

REPORT FOR NATION

Substandard and falsified medical products, learnings from COVID-19 pandemic & technological tools to ensure medicines & patient safety

नकली पीपीई किट बनाने लगे जालसाज

Mumbai fake vaccination scam:
Police lodges 11th FIR; first case filed
in Navi Mumbai

दिल्ली में एक स्टॉल में सही तरह गाजियाबाद में 15 से 20 हजार रुपये में बेचते थे
सख्ती: ऑक्सीपलो मीटर की
कालाबाजारी में तीन पकड़े

रेमडेसिविर की खेप के साथ
एम्स का डॉक्टर गिरफ्तार

Fake Covid Vaccination Camps
Reported In UP, Maharashtra, Bengal:
Centre

पुलिस ने टोबिकॉविले के क्वार्टर पर छापा मारा, तीन आरोपी गिरफ्तार, घेने के बाद पैक करके एनसीआर में आपूर्ति करते थे
इस्तेमाल हुए सर्जिकल दस्ताने बेचने वाले धरे

Madhya Pradesh:
ED gets into fake Remdesivir probe

राज्य और पुलिस ने 21 अप्रैल को खेप पकड़कर नगले का खुलासा किया था
नोएडा में पकड़े गए रेमडेसिविर
के इंजेक्शन नकली निकले

नकली टीकों की बिक्री वाली
याचिका पर सुनवाई नहीं

Arrested for running fake Remdesivir injection
factory in Uttarakhand, already sold
2,000 injections

ऑक्सीजन सिलेंडर और ऑक्सीपलो
मीटर की कालाबाजारी में चार धरे

Issue Date

March 2022

Published by:

This report has been prepared by the Authentication Solution Providers' Association (ASPA).

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FOREWORD

On behalf of ASPA, we feel privileged to present this White Paper, “**Substandard & falsified (SF) medical products, learnings from COVID-19 pandemic & technological tools to ensure medicines safety**”.

We all understand the magnitude of counterfeiting as it has a long and sordid history. It is impacting both economically and socially. Perhaps, unlike other industries, counterfeiting in the Pharmaceutical industry may have life or death consequences.

Though we know SF medical products enter the supply chain, the time and place of their entry are unpredictable. Managing this uncertainty has become more critical due to the recent rise in the incidence of counterfeit reporting. We must reduce the entry and effects of counterfeit parts through increased diligence and active control measures. It is necessary to have greater collaboration both within the industry and with the government to accomplish this.

At ASPA, we believe that we can contribute in a small way in fighting this menace by bringing this issue into the limelight at all Industry and government forums. Our members are also working with brand owners and Government bodies in providing technologically advanced solutions in fighting this menace.

We strongly believe that the recommendations offered in this report will help the pharmaceutical industry to enhance its fight counterfeit products. Moreover, we invite government and like-minded stakeholders to join us in further improving and designing solutions. We are confident that with the support of all affected parties, we can help curb the impact of counterfeiting.

This report is part of our initiative in building awareness on the Economic and Societal impact of Counterfeiting and enabling all stakeholders to priorities combating this menace, often called the “Crime of 21st Century”.

We hope you find this report useful.



Nakul Pasricha
President



Luv D Shriram
General Secretary &
Treasurer



Chander S Jeena
Secretary

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EXECUTIVE SUMMARY

About the White Paper

Substandard and Falsified (hereinafter SF) medical products are not a new problem; however, this White Paper provides the latest update on this issue in light of recent incidents that happened during the COVID-19 pandemic, key learnings and the recommendations by ASPA to combat this menace. The report is the part of ASPA initiative in building awareness on the Economic and Societal impact of counterfeiting.

Purpose of the White Paper

Various factors which contribute to the increase in counterfeiting. The foremost factor is the lack of awareness about the severity and impact of this menace. This White Paper is designed to provide insight to all stakeholders (including brand owners and government authorities) to deepen their understanding of counterfeiting activities and help policymakers formulate more robust strategies and policies to fight this menace. The purpose of this White Paper is to raise awareness and mitigate the risk associated with SF medical products.

Key highlights of this White Paper

- Trend on pharmaceutical crime & incidents of SF medical products happened during COVID-19
 - WHO alerts for falsified vaccines & medicines in 2020 and 2021.
 - Incidents of counterfeiting of COVID-19 products were observed in 23 out of 29 States & 7 Union Territories in India.
 - Spurious and sub-standards of pharmaceutical incidents increased by 47% from 2020 (91) to 2021 (134).
 - Counterfeit taken advantage of demand scarcity.

