

**Track and Trace Adoption in  
Indian Pharmaceutical Products**

**2011**



Confederation of Indian Industry





White Paper on

*“Track and Trace Adoption  
in  
Indian Pharmaceutical  
Products”*



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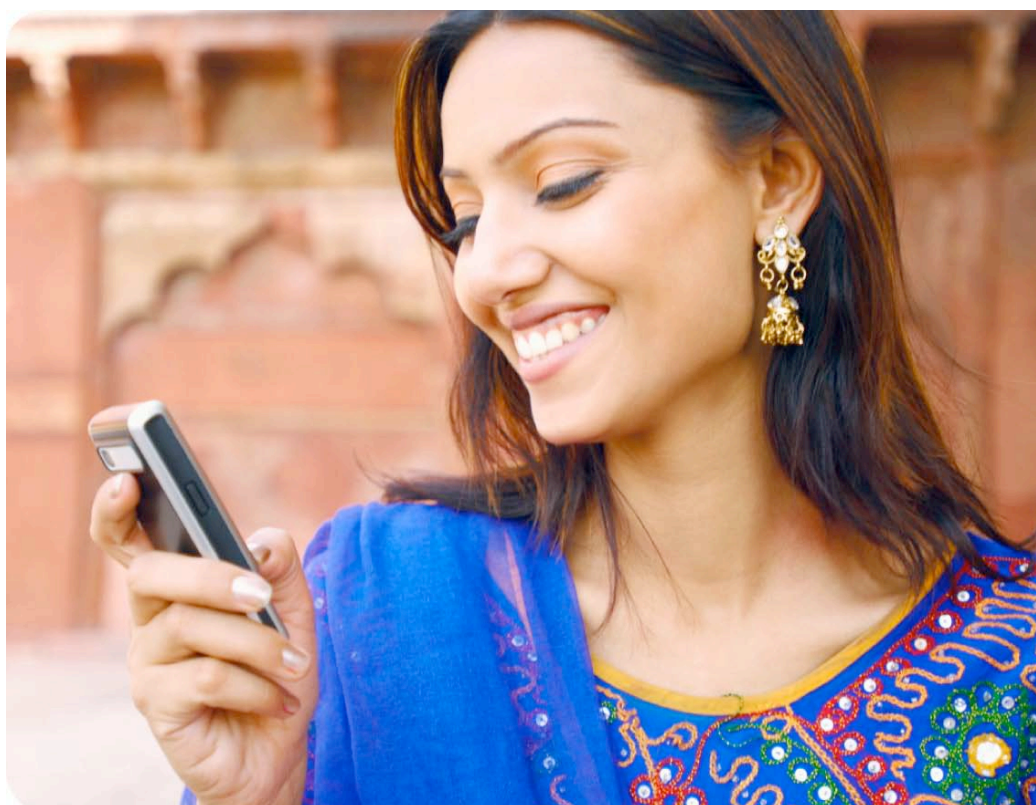
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## Introduction

Following the global trend to combat counterfeit medicine, and the local need to secure Indian pharmaceutical exports, The Directorate General of Foreign Trade (DGFT) in January 2011, issued a circular requiring the implementation of mass Serialization as part of a Track and Trace system on all pharmaceuticals manufactured in India for export.

In this paper we aim to review the global challenge of counterfeit medications before we analyze the DGFT regulations, the technology available for its implementation, how serialization will integrate into the global pharmaceutical regulatory environment, and the benefits of the DGFT regulation to the Indian pharmaceutical industry.



## Global Challenge of Counterfeit Medicine

Counterfeit medicine is a serious global problem. Ranging from random mixtures of harmful toxic substances to inactive, ineffective preparations they look so similar to the genuine product that they deceive health professionals as well as patients. WHO (2010), describes elimination of counterfeit medicine as a considerable public health challenge.

### Impact on public health

On an individual level, the public health risk of counterfeit medicine is high as their contents can be dangerous or they can lack active ingredients. This may result in treatment failure, increased resistance or even death.

On the other hand, for a public health system as a whole, difficulty in tracing the manufacturing and distribution channels of counterfeit medicine makes their circulation difficult to stop. As per the WHO (2010) fact sheet, even a single case of counterfeit medicine is unacceptable since it indicates that the pharmaceutical supply system in which it was detected is vulnerable. Worse, it undermines the credibility of national health and enforcement authorities.

The spread of counterfeit drugs is widespread internationally affecting developed and developing countries. However WHO states that the problem of counterfeiting of drugs is more pronounced in countries where the manufacture, importation, distribution, supply and sales on the drugs are less regulated or weakly enforced.

### The rise of the WHO response against counterfeiting

The public health and economic challenges posed by Spurious/Falsely-labeled/Falsified/Counterfeit (SFFC) drugs were first brought to the international agenda in 1985 at the Conference of Experts on Rational Drug Use in Nairobi, Kenya. The meeting recommended that WHO, together with other international and non-governmental organizations, should study the feasibility of setting up a clearing house to collect data and to inform governments about the nature and extent of counterfeiting.





