Regulatory Working Group online meeting
4th June 2020

Meeting participants:

DCVMN members: Monique Collaço de Moraes Stavale, Sebastian Comellas, Samir Desai, Shubhangi Ghadge, Venkataraman Hariharan, Roh Hyunsuk (Christopher), Srini Kosaraju, Aziz Al Mutairi, Ida Nurnaeni

IFPMA participants : Lorenz Scheppler, Norbert de Clercq, Paula Barbosa.

Secretariat: Maureen Dennehy, Nora Dellepiane and Sonia Pagliusi,

SESSION 1
Introduction by Sonia Pagliusi-

The objective of DCVMN is to work more with members through the working groups. In addition to the Regulatory working group which is the oldest, other working groups have been recently established (Supply Chain, Pharmacovigilance and 3Rs). Information on each of the working groups can be found on the DCVMN website under the knowledge section.

DCVMN works for members, with the members and through the members, which means to meet the members' needs, with the members in order to understand what the needs are and through the members because it is expected that they will take the leadership and ownership of the network.

Election of Chair and Co-Chair-

The working groups decide their priorities and activities and elect a Chair and a Co-chair to drive the working group forward. The roles and eligibility criteria for Chair and Co- Chair have been shared with the group members in advance, there were no objections to the terms.
Two members volunteered for the role of Chair and Co- Chair, Samir Desai and Ida Nurnaeni. Members proceeded to elect the Chair. 5 participants voted for Samir, 3 voted for Ida and 1 member did not vote. Samir was designated Chair and Ida Co-Chair. Their roles are interchangeable depending on availability and they are expected to work closely together.
Sonia emphasized that the role of the Chair is to give everyone the opportunity to speak and to be listened to.

It is expected that the working group will have 4 meetings per year, be it face to face or online.

Invitation from WHO to attend the WLA policy paper meeting to be held on 2nd July 2020 online.

DCVMN is invited to have one representative at the meeting and a maximum of two observers. Any statement from the Network is to be channelled through the official representative. Hence, there needs to be communication between the DCVMN participants during the meeting to ensure that the official participant adequately communicates any inputs from the observers.

It was decided that the RWG Chair or the Co-Chair (when the Chair is not available), would be the natural representatives at all Regulatory meetings. In addition, one other member of the RWG would be invited to join and the other observer seat would be reserved to other DCVMN companies not represented in the RWG.

The DCVMN participant would provide a debriefing to other members within 24-48 h. Furthermore, the slides and main outcomes of the meeting would be circulated to all members, and DCVMN Secretariat will circulate the official meeting reports as they become available.

CRP implementation feedback

Srini, explained that BE has requested WHO to undergo the CRP for one product in a list of countries where the product needs to be registered. The list of countries includes some of the countries prioritized by DCVMN but is broader. They are awaiting feedback from WHO regarding willingness of countries to use the process.

Venkatraman mentioned that Bharat has initiated the CRP for selected vaccines in several countries, In one country they identified a gap which is pending resolution. While they have submitted all the required dossier documentation through their national agent, and the respective filled appendix submitted to the country NRA and WHO; on WHO's follow up with the country NRA regarding receipt of CTD dossier, the Country NRA responded in negative.(per our understanding this follow up is done by WHO as part of CRP procedure). Bharat is in contact with the country NRA and trying to resolve the issue.

Shubhangi, informed the group that DRC has invited to submit product registration applications through CRP. This is not useful to SIIPL at the moment because they have already initiated the registration process. Philippines has also invited manufacturers to use the CRP. CRP process is ongoing for one SIIPL product in Malaysia.

There is some progress in CRP implementation, however, processes are ongoing with no actual registrations completed yet.

The DCVMN objective as discussed with donors was to achieve implementation in five countries. However, 1 product registered in the coming 12 months in 1 country would be considered a success.

Manufacturers are encouraged to apply for the use of CRP in the coming months.

SESSION 2. IFPMA participants joined the meeting at this point.