- Incidents noticed of COVID-19 related medical products including vaccines, medicines, test kits, antibiotics, face masks and sanitizers.
- Pharmaceutical counterfeit incidents rose nearly 111% globally over the past ten years.
- Impact beyond economic losses
 - SF medical products derailing global efforts to fight life-threatening disease & to achieve its sustainability goals “Right to Health”.
 - SF medical products leading to Antimicrobial resistance.
- Recommendations for policymakers and stakeholders
 - India Export regulations for pharmaceutical traceability.
 - European Medicine Verification System.
- Update on anti-counterfeiting technological tools
 - Overt, Covert, Forensic & Digital technologies.

Methodology

This White Paper has been made by methodically monitoring and collating news from leading media across the country, WHO medical alert, Interpol, along-with database available at the ASPA established Counterfeit News Repository. (A single stop source for all counterfeiting incidents reported in India).

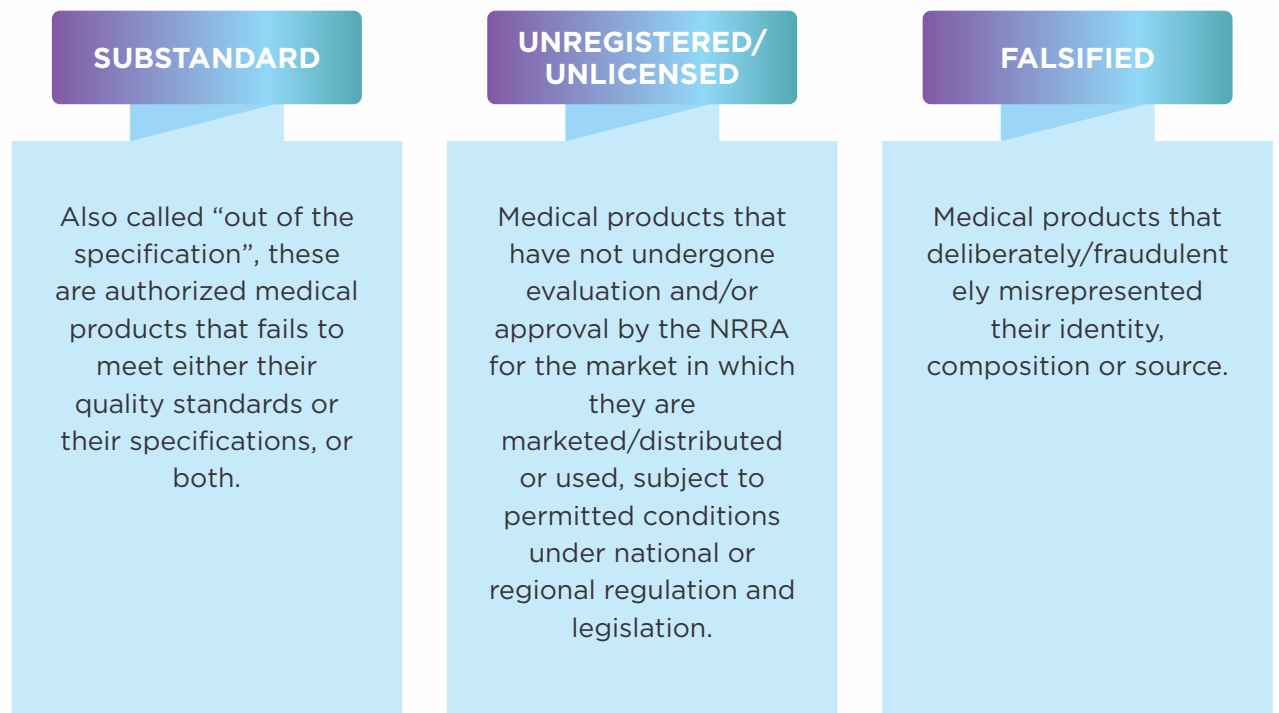
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<https://www.counterfeitrepository.com>).



INTRODUCTION

Substandard and Falsified (SF)¹ medical products are not a new problem and, are difficult to detect by their very nature. They are often designed to appear identical to the genuine product and may not cause an obvious adverse reaction; however, they will fail to treat the disease or condition for which they were intended. In the absence of no universally agreed definition of what used to be widely known as 'Counterfeit Medicine', World Health Organization (WHO) continues to use the term SF Medical Products. 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.

Figure 1. Classification of medical products used in the context of the World Health Organization Global Surveillance and Monitoring System and the Member States mechanism



Source WHO document A70/23, annex appendix 3.

Note: “NRRA” stands for national and/or regional regulatory authorities.

3.

MEASURING PHARMA CRIME - EXTENT OF THE ISSUE

While calculating the true extent of the problem is complex, various studies highlight the magnitude of the issue. Realizing this, in 2013, World Health Organization (WHO) launched a global surveillance and monitoring system to encourage the Member States to report SF medical products incidents in a structured and systematic format, to assist in arriving at a more accurate and validated assessment of the scope, scale, and harm caused by this issue². In between 2013-July 2017, the system received 1,500 reports of cases of substandard or falsified products. Of these, antimalarials and antibiotics are the most reported.

