EU and US Harmonise 'Orphan Drugs' Approval Procedures

The Commission, the European Medicines Agency (EMEA) and the United States Food and Drug Administration (FDA) adopted on 26 November 2007 a common application form for drug developers seeking approval for orphan medicines on both sides of the Atlantic. Both drug administrations will, however, continue conducting independent reviews to ensure compliance with their respective scientific requirements.

Orphan drugs are intended to treat diseases that are so rare that companies are reluctant to spend their R&D resources to develop them under usual marketing conditions, as they expect relatively low profit from sales or even financial loss. Some 30 million EU residents and 25 million Americans suffer from more than 6,000 rare diseases. Both the EU and US orphan drugs regulations aim to offer incentives for the pharmaceutical and biotechnological industry to develop and market these drugs.

The EU-US initiative, aimed at simplifying the application process in both jurisdictions, follows an agreement made in June 2007 between the Commission, EMEA and FDA to expand transatlantic regulatory cooperation on several issues to reduce unnecessary differences in regulations and associated costs for industry and consumers.

The European biotech industry welcomed the common application form for orphan drugs and awaits further transatlantic harmonisation in the field. Another 28 areas for simplification in the approval and marketing authorisation of medicines were presented to EU and US authorities by the industry during a transatlantic workshop on administrative simplification in medicines regulation on 28 November 2007.

From: www.euractiv.com

Published on : Thu, 6 Dec 2007