Attendees: Adriansjah Azhari (AA), Apoorv Kumar (AP), Dat Do (DD), Ladda Suwitruengrit (LS), Lingjiang Yang (LY), Marcos Freire (MF), Nora Dellepiane (ND), Rajinder Suri (RS), Sekar Thangaraj (ST), Sivakumar Sakthivel (SS), Sunil Gairola (SG), Valeria Brizzio (VB), Sonia Pagliusi (SP), and Sonia Villasenor (SV).
TC started at 12.05 CET and finished at 13:13 CET

AP gave the epidemiological update: There has been a small increase in the total number of cases, but a decrease in the active number of cases overall, throughout all regions. Europe still remains the most burdened region followed by the North America region, while showing a small decrease in active cases. In Asia and South America there is a small decrease in the number of active cases, although Peru shows a peak. In South Africa there has been a decrease as well; and the rest of Africa has been stable. A slight in increase observed in South East area, due to increase in Indonesia, likely due to travellers during the holidays.

Variants update: AA invited the participants to volunteer to update from time to time on new variants. There were no volunteers, so AP suggested to circulate a call to the members R&D groups.

VB gave an update on vaccination: Today the total number of doses administered increased to 180 million, now covering 79 countries. In average 6.9 million doses are being administered per day. USA is leading with largest number of doses administered per day, followed by China, EU, UK, India Brazil, etc. Israel is the leading country with 78% coverage for single doses, followed by United Arab Emirates, UK, USA, and Chile has given 12.43%.

VB also mentioned the vaccination policies, which include vaccination of one target group (e.g. health care workers); two groups (healthcare and aged), all vulnerable groups (people with underlying conditions), vulnerable plus frontline services critical to societal functioning, and finally universal vaccination. SP mentioned that Brazil is vaccinating healthcare workers and elderly, although not yet included in public data.

A vaccine tracker, from the London School of Hygiene and Tropical Medicine Vaccine Centre, showed that there are 10 vaccines in use/approved for Emergency or limited use (Pfizer, Moderna, Gamaleya, Oxford-Astra/Zeneca, CanSino, Vector Institute, Sinovac, Sinopharm-Wuhan, Sinopharm- BBIBO, Bharat Biotech), about 20 vaccines in phase 3, and around 60-70 vaccines in phase1/phase2. The Imperial College of London dropped which was a self-replicating mRNA candidate. SP mentioned that South Africa started vaccinating yesterday with the J&J vaccine.

RS suggested to add, on the vaccine tracker, a list of vaccines under development by Developing countries, like a replica of this slide but only showing the type of vaccine and the country, but not the company. SP calculated that 42% of the vaccines administered globally come from DCVMs including Bharat, Sinovac, Sinopharm, SII, and Gamaleya (although it is not a DCVMN member). Since it is time consuming, AA suggested to create a team to help VB with this task.

Regarding the partnerships update, AA suggested to circulate a call among members to join and replace YV.

There were no Clinical Trials updates, neither on QC topics.

ND presented on Regulatory pathways used for approval of COVID vaccines, which will be shared on DCVMN Covid-19 webpage. The presentation described the main regulatory pathways for registration and exemplified various terms used by NRA's (ANVISA, CDSCO, EMA, FDA, SAHPRA, and Swissmedic) to refer to the approval of a medicinal products for use in the market, and for authorization under emergency circumstances (including life-threatening diseases, diseases of public health concern such as epidemics and pandemics). ND highlighted the differences between EUA (Emergency Use Authorization) a temporary authorization issued by a National Regulatory Authority, and EUL (Emergency Use Listing), a special procedure followed by WHO to provide a time-limited listing to unlicensed products. EUL implies that the manufacturer will later submit for licensure and WHO PQ. ND shared some examples of some Covid-19 vaccines being processed by different authorities. Finally, ND showed the EUL submissions to WHO and their status. Cf. https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_16Feb2021.pdf

ND clarified that EUL can start before the pandemic is declared, in pre-pandemic period. After the emergency is over, EUL is also over, and the manufacturers commit to submit for WHO PQ.

SP mentioned that EMA is open to provide scientific opinion to companies developing Covid vaccines, which is not an authorization or a dossier, nor a EUA c.f. https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-vaccines-covid-19-research-development

Next meeting: 10th March

Pending activities:

- Send a call for the members and R&D group to join for the variants update
- Send a call for the members to volunteer to champion the partnerships sub-group
- Send a call for the members to participate in a group to support the preparation of slides for tracking vaccines under development by DCVMs

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Notes taken by SV, edited by SP

Adriansjah Azhari
Chair of DCVMN COVID-19 Committee
Nyon, February 18th, 2021