# FDA, European Agencies Extend Cooperation Pact

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Drug regulators in the United States and Europe have announced "intensified" information sharing and dialogue aimed at increasing cooperation in drug approval and surveillance activities 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 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 medicines.

The original agreement, signed in September 2003, paved the way for quarterly exchanges on 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 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. The first such parallel scientific meeting occurred in September 2003, and as part of the initial confidentiality arrangement a 1-year pilot project was initiated in 2005.

The focus of those parallel meetings is breakthrough drugs, those for rare conditions, medication for children, or other new medicines considered important.

The three agencies agreed to extend the pilot project, although the document released by the agencies did not give a time period. A spokesman for the European Commission said the meetings do not guarantee joint scientific advice from the three agencies but give applicants better guidance on how to proceed if they are seeking international drug approvals. ■



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