dcvmn
Developing Countries Vaccine Manufacturers Network

DCVMN COVID-19 Committee
Meeting Minutes
October 8th, 2020

Attendees: Adriansjah Azhari (AA), Anand Kumar (AK) Apoorv Kumar (AP), Dat Do (DD), Do Thien (DT), Ladda Suwitruengrit (LS), Lingjiang Yang (LY), Marcos Freire (MF), Martin Reers (MR), Rachel Park (RP) Raches Ella (RE), Ricardo Palacios Gomez (RPG), Sai Prasad (SDP), Samir Desai (SD), She Guangbiao (ShG), Sunil Gairola (SG), Valeria Brizzio (VB), Yuri Vasilev (YV), and Sonia Villasenor (SV).

TC started at 12.05 CET and finished at 12.47 CET

- RE started the meeting at 12:05
- SDP updated on ACT accelerator group. The group has been more focused on the vaccines pillar as it gets more funding focus. In last few weeks the UN General Assembly (UNGA) has had large discussions about increasing profile of the WHO ACT-Accelerator and to get additional funding.
  Another important issue ongoing emergency use of Covid vaccines, WHO has put out preliminary guidelines on this topic. Available on WHO website, he encourages everybody to review it. They are open to receive comments on how this process would work.
  A third issue which has been under discussion by WHO are the solidarity trials. WHO is asking developers and manufacturers to be part of it, it is a good opportunity to participate. It is an open call available on WHO site for companies interested in participating.
- For Covax facility, one of the arms of ACT -Accelerator, the financing objective has not been reached; there is a gap of approx. 14 billion USD, some countries have agreed to donate to Covax; UK, Canada, Germany and Sweden, all together reach approx. 1 billion USD, but there is still more funding required for Covax, mainly for LIC and MIC. There have also been discussions on Covax's operation line. There has been communication on Gavi Secretariat on it in Gavi's website. SDP Encourages all developers to review how Gavi and Covax facility will engage with self-financing countries and countries needing donations of vaccines as well as manufacturers.
- Gates Foundation has worked with manufacturers of vaccines, diagnostics and therapeutics from US and Europe, and constituted a CEO round table asking them to pledge that they will supply the developed products at minimal profit. Circulated to all members of the Act-Accelerator. SDP sent them feedback to also consider some DCVMN manufacturers and developers. Now they are talking to DCVMN secretariat, they will schedule a call with CEO's of DCVMN companies to be part of this discussion, he encouraged CEO's of these companies to participate. There might not be yet discussions on profit amount or capping the price but at least ensure it is always highly affordable.
- RE asked if there has been discussion on pricing approaches. SDP said yes, and it is all posted on Gavi secretariat's website. There is no guidance as to how companies should do or how much the prices should be. But Gavi is giving a modeling based on costs, companies can charge what they consider appropriate for their product.
- SG asked on how WHO is considering concentration for evaluation. There is a document that says only vaccines phase 2/3 studies that have received an authorization from a reference NRA. So, until NRA gives EUA or any other authorization manufacturers cannot go to WHO, this statement must be taken off; WHO must support NRA to get EUL or EUA, rather than asking to approach WHO only after regulatory authorization. SDP said WHO presented this last week and he raised this issue and other issue: They mentioned that there needs to be a reference NRA, this means that unless a vaccine is manufactured in a referenced NRA country, you will not be able to apply for EUA. So, this is a potential concern for many countries that are not a referenced NRA. Regarding whether vaccines needs to be registered before going to WHO, it needs to be discussed, but he thinks WHO will not review EUA submissions if it is not licensed before for local use, as it happens for routine PQ procedure.
- AP gave an epidemiological update. The number of active cases has been increasing in Asia and Europe.
- AK asked if there is information on the number of deaths comparing first and second wave country wise as it seems that the number of deaths is lower than in the first wave. AP said he could get the number for the next update.
- YV gave an update on the P&M subcommittee which has been working on the goals table, to be finalized next week. Companies would be able to describe their vaccine available, and what are they seeking for, so to do the match making. The other goals are almost finalized.

- For the short week digest YV showed data for last week on vaccine safety, it will be discussed in the subcommittee next week and will come back to the Committee for feedback.
- RE gave an update on Clinical trials subcommittee, they have had discussions on what to update. There are many assumptions and protocols for clinical trials publicly available from FDA, Indian NRA, WHO, and they are still trying to formulate an approach.
- SG gave and update on QC subcommittee. There was a Covid-19 call meeting on 16 September. There was a presentation from Ivana on DCVS summary, Valentina from CEPI on central lab network, David from UK university on new traditional assess, Mark from NBISC on preparation of reference and William from CEPI on a summary of their group. David updated on SACS initiative, they have done a collaborative study with 14 labs involved, tested assay with live virus and the single virion. Their data is yet to be published but there is a 2-log difference between the LV and PV titles in ID 50 and 1- 80 difference between 80 titles across LV and PV. However, one thing in common is a higher variability in labs performing the infective dose 50 values as compared to ID 80 (so this one has a potential for greater accuracy). Mark has presented on collaborative study to develop antibody std and ref panel. 15 labs from 14 countries participated and it is in progress; the report to CVS will be given in DEC 2020 and by then hopefully the common reference material for use of different reagents may be harmonized. Ivana from CVS said the data will be available in dec 2020.
- AA said that even if there are efforts to harmonize reagents & reference, there are several platforms for production. What are views of these organizations with respect of the different platforms in regards to reagents & references? SG said the reagents being prepared are the reference antisera, so this will be useful for all the platforms.
- AA asked if there is any chance of DCVMN to be involved in collaboration. SG said the call was taken one month back; the collaboration is on. He sent an email to Mark asking for this. It looks unlikely since the distribution of reagents and documentation is done, but if there is any communication from Mark he will share with the group.
- MF said it is important to have a reference to compare the vaccine
- SG said the reference antisera will not be directed to any antigen, it should be a high titer full convalescence sera from recovered patients and will not represent any antigen per se.
- MF said it is needed to compare difference serums using a reference. SG said make in-house reference and calibrate it against the reference reagent, which is the normal course.
- RPG said the next clinical workshop by Covax will be on Oct 28, the focus will be on how to deal with switching placebo arm to vaccine whenever a vaccine gets efficacious. Also related the need to create additional end points considering the severity of the disease in the clinical trials. The information was sent to SP, SV, AA and RE to be disseminated among all DCVMN members. He encourages members to join.
- AP said there was recently a presentation by CEPI, GAVI, UNICEV and PAHO regarding liability, indemnity and compensation, although they were asked not to disclose the content of the meeting, he encourages members to take part in such calls. There will be a consultation GPEI and OPV & IPV manufacturers and NRA, Monday 12-13 October. SP has disseminated the link to join the consultation. He encourages all manufacturers to join.
- The next Covid Committee meeting to be scheduled further on.

-----End-----

Notes taken by SV

Raches Ella
Chair of DCVMN COVID-19 Committee
Nyon, October 8th, 2020