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

AP started the meeting at 11:15 by welcoming all the participants.

1. Overview of meetings with COVAX
KH presented an overview of the discussions with COVAX. KH discussed with COVAX the open platforms where everybody from DCVMN could ask their PV-related questions. COVAX could set up an online platform where members could ask their questions, similar to the platform they already have for questions related to the COVAX WGs: link to the COVAX discussion forum; link to COVAX Vaccine Safety. The closed portal is not yet developed. COVAX already has a forum (i.e. meta DSMB) where experts are under confidentiality agreements, and companies can provide their safety and efficacy data from a running trial to be monitored by external experts. The closed session could be similar to this. KH will write a concept note regarding the sessions to detail what COVAX would support. LN asked about the timelines for the establishment of the open and closed forums. LN and VI do not have questions now but would have some in a few months. KH said that if the platforms are set up, it would be ideal to use them frequently. There could be many questions coming in as DCVMN has over 40 members. LN asked how much input would be needed to sustain this initiative. KH answered that this project would need to have a sound and sustainable background. The WG agreed on the usefulness of the initiative. Action: KH will write a concept about the closed sessions.
AP explained that more feedback from DCVMN members is needed. KH wondered if the people in relevant PV departments had received the letter. AP asked if we could get ask for the focal person from the PV area within DCVMN companies. SP suggested speaking about the letter during the PV e-workshop, as there are over 60 registrations, and send one reminder email before the webinar. Action: TM will send a reminder email to DCVMN members before the PV e-workshop.

1. Discuss feedback of PV needs from DCVMN members concerning the letter circulated about COVAX support
KH shared her screen to discuss the feedback received from DCVMN member companies. KH presented the PV challenges from company 1 and asked the WG for their comments:
1. Difficulty in receiving ICRs from NIP in due time. KH noted a general problem within many countries as NRAs are not always receiving the safety information from immunization programs. AP added that it is difficult to get information from the immunization program because of the limited information flow between the NRA and the immunization program. LN said that the expanded immunization program is person-dependent, the information is now sent straight to the NRA, and companies need to follow-up. The manufacturer does not receive the safety information. KH suggested addressing this to WHO as a developer’s request. ZL added that there is a shortage of human resources within PV teams and in national immunization programs, which do not have enough human resources to distribute and handle the data. The challenge comes from each stakeholder related to PV (clinical, national, and regional CDC and drug authorities).
2. Difficulty in receiving support for ICRs causality assessments from NIP and Health Departments in due time. AP said that manufacturers need to perform causality assessments, and the RA expects to receive the assessment. The national immunization program should also perform causality assessments. The challenge is that often the amount of information or notifications received is not sufficient to perform a causality assessment of an adverse event. In the situations where manufacturers get a causality assessment from the RA, sometimes causality assessments are not in agreement between the
manufacturer and the NIP / NRA. It is then difficult to get contact points within the national immunization program to discuss this issue. LN confirmed that the national immunization program does the causality assessment, and the manufacturer sees if they agree with the causality agreement. KH explained that it is frequent to have different causality assessments. The standard procedure is to reanalyze the causality assessment and see why regulators came to different conclusions. If the company keeps it as not related and NA keeps it as not related, it is best to keep it related. The best practice is to keep the most stringent assessment. However, the company should also keep its own assessment.

3. Failure in receiving ICSRs as there is no feedback from NRA. VI explained that the NRA has the application, and the manufacturer has to send its cases. Once the data entry is done, feedback may be given by the NRA.

4. Lack of budget for academic and scientific events due to bureaucratic issues and Cost containment imposed by Government

This was briefly touched on by the group but it was felt that further clarity was needed on this issue.

5. Lack of specific training in PV in the country

6. Reduced human resources given the diversity of products and their complex routine activities, as well as extra activities. LN explained that this is a problem within some companies, where PV departments are considered less important. KH added that companies increase their PV if they have an issue. KH explained the advantages of EMA in Europe, where regular PV inspections have led to companies putting more resources into their PV. In emerging countries, PV inspections are not as rigorous as in Europe. LN added that PV concerns not only manufacturers and NRAs but also doctors and other healthcare professionals. Within these healthcare professions, there is not a wide understanding of PV and reporting. New policies can partly improve this. AP noted the importance of teaching PV in health, nursing, and medical schools.

SP discussed the Sanofi Pasteur system of linking the batch number with the AE. KH noted that all the companies have some system linking the batch and AE because this is an inspection question that is routinely asked to companies. This was a question in the DCVMN survey on PV. Members have SOPs in place but may not have rigorously implemented them. KH noted that there is a general need for senior management to better understand PV. Often, if there is a safety issue, PV gets visibility and subsequently more resources are allocated. SP asked if COVAX could support PV functions. KH answered that COVAX could support functions within R&D. SP noted that phase 4 is the line between pre-and post-licensure. SP asked if DCVMN could ask CEPI if they could provide grants to companies that are developing a new vaccine to collect phase 4 info on safety. The vaccine should only be on a new product and limited to 2 years. KH suggested not limiting this to phase 4, as many LMIC companies may not have rigorous pre-licensure safety surveillance. AP noted that CEPI calls for studies on COVID vaccines. CEPI opened up this grant program to stimulate phase 4 studies. One way of supporting members would be to work on protocols for phase 4 studies, which companies could adapt and support sharing standardized protocols for phase 4. Companies could then apply for support on phase 4 studies.

Kh presented the PV challenges from company 2 and asked the WG for their comments:

1. How to effectively monitor the safety profile of our products in other countries, especially LMICs? KH explained that, in a foreign country, a local organization must legally apply for licensure and do the collection of safety data, and there must be a safety data exchange agreement in place. LN detailed her experience with safety data exchange agreements. Training people in the local country and regularly contacting the local team improved the safety data. SP suggested covering the topic of safety data exchange agreements during one of the PATH/DCVMN e-workshops briefly. For example, to give an exercise with examples of good, okay and bad agreement.

AP closed the meeting at 12:20 by thanking all participants