate, and the extension of the system to the enlarged EU. This includes organisational documents for the functioning of the PhVWP itself, as well as on the interactions and cooperation CPMP–PhVWP, MRFG–PhVWP and HoA–PhVWP. In particular, there is need for a document in relation to referral procedures. Drafting of the following document has already started in 2003: Principles for sharing the workload between Member States in relation to the assessment of periodic safety update reports for mutually recognised products

CPMP Safety Working Party (SWP)

Reference number	Document title	Status
CPMP/SWP/3404/01	Note for guidance on the need for pre-clinical testing of human pharmaceuticals in juvenile animals	Adopted by the CPMP in November 2001 Draft note for guidance expected to be released for consultation in 4Q 2004
CPMP/SWP/4447/00	Note for guidance on environmental risk assessments for pharmaceuticals	Guideline re-released for consultation in 2003 and expected to be finalised by 2004
	Position paper on control animals sampling in toxicology studies	Concept paper adopted by the CPMP in 2003. Draft position paper to be developed and discussed in 2004
CPMP/SWP/5958	Note for guidance on investigation of dependence potential of medicinal products (CNS drugs); Request from the EWP	Concept paper adopted by the CPMP in December 2003. Draft note for guidance to be developed and discussed in 2004
CPMP/SWP/2599/02	Position paper on the non-clinical safety studies to support single low dose clinical screening studies in man	Draft position paper released for 3-month consultation in June 2002 and finalised in 2003. Follow-up of implementation and possible revision of position paper
CPMP/SWP/7999/95	Note for guidance on the non-clinical documentation of medicinal products with 'well-established use'	Guideline released for consultation in 2002 and expected to be reviewed in 2004
CPMP/465/95	Note for guidance on preclinical and toxicological testing of vaccines	Guideline to be reviewed in the light of the SWP response on hexavalent vaccines
CPMP/SWP/QWP/4446/00	Note for guidance on specification limits for residues of heavy metal catalysts in medicinal products	Guideline re-released for 6-month consultation by CPMP in June 2002, reformulated in 2003 and expected to be finalised in 2004

Reference number	Document title	Status
CPMP/1199/02	Points to consider document on xenogeneic cell therapy Multidisciplinary guideline: involved working parties are BWP, SWP, EWP	Follow-up
CPMP/3097/02	Comparability of biotechnology products preclinical and clinical issues – annex to guideline Multidisciplinary guideline: involved working parties are BWP, EWP, SWP	Draft annex on non-clinical and clinical considerations released for 6-month consultation in July 02 and finalised in 2003. Follow-up
CPMP/986/96	Points to consider document on the assessment of the potential for qt interval prolongation by non-cardiovascular medicinal products Multidisciplinary guideline: involved working parties are SWP, EWP	To be replaced when ICH S7B comes into operation
CPMP/SWP/373/01	Note for guidance on risk assessment of medicinal products on human reproductive and development toxicities: from data to labelling Multidisciplinary guideline: involved working parties are SWP, EWP, PhVWP and SPC group	Concept paper (adopted by the CPMP in June 2001 Draft note for guidance expected to be released for consultation in 2004
	Position paper on the assessment of carcinogenic and mutagenic potential of anti-HIV medicinal products. Multidisciplinary position paper: involved ad hoc expert group – ad hoc group on AIDS	Draft position paper expected to be released for consultation in 4Q 2004
CPMP/SWP/5199/02	Position paper on the limits for genotoxic impurities Multidisciplinary position paper: Involved working parties are SWP and QWP	Position paper to be finalised in 1Q 2004
	Points to consider on investigations of medicinal products for the treatment of chemotherapy induced nasuea and vomiting Multidisciplinary guideline: involved working parties are EWP and SWP	Concept paper adopted by the CPMP in 4Q 2003/1Q 2004. Pre-clinical aspects to be developed and discussed in 2004
CPMP/17/03	Note for guidance on requirements for the evaluation of new adjuvants in vaccines Multidisciplinary guideline: involved working parties are BWP, SWP, EWP and VEG	Draft note for guidance to be developed and discussed in 2004
	Issues related to thiomersal or other preservatives in vaccines Multidisciplinary guideline: involved working parties are VEG and SWP	Revision of safety assessment of thiomersal