This conference also led to a series of resolutions adopted by the World Health Assembly which requested WHO to initiate programmes for the prevention and detection of the export, import and smuggling of falsely labeled, counterfeited or substandard pharmaceutical preparations (WHO, 2011).

The focus on counterfeiting led to the creation of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in Feb 2006.

IMPACT has defined the problem:

*"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."*

Since that time, the global scale of counterfeit medicine production and distribution has grown to an estimated 10% of medicines sold worldwide (Healthcare and Medical, 2011), and as high as 25% in developing countries (WHO, 2006).



Figure 1: Burnt counterfeit drugs; Source: Vanguard Newspaper

Recent studies have revealed the extent of counterfeit medications internationally. In 2004, they were estimated to account for 40% of drugs sold in

Nigeria and Pakistan (9); and over 10% for Mexico and Russia; in Mexico alone, this amounts to over \$650 million annually (1).

Counterfeiting is becoming more and more sophisticated; vital drugs such as antiretroviral are increasingly being noted to be counterfeited (2). A study done locally in India in 2002 showed that as many as 9 per cent of all drugs tested were substandard. In 2004 it was estimated to have reached over one billion in market value (7).

The “Report on Countrywide Survey for Spurious Drugs” release by the Central Drugs Standard Control Organization (CDSCO) outlines the level of counterfeit medicine to be around 0.04% in the market (13).

While this differs from other estimates there is significant concern for the increasing number of cases of drugs turning out to be substandard. The government of India has taken strong measures to protect the health of Indian pharmaceutical consumers.

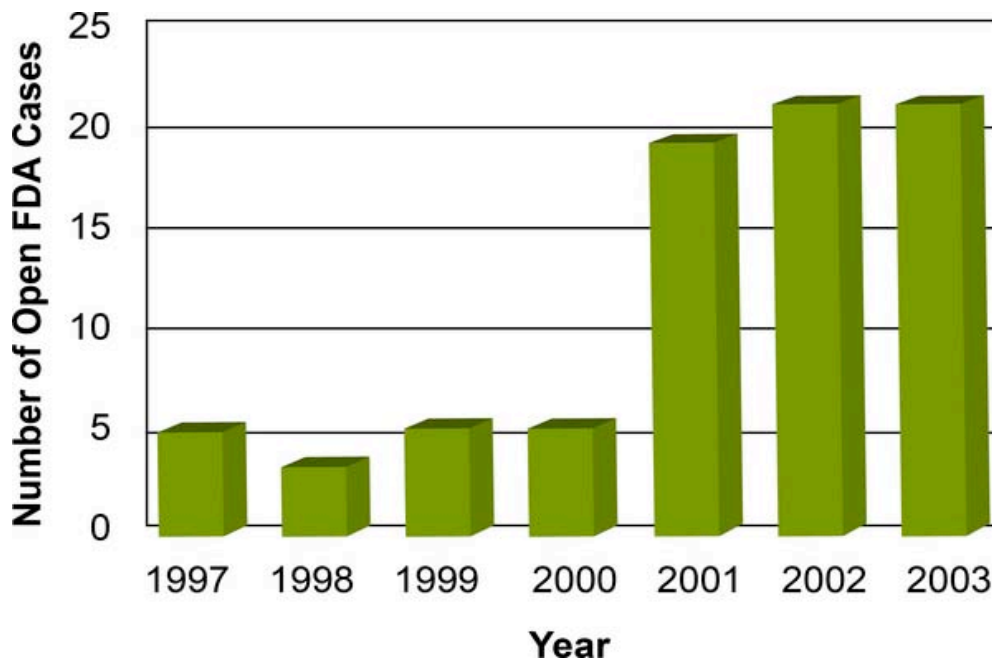


Figure 2: Rising cases of investigations of possible counterfeit drugs by USFDA (Dondorp AM, 2004)

The above diagram shows that there has been an increase in the number of cases being investigated for counterfeiting by the US Food and Drug Administration from 1997 to 2003.

### Medicine types being counterfeited

Virtually all categories of medicine have been counterfeited in various countries especially in the developing world. Counterfeiting is found in both branded and generic products with some containing similar compounds as the original product while others contain either very little of the original compound or a totally different compound, which may be harmful when consumed (Stevens, 2006)(IMPACT, 2010). See figure below:

