Executive Summary
Workshop: Global Registration and Vaccine Shortage
6-10 March 2017

The objective of the workshop was to discuss the potential reasons behind vaccine shortages with particular emphasis on the impact that challenges and delays in registration could have in vaccine availability and supply.

The workshop reviewed the pathways for registration of vaccines in different countries, including the legal frameworks, legislation and regulatory bodies in United States, European Union and Japan.

It looked specifically at the Common Technical Document which represents the harmonized dossier format proposed by ICH countries. This dossier format is slowly being adopted by more and more countries at global level. While modules 2 to 5 are grossly harmonized , module 1 which is dedicated to administrative and legal information, remains mostly dis-harmonized.

A comparison of CTD module 1 from different countries with similarities and differences was presented during the workshop. A broader comparison has been done including PAHO, India, Jordan, Thailand, EU, US and Australia. The audience was extremely interested in the role that manufacturers could play in bringing to the attention of regulators the magnitude of the differences in requirements in aspects that are really irrelevant but that represent time, resources and effort by manufacturers to comply with them in different countries.

The participants considered that the comparative work initiated was worth being supported and completed through the organization of a working group of manufacturers that would meet for a few days to put together a document that would evidence the level of divergence between country requirements, even among those that are “in principle” considered as harmonized or aligned.

It was thus proposed to convene a small working group of manufacturers from companies with prequalified vaccines or with extensive experience in global registration who would help finalize the job of making a comparison between CTD modules of different countries, as well as the proposed WHO/PQ supplement to a CTD dossier submitted for PQ evaluation of vaccines. It was in principle agreed that this WG could meet in Geneva in May 2017. Based on the outcome of such work, manufacturers would propose a common list of essential documents to WHO, partners and regulatory networks.

This suggestion is put forward for consideration by the Executive Board of DCVMN.

March 18, 2017