Present: Fernando Lobos (FL), Patrick Tippoo (PT), Sai D Prasad (SDP), Tiago Rocca (TR), Weidan Huang (WH), Sonia Pagliusi (SP), Maureen Dennehy (MD); WHO: Joachim Homback (JH), Kate O’Brien (KB), Mariangela Simao (MS), Emer Cook (EC), Soumya Swaminatha (SS), Carmen Rodriguez (CR).


1. Access to DCVMN members’ Manufacturing/filling capabilities to supply vaccines:
   - Participants introduced themselves, and SP reminded that DCVMN as public health driven Network is different from other global NGOs, because it represents manufacturers.
   - Based on an internal survey, DCVMN has identified 14 manufacturers with 17 candidate vaccines in development, most in preclinical stage. One reported Phase III (BCG vaccine).
   - 35 manufacturers who responded (of 41 surveyed) – supply over 3.5 billion doses of vaccines annually. Collectively manufacturing capacity is likely higher, due to trivalent (MMR), quadrivalent (Flu), pentavalent (DTPHH) vaccines; actual capacity is based on routine operations (Mo-Fri/9-5) rather than spare capacity. The Network is in a position to support large needs. Spare capacity will depend on several factors, and need granular survey/analysis.
   - SS encouraged DCVMN to explore the possibility to gather information on spare manufacturing, as well as F&F and vials etc. SDP suggested looking at laws, if feasible to request spare capacity information, anonymous.
   - EC mentioned that work led by CEPI, Gavi and BMGF, is assessing capacity for manufacturing and filling across all manufacturers not just focussed on PQd manufacture.

2. R&D for COVID vaccines:
   - SS clarified that WHO jointly with CEPI, coordinates working groups to provide guidance to harmonize, animal models, SOPs, assays, reagents, etc. However, is not coordinating any vaccines preclinical testing so far. WHO created a Solidarity Clinical trial sites across world, as global network in many regions, as disease keeps “moving”. Design is flexible to add new candidates to trials as some are eliminated and other candidate vaccines may come up. Phase III planned for July 2020, with results by the end of this year. SS mentioned the idea of having head-to-head trials to compare vaccines.
   - SDP mentioned that internally DCVMN did not discuss the option to support (or not) head to head trials of candidate vaccines. Many manufacturing technology platforms are significantly different, and sometime difficult to coordinate complex studies. Some traditional vector/inactivated, while others are newer such as RNA. Currently most studies are Phase I and II. Clarity is likely to emerge at later stage of clinical strategies.
   - MS mentioned that the usefulness of such approach will be discussed with vaccine partners in the context of the ACT Accelerator activities; under the vaccine steering group – including IFPMA and DCVMN - will have representatives.
   - SP added that DCVMN provides information to members for joint decisions to benefit public health. DCVMN will consult with manufacturers and come back with a consensus. DCVMN does not get involved if a company is contacted individually, for product specific business (e.g. prequalification dossiers, tender application, etc.). For global public health matters, contacting manufacturers individually could lead inadvertently to imbalance, as those not contacted may not able to support public health. So far DCVMN as a Network was not contacted to engage/contribute formally to join the ACT Accelerator.
   - SDP mentioned that Bharat and BioE were contacted to ACT Accelerator discussions, coordinated by Gavi and BMGF: information received was sent to Secretariat and transmitted to members.
• Policy and guidance as to target population for COVID vaccination may be relevant for manufacturing planning. SP added that estimate for manufacturing capacity, needs definition of target population would be helpful to draft capacity and plans, as early as possible. Important to keep manufacturers informed to facilitate accurate demand forecasting. Then manufacturers can take responsibility on actions, based on information received.

• JH agreed that it is a difficult question and risk mitigation on financial business side is important. Policy will depend on how pandemic evolves, as well as on product characteristics and ability to deliver. It will adjust as products become available. Speculations say that it may start with vulnerable subgroups.

3. Routine immunization matters:

• JH highlighted the importance to ensure continued vaccine supply, for routine and campaigns. Also to ensure no disruption in manufacturing by competing demands. Some campaigns were put on hold and will need catch up. Need buffer in supply and demand side for next 1-2 years.

• SP added that some manufacturers expressed concern from about lot release. Due to quarantine – some laboratories have reduced routine capacity to release vaccines. Thus produced vaccines cannot be released, shipped, supplied in near future.

• EC mentioned that RSS is monitoring all with UNICEF, in discussion with NRAs. Many have been flexible. If there is a specific problem, WHO will address it with NCL or UNICEF.

• CR added that lot release does not necessarily need testing, NCLs could take risk based approach, based on history to allow supply of products.

4. How can DCVMN support – Covid and immunization:

• MS expressed concern about equitable access, fair allocation of products, affordability, and availability. Gates is investing in manufacturing capacity on a bilateral basis, not via DCVMN. They know the manufacturers; have done so with Grants in the past.

• SP added that DCVMN can contribute to a global plan to deploy equitable, affordable, accessible, and could communicate to our members and give them the choice to opt in, to contribute. DCVMN cannot offer them funding etc. therefore bilateral actions.

• SDP mentioned that over the last 2 months Gavi contacted manufacturers directly to understand manufacturing and R&D capabilities, with surveys, based in existing relationships from other projects. We may discuss spare capacity (anonymized) as above.

• PT called as a general principle to be careful that actions, interventions do not immunize against too many enquiries (surveys). DCVMN could create a one page view on who is leading which activities. Could WHO request that CEPI shares available information, instead of creating another survey for manufacturers to respond.

• MS added that one function of the ACT accelerator is to ensure communication is shared within and across other constituencies. Could use the proposed structure to ensure external communications beyond ACT. DCVMN does have representation within ACT. Need clear communication outside, transparency on mechanisms of engagement. WHO is in a position to approach stakeholders to ask for this info to be shared globally.

Participants thanked for the opportunity to exchange information at this TC and look forward to continued conversation as information evolves on COVID. SDP reiterated that while DCVMN is ready and available to work on new COVID vaccines, strong focus remains on routine immunization. As a network we have a wide membership base to absorb technologies to manufacture and scale up options.

Approved by ______________________________ Location/Date: Hyderabad, India. 07Aug2020

Sai D. Prasad, DCVMN President