U.S. Food and Drug Administration

European Commission
Enterprise and Industry Directorate General

European Medicines Agency

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Press Release
Regulatory Cooperation Expanded

The US Food and Drug Administration (FDA), the European Commission (EC), and the European Medicines Agency (EMEA) have agreed to expand their current cooperative activities in several important areas. At a meeting June 14-15, 2007, the US and the EU reviewed the past year's activities under the existing Implementation Plan for the confidentiality arrangement. The ultimate goal of the initiative is to promote and protect public health, reducing regulatory burden and costs, and bringing innovative products to patients in a timely manner. Furthermore, important safety information about medicinal products is shared among the parties.

Building on the achievements in cooperation on vaccines, oncology, and pharmacogenomics, it was agreed to expand further the interactions in the areas of pediatrics and medicinal products for rare diseases ("orphan drugs"). Furthermore, scientific dialogue has been widened to include extensions of therapeutic indications and risk management plans. Based upon the newly adopted pediatric legislation in the EU, a "Principles of Interactions" document that will facilitate the timely exchange of information on scientific and ethical issues for pediatric therapeutics has been finalized and can be found here link.

The Implementation Plan on transatlantic medicines regulatory cooperation was revised to better describe the specifics of what information will be shared among the parties and under what circumstances, and the revised Plan has been finalized. Click here.

Following the Framework for Advancing Transatlantic Economic Integration between the EU and the USA, new areas of transatlantic regulatory cooperation were discussed notably regulatory cooperation on medical devices and on cosmetics. Discussions on the best ways to cooperate in these areas will continue intensively over the coming months.

In an effort to avoid future disharmony, upstream regulatory cooperation on new medicines legislation was intensively discussed. In addition, planning progressed on a Transatlantic Workshop on Administrative Simplification in Medicines Regulation. This workshop will be held on 28 November 2007 in Brussels, Belgium.

Transatlantic regulatory cooperation under the EC, EMEA and US FDA collaboration has allowed each side to share common experiences and gain an understanding of each other's regulatory system. Additionally, each side strives to reduce unnecessary differences in regulations and reduce associated costs to the consumer and industry. All

parties concur that this activity continues to be a success in fostering transatlantic cooperation and promoting public health protection.

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