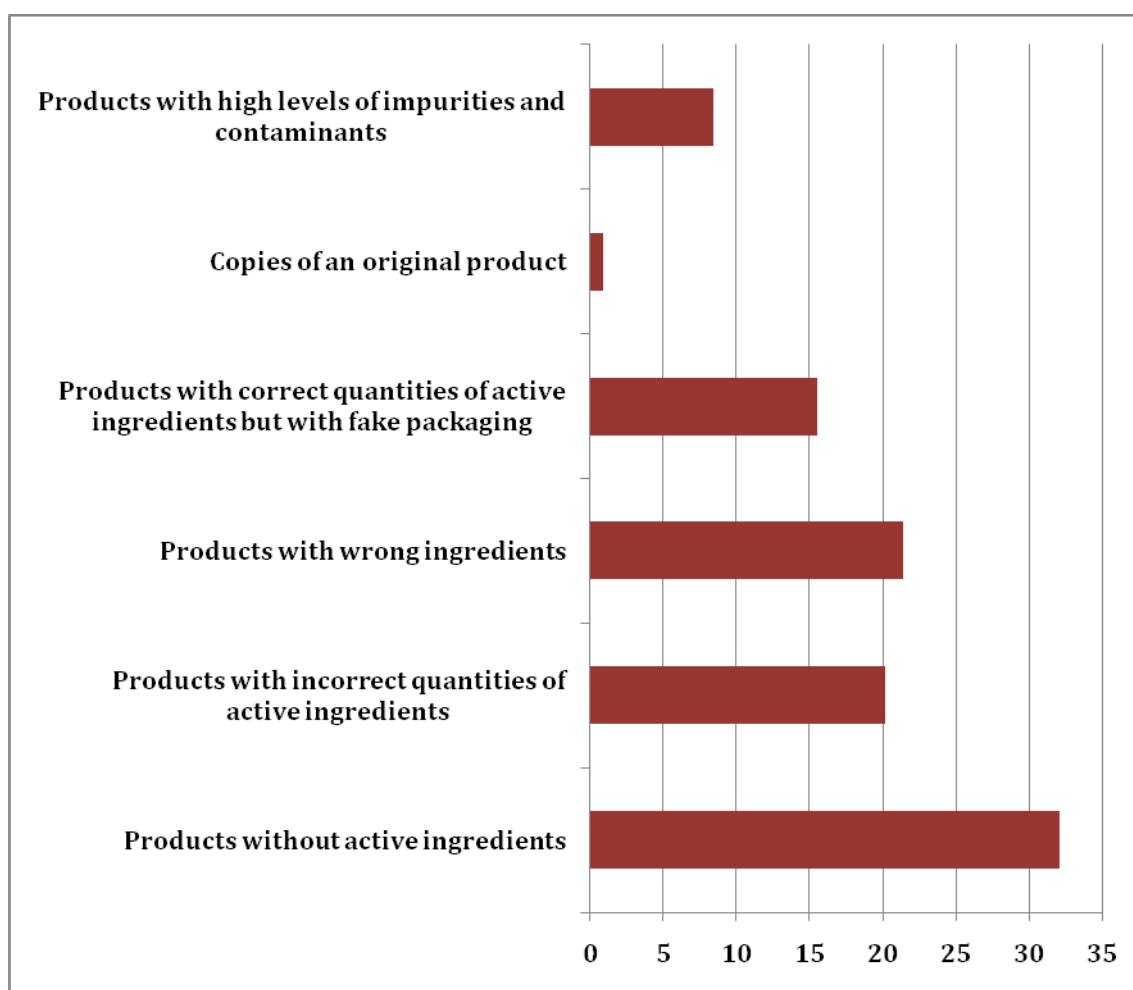
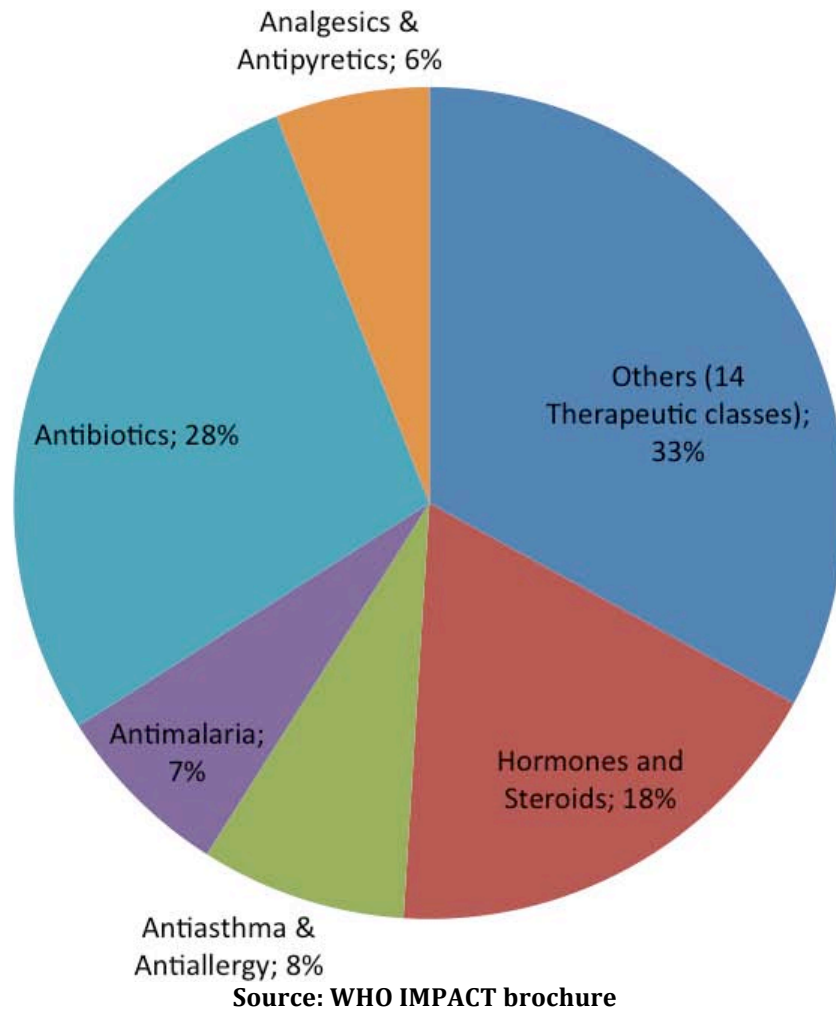


