

Participants:

Berniece Warley (BW), Lingjiang Yang (LY) - Chajr, Rachel Park (RP) Taufik Wilmansyah (TW), Vishnucharan Datta (VD), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Sonia Villaseñor (SV).

Meeting started at 12h05 and finished at 13h30.

LY acknowledged the work done by TW, SJ and SP on writing up the Bio Farma primary packaging barcoding case study, noting that the current meeting was called as a follow-on to review the primary packaging barcoding draft proposal which had been shared with WG members. She mentioned that in several meetings, such as VIPS and SAGE, the trend of global stakeholders was moving towards barcoding on primary packaging.

SJ acknowledged TW and Bio Farma for the traceability pilot on barcoding of primary packaging on vials, recognizing ampoules were more difficult due to a much smaller space for labelling. SJ went through the draft proposal point by point, indicating that the global immunization community is currently fostering the barcoding of primary packaging in the context of Covid-19 vaccines.

The draft proposal aims to create a consortium of members and provide some initial support for up to 5 members for traceability pilots. It focuses on traceability from manufacturer to the individual being vaccinated, in line with systems in place in countries. The design is to add 2D data matrix barcodes to vials and establish SOPs on ensuring the accuracy of the labelling.

On point 1, in the Method section of the draft proposal, SP asked about the indicators for performance, whether time, the number of vaccine vials supplied or other indicators, so that manufacturers can use the same metrics. SJ suggested accuracy, related to readability, as a main metric of performance. Another is whether it is better than manual reading and is time saving. LY added the feasibility of implementing a GS1 2D barcode on the primary packaging of the vaccine, vial or pre-filled syringe and whether the right information is included and can be read, recorded and traced. She suggested a pilot distribution study in one country or area to show that traceability works, indicating there should be a system to manage the information. TW agreed with LY. VD said performance show it is possible to embed all the information required into the data matrix barcode, be able to get this information in a small space on the vial label and for the end customer to be able to scan it and see all the relevant information. TW indicated it is important to translate the data needed into the barcode and if this is readable the tracking of the vaccine would be feasible.

Referring to point 2 on the proposal's Method, SP asked if the 2D barcode could be the QR barcode. LY, SJ and VR clarified that it is not QR. The 2D data matrix barcode is used, which is a more generic standard and recommended in the health sector. No comments were made on the other points of the draft proposal sections on Method and Feasibility.

On DCVMN support, SJ indicated the invitation to join the consortium will be for any member considering the implementation of barcoding primary packaging and agreeing to share their experience. It is proposed to allocate 100k USD to provide consulting support for up to 5 manufacturers that join the consortium and are willing to pilot primary packaging barcoding. This will enable them to develop plans and decide on feasibility. Regarding the selection criteria on which companies to support, these may include: already using GS1, ability to use the data matrix barcode, supplying at a nationally or internationally scale, having WHO PQ and whether countries are able to scan barcodes and track vaccines at the point of vaccination.

SP noted the first point for the WG to consider is the concept of creating a consortium of manufacturers that would agree to follow the same points 1-8 under Method in the draft proposal. Manufacturers would work together using this scheme to test the data matrix barcode on primary containers and share

information among each other over a period during the design and piloting stages. Sharing information on how to go forward and solve issues jointly will be faster than working in isolation. Consortium participants will need to allocate their own resources for implementing the pilot, but first, members will be invited to join the consortium, and then select among them for receiving DCVMN support.

LY asked for a better definition of consortium; whether following SOPs and sharing experience is enough? SP invited the WG to visit the PSPT consortium webpage (cf. <https://www.dcvmn.org/-PSPT-consortium-57->). First a call for volunteers is made to all DCVMN members. Manufacturers expressing interest will sign an agreement with DCVMN, not with each other as it is not a partnership. They work in a coordinated way but individually and separately in doing the same things and at the same time. They commit to share all information related to the piloting, excluding any confidential information. Consortium is the word used for this individual working coordinated by DCVMN. Information will be shared with each other at monthly meetings.

Funds will be used for sponsoring expert consultants on barcoding to help each manufacturer on site on how to implement the practical aspects of labelling, printing, scanning and required modifications to packaging lines. Each manufacturer will have an expert consultant in their country identified by DCVMN.

LY suggested expanding this work to achieve a wider impact to all DCVMN members. SP suggested that the consortium should have representation from at least 3 continents. Relevant information will be drafted as a report similar to the Bio Farma case study and then circulated and presented for others to follow. After an initial 5 collaborating companies, another 3 to 5 might be included next year. LY suggested to modify the proposal, with the intention to spread the experience widely and commit to share with others. LY asked to consider that the experts supporting consortium manufacturers allocate 1 or 2 days during the contracting period to making webinars in their native language for the members of the respective region. SP said this could be done in the course of or after the project, after working some time with the participating manufacturers to illustrate different views. LY proposed to include this requirement in the experts' contracts.

SP suggested rewording this draft proposal, sharing it again to the WG for further comments and then circulating it to all DCVMN members to elicit expressions of interest. In parallel, SJ has been exploring experts' availability in the countries where members are located, adding that all these countries have GS1 offices and provide consultancy services with the exception of Bangladesh.

SJ asked for clarification whether the consortium is only for those members who are willing to go ahead with piloting or whether any member can join the consortium. SP confirmed that only those who are committed to piloting barcoding on primary packaging would join the consortium because it will take time to participate in meetings, workshops, and exchanges in terms of communication and data. Observers, such as the expert consultants, may be considered for specific meetings as needed.

RP agreed with what had been discussed. EuBiologics is working on barcoding of secondary packaging on one product, since it is a requirement from UNICEF. BW also indicated the potential interest of Biovac in piloting these traceability standards. SJ agreed to re-edit the proposal and circulate it again to the WG. SP suggested, once it is re-edited and has the agreement of the group, it would be presented to the Advisory Committee (AC). The Committee had agreed to the use of the funds for this project but have not seen the project proposal. It can be circulated by email to speed up the process, as the next meeting of the AC will be end November or beginning December. LY asked if it is possible to get the approval before the AGM to announce it there. SP said she can try, but they need about one week to review.

SP reminded a point on the meeting agenda was a proposal of selection of new chair of the group. LY has been an excellent Chair but maybe too busy with many things and should have the opportunity to continue

or recommend another chair be selected. LY expressed a desire to continue, but if the group wished to select another one, she would support. It was agreed to renew her as Chairman, and call for volunteers to select a Co-chair in case LY is not available. LY suggested sending an email to invite volunteers, ideally someone already part of this group; if there is no volunteer, an invite could be sent to potential volunteers among all members. In the next meeting, the selection of the Co-chair will be made.

Action points:

1. re-editing of the proposal to include points discussed (SJ) for further comments from the WG
2. seek volunteers for the position of Co-Chair (next meeting)

Nyon, October 14, 2020

Notes by Sonia Villasenor, edited by Sonia Pagliusi and Stephen Jarrett

Approved: Lingjiang Yang, Chair
Chengdu



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