European Medicines Agency | European Commission | US Food and Drug Administration

Medicines Regulation:

Transatlantic Administrative Simplification Action Plan

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.

During the workshop industry presented a diverse range of proposals for administrative simplification through transatlantic and international collaboration and harmonisation. The proposals were presented in four thematic panels (on 1. quality and inspections, 2. pharmacovigilance, 3. scientific collaboration, 4. guidelines, format harmonisation and electronic submission).

Deliverables

Relieving unnecessary burdens of administrative practices through a careful selection of simplification projects proposed at the workshop could allow more human and fiscal resources to be focused by the industry on greater innovation and efficiency in development of quality products and thereby to greater access to these products by patient populations on both sides of the Atlantic.

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Within the framework of the Workshop it was agreed that the next steps in the transatlantic administrative simplification process would be careful public health, legal and practical consideration of the proposals by the EU and U.S. regulators with a view to making public a joint action plan for administrative simplification. Actions should be carried out, either:

- through bilateral work (e.g. under the existing EU-US confidentiality arrangements for medicinal products), or,
- through multilateral work (e.g. through the International Conference on Harmonisation - ICH)

The Medicines Regulation Transatlantic Administrative Simplification Action Plan is 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.

The parties have agreed the following administrative simplification projects:

Project title	Note
Collaboration on inspections	The Commission/EMEA and the FDA will pilot joint inspections of companies manufacturing pharmaceuticals in the U.S. and in the EU and of companies manufacturing active pharmaceutical ingredients in third countries.
Collaboration on 3rd country inspection	The Commission/EMEA and the FDA will pilot the exchange of inspection schedules, results, and information on inspected manufacturing sites in order to attain more GMP inspection coverage collectively and to better identify manufacturing sites producing active pharmaceutical ingredients in third countries.
Dedicated facilities for high risk products	The Commission/EMEA and the FDA will step up collaboration to determine to what extent dedicated production facilities are necessary for certain pharmaceuticals taking into account a risk based approach. Subsequently, it is expected that a revised EU guideline will be published for public consultation in the first quarter of 2009. FDA is also in the process of clarifying this issue through proposing amendments to existing regulations and draft guidances that are in the process for issuance.
Biomarkers	The EMEA and the FDA have recently announced successes in their transatlantic work on biomarker development and joint validation for various product development purposes. Both parties will continue to work on this initiative with a view to further biomarker development and joint validation.
Regulatory collaboration on the outputs of the Critical Path and Innovative Medicines Initiatives	EMEA and FDA will exchange assessments of the outputs of the Critical Path and Innovative Medicines Initiatives relevant to medicines regulation and will report findings to the 2009 EC/EMEA/FDA Bilateral meeting.

Project title	Note
Combating counterfeit medicines	In addition to the collaborative work with the WHO IMPACT initiative, the Commission and FDA will exchange information on future requirements for track and trace and authentication systems. Commission/EMEA and FDA will exchange information on specific cases of counterfeits.
Collaboration on product specific Risk Management	Under the EC/EMEA/FDA confidentiality arrangements, the EMEA and FDA will intensify bilateral discussion on proposed specific risk management initiatives for specific new medicinal products and report to the 2009 EC/EMEA/FDA Bilateral meeting.
Convergence of Risk Management formats	The EU and U.S. pharmaceutical industry are 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.
Increasing the uptake of parallel transatlantic scientific advice	Voluntary industry Parallel Scientific Advice for human medicines to be opened to all medicinal products covered by clusters (e.g. paediatrics, oncology, vaccines, pharmacogenomics, orphans). Review of industry uptake and recommendations on procedures by end 2009.
Exchange on Information on herbal medicines	EMEA Committee on Herbal Medicinal Products to provide draft and final monographs to FDA.
Collaboration on biosimilar medicinal products / follow on biologicals	EMEA and FDA will compare their experience of biosimilar medicinal products / follow on biologicals and will report to the EC/EMEA/FDA Bilateral meeting by end 2009.
Collaboration on development of medicinal products for children	Under the EC/EMEA/FDA confidentiality arrangements, the EMEA and FDA will intensify bilateral discussion on the development of specific medicinal products for children and will report to the 2009 EC/EMEA/FDA Bilateral meeting.
Convergence in paediatric submissions	In 2009 EC/EMEA will conduct 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	Under the EC/EMEA/FDA confidentiality arrangements, by end 2008, establish a "cluster" on Advanced Therapy Medicinal Products. The cluster to strive 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.
Safety reporting from clinical trials	EU/FDA reconfirm their commitment to pursue these topics through ICH.
Harmonisation of business rules for single case reports	
Maintenance and updating of the ICH Common Technical Document (CTD)	
Electronic-CTD	

17 June 2008