DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Regulatory Working Group Meeting

16th May 2024 - Zoom

Participants:

Cleber Gomes (CG), Cong Wu (CW), Mic McGoldrick (MM), Pradip Das (PD), Subhodeep Chakraborty (SCh), Sunil Goel (SG), Pieter Neels (PN), Prerna Kumar (PK), **Meeting started 14:05 CET and ended at 15:00 CET**

SCh facilitated the meeting in absence of VD. PK conveyed the group a message from VD to the group: in which he apologizes for not being present, and inviting the group to modify our action plan right now to fit the global need, and each member should begin actively participating and bringing up new topics of interest. He emphasized that Mr. Suri had requested to redefine the objectives and talk about subjects that were more important to the group. Individual contributions will enable the group to complete the project on time and help us to make appropriate use of the DCVMN platform to learn and address unresolved issues.

SCh provided a review on the group's action plan,

1. The first point focused on harmonizing post-approval changes between the WHO TRS 993 and Version 7 guidelines for PQd vaccines. SCh had circulated the comparison analysis and is awaiting final comments from members before presenting the plan to WHO next month, having removed the Indian guideline from the comparison as suggested by RS.
2. Regarding the harmonization of pharmacopeia, RS had recommended not to focus on the Indian Pharmacopeia, but to make it more global, e.g. EP, BP, etc.
3. The Adaptive clinical trial design publication. SV had shared the basic outline of the paper created by the CDMA WG, for comments of the Reg WG. SCh proposed to create a group to provide inputs to the different sections, as we need to find literature before giving the inputs.

SCh invited the participants to suggest if there is any topic of interest as to redefine the objectives.

1. On harmonization of PAC guidelines, the group had an in-depth discussion on the differences between the WHO TRS 993 and Version 7 guidelines, and how to best present these findings to WHO; in principle what we would request is that these both two guidelines should be synced in terms of categorization, which is not the case. They agreed that the Version 7 guidelines should take precedence for pre-qualified vaccines, and that the team should avoid comparing to the Indian PAC guidelines to keep the focus global.

2. On pharmacopeia harmonization SG suggested that if we first correlate EP and BP definitely IP is going to match with it because now Indian pharmacopoeia is a member of pharmacopoeial development group within European pharmacopoeia. Also suggested to focus on the monographs of vaccines of greater interest. SCh is already working on rabies and MMR. SG offered his support to compare some other monographs (BCG and then polysaccharide conjugate vaccines: meningococcal, Hib, pneumo). PD will take DPT group of combination vaccines and pentavalent and hexavalent.

SG suggested that when comparing EP/BP they could parallelly compare WHO TRS 993. PD added that the format will be, on the left-hand side the list of the tests and in the right-hand side will be IP, BP, WHO TRS, and then circulate for comments of the members. PD will prepare and circulate the format. SG also expressed his concern on the variability of tests in Latin American Pharmacopeias. He requested some Latam member to take the comparison of the pharmacopeias of the region and then with EP and BP.

Initiative on formulations without preservatives. MM provided an update on IFPMA efforts to prepare a slides deck for BMGF and CEPI. The issue is that for lyophilized vaccines, the guidance from WHO allows up to 10 doses, but for ready to use vaccines without preservative, they only allow 2 doses. However, data from manufacturers show that up to 4 or 6 doses it is fine, that was demonstrated during COVID-19. They will work with WHO, CEPI, and others to advocate for increasing the number of doses allowed in multi-dose vials without preservatives. SG and others shared their experience of having got a waiver for one 5 dose vial vaccine by their local regulator and by WHO. MM said that having SII on board saying that this has already occurred, might reduce WHO hesitancy to update the guidelines. The group agreed this would be an important topic to further explore. MM will share the slides when they are finished and invited SG and others to add inputs and a slide with this example.

3. On the collaboration with CDMA WG to publish a paper on Adaptive Clinical Trial, PN suggested the group to first have a look at the two documents from EMA and FDA and make an extract and see whether they are in line to each other and then conclude for our document what we can use from these documents. SCh suggested companies to take support from their medical teams to validate some points. PN offered himself to come up with the two documents and spread it to the WG members and then find a rapporteur to write it.

4. SCh also reminded the group of the proposal that RS made during the last meeting regarding that somebody who is knowledgeable about the pathways should make a presentation to the group on which are the pathways which are available for EUL for vaccines like Zika, other diseases to focus could be Ebola, Dengue, NEPA, monkeypox. Dengue has become a first priority mainly for Latam countries. We need to find within DCVMN who is going to coordinate it. SG proposed to decide on which vaccines we will focus and then who are the proposed manufacturers involved in those vaccines; and key in person from those organizations, because they must know their strategies, how to go out for emergency use authorization. PD also suggested to approach CEPI for guidance.

5. On the DCVRN, SCh said we have not yet received any suggestion, and since the group had decided to focus on the low hanging fruits, and this is a high hanging one, we might not give priority. SG suggested then to focus on good reliance practices to save a lot of time. MM offered to share some data and presentations that IFPMA has put together in this regard.

As for the DCVRN, SG suggested to try to work per regions to facilitate the approval of dossier by other countries as it happens in EMA. PN clarified that still in EMA it is not automatic, dossiers need to undergo the process of recognition and it is not always so smooth. But it is a good idea that will be very helpful. And was a lengthy process; what took the most time was that every member state should go to the same level of evaluation strength.

MM reviewed the assessment comparison between the PAC guidance and the guidance for PQ changes, there are instances where they say that the TRS guidance does not have that change, but they're actually in there. Some changes that are relevant to the PQ changes, and some of the TRS have lower categories, but some of those are because of conditions, and if you don't meet those conditions, they would be the same as the PQ. PQ does not have conditions. There are type A does cover major and moderate. They took some of the moderates and moved them to major to a type A just because they wanted those things. MM said the comparison is a great effort but suggested the team to be very cautious on how to present the information, as to avoid turning the PQ guidance into the guidance for the TRS and having then to file up many more things.

End of minutes

Notes taken by SV based on the recording
16th May'24

Subhodeep Chakraborty
Facilitator of Regulatory Working Group –DCVMN for this meeting

Vipul Doshi
Chair of Regulatory Working Group-DCVMN