

Attendees: Alexander Precioso (AP), Chetanraj Bhamare (CB), Katharina Hartmann (KH), Linda Nesbitt (LN), Paulo Takey (PT), Phan Honghoa (PH), Zhang Lei (ZL), Sonia Pagliusi (SP), Sonia Villasenor (SV) minutes.

1. AP welcomed the participants inviting them to participate in each of the points of the agenda.
2. **Discussion and official approval of the Audit Check List.** KH presented the Pharmacovigilance (PV) audit checklist which was first discussed by the group at the first meeting on December 1, 2019. This checklist is meant to be an aide-memoire for risk-based PV audits to identify problem areas; it is not an audit assessment template. The Pharmacovigilance Landscape analysis published in Vaccine in July 2020 identifies areas where the DCVMN companies might need to increase their auditing activities. The group agreed that the proposed checklist is of overall benefit for all members and was approved by the group. ACTION: to be uploaded on the DCVMN PV WG webpage.

3. **Discussion on Covid-19 vaccines:**

c) Brighton collaboration webinar held on August 27, 2020: KH provided information on the webinar on Tools for Covid-19 Vaccine Safety Assessment was open to everybody and the slides are available at <https://brightoncollaboration.us/webinar-on-tools-for-covid-19-vaccine-safety-assessment/>. This webinar was mainly an introduction to the Brighton Collaboration safety platform for emergency vaccines (SPEAC) and included the assessment of adverse events of special interest (AESI) for the covid-19 vaccine candidates, the assessment of vaccine-associated enhanced disease (VAED) and the respective standard case definition, presenting the vaccine technology safety templates.

The Covax Vaccine Safety Developers Workshop on August 31st, 2020: KH also informed about on the workshop to companies with promising Covid-19 vaccine candidates already in an advanced clinical stages (phase 2 or phase 3). The results of a survey on the developers' needs was presented: the results are based on 29 responders (the response rate was not mentioned), 8 responses came from DCVMN members, 9 from IFPMA, 7 from companies being neither a DCVMN or IFPMA member and 5 responses from experts supporting Covid-19 vaccine development. The topics of the survey included 7 development milestones and were ranked according to the highest need for external guidance: the highest need was the risk management planning, 2nd the post-licensure safety surveillance, 3rd the phase 2 and 3 trials and challenges regarding safety, especially assessing the potential VAED; 4th licensure applications, 5th WHO prequalification, 6th first in human trials, 7th Communication planning. The discussions at this workshop was on how these needs can be covered by the Covax vaccine safety working group. It was communicated that the results of this workshop will be shared with DCVMN and IFPMA, however it was not mentioned how the information will be shared. AP highlighted that the global movement is centered in the post licensure period which requires strategic decisions, since many of the activities performed before licensure will not happen completely. PV is an item in which all regulators will pay attention during the process of vaccine licensure and will evaluate the commitment from companies for the post-licensure period in order to maintain the licensure.

AP informed the group that the COVAX Vaccine Safety WG co-lead, contacted him as Chair of the DCVMN PV WG asking if the WG would be open to have the COVAX Vaccine Safety Group as observers in the PV WG sessions; They are having the same approach with IFPMA PV group. AP's opinion was that it would be very important not only to have them as observers but also as hands-on support for the PV WG. However, before starting discussions on Covid-19 vaccine development and respective safety assessment, a observers' space within the PV WG should be created. Perspectives in vaccine safety could be an opportunity for DCVMN members to have input in discussions regarding Covid-19 vaccine safety. KH also highlighted that AESIs and how to detect VEAD were important topics raised at the August 31st workshop. AP asked the WG members on their opinion on creating a space within the PV workstream to discuss Covid-19 vaccine development and safety:

