Transatlantic Cooperation in Pharmaceutical Regulation: Identifying Opportunities for Administrative Simplification

In Brussels on 28 November 2007, in the field of pharmaceutical regulation, the European Commission hosted the Transatlantic Administrative Simplification Workshop which was co-chaired by the European Commission and the United States (U.S.) Food and Drug Administration (FDA) and organised in collaboration with the European Medicines Agency (EMEA) and the Heads of the EU National Medicines Agencies (HMA).

This Workshop was held under the auspices of the Transatlantic Economic Council and is an important step towards "promoting administrative simplification in the application of regulation of medicinal products", as is foreseen in the "Framework for Advancing Transatlantic Economic Integration between the European Union and the United States of America" signed by President Bush, President Barroso and Chancellor Merkel in April 2007.

The overall project objectives are to identify opportunities for administrative simplification through transatlantic cooperation and the Workshop provided the transatlantic pharmaceutical regulatory partners a unique opportunity to hear the pharmaceutical and biotechnology industries proposals.

Proposals for administrative simplification include harmonisation of administrative practices and guidelines and should not necessitate changes to legislation. Proposals for administrative simplification should maintain or increase the current levels of public health protection in the EU and U.S. By freeing up resources, administrative simplification through transatlantic cooperation will allow the industry to focus more of its resources on developing and supplying high quality medicines to meet the needs of patients. Transatlantic regulatory partnership allows the sharing of regulatory expertise and best regulatory practice.

This Workshop builds on existing successes notably the EU / U.S. Confidentiality Arrangements on Medicinal Products and the International Conference on Harmonisation which have proven to deliver on bilateral and international collaboration and harmonisation. The European Commission, EMEA and FDA remain committed to both, and any work items that are agreed following the Workshop will be delivered through these successful structures and processes.

Industry presented a diverse range of excellent proposals for administrative simplification through transatlantic and international collaboration and harmonisation. The proposals were presented in four panels on: 1. quality and inspections, 2. pharmacovigilance, 3. scientific collaboration, 4. guidelines, format harmonisation and electronic submission.

The next steps in the process will be careful public health, legal, practical consideration of the proposals by the EU and U.S. regulators with a view to making public, in the context of the bilateral collaboration, joint prioritised roadmaps for administrative simplification by June 2008.

For more information see:
Concluding remarks by G. Lalis, Director, Directorate for Consumer Goods, Directorate-General for Enterprise and Industry
List of proposals
Commission / EMEA / FDA confidentiality arrangements implementation plan