Similarly, Pharmaceutical Security Institute, a trade group, reported that theft and counterfeiting of pharmaceutical

products increased over the past decade³. Understanding its gravity, Interpol is also running Operation Pangea, a well-established international effort to disrupt the online sale of counterfeit and illicit health products. Since its launch in 2008, the operation has removed more than 105 million units (pills, ampoules, sachets, bottles, and so on) from circulation and made more than 3,000 arrests⁴.

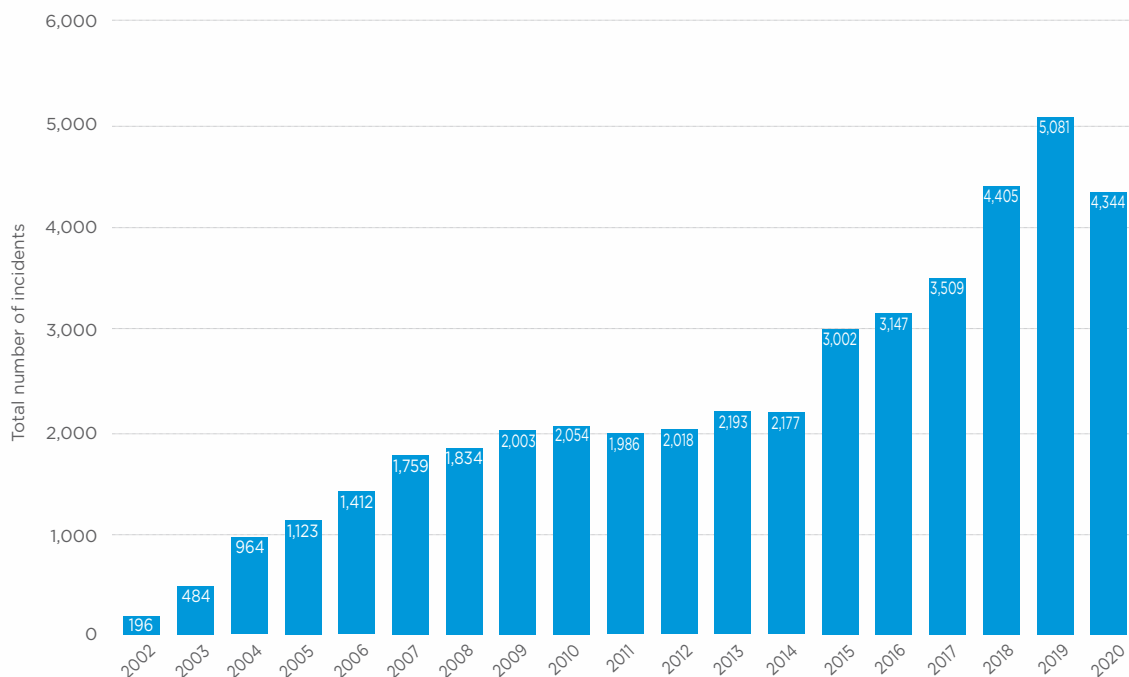


Figure: Total number of counterfeit incidents concerning pharmaceuticals worldwide from 2002 to 2020

Source: <https://www.psi-inc.org/incident-trends>

4.

IMPACT BEYOND ECONOMIC LOSSES

Counterfeiting, harm all stakeholders. While the drug manufacturers' brand integrity and sales are always at risk, there are issues with product recalls and liability clauses. Healthcare providers and governments, lead to a decline of public confidence and trust in their health care system, professionals, agencies and increased enforcement costs. Beyond economic losses, it is affecting almost all countries and humans. There are cases filled with tragedies that happened due to SF medical products, the few of the noted ones are as follows:

1982, USA: The one well-known example of pharmaceutical tampering occurred in 1982 when Johnson & Johnson discovered that bottles of its Extra-Strength Tylenol capsules had been laced with cyanide. By the end of the scare, seven people had died, and Johnson & Johnson had spent more than \$100 million to recall 31 million bottles of Tylenol.⁵

1986, Mumbai: Twenty-one patients died of kidney failure when glycerin was contaminated with diethylene glycol (DEG). In

