DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

Regulatory Working Group Meeting

15th April 2024 - Zoom

Participants:

Rajinder Suri (RS), Vipul Doshi (VD), Abdul Aziz (AA), Cleber Gomes (CG), Cong Wu (CW), Jeongha Kwon (JK), Monique Cruz (MC), Mic McGoldrick (MM), Subhodeep Chakraborty (SCh), Pradip Das (PD), Prerna Kumar (PK), Sonia Villaseñor (SV)-**Meeting started 14:01 CET and ended at 15:05 CET**

VD as the Chair of the RWG welcomed the participants, and reviewing the main points of the minutes of the previous meeting. He requested the team to finalize the action plan for the objectives set. He requested all the members of the team to contribute fairly as possible to meet the timelines.

SCh shared with the group the tracking document for the objectives set and went through each of them.

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 they have completed all the tasks in terms of comparing the two guidelines above and the Indian CDSCO standard "PAC in Biological products: Quality Safety and Efficacy Documents PAC/2024" and proposed to share the comparison and excel used for comparison with the team for their inputs. RS requested to clarify so that the deliverable clear on what should we ask to Carmen Rodriguez (WHO). RS suggested that the comparison table shall have three columns, one for TRS 993, and the second V.7 and in the third column, the gaps or problems found e.g. they do not use the same terminology. Don't keep to many slides. SCh shared some examples, 43 Type A variations of V7 were compared with major category of TRS 993, Annex 4. There are 53% differences in the categories of major change observed.
   RS requested to separate the presentations. If we are to talk to WHO, do not include the information about the Indian NRA. There might be problems with several NRA and brought directly to each NRA. MM suggested not to push to align to India because it will be misaligned with everybody else. It is ok to give an example, but this is beyond India.
   SCh identified the risks by performing the comparison.
   RS requested SCh to share the detailed comparison of the two WHO guidelines with the team for them to study and give their inputs. So the main point to be communicated with WHO is that there is a clear difference between V7 and 993 and therefore, that requires a change and clear guidance. The problem statement should be refined and defined in a very crystal-clear manner. And this should be highlighted there that the first problem and then that is associated and then the mitigation or the solution thereof.
   RS suggested SCh to share the information of the PAC 1.2 with Indian manufacturers only, and ask them to take action forward; but since it does not concern all manufacturers, there is no need to share with all.
   RS suggested to use color coding about the topics, e.g. the things that don't need change are in green, those that are problematic, in yellow; and those that need urgent action, in red. So that the message is clear to the regulator.

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. SCh proposed by adding some sub action plans or sub-items and requested the team to give inputs on further points. The action plan tracker has already been shared with the WG.
   Although there is already a pathway existing, in our joint working group different members suggested this pathway may be refined. RS said that somebody who is knowledgeable about the pathways should make a presentation to the group on which are the pathways which are available.

Identify the bottlenecks or challenges amongst the vaccines selected as priority. Suggest a pathway that should be discussed with the rest of the team to add value to that. So, the action plan should be

a. Identify knowledgeable person on the regulatory pathways of each of the vaccine that are priority (or all vaccines)
b. This person should make a table with the regulatory pathways, identify the challenges that either WHO or regulators in the countries are facing, or the manufacturers.
c. From that perspective suggest which could be the change and who will bring that change.

PD mentioned that the inputs from the IFPMA members that have already licensed some of these vaccines will be very valuable. RS also suggested to approach CEPI consultants and regulatory to give guidance or a presentation on that.

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.
   RS suggested to remove this objective and keep only those that are of the concern of all the members and not only Indian.
   VD indicated that global harmonization perspective can be considered for the objective and thereby proposed modification by removing Indian Pharmacopoeia and consider product specific monograph from all active Pharmacopoeias, so that all members are interested.
   RS also questioned that SCh should not be the RC for all the action plans. He requested the members to participate and take responsibility for some items actively, who can identify challenges and propose mitigation strategies.

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 SCh added one sub-action plan but requested the team to give their inputs.

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. The WG is waiting for the CDMA WG to start this action plan. RS suggested that there should be inter communication between the working group of CDMA to understand the progress of work.

RS questioned the members on why are not they giving inputs. All members are expected to give their inputs instead of just participating as spectators. If this continues as such, no results will be obtained. If other different topics are of higher relevance for the group, the objectives can be redefined. Each member of the group is requested shall come with a topic of interest.
VD also proposed that rather than waiting for monthly meetings, should the members feel the requirement they are free to approach for discussion related to action plan and small group meetings can also be planned.

End of minutes

Notes taken by SV
15th April '24

Approved

Vipul Doshi
Chair of Regulatory Working Group –DCVMN'