4.2 Document management and publishing

Product information

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

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

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

Electronic submission

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

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

Document management

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

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