DCVMN
Regulatory Affairs WG

Thursday March 24th 2021

Attendees: Nirav Chokshi, Sebastian Comellas Bernadette Hendrickx, Mic McGoldrick, Sunil Gairola, Chaiti Roy, Julian Jellin, Rajinder Suri, Sivashen Cunden

Apologies: Ye Xu, Ida Nurnaeni, Andrew Wong, Jun Chen, Weidan Huang

Welcome and AOB **NC**

- RAWG Chair Nirav Chokshi (NC) welcomed all members to the WG meeting.
- NC introduced the 5 agenda points that will be discussed in the meeting.
- NC reminded WG that CRP (Agenda Item 2) is crucially important and DCVMN is expected to submit **3 voluntary CRP applications** within the next 6 months.
- Agenda Item 3 will discuss training and skill development which can be applicable to the DCVMN members in CRP, Registration Dossier Development and PACs.

1. Regulatory affairs – Ways of Working **NC**

- NC stated the internal goal for the RAWG for 2022 is establish open collaboration and dialogue within the WG.
- The active participation and knowledge sharing will be essential for achieving the 2022 objectives therefore feedback on topics discussed during meetings can be given during WG meeting or offline, if needed.
- Through the year the RAWG will be sent pre and post meeting surveys (Microsoft Forms) to gain insight on topics, therefore NC asks all members to please promptly complete surveys when distributed.
- Sebastian Comellas (SC) added that increasing the participation is important, and the RAWG leads are aware of differences in experience and language barriers but asks all members to join the conversation.
- NC stated if members find any conversation topic challenging due to language barriers, members can reach out to the DCVMN, before the meeting after receiving the agenda or after the meeting via email if further explanation is needed or if you would like to comment on an item that has been discussed.

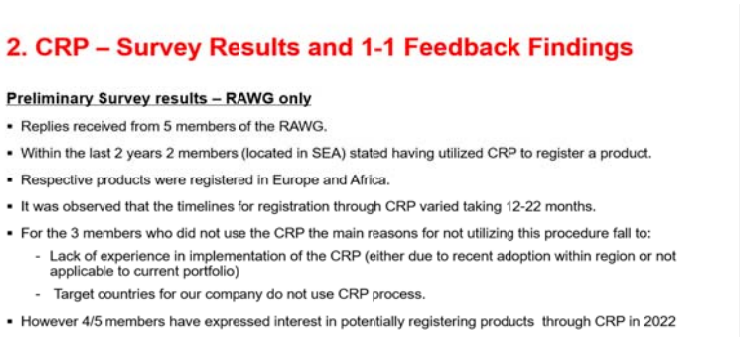
2. Collaborative Review Procedure **NC/All**

Voluntary submission of 3 CRP by September 2022

- NC restated to the WG that as part of the 2022 workplan voluntary submission of 3 CRPs will need to be done by September 2022.
- Approval of the CRPs is not required but the application must be underway.
- This workplan objective is in agreement with PATH and therefore should be taken as priority.
- NC asked all members of the RAWG to notify the DCVMN if there are any plans to submit a CRP in 2022.
- Bernadette Hendrickx (BH) added that RAWG should voice their opinions regarding CRP to understand whether CRP is a priority to manufacturers.
- Rajinder Suri (RS) clarified that RAWG should focus on members who consider CRP a priority and agree upon on a consensus vaccine which CRP can be developed.
- RS suggested that the pros and cons of CRP should be discussed with members who will utilize CRP in a separate meeting.

Summary of regional feedback on CRP procedure from RAWG 1-1 sessions

- NC presented the preliminary findings of the survey which focused on the RAWG to identify those who will submit a CRP in 2022



2. CRP – Survey Results and 1-1 Feedback Findings

Preliminary Survey results – RAWG only

- Replies received from 5 members of the RAWG.
- Within the last 2 years 2 members (located in SEA) stated having utilized CRP to register a product.
- Respective products were registered in Europe and Africa.
- It was observed that the timelines for registration through CRP varied taking 12-22 months.
- For the 3 members who did not use the CRP the main reasons for not utilizing this procedure fall to:
  - Lack of experience in implementation of the CRP (either due to recent adoption within region or not applicable to current portfolio)
  - Target countries for our company do not use CRP process.
- However 4/5 members have expressed interest in potentially registering products through CRP in 2022

