Pharmaceutical Regulatory Affairs 2012: A convergence of regulatory policies at FDA and EMA - Aris Global Software Private Limited, India

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Abstract

I n December 2010 the EU parliament passed the XEVMPD [Article 57 (2)] regulation mandatingelectronicsubmissions to the EMA's medicinal products dictionary. With the passing of this regulation, the EuropeanMedicines Agency also made public its plan to adopt ISO IDMP standards in support of ICH M5 initiative by 2015-16. The USFDA followed suit in August 2011 with the'Advancing Regulatory Science Strategic Plan'. The FDA indicated that it will also mandate similar standards by 2015. Most important global pharmaceutical regulatory authorities including PMDA, Japan are expected to follow in ICH's footsteps. This is setting in motion a global convergence on ISO IDMP standards. The first authority to get there willbe the EMA. The impact of this convergence will be comprehensive and long term, demanding a change in the conventional outlook to regulatory affairs. Pharmaceutical companies will now have to become more proactive by driving compliance and supporting strategic decision making.From a strategic perspective, it will be important for all pharmaceutical, biotechnology and/or medical devices companies to know the plans and ways of functioning of their regulatory agencies in order to remain ahead of the curve in preparing for upcoming regulatory mandates. Functionally, this increases workloads on all major compliance functions need dynamic resource-activity-roadmap planning. In this session, we will discuss some of the strategies for pharmaceutical companies to prepare themselves for this regulatory convergence well in advance. The term "regulatory harmonization" can have different definitions depending on the context of its usage. One definition that is applicable to those efforts CBER is involved with is: the process by which technical guidelines are developed to be uniform across participating authorities. "Regulatory convergence," on the other hand, represents a process whereby the regulatory requirements across countries or regions become more similar or "aligned" over time as a result of the gradual adoption of internationally recognized technical guidance documents, standards and scientific principles, common or similar practices and procedures, or adoption of regulatory mechanisms that might be specific to a local legal context but that align with shared principles to achieve a common public health goal. It does not necessarily represent the harmonization of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation. The Agency engages in a range of explicit harmonization initiatives as well as convergence activities, a number of which include the participation of CBER.