

Regulatory harmonization - Updates from the field

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The challenge of registering pharmaceuticals must be faced in every market and is a barrier that hampers efforts to efficiently distribute medicines where needed. Many countries don't have well functioning medicines regulatory agencies and thus the process is even more difficult. And some don't have an adequate legal or regulatory framework at all.

To solve this problem there are now eight regional harmonization initiatives. Major elements of each and a more detailed look at the African Union's approach will be explored. The 55th Decision of the AU in 2005 and subsequent endorsement of the Pharmaceutical Manufacturing Plan for Africa (PMPA) in 2007 by African union Ministers of Health provides a framework for improving medicines access to the African population. Other AU decisions emphasize the need to accelerate and strengthen regional medicines regulatory harmonization initiatives and lay foundations for a single African regulatory agency.

A model law is under consideration at this moment in Africa that aims to address legislative gaps that hamper effective medicines regulation and regional harmonization thereby supporting the African Union goal of promoting local production of pharmaceuticals to protect public health and contribute to economic growth. If adopted can companies expect to have a clearer and more efficient path to marketing authorization? If adopted can local production thrive and patients get access to the medicines they need? Prof. Forzley will explore these questions, present her conclusions and industry recommendations.

Biography

Michele Forzley holds a JD from New England School of Law and an MPH from Johns Hopkins. Currently she is a senior scholar at the O'Neill Institute on National and Global Health Law at Georgetown Law School and is a practicing global health lawyer. As such she consults to the WB, WHO, PEPFAR/SCMS, SIAPS, HPP and other organizations engaged in health and pharmaceutical sector reform, governance, legislation, policy and planning, and institutional development. She has authored numerous publications including her most recent work in the SEARO Journal of Public Health titled Legislation an essential tool to ensure meeting medicines policy goals, to be published shortly.

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