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# Brief study of regulations for preventing counterfeit drugs in USA, Europe, India and Brazil

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**Abstract**
Counterfeit medications are a worldwide issue with huge and well-documented outcomes for worldwide well being and patient security, including drug protection and patient passing. The quintessence of fake items and the reason they are so hazardous is the total nonattendance of value control, since they are regularly indistinct from the certified item. The presence of fake medications has for quite some time been disregarded both by the pharmaceutical business and by tranquilize administrative experts. At present initiative are being taken, broadly and universally, to control counterfeit drugs. In context to battle against counterfeit medications, governments over the globe are taking steps to stringent pharmaceutical controls, making pharmaceutical serialization mandatory.

**Keywords:** counterfeit drugs, pharmaceutical serialization, anti-counterfeit technology

## 1. Introduction

### Counterfeit drug

According to WHO,

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to its identity 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 ingredient or with fake packaging [1]."

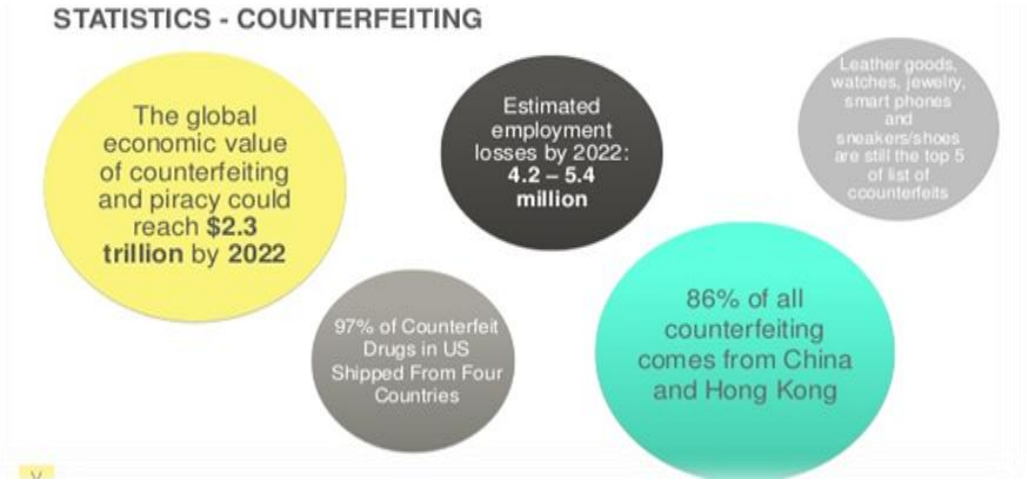


**Fig 1**

### Risk associated with counterfeit drugs [2]:

- Lack of therapeutic efficacy.
- Endanger patient's health.
- Produce harm and cost for caregivers, health system resources, and the health delivery.

### Approaches to prevent counterfeit drugs

Anti counterfeiting techniques involve:

- Hologram labels
- Laser codes
- Invisible printing
- Digital water marks

Now-a-days drug regulatory authorities of various countries have found that the use of this above techniques is not sufficient for the prevention of counterfeit drugs. Thus there is a need to bring other stringent regulations for the prevention of counterfeit drugs. Thus pharmaceutical serialization is being adopted to secure the supply chain.

**Pharmaceutical serialization**

Serialization is defined as,

"Assigning of a unique serial number to each saleable unit of each prescription product, which is linked to information about the product's origin, batch number and expiration date. The units can then be tracked through its entire supply chain — from production to retail distribution to the final dispensation to the patient."