Reference number	Document title	Status
	CTD – ICH M4 Multidisciplinary guideline: other involved working parties: QWP, SWP and BWP	Follow-up of the implementation of the CTD in 2004/2005
	S7B – Non clinical studies for assessing risk of repolarisation associated ventricular tachyarrhythmia	Step 3 adopted and released for 6-month consultation in February 2002. Follow-up of development in 2004/2005
	Immunotoxicity	Concept paper to be developed in 2004 for the development of a guidance document. Evaluation and follow-up of the data collected in the ICH immunotoxicology survey
	Position paper on non clinical studies for combination therapy	Concept paper expected to be adopted by the CPMP in 2004
	Position paper on reproductive toxicology studies for cancer vaccines and anticancer medicinal products	Concept paper expected to be adopted by the CPMP in 2004
	Note for guidance non-clinical studies needed to support the early clinical development of pharmaceuticals	Concept paper expected to be adopted by the CPMP in 2004

EMEA Herbal Medicinal Products Working Party (HMPWP)

Reference number	Document title	Status
EMEA/HMPWP/344/03	Points to consider on the biopharmaceutical characterisation of herbal medicinal products	Document to be finalised after receipt of comments from interested parties
EMEA/18123/00	Compilation of general quality questions answered by the HMPWP	Constant update of the question & answer document in the light of new questions and criteria
EMEA/HMPWP/31/99	Points to consider on good agricultural and collection practice for starting materials of herbal origin	Document to be revised on the basis of the final WHO guideline on good sourcing practices
	CPMP list of herbal drugs with serious risks dated October 1992	HMPWP to carry out a revision/update of the list according to the strategy adopted by CPMP
	HMPWP position paper on pulegone containing herbal medicinal products	Position paper to be finalised in 4Q 2004
	HMPWP position paper on menthofuran containing herbal medicinal products	Position paper to be finalised in 4Q 2004
	HMPWP position paper on quassin (Quassia amara) containing herbal medicinal products	Position paper to be finalised in 4Q 2004
	HMPWP position paper on hypericine (hypericum perforatum) containing herbal medicinal products	Position paper to be finalised in 4Q 2004
EMEA/HMPWG/11/99	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	Document to be updated after publication of final CPMP Note for guidance on the non-clinical documentation of medicinal products with well-established use (CPMP/SWP/799/95)

Reference number	Document title	Status
	Core-data following assessment of ESCOP monographs	Preparation of core data according to agreed timetable.
EMEA/HMPWP/41/01	Standard operating procedure recording of core-data for herbal drugs/products	Constant update of the document taking into account experiences gathered during drafting core data
	Proposal for a directive of the European Parliament and of the Council amending, as regards traditional herbal medicinal products, directive 2001/83/EC on the community code relating to medicinal products for human use	HMPWP to prepare for the implementation of the directive
	Proposal for a future EU list (database) of herbal substances, preparations and combinations with traditional indications	HMPWP to prepare proposals for the possible format of such list, on the IT requirements for EU database and to reflect on future content of this list in anticipation of coming into force of new directive
EMEA/HMPWP/23/99	Updated draft points to consider on the evidence of safety and efficacy required for well-established herbal medicinal products in bibliographic applications	Document to be updated. Update of the document following progress on the directive on traditional herbal medicinal products and taking into account CPMP guidance documents
EMEA/HMPWP/1156/03	Draft concept paper on the implementation of different levels of scientific evidence in core-data for herbal drugs	Document to be updated following receipt of comments from Interested Parties. Update of the document following progress on the directive on traditional herbal medicinal products

Scientific Advice Working Group (SAWG)

No guidelines

Paediatric Expert Group (PEG)