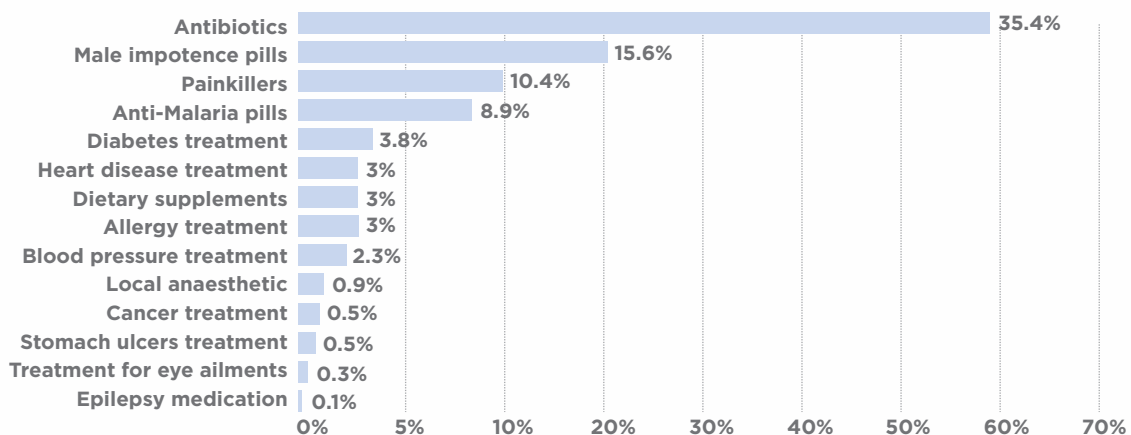
similar incidents in 1998, in Delhi, thirty-three children died between April 1st and June 9th, when the solvent syrup contained DEG. Similar cases happened in Bangladesh in 1992, Haiti in 1996, Panama in 2006, Nigeria in 1990 & 2008.⁶

SF medicines are one of the reasons for up to 116,000 malaria deaths annually in sub-Saharan Africa alone⁷. It directly impacts the fundamental human right the "Right to Health". Good health is essential to sustainable development and SF medical products' issue derailed the global efforts to achieve it.

SF medical products lead to drug resistance and threaten population health today and for future generations. It has been noted that anti-malarial and antibiotics are amongst the most reported substandard and falsified medical products⁸. The quality of anti-biotics leads to their increased use and antimicrobial resistance (AMR). Poor quality drugs have been cited as a causal factor for the rise of multidrug-resistant tuberculosis.

Graph: The most counterfeited pharmaceuticals

Share of the global value of seizures of fake pharmaceuticals



Source: <https://www.oecd.org/industry/covid-19-crisis-underscores-need-to-address-trade-in-fake-pharmaceuticals-say-oecd-and-euipo.htm>

5.

THE TRADE-IN PHARMACEUTICAL COUNTERFEITS DURING COVID-19 PANDEMIC



Figure: An SIT was formed after 3,000 vials, including 621 of Remdesivir, were recovered in Punjab on May 6, Image courtesy: Punjab Police

While the problem is as old as the drugs themselves, the ongoing COVID-19 pandemic has triggered an enormous crisis that has had and will continue to have a significant impact on the illicit trade in counterfeit goods.

The National Medicine Regulatory Authority of India, CDSCO (Central Drugs Standards Control Organization), conducts a monthly analysis of samples collected across the country. From January to December 2020, 39 instances of substandard hand sanitizers containing methanol were reported.⁹ There were also reports of substandard personal protective equipment (PPE) kits, including N95 masks, being supplied to frontline hospital workers.

In the last two-years incidents of counterfeiting of COVID-19 products were observed in 23 out of 29 States & 7 Union Territories in India. The trends goes in 2021, with various incidents noted across the country. Spurious and sub-standards of pharmaceutical incidents increased by

47% from 2020 to 2021. Counterfeit taken the advantage of demand scarcity and incidents noticed of COVID-19 related medical products including vaccines, medicines, test kits, anti-biotics, face masks and sanitizers.

- **February 2021: A firm was seized in Agra, involved in purchasing of expired drugs at low cost and re-selling them on real values after new packaging.**
- **June 2021: Post COVID-19 as soon as black fungus cases started reporting in Hospitals, criminals started taking benefit. More than 3500+ vials of black fungus injections were found in a raid in New Delhi.**



- **June 2021: Gujarat FDA busted racket selling fake anti-viral drugs Favimax-400 and Favimax-200.**
- **June 2021: Mumbai police arrested a factory owner in Meerut, Uttar Pradesh for allegedly supplying counterfeit Paracetamol and Diclofenic medicines.**
- **July 2021: Kanpur crime branch arrested gang and seized fake medicine worth Rs 4 crore. The criminals accepted that they were producing medicines as per the demand and using UP Transportation Buses as modus operandi for distribution. The code word Parle-G and Cadbury were used for order bookings.**

There were similar cases reported in other parts of the world. Globally, over 200 quality incidents involving alcohol-based hand sanitizer were reported in 2020. SF versions of COVID-19 vaccines are assumed to be on the European market already, as warned in early 2021 by Germany's international broadcaster Deutsche Welle and in December 2020 by Europol in an Early Warning Notification. Between March and September 2020, Europol coordinated Operation Shield, a global effort to target trafficking of counterfeit and misused medicines and doping substances.

