

**Participants:**

Berniece Warley (BW), Komarapuram Krishnamurthy (KK), Lingjiang Yang (LY), Rachel Park (RP) Taufik Wilmansyah (TW), Tianping Wang (TW), Vishnucharan Datta (VD), Samir Desai (SD), Yudha Bramanti (YB), Sonia Pagliusi (SP), Steve Jarrett (SJ), Sonia Villaseñor (SV).

**Meeting** started at 12h00 and finished at 14h00.

LY informed the group that 2 papers had been prepared for publishing in the current year. One was based on a survey of DCVMN members on responding to global trends in supply chain optimization including traceability and packaging innovations. These WG meetings are key for collecting ideas and comments from members relevant for addressing stakeholders' expectation.

SJ showed 2 presentations, one summarizing the reviews and analyses made last year and the other on the areas that have been determined for the focus of the WG. The first presentation articulated the importance of the supply chain to the reputation of manufacturers based on the successful use of their vaccines at the point of vaccination. In some countries the vaccine supply chain is not optimal in relation to standards that have been set by WHO. Thus, the main focus is on the innovations where manufacturers can exchange information and develop studies to get a common sense of what manufacturers can do in order to have a positive impact in the countries' supply chain. Eight areas were initially identified as having an impact in supply chain: Traceability, Sharing supplier audits, Vaccine exposure monitoring, Heat stability testing, Stockpiling, Environmental impact, New packaging and delivery technologies and Direct participation in the distribution chain. However, the issue of cost will be always a factor to consider. A survey with 26 respondents followed by 9 interviews of DCVMN members showed there was an agreement on focusing attention on 4 of the areas. There is a need for establishing a work plan with specific objectives with topics to be covered with timelines and deliverables.

SJ confirmed that the work to date had been put into an article that had been accepted by the Vaccine Journal which would come out soon. In this way the world would see the results of last years' work. SJ emphasized the importance of the supply chain. It had been determined that the WG should focus on 3 priorities:

1. Track and trace – traceability - where the use of GS1 standards has been adopted by WHO, UNICEF & GAVI. Barcoding is the main tool used in traceability and barcoding on primary package is of particular importance.
2. Vaccines stockpiling. There are cost concerns machine with storage plus potential remaining shelf-life challenges.
3. New packaging technologies.

SJ indicated that a second paper has also been accepted by the Vaccine Journal on the engagement of DCVMN members in the research and development of COVID vaccines.

**TRACEABILITY Discussion.**

The discussion was an opportunity for members to raise issues around traceability:

- LY expressed her concern due to the situation of companies in China, where QR coding has been widely established instead of the GS1 Data Matrix barcode. Although there is a way to translate information to the Data Matrix, the concern is how will receiving countries with potentially different systems handle and maintain vaccine information.
- YB gave a short presentation on how Bio Farma has approached the problem through implementing hardware and software solutions including specific applications: Biotracking and Biodetect. As a requirement of their local NRA, all the pharmaceutical and vaccine industry in Indonesia has to implement and follow a 2D barcode system. Thus, Bio Farma needed to quickly implement GS1 Data Matrix barcoding on primary package. They made some modifications on their production line. Biotracking is used to verify the product with a mobile scanner which connects to a database center. The customer or distributor will know the product's origin is Bio Farma. The medical staff updates the

status of the vaccine (e.g. if a multi-dose vial is being used 5 times). This application involves anyone in the supply chain who enters in contact with the vaccine. They scan the barcode which uploads the information to the database. The Biodetect application is publicly available so any user can know the information on the vaccine.

