

**DCVMN 1st PV WG meeting – Royal Manotel, Salon Eaux-Vives, Geneva
1st December 2019 14.00h – 19.00h**

Participants: Linda Nesbitt (Biovac), Zhang Lei (CNBG/Chengdu), Phan Hong Hoa (Vabiotech), Chetanraj Bhamare (SII), Alexander Precioso (Butantan), Katharina Hartman (DCVMN consultant), Sonia Pagliusi (DCVMN). **Excused:** Viska Indriani (Biofarma), Paulo Takey (Biomanguinhos)

Meeting started 15:30 pm and ended 19:30 pm

Welcome and self-introduction was followed by a presentation by SP reminding everyone of the DCVMN mission, operating principles, support to manufacturers to achieve PQ and sustainable supply.

Six main activities funded by charitable and development donors aim to increase availability of high-quality vaccines globally to achieve 3 major agreed goals :1) build technical capabilities and strengthen capacity of MFs to produce and deliver quality vaccines across the long-term; 2) proactively engage DCVMN members on priority global health issues, understanding the broader landscape (e.g., regulatory approaches, supply chain knowledge, Safety monitoring, etc.); 3) establish more systematic and proactive dialogue with international bodies to shape the thinking on high priority DCVM issues. Strengthening pharmacovigilance to enhance vaccine safety monitoring was identified by manufacturers as a topic of high interest and priority.

KH reviewed the results of the survey to better understand PV landscape among network members.

Results indicated 11 specific functions that warrant strengthening; in addition, databases and safety signal detection and risk management showed in general 50% or less implementation among respondents and were discussed.

1. Inspections by NRAs or WHO
2. Audit by vendors/third parties
3. Vaccine Safety Committee
4. Global Safety Board
5. Access to monitor spontaneous reported AEFIs (post-marketing) from international electronic databases (eg., WHO Vigibase, FDA VAERS)
6. Brighton case definition use
7. Health hazard evaluation
8. Preparation of DSURs
9. SOPs for preparing specific safety reports
10. SOPs for preparing for inspections/audits
11. SOPs for use of medical coding/MedDRA

Regarding the low usage of electronic safety databases systems, it was felt that this is not necessary if not many products nor high vaccine doses are supplied. Regarding safety signal and

risk management it was felt that the around 50% should be higher in all related activities, and thus it was prioritized for training and strengthened support.

Summarizing, KH recommended to focus on 5 points for DCVMN support and these were agreed by the WG:

- Standardized description of all key PV procedures and processes (SOPs and other controlled documents). Notably, PV corporate policy would facilitate PV operations.
- Improvement in the AEFI case management (coding, medical review, causality and expectedness assessment)
- Signal detection and risk management
- Handling of PQCs and reconciliation with AEFIs; analysis of safety impact of a technical complaint
- Various areas of the PV Quality system, including internal PV audits

Next steps were agreed upon:

- Publication of the survey results to increase awareness and stimulate discussions
- Sharing information to align with WHO Safety Blueprint goals (2nd Dec 2019)
- Further develop PV checklist to facilitate internal PV audits and evaluation (a draft was shared for perusal)
- Develop algorithms to facilitate the implementation of safety governance
- Organize training workshops to discuss PV best practices and databases for SMEs, and training in communication with NRA and the public in general.

SP suggested a workshop to be held in mid-March 2020, in China and the last day would be dedicated to WG discussion. Hard copies of draft audit-points check-list and SOP master list were shared with the WG members for further comments. A more in-depth discussion and prioritization will follow. The activities of the PV WG will be reported to the donor by end January by WebEx.

The terms of reference for the WG were discussed and main principles outlined and agreed upon:

The main goal of the WG is to support and strengthen pharmacovigilance systems at corporate level to achieve global vaccine safety monitoring so that DCVMN member companies are equipped with up-to-date knowledge to implement best practices and formal training according to state-of-the-art pharmacovigilance, aligned with WHO and relevant national regulatory requirements. An E-learning course was developed by KH and will be circulated for validation and approval by the experts.

