

Workshop: Fostering Regulatory Convergence Dialogue in Asia 25th & 26th March 2019, Singapore

Objectives

- 1) The objective of the first part of the meeting is for DCVMN and CoRE to share and understand about the scope of work of each organization and determine if there is any potential for collaboration.
- 2) The objective of the second part of the meeting (day 2) is to work with the regulatory experts working group focusing on challenges faced for the review and approval of variations in vaccine importing countries. For members only.

Expected outcomes

- 1) To determine if there is scope for collaboration between CoRE and DCVMN, and if so, explore potential areas for partnership
- 2) A consensus on the contents of a draft paper, describing the challenges faced for the review and approval of variations is reached.

DAY 1, Monday 25 March -		
Time	Topic	Speaker
8:30-9:00	Welcome and introductions	DCVMN/CoRE
9:00-10:00	Updates: alignment of registration procedures and open proposals	Dr. N. Dellepiane Independent Consultant
10:00-11:00	CoRE: history, scope, structure and activities to date and regional initiatives for regulatory dialogue: Examples in ASEAN and APEC	Dr. John Lim Executive Director, CoRE
11:00-11:30	Coffee Break	
11:30-12:00	Future needs in regulatory dialogue: regional & global approaches for emergency vaccines	Mr. Svein R. Andersen, CEPI
12:00-12:30	Q&A	All Participants
12:30-13:30	Lunch	
13:30-14:30	Groups discussions on global vs regional needs for vaccines registration: APEC and ASEAN needs	All Participants
14:30-15:30	Feedback and priorities for advancement of regional dialogue	All Participants
15:30-16:00	Coffee Break	
16:00-17:00	How to work together and next steps	All participants
17:00	Adjourn	

DAY 2, Tuesday 26 March- Regulatory working group session – for members only		
Time	Topic	Speaker
9:00-10:30	Overview of variations management principles and issues <ul style="list-style-type: none"> • WHO guidelines on variations: pros and cons. • Variations management in vaccine importing countries: what works and what does not work 	Discussion moderated by N.Dellepiane
10:30-11:00	Coffee Break	
11:00-12:00	Overview of variations management principles and issues (continued) <ul style="list-style-type: none"> • Variations management in the context of the WHO vaccines CRP: What works and what does not work 	Discussion moderated by N.Dellepiane
12:00-13:00	Lunch	
13:00-15:00	Concept paper on issues with variations management: Small groups discussion	Three working groups as to topics (tbd)
15:00-15:30	Coffee Break	
15:30-16:30	Concept paper on issues with variations management: Small groups discussion (continued)	Three working groups as to topics (tbd)
16:30-17:30	Presentation by each of the working groups General discussion and Conclusions	20 minutes presentation by each group All