U.S. Food and Drug Administration

European Commission

European Medicines Agency

Medicines Regulation: Transatlantic Administrative Simplification Action Plan

Implementation report - 2009

Introduction:

Under the auspices of the Transatlantic Economic Council, on 28 November 2007 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). The key objective was to identify opportunities for administrative simplification through transatlantic cooperation at the level of administrative practices and guidelines. The key guiding principles for the proposals were that:

- No change to legislation should be required, and,
- The simplifications should maintain or increase current levels of public health protection.

As a follow up of the workshop, the Medicines Regulation Transatlantic Administrative Simplification Action Plan, published in June 2008, was an agreed action plan between the European Commission DG Enterprise and Industry and the United States Food and Drug Administration. On the EU side the Action Plan involves collaboration with the European Medicines Agency and the national medicines agencies of the EEA Member States.

During the recent annual EU-EMEA/FDA bilateral meeting in September 2009, the parties updated on the progress with implementation of the administrative simplification projects as follows:

Project title	Status as of October 2009
Collaboration on inspections in the US and EU	The Commission/EMEA and the FDA have piloted joint inspections of companies manufacturing pharmaceuticals in the U.S. and in the EU. Two joint inspections of manufacturing sites in the EU were completed successfully in April and July 2009 respectively. An observed inspection was carried out in the US. The experience from these inspections has resulted in some agreed opportunities for improvement which will be developed as part of the ongoing collaborative activities.

Project title	Note
Collaboration on 3rd country inspections of active pharmaceutical ingredients	In November 2008, the Commission/EMEA and the FDA, in collaboration with TGA, Australia, published an 18 month pilot project for exchange of inspection schedules, results, and information on inspections of active pharmaceutical ingredient manufacturing sites in third countries. Information is exchanged on an ongoing basis. To-date 80 sites have been identified for joint collaboration, 4 inspection reports have been exchanged and 1 joint inspection performed in June 2009, thus facilitating better use of EU/FDA combined inspectional resources,
Dedicated facilities for high risk products	The Commission/EMEA and the FDA continue to share experience with a view towards determining the best international approach to the extent to which dedicated production facilities may be necessary for certain pharmaceuticals taking into account a risk based approach.
Biomarkers	The EMEA and the FDA have had continued success in their transatlantic work on biomarker development and joint qualification for various product development purposes. Both parties continue to work on this initiative with a view to further biomarker development and joint qualification. Three common EMEA-FDA procedures (biomarker qualification submissions) have been initiated.
Regulatory collaboration on the outputs of the Critical Path and Innovative Medicines Initiatives	EMEA and FDA have initiated exchanges on the outputs of the Critical Path and Innovative Medicines Initiatives relevant to medicines regulation and reported findings to the 2009 EC/EMEA/FDA Bilateral meeting.
Combating counterfeit medicines	In addition to the collaborative work with the WHO IMPACT initiative, the Commission and FDA exchange information on a regular basis. The European Commission has launched a legal proposal on falsified medicines and the FDA has published draft guidance on numerical identifiers and authentication methods on which the EU has been consulted.
Collaboration on product specific Risk Management	The EMEA and FDA continue to collaborate on risk management initiatives for specific new medicinal products.
Convergence of Risk Management formats	The EU and U.S. pharmaceutical industry have been invited to conduct a study to compare the EU and U.S. approaches to risk management formats (e.g. E2E, Volume 9a RMP Guidance, REMS, etc.) and to identify opportunities for convergence. FDA and EC/EMEA await the results of the industry study with a view to working together on risk management formats.
Increasing the uptake of parallel transatlantic scientific advice	Voluntary industry Parallel Scientific Advice for human medicines has been encouraged both for medicinal products covered by clusters (e.g. paediatrics, oncology, vaccines, pharmacogenomics, orphans) as well as for other therapeutic areas (e.g.,cardiovascular). Revised procedures reflecting this were published in October 2009.

Project title	Note
Exchange on Information on herbal medicines	EMEA's Committee on Herbal Medicinal Products provides finalised monographs on herbal medicinal products to FDA on a six- monthly basis.
Collaboration on biosimilar medicinal products / follow on biologicals	EMEA and FDA continue to compare their experience of biosimilar medicinal products / follow on biologicals. FDA experts attended an EMEA workshop on biosimilar monoclonal antibodies in February 2009.
Collaboration on development of medicinal products for children	The EMEA and FDA have intensified bilateral discussion on the development of specific medicinal products for children. There have been monthly teleconferences since September 2007. Information has been exchanged for more than 450 products, of which 172 products have been discussed (trial design, safety).
Convergence in paediatric submissions	In 2009 EC/EMEA will initiate a review of the Commission Paediatric Investigation Plan Guideline, based on experiences to date, with a view to identifying opportunities for transatlantic convergence of submission formats.
Advanced Therapy Medicinal Products	In 2008, a "cluster" on Advanced Therapy Medicinal Products was established under the EC/EMEA/FDA confidentiality arrangements. The cluster is striving for scientific excellence, harmonisation of terminology for new technologies and to make recommendations for transatlantic convergence in the administration of regulations for these medicinal products. In 2009, five teleconference calls will have been held. Agendas have included discussion of the legal framework for genes, cells, and tissues in both regions; scientific guidelines available and in preparation; and experience with specific applications.
Safety reporting from clinical trials	EU/FDA reconfirmed their commitment to pursue these topics through ICH. Guideline on development safety update report (E2F) shall be signed-off soon. Remaining three topics are being intensively discussed in E2B, M5 and M2 expert working groups.
Harmonisation of business rules for single case reports	
Maintenance and updating of the ICH Common Technical Document (CTD)	
Electronic-CTD	

EC contact:

Matus Ferech

Pharmaceuticals Unit F2,
DG Enterprise and Industry
European Commission

FDA contact:

Linda Tollefson

Director, Europe Office, OIP
U.S. Food and Drug Administration