Figure 3: Medicine Types being counterfeited

Source <http://www.who.int/medicines/services/counterfeit/overview/en/>

WHO put together reports of counterfeit medications from various countries sent to them from 1999 to 2003, and concluded that virtually no class of medicine was left out by counterfeiters (IMPACT, 2010). See figure below.

Figure 4: Report of counterfeit drugs by therapeutic class received by WHO 1999 -2002



### Counterfeit Medicine and Healthcare

The negative effect of counterfeit medicine to healthcare cannot be overemphasized. It has led to a global public health crisis being felt in all parts of the globe (IMPACT, 2010). According to a WHO report in 2006, the use of fake vaccine lead to the death of 2500 persons in Niger during meningitis epidemics in 1995(WHO, 2006). The same report noted that in the same year, 89 infants died in Haiti following consumption of paracetamol cough syrup prepared with diethylene glycol. Similar chemicals resulted in the deaths of 30 infants in India in 1998. Consumption of counterfeit medicine caused a series of deaths in 2004(IMPACT, 2010). In 2001, 192,000 patients died in China as a result of fake drugs (Robert Cockburn, 2005).

One major threat being posed by counterfeit medicine is increased emergence of drug resistance disease causing organisms (Stevens, 2006). This is because most counterfeit medicine contains inadequate concentration of active ingredients leading to exposure of agents to low concentration of such drugs.

The resistant organisms are then able to multiply and spread. The control of diseases like Malaria, HIV/AIDS and Tuberculosis in many developing countries will continue to be a major challenge if the problem of spurious and substandard medicine is not tackled.

## Regulatory Environment

### Global context

IMPACT comprises of all 193 WHO member states on a voluntary basis and includes international organizations, enforcement agencies, national drug regulatory authorities, customs and police organizations, etc and receives support from them. It assists member states to develop and implement legislation to tackle counterfeit medicine and also offers an important avenue for improved communication among different national enforcement officials. As a result, many developed and developing countries of the world established National Medicines Regulatory Authorities to combat counterfeiting to ensure that quality, safe and efficacious medicines are available for use in their countries.

WHO also organized an international conference on 'Combating Counterfeit Drugs: Building Effective International Collaboration' in Rome in February 18<sup>th</sup> 2008 which gave rise to what is known as the Declaration of Rome.

The following chart shows the global regulatory requirement for serialization/track and trace for pharmaceutical manufacturers.



