Participants: Sebastian Comellas (SC)-Sinergium, Cleber Gomez (CG)-Instituto Butantan, Wu Cong (WC)-CNBG, Chaiti Roy (CR)-Bharat Biotech, Monique Cruz (MC)- Bio-Manguinhos, Subhodeep Chakraborty (SCh)-Zydus, Varma Bhupathiraju (VB)- Biological E, Lyne Le Palaire (LL)- IFPMA, Mic McGoldrick (MM)-IFPMA, Rajinder Suri (RS)-DCVMN, Sonia Villaseñor (SV)-DCVMN. **Meeting started at 12:00 pm CET and adjourned at 13:01 pm CET.**

SC welcomed the new member of the Reg WG, MC and gave the floor for her to introduce herself. SC mentioned that in the coming weeks he will be sharing the draft of the training course to be included in the Moodle platform on post-approval change management. It is important for the different manufacturers to share their experience in different countries.

SC made some proposals of topics for the WG to work during the year and to publish a paper.

1. CRP (Collaborative Registration Procedure)
2. Post approval changes (PAS)
3. Real World data
4. ICH CTD and lack of specific sections for vaccines
5. Reliance and post approval changes

Real World Data. CG said some NRAs are starting to discuss about it. ANVISA is evaluating for some kind of submissions. The WG could raise the regulatory background around this topic. CG suggested to make a comparison between the situation in Brazil and Latin America.

CRP (Collaborative Registration Procedure). VB mentioned that at Bio E they have submitted several applications and succeeded in some of them, but it is not as effective as expected. He offered to give a short update on this in the next meeting. WHO is considering only for the recent vaccines that are PQ because of the lack of full database of the vaccines PQ several years ago.

SCh mentioned that ICH CTD on the developing part mostly talks about biologics and small molecules, so it is not applicable for vaccines. So, when we look in this harmonized platform on how the things should be for vaccines, there is continuous shift to be made in terms of WHO TRS and implementing or adopting few of the things of the ICH. He shared he attended a workshop with WHO on specifications, and there is some expectation on what needs to be considered in clinical development to be taken in account while filling the CTD in terms of specifications. There should be a complete path on how the section should look, so that the PQ team, when we approach different countries.

Regarding Post-approval changes, SCh shared that some countries do not have specific vaccinology guidance. There are no harmonized terms. We could propose harmonization or detailed changes to be listed and proposing a new identified variation category. VB added that WHO has two guidelines for the variations of vaccines; one is TRS 993 Annex 4 and the other is variations to PQ vaccines. It would be good if WHO can adopt these guidelines also with the Regulatory Authorities as a guidance.

MM mentioned that he worked for the guidance of post-approval changes to vaccine medicine, and that one was for regulators to adopt. The changes to a PQ vaccine are what the manufacturer would submit to WHO to have them approve the changes, not necessarily what a regulatory agency would use. They could keep pushing the agencies towards the 2015 guidance.

SC commented that the WG should continue working on post-approval changes, but the greatest challenge is what can manufacturers do to make the NRAs adopt these guidelines.

MM said that IFMPA has been working with WHO to try to update that to get it closer to the EMA guidelines to make it easier for post-approval change reliance. Some regions like Africa and ASEAN are working towards harmonized guidelines in their regions.

Regarding the CTD, MM mentioned that the IFPMA created one dossier that is the one they try to send everywhere. They don't change it for vaccines. MM asked if some member of DCVMN is part of ICH; but DCVMN has no representative in ICH. MM said that they are redoing that guidance for CTD to try to make it work better. This could take a couple of years and try to make it adopted by different agencies. VB suggested to create a checklist for the current version for all the CTD elements and include columns for the different kind of products, and mark whether it is applicable or not. MM does not think they would do that since they are now working on redoing the guidelines.

MM gave feedback on what IFPMA is working on; they are pushing for reliance and post-approval changes. They put together a reliance toolkit. Reliance should be used for the entire lifecycle from clinical to post-approval changes. He could share some of the documents they have issued. Or they could invite some of the members to the Reliance Taskforce.

MM also mentioned that CEPI is working on templates for process validation and for comparability, of which Adriansjah Azhari is part of the team. They are close to finalize a draft to be sent out in September to 6 agencies globally to get their feedback (FDA, EMA, Health Canada, ANVISA, ECGI and Singapore). He would like to invite SC to talk to Olga and MM if there is a way to get feedback with ANVISA and ECGI from DCVMN members or if we can get them to work with the other agencies as a group. This is more for pandemic and emergency situations for the moment given, but could later be used for regular vaccines. SC mentioned that he already made a proposal to Olga to go mainly through ANVISA and ANMAT. Once the draft is ready the idea is to share it with other DCVMN members for their inputs. Olga, MM and SC will meet to find out how to make this initial approach to the agencies.

SC invited the WG members to vote for the topic for the WG to work this year. Based on the votes received, the group decided to work on **post-approval changes** as the first priority.

SC said the next steps is to work and make a proposal for a publication, maybe in collaboration with IFPMA. Also, a workshop would be useful on the second half of the year. Last year the WG made a workshop on post-approval changes.
MM said IFPMA is not currently planning of publishing any paper. From the COVAX manufacturing team they are working on tiers and pandemic preparedness, but in post-approval changes there have already been a lot of scattered papers, once the group defines where the problems are where it wants to put a paper on, we can look if a paper already exists on that or if it is something unique. It is best if it is something unique.
Sch shared an idea also to work on patient-centric specification and the design specs for vaccine, taking the upper and lower limits in terms of clinical aspect and then relating the same to the product life cycle; and then control the design specs of the vaccine.

Sebastian Comellas
Chair of the Regulatory WG

Sebastian Comellas
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