Infrastructure services

The sector came into existence in September 2001 and provides facilities management, archiving, reprographics and mail room services.

Office and meeting space was a priority in 2001. New conference facilities on the third floor were completed at the beginning of 2001, together with new mailing and reprographics areas. Additional available space was identified and work began on procurement of architect and other services for the fitting out work to be carried out in 2002.

Work began on the preparation of a business contingency plan for the EMEA.

Improvements to the archiving and retrieval of EMEA documents were introduced in 2001 following an internal audit.

Accounting

The principal challenge for the Accounting Sector in 2001 was to absorb the increased level of operations due to the expansion of activities of the operational units, particularly in the areas of meetings and revenue, with a staffing level unchanged since 1996.
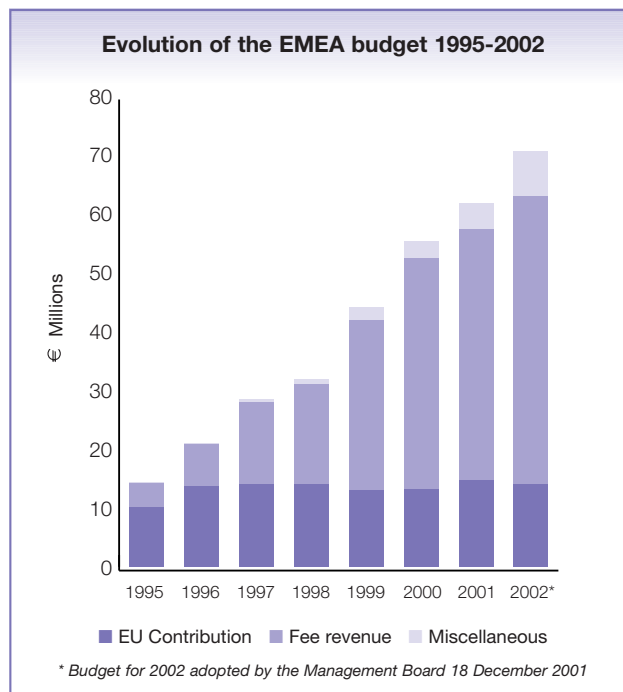
The sector handled approximately 33 000 transactions in 2001 compared to 27 150 in 2000.

The sector contributed to the analytical and activity costing exercise for the EMEA. It also looked at a number of opportunities to implement electronic data exchange within EMEA accounting systems and also with third parties, such as suppliers and customers, in order to make productivity gains.

5.2 Document management and publishing

Document management

The project to introduce an electronic document management system (EDMS) at the EMEA aims to ensure transparency and integrity of the Agency's work processes by introducing a system to hold documents in a central repository, ensure that documents are forwarded to and accessible by all authorised staff; ensure the registration of documents to reflect their history; and ensure that staff always have access to the latest version of a document.

Evolution of the EMEA budget 1995-2002

EU Contribution — Fee revenue — Miscellaneous

* Budget for 2002 adopted by the Management Board 18 December 2001

Following acceptance of the feasibility study commissioned at the end of 2000, work began on the implementation of the EDMS at the EMEA. Basic installation (servers, software, system configuration and testing) was completed in 2001, and implementation of the publishing process was progressed.

Electronic submission

Two projects were run in parallel in the area of electronic submissions: the definition of the electronic common technical document (eCTD) and the product information management (PIM) project.