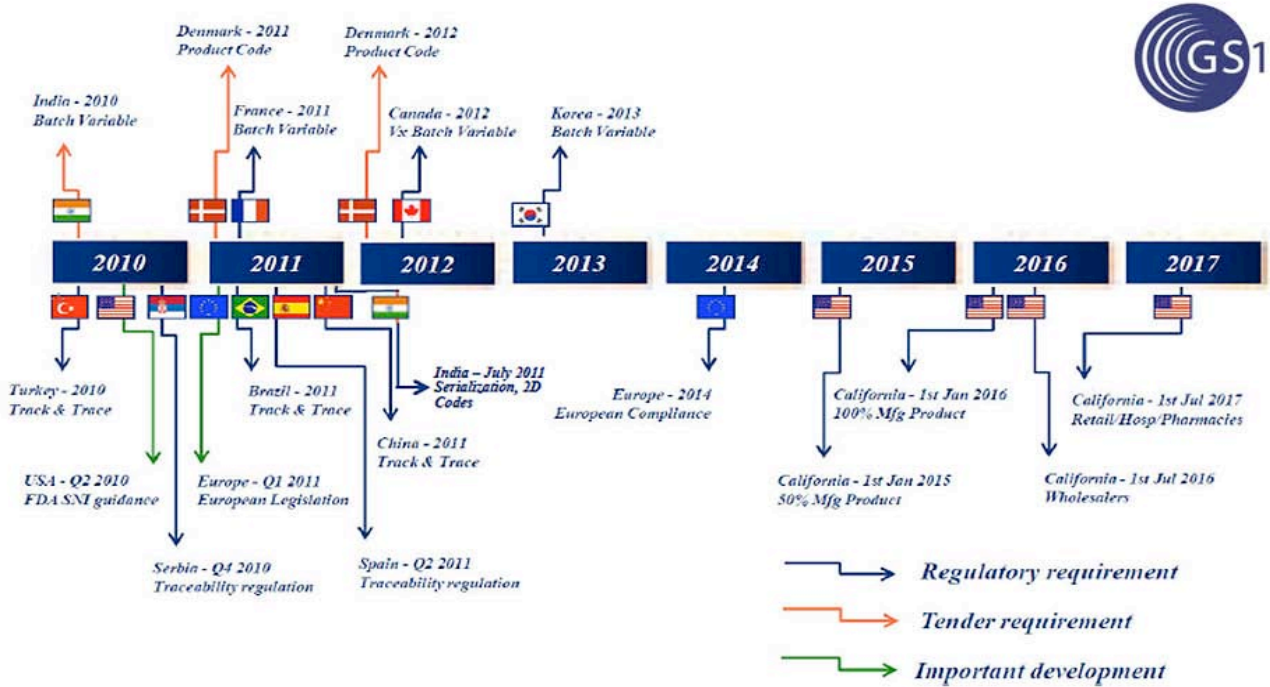


Figure 5: Global regulatory requirements; Courtesy: GS1 UK

### Indian scenario: the DGFT Track and Trace Regulations

In January 2011 and subsequently in June 2011, the Directorate General of Foreign Trade (DGFT) issued a circular (*Public Notice No.21 (RE-2011)/2009-2014 & Public Notice No. 59 (RE-2010)/2009-2014*), requiring the implementation of mass serialization as part of a track and trace system on all pharmaceuticals manufactured within India for export. The regulations requires all of India's pharmaceutical exporters to build track and trace capability by serializing products adhering to the GS1 Global Standards at the primary, secondary, and tertiary packaging levels as defined below:

**Primary Packaging:** Incorporation of 2D (GS1 Data matrix) barcodes on medicines at strip/vial/bottle, etc. encoding unique product identification code (GTIN) and Unique Serial Number of the Primary pack


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

**Tertiary Packaging:** Incorporation of barcodes (1D) encoding unique product identification code (GTIN), Batch Number, Expiry Date and Unique Serial Number of the Tertiary pack (shipper/carton)


*As of June 2011, full compliance to these regulations must be in effect by October 1, 2011 for tertiary packaging; January 1, 2012 for secondary packaging; and July 1, 2012 for primary packaging.*

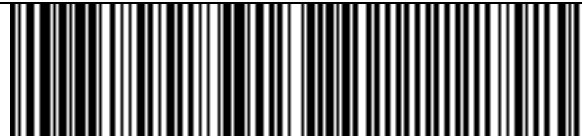
If, however, the country importing pharmaceuticals from India has mandated an alternate or more specific requirement, it will be possible to replace this regulatory requirement with those described above. Also, the manufacturer will be required to maintain the data associated with primary, secondary, and tertiary serialization for at least 6 months after the product's expiration. In time, authentication features will also be made mandatory. The government is working on building a central portal for the tracking and tracing of export pharmaceutical products.

Below, we can see the standard serialization requirements for primary, secondary, and tertiary packaging as per the GS1 Standards.

 <p>(01)07612345678900 (21)tbgmjuja5</p>	<p><b>Primary Coding Information</b></p> <ol style="list-style-type: none"> <li>1. GTIN: Global Trade Item Number</li> <li>2. Unique Serial Number of Primary Pack using GS1 Application Identifier (21)</li> </ol>
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 <p>(01)07612345678900 (17)110829 (10)abc123 (21)tbgmjuja6</p>	<p><b>Secondary Coding Information</b></p> <ol style="list-style-type: none"> <li>1. GTIN: Global Trade Item number</li> <li>2. Batch Number of Product: using GS1 Application Identifier (10)</li> <li>3. Expiry Date of Product: using GS1 Application Identifier (17)</li> <li>4. Unique Serial Number of Secondary Pack: using GS1 Application Identifier (21)</li> </ol>
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<p><b>Tertiary Coding Information</b></p> <p><b>First Barcode</b></p> <ol style="list-style-type: none"> <li>1. GTIN: Global Trade Item number</li> <li>2. Batch Number of Product using GS1 Application Identifier (10)</li> <li>3. Expiry Date of Product using GS1 Application Identifier (17)</li> </ol>
 <p>( 0 1 ) 0 7 6 1 2 3 4 5 6 7 8 9 0 0 ( 1 7 ) 1 1 0 8 2 9 ( 1 0 ) a b c 1 2 3 4</p>

<p><b>Tertiary Coding Information</b></p> <p><b>Second Barcode</b></p> <ol style="list-style-type: none"> <li>1. SSCC: Serial Shipping Container Code using GS1 Application Identifier (00)</li> </ol>
 <p>( 0 0 ) 1 7 6 1 2 3 4 5 0 0 0 0 0 0 0 1 1</p>



The primary difference between 1D and 2D barcodes are that 2D codes can encode more information, occupy less space, and can be more resilient when damaged. Also, 1D codes are typically read with laser scanners, while 2D codes are read with image scanners. Below we see how the same information can be encoded with either format of code.

