Notes from Regulatory Experts Working Group
30th July 2019
Participants: Sebastian Comellas, Samir Desai, Shubhangi Ghadge Mic Mc Goldrick Venkataraman Hariharan, Ida Nurnaeni, Sonia Pagliusi, Sonia Villaseñor and Nora Dellepiane

Agenda

Time	Topic	Speaker
12:15-12:30	Introduction	DCVMN
12:30-12:40 (CET)	Briefing on WHO meeting on WLA held on 2nd July 2020	S. Desai
12:40-13:00 (CET)	Activities of the IFPMA Regulatory Network in Africa	M. McGoldrick
13:00-13:15 (CET)	Priorities: CRP follow up, alignment	N. Dellepiane
13:15-13:45	Discussion and next steps	All WG members

Summary of meeting discussions

- Samir Desai gave a briefing about the meeting held by WHO on 2nd July regarding the policy document on WHO listed authorities. The statement and comments from DCVMN were well received and will be taken into account in the new revision.
- Mic gave a brief presentation on the objectives and activities of the IFPMA African Regulatory Network. Current objectives include to strengthen reach of IFPMA in Africa, build trust among key stakeholders, support increased capacity for policy and advocacy and serve as one voice for industry to advance policy priorities. Main activities include engaging with the African Union and NEPAD in establishing the African Medicines Agency, sharing best practices and harmonization efforts, establish a relation of trust with RECs and AMRH and provide other technical input.
- Nora gave a presentation to update the group on the current progress on objectives and facilitated a discussion on future priorities and focus of the efforts by DCVMs in harmonization of requirements and facilitation of registration, PACs and emergency use of vaccines.
- Shubhangi and Venkat reported that two products (one from SIIPL and one from Bharat) had been registered following the CRP in Malaysia and Nigeria respectively. This represents a progress and encourages the group to move forward with CRP.

Next steps

- Samir will circulate the presentations from the WHO meeting to all members in the group
- Although there was not much scope with ICH in moving towards the harmonization of module 1, Mic thinks that the current COVID 19 pandemic provides a new opportunity to approach ICH with a proposal. He will follow up the matter with colleagues at IFPMA
- The group agreed that CRP is a high priority objective and that additional efforts should be made to push its implementation. Critical aspects required include:

- Ability by DCVMs to prepare the dossier in ICH CTD and to submit using only such format to WHO-PQ. DCVMs may need support to learn how to prepare CTD (training planned in September)
- All manufacturers should align in using the ICH CTD format for PQ submissions ideally using the EU guideline for its preparation
- Manufacturers should discuss with own NRAs to foster acceptance of ICH CTD as an alternative to the national format required

- The group agreed with respect to PACs that the first step is to share the publication, once available, with regulators in own country and other countries as feasible and to use all possible opportunities to share the paper with stakeholders
- With regards to the harmonization of module 1, it was agreed that Mic would follow up the matter for feasibility of approaching ICH. Also, Diadié Maiga, AVAREF facilitator is interested and expressed the willingness (pending approval of the Executive Committee) to work with regulators in the development of a common format for module 1 to be used for the registration of COVID 19 vaccines. This last opportunity does not require any investment from DCMVN.

Samir Dosai
21/08/20