DCVMN COVID-19 Committee
Meeting Minutes
January 28th, 2021

Attendees: Adriansjah Azhari (AA), Apoorv Kumar (AP), Ladda Suwitruengrit (LS), Lingjiang Yang (LY), Linsen Du (LD), Marcos Freire (MF), Raches Ella (RE), Ricardo Palacios (RPG), Sekar Thangaraj (ST) Sunil Gairola (SG), Valeria Brizzio (VB), Yuri Vasilev (YV), Sonia Pagliusi (SP), and Sonia Villasenor (SV).
TC started at 12.05 CET and finished at 13.09 CET

AP gave the epidemiological update. Since our last meeting there has been an increase of million cases: North America with the highest number, followed by Europe and Asia. It is also concerning that an increase in the African region of cases and deaths was observed. Asia has remained relatively consistently low in the number of cases. Country specific profile showed a sudden increase of case in Thailand, despite very low number of cases for several months.

YV presented a timeline of the identification of SARS-Cov-2 variants: The variants of greatest concern are the ones from December 2020: VOC 202012/01 (UK) and 501Y.V2 (South Africa) and the one from January 2021- B.1.1.28 (Brazil/Japan) named P1. The UK variant has a variation del69-70 called SGTF. All of them have N501Y and D614G and the Brazil/Japan has an E484K mutation responsible for escaping from neutralizing Ab of previously infected and some of the vaccines currently developed. There are some pre-prints circulating and very little published data. Pfizer indicated that their vaccine does neutralize the variants. YV also mentioned an WHO extraordinary conference on variants on January 12th and another one on 28th January. He will share the minutes when available. Two main messages are: 1. All manufacturers are urged to check on immunogenicity and effectiveness of their vaccines against the published variants. 2. WHO anticipated the potential need to modify the strains in the vaccine perhaps seasonally. SP commented, regarding UK variant, it was said initially that it increased transmissibility but recently it was announced that this variant increases morbidity and mortality as well. AA mentioned concerns on the effectiveness of the already deployed vaccines against the mutations/variants. AP mentioned that Bharat has recently generated data of neutralizing Ab being developed against the UK variant after administration; they are in the process of publishing it. SP said that apparently some companies (e.g. Pfizer, Moderna, Astra-Zeneca) are already developing vaccines against the new variants. MF said that if it is confirmed that the variants escape from the vaccine, it is a problem for the ones with inactivated platform. For RNA platform it easier to have a new strain. For adenovirus platform it is more complex and time consuming to develop new cell bank. YV said that in the WHO meeting, Moderna stated that they are developing a second dose with a different variant.

He presented and suggested the following links on the SARS-CoV-2 variants:

- WHO DONs: www.who.int/csr/don/en/
- WHO COVID-19 weekly epidemiological update: www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports/
- CDC MMWR: www.cdc.gov/mmwr/index.html

VB gave an update on vaccination, the total administered doses since December 2020 up to Jan 26th are 71.3 M doses. In 57 countries; on average 3.57M doses per day so far. The countries with most doses given are US, China, UK and Israel. Israel is the country with most doses administered, 47.9 doses/100 persons. VB also mentioned the logistic complexity of administering the vaccines. She showed a table of the vaccines that have received Emergency use authorization (also called conditional approval in some jurisdictions), limited use or full approval in different countries.

SP said that given that Israel is only administering one type of vaccine and already has covered 50% of their population, will have data to study the impact of vaccination, at least for the Pfizer vaccine. Regarding the logistics for the vaccines, SP observed that Pfizer and Gamaleya are both to be kept at -70°C or -20°C, thus more challenging for supply chain. MF said that the Pfizer vaccine is not very stable and they should work on improving it. AA mentioned that the vaccines being deployed in many country result from B2B arrangements, and there is no supply from Covax so far.
VB said the Gamaleya vaccine has been approved in Argentina, 300 K doses have already been given. VB added that other vaccines were also given limited or emergency use e.g. Bharat, Vector Institute and Sinopharm. VB showed the vaccine contracts per company including those not yet approved. SP said that Sanofi Pasteur announced yesterday that have an agreement to fill the Pfizer vaccine. VB then showed the vaccine development tracker; 66 vaccines in

early phase1/2, 20 in phase 3, 8 in Limited use, 2 approved (Pfizer and Sinopharm) and 3 abandoned (CSL and 2 from Merck).

AA asked the difference between Limited use and approved for full use. SP said limited use is when the vaccine is not approved even for Emergency Use, it is experimental use, before any approval or any NRA scientific opinion. Emergency approval is not full approval but the NRA gives authorization to use the vaccine for large scale, after reviewing phase 3 trails, it is no longer experimental. The companies still have the commitment to show data on safety and efficacy at large scale. LY said that Sinopharm got the approval with provision, which is similar to "conditional approval" or EUA. SP suggested next time to touch on vaccination policy in each country.

YV proposed sending SP the matchmaking table advances. SP said DCVMN has to be cautious to suggest "matching" between companies, it may be wise to review by the legal advisor. We need to be careful, because it is not the role of the association to make merges, acquisitions, or joint-ventures; SP suggested YV to keep it for next time and wait for YV explanation and avoid misinterpretation.

RE said to anticipate the J&J vaccine to provide phase 3 efficacy data soon: they had 60k participants across various countries; it is single dose vaccine. There have been some reports form Sinovac vaccine from the Brazil and Turkey data of their clinical trials also across various populations. They have reached their estimate above 50% in Brazil and about 75 % in Turkey. A big issue is the efficacy-based placebo-controlled trials: there is an ethical argument about giving a placebo to a participant when vaccine efficacy is high. As more manufacturers enter late clinical trials, anticipating correlates of protection based on the vaccine manufacturing platform may be a solution. Companies will have to show that immunogenicity are beyond this correlate of protection. Sinovac and AZ are working with PATH to establish a correlate of protection. By June or July, the correlates should be ready, but now it is not clear whether they would be serum neutralizing Ab titters or binding Ab titters, as ELISA or cell mediate responses T-cell or B-cell responses, apparently everyone's moving towards serum nAb titters. There are periodic events with BMGF.

SP asked RPG if Brazil approved used of Sinovac and AZ vaccines. RPG said they have EUA, a new procedure for ANVISA, per lot, more than 10M doses for Sinovac-Butantan vaccine and 2M for AZ-Oxford Fiocruz vaccine. They are working with PATH and Sinovac on the correlates of protection; one concern is the variant. He strongly advises companies to try to determine which lineage the positive cases samples belong to, because it will be determinant for the efficacy result. They have a great concern regarding the P1 variant, and have to analyse more data.

SG said most of the QC tests are in place and there is a harmonization of the assays. He proposed, since the South Africa variant is more critical than the UK variant, if DCVMN platform can help provide those isolates from South Africa at least for those labs being able to handle it, to see whether their product is producing nAb against those isolates. RE said they are evaluating this, about bringing the strain to India perhaps the government will take decision. There has been some genomic characterisation to see if the strain is already in India, but still not found. RE said there is an institute in South Africa willing to take human sera and do a nAb assay. AA said we should explore all possibilities.

Next meeting 18th February

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Notes taken by SV, edited by SP

Adriansjah Azhari
Chair of DCVMN COVID-19 Committee
Nyon, January 28th, 2021