**Participants:** Rajendra Kasi (RK)-Zydus, Aminata Diagne (AD)- Institut Pasteur de Dakar, Beatriz Lucchesi (BL)-Butantan, Devi Sahoo (DS)-Indian Immunologicals, Linda Nesbitt (LN)-Biovac, Varun Sharma (VS)-PATH, Vijay Yerroju (VY)-Biological E, Viska Indriani (VI)-BioFarma, Rajinder Suri (RS)-DCVMN, Katharina Hartmann (KH)-Consultant, Sonia Villaseñor (SV)-DCVMN. **Meeting started at 12:05 pm CET and adjourned at 1:10 pm CET.**

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1. **Descriptions of actions taken during 2022 by the WG.** KH debriefed the WG about the Risk Management Plan (RMP) project and the AVSS Workshop.

The objective of the RMP was to strengthen the capacity of DCVMs for developing a RMP for vaccine registration and PQ submissions, through the establishment of company-wise multidisciplinary teams working on a hands-on project to prepare their own robust RMP to be integrated into the CTD to register their vaccine. It started with a learning course that is now openly available on DCVMN website cf. https://moodle.dcvmn.net/. Followed by an RMP webinar and regular workshops to go through every chapter of the RMP where participants discussed their experiences and issues faced. 3 expert consultants reviewed the RMPs and gave individual feedback with each of the 9 companies. Learnings found are also available in DCVMN's website cf. https://dcvmn.org/pharmacovigilance-working-group-2/ The feedback was very good.

KH also mentioned that last year, through 1-to-1 meetings with the PV WG members, it was established that it is of their interest to work on an Active Vaccine Safety Surveillance (AVSS) Project with a series of online trainings, workshops and a mock AVSS plan submission. A 2-day workshop was held in February 2023. The timeline originally proposed is now delayed due to the change of Chair, Co-chair and members of the WG. The scope of work is to share best practices and AVSS tools for the development of AVSS project. The recordings of the Workshop are available in DCVMN website cf. https://dcvmn.org/avss-pharmacovigilance-workshop/

LN mentioned that before moving forward with the project we need to make a full assessment of what the project is going to involve, how much is going to cost with all the activities and responsibilities and then submit it for approval to RS, for requesting if there is funding available for this project. RS added he would need a list of the project goals, what needs to be done, timeline and the budget requirement. He would like to support it but facts and figures are needed.

KH added that first of all we would need the confirmation of the interest of the member companies in submitting the AVSS project, then list which companies are interested and what would be their desired outcome (e.g. a full protocol, an understanding of what needs to be done, etc.). So, we need to discuss again with the members on how they would like to proceed.

BL expressed that Butantan would be very interested in continuing with this project.

VS asked if the AVSS project would be dummy protocol or real ones. KH said that it would depend of the needs of each company, their NRA's requirements and other factors. VS asked if they have considered to create a generic protocol. KH said that there are already generic protocols that have been shared during the workshop.

AD said that their company is at the beginning of implementing AVSS so asked if an additional person form her company could join the project. KH added that these projects need to be carried out by multidisciplinary teams.

KH added it would be a good idea to send this initiative to all DCVMN members and a questionnaire to understand the needs of the various companies. SV will resend the initiative sent early this year for the members to review the project proposal. VI added that we already have a list of the

companies interested in the workshop, but we can check again with the companies in 1-to-1 call and see what are their needs, and if they have new ideas for initiatives.

**2. INCLEN Project from Prof. Arora.** KH gave a brief summary of the project proposal, which is aimed to improve the vaccine safety evidence base through an integrated approach of strengthening the AEFI surveillance, documenting the background rates in different age groups and risk of serious adverse events following vaccination through integrated population surveillance and linked hospital sentinel surveillance in LMICs. This project does not only focus on COVID-19 vaccines but aims to expand to other routine vaccines. This study will take place in India, Indonesia, Ethiopia, Brazil, South Africa and Kenya. Funding by CEPI is being sought.
Highlighting the benefits of the CEPI grant to DCVMN member companies, RS added that the post-design of the AVSS project can provide local background rates of concerned safety issues such as TTS, GBS, anaphylaxis in LMICs. Also availability of local background rates of specific medical conditions, will be of great value for manufacturers in early signal detection and risk mitigation for new vaccines. Strengthening the AVSS system would help in obtaining good quality safety data. It will help the rapid introduction of new vaccines in case of an emergency. The information has been shared with CEPI, whose initial reactions have been positive, but we are still waiting for their feedback.
BL asked if this project will be handled in partnership with MoHs of the countries involved. RS said that not in partnership but in collaboration with them because they may not be directly involved but will certainly be kept in loop for guidance and support. LN added that also some Universities will be collaborating in collecting information and also community input.

**3. Publications**. LN debriefed that some of the discussions that have been held with the previous WG was that maybe after each meeting we could issue a poster or a newsletter that can be sent out to each of the PV officers in each of the member companies to try to open the information to all levels in the companies and not only to the participants of the WG.

**4. Open discussion for new topics/needs to address.** KH said that a discussion of the Benefit Risk Assessment (BRA) was initiated last year together with the Clinical and Medical Affairs Working Group. BRA needs to be done from pre-licensure during the whole life cycle of the project.
LN also invited the group to think which other topics the members consider most important to work on. KH will share a survey that was made 2 years ago where members established the topics they were interested in working on, so that the WG members can decide if these topics are still of interest or if there would be new ones, mostly after COVID.
BL said that looking after safety in pre-licensure is very important. Also added that in Brazil they have started to discuss with the NRA and UMC about the WHO Drug Dictionary implementation and asked if this is also being discussed in other countries with NRAs. KH said there have been discussions for implementing the Brighton case definitions into the case management, but this only makes sense if manufacturers have an electronic safety database system, so it is important to understand how many of the members have already implemented an electronic PV safety system. There are different levels of implementation within the members and may need adaptations. This could be an interesting topic to discuss. This will be added to the questionnaire to be sent to the members.
VS shared his experience with different manufacturers. They are increasingly investing in

electronic databases that range from state-of-the-art products to local domestic IV products but the common issue is how to integrate the database to the current paper-based system and this causes confusion and how to migrate their paper-based data to the electronic system. There are some companies that are outsourcing a CRO who is maintaining the databases. How to integrate and make the best use of electronic systems. Members agreed that this is a challenge they are commonly facing. BL added that in some cases, they are facing the challenge of having two different systems, the clinical database from one vendor and a safety database from another vendor and it is a challenge to have them integrated and updated. LN said that data migration to an electronic system is very challenging and it is very important to define the expectations when going to an electronic system before going into it (medical history, adverse events, laboratory trace, etc.). KH said that sometimes the easiest is to outsource it and enter only the most important information from the paper-based data into the electronic system. We could plan for a larger workshop and invite some vendors and CROs to come with their proposals.

RK added that the Vaccine Safety Working Group is working on some manuscript related to the COVAX. KH added that they will be publishing soon the lessons learnt, submitted to the Lancet. KH will share it with the group it once it is published. KH added that the PV WG had already discussed about the differences in PV in LICs so this could be a publication from the DCVMN WG.

Rajendra Kumar Kasi

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**Rajendra Kasi**
**Chair of the PV WG**