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Developing Countries Vaccine Manufacturers Network

DCVMN Vaccine Supply Chain Working Group
Traceability Consortium 2nd Meeting
24 August 2021
Webex

Participants:
Lingjiang Yang (LY) - Chair, Analia Acebal (AA), Claudio Guzzo (CG), Huilin (Linda) Yu (HY), Kamesh Chimalakonda (KC), KR Krishnamurthy (KR), Rajinder Suri (RS), Taufik Wilmansyah (TW), Sonia Pagliusi (SP), Stephen Jarrett (SJ), Sonia Villaseñor (SV); **Excused:** Ganapathi Indukuri (GI).
Meeting started at 12h00 and finished at 12h50.

LY opened the meeting welcoming the consortium members as well as Sinergium Biotech attendees AA and CG.

AA gave the first presentation describing the traceability project being undertaken by Sinergium Biotech (Argentina), which is not as yet a member of the consortium. The company has vaccines and monoclonal antibodies in its product portfolio. The national regulatory agency (ANMAT) has established a traceability system which manufacturers must implement from the production or import of products through the acquisition by the user or patient, allowing the monitoring of each unit through the entire chain of distribution. At present, the unit is identified at the secondary packaging level. A specific track and trace software has been developed in country – Verifarma. Currently in use for monoclonal antibody products, a manual process is being used with barcoded labels stuck on the secondary packaging, with associated labeling at the case and pallet levels. The project is now installing an Italian-made (Marchesini), high-speed automated packaging equipment for pre-filled syringes, using Verifarma software with standard GS1 GTIN and serialization of units, each unit associated with a case and each case with a pallet, replicating the manual system. The plan is to add traceability to primary packaging by 2024. ANMAT has instructed that new vaccines being introduced need to implement the national traceability system at a secondary level; it is not yet mandatory for existing products. Sinergium Biotech is, therefore, focusing on quadrivalent flu vaccine for traceability implementation by end-2021. This vaccine comes in a mono-dose form with 300 packed in each case. Regarding their relationship with GS1, AA confirmed that they do not use a GS1-certified consulting company; they do pay the annual GS1 fee. AA also confirmed that product buyers in country need to use the Verifarma software for validation purposes.

HY for Xiamen Innovax in a second presentation indicated the progress of their traceability pilot for barcoding on secondary packaging with serialization of their HPV bi-valent vaccine. Equipment is installed on site and undergoing a SAT (site acceptance test); it will be validated (IQ, OQ, PQ) by October. The consultants supported by DCVMN, Acctrue, have conducted two (remote) trainings, on GS1 barcoding introductory and barcoding principles and they have sent some validation documentation templates and have helped with the review of some documents. A two-month delay has occurred given disruptions in domestic travel due to the COVID pandemic; the consultancy timing will be extended by two months to cover the agreed-upon support through to the eventual validation of hardware and software. The consultants do have local subsidiaries in southern China which facilitates communication and contacts with Innovax. A pilot run of the traceability system is now scheduled for early 2022.

KR introduced progress in Bharat Biotech as a third presentation. The company has to date focused on the barcoding of secondary packaging as required principally by UNICEF and in order to meet the UNICEF/Gavi deadline of end-2021. Equipment has been installed, with IQ, OQ and PQ completed, and are ready for the trial runs. Implementation should be on line for secondary and tertiary packaging by end-year, before UNICEF's deadline. At the same time, they are looking for automating their packaging lines. The company is exploring with its consultants (Propix) an assessment of requirements for the barcoding of primary packaging; Propix should be providing the DCVMN Secretariat in the upcoming days their proposal for consultancy support to Bharat Biotech. KR explained that delays have been due to the company's urgent action in supplying COVID vaccines nationally, noting the current ban on Indian-produced exports of these vaccines.

KR confirmed their commitment to comply with UNICEF requirements first, before applying to other vaccines for both domestic use and direct export. The more vaccines covered will improve the cost-benefit ratio.

As a final presentation, TW indicated that progress for Bio Farma was essentially the same as described in the first meeting of the traceability consortium, focused on COVID vaccines which they fill and finish in their facility before national distribution. The automated national track and trace system has been implemented. In terms of ongoing challenges, TW indicated the most difficult part is being the buy-in of all stakeholders, principally sub-national health departments noting that COVID vaccine distribution and use is all in the public sector.

SJ in summary highlighted the progress of the pilots, indicating that he will consult with Sinergium Biotech about officially joining the consortium. RS indicated the need to follow up with Biological E to clarify their intent to move forward with a pilot.

LY closed the meeting thanking consortium members for their inputs and agreeing to the next meeting of the consortium to be held early November.

Notes by Steve Jarrett
24 August 2021

Lingjiang Yang
Chair of the Supply Chain Working Group
24 August 2021