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

AP started the meeting at 12:13 by welcoming all the participants.

1. Update on monthly PATH/DCVMN PV e-training

KH asked about participant's experience and feedback on the PATH/DCVMN e-training. The WG agreed on the usefulness of the training and its benefits.

2. RMP project updates

KH went over the main objective and outcome of the RMP project and informed that the application deadline is Friday April 9. KH also encouraged the WG to complete the RMP e-learning course that is open to all DCVMN members, not only to those who participate in the project. The e-learning course will soon be available on the DCVMN e-learning platform.

3. Updates on the PV platforms (COVAX Vaccine Safety Working Group to support DCVMN Pharmacovigilance activities)

KH presented the CEPI meta-data safety monitoring board (mDSMB), which is planned by CEPI to be open to all manufacturers, even if they don't develop COVID-19 vaccines. The open platform, that was discussed at previous meetings is planned to support technical/practical/general PV questions in the context of handling vaccine safety in the pre-/peri- and post-introduction phase of COVID-19 vaccine of interest to all DCVMN developers, e.g., format question of RMP/PSURs/simplified PSURs/benefit-risk assessment template, etc. There are ongoing discussions within CEPI/COVAX to understand how to implement this in a way to benefit all. It was discussed that the closed platform (also presented at previous meetings) could be set up by CEPI in association with the CEPI mDSMB. The primary support of the closed sessions would be to support DCVMN (not only members developing COVID-19 vaccines) on specific vaccine safety questions in a confidential manner, e.g., safety data handling and statistical analyses of safety data in clinical trials, monitoring and analyses of safety data in the clinical setting as well as post-introduction, analyses of unexpected AEFIs/AESIs considering background incidence, causality assessment, and benefit-risk evaluation. AP replied that this is a considerable achievement and opportunity for all DCVMN members.

4. COVID-19 vaccine interesting/important links

KH shared the links to websites related to COVID-19 vaccine PV. KH explained that in the WHO database (VigiBase), one can search for adverse advents from COVID 19 vaccine; however, it is not specified which vaccine it is. WHO informed that companies should soon have full access to VigiBase free of charge for COVID-19 vaccines. KH also noted that with the WHO global benchmarking tool, it is possible to see which regulatory agencies the WHO sees as stringent and functional. It also shows which regulatory agencies need to comply with to become stringent or functional. KH then presented GACVS, who do the communication of safety issues for COVID vaccines.

5. COVAX/WHO Vaccine Safety WG Webinar

KH presented the vaccine safety WG webinar that will take place on April 28th, where the WHO, regulatory agencies and developers, such as J&J, Gamaleya, AstraZeneca and Pfizer , will participate, Moderna cannot

attend and Sinovac has not yet answered. **ACTION:** KH will send invites to the WG members, who can then distribute them within their companies.
AP asked the WG about the COVID-19 vaccines they had in their respective countries. VI replied that in Indonesia, they have the Sinovac and AstraZeneca vaccines. LN replied that originally South Africa should have received the AstraZeneca vaccine. However, there were problems with the South African variant. Now South Africa is conducting a clinical trial with healthcare professionals with the J&J vaccine. AP asked about the regulatory agencies that would join the webinar. KH answered that EMA and WHO will join and that they have reached out to Ghana, Chile and Israel. AP asked whether the FDA could join. KH explained that the focus would be on low and middle-income countries, and the FDA does not request an RMP. The other countries follow European RMP. KH will also try to contact the Indonesian RA.

5. AOB

LN updated the WG on the data safety monitoring board training, sponsored by CEPI, which is for the African region and will take place in May for eight weeks. KH agreed that this training would be a significant advantage for all developers.

AP closed the meeting at **13:02 by thanking all participants.**

Dr. Alexander Precioso
Chair of the Pharmacovigilance Working Group
April 15th, 2021