Figure 6: 1D and 2D bar codes



## Achieving Serialization/Track and Trace in India

### Compliance:

A phase wise process was suggested by the DGFT in the adoption of this technology by the industry. The first phase requires serialization of all tertiary packages to be completed by October 1<sup>st</sup>, 2011, followed by secondary packaging level serialization by January 1<sup>st</sup>, 2012 and finally Primary packaging level by July 1<sup>st</sup>, 2012. The technological sophistication rises as we go down the packaging hierarchy. A staggered method enables the industry to ease in the technology by adding additional levels of packaging one by one.

### Phase 1: Tertiary packaging level

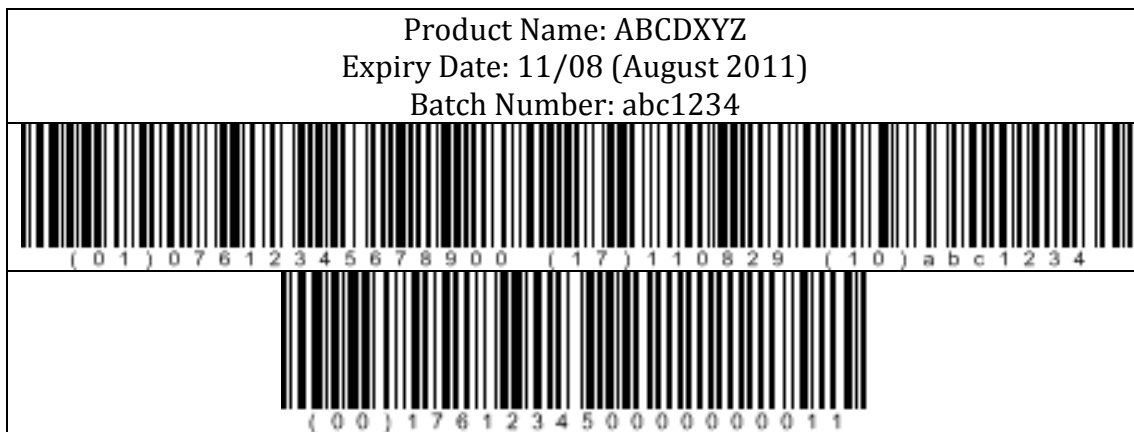
Tertiary packaging is defined as a level of packaging that shall contain one or more primary/secondary levels of packaging and can be considered as logistics unit (homogeneous/heterogeneous packages).



*Requirements at Shipper/Carton/Tertiary level packaging: - Incorporation of GS1-128 barcode symbology (1D) encoding GTIN of the Shipper/Carton/Tertiary level packaging package, expiry date, batch number of the product and serial number (SSCC) of the Shipper/Carton/Tertiary level packaging.*

Barcode Symbology: GS1-128

SSCC (Serial Shipping Container Code): Is used for the unique identification of each Shipper/Carton/Tertiary level package as a logistic unit. It is composed of an extension digit, GS1 Company Prefix number, serial number of the Shipper/Carton/Tertiary level packaging and a check digit.



#### **First Barcode:**

1. Product Identification (unique GTIN of shipper pack) using Application Identifier (01)
2. Expiry Date in YYMMDD format using Application Identifier (17)
3. Batch/Lot Number using Application Identifier (10)

#### **Second Barcode:**

1. SSCC (Serial Shipping Container Code) to identify individual carton uniquely using Application Identifier (00)

### **Technology needed to implement Tertiary level serialization**

1. Industrial Grade Printer
2. Handheld scanner for input into database
3. Serialization software, database management tools, and label art software

### **Typical Implementation Scenario**

Our observations in multiple production scenarios have been that tertiary coding of guidelines is done on shipper labels using an industrial grade printer. These are then directly applied onto the tertiary packaging, either through adhesive or sticky backed labels.

In production scenarios where tertiary volume is high, printing can also be done directly onto the packaging.

### **Challenges in Tertiary Coding process**

Tertiary coding is fairly straightforward with either printing of shipper labels or direct printing onto packaging. In certain cases, due to hard handling of tertiary packages, labels tend to get destroyed or damaged rendering the bar codes unreadable. In such scenarios, replacement labels need to be issued and applied.

### **Phase 2: Secondary packaging level**

Secondary 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.

*Requirements at Secondary Level Packaging: - Incorporation of barcodes (GS1 – 128 i.e. 1D or GS1 Data Matrix i.e. 2D) encoding unique product identification code (GTIN), Expiry Date, Batch Number and Serial Number of the Secondary package.*

Barcode Symbology: GS1-128 or GS1 Data Matrix or GS1 Databar





At Secondary level packaging, the barcode should encode the following information:

- 1) GTIN using application identifier (01)
- 2) Expiry Date in YYMMDD format using application identifier (17)
- 3) Batch/Lot Number using application identifier (10)
- 4) Serial No. of the secondary package using application identifier (21)

### **Technology needed to implement secondary level serialization**

1. Online printing on secondary packaging using industrial grade inkjet printer
2. Available space on secondary packaging artwork for Data Matrix and human readable data
3. Mounted scanner for input into database
4. Serialization software and database management tools

### **Typical Implementation Scenario**

Our observations in multiple production scenarios have been that secondary coding is done on mono-cartons, multi-cartons or shrink-wrapping. This is achieved through online printing using an appropriate inkjet printer. Post printing the code and just before it is packed into tertiary packages, the code is scanned using a mounted scanner and input is sent into the database. Therefore a record is maintained of the serialized products.