During the operation, law enforcement officers dismantled 25 criminal groups, arrested nearly 700 suspects, and seized substantial amounts of drugs including 33 million face masks, tests, and diagnostic kits; 8 tons of raw materials, chemicals, and antivirals; and 70,000 liters of sanitizers.

In Costa Rica, Interpol's Operation Pangea XIII seized more than 11,000 units of illegal products, including drugs and false medicinal products worth almost US \$ 125,000¹⁰. Health authorities in Peru seized 4 tons of falsified medicines during the COVID-19 pandemic¹¹. In Mexico, the

In the last two-years incidents of counterfeiting of COVID-19 products were observed in 23 out of 29 States & 7 Union Territories in India.

Federal Commission for the Protection against Sanitary Risks (COFEPRIS) issued a health alert about falsification and illegal marketing of the drugs ivermectin, ivermin, and hydroxychloroquine, known for their unproven claims of efficacy in preventing or combating COVID-19.^{12 & 13}

- an intensified misuse of the online environment because of lockdowns and broken supply chains.
- a change in the structure of trade in fakes.
- a change in enforcement priorities.

The situation is dynamic, and it is too early to conclude the overall effect the pandemic has had on the illicit trade in fake goods. However, exchanges with enforcement officials and industry representatives, plus ongoing reports, have allowed us to tease out certain trends:

Table: WHO Medical Product Alert released in 2020 & 2021

Month	Medical Product Alert No	Pharmaceutical Product	WHO Region
November 2021	7/2021	Falsified COVID-19 vaccine	Eastern Mediterranean
November 2021	6/2021	Falsified COVID-19 vaccine	Eastern Mediterranean
August 2021	5/2021	Falsified COVID-19 vaccine	Africa & South East Asia
August 2021	4/2021	Falsified Remdesivir	Americas
August 2021	3/2021	Falsified Cytotec	Africa
March 2021	2/2021	Falsified COVID-19 vaccine	Americas
March 2021	1/2021	Falsified Vitamin A	Africa
December 2020	7/2020	Falsified Harvoni	Americas and Europe
October 2020	6/2020	Falsified Fluzone	Americas
May 2020	5/2020	Falsified & contaminated Defibrotide	Western Pacific, Europe & Eastern Mediterranean
April 2020	4/2020	Falsified Chloroquine	Africa
March 2020	3/2020	Falsified medical products, including vitro diagnostics, that claim to prevent, detect, treat or cure COVID-19	Global
March 2020	2/2020	Falsified HIV rapid diagnostic test	Africa
March 2020	1/2020	Falsified Anti-malarial	West and Central Africa

Source: <https://www.who.int>

Issues of SF Cases in 2020 & 2021



Hand sanitizer plant busted in J&K, The Hindu Business Line, March 11, 2020

Punjab

- Man held with 2K fake sanitiser bottles, May 25, 2021
- Mohali: The accused arrested for putting a reaper on a fake remdesivir injection vial, Oct 8, 2021
- Barnala: One person arrested selling sanitizer illegally, Amar Ujala, April 7, 2020
- Ludhiana: Father-son duo arrested making counterfeit of Brand sanitizer, Dainik Bhaskar, June 16, 2020
- Fake sanitizer factory busted in Rajpura, Times of India, December 17, 2020

Accused arrested for supplying fake medicine, Apr 23, 2021

- In the case of selling fake oximeters in Bhiwani, the price was Rs 500, May 24, 2021
- Thief racket busted in Haryana, 11 arrested, May 26, 2021
- fake hand sanitizers seized in Gurugram, NDTV, March 13, 2020
- factory seized, operated from Govt. house, Danik Bhaskar, March 22, 2020
- making factory unearthed in Sonipat, Jagran, April 13, 2020
- in Bhiwani; using tent cloth for making sub-standard PPE kit, Amar Ujala, April 15, 2020
- sanitizer unit busted in Haryana, The Hindu, April 20, 2020
- business: Criminals duping authorities by sending fake approval orders. Amar Ujala, April 22, 2020
- shipment seized 21 boxes of fake sanitizer, Jagran, June 20, 2020

- 50 lakh seized in Vadodara, Apr 20, 2021
- scam of fake medicine for the treatment of black fungus, busted, July 7, 2021
- N95 masks now after fake injection, Patrika, August 09, 2020
- making sanitizer, seizes items worth Rs 34 lakh in Ahmedabad, Times of India,

