

SUPPLY CHAIN INITIATIVE: SUMMARIZING AND HIGHLIGHTING PROGRESS

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NOVEMBER 22, 2022



PURPOSE OF SUPPLY CHAIN INITIATIVE

WITHIN DCVMN'S STRATEGIC GOAL OF PROMOTING STABLE AND SUSTAINABLE SUPPLY OF HIGH QUALITY VACCINES,

SEEKS TO IMPROVE THE EFFICIENCY AND EFFECTIVENESS OF SUPPLY CHAINS,

BY IDENTIFYING AND EXPLORING AREAS, WITH AN EMPHASIS ON THE SECONDARY STAGE OF PRODUCTION, WHERE DEVELOPING COUNTRY MANUFACTURERS CAN HAVE A POSITIVE IMPACT.

OVERVIEW OF MEETINGS

	2019			2020			2021			2022		
SCW=Supply Chain Workshop	SCW	ip	Jan 21-24	SCWGM	tc	Jun-18	SCWGM	tc	Jan-26	TPSC	tc	Jan-18
SCWGM=Supply Chain Working Group Meeting	<i>China</i>											
SCWGW=Supply Chain Working Group Workshop	SCWGM	ip	Jun-25	SCWGM	tc	Oct-14	TPSC	tc	Feb-10	SCWGM	tc	Feb-16
TPSC Traceability Pilot Study Consortium	<i>Switzerland</i>											
Proposal Review	SCWGM	ip	Nov-28				SCWGW	tc	Mar 30-31	TPSC	tc	Mar-23
	<i>Vietnam</i>											
							TPSC	tc	Jun-09	SCWGM	tc	Apr-26
							SCWGM	tc	Jul-27	SCWGW	tc	May-11
							SCWGM	tc	Aug-17	PR	tc	Jun-08
							TPSC	tc	Aug-24	TPSC	ip	Jun 23-24 3
							TPSC	tc	Nov-10	SCWGM	tc	Nov-22

ip= in person
and/or mixed

tc= teleconference
only

EVOLUTION

1/19
Creation of
initiative

Supply
Chain
Working
Group
(SCWG)

6/19

Prioritize:

- Traceability
- Stockpiles
- Packaging Innovation

Roadmap paper,
08/2020

03/21
Stockpiling workshop

Vx Stockpiling paper,
12/2021

05/2
Package Innovation
Workshop

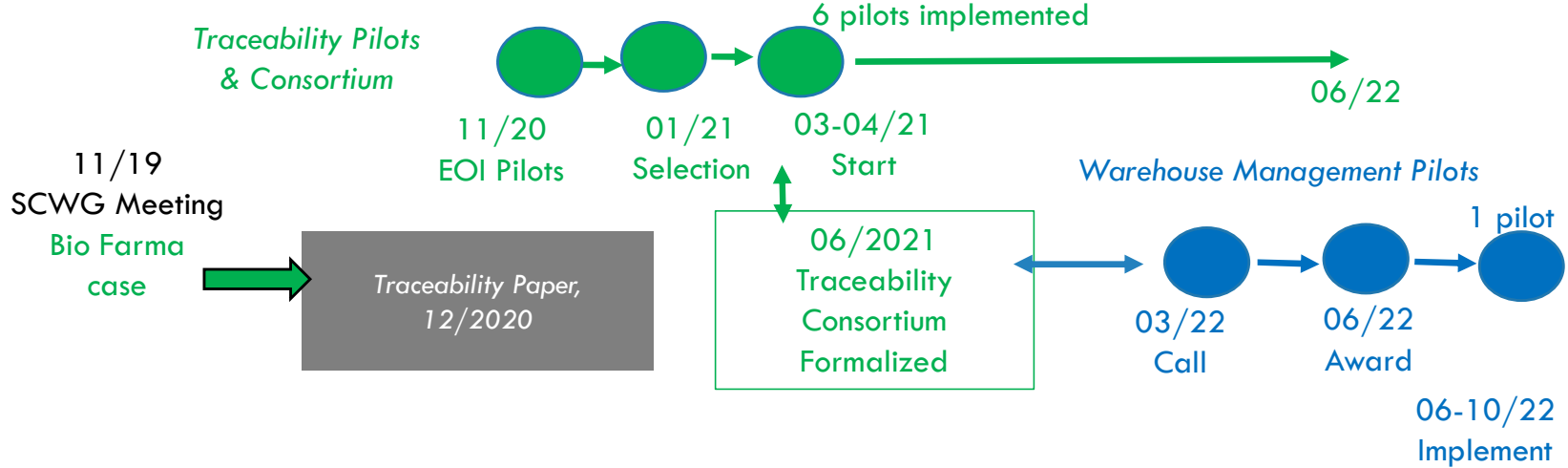
Packaging
innovation paper,
submitted 11/2022

