Implementing Traceability for Patient Safety

Pfizer Global Serialization Program

African GS1 Healthcare Conference – Ethiopia

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Agenda

- Introduction to Pfizer
- GS1 Standards Application
- Why Traceability?
- How to achieve traceability?



About Pfizer

Our Purpose:

Innovate to bring therapies to patients that significantly improve their lives

Our Mission:

To be the premier, innovative biopharmaceutical company

Our Four Imperatives:





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Company Overview

- \$52.8 Billion in revenue \succ
- \geq 96,000+ employees
- ~ 63 Internal Manufacturing Plants \geq
- ~ 450 Contract Manufacturers >
- ~ 13,000 Supply Partners \geq
- 850+ major product groups \geq
- 25,000+ SKUs \geq
- \geq Diverse Operating Units covering key product areas such as:
 - **Bio Pharmaceuticals** \geq
 - Vaccines \geq
 - \geq Solid Oral Dose
 - Aseptic \geq
 - **Sterile Injectables** \geq
 - Consumer Healthcare \geq



Once-Daily 5-mg and 10-mg tablets

amlodipine besylate













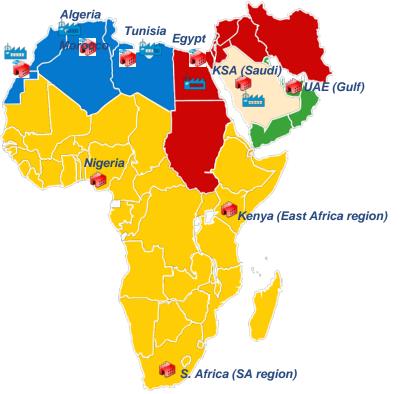








Pfizer Global Supply Operations



PGS Operations:



LMS Site (5)

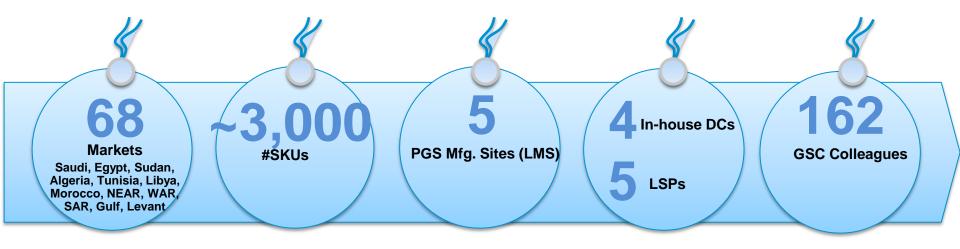


In-house DC (4)

) 3PLs (5)



AfME Operations





GS1 Standards Application

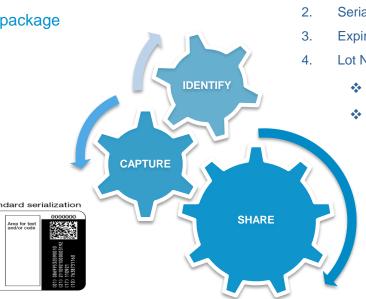
GS1 DataMatrix as Data Carrier

- High-density and smallest size barcode
- Small footprint fits on most package sizes



Label for square bottle with standard serialization





Key Data Elements / Application Identifiers:

- 1. GTIN (01)
- 2. Serial Number (21)
- Expiry Date (17)
- . Lot Number (10)



- Unique identification of a unit
- Regulated by most worldwide mandates

Interoperability

- 1. GS1 GDSN for master data
- 2. EDI for transaction data



- Common language between partners
- Master data is DNA for Serialization



Why Traceability?

Simple interventions can save many young lives each year.



Clean Water



Vaccination



Nutrition



Why Traceability?

Are vaccines getting to the children in need?





A Solution - Barcodes

A focus on vaccine presentation and packaging.





Why a Barcode?



Scanning the 2D barcode will eliminate human data entry errors



Scanning will speed up data entry

Visibility

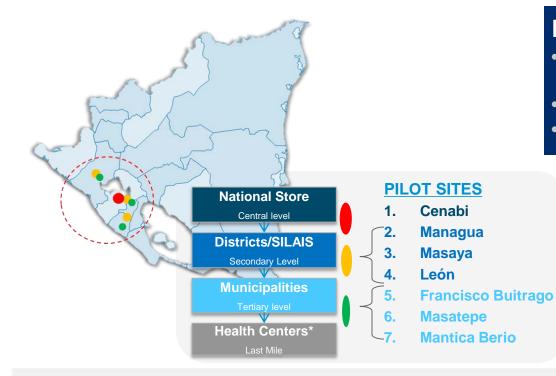
Real-time inventory reporting allows for quicker decision-making at intermediate and central levels



All system data is hosted centrally on a server – no need for local system copies at each site location



Pfizer's 2D Barcode Pilot Program



Program Objectives

- Demonstrate compelling evidence and advance the dialogue
- Enrich open-source supply chain solutions
- Accelerate impact on global health



Implementation Methodology

July 2015	SCOPING & PLANNING	 Reviewed current MoH processes Conducted gap assessment
Aug 2015	DESIGN	Delivered finalized technical design specifications
Sept 2015	BUILD & TEST	✤ Completed system development
Oct & Nov 2015	DEPLOY & PILOT	 Rolled out 2D barcoding solution to 7 sites Conducted user training
Dec	PILOT MONITORING	 Monitored system usage directly after go-live Continued to troubleshoot system issues on an ongoing basis
2015 Jan-Apr 2016	PILOT EVALUATION*	✤ Pilot period extended✤ Feedback gathering
		*Pilot Extension through April 2016







Total number of adjustments made across all levels:

One in 223 Transactions

Efficiency

68% less time needed for one transaction vs. manual system

Manual entry: 1 minute

Scanned entry: 18 seconds

Visibility and Operational

Ability to see stocks at all levels:

All levels of system used

100%

Data Security

- All system data hosted centrally
- Removes need for local system copies at each site location, reducing data management costs and possible security breaches



Vaccine Presentation and Packaging Advisory Group

Established 2007 by the GAVI Alliance

- Initially Charged to Aid with Questions from Industry on Rotavirus and Pneumococcal Vaccines
- World Health Organization Assumed Responsibility in 2008
 - Expanded Scope to all Vaccines

Barcode Working Group

Established 2011



- Barcoding becoming prevalent for medicinal products to improve Inventory Visibility and patient safety in developed markets
- How to leverage for vaccines in Developing Markets
- Challenges Data Definition, Structures, symbologies; Investment into Marking Technologies; Integration into existing systems in the field
- Alignment to Global Standards Critical



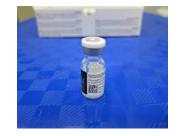
Recommendations

Barcodes are recommended on all packaging levels used by manufacturers, with the exception of the primary packaging level, and should conform to GS1 standards and associated specifications.

Barcode data should include the Global Trade Item Number (GTIN), lot number, and expiry date.

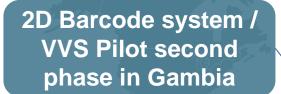








Barcode Landscape in the Developing World



Barcode Proof of Principle in Tanzania

Ethiopia Pilot for E2E Supply Chain Visibility

Implementation of GS1 Standards in Pakistan



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Call to Action

It's time to partner together – both governments and pharmaceutical companies – to operationalize and improve technology for the most impact.

What We Need:

- Government participation
- Pharma EPI programs alignment
- Alliance partners engagement
- Get the message out!
- Make this a priority







Barcode technology can increase access to potentially life saving vaccines.



Safer, more efficient care starts with a simple scan.



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