

# Pharmaceuticals

## Industry overview

**T**he Indian pharmaceutical industry is the world's third largest by volume and 14th largest by value. **According to CRISIL MI&A, the Rs 3,136 billion pharmaceutical market (fiscal 2021 estimate) is projected to reach Rs 3,607 billion in fiscal 2023.**

Even though India is one of the largest manufacturers of generic medicines across the globe, the penetration of organised pharmaceutical chains within the country is limited owing to lower reach of healthcare services, a poor supply chain network and high costs. The demand-supply gap and low affordability ultimately lead to counterfeit/ grey market of medicines, especially for lifestyle diseases.

## Distributors and consumers have higher estimate of counterfeit products in pharma than retailers/ manufacturers

The supply of counterfeit products is prevalent across the country, but more so in tier II/III cities and villages. As per industry experts and a consumer survey, the level of counterfeiting is on the higher side in spite of low figures reported by the survey conducted by the regulatory authority Central Drugs Standard Control Organisation (CDSCO) and the Government of India. According to the industry people, about 0.1-3% of medicines manufactured and sold are counterfeit. As per distributors and authentication solution providers, it is

**Table 5 : Stakeholder/reports for counterfeit expectations-Pharmaceuticals**

Stakeholders / Reports		Counterfeit expectation
Regulatory authorities*, government bodies*, manufacturers and retailers		0.1-3%
Distributors and authentication solution providers		10-20%
Survey: Consumer's perception		~20%
World Health Organization (low- and middle-income countries)		10%
<b>Consumers</b>	Consumers, based on their experience, expect counterfeiting to be approximately 20%. They typically return the product or complain to the retailer, but rarely report the incidence to the manufacturer's consumer helpline.	
<b>Retailers and distributors</b>	Most retailers and distributors do not agree that the prevalence of counterfeiting in pharma products is high. Some distributors expect counterfeiting to be 10-20% across select categories of pharma products.	
<b>Industry players – manufacturers / industry experts</b>	Manufacturers expect higher counterfeiting in high-volume products, but lower prevalence in niche high-value products. Common over-the-counter medical devices have seen an increase in counterfeiting post-Covid-19.	

\*Report on country-wide survey for spurious drugs [https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=M TU1Nw==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=M TU1Nw==) Source: CRISIL MI&A

perceived to be 10-20% of the overall pharmaceutical market in India. Consumer perception of the extent of counterfeiting in the pharma market is higher at 20% as per a consumer survey conducted across 12 key cities.

As per the report on Countrywide Survey for Spurious Drugs published by CDSCO in 2018 on behalf of the Directorate General of Health Services, the Ministry of Health & Family Welfare, Government of India, the extent of spurious drug in retail pharmacy is much below the projections made by various media, WHO, SEARO, and other studies i.e. only 0.046 % (11 samples out of 24,136 samples). The report mentions according to State Drug Controller, the extent of circulation of spurious drug is about 0.3%, which is way lower than the World Health Organization (WHO) figure of ~10% substandard and falsified medical products in developing countries. As per industry experts, the WHO figure of 10% includes substandard, unregistered and falsified product as well.

The situation worsened during the COVID-19 pandemic. There was a massive jump in counterfeit drugs as the pandemic significantly incentivised illicit products as official supply was restricted and the supply chain was disrupted. The WHO has flagged the threat of fake COVID-19 vaccines circulating in the global market, and many have been arrested for administering falsified vaccines in India.

### Unavailability: Key reasons for purchasing counterfeit medicines

Counterfeiting is prevalent in pharmaceutical products whose volumes are very high and value is high. The major reasons of counterfeiting are

leakages in the supply chain and demand and supply gaps. **According to the consumer survey, about 25% of the total respondents willingly purchased counterfeit/duplicate pharma products owing to unavailability of original brands and lower costs.** Pharmaceutical products refer to all healthcare products such as medicines, medical devices, OTC drugs, OTC consumables such as bandages, cotton, ear buds, etc. Counterfeit pharmaceutical products easily enter into the supply chain also due to the demand-supply gap in the domestic market – especially in non-metro cities. Also, out of the total consumers surveyed across different cities; 29% in Indore, 32% in Hyderabad, 23% in Jalandhar and 25% in Chennai came across counterfeit pharmaceutical products.