- The eCTD defines a harmonised format (but not harmonised content) for the electronic submission of marketing authorisation applications in the European Union, Japan and the United States – the three regulatory partners in the ICH process. The eCTD is being defined as part of the ICH process in the M2 Electronic Standards for the Transfer of Regulatory Information Experts Working Group

- The specifications document for the eCTD was released for testing in May 2001. The expert group met by videoconference in October 2001 and expect to be able to recommend that the specifications be released for general consultation by the ICH Steering Committee early in 2002

- PIM is a joint initiative between the EMEA and the European Federation of Pharmaceutical Industries and Associations (EFPIA). Its purpose is to develop an exchange standard for product information that is used in the summary of product characteristics, patient information leaflet and product packaging. In developing the standard, the project aims to ease the exchange of information between applicants and competent authorities, mostly through the automated reuse of data to eliminate multiple input and review of changes during the review cycle. A second prototype application was developed in 2001 in support of a revised exchange standard

The specification document and other work in progress relevant to the eCTD, together with information on other aspects of electronic submission, is available at the EMEA electronic submission web site: *http://esubmission.eudra.org*

Quality and coherence of regulatory documents

The Quality Review of Documents Group (QRD) continued its work with the increased use of secure electronic exchange of documents, requiring fewer meetings during the year.

A cross-Agency working group established to review the amount and timing of translation work carried out on product information submitted with marketing authorisation applications concluded, in consultation with a similar working group established within EFPIA, that it would be more efficient to work in the English-language only until the second phase of the assessment.

The heads of national competent authorities meeting in November 2001 endorsed this proposal and it is expected to become operational during 2002.

5.3 Meeting management and conferences

Meetings

The level of meeting-related activities in 2001 increased by some 30 % compared with 2000. The EMEA services organised a total of 327 meetings in 2001, with a total of 516 meeting days. A total of 3 530 delegates were reimbursed.

The new meeting facilities at the EMEA became operational in the second quarter of 2001, resulting in a doubling of the Agency's conference room capacity.

Meetings at the EMEA 1999-2001

Legend:
- ■ Number of meeting days at the EMEA
- ■ Number of reimbursed delegates
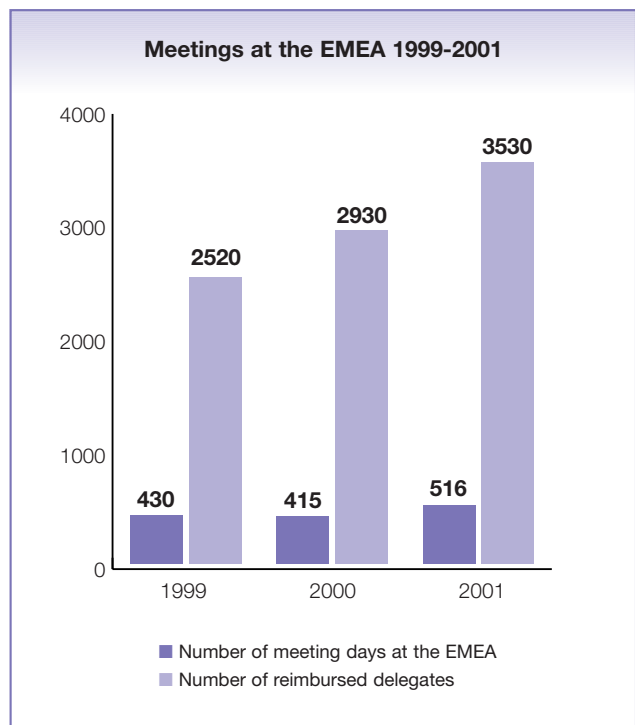
Meeting management

The rules on reimbursement of delegates and experts attending meetings were revised by the Management Board in June 2001.

A number of aspects relating to meeting organisation were also revised in 2001, including internal procedures for requesting meetings, travel and accommodation bookings, invitations and other practical organisational issues. The first module of a computerised meeting management system was launched in November 2001. The system is designed to automate meeting room bookings and scheduling.

Partners

The provision and support of technical equipment and facilities for meeting rooms were reviewed, in particular as part of preparations for future enlargement of the EU.

As part of ongoing efforts to facilitate relations with external partners, the sector developed the provision of videoconferencing and teleconferencing facilities and the organisation of satellite meetings. This was in particularly important it the context of the organisation of the PERF programme.