

The background of the slide features three glass vials and a syringe. The vials are arranged in a row, with the one on the right being the tallest and the one on the left being the shortest. The syringe is positioned diagonally in the foreground, pointing towards the top left. The entire scene is set against a light blue background with soft shadows.

# **Vaccine Supply Chain Working Group Session 2: Focus Areas**

**Steve Jarrett, Gracious International Inc.  
WG Meeting, 18 June 2020**

# 1) Traceability – track and trace

Ability to track vaccines through the supply chain from manufacturer to patient with key information items such as the Global Trade Item Number (GTIN), lot number and expiry date – to improve ordering and inventory control, supply chain management, safety monitoring including AEFI reporting and minimizing stock-outs.

Barcoding is a principal tool used in traceability providing immediate access to data. Use of GS1 standards adopted by WHO, UNICEF, Gavi.

# In healthcare preference is for the use of GS1 DataMatrix



## IDENTIFY



## CAPTURE



## SHARE

**GS1 Standards for Identification**

**COMPANY & LOCATION**  
Global Location Number (GLN)

**PRODUCT**  
Global Trade Item Number (GTIN)  
Serialized Global Trade Item Number (SGTIN)

**LOGISTICS & SHIPPING**  
Serial Shipping Container Code (SSCC)  
Global Shipment Identification Number (GSIN)  
Global Identification Number for Consignment (GINC)

**ASSETS**  
Global Individual Asset Identifier (GIAI)  
Global Returnable Asset Identifier (GRAI)

**SERVICES & MORE**  
Global Service Relation Number (GSRN)  
Global Document Type Identifier (GDTI)  
Global Coupon Number (GCN)

**GS1 Standards for Barcodes & EPC/RFID**

**GS1 BARCODES**

EAN/UPC

GS1-128

ITF-14

GS1 DataBar

GS1 DataMatrix

GS1 QR Code

GS1 Composite Barcode

**GS1 EPC/RFID**

Electronic Product Code (EPC) RFID

EPC HF Gen 2

EPC UHF Gen 2

**GS1 Standards for Data Exchange**

**MASTER DATA**  
Global Data Synchronization Network (GDSN)

**TRANSACTIONAL DATA**  
eCom (EDI): EANCOM, GS1 XML

**EVENT DATA**  
EPC Information Services (EPCIS)

# Adding matrix barcodes to packaging for end-to-end identification

The demands on manufacturers to support traceability down to the individual being vaccinated will increase as countries scale digital health (e.g. mHealth) within their immunization information systems, and those manufacturers able to support this could have market advantage.



## Traceability feedback from the Hanoi workshop on supply chain management, November 2019

- Barcoding on primary packaging is already being pursued
- Vial size and plastic tube – may lack space for barcode and VVMs but some manufacturers experimenting
- Research into extended labeling may be an option
- Cost concerns – license, printing
- Regulatory requirements need to be known
- Product security is an increasing concern – avoidance of counterfeiting
- Uncertain demand on barcoding from countries
- Lack of country infrastructure and system to read barcodes
- More information on GS1 needed
- Clarity needed on UNICEF/Gavi requirements on secondary packaging
- Possibility for modeling barcoding feasibility and costs on multiple packaging

## WG considerations

Issues for manufacturers to consider in their engagement in traceability:

- Understand the specific demand of country immunization systems in terms of tracking vaccines down to individuals being vaccinated;
- Model the options for including barcodes using GS1 standards, including at the primary packaging level;
- Estimate the potential capital and operating costs involved;
- Articulate financing options, which could include third-party grants to subsidize investment costs, advance market commitments to guarantee vaccine volumes, raising of vaccine costs, or other financing means;
- Showcase pilots in improving traceability.



## 2) Vaccine stockpiling (inc. buffer stocks)

Stockpile investments are an integral part of comprehensive disease strategies - they can mitigate uncertain demand forecasts and stock-outs and respond to emergencies.

The increasing risk of large-scale outbreaks and urban epidemics are likely to overstretch vaccine supplies and continuously re-define the role and size of vaccine stockpiles (Gavi).

# Stockpiles facilitate rapid deployment of vaccines



The need for stockpiles relates to the demand for the fast deployment of vaccines, not knowing when shortages or outbreaks might occur and how much vaccine is needed ahead of time.