Reference number	Document title	Status
	Concept paper on investigation of immune system in children	To be drafted
	Concept paper on renal maturation and function, and drug evaluation in neonates	First draft to be finalised in January 2004
	Discussion paper on clinical trials in small populations	To be drafted with EWP and COMP
	Points to consider on pharmacokinetics of medicinal products for the paediatric population	To be drafted with EWP
	Note for guidance on formulations of choice for medicines used in children	First draft with QWP
	Note for guidance on the need for pre-clinical testing of medicinal products in juvenile animals	First draft with CPMP SWP
	Note for guidance on the conduct of pharmacovigilance for vaccines	To be drafted with CPMP PhVWP
	Note for guidance on the conduct of pharmacovigilance for medicines used in children	To be drafted with CPMP PhVWP

Invented Name Review Group

Reference number	Document title	Status
CPMP/328/98 Rev. 4	Guidelines on the acceptability of invented names for medicinal products processed through the centralised procedure	To be confirmed

CVMP Efficacy Working Party (EWP)

Reference number	Document title	Status
CVMP/EWP/001/03	Efficacy requirements for ectoparasiticides for cattle	Guideline to be finalised after consultation period (end of consultation in January 2004)
	VICH guideline on target animal safety for veterinary pharmaceuticals	Work ongoing from 2003 and continuing in 2004
EMEA/CVMP/VICH/833/99 EMEA/CVMP/VICH/834/99 EMEA/CVMP/VICH/835/99 EMEA/CVMP/VICH/839/99 EMEA/CVMP/VICH/840/99 EMEA/CVMP/VICH/841/99 EMEA/CVMP/VICH/845/00 EMEA/CVMP/VICH/846/00	VICH guidelines on anthelmintics	Revision of the existing guidelines in relation to resistance data, concept paper for CVMP anticipated for 2Q 2004
	Data requirements for combination products	Concept paper for CVMP anticipated in 2Q 2004
	Scientific memory	Concept paper for CVMP anticipated in 2Q 2004
	Existing guidelines and new guidance documents (if needed)	Revision of existing guidelines/development of new guidance (if needed) in relation to 'Minor use - minor species' policy

CVMP Immunologicals Working Party (IWP)

Reference number	Document title	Status
EMEA/CVMP/775/02	Position paper on requirements for foot-and-mouth disease vaccines	New
EMEA/CVMP/477/03-consultation	Data requirements for immunological veterinary medicinal products for minor uses and minor species	New
CVMP/IWP/108/03-rev. 1	Proposed approach for the consideration of substances other than the active ingredients present in veterinary medicinal products, under Council Regulation (EEC) No 2377/90 laying down a community procedure for the establishment of veterinary medicinal products in foodstuffs of animal origin	New
CVMP/IWP/52/97	Requirements for combined vaccines	New revision
EMEA/CVMP/865/03	Data requirements for removing the target animal batch safety tests for immunological veterinary medicinal products in the EU	New
CVMP/IWP/128/03	Guideline on live recombinant vector vaccines for veterinary use	Work ongoing from 2003 and continuing in 2004

Reference number	Document title	Status
CVMP/IWP/21/03	Guideline on EU requirements for batches with maximum and minimum titre or batch potency for developmental safety and efficacy studies	Work ongoing from 2003 and continuing in 2004
EMEA/CVMP/743/00	Note for guidance on the requirements and controls applied to bovine serum (foetal or calf)	Work continuing in 2004
	VICH guideline on the detection of mycoplasma	Work ongoing from 2003 and continuing in 2004
	VICH guideline for the tests on the presence of extraneous viruses in veterinary viral vaccines	Work ongoing from 2003 and continuing in 2004
	VICH guideline on target animal safety for veterinary biological products	Work ongoing from 2003 and continuing in 2004
	VICH guideline on reversion to (or increase in) virulence for veterinary live vaccines	Work ongoing from 2003 and continuing in 2004

CVMP Pharmacovigilance Working Party (PhVWP-V)