Maharashtra

- Fake Johnson and Johnson sutures racket busted in Mumbai, Jan 19, 2021
- Nagpur: Two accused arrested for selling fake Remdesivir, April 21, 2021
- Pune: Man in custody for selling duplicate drugs from fake company, June 22, 2021
- Fake Drugs Indore: Crime Branch raids drug market, seized fake antibiotics, Sep 24, 2021
- Mumbai: Woman held for selling counterfeit cancer drugs, Oct 2, 2021
- Coronavirus scare: Rs 2 lakh fake sanitizers seized in Mumbai, TOI, March 13, 2020
- Over 57,000 three-ply masks seized from an illegal unit in Agri, Mumbai Mirror, April 8, 2020
- Nurses criticize sub-standard PPEs, TOI, April 9, 2020
- Fake N-95 Masks Worth ₹21 Lakh Seized from Lower Parel, Mumbai Live, July 31, 2020

Karnataka

- CB Cops bust fake Ayurveda medicine gang: Four held, Jan 9, 2021
- fake sanitizers worth Rs 56 lakh seized by EOW in Karnataka, New Indian Express, March 21, 2020
- police seized a medical shop in Bengaluru, seized 70 counterfeit thermometers, Jagran, April 1, 2020
- fake masks glutting market, Sentinel, April 2, 2020
- Bengaluru Police nabs online gamblers, black marketers & fake mask makers, Business Line, April 5, 2020
- medical staff wary as lack of quality protection gear ails hospitals, Mint, April 7, 2020

8. Uttar Pradesh

- Fake oxytocin was supplied in Bareilly district, police raided factory, Jan 18, 2021
- Illegal painkillers factory sealed in Hathras, Jan 13, 2021
- Counterfeit medicine racket busted, selling Rs 15 strip sold for Rs 800, used to pay commi doctors and medical stores, Feb 10, 2021
- Agra: Expire medicines were being repackaged and sold, firm owner in custody, Feb 9, 2020
- Mathura: Fake drugs were being manufactured in food factory, Feb 9, 2021
- Mathura, Fake medicines caught, two arrested, Mar 03, 2021
- Mathura, Fake medicine caught in Saharanpur, Mar 03, 2021
- Baranbanki: Fake injection of strength was being sold from the medical store, Mar 24, 2020
- Fake hand sanitizer, mask factory busted in Noida; March 15, 2020.
- Fake sanitizer unit busted, raw material worth Rs 12 lakh seized, Deccan Herald, March 17, 2020
- Health Department procures sub-standard masks and kit worth Rs 15 lakh, Hindustan, April 1, 2020
- Rampant sale of fake water-spirit based sanitizer in Meerut, June 15, 2020

9. Bihar

- Fake cough syrup worth Rs 10 lakh recovered in Muzaffarpur, Oct 2020
- Laheri: Fake medicine and beauty products worth one crore seized
- Fake medicine, oil and other items exposed in Muzaffarpur's Ahi
- Chapra: Raid on shop selling fake medicine and cosmetic products
- City raid in a surgical shop used masks and fake sanitizer recovered, May 6, 2020

10. New Delhi

- Fake cough medicine
- Coronavirus scam in J&K, The Hindu
- Police busted fake Avalanches, M
- Shops selling fake Outlook, May 2020

11. Manipur

- Coronavirus: Manipur supplying substandard India Today, April 20, 2020

12. Jharkhand

- Fake hand sanitizer racket busted, 20, 2020
- Criminals duping consumer fake sanitizer, Next Live, April 2020

