

Attendees: Alexander Precioso (AP), Viska Indriani (VI), Katharina Hartmann (KH), Linda Nesbitt (LN), Paulo Takey (PT), Zhang Lei (ZL), Sonia Pagliusi (SP), Tana McCauley (TM) minutes.

AP started the meeting at 12:03. AP welcomed the participants inviting them to participate in each point of the agenda.

- 1. Approval of the Meeting Minutes of the 9th of September 2020.** AP asked the WG members for their comments on the minutes from the PV WG meeting on the 9th of September 2020. SP shared her comments on the minutes. She stated that the DCVMN WGs do not need a quorum and in item 3, there is a reference to the DCVMN COVID Committee, which should be changed to COVAX instead. The group approved the minutes. ACTION: upload on DCVMN webpage
- 2. Discussion and approval of the PV SOP Masterlist.** AP shared the PV SOP Masterlist and asked the WG members for comments on the document. All WG members agreed on the usefulness of the Masterlist. VI raised a question on the SOP on Point 14, «crisis management». VI asked what can be done to make PV work when there is a safety crisis. SP asked if the SOP «crisis management» includes situations where products already on the market have serious adverse events that would require a recall. KH replied that it depends on how companies define their crisis management; but PV has to be involved if a recall concerns a safety issue. SP suggested defining crisis in point 14. KH added that the ideal way to operate is to have specific crisis management SOPs for specific crises. PT asked if companies should set up a crisis group. KH answered that there should be a crisis management group that includes the head of PV. PT suggested this to be formalized as an item on the list. The group agreed that the proposed Masterlist is of overall benefit for all members and was approved by the group. ACTION: upload on DCVMN webpage.
- 3. COVAX Vaccine Safety Working Group (VS WG).** KH started by presenting the general COVAX structure. The COVAX PV WG is located within the Development & Manufacturing section of COVAX led by CEPI and industry. DCVMN will have two representatives in the COVAX VS WG, AP and PT. SP explained further details about DCVMN's representation in the COVAX facility. DCVMN has representatives in the COVAX Coordination Committee, in the Workstream Group and an independent consultant, outside of DCVMN, has been nominated for the SWAT Team. KH added that the COVAX VS WG would start soon. In October 2020 clarification on the objectives of this COVAX VS WG (e.g., act as an open source of information for vaccine developers and bringing together different stakeholders and coordinate with other players in the vaccine safety ecosystem) was reached. KH accepted to take the role of a co-lead of the VS WG. A kick-off meeting will take place within a few weeks. To define the deliverables that focus on DCVMN's needs, the Questionnaire responses, as well as DCVMN PV WG's input, will be essential.
- 4. Activities of COVAX and interlinkages with DCVMN/DCVMN PV WG.** AP explained his recent communications with Bob Chen, CEPI, BMGF, IFPMA to see the possibility of working together; however, no decision has been made. KH suggested that IFPMA and the DCVMN PV WG could collaborate under the COVAX facility. As there was a query from the PV WG to contact IFPMA, SP contacted IFPMA, and after some consideration, they expressed interest in joining the PV WG's meetings informally. SP noted that this would not be a formal collaboration, but that IFPMA could join the DCVMN PV WG's meetings informally. AP and KH both agreed on the complexity of the COVAX environment, and AP noted the need for clear and efficient communication between all stakeholders.

5. **Discussion of the Questionnaire results and priority setting of different needs.** SP explained to the group that five responses to the questionnaire had been received so far. SP asked if the reminders should be sent to the other COVAX vaccine developers. KH explained that it would be important to understand the needs of the COVAX COVID vaccine developers. However, the WG agreed that it would be best to distribute the questionnaire to the DCVMN COVID Committee first. KH emphasized that the questionnaire should be sent out to the relevant members working in safety in the COVID Committee. SP answered that most members of the Committee are involved in R&D and clinical trials and can answer the questionnaire. SP suggested the time-frame for receiving answers should be one or two weeks. The group agreed the results could be presented at the COVAX VS WG kick-off meeting and at DCVMN's Donor Advisory meeting.

6. **Action Plan/Way of Working.** AP commented on the need for effective communication among the WG and with other stakeholders. AP proposed a call to discuss future communications and come up with a communications proposal. ACTION: schedule a call with AP, LN, KH and SP to discuss future communications and interactions, after the COVAX VS WG kick-off meeting.

AP closed the meeting at 13:27 by thanking all participants.

