DCVMN
Regulatory Affairs WG

January 11th 2022

Attendees: Andrew Wong, Ana Basso, Bernadette Hendrickx, Laura Viviani, Lokender, Mic McGoldrick, Nirav Chokshi, Prerna Kumar, Rajinder Suri, Samir Desai, Sebastian Comellas, Shubhangi Ghadge, Sivashen Cunden, Sonia Pagliusi, Sunil Gairola, Venkataraman Hariharan

Apologies: Abdul Aziz Al Mutairi, Norbert De Clercq, Thierry Gastineau, Lorenz Scheppler, Jacqueline Dias, Paula Barbosa, Qiaoruo Xiong, Roh Hyunsuk, Srinivas Kosaraju, Ida Nurnaeni, Monique Collaço de Moraes Stávale, Ye Xu, Chaiti Roy, Julian Jellin, Jun Chen, Weidan Huang

Welcome and AOB

- DCVMN CEO Rajinder Suri (RS) welcomed all attendees and thanked Samir Desai (SD) and Ida Nurnaeni (IN) for their engagement as Chair and Co-Chair since the formation of the RAWG.
- Samir Desai (SD) addressed the RAWG and thanked all for their work and contribution and handed over to the new RAWG Chair Nirav Chokshi (NC)
- Nirav Chokshi - Senior General Manager at Cadila Healthcare Limited. NC obtained Master's degree in Pharmaceutical Technology and holds a graduate certificate in Health product regulations specializing in Biotherapeutics, Biosimilars and Pharmacovigilance. He also has 22 years of industry experience ranging from technical application to Global Regulatory Submissions and Quality assurance and compliance.
- Sebastian Comellas (SC) new 2022 RAWG Co-Chair provided brief introduction of background as Head Pharmacist Sinerguim Biotech.

1.Industry Challenges and main objectives for 2022 — BH

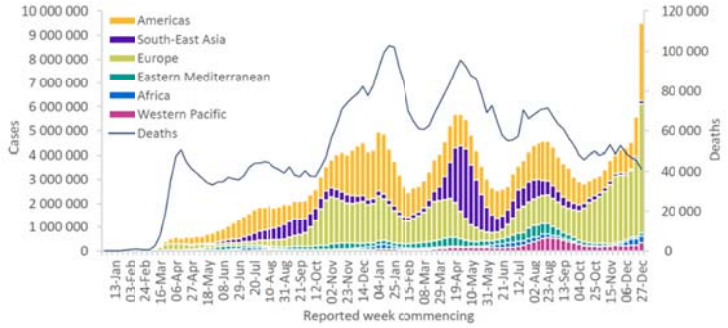
- BH stated that for 2022 2 priority topics have been identified
  1. COVID 19
  - Addressing emerging variants
  - Required regulatory change to push forward in 2022
  - Liaise with Covid committee to align on priorities for 2022
  - Management of the huge number of projects ongoing

  2. Collaborative Registration Procedure
  - Priority for the DCVMN membership for 2022
  - Feedback and learnings from members on CRP procedure

- BH presented the COVID19 challenges, currently there are 137 vaccines in clinical development – 19 in phase 3 (Phase 1-Phase 4) for COVID19 and 194 vaccines are in the clinical stage.
- Mic McGoldrick (MMG) stated that of the majority of products in the development a large portion are not being developed by vaccine manufacturers and instead are developed by small institutes releasing new vaccines for the first time. Therefore, unlikely to impact the vaccines with the largest market share. A larger concern is the supply, distribution and manufacturing of vaccines outside of COVID19 vaccines.
- NC further added that majority of the vaccines in development are mRNA platforms and have stringent storage conditions. Looking at local manufacturing of these approved vaccines and site-shift might be more prudent to focus on by the RAWG.
- Andrew Wong (AW) also pointed that of the 137 vaccines in development it is unclear how many will be approved and make it out of the pipeline.
- AW stated that the research COVID and investment will most likely drive the next generation of vaccines.

- BH provided update on Omnicron and epidemiology and that there are surges in infection as expected. Additionally how the variant will effect the vaccine pipeline is still to be determined.

Figure 1. COVID-19 cases reported weekly by WHO Region, and global deaths, as of 2 January 2022**



**See *Annex 1: Data, table, and figure notes*

Collaborative registration procedures (CRP)