13. Assam

- Drugs worth Rs 20 crore seized in Mizoram, Aug 28, 2021

14. West Bengal

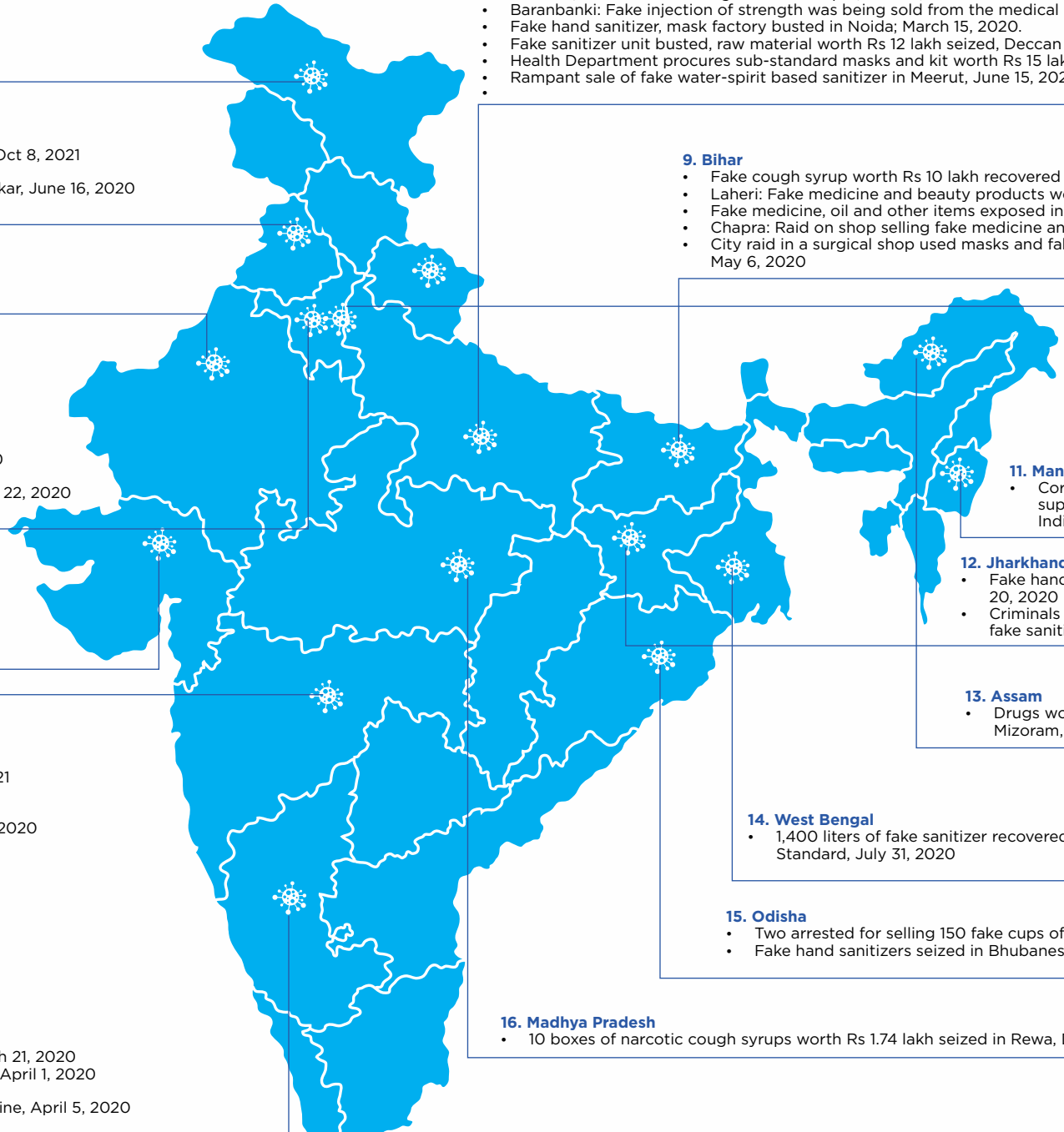
- 1,400 liters of fake sanitizer recovered from Kolkata shop Standard, July 31, 2020

15. Odisha

- Two arrested for selling 150 fake cups of syrup brought from
- Fake hand sanitizers seized in Bhubaneswar, two held, Kali

16. Madhya Pradesh

- 10 boxes of narcotic cough syrups worth Rs 1.74 lakh seized in Rewa, Dec 12, 2021



6.

ROLE OF INDIA IN THE WORLD HEALTHCARE ECOSYSTEM

Playing a critical part in the world healthcare ecosystem, India has a bigger role to play in worldwide drug security and availability. While we are taking global patient care, we must address the issues in the country e.g. low ranking in health and survival, domestic regulations, hoarding, and falsified medicines (*Source: World Economic Forum, <https://medicaldialogues.in/india-slips-to-150th-rank-in-healthcare-world-economic-forum>*).

In 2011, the Indian Government implemented traceability solutions for exports and the pharmaceutical industry adheres to international standards and authentication protocols¹⁴. Unfortunately, the domestic regulations and legal structures are not as well defined as required. Lack of this structure and gaps in implementation gives criminals a chance to take advantage of the system by plaguing it with substandard, falsified, spurious, or counterfeit medicines and medical equipment. Making the whole system sick from the inside and weakening its ability to attend to patients properly. It also robs the end-users of their right to good quality medication, damages the reputation of the healthcare system, harms brand equity of pharmaceutical companies, and erodes public trust in the healthcare system.

The surge in spurious drugs in the country is not only a potential threat to the lives of its citizens but also dents its image as being one of the largest suppliers of drugs and pharmaceuticals in the world, stated the committee in its report presented to Rajya Sabha and Lok Sabha on July 23, 2021¹⁵.

