



The Global Language of Business

What Is Next After the Results of Implementing GS1 Pilot in the Public Health Supply Chains! ongoing progress in Pakistan

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Envisioning a track & trace in Pharmaceutical Systems; lives can be saved when implemented (Lahore Tragedy)



Case of IsoTab and Tyno Syrup

Deaths of 186 patients in 2012 at PIC due to Adverse Drug Reaction by ISOTAB; another 1000 patients

Likewise, in the same year, many patient died due to Tyno Syrup

Federal Ombudsman 9th Recommendation

Forfeit and spurious drugs





GS1 standards pilot in Pakistan

- First GS1 standards pilot by EPI / PPW and USAID DELVIER Project on vaccine and contraceptives products during 2015.
- GS1 standards were tested and following recommendation for GS1 legislations
 - Standards explicitly defined in local context e.g. GTIN, GLIN and data sharing protocols
 - Industry regulations required
 - Packaging levels
 - Printed barcodes
 - Serialization to enable track and trace
 - Inventory accuracy
 - Batch tracing



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What benefits Pakistani pharmaceutical industry is looking for?



- Provides traceability of authentic products to patients
- One standard for use with all pharmaceutical partners
- Fast and accurate data capture at every point in the supply chain
- Recognition of goods that allows efficient, accurate and targeted recalls
- Improved company to company communications throughout the supply chain
- The ability to automate warehousing
- GS1 at services level – time and cost saving for healthcare providers
- B2C enabling environment as an initial step towards ensuring public protection and patient safety against spurious, falsified and



counterfeit drug

Secretary, MoNHSR&C; CEO, DRAP; USAID; and Global Health Supply Chain Program discussing GS 1 summary for the Prime Minister





GS1 Legislation and Implementation

- The new rules added to the existing Pharmaceutical Labelling rules, as an additional requirement to the existing ones.
 - Requirement for GS1 Global Standards after hectic debates and negotiations at all levels of public offices, regulatory frame work and with private sector.
 - Phase wise implementation strategy – initial 6 months voluntarily submission, starting with secondary (saleable) pack, followed by primary and tertiary and serialization with two years grace period for preparedness.
 - Firms are free to contact any solution provider but to be GS1 compliant. Simple ways and means to start with available flexibilities.
 - GS1 guidelines and printing and scanning requirements to follow. GTIN – No 14
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- National Registry with GS1 compliant features and requirements



Political Commitment and Stakeholders' Engagement



- Due to strong desire and political commitment to safe people from the menace of spurious, falsified, counterfeit and fake pharmaceutical products; and tools for track and track system in domestic and international supply chain; the initiative of implementation of 2D data matrix, as a starting point has been presented:
- After various awareness marathon meetings, national consultative meetings were held with all stake holders, including Pharmaceutical Manufacturer's Association, Pharma Bureau, Pakistan Drug importers associations, representatives of manufacturers, importers, distributors, retail pharmacies, consumer association, provincial governments, etc.
- Trainings and educations, pilot studies, hands on training for 2D Data matrix on secondary packaging on routine packaging line, with almost no additional cost.
- Benefit to industry, public procurement, institutions, pharmacies, patient use and safety.



Way forward

- Drug Regulatory Authority of Pakistan
 - GS1 Standards Legislation in Pakistan - Summary approved by Prime Minister (formal approval awaited from Cabinet Division, Government of Pakistan)
- Drug Regulatory Authority of Punjab Province issued notification / Public Awareness for Implementation of 2D Data Matrix Bar Code Serialization System on Medicines to be Procured During 2017-18 & onwards.
- Barcode compliance to some imported products has started already (e.g., Pentavalent, BCG, Measles and Pregna)
- Pakistan LMIS platform can track and trace a few products at some locations
- A 3 year 2 D Datamatrix deployment strategy is planned to enforce regulatory progress/compliance and infrastructural/HR capabilities (hardware and software)