- Sivashen Cunden (SC) stated that the survey will be distributed to all DCVMN members as the next step ASAP and query members opinions on the pros and cons on CRP process.
- NC presented the regional findings for CRP noting that the major barriers for adoption of CRP within the WG is inexperience with the process and the lack of PACs harmonization/acknowledgement in the CRP process obliging members to engage with the NRA.
- NC additionally presented the highlighted the disadvantages that were pointed at by members in the survey that need to be considered.
  1. CRP does not take into consideration the PACs
     -If CRP is used any PACs must be reported and approved by the local NRA the product is registered in and cannot be managed through the CRP.
  2. Unclear timelines of product approval through CRP
     - Members have reported shorter registration periods through local NRA
  3. Lack of transparency
     - Once CRP is sent to WHO, manufacturers have no visibility of conversation between HA and WHO so further information cannot be provided
  4. Lack of understanding of CRP process from NRAs
     - Once CRP is sent to WHO, manufacturers have no visibility of conversation between HA and WHO so further information cannot be provided
  5. Perceived Fast tracking
     - New products in demand seem to move through CRP process quicker than older PQ products
- RS suggested to hold a session/workshop on CRP to discuss – challenges, mitigations and solutions with the members who are interested in CRP.
- RS stated that a from the dedicated CRP session a strategy with short-, medium- and long-term goals should be drafted.
- RS suggested that the collected opinions and challenges can be shared at ICDRA/ICMRA.
- Sunil Gairola (SG) in support of a CRP dedicated session with not just RAWG but all members engaged in CRP.
- BH added that a clear picture of CRP needs to be presented to members so that there in a complete understanding of what a CRP submission entails before a CRP session is held.

- NC in agreement and a CRP session will be discussed after the survey has been completed.

3. Development of Regulatory Training **NC**

- NC presented the 3 topics which have been identified that members would like to build upon via trainings – webinars, workshops and e-modules:
  1. **CRP process and procedures**
     - ✓ Identifying the applicability of CRP
     - ✓ Essential elements of a registration system
     - ✓ Implementing the CRP
  2. **Registration dossier development**
     - ✓ Good practice and reporting from regulatory view point
     - ✓ Emphasis on Preclinical, Clinical data reporting and non-clinical
  3. **Post approval change management**
     - ✓ Building/improving the on the current DCVMN moodle course

- NC asked RAWG for approval and comments on the suggested topics.
- As no disapproval was noted training on these 3 topics will be moved forward.

4. CEPI Update **BH**

- Meeting with CEPI RA Head (Adam Hacker) and Head of Clinical (Jacob Cramer)
- CEPI and DCVMN common RA collaborative goals still to be identified.
- CEPI goal extends further than registration/submission and therefore aligning on the topics needs to well defined.
- A secondary meeting will be held with PV and RA leads to discuss the needs and strategy with CEPI.

5. Member Update & Closing remarks **All**

- Mic McGoldrick (MM) presented IFPMA collaboration with CEPI and DCVMN (Mr Adriansjah – Biofarma) in which the goal is to prepare templates for comparability and process validation to create a guide for the next pandemic and demonstrate that platform technologies can be leveraged.
- MM asked that if any members are interested in joining the initiative that should reach out to Mr Adriansjah
- MM followed by presenting the IFPMA strategic engagement on PACs for targeted countries (Presentation previously distributed) which aims to establish WG in 8 identified countries to address the various issues with PACs and engage with the relevant agencies.
- RS replied that Mr Adriansjah will be contacting CEPI with the 2 nominations for the DCVMN.

Actions

- ❖ CRP survey to be distributed to the whole DCVMN membership.
- ❖ CRP session a strategy with short-, medium- and long-term goals should be drafted.
- ❖ CRP process and procedures training to be discussed and module outline drafted
- ❖ WG to review current DCVMN moodle “Post approval change management” course to discuss needed improvements in next meeting.

Notes taken by SC.

Signed