

# European Regulatory Agencies

## Lull Before the Storm at the EMEA

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Change is in the air for pharmaceutical regulation in the European Union. Five years after it came into operation, plans are in preparation to upgrade and update the European Agency for the Evaluation of Medicinal Products. Throughout 2001, the shape of the likely changes has become clearer—although the formal legislative proposals might not appear until 2002, and will then take more than a year to win approval and come into effect.

Among the principal elements of the impending changes are that the EMEA will be able to call on more experts (including those from the industry) to boost its professional capacities for evaluating new medicines. It will have wider responsibilities—ranging from pharmacovigilance and inspections to international relations and orphan drugs. And, although the centralized and decentralized authorization procedures will stay in place, both will be modified. The centralized procedure will become obligatory for all new medicines, not just for biotechnology-derived products. The decentralized procedure will be more finely tuned, partly so that EU member states will have less scope for refusing to recognize one another's authorizations. Both systems will be accelerated, with shorter processing times for all evaluations and fast-track mechanisms for valuable new products through the centralized procedure.

During 2001, the new Director of the EMEA already spearheaded some voluntary management changes to bring greater professionalism into the current systems: New expert groups have been set and have started work on pediatric testing procedures and on gene therapy products, and work has advanced on a new plant-based medicines working party.

During the year, the EMEA modified

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#### Administration Unit

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**Head of Sector, Personnel and Support Services**  
Frances Nuttall . . . . .8475

**Head of Sector, Accounting**  
Gerard O'Malley . . . . .8466

#### Communications & Networking

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Post Vacanti . . . . .8429

**Head of Sector, Inspections**  
Sheila Kennedy (Acting Head) . . .8508

**Head of Sector, Conferences**  
Sylvie Bénédice . . . . .8651

**Head of Sector, Document Management and Publishing**  
Beatrice Fayl . . . . .8426

#### European Technical Office for Medicinal Products (ETOMEP)

**Responsible for Sector**  
Flavio Argentesi . . . . .8442

its internal structures—splitting its human medicines operations into two divisions, one responsible for preauthorization affairs, and the other responsible for authorized products. □

## CPMP Working Parties

The CPMP, chaired by Dr. Daniel Brasseur, is responsible for formulating the opinion of the EMEA on all questions about human medicinal products. Working parties provide additional advice on specific matters related to the quality, efficacy, and safety of those products. EU member states put a support pool of 1200 experts at the disposal of the CPMP. The experts may also participate in the following working parties and in ICH activities.

**Biotechnology working party** (chair, Professor Jean-Hughes Trouvin) advises CPMP on any matter concerning biotech-derived products and biologicals. It deals with centralized procedure applications and scientific questions of general interest.

**Efficacy working party** (chair, Dr. Barbara van Zweiten-Boot) draws up and updates methodological guidelines in established

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therapeutic areas and elaborates position papers on efficacy issues of developing areas.

**Safety working party** (chair, Professor Beatriz Silva Lima) provides a forum for dialogue and understanding on preclinical safety issues and methodological guidelines.

**Pharmacovigilance working party** (chair, Dr. Fernando Garcia Alonso) provides a forum for dialogue and understanding between national authorities and EMEA on pharmacovigilance (harmonizing terminology, developing IT communication facilities, establishing pharmacovigilance procedures for member states) and examines questions related to drug hazards.

**Joint CVMP/CPMP quality working party** (chair, Dr. Jean-Louis Robert) provides on request of the two committees a forum for dialogue and understanding between pharmaceutical experts to maintain a harmonized approach to quality issues and to eliminate national divergences in assessing quality problems. More information is available at [www.eudra.org/en\\_home.htm](http://www.eudra.org/en_home.htm).

## EMA Board

The management board is the supervisory body of the EMA. Representatives are appointed for three years. The board appoints the executive director and adopts financial regulation.

**Chairman** Keith Jones

**Vice Chairman** Gerhard Josef Kothmann

**European Commission** Bertrand Carsin, Paul Weissenberg, Philippe Brunet

**European Parliament** Gianmartino Benzi, José-Luis Valverdex, Dietrich Henschler, Jean-Pierre Reynier

**Austria** Alexander Jenzch, Ernest Luszczak, Christian Kalcher

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**Ireland** Tom Mooney, Colm Gaynor, Noel Usher, Frank Hallinan

**Italy** Nello Martini, Romano Marabelli, Silvia Fabiani, Agostino Macri

**Lichtenstein** Brigitte Batliner, Peter Malin

**Luxembourg** Mariette Backes-Lies

**The Netherlands** John Lisman, Frits Pluimers, Kees Kuiper

**Norway** Andreas Disen, Gro Ramsten Wesenberg

**Portugal** Miguel Andrade, Rogério Gaspar, Rosário Sobral

**Spain** Victoria de la Cuesta Garcia, Ramon Palop Baixauli

**Sweden** Anders Broström, Birgitta Bratthall

**United Kingdom** Roy Alder, Michael Rutter

## Who does what

The key regulatory contacts at the European level are the European Union (EU) institutions. The best known is the European Agency for the Evaluation of Medicinal Products (EMA) in London, which conducts regulatory activities on behalf of the 15 EU member states. EMA is advised by the Committee on Proprietary Medicinal Products, 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 Fabio Colasanti. □

*European Regulatory Agencies pages prepared by Peter O'Donnell and Jeremiah Kerber, assistant editor, Applied Clinical Trials. Information current as of November 2001.*