

European Regulatory Agencies

Evolution Across Europe

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Europe is getting used to continual change in its pharmaceutical regulation. The plans to update the European Agency for the Evaluation of Medicinal Products (EMA)—and nearly every aspect of European Union medicines legislation—emerged more clearly during 2002. But as the year closed, the plans were still under intense discussion, with any possibility of agreement fading into the further reaches of 2003.

A larger role for EMA. As expected, the proposed legislative changes included proposals to provide the EMA with more experts (including those from the industry) to boost its professional capacities, and to give it wider responsibilities, ranging from pharmacovigilance and inspections to international relations and orphan drugs. More controversially, the European Commission, which has the power of initiative in EU rule changes, insisted that the centralized authorization procedure should become obligatory for all new medicines, not just for biotechnology-derived products. At the same time, it is urging that decentralized procedure should be more finely tuned, partly so that EU member states will have less scope for refusing to recognize one another's authorizations. And there are plans to accelerate both systems, with shorter processing times for all evaluations and fast-track mechanisms for valuable new products through the centralized procedure. The proposals went much wider, though, recommending new incentives for innovation (through improved protection of regulatory data), and a pilot scheme to bring Europe closer to U.S. practice in direct-to-consumer advertising.

The year has seen intense lobbying from all sides on most of these proposals, and the latest stage of play suggests that the Commission will win its argument on

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forcing all new products through the centralized authorization procedure (much against the industry's desires), but will lose its argument on bringing more product information directly to patients (much to the glee of European consumerists and health activists, who feared what they saw as a charter for the drug industry to push prescription products even harder). Meanwhile, innovator drug firms are claiming the proposals will not give them enough incentives for additional research, while generic companies say the proposals as they stand will be a catastrophe for their bid to bring cheaper copy products to market faster.

New clinical trials rules. In the clinical trials area, the year has seen controversy between the European clinical trial

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community and EU regulators over the details of the new EU clinical trials rules. Clinical trial practitioners fear that the way the EU is demanding implementation of the new rules is so complicated that it will increase, rather than decrease, the divergent bureaucratic obstacles in EU member states—in total contradiction of the objective of the new rules. The outcome of that debate too hangs in the balance as the year ends.

Meanwhile, the modifications introduced to the EMA's own internal procedures are shaking down into what the industry is finding to be a more efficient organization, although it is still under the shadow of the other impending changes in the broader legislative framework.

The principal working parties

The Committee for Proprietary Medicinal Products (CPMP), chaired by Dr. Daniel Brasseur, is responsible for formulating the opinion of the EMEA on all questions about human medicinal products. Orphan drugs are the responsibility of the Committee on Orphan Medicinal Products, chaired by Josep Torrent-Farnell. Working parties provide additional advice on specific matters related to the quality, efficacy, and safety of products. The principal ones are: a biotechnology working party, an efficacy working party, a safety working party, a pharmacovigilance working party, and a quality working party that operates jointly on human and veterinary medicines. EU member states also supply a support pool of 1200 experts to assist the CPMP. The experts may also participate in other working parties and in ICH activities.

More information is available at www.eudra.org/en_home.htm.

Who does what

At the EU level, the key regulatory contact is the EMEA in London, which conducts regulatory activities on behalf of the 15 EU member states. EMEA is advised by the CPMP, which is in turn advised by a number of specialized working parties and can draw on expertise across Europe. The agency can, however, only make recommendations in most cases, such as product authorizations, and its decisions require endorsement by the European Commission in Brussels. Within the European Commission, the unit responsible for pharmaceuticals is located in the Directorate General for Enterprise, which covers industry affairs. The Directorate General is under the responsibility of European Commissioner Erkki Liikanen, and the director general is Jean Mingasson. □



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