FDA, European Drug Agencies Extend Agreement

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

At a March review meeting in Brussels, 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 agencies hope to particularly 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 drugs.

The original agreement, signed in September 2003, paved the way for quarterly exchanges of information 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 regulatory actions such as pulling drugs from the market.

Such an exchange prevents other agencies from issuing contradictory advice when one agency takes 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. The first such meeting was in September 2003, and as part of the initial confidentiality arrangement, a 1-year pilot project was begun in 2005.

Those parallel meetings focus on breakthrough drugs, drugs for rare conditions, medication for children, or other new medicines considered important.

The agencies agreed to extend the project but did not say for how long. A spokesman for the European Commission said the meetings do not guarantee joint advice from the agencies but give applicants guidance on how to seek international drug approvals. ■

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