

Absence of Good Practices a Flaw in Global Drug Harmonization Activities

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The current lack of good harmonization practice guidelines may be standing in the way of efforts around the globe to harmonize and converge drug regulations between different countries and regions.

Numerous inter-regional, regional and sub-regional regulatory harmonization and convergence initiatives continue to be very active around the world, but none of them is harmonized with each other, said Lembit Rägo, the World Health Organization's head of regulation of medicines and other health technologies, essential medicines and health products.

Initiatives including the International Conference on Harmonisation, the Pan American Network for Drug Regulatory Harmonization, the African Vaccine Regulatory Forum and the International Generic Drug Regulators Pilot, for example, comprise different organizational setups, with not all of them having a strong secretariat. These and other harmonization initiatives such as the Association of Southeast Asian Nations, the Gulf Cooperation Council and the Southern African Development Community involve industries and other parties to different

degrees. Some of them are very much focused on implementation, while others are more focused on convergence and regulatory thinking. "Harmonization is absolutely not harmonized," Dr. Rägo said at the 26th annual DIA EuroMeeting in Vienna, Austria, on 25 March.

The development of good harmonization practices, Dr. Rägo believes, could help those involved in the various initiatives achieve global harmonization and convergence more efficiently.

"There are lot of lessons to be learnt [on] what makes harmonization and convergence initiatives work and also... on what [causes] them not to work," Dr. Rägo told *Scrip Regulatory Affairs*.

Calling for the development of a common set of good harmonization practice guidelines, the WHO officer identified a number of key elements for facilitating the success of a harmonization or convergence initiative. For instance, the initiative should have an "enabling environment" and a solid foundation through the implementation of good governance principles and a centralized mandate and/or participants' commitment,

Dr. Rāgo said. It should have effective governance and a secretariat.

The socioeconomic development of the participating countries should also be more or less the same. Participants should be functional regulatory authorities with the necessary capacity and resources available. There should be a "political will and shared common vision" and a willingness to invest in harmonization and convergence "because nothing comes without investment," Dr. Rāgo said.

As for other elements for success, there must be willingness to co-operate and

compromise, Dr. Rāgo believes. In addition, there should be commitment with regard to implementing harmonization outcomes and making updates and revisions, "otherwise it is all useless", he said. Also, there should also be a commitment to apply good regulatory practice during implementation.

Regulatory harmonization and convergence both aim to diminish duplicative efforts, create a "common language" for decision making and facilitate co-operation, work sharing and, most importantly, access to medicines, Dr. Rāgo said. In both cases, the main objective should be "measurable public health gains," the WHO officer concluded.