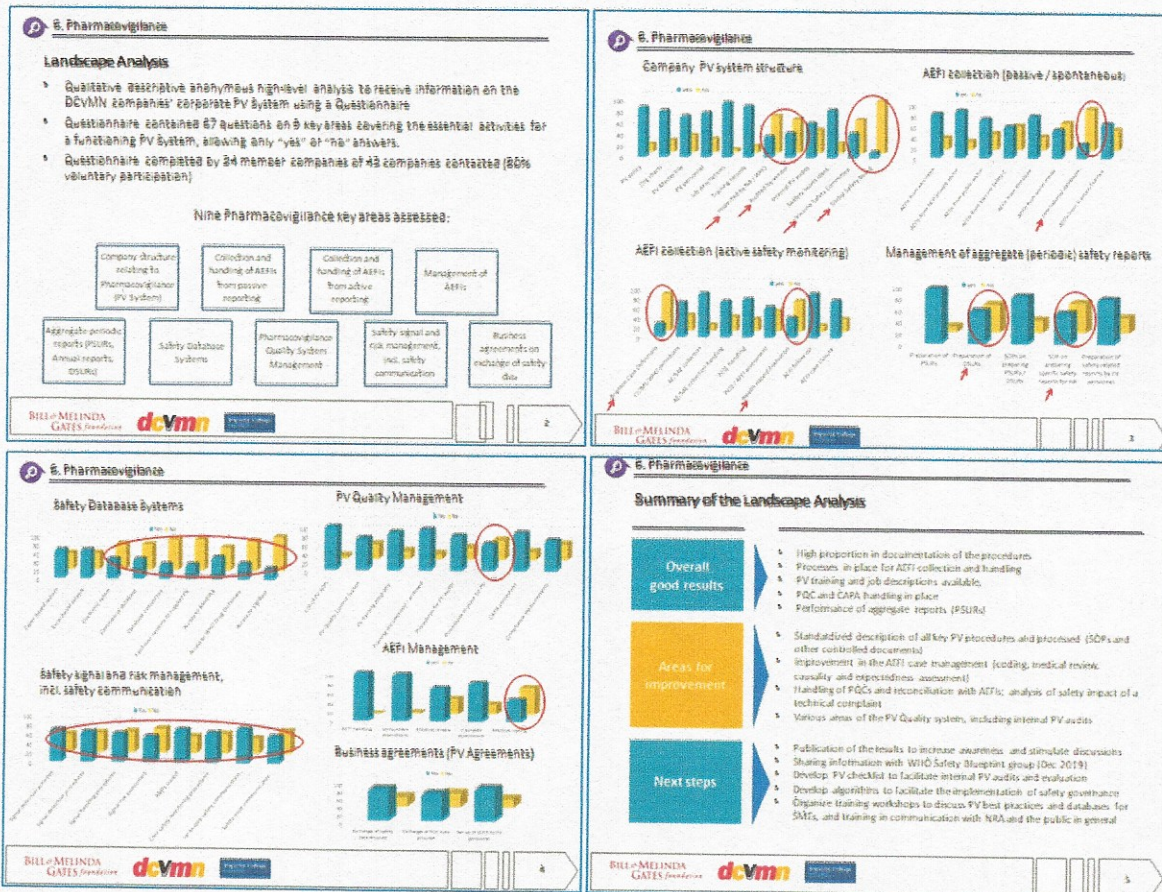
Cf. <https://moodle.dcvmn.net/> : please create an account in order to be able to view and follow the E-learning course. Each WG member should review and achieve a certificate in order to validate the course on behalf of all members. If adequate the course will be disseminated.

The working group shall have the following characteristics:

- Participation at Working Group meetings is voluntary (no honorary paid by DCVMN, only some lodging during such meetings are budgeted).
- WG Members represent their companies and must be qualified in PV, have an active role in PV and at least 2 years working experience in this area.
- the WG shall meet in face to face twice annually, and at least twice by WebEx conference.

The group agreed unanimously that Alexander Precioso, Butantan, would be the Chair of this DCVMN PV WG for the first year. A DRAFT term of reference will be circulated for comments.

It was considered timely to hold the next meeting in March 2020, so to pursue the discussions and expand the group, as possible to have up to 10 DCVMN members actively represented.



Nyon, 9th December 2019

Sonia Pagliusi

Alexander Precioso
Chair of DCVMN Pharmacovigilance Working Group
Approved 28.3.2020