**Participants:** Sebastian Comellas (SC)-Sinergium, Sunil Tiwari (ST)-Indian Immunolgical, Clayton Lage (CL)-Bio-Manguinos), Cleber Gomez (CG)-Instituto Butantan, Wu Cong (WC)-CNBG, Chaiti Roy (CR)-Bharat Biotech, Subhodeep Chakraborty (SCh)-Zydus, Mic McGoldrick (MM)-IFPMA, Rajinder Suri (RS)-DCVMN, Sonia Villaseñor (SV)-DCVMN. **Meeting started at 12:00 pm CET and adjourned at 12:54 pm CET.**

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RS welcomed the participants of the new WG saying that the Regulatory WG will be one of the most critical WG in DCVMN as many challenges are coming up on the Regulatory front. We are working with WHO to see that whatever regulatory challenges and issues are being faced by the manufacturers should be given a priority. Therefore, this group is expected to define the challenges, issues and critical areas where the attention wishes to be focused as a team. Bring out real practical issues, which need attention and list them in order of what the group wants to achieve.

SC introduced himself and initiated a round of introductions with all the participants.
SC made a summary of the topics that the Reg WG worked upon in 2022. The main topic that the group worked on was the effective use of CRP. Last year the WG had a meeting with WHO to improve the situation regarding the use of the procedure. RS shared the minutes of the meeting held with WHO in Sept. 2022 with the new members of the WG. RS said that the main topic discussed in that meeting is that WHO was planning to have 6 CRP workshops in the first half of 2023. RS is discussing with them as to when and where these will take place.
SC said that in order to move forward with this topic, we need members with experience with the use of this procedure and emphasized that participation from the WG members is crucial in order to advance. CL said that in his company, some colleagues are working with it for some vaccines.

SC mentioned that last year the Reg WG made a workshop on Post Approval Changes (PAC). They made a short review about the Technical Report Series TRS-993 and discussed about a paper that the WG published in 2020 where they mapped the situation regarding the lack of harmonization on PAC. During that Workshop the group agreed to work with IFPMA to issue a new version of the TRS-993 to propose to WHO. MM added that there had been many discussions and right now WHO is overwhelmed and has not come back on this initiative, so even if they show interest, they have not gotten any traction on that. He is meeting next week with the DG team to find if there are any updates. SC will be sharing the ppt for the group to understand deeply this proposal inviting the team to push on this topic.

SC then mentioned that they had some discussions with CEPI to identify topics to work together on regulatory. Although CEPI focuses mainly on pandemic vaccines and not all manufacturers have this priority, so not many advances were made. RS added that DCVMN has shared a proposal to CEPI and they are reviewing it, but are also overwhelmed with work. RS recently met the head of regulatory at CEPI during the World Vaccine Congress. CEPI has certain disease segments where today most of DCVMN companies are not involved; so RS invited the WG to find some common ground and harmonized areas where we can work together. This could be in two ways, one between CEPI-DCVMN and other CEPI-IFPMA. RS will remind CEPI team to revert and invited the team to go through the notes shared from the last meeting and take up actions required as a priority for this group to debate and come with a consensus to move forward.

SC then shared some ideas of topics that the WG could work on this year:
1. Continue the work with CRP and interaction with WHO.

2. PAC together with IFPMA
3. Publish a "post approval change management" training on DCVMN Moodle. Taking as a base the paper published in 2020 and the workshop held in November. The current course available on PAC was made by Merck and although it is good, it is very short.
4. Writing a paper on a regulatory topic to send for publication. The group could work together with IFPMA.

RS emphasized that the group should work on real challenges that manufacturers are facing on an individual basis and discussed as a group to then be brought to WHO. SC reminded that during the workshop held last year, Thierry suggested WHO to make a training to NRAs to improve their skills in PACs. SC added that this is one of the most important issues they are facing at his company due to the lack of harmonization in this regard. MM added that this has been discussed in several industry groups, but the main problem is being able to implement those changes, especially when trying to file in different countries with different requirements. A different tact could be perhaps if a change has been approved by an SRA that is a reference country, that would allow a lot more reliance and other may feel more comfortable in implementing it. He said that coming from DCVMN this proposal may be more influential to the agencies that are having problems.

CG said that in Brazil ANVISA recently published a legislation for reliance on other NRAs but created many rules to accept these agencies and it causes confusion, so ANVISA postponed the implementation of this legislation. This example may be used to discuss about this point. CL added that is likely to accept documents from ICH agencies but requests to see the full dossier, which takes time, and they don't have the capacity to perform those full reviews, so they have a huge delay. SC said that for a decade ANMAT and ANVISA have been working together to harmonize different aspects of regulation, but results were obtained in very few topics like inspections.

SC invited the participants to propose other topics for the WG to work on. SCh mentioned CTD is a submission that WHO is accepting for PQ and the section 32P2 contains the requirements for pharmaceutical development, so when referring to the ICH, it lacks specific sections for vaccines and their requirements. Moreover, the CTD maintenance; There should be a mechanism wherein all the changes, if they impact the CTD section, and during the time of submission, updated versions of the dossier can be handled. These are the kinds of things to propose to WHO.
Regarding reliance and post approval changes, SCh said that there are still gaps in categorization of variations. Until we all speak the same language, it will be very challenging to have a reliance. Categorization should also be elaborated so the guideline tells when there is a variation, if it should be filed or not.
CG also suggested the group to discuss on real world data, which can be used for approval licenses.
SC then offered to make a proposal with the topics for the group to start working on. The group can have a meeting every 2 months or if the group considers it necessary, every month. RS advised it to be crisp and clear.
SV shared that for the Moodle platform, it is important for the WG to focus on the content of a ppt presentation of approx. 100 slides and DCVMN will take care of the technical issues.
SC thanked the participants and closed the session.

**Sebastian Comellas**
**Chair of the Regulatory WG**

Sebastian Comellas
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