NEXUS '16

Mastering Global Traceability
with a Digital Supply Chain Network

India : Market, Compliance and Working with the Regulators

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Greetings from India

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India: Market, Compliance and working with Regulators

Discussion Points

Overview of Indian Pharma Industry and Market

Patient Safety Initiatives by India – Control of Counterfeit (Spurious) Drugs

Serialization / Track & Trace – Genesis of DGFT Public Notice

Present Challenges for TnT Implementation

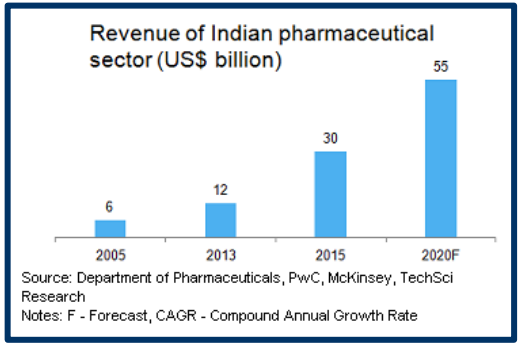
Collaboration with Industry and Regulators

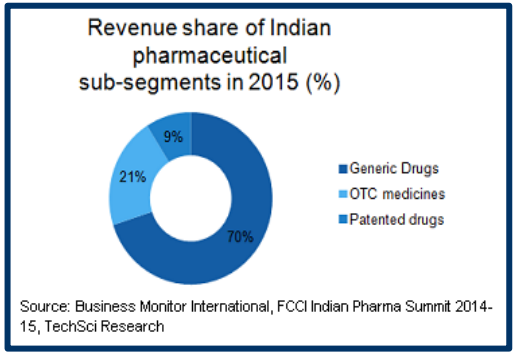
Indian Pharmaceutical Industry

Third largest producer of generic medicines by volume with an export turnover of US$ 16 billion and growing at 15% CAGR , supplying quality medicines to over 220 countries.

Highest number of FDA & MHRA approved facilities out side of USA and UK

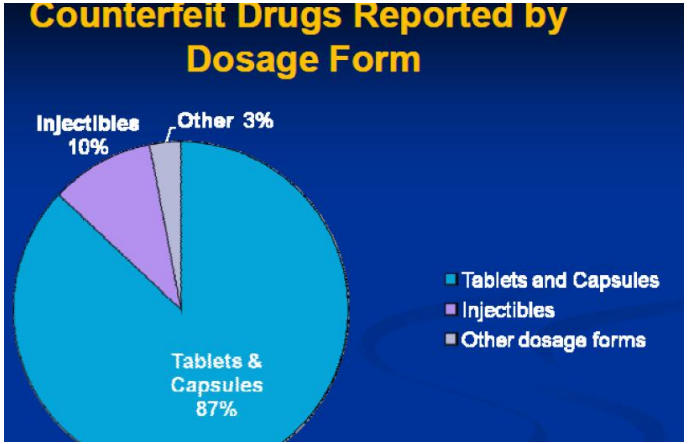
The domestic industry turnover of over US$ 15 billion and is estimated to grow at CAGR12.1% (2012-2020)





India is regarded as 'Pharmacy of the World

Global Counterfeit Industry



Facilitation of Counterfeit Drug Products

- **Price differentials create drug diversion within and between distribution channels.**
- **Weak regulatory control and enforcement.**
- **Extended and unregulated markets and distribution channels.**
- **Weak legal processes for remedial action and poor penalties against counterfeiters**

Estimate of Counterfeit Market :

USD 75 Billion to USD 200 Billion, which means that between 8 percent and 15 percent of all medicines sold worldwide appear to be fake.

International Policy Network report puts the number of deaths due to fake tuberculosis and malaria drugs alone at 700,000 per year.

Today it is estimated that counterfeit versions of more than **800** pharmaceutical drugs are circulating in markets globally. (Osteoporosis, Cancer, HIV/AIDS, Blood thinning, etc.)

Source : www.worldfinance.com

Control of Spurious Drugs – A Patient Safety Initiative

Being a Pharmacy to the World with strong presence in Global and Domestic markets, India is committed to ensure PATIENT SAFETY and shares the global concern of dealing with the menace of Counterfeit Medicines.

