DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Regulatory Working Group Meeting

8th March 2024 - Zoom

Participants:

Rajinder Suri (RS), Vipul Doshi (VD), Sebastian Comellas (SC), Cleber Gomes (CG), Cong Wu (CW), Monique Cruz (MC), Subhodeep Chakraborty (SCh), Sunil Goel (SG), Pradip Das (PD) Tina Wang (TW), Vivek Bansal (VB), Lyne Le Palaire (LP)-Sanofi/IFPMA, Mic McGoldrick (MM)-IFPMA, Dr. Pieter Neels (PN), Prerna Kumar (PK), Sonia Villaseñor (SV)-**Meeting started 12:01 CET and ended at 12:59 CET**

RS welcomed the participants and invited them to focus on defining the objective of the meeting in Brussels. The main purpose is to advance on the Regulatory WG matters and the side agenda is NGS. The results from the JWG were so encouraging that things are on the right track. He encouraged them to continue on that track.
PN said that the objective of the part of the agenda for NGS meeting is for people to learn what NGS is all about. Regulators are more and more opening to this technology for new and also old vaccines to change the *In Vivo* testing by NGS. Already 3 companies are willing to give their presentation of their testing in the workshop.

VD as the Chair of the RWG welcomed the participants, and thanked RS and all the participants for their commitment to global health. He started a round of introductions.

SC updated the RWG on the attempts he has made to contact Ma. Luz Pombo from PAHO, to ask for a meeting to discuss PACs, but no response has been received. SC will try to discuss this topic in a higher level. But from his point of view, bringing PAHO to the table to discuss this topic will be very difficult.

SV asked if the IFPMA colleagues could suggest another contact point or another way to approach PAHO. MM mentioned it is very difficult to get in contact with PAHO. LP said she has been working with Maria Luz regarding reliance pilot and PACs. She asked for more context.
SC said that in the past 3-4 years the RWG has been working together with IFPMA to evaluate the PAC situation in different developing countries. The idea is to share this information with PAHO and try to define if we can work together to improve the situation and get some harmonization.

LP mentioned that at DIA Europe next week there's a specific session on LATAM, on regulatory aspects. She offered that maybe we could gather some other names of people from PAHO or WHO headquarters or from people who are attending this session or participating in the panel.

SCh then shared some slides summarizing the objectives set for the RWG at the JWG meeting in February and gave some context and summary of each of the points, to update those who were not able to attend. And made the following updates for each of the objectives:

1. To seek clarity from WHO Team on WHO variation guideline i.e. "Guidance on Variation to a Prequalified Vaccine, V.7 July 2015" & "TRS 993, Annex-4"- (End date:17.04.24.)- SCh updated that the Indian CDSCO has just published the standard "PAC in Biological products: Quality Safety and Efficacy Documents PAC/2024" adopting WHO TRS 993, 2015 Annex 4 for comments. SCh invited all RWG members to collaborate and give their comments.
2. EUL for newer vaccines meant for outbreaks or Pandemic situation e.g. Ebola, Dengue, Zika, Nipah etc. By evaluating the information already available at various platform like that of CEPI, GAVI & WHO. The proposal is to understand the gap in the current procedure and suggest effective regulatory pathways for outbreak or pandemic situation. Deadline for this is September, 2024 in order to be able to showcase the results in the AGM in October, 2024.

3. To propose Pharmacopeial Harmonization of Indian Pharmacopoeia in line with EP/BP for individual vaccine monograph. (End date: 31.12.24)- The proposal is to have a comparison of vaccine product monograph and propose changing for individual monograph harmonization. The Indian Pharmacopoeia Commission, now is a member of Pharmacopoeia Discussion Group, which is established by European pharmacopoeia, Japanese Pharmacopoeia and USP and WHO is the observer for this group. Deadline: 31.12.24
4. To propose activation of DCVRN (Developing Countries Vaccine Regulatory Network) on the similar line of WHO NCL Networking. - The proposal is to make a benefit risk analysis of such Network and present to WHO through DCVMN platform. Deadline: 31.12.24
5. The proposal is to support the CDMA WG on issuing a position paper/ systematic review on Adaptive Clinical Trial design. Deadline 17.09.24

VD suggested he and SCh will prepare the action plan from their side and SV will circulate it to the entire WG and then receive feedback on KPIs and RC and will start monitoring.

Regarding the NGS topics for the RWG workshop in Brussels, PN said the idea is to have 2 or 3 DCVMN members with experience in NGS to give a presentation of 15 minutes. PN will also invite Sanofi Pasteur, Pfizer, Janssen to send somebody. PN is also asking European, US people to give inputs and to come to a broader round table discussion on regulatory affairs with the regulators attending the meeting. Somebody from the Spanish NRA requested to attend as well. This would set a base to start discussions with NRAs in other countries of South East Asia and LATAM. SV asked PN to send an updated version of the agenda based on the confirmations received.

SCh mentioned that in Singapore Zydus made a technical presentation on NGS and it would be good to have a discussion on how NGS can become part of the early development of vaccines. Validation is also an important topic to discuss. VD added that the members can prepare their presentations based on what regulators will ask for: the development programs, technology transfer, consistency, sensitivity and then the validation. PN added that this needs to involve regulators and also CMC people in order to move forward with implementation. We will also have the participation of Johannes Blumel who is a member of the ICH Q5A WG and will show us how it has been implemented there.

MM brought the point of discussion the WHO guidelines on how to utilize multi-dose vials; for Lyo products, up to 10-dose vial is allowed without preservative, but for non-Lyo products it can only be 2 doses without preservative. And it seems they are not looking at a scientific justification for more than 2 doses for liquid products. This is causing problems in terms of the ability to make a cheaper vaccine and to cut down on cold chain. IFPMA is working with CEPI and will talk with BMGF to see about their interests in this and propose if DCVMN would be interested in joining them and create a small team to go forward. VD expressed that Zydus would be interested and we can gather information about the problems being faced, about stability assurance and to maintain sterile condition whether it is 2 or 10- doses.

VD proposed to have monthly meetings for RWG instead of bimonthly to achieve the goal for the action plan.

The group agreed to have monthly meetings, provided we have action items and sub-action items. VD thanked the participants and closed the meeting.

End of minutes

Notes taken by SV
8th March '24

Vipul Doshi
Chair of Regulatory Working Group –DCVMN'