## Challenges in Secondary Coding process

Possible challenges during secondary coding could be the following:

- 1. 2D Data Matrix grading** - Each 2D Data Matrix is graded on a scale of A to F, where the acceptable levels are between A to C. Line speeds, carton orientation, ink quality and room humidity are some of the factors that affect the data matrix quality.
- 2. Production process optimization** - Due to some secondary packaging lines being manual, the addition of an extra conveyor may require some innovation to achieve the same production speed.
- 3. Finding the right pair of printer and serialization software** - Due to multiple printer models/types in the market together with various serialization software, it is important to find the right match of printer and software. A mismatch might lead to production downtime and improper data streaming to printer, leading to production losses.
- 4. Secure process to transfer codes** - A lot of solutions in the market transfer the data to the printer in open file formats (.csv, .xls, etc.). These pose a grave security threat to the entire process. Transfer of codes needs to be a very secure process, ensuring that no leakage of codes is possible.

## Phase 3: Primary packaging level

Is defined as the first level of packaging in direct contact with the product and marked with an AIDC (Automatic Identification and Data Capture) data carrier either on the packaging or on a label affixed to the packaging. It may consist of a single item or group of items for a single therapy such as a Kit.

*Requirement at Primary Level Packaging: -*

*Incorporation of 2D (GS1 Data Matrix) barcodes on medicines at primary level packaging encoding unique product identification code (GTIN) and Unique Serial Number following GS1 global standards.*



## Barcode Symbology: GS1 Data Matrix



At primary level packaging, the barcode should encode the following information:

- 1) GTIN using application identifier (01)
- 2) Serial No. of the secondary package using application identifier (21)

#### **Technology needed to implement primary level serialization**

1. Online printing on primary packaging using industrial grade inkjet printer
2. Available space on primary packaging artwork for Data Matrix and human readable data. (For primary packaging of small pharmaceuticals where due to space constraints, bar-coding may not be possible, GTIN and unique serial number shall be printed in human readable form following GS1 standards: refer GS1 implementation handbook on DGFT guidelines)
3. Mounted scanner to scan into database printed codes
4. Serialization software and database management tools

#### **Typical Implementation Scenario**

Our observations in multiple production scenarios have been that primary coding is done on either blisters/strips/vials/bottles/tubes or even unit-cartons. This is achieved through online printing using an appropriate inkjet printer. Post printing the code and just before it is packed into secondary or tertiary packages, the code is scanned using a mounted scanner and input is sent into the database. Therefore a record is maintained of the serialized products.

## Challenges in Primary Coding process

Possible challenges during primary coding could be the following

1. **2D Data Matrix grading** - Each 2D Data Matrix is graded on a scale of A to F, where the acceptable levels are between A to C. Line speeds, carton orientation, ink quality and room humidity are some of the factors that affect the data matrix quality.
2. **2D Data Matrix readability** - Due to small space availability and reflective nature of primary packaging material, there can be difficulty achieving 100% read rates of codes on primary packaging.
3. **Finding the right pair of printer and serialization software** - Due to multiple printer models/types in the market together with various serialization software, it is important to find the right match of printer and software. A mismatch might lead to production downtime and improper data streaming to printer, leading to production losses.
4. **Secure process to transfer codes** - A lot of solutions in the market transfer the data to the printer in open file formats (.csv, .xls, etc.). These pose a grave security threat to the entire process. Transfer of codes needs to be a very secure process, ensuring that no leakage of codes is possible.

## Advantages of Implementing Track and Trace

- Implementation of Track and Trace in Indian Pharmaceuticals will strengthen the leadership position of the Indian pharmaceutical industry.
- Implementation can reduce diversion by 18 percent in the first year, and lower inventory holding cost by 6 percent (Zebra Technologies Ref:A.T Kearney, 2010). Improve delivery and processing speed and reducing distribution errors. Track and trace is a major aspect of the war against counterfeit medicine. It provides an adequate drug 'lineage' in a secure form which can be integrated into hospital environments and stores for supply chain management, receiving, storage and unit labeling, picking and transfer of medicine, etc.
- Importers, marketers and users will be able to authenticate the source of drugs. Allowing multiple stakeholders to authenticate a product at the item/ dose level, both locally and internationally with simple processes like SMS and web-based authentication is of great benefit.
- Companies will be able to trace where their products are distributed to without superimposing proprietary processes.
- Managing recalls will be enhanced, as distribution routes will be easily traceable.
- Improves inventory management and reduces cost by reducing personnel usage for manual checks and reducing inventory level.
- It will improve data inputs reporting systems and manufacturing execution system. The integration of data from point of production to point of care creates a wealth of opportunities for improving efficiencies from multifaceted angles.