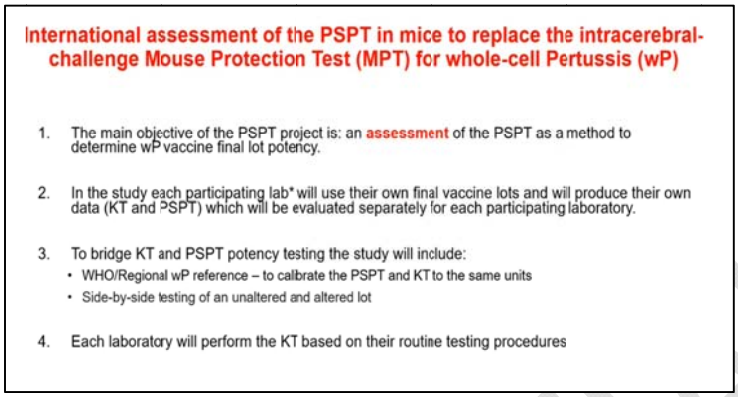
- BH stated that CRP is a crucial topic for all DCVMN members and would like to have a clear view of the experience from the manufacturers who have worked on/considered implementing a CRP.
- The CRP experiences shared will be taken to and shared with the WHO (Rogerio Gasper) for consideration to help improve the quality of the CRPs and to improve the procedure.
- NRAs will play a significant role in adoption of CRP as local regulation will also have to be considered in the experiences shared. Currently 45 NRAS and 1 Regional economic community has joined efforts in CRP initiatives.

- Pushing forward with the efforts in CRP may positively impact the timelines for registration and thereby have an economic impact for members.
- NC added that a hinderance to CRP is the Post Approval Change Management as minor changes for a product registered via CRP in multiple countries is at the discretion of the local NRA. Therefore, harmonization of PAC and CRP procedure is a topic of interest for the industry.

- SP stated that there 2 forms of CRP procedure – the DCVMN should focus on the PQ based form.
- MMG added that a disadvantage of the CRP process is that it is not accepted in many countries and does not take the median number of 90 days (which relates more to small molecules in CRP process) stated by the WHO. Rather for vaccine products the registration via CRP takes longer
- Furthermore, once accepted, the PAC that may need to be made may outweigh the expedited timeline of the CRP as the NRA will have to be engaged.
- Venkataraman Hariharan (VH) commented that within Bharat Biotech, while there has been a delay, there have been products that have been registered through the CRP even in the pandemic.
- VH added that, from Bharat Biotech's perspective, at a country level there is a misunderstanding as to the benefits of CRP and a majority of the questions that come from the NRAs when using CRP can be answered by the WHO i.e., if a product is prequalified etc. This lack of communication between the parties involved may be the cause of the long process time of CRP.
- Shubhangi Ghadge (ShG) commented that within SII registration for products through CRP that have received WHO-PQ 5 years ago has been challenging. The HA was aware and willing to use CRP but due to some challenges with WHO the HA advised SII to register using the country specific procedure.
- ShG added during the pandemic only 1 newly WHO-PQ product was accepted through CRP the older WHO-PQ products were unsuccessful
- ShG added that for manufacturers there is a lack transparency on the process after it is handed over to the HA and WHO. If there is more transparency the potential challenges can be addressed and this should be discussed with WHO.
- Sunil Gairola (SG) queried if a factor affecting the acceptance of the CRP is the need of the vaccine in the country i.e., if a new WHO-PQ product is needed within a certain market is it more likely to be successful in receiving approval through CRP than old WHO-PQ products that are not in demand.

2. 3Rs Update **LV &SC**

- Laura Viviani updated the RAWG that the 3RWG has undergone restructuring and is now composed of over 20 member representatives from all major geographical locations.
- The goal of the 3R WG is to implement as many 3R opportunities as possible that are accepted by the WHO.
- However, implementing 3R changes is connected with the PAC which is under the purview of RAWG and therefore working closely together is important.
- LV handed to Sivashen Cunden (SC) to update group on current 3R WG activities
- SC briefly described the major 3R project the "International assessment of the Pertussis Serological Potency Test to replace the intracerebral mouse protection test"



- The project is funded by NIIMBL and has now been granted a no cost extension of 6 months within which activities have been determined that would benefit from RAWG member engagement such as:
    - Scientific paper to be published in Biologicals or Vaccines
    - Technical support for planning full validation studies
    - Content creation for external communication
    - Final project workshop where participants and QC/RA representees can interact
- SC further provided the update regarding the 3R activities and discussion on the following and asked the RAWG to keep in mind possible synergies:
    - Abnormal Toxicity Test
    - Deletion of Specific Toxicity Test for Tetanus
    - Deletion of the pertussis irreversibility test and replacement of HIST with CHO-cell assays
    - Next Generation Sequencing (adventitious viruses/agents)
    - Pyrogenicity Testing

3. Closing Remarks

- NC stated as this meeting is a warm-up to the new year new members should try to maintain contact to share feedback on topics discussed and be prepared to engage more in the upcoming meetings
- NC called for the creation of a RAWG Whatsapp group so updates can be given more readily.
- NC and RS voiced that the priorities and objectives for the RAWG should be set ASAP so movement can be made and deliverables met at the end of year.

Actions

- ❖ WG members to identify new priorities within topics of CRP, PACs, COVID and WHO.
- ❖ DCVMN (SC) to set up all meeting for 2022
- ❖ RAWG WhatsApp group to be set up for communications

Notes taken by SC.

Signed