

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

AP started the meeting at 11:03 by welcoming all the participants.

1. Approval of the minutes of the PV WG meeting on November 12, 2020

The WG approved the minutes of the previous PV WG meeting. ACTION: sign and upload all the meeting minutes on the DCVMN webpage.

2. Discussion of the Results of the Questionnaire

KH presented to the WG the results of the questionnaire that was sent out in October. Feedback was received from 8 DCVMN member companies. KH designed the questionnaire with AP. The questionnaire aimed to understand DCVMN members' needs in terms of risk management planning. CEPI subsequently proposed to support DCVMN members for risk management planning. The questionnaire was developed to support DCVMN members' needs and then served as support to the request from CEPI.

The results showed that the main areas for support were safety governance, safety statistics, safety databases, signal management, and risk management strategies and plans. Companies also require support in benefit/risk assessment.

KH noted that it is unclear what WHO accepts as RMP for PQ. WHO requires simple RMPs, whereas high-income companies need sophisticated RMPs. Simple RMPs submitted to WHO would not meet the standards of high-income countries.

KH added that CEPI would like to provide a list of consultants for support.

SP suggested to develop a framework to align the needs in the questionnaire with requirements for vaccine EUL approval, and then establishing priorities for supporting the manufacturers.

KH opened the floor for comments.

AP noted that it is crucial to identify the members' general PV needs and the specific needs regarding COVID 19 vaccine programs. COVAX is trying to identify the needs for COVID 19 vaccine developers. It is essential to understand the companies' goals and expectations for their COVID 19 vaccines.

ZL explained that it would be helpful to share a PV plan for PQ. As COVID 19 vaccines are a new vaccine, it would be useful to explain how to conduct the benefit/risk (B/R) assessment and the document format for the benefit/risk reporting of COVID 19 vaccines.

VI added that further clarification on the format of B/R summaries for PSURs would also be useful. KH replied that as of today, there is no clear requirement for a format on B/R summaries for simplified Covid-19 PSURs.

3. COVAX initiative to support COVID-19 vaccine developer's needs

The WG members agreed to share the summary of the PV needs of the 8 DCVMN members that replied to the questionnaire with the COVAX VS WG.

ACTION 1: circulate summary slide.

ACTION 2: PV WG members should provide additional feedback and prepare material to be shared with COVAX VS WG on Monday 21.12.2020.

KH suggested to establish an independent advisory board to support COVID 19 manufacturers on COVID 19 vaccines, which would help resolve safety questions and technical PV issues in a quicker way. The

board would help with scientific and technical questions. AP welcomed the idea and noted that CEPI is willing to help with an independent advisory board. The WG would need to discuss how to communicate with CEPI. SP suggested naming it a scientific advisory board. LN noted that during the H1N1 pandemic, many safety issues came in. With COVID 19, it would be useful to have this type of support for manufacturers. KH noted the COVAX VS WG is also working on handling these types of issues. The WG members agreed on the usefulness of a scientific and technical advisory board. ZL noted that questions to the board should be accessible also to others. It was decided that such a board should have open and closed discussion sections.

4. Create subgroup to work on detailed lists on respective needs to be shared with COVAX / DCVMN

AP proposed to create a subgroup of the PV WG to work only on COVID 19 vaccine PV issues. The subgroup would share the content of their discussions with the PV WG.

SP noted that companies do not typically openly share safety data before licensing. KH explained that this subgroup is not intended to share data; in general, adverse events and signals is openly accessible information in respective databases (e.g., VAERS, Vigibase, etc.); and study results are also only shared when published. SP wanted to make sure confidentiality and companies' freedom of operation is respected. KH noted that there will be no sharing of data before it is published. Strict confidentiality will be observed. If safety data were to be shared with an advisor, it would be in a confidential manner.

All WG members considered the COVID 19 PV subgroup to be useful. The WG decided to establish a COVID 19 PV subgroup that would share its discussions with the entire PV WG and then potentially share its findings with other actors (e.g., other DCVMN members or COVAX).

5. AOB

SP informed the WG that the contact person for the DCVMN/PATH collaboration for PV training had left PATH; thus the proposed PV training plan is delayed. A new person will join PATH in January 2021. From January, one PV workshop per month will take place, as per DCVMN/PATH PV training plan.

SP also gave an update about the DCVMN e-learning platform. The two PV certificates have been successful (around 100 people enrolled and 80 certificates). SP suggested developing a new e-learning course on the members' needs (derived from the survey responses). The course could be on the statistical analysis of safety data, signal management, or risk-benefit assessment.

AP closed the meeting at 12:19 by thanking all participants.

Alexander P. Amunoro