**Serialization process**

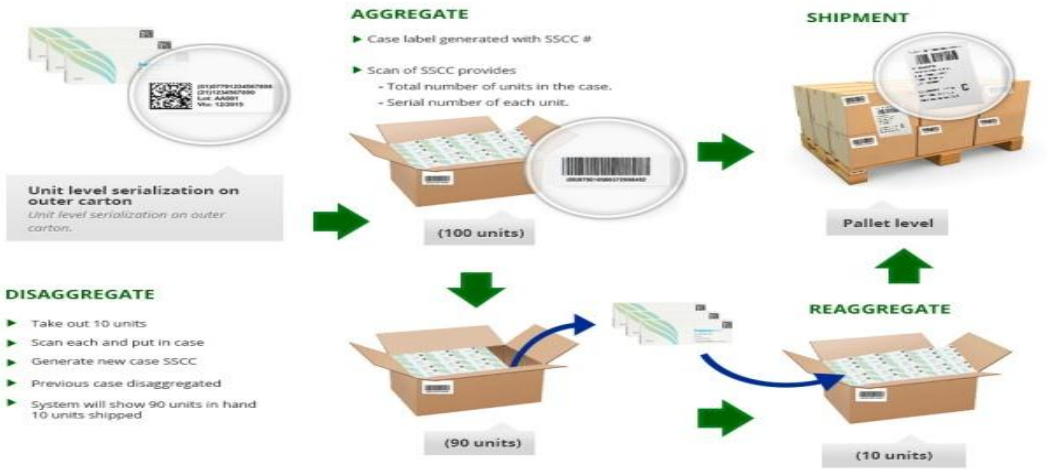


**Fig 2**

**Benefits of Pharmaceutical Serialization:**

- Fighting against Counterfeit drugs
- Smoother refunds and recalls
- Product authentication
- Product verification
- Improve shelf life management

**Regulations for Preventing Counterfeit Drugs in Various Countries**

In response to counterfeit drugs, governments across the globe are beginning to tighten up pharmaceutical regulations, making pharmaceutical serialization as an obligation for the industry.

**USA** [3]

USA has passed Drug Supply chain security Act to prevent counterfeit drugs from entering the supply chain in the US market. It outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. It also addresses the requirements in section 582(b)(4) that manufacturers must: (1) use the standard numerical identifier, which is part of the product identifier, to verify product at the package level, when investigating suspect product or upon receiving a verification request from FDA (2) verify the product identifier of product in the possession or control of an authorized re-packager, wholesale distributor, or dispenser who believes that such product was manufactured by the manufacturer and who submits a request for verification to the manufacturer, and (3) verify the product identifier on each package or sealed homogenous case of such product that they intended to further distribute as a saleable return.

**Europe** [4]

The falsified medicines Directive introduces tougher rules to improve the protection of public health with new harmonized, European measures to ensure that medicines are safe and that the trade in medicines is rigorously controlled. To this end, these new measures include:

- Obligatory safety features on the outer packaging of the medicines, to be detailed via a delegated act;
- A common, EU-wide logo to identify legal online pharmacies. This would make it easier to distinguish between legal and illegal online pharmacies throughout the European Union;
- Tougher rules on the controls and inspections of producers of active pharmaceutical ingredients; and Strengthened record-keeping requirements for wholesale distributors.

Falsified Medicines Directive (211-62-EU) requires unit-level serialization for pharmaceutical products. The FMD recommends using a bar code with product code, serial number, expiration date, lot number and NHRN. All serial numbers will need to be registered in a central government database and verified at the point of dispense.

**India** [5-6]

Directorate General of Foreign Trade (DGFT) announced the implementation of a track and trace system incorporating barcode technology as per GS1 standards for all drugs and pharmaceutical products exported from India. Under this, all export pharmaceutical consignments should be marked and coded at various packaging levels using GS1 barcode standards. DGFT issued this mandate as a step towards

implementing a traceability system to address Counterfeit and ineffective product recall challenges, which affects the entire healthcare supply chain, from manufacturers all the way to patients, wholesalers, distributors, exporters and healthcare providers. Adopting globally harmonized standards for product identification and data exchange, is a critical step in addressing these issues.

**Brazil** [7]

RDC54= ANVISA Collegiate Board Resolution # 54 defines requirements for serialization and traceability and also track and trace for prescriptions and OTCs.

ANVISA, the Brazilian Health Surveillance Agency, has issued regulations requiring the serialization, tracking and tracing, and government reporting of supply chain activity for all pharmaceutical products. The regulations require all pharmaceutical products to have a unique medicine identifier (UMI) applied into 2D Data Matrix barcodes for each saleable unit that can be used to track product throughout the supply chain. The regulations also require manufacturers to serialize each transport container (case) and ensure aggregation relationships.

## 2. Conclusions

The threat of counterfeit drugs is increasing rapidly and various regulated countries like USA, Europe have adopted stringent rules for preventing counterfeit drugs from entering the market. Semi regulated countries like India and Brazil have also developed their guidelines for the track and trace of product. Most of the countries have realized that implementation of pharmaceutical serialization is beneficial for prevention of counterfeit drugs.

## 3. Acknowledgments

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