Reference number	Document title	Status
EMEA/CVMP/183/96, Volume 9 of the rules governing medicinal products in the European Union	Guideline on pharmacovigilance of veterinary medicinal products - notice to marketing authorisation holders	Finalisation of review in January 2004
	Guideline on mechanisms to trigger investigations of the safety of veterinary medicinal products by EU competent authorities	Finalisation by 2Q 2004
Volume 9	Review of the guidance further to the review of the EU pharmaceutical legislation	To be initiated in 2004 dependent on progress of review process
EMEA/CVMP/413/99	VEDDRA – CVMP list of clinical terms, annual review	Annual review by early 3Q 2004
	Standardised terminology for use with Eudravigilance – coding of human adverse reactions	Development of a terminology based on VEDDRA during 1Q/2Q 2004
	Standardised terminology for use with Eudravigilance – other required terminology	Finalisation during 1Q 2004
	Annual update to HEVRA on veterinary pharmacovigilance	Finalisation January 2004
	Annual summary on the veterinary pharmacovigilance system to the interested public (in particular with regard to centrally authorised products)	Drafting during 1Q 2004
	Development of a common EU adverse reaction reporting form for veterinarians	Drafting during 1/2Q 2004
	Simple guide to veterinary pharmacovigilance in the EU	Drafting by end 3Q 2004
	Development of programmes for specific training workshops	Drafting by 1Q/4Q 2004

CVMP Safety Working Party (SWP)

Reference number	Document title	Status
III/5933/94-EN	Revision of injection site residues guideline	CVMP discussion during 1Q 2004
	Data requirements for products for minor uses / minor species	Revision of existing guidelines in relation to 'Minor use - minor species' policy, 1Q 2004
CVMP/VICH/467/03	VICH guideline GL36 on general approach to establish a microbiological ADI	To be adopted by VICH steering committee
CVMP/VICH/468/03	VICH guideline GL37 on repeat-dose (chronic) toxicity testing	To be adopted by VICH steering committee

Joint CPMP/CVMP Quality Working Party (QWP)

Reference number	Document title	Status
CPMP/QWP/3015/99	CPMP/CVMP guideline on parametric release	To be revised with GMP Inspectors
CPMP/QWP/155/96 EMEA/CVMP/065/99	CPMP/CVMP guideline on pharmaceutical development	To be developed in ICH
CPMP/QWP/227/02 EMEA/CVMP/134/02	CPMP/CVMP guideline on active substance master file (EDMF)	Revision of 3AQ7A. To be finished Q1 2004
	Procedure on handling and assessment of active substance master files	New
EMEA/CVMP/541/03	CVMP guideline on the chemistry of new active substance	End of public consultation on 31 January 2004. To be finished Q3 2004
CPMP/QWP/297/97 EMEA/CVMP/1069/02	CPMP/CVMP guideline on summary of requirements for active substances in the quality part of the dossier	To be finished Q1 2004
CPMP/QWP/6142/03	CPMP guideline on quality requirements for manufacturing in and distribution from climatic zones 3 and 4	To be finished Q2 2004
	CPMP guideline on formulations of choice for paediatric population	New
CPMP/QWP/6144/03 EMEA/CVMP/	Concept paper on the updating/revision of the quality part of existing marketing authorisation dossiers	New
CPMP/SWP/QWP/4446/00	CPMP guideline on specification limits for residues of heavy metal catalysts	Finalisation with SWP following end of consultation
CPMP/SWP/5199/02	Position paper on the limits of genotoxic impurities	Finalisation with SWP following end of consultation
CPMP/QWP/419/03	CPMP Guideline on excipients, antioxidants and antimicrobial preservatives	Combined guideline. To be finished Q3 2004
EMEA/CVMP/540/03	CVMP guideline on quality aspects of pharmaceutical veterinary medicinal products administered via drinking water	Finalisation after end of consultation on 31 January 2004
	CPMP guideline on positron emission tomography	New. Concept paper to be developed
	CPMP/CVMP guideline on graduation of syringes	New. Concept paper to be developed

