



# Implications of recent notifications regarding Anti- Counterfeit Labelling Solutions

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# Introduction

- 1D Barcodes: Appear as vertical parallel lines of varying thickness 
- 2D Barcodes: Barcode evolved into another geometric patterns 
- Barcode scanner 
- June 1974: Wrigleys pack was scanned at the sale counter



# Benefits of Barcodes

- Automated Data capture, 100% accuracy
- Real time inventory control
- Fast and accurate data recovery on product, movement and track and trace.
- Easy integration with existing software
- Compliance with Government regulations and market requirements
- In-line with international needs
- Gives that international look



# Counterfeiting?

- A deliberate attempt to deceive consumers by copying and marketing goods bearing well known trademarks, so that they look like the original products made by a reputed manufacturer
- Counterfeiting is one of the fastest growing financial crimes



# Counterfeiting?

- Annual global trade in illegitimate goods is about \$600 billion
- Expected to rise to \$1.7 trillion by 2015, representing 5% to 7% of all worldwide trade.
- The size of global fake drugs industry is estimated to be 90 billion US Dollars.



# Barcodes in India

- GS1 promoted jointly by government and industry in 1996
- Financial assistance scheme introduced for implementation of barcodes by MSME
- 20<sup>th</sup> October 2009, The Ministry of health and family welfare, made GS1 barcodes mandatory on all drugs, devices, etc.



# Barcodes in India

- Government wants to take decisive action against the menace of substandard and spurious medicines being pumped into the public healthcare system
- January 10<sup>th</sup>, 2011 Government makes it mandatory for exporters of pharmaceutical products to build track and trace capability. Barcodes made mandatory on primary, secondary and tertiary packaging for pharmaceutical exports.



# Barcodes in India



Salient features of the order;

❖ Barcodes on tertiary packaging from 1<sup>st</sup> October, 2011

(Tertiary packaging or Shipper/Carton Level Packaging: Is defined as a level of packaging that may contain one or more primary/secondary levels of packaging.) Incorporation of barcodes **Requirement:** (1 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Tertiary pack (shipper/carton)



# Barcodes in India



❖ On Secondary packaging from 1<sup>st</sup> January, 2012

(Secondary Level Packaging: Is defined as a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.)

- **Requirement:** Incorporation of barcodes (1D or 2 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Secondary pack



# Barcodes in India



❖ On Primary packaging from 1<sup>st</sup> July, 2012

(Primary Level Packaging: Is defined as the first level of packaging in direct contact with the product)

**Requirement:** Incorporation of 2D (GS 1 Data matrix) barcodes on medicines at strip/vial/bottle level encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Primary pack.



# Barcodes in India

- In case of specific mandate by importing country, adhere to that.
- Manufacturer required to maintain serialized record of exported products for 6 months
- Authentication features to be added and integrated to Track N Trace system
- Govt. to setup central portal for tracking exported products



# Barcodes in India

- There are about 6000 SMEs in the pharma sector. Their concerns are
  - Products costlier
  - Loose sales due to already existing tough competition
  - High cost of implementation
  - Cost of barcode per strip or vial will make the product unsalable
  - SMEs have mostly manual packing facilities.



## Barcodes in India

- Government under pressure to eradicate fake drugs
- Government in no mood to relent and is enforcing implementation.



# Barcodes in India



- On 25.10.11 government issues another notification as clarification.
- As per Public Notice No. 59 (RE-2010)/2009-14 dated 30.06.2011, incorporation of barcodes (1 D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Tertiary pack (shipper/carton) on export consignments of pharmaceuticals and drugs has come into effect from 01.10.2011.
- 2. It is clarified that the above barcoding requirement is compulsory for pharmaceuticals and drugs manufactured on or after 01.10.2011.

# Barcodes in India

- Harsh steps to ensure public health and safety
- The order will be implemented!
- Pharma exporters will have to comply with the order





• Thank you