### Extent of counterfeiting: City-wise consumers who have come across counterfeit products in the pharmaceutical sector

Most of the pharmaceutical manufacturers/brands and associations downplay the actual counterfeiting data in the segment. Few years ago, acceptance of counterfeit products was a major issue in the pharmaceutical industry. However, brands have started looking at counterfeiting as a problem as end users have become more vocal about the issue on social media and consumer forums. So brands are more

proactively working to check counterfeiting through various measures such as security holograms, optical variable devices (OVDs), security seal labels and tamper proof packaging. Some brands are also using digital technologies, including coding and serialization which cover components such as barcode, data matrix and radio frequency identification (RFID). Further, digital technologies can help track-and-trace products through the supply chain and also remotely authenticate a product by scanning a product label with a smartphone or by entering a code into a web-platform.

Despite these efforts, many consumers are still clueless on how to check the authenticity of a product. According to the consumer survey, about 33% of total consumers who came across counterfeit products in the pharmaceutical segment were unaware that the product was counterfeit at the time of purchase. Hence, brands should increase consumer awareness on verifying the authenticity of the products before buying them to curb counterfeiting.

DELHI NCR	AGRA	JALANDHAR	MUMBAI	AHMEDABAD	JAIPUR
15%	13%	23%	18%	21%	14%
INDORE	KOLKATA	PATNA	CHENNAI	BANGALORE	HYDERABAD
29%	22%	18%	25%	18%	32%

Figure 12: City wise extent of counterfeits-Pharmaceuticals

# Supply Chain Traceability

## Secure Your Supply Chain With A Patented Proven System

Our Track & Trace solution helps you uniquely identify products and secure as well as gain insights into your supply chain



## Solution For **QR Code on Top 300 Drug Brands\*** Features:

- AI-based Authentication
- Complete Hardware & Software Solution
- Encryption- based Databaseless Code Generation

\*As per government notification GSR 823 (E) Dated 17.11.2022



For further information: [www.pharmasecure.com](http://www.pharmasecure.com), [sales@pharmasecure.com](mailto:sales@pharmasecure.com)



## Types of counterfeiting in the pharmaceutical industry

WHO has defined counterfeit drugs as:

- **Substandard:** Also 'out of specification', these are authorised medical products that fail to meet either quality standards or specifications, or both.
- **Unregistered/unlicensed:** Medical products that have not undergone evaluation and/or approval by the national or regional regulatory authority for the market.
- **Falsified:** Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

## Counterfeit medicines/drugs have substandard APIs in many cases

The situation is complicated by counterfeit drugs often containing substandard APIs because the producers are keen to avoid detection as well as generate repeat business. The drugs may be ineffective and dangerous as well as difficult to spot because they use APIs from a similar class.

The modus operandi of counterfeiters includes using sub-standard APIs to manufacture drugs and selling them under the original brand name, recycling used vials with intact labels, refilling and re-labelling with packaging similar to branded drugs, imitation, manufacturing without knowledge, reuse beyond the expiry date, and large-scale counterfeiting. Some examples are neomycin eye drops and meningococcal vaccine made with tap water; paracetamol syrup made with industrial solvent; ampicillin replaced by

turmeric; contraceptive pills substituted with wheat flour; and anti-malarials, antibiotics and snake anti-venom containing no active ingredients.

The intensity and number of counterfeit pharmaceutical products are alarming. A more detailed review of the customs data shows that anti-biotics, lifestyle drugs and painkillers were the most targeted by counterfeiters, but also included medicaments for various diseases such as malaria, HIV/AIDS and cancer.

**Spurious trade goods:** According to an OECD 2020 report, Trade in counterfeit pharmaceutical products, India is the main production / transit location for counterfeit drugs shipped to the EU. It is the origin of 47% of the total value of counterfeit pharmaceutical products seized by EU customs authorities, followed by China (37%) and Hong Kong (8%). Counterfeit seizures can seriously impact exports. As per 2016 data from OECD / EU Intellectual Property Office (EUIPO), India was origin of 53% of the total seized value of counterfeit pharmaceutical products and medicines worldwide.

A recent study by OECD and EUIPO - Trade in Counterfeit Pharmaceutical Products, found that China, India, Philippines, Vietnam, Indonesia, and Pakistan are the leading sources of counterfeit medicines distributed globally.

## Less prevalence of counterfeit medicines in organised pharmacy

As per CRISIL MI&A survey, the presence of counterfeit products in the organised supply chain network is negligible as all the transactions take place along with invoice and Goods and Services Tax (GST), which has the manufacturing

date, expiry date and batch code of the medicine. Organised large distributors directly deal with brands and supply to reliable retail pharmacy shops and also provide ERP solutions to retailers to minimise spurious drugs sales.