2019

2020

2021

2022



MANAGEMENT & TRACEABILITY

Driven by manufacturer

Can support regulatory compliance

Driven by customer and regulatory requirements

Gavi/UNICEF
requirement for
GS1 barcodes on
secondary
packaging

National
traceability
plans

Inputs

Finished Product

Patient

Traceability

Warehouse Management System

Secondary
Packaging

Primary with
Serialization

Supply chain
Visibility and anti-counterfeiting

End-to-End

PILOTS

*with support from DCVMN Donor

TRACEABILITY

Secondary Packaging

Primary packaging

WMS

Warehouse Management System (End-to-End)

Innovax*

CNBG*

Sinergium

For private market

EU Biologics, not part of consortium due to earlier start, also implemented

Bharat*

Biological E*

Serialization of all levels of packaging

Bio Farma

also supported software for EPI track and trace

Data sharing (EPCIS) For other countries

Biological E*

CNBG-CIBP, CNBG-Viriogen, Innovax, Bio Farma have shared information on adoption of WMS systems (some focused on specific efficiencies, others broader)

FOR
DISCUSSION

FRAMEWORK TO ASSESS TRACEABILITY PILOTS (FROM FINISHED PRODUCT)

Dependent on scope (level of packaging, serialization, number of vaccines/lines, etc.) and past experience

Costs

INVESTMENT

- HARDWARE
- SOFTWARE

Time to Implement

- PREPARATION AND PLANNING
- IMPLEMENTATION, VALIDATION, TRAINING

Common Challenges

- COVID-19
- HARDWARE
- SOFTWARE
- ARTWORK/SPACE
- ?

Best approaches

- NO "ONE" WAY
- REALISTIC, STEP-WISE GOALS
- MULTI-DISCIPLINARY TEAMS
- REGULAR DISCUSSIONS WITH REGULATORS/WHO PQ/UNICEF
- SUPPORT FROM GS1

Key Achievements

- LEARNING FROM EACH OTHER WAS SUCCESSFULLY FACILITATED
- PILOT OBJECTIVES REALIZED, SUCCESSFUL "LEARN BY DOING"
- SEVERAL PILOTS ARE PART OF EXTENDED EFFORTS TO ADOPT STANDARDS :
 - SERIALIZATION
 - EXTEND USE OF BARCODES TO ALL PACKAGING LEVELS
 - IMPROVE SHARING OF DATA

Future Challenges

- TRACEABILITY ACROSS BORDERS
- ?