India is committed to adoption of modern technology for ensuring supply chain integrity of medicines besides creating strong regulatory framework for enforcement of newly introduced specific regulations *(covered in subsequent slides).*

Control of Spurious Drugs – A Patient Safety Initiative

Patient-focused Manufacturing, Quality & Regulatory Solutions

There has been a paradigm shift in the industry's approach for determination of quality and safety of drug products going beyond the end product testing and GMP compliance during manufacturing

The industry is moving towards the desired state of Achieving Product Realization that requires the drug products to have quality attributes appropriate to meet the needs of Patients, Healthcare professionals, Regulators and internal and external customers through the product lifecycle.

Thus, supply chain integrity has become one of the essential quality attributes of medicines and the industry focus is on adopting appropriate anti-counterfeit measures for ensuring access of safe medicines to patients

Control of Spurious Drugs – A Patient Safety Initiative

Definition of Counterfeit and Spurious Drugs

A Counterfeit Medicine is the one which is deliberately and fraudulently mislabelled with respect to identity and / or source
Counterfeit products may include products with
- the correct ingredients or with
- the wrong ingredients
- without active ingredient with
- insufficient / inadequate quantities of ingredient(s) or with
- fake packing

The term Counterfeit Medicine is not defined in the Indian Drugs & Cosmetics Act 1940 (D&C Act). Instead the terms Spurious Drugs and Adulterated Drugs are defined in the D&C Act

Control of Spurious Drugs – A Patient Safety Initiative

Definition of Spurious Drugs in D&C Act 1940

(a) If it is manufactured under a name which belongs to another drug; or
(b) If it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or
(c) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
(d) If it has been substituted wholly or in part by another drug or substance; or
(e) If it purports to be the product of a manufacturer of whom it is not truly a product.

Control of Spurious Drugs – A Patient Safety Initiative

Definition of Counterfeit and Spurious Drugs

There is no universally agreed definition of the term Counterfeit yet. WHO uses the term
- Substandard,
- Spurious,
- Falsely labeled,
- Falsified and
- Counterfeit (SSFFC).

The term counterfeit is closely associated with intellectual property related legislation that seems to have reduced the focus from what is first and foremost a Public Health issue.

The term Spurious drugs as defined in D&C Act focuses on drugs manufactured

- in the name of another drug,
- resembling another drug,
- in the name of another person,
- in fictitious name and
- by substituting the drug in part or full

Control of Spurious Drugs – A Patient Safety Initiative

Definition of Counterfeit and Spurious Drugs

It is widely accepted that whilst spurious, falsely labelled, falsified or counterfeit medicines are substandard, it is not necessarily the case that all substandard medicines are spurious, falsely labelled, falsified or counterfeit. The substandard, may include accidental manufacturing errors

In terms of data collection and analysis it is important to identify and examine the characteristics peculiar to each suspected SSFFC medical product in order to determine the intentional or accidental aspects of the incident.

This approach does not necessarily require a universally agreed definition since focus is on identifying and controlling harmful drugs manufactured with fraudulent intent.

Control of Spurious Drugs – A Patient Safety Initiative

Several initiatives are taken by Indian Government to control the menace of spurious Drugs

1. Surveys to assess the extent of the counterfeit products

- SearPharm Report on Extent of Spurious (Counterfeit), Medicines in India in 2007 studied over 10,000 packs estimated it at 0.46%
- CDSCO conducted a survey between April and July 2012 and a total of 18,262 samples were tested, out of which only 25 were found to be spurious
- National Institute of Biologicals under CDSCO is in the process of scrutinizing over 47,000 drug samples, as reported by DCG(I) in 2015

Control of Spurious Drugs – A Patient Safety Initiative

2. D&C Act Amendment Bill 2008 for stringent punishment

- Notwithstanding the extent of the problem, Government of India amended the Drugs & Cosmetics Act in 2008
- Introduced stringent punishment and penalties for the manufacturer of Spurious Drugs and Adulterated Drugs and made the offence non-bailable.

3. Feasibility Study for Drug Track and Trace in domestic market.

- Public welfare and consumer empowerment measure initiated by Ministry of Health and Family Welfare
- Simpler means and ways to establish drug authentication and secure distribution network of drugs in domestic and international market
- Feasibility Study for Drug Track and Trace for drugs marketed in India by WIPRO in 2012

Keeping the focus on primary objective of ensuring patient safety , whether the definition of the term Counterfeit Medicine should include the following?