- LY asked how much investment was needed to develop the system and how big is the group to maintain the data in the company. YB said the investment was about 1 million USD but it can be used for all products and it is applicable for both domestic and overseas markets. The key players are the IT and production departments.
- BW asked if the packaging material (label) with the GS1 barcode is printed in-house. TW answered they generate the code and print it in-house. First, they had to ensure an inject or laser printer is available, also a camera system to scan and verify that printing complies with database information.
- LY asked if the whole packaging line had to be changed or only adapted to use this barcoding. TW said they used the existing lines and modified the packing line. A printer and a camera system were installed, it is important for the software to communicate between the label and carton line to verify and aggregate the code.
- SP said that big countries seem to have issues of authentication of health products, so it is a question of safety for people and the credibility of companies. If you have a system that is not recognized globally, your products will be not recognized and not secure credibility. For big countries like China, Indonesia, India, Brazil, US, traceability becomes an issue; with big distances between manufacturer and user, incidents may happen in distribution. It is a solution to engage in global supply and the solution from Bio Farma seems to be affordable and already validated in the pilot stage.
- VD asked how can the process they have shared be applied by other companies in the world. The use of GS1 is standard in primary and secondary packaging. By oct 1<sup>st</sup>, 2020 every vaccine supplied from India should have GS1 barcode on it, but not mandatory on primary packaging.
- LY said each company has to modify their own systems. Copying does not apply because GS1 is universal, anyone using a mobile can scan the information. Any scan coder can interpret the information scanned. VD said in India there is a portal for GS1 where you need to add images of the product and other information for it to become valid. Some companies are reluctant to upload all data like pricing information and keep updating the portal. Once the data are there and the vaccine packaging has the GS1 barcode, everybody will know where it comes from and this avoids counterfeiting. As Bio Farma has done, it is good to have a barcode on the label of the primary package. It is a big challenge to change all the labels. It can be extended to more products but all those changes are time consuming and need investment.
- LY asked how much investment is needed in India. VD said there are no calculations, but for rabies vaccine where they are installing some hardware with robotic arms and barcode readers, there is investment needed because the vaccine goes to several countries in world - he will send the information to SP.
- SP said in the Paper prepared there is a Table showing the ability of companies to use those standards and which are in position to distribute globally: Bharat Biotech, Biological E, SII, Indian Immunologicals, Zydus Cadila already use GS1.
- RP said they have not as yet updated their export vaccine to the GS1 standard, noting the Korean FDA does not have this requirement. They have hired a consultant for adoption and to work on quotations. She has not been able to estimate costs yet but they can share estimate quotations.
- SD said they use GS1 standards and export a lot of vaccines. He will check with his manufacturing team about the investment made for GS1 introduction. For intra-ocular lenses implanted a track and trace system was implemented, as it goes beyond tracing a product needing to marry with the person whose

eye is being implanted. If there is any complication, you need to track the exact lens. There are sophisticated systems like this that can be used to prevent counterfeiting.

- SP said full traceability tools increase trust for manufacturers. The estimated potential capital may be necessary for between 1 and 4 vaccines, depending on the vaccine portfolio and production schedules. These tools will enable your companies to be able to collaborate with larger companies in the future. We can discuss on how to find funding for implementation so that our members could be faster to market and guarantee vaccine volumes enhancing their profile. DCVMN can explore with BMGF for an umbrella grant or with the UN in Geneva that supports industry or with UNIDO in Vienna.
- LY asked if it is possible that this initiative can be adopted by any DCVMN member for the packaging of vaccines. If we find co-funders for adoption by members it will be easier to get matching funds. It should be in agreement with our member companies. SP said we need to make a list of the needs and costs and to create a proposal but she requested the help of this group and experts to propose this to a donor willing to support traceability measures for increased safety. We will make a portfolio of options so members can choose and the donor can support.
- SJ suggested that Bio Farma put together a case study of their operation. This could help members put together a financing proposal to implement traceability systems.
- SP said the International Finance Corporation supports companies for hardware investment and sometimes gives financial support at zero interest. They provide funds for companies to implement and the company pays back based on a successful outcome. By having a traceability system, members' business can increase. Global Health Investment also can provide funds very quickly for implementation, mostly reimbursable at small interest rates. We can explore creating a group with the International Finance Corporation, UNIDO or Global Health Technology Fund. But we need a proposal and ask them if they are willing to support this technology.
- VD said as a starting point that maybe Bio Farma can help DCVMN by making a list of the software and costs they have invested, not a detailed list, only the rough total investment; and ask the members if they need any financial support. These members would be able to take the initiative forward.
- SP said the starting point is the case study by Bio Farma. SJ said he can develop the case study with Bio Farma and create a report to be shared with members, then circulate and publish it. If Bio Farma and LY agree, SJ can work over the next months with TW and colleagues to put on paper the story and develop an investment case.
- TW requested DCVMN to send an email or letter to their management because data are secured and confidential, requesting if they are safe to share the data. SP said confidential information can be excluded. Bio Farma will be in control of what is put in the report and shared with members or not. SJ can collect information and develop the report to present to members and donors. SP asked TW if the video can be shared to be uploaded on DCVMN's website. TW will ask his management on this.
- SP said once this is done, the group can then go to the other topics of discussion for next time. We could convene and discuss further the next time, possibly discussing stockpiling and new technologies.
- LY wrapped up the meeting by saying that Traceability is the current priority.

**Nyon, June 18, 2020.**

**Notes by Sonia Villasenor, edited by Sonia Pagliusi and Steve Jarrett**

**Approved: Lingjiang Yang, Chair.  
Chengdu**



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