STOCKPILES

SHARED EXPERIENCES

- EUBIOLOGICS: CHOLERA
- BIO-MANGUINHOS/FIOCRUZ, YELLOW FEVER
- SERUM INSTITUTE, MENINGOCOCCAL A
- BIO FARMA, ORAL POLIO
- BHARAT, MFT. VOLUNTARY STRATEGIC STOCK

SUMMARY

- BROADLY, TWO TYPES OF STOCKPILES, STATIC AND ROTATING, WITH DIFFERENT RISK PROFILES.
- LIKELY TO BE INCREASING NEED FOR STOCKPILES GIVEN INCREASED EFFORTS TO DEVELOP OUTBREAK VACCINES.
- ALL RELEVANT STAKEHOLDERS SHOULD WORK TOGETHER ON TAILORING AND OPTIMIZING STOCKPILES FOR EACH VACCINE.
- MFTS NEED FULL COSTS TO BE RECOGNIZED.
- VOLATILITY IN DEMAND PRESENTS RISK WHICH ALSO SHOULD BE REFLECTED IN NATURE OF FINANCING.
- AGREEMENTS ON LOWERING SHELF-LIFE FOR USE IN OUTBREAKS CAN IMPROVE MANAGEMENT.

PACKAGING INNOVATION

SHARED EXPERIENCES

- EXPLORED
 - PRE-FILLED AUTO-DISABLE DEVICES (CPADS)
 - POLYMER-BASED PRIMARY CONTAINERS
 - DUAL CHAMBER DELIVERY DEVICES
- BIOFARMA-UNIJECT (CPAD) FOR HEPB
- EUBIOLOGICS-POLYMER CONTAINER FOR ORAL CHOLERA
- SERUM INSTITUTE-POLYMER AMPULES FOR ORAL ROTAVIRUS

SUMMARY

- SOME INNOVATIONS ALREADY AVAILABLE OR POSSIBLE, OTHERS REQUIRE FURTHER ADAPTATION.
- VACCINE PACKAGING CAN PLAY AN IMPORTANT ROLE FOR BOTH INJECTABLE AND ORAL VACCINES.
- BENEFITS: SAFETY, EASE OF ADMINISTRATION, EXPANDED COVERAGE, REDUCED WASTE
- LIMITATIONS: PURCHASERS UNWILLING TO PAY HIGHER PRICE, UNCERTAIN IMPACT ON COLD CHAIN AND DISTRIBUTION COSTS
- ADDITIONAL DATA NEEDED ON THE TRADE-OFFS BETWEEN EASE OF ADMINISTRATION, SAFETY, COVERAGE, WASTAGE, AND COSTS TO STIMULATE INTEREST AND UPTAKE

OVERALL CONCLUSIONS

- **SUPPLY CHAIN IMPROVEMENTS ASSOCIATED WITH SECONDARY PRODUCTION** CAN HAVE CONSIDERABLE **POSITIVE IMPACT ON IMMUNIZATION OBJECTIVES** (E.G. INCREASING EASE OF USE AND COVERAGE; GREATER VISIBILITY, SAFETY, AND EFFICIENCY IN SUPPLY CHAINS)
- **MANUFACTURERS** HAVE **A KEY ROLE** IN THESE SUPPLY CHAIN IMPROVEMENTS, **BUT THEY CANNOT DRIVE THESE ALONE.**
 - FOR THE MOST PART, IMPROVEMENTS IN TRACEABILITY, STOCKPILES, AND PACKAGING TECHNOLOGY SHOULD BE SEEN AS **REQUIRING SYSTEMIC SHIFTS** WHERE **MANUFACTURERS** TOGETHER WITH **OTHER STAKEHOLDERS** (REGULATORS, PURCHASERS INCLUDING COUNTRIES AND INTERNATIONAL BODIES) **ALIGN THEIR EFFORTS.**
 - THIS INCLUDES
 - CO-ORDINATION OF EFFORTS TO EXPAND TRACEABILITY GLOBALLY;
 - SUITABLE FINANCIAL APPROACHES WHEN DEMAND IS HIGHLY VOLATILE (FOR STOCKPILES); AND
 - REALISTIC EXPECTATIONS REGARDING NATURE AND PREDICTABILITY OF DEMAND (TAKING INTO ACCOUNT WILLINGNESS TO PAY) FOR PACKAGING INNOVATIONS.