However, as per the respondents, counterfeiting still takes place mostly in wholesale markets, tier II/III cities and villages where unbilled products without GST are bought and sold. Fake product manufacturers copy the formula and source the raw material (API) locally or from China to manufacture fake copies of the original medicine, which are usually sub-standard, then use the same kind of packaging and brand name to sell the product in the market. These drugs are not as effective as the authentic ones, but they may still work as the formulation is same.

Fake drug manufacturers offer more than 50% margin to wholesale distributors, who further pass on these products in the supply chain, along with original products. End users unknowingly purchase fake products on MRP.

## Key markets for counterfeit pharmaceutical products

In India, Bhagirath Palace, Chandni Chowk, New Delhi is said to be the hub for counterfeit and spurious drugs. Bihar, West Bengal, Uttar Pradesh and Gujarat are states where cases of fake and spurious drugs were found in the local markets.

Two other infamous places are Govind Mitra Road, Patna, Bihar (products such as capsules, tablets, injections, powders and syrups); and Fountain Market, Mantola, Agra, Uttar Pradesh (medicines and medical devices such as surgical instruments, capsules, tablets, injections, powders and syrups).

## WHO lists ways to identify substandard or falsified medical products

Some falsified medical products are almost visually identical to genuine products and very difficult to detect. WHO too puts down visual examination as the first step by checking the packaging for condition, spelling mistakes or grammatical errors. Then people should check the manufacturing and expiry date and ensure the details on the outer packaging match the dates printed in inner packaging. The medicine should not look discoloured, degraded or have an unusual smell. And any adverse symptom or suspicion needs to be discussed with your doctor.

## Methods adopted by the industry to check counterfeiting

The most common method to check counterfeiting by the pharmaceutical company is batch coding, which can be tracked and traced easily for confirming the authenticity of the medicine. Some other measures are:

**Tamper evident label:** A sealing material for a package or bottle that is typically irreparable once opened, indicating tampering.

**Security label:** Most brands contain a high security MRP label on their products for easy identification. These labels comply to stringent quality norms and meet the brand's global quality standards.

**Serialisation:** A unique serial number is assigned to each saleable unit of each prescription product that is linked to information about the product's origin, batch number and expiration date.

**Security tear tape:** The tear tape is also called tear strip and mainly used for opening and unsealing of products with transparent film packaging. Holographic tear tape technology provides high security and protects brands from counterfeiting.

**Tagger foil:** Holographic tagger foils come with a hologram of the client's company engraved on it. Using foils helps in portraying products as hygienic, as they have an extra layer of shield from the internal side of the packaging.

**Security blister foils:** High security blister foil packaging for pharmaceutical manufacturers prevents tampering or counterfeiting, maintaining the uniqueness, originality and authenticity of the products.

*GlaxoSmithKline Consumer Health care* has each tablet of crocin embossed with 'CROCIN' lettering as an anti-counterfeiting measure.

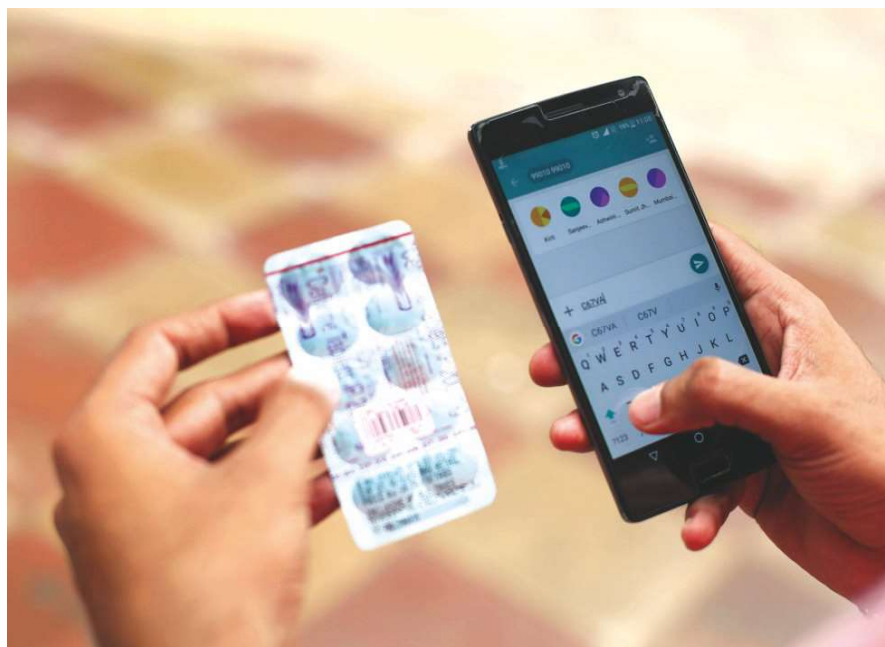
*Pfizer India* has a dedicated investigative wing, which gathers discrete information. It has a close association with its sub-contractors,