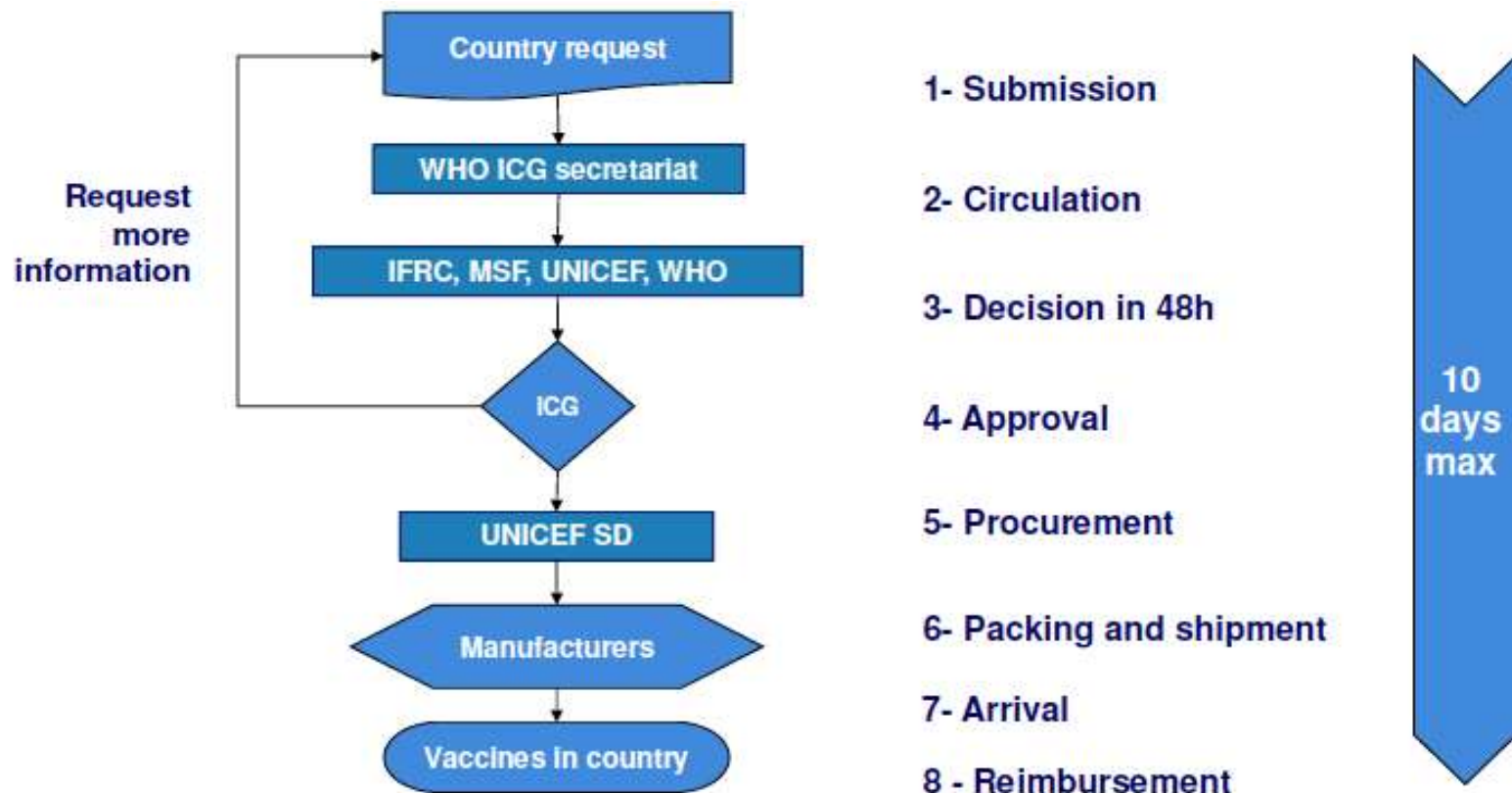
Many countries do not hold sufficient buffer stock in the event of shortages or sudden increased demand.

Vaccine shortages cause significant risk in populations not being vaccinated and thus prone to contracting infectious diseases leading to illness or death.



