DCVMN
Developing Countries Vaccine Manufacturers Network

Supply Chain Working Group meeting on traceability and warehouse management system - 22 November 2022 by Zoom/ started at 11 am finished at 12:50 pm

Participants:
Lingjiang Yang (CNBG); Padmakar.Jadhav (BioE); Krishnamurthy (Bharat); Shiva kumar (Indian Immunologicals); Berniece Waley (Biovac); Taufik Wilmansyah (BioFarma); Rachel Park (Eubiologics) ; Yudha Bramanti (BioFarma) ; Analia Acebal (Sinergium) ; Brian Taliesin (PATH) ; Géraldine Lissalde-Bonnet (GS1) ; Yvette Madrid (consultant). Secretariat : Sonia Villasenor; Rajinder Suri ; Sonia Pagliusi.

The WG Cochair opened the meeting by mentioning the three objectives:

1. Share experiences from pilot studies to set up and implement vaccine traceability through GS1 barcoding on the secondary & primary packaging to comply with global supply
2. Share experiences from implementation of Warehouse Management System upgrade pilot, to enable end-to-end traceability of vaccines.
3. Draw lessons learnt to be shared with the broader global supply community, in form of a report/publication(s)

An outline of Supply Chain WG activities from January 2019 to present, and priorities on traceability, stockpile and packaging innovation was shred. The use of barcodes to trace products from the factory to the immunization centers helps to improve efficiency of supply, enables regulatory compliance and to fight counterfeit, as illustrated by the projects implemented by six manufacturers. In addition, Eubiologics had implemented the bar code on secondary packaging of OCV before the project started. Stockpiles and packaging innovations were discussed with manufacturers in punctual workshops, and conclusions were published.

The feasibility study of GS1 barcodes on primary packaging, carried out by Bharat from August to October 2022, was shred. Reducing font, reducing artwork and realignment of text to save space were key features. The hardware adaptations were done, with 2 printing options: 8x8 mm or 6X6mm 2D code, and the 8x8 mm was recommended, to avoid readability errors in the field. Fully automated solutions are being developed. Bharat was successful in achieving primary packaging 2D codes labelling to ensure traceability, enhancing the safety and fight counterfeited. The project was timely, because the local government has now requirements for primary packaging. Team-work and expert support for artwork modification and designing were essential for success. The benefits of the 2D codes on primary packaging include to defend entry of spurious products in the market, defend brand products and protect safety of vaccine recipients.

The completion of the warehouse management system implementation project carried outby BioE from July to October 2022 was presented. The key challenges included the multiple material handling, multistage labelling (quarantine, undertest, approved, rejected) and separate storage areas, as well as manual tracking of materials, and human errors. WiFi access points were also challenges. After vendor selection, training and IQ/OQ/PQ[1] were carried out, as well as user acceptance test. The benefits of the project, included the use of single stage QR code label instead of multi-stage labelling, easy tracking of materials using handheld devices, reduction in material handling, better regulatory compliance due to electronic controls, optimized space utilization and elimination of human errors. The new system showed higher efficiency due to reduction in material handling, as SAP enables virtual segregation of materials.

An update of the implementation of traceability at Sinergium was provided. ANMAT resolution 435/11 requires unambiguous identification of medicinal products from production or import, until the end

[1] Installation Qualification/ Operational Qualification/ Performance Qualification

user. Various teams across Sinergium started the implementation of traceability system, through urs definition, design, installation and validation of equipment, with an investment of ca. 300 thousand USD, joining this consortium as observer. They used Verifarma software, which is aligned with GS1 standards, and integrated with the hardware (cf. slides XYZ). A major challenge was the delays due to the pandemic travel restrictions, and technical issues with the reading system cameras, with high rejection rates. The first product with traceability code was produced in January 2022, and the launch is planned for January 2023. The 2D code includes GTIN, VTO (expiration date), lot number and serial number. So far, the tracking system is aimed to private market distribution.

Suggestions included: 1) To synthesize the outputs of each report and focus on key benefits for vaccine recipients, for the health system and for manufacturers. A key challenge is that benefits of reducing counterfeit and improving immunization are measured much later, after introduction of such products. This project has demonstrated the feasibility of barcode on different levels of packaging, removing hesitancy to vaccines, as they can now be traceable at all levels for shipping control, and for users. 2) Analyse the benefits at three dimensions: for the vaccinees (for example the ability to detect adverse events that can be linked to particular batch or pack), for detection of counterfeit products on the market (if the health provider uses the track-and-trace tools before administering vaccines), and for linking the benefits downstream (e.g. efficiencies in stock management). 3) highlight benefits for the immunization systems dynamics, such as reliable data collection opportunities (and data linking), inventory management, and supply in countries. With secondary packaging traceability the possibilities are limited to inventory management, while end-user data linkage requires primary packaging codes. 4) Evaluate how to increase adoption of bar code by manufacturers in developing countries. Perhaps those who implemented (BioFarma, Bharat, BioE, Sinergium, Eubiologics, CNBG) could provide feedback.

It is helpful to understand both private and public markets set up for traceability (example of Argentina was articulated). The countries need to be willing and ready to implement the system at county, province or community levels in order to make it work. Tools and digital systems are necessary, which have a cost, thus large-scale implementation may take longer, particularly in developing countries. UNICEF has announced the implementation of TRVST being developed under the Verification and Traceability Initiative (VTI), a multi-stakeholder partnership composed of UNICEF, Gavi, BMGF, GF, USAID, WB, particularly for African countries[2], and a training workshop has been scheduled for December 2022. Improved coordination with UNICEF is a positive outcome.

Next steps:

- Develop a questionnaire to the projects to fill up, and use the responses to develop an overview.
- Develop a slide deck compiling all projects for future use
- Overall report to be available by December for review
- Draft paper to be available prior to Xmas break

WG Chair concluded that within a month the work shall be closed, and adjourned the meeting.

Date: Dec. 01, 2022

Signature: _____
Ms. Lingjiang Yang, CNBG/Chengdu

[2] https://www.unicef.org/supply/stories/first-serialized-vaccine-scan-africa-marks-milestone-tackling-falsified-medical-products