Regulatory Experts Working Group
Final Meeting Minutes
October 13th, 2020

Attendees: Nirav Chokshi (NC), Norbert de Clerq (NdC), Sebastian Comellas (SC), Shiubanghi Ghadge (SG), Venkataraman Hariharan (VH), Wendy Huang (WH), Mic McGoldrick (MM), Ida Nurnaeini (IN), Cristopher Roh (CR), Lorenz Scheppler (LS), Monique Stavale (MS), Nora Dellepiane (ND), Sonia Pagliusi (SP), Sonia Villasenior (SV), Tana McCauley (TM)

TC started at 12.16 CET and finished at 14.52 CET

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1. Ida Nurnaeni replaced Samir Desai in chairing the meeting, which started the meeting at 12:16
   IN thanked everyone for attending.
2. Update from IFPMA on meeting in Asia rescheduling: During the upcoming IFPMA meeting in Asia (virtual), Samir Desai will represent DCVMN and give a 15-min presentation on DCVMN's work in Asia. The draft presentation was shared with the participants and discussed slide by slide. The presentation makes an introduction to DCVMN initiatives and working groups and goes then into the details of the objectives and activities of the regulatory working group. The outcome of the slide by slide discussion, in particular the decision taken is stated below. The priorities of the RWG are to continue to promote CRP implementation, promote alignment among manufacturers with EU ICH format for prequalification, work with NRAs in the country of manufacturing to seek acceptance of CTD format and work with NRAs in user countries to foster the adoption of CRP. Other priorities are to assist members to fully understand the recently published WHO document on considerations for eligibility for EUL applications for COVID-19 vaccines. The impact of this work in Asian countries, where CRP has been adopted will be increased alignment in dossier format. In addition, development by ASEAN of a standardized part I format may simplify the task for providing administrative data and product information in the ASEAN CTD. An additional opportunity to improve regulatory efficiency would be the availability of legislation and procedures for the use of emergency vaccines and acceptance of the WHO EUL outcome for automatic approval of emergency vaccines. Slides were presented one by one for agreement by participants.
   - Slide 2: Describes DCVMN goals No comments. Agreed
   - Slide 3: Scheme of the six DCVMN initiatives In order to avoid confusion, it was agreed that the slide should be kept but initiative 3 be somehow highlighted and adding a script for the speaker would be useful.
   - Slide 4: Shows picture of the four working groups. No comments. Agreed.
   - Slide 5: Explains the focus and role of the regulatory working group. No comments. Agreed.
   - Slide 6: Describes the priorities and achievements of the working group. It was agreed that the link to the publications would be added, as it would facilitate people accessing the publication.
   - Slide 7: Summarizes the RWG priority activities. It was agreed that abbreviations would be written in full the first time they appear, bullets would be replaced by numbers to make it clearer. It was agreed that the future activities would be rephrased to reflect what the group decided during the present meeting.
   - Slide 8: Describes the potential impact of work done by the RWG and proposes additional opportunities in Asia. Impact of work actually performed by DCVMN RWG would be segregated from other opportunities in Asia that could help to improve efficiency.
3. Updates from the members or comments about the meeting in Asia: MM talked about the IFPMA Africa regulatory network and asked DCVMN to think about what kind of collaboration it could have with the network.
4. Presentation on CRP implementation: ND described briefly the steps of the CRP, the role of the three stakeholders (WHO, NRA and manufacturer) and the steps that manufacturers needed to follow in order to foster implementation. She also explained that the current disagreements at WHO regarding ownership of the procedure might put at risk its implementation and requested ideas from the group as to how this issue could be tackled from manufacturers' perspective. SP noted that since the process has worked for some vaccines it means that the principle works- The only way forward is to have manufacturers to ask for CRPs. It was pointed out that all manufacturers that want prequalification should have ICH CTD and all be as aligned as possible. SP suggested to put out a statement about how CRP has worked for X countries and X vaccines. We could use that as a reference to show that it can work and that we would like to pursue this path. SP said

that the WG needs to disseminate this information so that others can see the work on CRP and can start to do the same. Feedback from the group was sought through voting of proposals

- Proposal 1: Put a general statement on IFPMA presentation about CRP progress and replace several countries with two countries and x number of vaccines. VOTE: 9 Yes, Agreed
- Proposal 2: Continue to push for the CRP procedure. Would members like to invite NRAs to follow the procedure for vaccines to be registered in their countries (only recently prequalified)? VOTE: 9 Yes, Agreed
- Proposal 3: Help WHO with the efficiency of this procedure. Some options were laid out. There is the approach of making a complaint or that of just making suggestions for improvement. The WG could bring up successes and shortcomings and ask WHO how can DCVMN help improve the process. The group voted on the proposal of sending a letter or an email to WHO asking for an opportunity to discuss VOTE: 7 Yes, 2 No, Agreed

5. Potential regulatory pathways for COVID Vaccines: IN presented the procedure in Indonesia for evaluation of emergency vaccines including COVID vaccines and the use of WHO EUL for the approval of the novel polio vaccine. In March 2020, new regulations came into place to adjust regular procedures into emergency procedures. For both regular and emergency registration, there is the same process flow and the required documents are the same, except for quality-clinical-non-clinical data in the dossier. In Indonesia, there is an accelerated timeline in emergency procedure. The biggest challenge in preparing registration document for emergency process, is that there is limited time with limited data. In Indonesia, to improve the emergency registration, the suggestion would be to simplify the process, ex: remove site inspections, reduce the number of evaluation rounds, be radically open to accept any on-going data as a commitment post licensure
SP noted that Bio-M has a collaboration with AstraZeneca for a COVID vaccine in Brazil and invited MS to comment: Bio-M is engaged in pre-submission meetings with ANVISA. The approach of the agency towards COVID emergency vaccines is to accept rolling submission, hence data will be accepted as they are being produced, this might accelerate the process but the requirements in terms of data is similar to a regular registration and the vaccine, if approved will be granted a normal registration.

6. The process for EUL evaluation of nOPV started in February and is still ongoing. In EUL, phase III data would not be included; there is a possibility to focus on phase I and II data. However, for quality aspect, all supporting documents are almost the same as a standard PQ procedure. Evaluators should be open to accepting any 'ongoing' data as a commitment after approval. Potential regulatory pathways for COVID vaccines: discussion and planning next steps. ND updated the WG on the WHO document for the acceptance of submission of COVID vaccines following the EUL procedure. The new WHO document is crucial, and manufacturers should not miss the opportunity to fully understand and comment on the document, for their respective COVID vaccines.
7. Finally, it was agreed to hold a meeting within two weeks to discuss the Considerations document on eligibility for EUL pathway for evaluation of COVID vaccines. SP added that the document was received and circulated to all manufacturers on the 1st of October. Even though the consultation period for the document finished on the 8th of October, there is added value in discussing it. The WG voted on a TC to discuss the WHO document for COVID vaccines. VOTE: Agreed
The next TC will take place on Teams in about 2 weeks to discuss the WHO document. IN thanked all the WG members for their time.

Notes taken by TM and edited by ND

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Read, understood and approved by Ms. Ida Nurnaeni
Co- chair of the Regulatory Working Group
Nyon, 20 October, 2020