distributors and retailers to get information on counterfeiting from the market. It also follows enforcement action through exchange of information with police officials.

*Roche* has engaged supply chain security to provide encryption software that enables consumers to verify that their medicine is genuine.

Several companies also use holographic images on medicine foil to prevent counterfeiting of high demand high value drugs

Suspicious medical products should be reported to the National Medicines Regulatory Authority – CDSCO – and not just reported to the shopkeeper or owner or manufacturer.



## Laws to protect against counterfeiting

### The Drugs and Cosmetics Act 1940:

This Act regulates the import, manufacture and distribution of drugs in India. Its primary objective is to ensure that drugs and cosmetics sold in India are safe, effective and conform to state quality standards. The related Drugs and Cosmetics Rules, 1945 contain provisions for classification of drugs under given schedules, and there are guidelines for the storage, sale, display and prescription of each schedule.

### Drugs (Amendment) Rules, 2022:

According to the notification, the new rule, named Drugs (Amendment) Rules, 2022, inserts a sub-rule (5) after the existing sub-rule (4) under Rule 96 of the Drugs Rules, 1945, related to the manner of labelling. The new sub-rule says, “**Every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear quick response code on its label at each level**

**packaging that store data or information readable with software application to facilitate tracking and tracing.”**

The stored data or information shall include the minimum particulars including unique product identification code, name of the API, brand name (if any), name and address of the manufacturer, batch number, batch size, date of manufacturing, date of expiry or retesting, serial shipping container code, manufacturing licence number or import licence number and special storage conditions required (if any).

The authorities have been considering options to implement technology to track and trace the drugs and raw materials in the past few years.

**Recently, as per Government notification GSR 823 (E), Dated November 17, 2022, it has been announced that the top 300 brands of drugs available in the Indian market will need to have QR codes/barcodes to prevent counterfeiting.**

## Instance of counterfeit pharmaceutical seizures in India

ASPA reported a total of 134 incidence of pharmaceutical counterfeiting in 2021 and 94 in 2020. COVID-19 pandemic led to an increase in counterfeiting incidence in the market especially around products such as PPE kits, masks, medicines for treatment of cough, cold and other covid -symptoms, cased of spurious vaccinations etc. Uttar Pradesh accounted for the highest share in counterfeiting instances for pharma segment, followed by Bihar, Madhya Pradesh and Haryana.

**Table 6: Instance of counterfeit pharmaceuticals seizures in India**

Sr no.	DD/MM/YY	Location	Incident
1.	13-02-2022	Jaunpur, Uttar Pradesh	Fake antibiotics worth lakhs recovered
2.	27-12-2021	Raipur, Chhattisgarh	Two arrested for selling fake cough syrup brought from Odisha
3.	20-11-2021	Noida, Uttar Pradesh	Fake steroids worth Rs 1.5 crore recovered, three arrested
4.	02-10-2021	Mumbai, Maharashtra	Woman held for selling counterfeit cancer drugs, drugs worth Rs 67.60 lakh seized
5.	03-08-2021	Sasaram, Bihar	Fake cough medicine recovered on NH-2
6.	12-06-2021	Cuttack, Odisha	Fake medicines worth Rs 70 lakh, including Favipiravir recovered in Cuttack
7.	08-06-2021	Mumbai, Maharashtra	The Mumbai Police seize a stock of Favimax 400 and 200 (Favipravir tablets) and hydroxychloroquine tablets worth Rs 1.5 crore
8.	06-05-2021	Panipat, Haryana	Supplier arrested for giving 800 fake Remdesivir injections for 96 lakhs to a medical store operator
9.	16-04-2021	Dharamshala, Himachal Pradesh	Fake Remdesivir drug maker busted in Himachal Pradesh; probe ordered
10.	18-01-2021	Bareilly, Uttar Pradesh	Fake oxytocin supplied in Bareilly district; police raid the factory