# Countries already have access to internationally-managed stockpiles

Cholera, Yellow fever, Meningitis + OPV:  
Global vaccine stockpiles have provided countries with the capacity for rapid response to emergency situations



## Stockpiling feedback from the Hanoi workshop on supply chain management, November 2019

- Bulk stockpiles exist but when to start filling needs has to be determined
- Regulatory releases of filled product (takes ~3 months) so cannot address stock-outs or outbreaks
- Problems with filled product stockpiles – storage, cost
- Capital and operating costs – loss of financial interest by holding stock
- Remaining shelf life challenges
- Manufacturer risk needs to be addressed
- Possible quality loss in transportation and storage (off-site)
- Quantification of stockpile
- Short-life vaccines (e.g. flu) limit stockpiling
- How to finance stockpiles?
- Need to also stockpile labels etc.

## WG considerations

Issues for manufacturers to consider in their engagement in retaining and expanding vaccine stockpiling:

- Collect more information on global and regional stockpiling policies for both creating and financing stockpiles;
- Determine main actions for manufacturers in creating, financing and maintaining stockpiles;
- Identify potential efficiencies and financing options in stockpile management.

### 3) New packaging technologies

There is increasing attention by the global immunization community to new packaging and delivery technologies. Gavi, WHO, BMGF, PATH, UNICEF and CHAI have formed an alliance creating a vaccine innovation prioritization strategy (VIPS). The vision is to drive vaccine product innovation to better meet country needs and support immunization coverage and equity goals.

Apart from staying informed of new technologies and their potential for adoption by manufacturers DCVMN members should have a voice about which technologies are most appropriate and cost-effective to them.

# Innovations short-listed by VIPS – CTC already identified as a priority



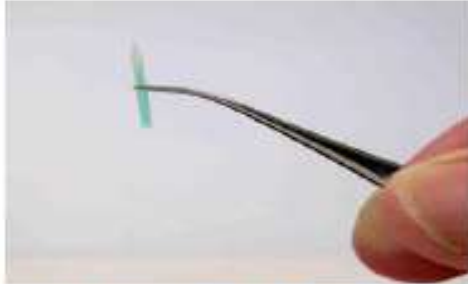
**Microarray patches (MAPs)**



**Compact prefilled auto-disable devices (CPADs)**



**AD sharps-injury protection (SIP) syringes**



**Solid-dose implants**



**Dual-chamber delivery devices**



**Freeze damage resistant liquid formulations**



**Heat stable/controlled temperature chain (CTC) qualified liquid formulations**



**Combined Vaccine vial Monitor (VVM) and Threshold Indicator (TI)**

*Note: Innovation pictures are just examples of innovations*



**Barcodes / Radio Frequency Identification (RFID)**

# Blow-fill-seal (BFS) technology for oral vaccines



Pre-filled BFS for liquid vaccines - a continuous process of extruding thermo plastic resin into a tubular mold, blowing to the desired shape, precision filling, sealing the container and releasing it from the mold - has the advantage of break-proof containers, aseptic filling, fully-automated manufacturing, smaller spatial requirements, automatic cleaning, sterilization processes and the least expensive option for oral vaccines in terms of total cost of delivery.



## New packaging technologies feedback from the Hanoi workshop on supply chain management, November 2019

- Cost of innovation – who pays?
- Needed machinery and materials
- Regulatory requirements
- Acceptability to countries – bias to private market?
- Product security enhanced?
- Need for training of field staff and managers
- Storage and transport requirements – footprint
- Access to information about innovations
- Lead times for innovations to be accepted?

## WG considerations

Issue for manufacturers to consider in partnering with innovation developers to ensure that innovations are feasible and cost-comparable with current technologies:

- Review and become familiar with the multiple innovations being prioritized by global stakeholders;
- Determine if additional innovations might be pursued by manufacturers;
- Focus initially on CTC, VVMs+TI and barcoding;
- Intervene in design, prototyping and piloting phases;
- Identify any IP issues;
- Estimate the projected fixed and operating costs of selected innovations;
- Signal potential financing options for the introduction of innovations.

## Suggested work plan deliverables aimed at information exchange among members

- Document the adoption, costs and operational experience in adopting GS1 standards;
- Model the options for including barcodes, including at the primary packaging level, estimating the capital and operational costs involved;
- Determine the main actions for manufacturers in creating, financing and maintaining stockpiles;
- Document experiences with the adoption of CTC with VVMs+TI with a focus on feasibility and costs.