

Pharmaceuticals

October 2009

Communication between FDA, the European Commission and the European Medicines Agency (EMA) increased significantly during the last year, due to greater maturity of activities in cluster areas, enhanced discussion on pandemic issues, and the launch of several pilot projects. This interaction has been facilitated by placement of a U.S. liaison staffer in EMA in June 2009 and the planned placement of an EU liaison staffer in FDA in 2010.

Arrangements allowing the EMA and the FDA to exchange confidential information as part of their regulatory processes relating to medicines were extended in September 2005 for five years. The September annual meeting between the Commission, EMA, and the FDA confirmed our joint interest in prolonging confidentiality arrangements beyond 2010 and extending their scope to the exchange of safety-related information for non-centrally authorised medicines. The Commission, EMA, and FDA discussed whether and how drug-medical device combination products should be taken into the international harmonization sphere. During the September meeting, we also discussed the important public health issue of antimicrobial resistance, including possible transatlantic cooperation on regulatory and scientific approaches to provide incentives to develop new antimicrobials for treatment of infections caused by multi-drug-resistant bacteria.

Finally, we made significant progress on implementation of the Transatlantic Administrative Simplification Action Plan of June 17, 2008, in projects spanning 18 different areas, including inspections, biosimilars, scientific advice and counterfeiting.

December 2008

Active Pharmaceutical Ingredient (API) Tri-Party Pilot Program: The United States and the European Union (together with Australia) have finalized the terms of reference for an agreement to jointly plan inspections of API production facilities in third countries over the eighteen months beginning November 2008. By sharing inspection reports and leveraging each other's resources in this manner, it is expected that more information can be obtained than by each party following its own inspection plan alone. The inspection component of this program started in November 2008. Moreover, the first "test-case" joint inspection between the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) of an API plant in China has been recently concluded. Results of that inspection are pending.

Advanced Therapies Cooperation: In August 2008, FDA and EMA launched a technical level work "cluster" on advanced therapy medicinal products. These are new medical products based on genes (gene therapy), cells (cell therapy) and tissues (tissue engineering). This new work cluster builds on the ongoing FDA-EMA workplan, which already included work clusters on pediatric drugs, vaccines, oncology drugs, orphan drugs, drug safety, and pharmacogenomics.

Embeds at FDA/EMEA: FDA and EMEA have agreed to co-locate a senior-level agency representative/expert within each other's offices to work on medical product regulatory issues. This exchange is expected to begin as soon as all logistical and foreign ministry arrangements for such bilateral in-country placements can be finalized. It is hoped that this will occur in late 2008 or early 2009.

May 2008

A first set of specific projects on medicinal products have been agreed following the administrative simplification workshop held in Brussels in November 2007. These results will provide important benefits for industry, patients, and regulatory authorities. The collaboration on inspections will result in more effective use of resources and a higher safety level of products from third countries. Work will continue to identify other areas for intensified collaboration. In addition, U.S. and EU authorities have recently announced a series of successes in their work on biomarker development and validation for various medicinal product development purposes. Finally, FDA and the European Medicines Agency (EMA) have agreed recently on an implementation work plan for veterinary medicinal products regulation and have agreed on a process for offering parallel scientific advice to veterinary medicinal products manufacturers that wish to receive such advice simultaneously from the FDA and EMA.

November 2007

The European Commission will release a communication on providing access to information to patients on legal pharmaceuticals, and will table a legislative proposal allowing such access to the European Parliament and Council as soon as possible in 2008 in line with the Commission's 2008 legislative work programme.

The United States and the European Commission have also reached agreement on a common format for data submission to FDA and European Agency for the Evaluation of Medicinal Products for orphan drug designations. This will simplify the process for applying for orphan drug designation in both jurisdictions.