FDA, European Drug Agencies Extend Cooperation

BY JONATHAN GARDNER
Contributing Writer

U.S. and European drug regulators have announced "intensified" information sharing and dialogue aimed at increasing cooperation in drug approval and surveillance in the world's two largest pharmaceutical markets.

At a March review meeting in Brussels, representatives from the Food and Drug Administration, the European Medicines Agency, and the European Commission judged as a success the implementation of a confidentiality agreement that has enabled greater transatlantic information sharing and dialogue on pharmaceutical regulations protecting 753 million people in 26 countries.

The three agencies hope to strengthen joint activities on vaccines in preparation for potential pandemic flu outbreaks, as well as cancer, children's, and orphan drugs, and pharmacogenomics. Future activities will address counterfeit medicines.

The original agreement, signed in September 2003, paved the way for quarterly information exchanges on new drug applications, regulatory guidance, and inspections of manufacturing plants, which began in 2004. The agreement also authorized ad hoc exchanges of information on drug safety and public health, including advance notice of significant regulatory actions such as pulling drugs from the market. Such an exchange prevents other agencies from issuing contradictory advice when one agency takes significant regulatory action.

The ad hoc exchanges also have enabled "parallel" scientific guidance for drug applicants seeking the advice of the three agencies on how to proceed with research at such milestones as the conclusion of clinical trials. As part of the initial confidentiality arrangement a 1-year pilot project was initiated in 2005. The three agencies agreed to extend the pilot project, although the document released by the agencies did not say how long it would be extended. ■

Index of Advertisers