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Developing Countries Vaccine Manufacturers Network

DCVMN Vaccine Supply Chain Working Group
Traceability Consortium 5th Meeting
23 March 2022
Zoom

Participants:
Lingjiang Yang (LY) - Chair, Brian Taliesin (BT), David Kaslow (DK), Claudio Guzzo (CG), Marina Aulet (MA), Huilin (Linda) Yu (HY), Kamesh Chimalakonda (KC), Rajinder Suri (RS), Taufik Wilmansyah (TW), Ulrike Kreysa (UK), Ricardo Cyster (RC), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Sonia Villaseñor (SV); **Excused:** KR Krishnamurthy (KR).
Meeting started at 12h00 and finished at 13h00.

LY opened the meeting welcoming the consortium members and the independent advisers attending, indicating that this was the fifth meeting of the Traceability Consortium to view progress being made in the traceability pilots.

HY briefly updated on progress with the Innovax barcoding of **secondary packaging** of its WHO-prequalified bivalent HPV vaccine, which includes serialization. The packaging line and software system have been installed and validation will be completed in March; SOP revisions will follow in April. They will be ready for implementing a full batch run starting in July, depending on orders being received for their vaccine.

KC provided details on the traceability pilot at Biological E for the barcoding of **primary packaging**, without serialization. They are implementing barcoding on a 15 ml, 20-dose, vial of their COVID-19 vaccine for the India market, on a label 62x26mm. This follows their successful implementation of barcoding on secondary and tertiary packaging. So far, the carton coding machine has been installed and IQ completed. The labeling machine is under purchase order but not yet delivered, which is delaying the pilot. URL, their GS1-certified solution provider has completed the appropriate training. Biological E is aiming at completion of the pilot by mid-year. DK indicated that he understood that each level of packaging had a different GTIN and KC confirmed that the primary level was designated as 01 in the GTIN, secondary or intermediate level as 02 and tertiary as 05. UK confirmed that there should be 3 different codes to be able to differentiate the level of packaging. LY said it was clear to her that this was the case. SJ enquired as to whether a VVM, not currently required for the Indian market, would also fit on the label and KC confirmed that it would for international sales.

LY updated the work of the Chengdu Institute of Biological Products (CNBG-Sinopharm) on the traceability pilot for its WHO-prequalified 2ml. Japanese Encephalitis (JE) vaccine, packed in 10 vials to a box, which it supplies to UNICEF. The pilot is implementing the barcoding of **secondary packaging** with serialization. She clarified that the expiry date format on the code had been confirmed by UNICEF as MM.YYYY. Their target date of completion is mid-April, as there had been some delay in the receipt of equipment (received early March). The upgrading and installation of the packaging line has been done with needed adjustments underway. The equipment engineers are working through March in order to commission the equipment, with finalization of SOPs. Current planning is for training to be completed by 10 April, validation by 15 April and ready-for-use a day later. In this way, the Institute will be ready for supply to UNICEF. LY indicated that Minze-Shanghai are staying on site through implementation, with a final date yet to be determined. RS suggested that Minze-Shanghai should stay there for as long as necessary.

Bharat Biotech were not participating in the meeting and RS suggested they be asked to provide a written update on their pilot for the barcoding of **primary packaging** in order to share with all the participants.

MA indicated that there was no update on the Synergium pilot from the last meeting and that validation of the Verifarma software was expected by May/June in their barcoding of **secondary packaging**. SJ indicated to the meeting participants that Synergium had indicated to him a potential move to the barcoding of primary packaging in the next two years and he had told Synergium that if they needed to carry out a feasibility analysis for this during the 2022, this may be an initiative that DCVMN could consider supporting in the future.

TW confirmed that Bio Farma had fully implemented barcoding on **primary packaging** for the imported Covid-19 vaccines it packages, as presented in earlier consortium meetings. The next stage will be to replicate this process on oral polio and bacterial vaccines. Regarding the challenges in nationwide implementation of the barcoding of primary packaging, TW indicated that the main challenges related to the ability and response of users (health workers in the public health system, recognizing there were still some gaps in compliance.

RS highlighted the progress of the pilots, suggesting it would be helpful to have company information on the pilots a day before the meeting. LY agreed that this would be helpful and also indicated the significant progress that had been achieved with the plots.

SJ in summary highlighted that the pilots were on schedule to meet the June deadline of the consortium, with 3 pilots focused on primary packaging and 3 on secondary packaging. The next meeting would be the opportunity to fully assess the experience of the pilots leading to both a report and from there a peer-reviewed publication. Consideration might be given to having a face-to-face meeting for this assessment but LY indicated that Chinese participants would be unable to travel internationally; RS indicated a hybrid meeting might be possible. In answer to LY enquiring as to the next stage of work after June, SJ confirmed that both Innovax and Synergium were potentially interested in the barcoding of primary packaging, which DCVMN could consider supporting. At the same time, an integrated warehouse system innovation is being pursued; currently a call for proposals has been issued and circulated to all DCVMN members on 17 March, which will indicate the interest of members in this innovation by 30th April 2022.

In further discussion, DK asked about the way knowledge would be used and how to train other companies. SJ indicated the assessment report would be available to members and to the public at large, noting the prominent role of GS1 solution providers in providing training. SP suggested the possibility of putting together an e-learning module based on slides describing and depicting the experience of the pilots. UK considered the pilots to be very positive and encouraged the issue of a peer-reviewed paper. She felt that these barcoding initiatives gave a competitive advantage to manufacturers, and recognized the leading work in the barcoding of primary packaging. DK felt it would be important to survey the impact at end-users (Ministries of Health) in the use of barcoding; he suggested a focus also on the value added and improvements secured through traceability. LY indicated that UNICEF had already put out to tender a call for consultants to establish a Global Trust Repository for monitoring the implementation of national traceability systems, which will be connected to manufacturers in the supply of vaccines. RS said the value of traceability would be the link to reporting on adverse events, also to tackling the increasing problem of counterfeit vaccines. UK indicated it was important to show companies are ready with traceability solutions, citing Nigeria which has started a traceability system and needs barcoded products. She also reminded the participants that the barcoding of primary packaging was a priority of international immunization stakeholders. LY did indicate though the challenge of barcoding small-size vials.

LY closed the meeting thanking consortium members for their inputs and noting the overall progress. It was agreed that the next meeting of the consortium will be scheduled for May/June.

Notes by Steve Jarrett
23 March 2022

Lingjiang Yang
Chair of the Supply Chain Working Group