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Developing Countries Vaccine Manufacturers Network

DCVMN Vaccine Supply Chain Working Group
Traceability Consortium 3rd Meeting
10 November 2021
Webex

Participants:
Lingjiang Yang (LY) - Chair, Analia Acebal (AA), Claudio Guzzo (CG), Ganapathi Indukuri (GI), Kamesh Chimalakonda (KC), KR Krishnamurthy (KR), Rajinder Suri (RS), Taufik Wilmansyah (TW), Yudha Bramanti (YB), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Sonia Villaseñor (SV); **Excused:** Huilin (Linda) Yu (HY).
Meeting started at 12h00 and finished at 13h35.

LY opened the meeting welcoming the consortium members.

SJ indicated that HY from Innovax was not able to attend but had provided one or two points, noting that the Innovax bivalent HPV vaccine had recently been pre-qualified by WHO. The Innovax traceability pilot for barcoding on secondary packaging had recently been delayed due to the COVID-19 pandemic and was now scheduled to be completed mid-January. IQ is currently underway and the pilot is well on its way to meeting the UNICEF barcoding requirements on secondary and tertiary packaging.

KC introduced the work being completed at BiologicalE. The company, which has had a GS1 membership since 2012, has fully completed barcoding with serialization on secondary and tertiary packaging. The pilot is now looking at the barcoding on primary packaging, having selected their largest 15ml, 20-dose to include the GTIN, batch number and expiry date. Serialization at this level would be explored in a second phase of the pilot. They now have a focus on their COVID-19 vaccine. Their consultants, supported by DCVMN, are starting shortly looking at different options in terms of label design. The timeline for the delivery of equipment, which includes an autowinder, printer and camera, is 3 months and BiologicalE expects to be trialing their primary packaging barcoding next March with a view to sales by next May. SJ asked if the label would include a VVM, but this as yet has not been a requirement for the COVID-19 vaccines.

KR introduced progress in Bharat Biotech, which to date has focused on the barcoding of secondary packaging as required by the Government of India for exports and in order to meet the UNICEF/Gavi deadline of end-2021. An internal project team has been working on this project. Equipment has been installed, with IQ, OQ and PQ completed, and SOPs set up. Secondary packaging includes the 2D barcode and tertiary the 1D barcode. Vaccines procured by UNICEF will include the barcoding requirements as of January. The company is exploring with its consultants (Propix) an assessment of requirements for the barcoding of primary packaging; the plan is looking at situating a consultant in Bharat Biotech for 6 months in order to accomplish this assessment and provide training. Propix should be providing the DCVMN Secretariat in the upcoming days their proposal for consultancy support to Bharat Biotech.

AA updated the participants on the traceability project being undertaken by Sinergium Biotech. They are following the national regulatory agency (ANMAT) requirement of implementing a traceability system which in the case of vaccines applies to new products being introduced into the country. The pilot is focused on the barcoding of secondary packaging of their quadrivalent flu vaccine, using the Verifarma software which is standard in Argentina and linked to ANMAT. The pilot has installed Italian-made (Marchesini), high-speed automated packaging equipment for packages with single pre-filled syringes or for 10 pre-filed syringes. There were some delays with installation, training and validation support from the Italian company due to COVID-19 travel restrictions; training has now been completed. Software will be validated in December, however, the first vaccine batch release is delayed due to technical issues. Sinergium is putting in place by Q1, 2024, a new vial filling line with a speed of up to 24,000 units per hour, which will include the barcoding at secondary, tertiary and pallet packaging levels. They also intend to move to barcoding on primary packaging at that time.

LY introduced the work of the Chengdu Institute of Biological Products (CDIBP) (CNBG-Sinopharm) on its traceability pilot, noting that its agreement on joining the consortium was shortly to be finalized. The Chengdu Institute portfolio, with a total of 25 vaccine licenses, includes Japanese Encephalitis (JE), BCG, DTaP and polysaccharide pneumococcal vaccine. The JE vaccine, 2ml., 10 vials to a box, is sold to UNICEF and the pilot is to implement the barcoding of secondary packaging in accordance with UNICEF/Gavi requirements. The barcode will include GTIN, batch number, expiry date and serial number recognizing that UNICEF prefers serialization on secondary packaging. One packaging line for sales to the international market is scheduled to be ready by March 2022 using GS1 barcoding, separate from the Chinese-standard barcoding for the national track and trace system. A consulting company has been selected to support the pilot, having already visited the site and discussed a plan with the Institute. As it currently stands, the packaging line will be ready mid-January along with the corresponding SOPs, IQ/OQ/PQ validation by end-January, followed by validation and training in February.

YB gave an update on the progress for Bio Farma, focused on COVID-19 vaccines which they fill and finish in their facility before national distribution. Barcoding on primary packaging is being implemented to include the GTIN, batch number, expiry date and serial number. The packaging line is fully automated to achieve this. At the same time, Bio Farma receives filled Astra Zeneca COVID-19 vaccines with the GS1 barcode on the secondary packaging, which it is able to link to the national track and trace system by scanning the 2D barcode on the secondary package. SJ indicated this was a challenge when a company is both a manufacturer (in this case a fill-finisher of COVID-19 vaccines) as well as a distributor of imported COVID-19 vaccines. -YB clarified that in case of imported vaccines, they only implement the T&T system from the secondary packaging only.

SJ in summary highlighted the progress of the pilots, with 2 pilots focused on the barcoding of primary packaging and four on the barcoding of secondary packaging. As there have been delays mostly due to the COVID-19 pandemic, he suggested that the consortium continue through 30 June 2022 which would give time for pilots to be completed and for the lessons learnt and reporting to be documented. LY and AA agreed to this extension and there was no objection registered from other consortium members. RS noted the excellent presentations and stressed the need for companies to complete the pilots expeditiously in order to complete all the work along with analysis and reporting by mid-2022.

RS congratulated all the participants, and encouraged them not to take the extension of the deadline for granted, thinking that it may be extended again; instead, he invited them to try to complete all the projects by June 2022.

SP indicated that of the 6 pilots there were 2 contracts signed for DCVMN support, 2 pending and 2 which have not requested DCVMN support. She further enquired whether the members of the independent review group that vets the pilots should be invited to the next meeting. After some discussion, it was agreed to invite them.

LY closed the meeting thanking consortium members for their inputs and agreeing to the next meeting of the consortium to be held mid-January.

Notes by Steve Jarrett
10 November 2021

Lingjiang Yang
Chair of the Supply Chain Working Group
10 November 2021