Nora Dellepiane opened the second session by introducing new members of RWG, i.e., Venkataraman Hariharan from Bharat Biotech International Ltd; Srinivas Kosaraju from Biological E, and R. Hyunsuk from LG Chem and welcoming back Monique Callaço from Biomanguinhos and Aziz Al Mutairi from Arabio.

Training needs

Nora presented briefly the results of the training needs' poll run during the recent e workshop on regulatory pathways.

Three of the proposed trainings endorsed by the training participants, were prioritized by the RWG:

1) Preparation and management of regulatory pre-submission meetings
2) ICHQ10 implementation
3) ICH Q12 linked to PACs WHO guidelines

Additional training needs identified by participants included:

1) New vaccines testing methods (role of the 3Rs working group, info already shared)
2) WHO Benchmarking tool (GBT) for NRAs

Courses 1 to 3 and the WHO GBT training were prioritized by the RWG. Additional prioritization may need to be done by member companies based on funding and other considerations.

Norbert mentioned that GBT is not yet finalized, and Nora replied that the GBT is an ongoing tool which is never final in itself and took the opportunity to remind the upcoming meeting on WHO Listed Authorities Policy Document to be organised by RSS in July.

IFPMA members asked whether they could provide speakers to support DCVMN training courses, they will consult and answer. GSK provides training to companies in the context of tech transfer but these courses do not focus on regulatory (info provided by Monique from Biomanguinhos).

Sonia explained that it is important to have effective trainings, to enable companies to move forward. The recent trainings on Barcodes and VVMs were considered effective because many companies implemented either of these technologies after the training was conducted.

Upcoming priorities and action steps for implementation of RWG proposals

The group is challenged with two important issues: fatigue, and actual implementation of its proposals by countries.

The objective of this part of the session was to re think the approach to meet the objectives. The objectives remain the same: facilitating the process for registration and post-approval changes management in countries and alignment of requirements in order to improve access to vaccines in user countries.
The main activities towards the achievement of the objectives are:

a) CRP implementation

Proposed performance indicator: Number of countries successfully adopting the CRP for vaccines registration
Expected outcome: At least one vaccine product is registered in one country in the next 12 months.

b) Alignment of requirements: Use of standard application form and model module 1.

There was significant discussion around this topic, however no consensus could be reached as to whether there is any likelihood of implementing these proposals. One option to be further explored could be either adoption in country of origin and/or adoption in some importing countries through direct work of local agents with the relevant NRAs. <u>No final decision made and the topic is open to further discussion/ thoughts.</u>

c) Adoption of EU CTD in countries

Proposed performance indicators:
• Number of countries of origin adopting or accepting as an alternative, submissions in EU CTD format
• Number of user countries adopting or accepting as an alternative, submissions in EU CTD format
Expected outcome: To be defined

Next steps

The highest priority is to get the PACs paper submitted for publication in the coming month or two.
A RWG teleconference with participation of the whole group and IFPMA representatives is planned for September.
A shorter teleconference with members of the RWG available and interested, to be performed in July in order to brainstorm and advance around the working group priority activities and future work plan.

Agreements with IFPMA members present at the meeting

IFPMA participants to consult with Sarah Adams from the African Regulatory Network whether some of the proposals can be moved forward through the Economic Blocks in Africa.

Approaching ICH for support in implementation? Lorenz informed that since ICH does not recommend a standard format for module 1 and application form, this may be a no go. This topic was insufficiently discussed.

Norbert proposed to have a separate communication with Nora to discuss other potential ideas, since he had to leave the meeting earlier.

Norbert will consult with IFPMA whether companies could offer speakers for certain DCVMN training courses.

Agenda of DCVMN Regulatory Working Group

No.	Workplan	July-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21	Jun-21
1	Quarterly routine meeting												
2	WLA policy meeting	2nd July											
3	PAC paper submission												
4	RWG TC on workplan												

Samir Desai