Committee for Orphan Medicinal Products (COMP)

Reference number	Document title	Status
ENT/6283/00 Rev. 1	Guideline on the format and content of applications for designation as orphan medicinal products	Rev. 2 released for Consultation in January 2004
COMP/436/01	Points to consider on the calculation and reporting of the prevalence of a condition for orphan designation	Work ongoing. To be finished Q1 2004
COMP/1527/03	Discussion paper on the elements required for the purposes of orphan drug designation to support the rationale for use in a particular condition and the assumption of significant benefit	Work ongoing. To be finished Q1 2004

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	E-mail: certificate@emea.eu.int Fax: (44-20) 74 18 85 95

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 4HB

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

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Annex 5
Profiles of EMEA personalities

Philippe Duneton, 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 Secrear7 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 2003. He was elected chairman of the Board in 2004.

Jytte Lyngvig, Vice-chairman of the Management Board, b.13 October 1953, n. Danish

Education: Graduate in chemical engineering from the Technical University of Denmark. Post-graduate studies include a PhD in socio-economic planning.
Career to date: From 1976 to 1980, Dr Lyngvig was research-assistant and lecturer at the Technical University of Denmark. She worked at the Danish Environment Ministry from 1979 to 1985, first as a consultant and later as an official, before moving to the City of Copenhagen Environment Protection Agency until 1988. Dr Lyngvig has 12 years' private sector experience in the transport and consultancy industries and was appointed Chief Executive Office of the Danish Medicines Agency in 2000. She joined the EMEA Management Board in the same year and was elected vice-chairman in 2003.

Thomas Lönngren, 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 Lönngren 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.

EMEA 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. He was re-elected as chairman in 2004.

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. He was re-elected as vice-chairman in 2004.

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). He was re-elected as chairman in 2004.

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. He was re-elected as vice-chairman of the CVMP in 2004.

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 re-elected chairman of the Committee for Orphan Medicinal Products in May 2003. 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. He was re-elected vice-chairman of the COMP in June 2003.

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.

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.

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.

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

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.

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.

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 EMEA 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.

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.

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

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.

David Drakeford, 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.

Riccardo Ettore, Deputy Head of Sector for information technology, b. 8 April 1953, n. Italian

Education: Diploma in conference interpretation and translation from Scuola Superiore per Interpreti, Milan.
Career to date: Mr Ettore joined the European Commission as conference interpreter in 1976. During the 1980s, he developed a computer system to support the complex task of editing and managing the assignment of European Commission interpreters to meetings. By 1987, he had gradually moved from full-time interpreting to full-time software development. His published works include scores of articles in computer journals during the 1980s and several popular software packages. He joined EMEA in May 1995 and was appointed Deputy Head of Sector in July 2003.

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.

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.

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.

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.

Services attached to the Executive Director

Marijke Korteweg, Integrated quality management advisor, b. 29 May 1947, n. Belgian

Education: PhD (Chemistry) and PhD (Biochemistry), University of Ghent, Belgium. Fellow of the Institute of Quality Assurance, UK.
Career to date: After 10 years of fundamental prostaglandin research she joined the pharmaceutical industry in 1981 as a clinical research associate. In 1984 Dr Korteweg created the regulatory compliance/quality assurance audit department for the European Pharmaceutical R&D Division of Bristol-Myers Squibb, later becoming Director of Worldwide Regulatory Compliance (auditing). She was editor for the ICH GCP guideline from February 1992 until its adoption in May 1996. Dr Korteweg joined the EMEA in August 1997 and has acted as EMEA quality manager since July 1998. She has led the Agency's integrated quality management system and internal audit system since November 1999. She was appointed integrated quality management advisor in January 2004.

Martin Harvey Allchurch, Head of Sector for executive support and 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 EMEA in September 1995. He was nominated as press officer in September 2001 and appointed Head of Executive Support in January 2004.