- Substandard drugs having no potential for adverse impact on Patients
- Drugs manufactured without permission from the license holder even if they are of good quality
- Drugs of standard quality labeled with the name of another manufacturer, another brand name with an intent to deceive the consumer of its identity and /or source
- Drugs that are falsely labeled with respect to identity and / or source, manufactured without license and of suspect quality that may cause harm to Patients

Control of Spurious Drugs – A Patient Safety Initiative

4. Industry Initiative Anti-Counterfeiting Measures

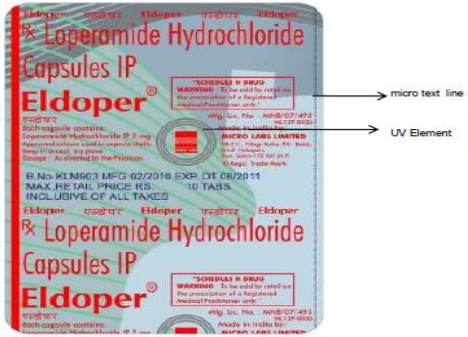
Technological Anti-Counterfeiting Measures

Major Types:

- Overt technologies-(Visible Features)
- Covert technologies -(Hidden Features)
- Forensic technologies
- Serialization / Track-n-trace technologies

Desirable Technology for assuring e-pedigree

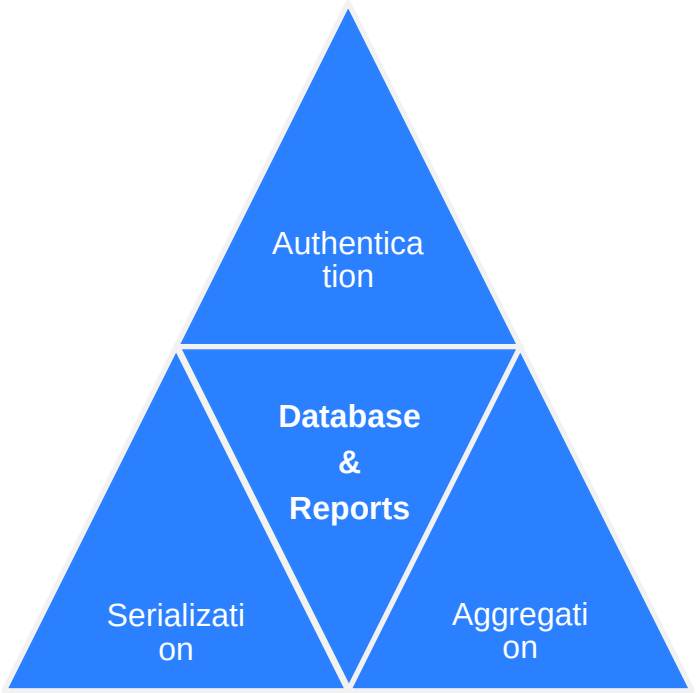
An ideal technology should provide a comprehensive solution for addressing ***identity, authenticity and secure real-time track-n-trace.***



Industry Initiative Anti-Counterfeiting Measures

Serialization / Track-n-trace technology was considered appropriate for assuring a secure e-pedigree for a medical product enabling its safeguard against imminent duplication

Track & Trace Pyramid



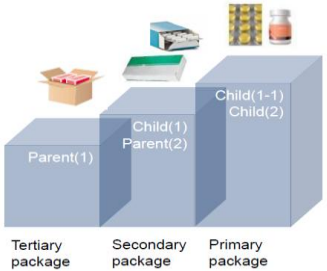
India Regulations for Export Products

5. Director General of Foreign Trade (DGFT) Public Notice:

- Global Trade Item Number (GTIN) (01)
- Batch Number of Product (10)
- Expiry Date of Product (17)
- Unique Serial Number (21)

Serialization

Drug Authentication & Verification Application



Aggregation

Public Notice relating to Tracing & Tracking of Export Consignments of Pharmaceuticals & Drugs using Bar code technology as per GS1 global standards has been introduced by DGFT, Ministry of Commerce and Industry, Government of India in 2011.

- Constant dialogue between the Industry & Ministry of Commerce has led to various changes to the notification to encourage industry for compliance

10th January 2011	11th July 2012	26th June 2014
30th June 2011	5th April 2013	6th August 2014
25th October 2011	17th October 2013	1st April 2015
28th November 2011	1st April 2014	22nd May 2015
22nd December 2011	15th April 2014	5th Jan 2016

DGFT Compliance & Challenges

1.The Compliance to export regulations is satisfactory for tertiary packs however, the compliance of 2D bar coding for secondary packs needs to be improved

2. Some of the issues to be resolved

- Customer & Importing countries' requirements,
-Efficiency of DAVA Portal
-Ability to decode the information by the importing country

-Change in artworks / Prior approval from MoH,

-Exemption from the DGFT requirements

Operational Challenges:

Total System Validation / Regulatory Compliance

Integration : CMO , WH and DC , Government

T & T Architecture – Global / Local , Site Server or Cloud

OEE and Down Time

I T Challenges : Integration with ERP / WMS

DGFT Compliance & Challenges

Packing Line Challenges:

Space Constraint

Packaging Layout and Line Modification / Retrofitting

Multi Department Involvement

Integration with various Indian Packaging Machinery

Casual Labour on Packaging Line

Productivity / Overall Line Efficiency Drop ?

