

Attendees: Adriansjah Azhari (AA), Apoorv Kumar (AP), Benoit Hayman (BH), Ladda Suwitruengrit (LS), Linsen Du (LD), Marcos Freire (MF), Martin Reers (MR), Raches Ella (RE), Ricardo Palacios (RPG), Sekar Thangaraj (ST) Sunil Gairola (SG), Valeria Brizzio (VB), Yuri Vasilev (YV), Zhang Yang (ZY), Sonia Pagliusi (SP), and Sonia Villasenor (SV).

TC started at 12.00 CET and finished at 12.52 CET

BH presented the results of the Manufacturing capability survey, an initiative of SDP, with the purpose of qualifying the present manufacturing capabilities of DCVMN members and their tentative capacities to scale-up production of Covid-19 vaccine candidates; it focused on 4 topics: 1. Technology platforms, 2. Cell-cultures, 3. Formulating capacity and 4. Filling Technologies. In total, 26 manufacturers completed the survey (63% response rate) and results were analyzed geographically as to WHO regions. The results were circulated to all members. The two key takeaways of the survey are that across the network there are broad capabilities for all different aspects of manufacturing and within these, the utilization of different technologies, which could benefit the Covid-19 vaccine production. The second is that there is a significant capacity of manufacturing for the eventual scale-up of Covid vaccines. The report will be submitted for publication.

AP presented the epidemiological updates. a total of 20 million cases have been accumulated since our last meeting as of November 26 with a high second wave in several regions; Europe and North America holding the highest disease burden now. South America shows a rise in active cases, and Asia shows a drop. Africa and Oceania have remained consistent. Several articles published elude the increase in transmission due to new strains of the virus.

SP suggested that, since vaccines have been started to be administered in several countries, in the next meetings it would be interesting to complement with updates in vaccination. There is a website that shows the number of vaccines being administered daily, which she shared later on: cf. <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>. AA also suggested to update the group on the variants. YV agreed to provide updates on the variants, and also shared a link, cf. <https://www.who.int/csr/don/31-december-2020-sars-cov2-variants/en/>. VB will take the part of implementation of vaccination. Regarding the Partnership update, YV said that the group met before the holidays, and will be meeting next week and will be able to update afterwards.

RE updated on the Clinical trials. The subgroup has not been very active lately since its members have been preoccupied with other activities, so he updated on other companies' clinical trials: Novavax clinical trials is in phase 3 in USA and Mexico. The UK phase 3 could be done in 1Q 2021. Sinovac completed Phase 3 Clinical trials in Turkey and Brazil, showing two different efficacy numbers, but he assumes that the numbers 50% and 90% are due to different definitions of primary efficacy end points. CanSino will soon share their efficacy results in Mexico. Bharat is working on a whole virion vaccine and expect to share their efficacy numbers within few months. CNBG Sinopharm reported vaccine efficacy 86% in the UAE and new press release stated it is 79%. In India, SII (working on the AZ vaccine) and Bharat have received the emergency use authorization for both respective vaccines, and will be rolled out within 2 to 3 weeks. AA said Bio Farma is also waiting for the outcome of its trials in the coming weeks. It is efficacy study of the vaccine from Sinovac.

Regarding the QC update, SG shared that Sino Biologicals has developed a recombinant antigen variant which could be useful to evaluate the efficacy of the new variants. It is a binding antibody for ELISA; they say they have taken care of the B.1.1 C lineage and they are addressing the N-501 because it has lot of binding efficacy for phase 2; in addition to that, it has more binding sites than B.1.1.7, which was previously reported, so they are including all the current mutants and have generated a battery of recombinant antigens.

Regarding the CEPI SWAT Team, AA, as member of the Manufacturing team, said that there are plans for a Tech Transfer Workshop on 27th January. RPG added that the Clinical Swap Team was satisfied with the Workshops organized last December on submission and maternal immunization. This strategy is working to disseminate knowledge. There are two issues being considered for future workshops, and if there are any suggestions, he will take

them to the Team. One is the variants and its' implications in terms of regulatory requirements, e.g. any kind of testing of serological samples. The other is how to conduct clinical trials after the vaccination mass campaigns have started in several countries, because it can jeopardize the conventional design of placebo, and also the issue of correlates of protection found in earlier trials, which became more important for the support and development of new vaccines in the 2nd and 3rd wave of manufacturers reaching phase 3. He also mentioned that WHO in cooperation with NIBSC in UK have developed a standard for antibody testing, and all manufacturers are invited to request the standard to be used in the labs that are testing the clinical samples. Comparability of results within vaccines might make easier for the 2nd or 3rd wave of manufacturers doing clinical trials in large scale.

AA requested more in depth of overview of maternal immunization. RPG said that the US advisory group allowed pregnant women, mainly health workers, who are at a higher risk of being infected by Covid, to receive vaccination. Some manufacturers are planning specific trials in this regard. They will also start looking at the post -marketing surveillance to get more information in terms of immunization of pregnant women.

SP said yesterday there was an extraordinary SAGE meeting with the recommendations for the Pfizer BioNTech vaccine and said that pregnant women should not be vaccinated for the moment. The meeting was only focusing on Pfizer's vaccine because this vaccine received the WHO EUL. (cf. https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1). As more vaccines will go through the WHO EUL, SAGE will also provide more product specific recommendations. Pfizer BioNtech said they will conduct some studies and will come back with data. RPG clarified that the recommendation he mentioned was only in the US because the FDA was no so restrictive. Since US recommendations are followed by other several countries, it is a topic for which we need to be aware of. AA asked SP if the not-recommendation of pregnant women immunization of Pfizer's vaccine could also apply for other vaccines on the same platform. SP said yesterday's meeting was only for Pfizer vaccines and did not discuss platforms in general.

SG said that what he understood is that all the precautions, follow-up and the safety aspects will be seen as per the clinical trials protocols, which are approved for phase 3 clinical trials. These are the things that have to be meticulously observed and followed-up upon.

Next meeting 28th January.

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Notes taken by SV, edited by SP



Adriansjah Azhari
Chair of DCVMN COVID-19 Committee
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