

Attendees: Alexander Precioso (AP), Viska Indriani (VI), Linda Nesbitt (LN), Paulo Takey (PT), Zhang Lei (ZL), Katharina Hartmann (KH), Rajinder Kumar Suri (RS), Sonia Pagliusi (SP), Laura Viviani (LV), Tana McCauley (TM) minutes

AP started the meeting at 12:07 by welcoming all the participants.

1. Monthly PV trainings (PATH/DCVMN) – Feedback

The WG agreed on the usefulness of the workshops. AP agreed it was beneficial to have an overview of the main PV concepts. KH asked if reviewing the concepts helps the WG members in their day to day work and if they had started to implement these concepts into their own PV system. LN replied that they help prioritise the most important gaps and see what the most important issues are. However, it is difficult to address these issues with day to day activities.

2. Brainstorm session focusing on previous priorities to define which priorities to be addressed first (incl. how and respective timelines):

Priorities include COVAX initiative: Planning of the open/closed platforms, Benefit/risk assessments for PBRER/ PSURs and RMP alignment, Safety Governance: Generic documents (e.g., Safety Board Charter, Safety Management Charter), evaluation (e.g., preparation of a White Paper) on the evaluation of different PV safety databases/software tools/analytics, incl generic RfP specifications, COVID-19 vaccines: Strategies regarding accelerated approval and PV requirements (i.e., parallel processes compiling RMP and Phase III trials).

LN asked if responses had been received regarding open and closed platforms and if it would be possible to access the platforms at a later stage. AP replied that, within the COVAX group, it needs to be defined what would be the possible strategies to get connected to this initiative, and it has not been decided how members could get access to these open and closed platforms. KH noted that there was a possibility for open platforms, but the technology was not clear. From the technical standpoint, there is a need for a good platform. Content-wise, IFPMA could provide support. The open platform is something that needs to be focused on more. The closed platform is more complex. KH had some high-level discussions with COVAX, regarding the meta safety data monitoring board and the experts on the board. It would be possible to have something similar, where member companies could ask their specific questions. KH added that there is missing information regarding DCVMN members' needs. RS enquired about the WG activities, and if there is anything that could be done at DCVMN's level. KH replied that there needs to be a concrete plan for CEPI. This should be put in writing as a clear project. AP explained that COVAX is open to give DCVMNs support for PV and safety. This is a chance for members to interact with COVAX through the open/closed platforms. There is a need for feedback from DCVMN members, and this is the main challenge. RS suggested all communications to CEPI are marked to Benoit Hayman with RS in copy. **ACTION:** KH will put the COVAX initiative in writing and share it with the WG and Secretariat.

Regarding other priorities, LN noted that safety governance could be put as a first priority. It would be helpful to know what to cover and what needs to be documented when creating a VS committee. VI agreed with putting safety governance as a priority. LN added that safety databases are also critical. Some safety databases are extremely expensive, and it would be good to know what questions to ask these PV safety database companies and what are the things that are useful. KH noted that this would be the idea of the white paper. Depending on the size of the company, the number of reports to be handled, amount of PSURs and analytics, the idea would be to see what would be considered a suitable PV safety database.

LN and AP volunteered to write the white paper. **ACTION 1:** other WG members can write by email if they agree on the order of priorities. **ACTION 2:** LN will discuss with AP and come up with a date. KH will provide documents to help LN in the writing of the white paper.

RS noted that priorities should be taken up by the members, and then meetings become more meaningful. KH summarised the main priorities: safety governance, safety databases and COVAX initiative.

3. June meeting: members to present and share to the group their PV experiences and challenges

AP suggested that members share their experiences and challenges in terms of PV during the next WG meeting. LN welcomed the idea. LN noted that some people have more experience than others and can give constructive feedback on how to address challenges. AP suggested bringing colleagues from their PV teams to the meeting, for example, colleagues with a more technical background. VI added that if challenges are discussed, other companies can help find solutions. KH also welcomed the idea, adding that it would be helpful to have a comprehensive view of what is happening in the different companies. It would be ideal to have 5 minutes per company and leave the rest of the time for the interaction. AP added that it would be best to limit to 1 additional representative to the company. RS welcomed the initiative. He also asked the WG to inform the Secretariat of those who will present (with name, qualifications, experience) to create a database.

4. Q + A

AP opened the floor to comments and questions.

KH updated the WG on the RMP project. The kick-off meeting took place on 17.05.2021. 11 companies are participating in the project, and the next workshop will take place on 31.05.2021. There are three consultants supporting. One consultant is an expert in medical writing, another consultant is an expert in doing RMPs in high-income countries, and the other consultant is from a regulatory background, specialising in RMP submissions. KH also updated the WG on the COVAX/WHO RMP webinar. The webinar report will come out soon, and KH will send it to the WG.

The WG congratulated Butantan for the pre-qualification of their seasonal influenza vaccine. AP participated in the process and coordinating interaction with WHO. In the process, it was essential to have PV in place. Any time a company goes for PQ, one of the major audited areas is PV.

AP closed the meeting at 13:03 by thanking all participants.

Alexander H. Munro