Impact on OEE / Line Efficiency due to Aggregation

India Specific Challenges for Export & Domestic Market

- Exporting Companies from SSI to MNC to 200 Countries
- TnT – A New Concept / Lack of Knowledge and Clarity
- Multiple Packaging Configuration on Same Line
- Low Skilled Packaging Operators
- ROI from Serialization ?
- Capital Investment / Affordability for Small Companies
- Complex labeling requirements with no space on small labels to introduce bar codes

India Regulations for Domestic Market

Ministry of Health (MoH) Government of India initiative

- A task force under the chairmanship of Dr.H.G.Koshia was formed to study the feasibility of introducing UID / bar coding system in 2011
- It was recommended to carry out the implementation of UID study in 2 phases starting with a pilot project in phase I for 1 year followed by extending it to 2000 companies in Phase II
- Track &Trace through bar code project would start thereafter also in 2 phases of 2 years each
- Phase III would cover all manufacturers with 6 monthly review of progress that would be followed by an amendment to the D&C Rules for introduction of Bar Codes for authentication and Track & Trace

India Regulations for Domestic Market

Ministry of Health (MoH) Government of India initiative

- A draft notification to amend Rule 96 of D&C Rules 1945 was issued on 3rd June 2015 to introduce Bar coding on all packs .
- This is under discussion since it has been notified without conducting the pilot studies as recommended by the task force
- The challenges of implementing serialization projects are many as discussed in subsequent part

India Regulations Compliance Challenges

The compliance with these requirements has been found to be challenging for various technical and commercial reasons

1. Over 15,000 manufacturers. The industry is fragmented and each sector , small , medium and large has it's own issues

2. TnT – A New Concept / Lack of Knowledge and Clarity

3. Capital Investment / Affordability for Small Companies. Estimated cost USD 30,000 per line

4.Low Skilled Packaging Operators

5.Complex labeling requirements with no space on small labels to introduce bar codes

6.Primary level implementation very complex

7. Inadequacy of DAVA Portal – Voluminous data to be handled, data over 60,000 formulations produced daily by 15,000 manufacturers supplying to 800,000 retailers

8. All stakeholders have to be aligned to provide and use facilities for TnT

9. Multiple Packaging Configuration on Same Line

Way Forward

Start Small

Follow the recommendations of the task force in implementing the project in phased manner . These projects would be manageable and it is easier to measure if the established objectives are being achieved.

Ensure Buy In

Gaining buy in from various sectors of the industry including distributors is still important to be able to track & trace all the way to the retail outlet, whether that is a hospital or a pharmacy.

Experience Matters

Choosing an experienced vendor will help reduce concerns and ensure that the solution is well designed for the particular pharmaceutical company.

Active Engagement with the regulators :

Proactive engagement with suggestions for compliance

Way Forward - Working with Regulators

IDMA: IDMA as a premier industry association representing close to 1000 companies is considered as voice of the National Pharma Sector

IDMA has been actively engaged with the government and regulators in finding workable solutions for implementation of Track and Trace initiatives.

IDMA has proposed amendment to D&C Rules to simplify the labeling requirements

Pharmexcil: Similarly, Pharmexcil is also very active in educating and encouraging the industry for implementation of Track and Trace initiatives.

Holistic Approach

The Industry through leading associations along with the Solution Providers has to work with the Regulatory Authorities and Government for finding out cost effective solutions of Authentication and TnT through reliable vendors

The needs of all Sectors and Stakeholders have to be addressed together in the overall interest of patient safety.

What are the measures for correctly estimating and controlling the nature and extent of the counterfeit drugs?

- Join WHO initiative for surveillance and information sharing to fight SSFFC medical products
- Redefine the term Counterfeit Medicine to make it universal by agreement of all stakeholders
- Ban Internet sale of medicines
- Develop an international convention and legislative framework applicable globally for dealing with SSFFC products

Conclusion

Together ,

Let us make a Better World : Safe and Healthy

Thank You for Your Attention

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