## Conclusion

*Counterfeiting is one of the serious global problems* due to the impact it can cause on various level of the healthcare system starting from the patient to the public health system and its credibility

*The difficulty in addressing the issue is increasing* with rapid development of new technologies like online drug purchases, making it difficult to track the infiltration of counterfeit drugs into the supply chain.

An overall quality monitoring system should be in place at the national level, which should have the capacity to *align Indian pharmaceuticals manufacturers, under one regulatory mechanism*. Track and trace adoption in Indian pharmaceutical products will help protect Indian pharmaceuticals and open up further opportunities for improved management of medicine in health sector. The GS1 registration and bar code implementation allows authentication of medicine at the user level without shifting cost to them. This encourages participation in the fight against counterfeiting at all levels from the producer to the final consumer.

At the national level, any difficulty or constraint in effective adoption of a regulatory mechanism like track and trace should be overcome by *combined participation and shared responsibility* at all the levels from the producers to the final consumer.



## PharmaSecure profile

PharmaSecure is a global innovator in drug authentication technologies and software, creating effective solutions to ensure consumers receive authentic medications from trusted pharmaceutical manufacturers in emerging markets. Founded in 2007, PharmaSecure is a fast-growing company with operations in the United States, Europe, India, Africa, and Southeast Asia.

### PharmaSecure core products and solutions include:

- Integrated Serialization Systems - PharmaSecure provides a complete suite of serialization and hardware integration services to print unique codes directly onto the drug packages for regulatory or authentication purposes.
- Mobile authentication - The global leader in SMS authentication, PharmaSecure allows consumers to authenticate medicines by mobile phone.
- Customized market data - PharmaSecure "turns the lights on" in emerging markets through real-time and historical visualizations of consumer needs and opportunities to address these needs.
- Customized intuitive software and hardware solutions - PharmaSecure user-driven solutions support marketing decisions and secure supply chains.

**Contact us at: [info@pharmasecure.com](mailto:info@pharmasecure.com)**



## Appendix

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GS1 Implementation Handbook for DGFT guidelines

[http://pharmexcil.org/index.php?option=com\\_content&view=article&id=1377](http://pharmexcil.org/index.php?option=com_content&view=article&id=1377)



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## Authors

**Dr. Godian Ezema** has been a public health researcher and practitioner for more than a decade. As a medical officer in East Timor, Dr. Ezema worked extensively in rural areas on programmes to counter HIV/AIDS, Dengue Fever and other deadly diseases. In Nigeria, Dr. Ezema has been a Medical Officer and the Registrar Public Health at the Nigerian Air Force Base in Makurdi, with responsibilities for disease control and HIV management. Previously, he served as the Resident Medical Officer at Kogi State Hospital in Nigeria, where he strengthened the hospital's community outreach centres through volunteer programmes and health management committees. Dr. Ezema holds a Bachelor of Medicine and Bachelor of Surgery from Ebonyi State University in Nigeria, as well as a Master of Public Health degree from the University of Leeds in the United Kingdom.

**Abhijit Acharya** leads PharmaSecure's research efforts to provide robust, scalable and cost-effective solutions to the pharmaceutical industry to comply with the recent export and domestic regulations. He works closely with industry experts to collate best practices and advise partners and clients on the latest technologies, as well as with internal teams to guide product development. Previously, Abhijit has served as President of AIESEC Denmark, overseeing operations and business development. Abhijit has a Master of Science degree from BITS Pilani and is currently pursuing an LL.B. from Delhi University.

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## Confederation of Indian Industry (CII)

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the growth of industry in India, partnering industry and government alike through advisory and consultative processes.

CII is a non-government, not-for-profit, industry led and industry managed organization, playing a proactive role in India's development process. Founded over 116 years ago, it is India's premier business association, with a direct membership of over 8100 organizations from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 90,000 companies from around 400 national and regional sectoral associations.

CII catalyses change by working closely with government on policy issues, enhancing efficiency, competitiveness and expanding business opportunities for industry through a range of specialized services and global linkages. It also provides a platform for sectoral consensus building and networking. Major emphasis is laid on projecting a positive image of business, assisting industry to identify and execute corporate citizenship programmes. Partnerships with over 120 NGOs across the country carry forward our initiatives in integrated and inclusive development, which include health, education, livelihood, diversity management, skill development and water, to name a few.

CII has taken up the agenda of "Business for Livelihood" for the year 2011-12. This converges the fundamental themes of spreading growth to disadvantaged sections of society, building skills for meeting emerging economic compulsions, and fostering a climate of good governance. In line with this, CII is placing increased focus on Affirmative Action, Skills Development and Governance during the year.

With 64 offices and 7 Centres of Excellence in India, and 7 overseas offices in Australia, China, France, Singapore, South Africa, UK, and USA, as well as institutional partnerships with 223 counterpart organizations in 90 countries, CII serves as a reference point for Indian industry and the international business community.

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