New law boosts EMEA role

Kathy Redmond

The new European pharmaceutical legislation came into force on 20 May. Its effect is to considerably enhance the role of the European Medicines Agency (formerly the European Medicines Evaluation Agency – it retains its acronym 'EMEA') in a number of areas. These include the provision of scientific advice to companies; giving opinions – in co-operation with the World Health Organization – on the use of medicines outside the European Union; and giving opinions on the compassionate use of unapproved medicines in Member States.

Under provisions which are due to be implemented in November 2005, EMEA will also take on a role in conditional approvals and fast-track reviews, and the scope of the centralised approval procedure will be extended in such a way that it covers all cancer drugs.

The Agency was also given a stronger role in the provision of information to patients and the public, including a mandate to develop a database of all medicines approved in the European Union ('EuroPharm'). Small- and medium-sized companies should benefit from provisions in the legislation enabling EMEA to offer them administrative and scientific support.

Other changes brought about by the legislation include:

- The Committee for Medicinal Products for Human Use replaces the Committee for Proprietary Medicinal Products. The new Committee will be known as the CHMP.
- A new Committee for Herbal Medicinal Products is created and is expected to begin activity later in 2004.
- The composition of the Management Board changes from two to one member per Member State, in addition to two representatives each of the European Parliament and the European Commission. They are joined by two representatives of patient organisations, one representative of doctors' organisations and one representative of veterinarians' organisations.

OVER THE PAST FEW MONTHS a number of cancer drugs have received EU marketing authorisation, including Velcade (bortezomib), Faslodex (fulvestrant) Photobarr (porfimer sodium) and Erbitux (cetuximab).

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ELI LILLY'S ALIMTA (pemetrexed), indicated for the treatment of malignant pleural mesothelioma and non-small cell lung cancer, has received a positive opinion from the CHMP.

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TWO OF ROCHE'S ONCOLOGY PRODUCTS have had their indications extended by the CHMP. One of these is MabThera (rituximab), which can now be used in previously untreated patients with indolent non-Hodgkin's Lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy. The other is Herceptin (trastuzumab), which is now indicated for use in combination with docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior chemotherapy for metastatic disease.

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NOVARTIS HAS SUBMITTED marketing authorisation applications in the United States, European Union and Switzerland for the use of Femara (letrozole) in the extended adjuvant treatment of early breast cancer in postmenopausal women who have completed standard adjuvant (post-surgery) tamoxifen therapy and remain disease-free.

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PHARMION CORPORATION has withdrawn its European marketing authorisation application for thalidomide for the treatment of multiple myeloma, and will now focus on preparing a new dossier containing the additional clinical data requested by EMEA. Thalidomide will continue to be available in Europe on a compassionate use basis. The agent is already approved in Australia, New Zealand and Turkey for the treatment of relapsed/refractory multiple myeloma.