LN suggested that even if a company is not currently involved in Covid vaccine development it would be a valuable experience to create that space to participate in such discussions of public health and learn what to do in case it happens again in the future so that we can all be on the same page on what is expected from each other in terms of reporting channels, risk management assessment. The group agreed that AP will respond to COVAX Vaccine Safety WG co-lead, copying DCVMN secretariat, informing that observers

would be welcome. The PV WG will need to open an additional discussion "channel" on Covid-19 vaccines development. SP asked the group if they would like to foster that important information on public health and share safety information with all DCVMN members, only within the PV WG or with only the DCVMN members developing a Covid-19 vaccine. This discussion will need to follow as it is important to ensure transparency, equal communication, also with WHO and to avoid mis-communication.

b) Interactions/joint meetings between DCVMN PV WG and Reg WG on Covid-19 vaccines programs. AP asked the group on their opinion regarding interactions between the PV WG and Reg WG regarding Covid-19 vaccine programs, esp. regarding regulatory commitments for post-licensure safety studies. SP suggested to invite one or two persons from the Reg WG to join a PV WG meeting to present their areas of activity and ask where they would see areas of interaction. AP supported the suggestion and considered that the way of interaction can be worked out later, e.g., by inviting the Reg WG Chair and co-chair or a technical person. The group agreed on having interactions with the Reg WG provided that, as suggested by CB, an agenda is created to define the areas of common interest. The areas of interest shall be within the scope of Covid-19 vaccines safety in the pre- and post-licensure period. It is of note that none of the PV WG members have yet discussed safety assessments of Covid-19 vaccine candidates. LN asked if there will be special reporting procedures for Covid-19 vaccines during the clinical and post-licensure period. SP suggested that the group members attend the WHO workshop later today, to provide first-hand information. From an industry perspective, harmonizing reporting procedures would be very helpful, discussions between regulatory authorities (e.g., NRAs, FDA EMA, WHO a.o.) have not yet started.

d) Interactions between DCVMN PV WG and IFPMA PV WG ON Covid-19 vaccines. The benefit of interactions between the DCVMN PV WG and the IFPMA PV WG was raised at the workshop on August 31st, and AP mentioned that there is an opportunity of potential interaction with the IFPMA PV WG specifically for Covid-19 vaccines. SP also explained that IFPMA has shared a letter that was a response from IFPMA to a concern that some vaccines may be released and put on the market without a thorough review of safety or without phase 3 trials. The opportunity for collaboration between DCVMN and IFPMA can be discussed later by email. ACTION: SP to find out about IFPMA PV group interest in having joined communication.

a) SP gave an update on DCVMN COVID-19 vaccine committees' activities and working groups. She presented the five WGs within DCVMN being Regulatory, Pharmacovigilance, Supply Chain, 3Rs and Covid-19, and a brief description of how they work. The WGs were created 2 years ago, based on good experience with the Regulatory WG formed in 2015, as a proposal to engage more members through the WGs and better understand international affairs. Most of the groups have papers published. The 3Rs WG made a proposal for a project and obtained a grant from NIMBL; they also created a Consortium with member and non-member companies and NCLs to run the project where DCVMN is providing SOPs and some materials for free to perform a study. The Supply Chain WG considers to form a consortium to do a pilot study on traceability. The Regulatory WG is the only WG which includes external company members in their WG (from IFPMA). The Covid-19 WG is the one most recently formed with twice-monthly meetings, while the other WGs meet every quarter. They are subdivided in 3 sub-groups: one for QC, Clinical Trials and Manufacturing.

4. Wrap up and conclusions. AP concluded that he will write a response letter on behalf of the DCVMN PV WG informing the COVAX Vaccine Safety WG co-lead that a Covid-19 vaccine safety space needs to be created in the PV WG and then they are welcome as observers, and also as supporters for the PV work on Covid-19 vaccine programs.

AP closed the meeting at 13:20 by thanking all the participants.



Alexander Precioso
Chair of DCVMN Pharmacovigilance Working Group

Nyon, 9 September, 2020