Expressing its concern on the rising incidences of spurious and adulterated drugs in India, the Parliamentary Standing Committee on Commerce has also recommended to the government to roll

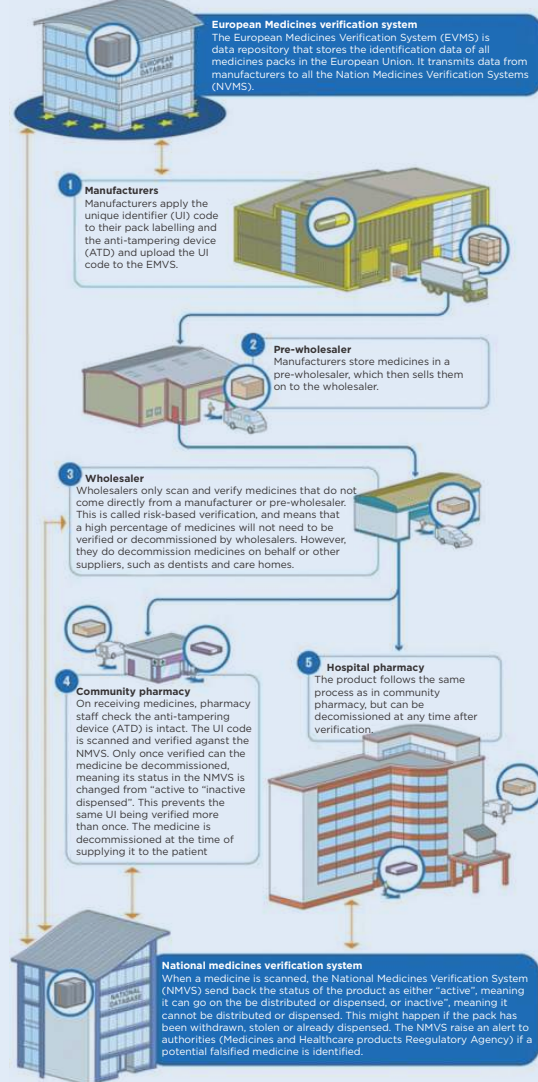


Image source: Infographic on The Falsified Medicines Directive (FMD) rolled out in Europe to address the threat of fake medicines, *The Pharmaceutical Journal*, Volume 300, No7910, February 2018

out a track and trace mechanism at the earliest for the detection of authenticity and genuineness of medicines and medical devices from manufacturers to end-users in the supply chain.

Recently, The Central government has mandated Quick Response (QR) code on the label of all active pharmaceutical ingredients (APIs) manufactured or imported in India, at each level packaging to enable tracking and tracing of the ingredients. The amendment Rule is scheduled to come into force from

Expressing its concern on the rising incidences of spurious and adulterated drugs in India, the Parliamentary Standing Committee on Commerce has also recommended to the government to roll out a track and trace mechanism at the earliest.

January 1, 2023. This is a significant step in the right direction. This step will help distinguish spurious and original medicines and make the ecosystem vulnerable to SF medical products. However, it is advisable to adopt a robust, comprehensive approach. The ideal solution must include physical and digital features providing authentication and increased digital security to reduce system vulnerability. The approach adopted by European Union, falsified medicine directives, is a good example. It introduced two new safety features that must be present on each pack or bottle of medicine: a unique identifier (a 2D barcode containing a unique 20-digit pack number and other data) and a physical anti-tampering device. India should implement these measures on formulated drugs as well.

The bottom line is that it is a huge problem and calls for immediate effective corrective action. There are immediate solutions available, however, as the issue is so big, it requires a collective effort from all stakeholders.

Role of government & policymakers:

Clearly defined mandatory regulations regarding secure packaging, authentication solutions implementation and robust track & trace mechanism from the government are the foremost actions required. The regulator can encourage and create incentives for genuine manufacturers and sellers of products in high demand to reduce the scarcity, adoption of authentication solutions and thus drive down the profitability for counterfeiters. Health must be our top priority and Govt. must ensure that consumers are not duped by counterfeit products. They must enhance how

counterfeiting is impacting the country's economic growth, eroding employment opportunities as well as the risk of health and life to citizens. This can be done through digital and media campaigns, or perhaps even mentioned as part of the Honourable Prime Minister's messages to the nation.

Role of the Pharma brands -

Reputed Pharma brands understand the benefits of anti-counterfeiting solutions and treat them as important tools to keep customers safe, ensure brand loyalty as well as protect revenue. Along with the implementation of user-friendly authentication solutions and building a robust track & trace structure, pharmaceutical companies also need to undertake the responsibility of communicating the presence of these to authorities, medical professionals, nursing staff, and end-users. So that they know the power which is being placed in their hands.

Role of users and end-users -

nursing staff, pharmacists, and medical professionals form the most crucial part of the defense against substandard and spurious drugs. Their expertise makes them an excellent judge of the authenticity of the product which they are handling. If they are aware of the process and if the right mechanism is available, they can identify a falsified product and report it. Users and end-users have the power to report and assist in spotting the criminals in the system.



TECHNOLOGICAL TOOLS AND SOLUTIONS TO ENSURE MEDICINES SAFETY

Protecting Pharmaceutical medicines and devices from counterfeiting, tampering, and diversion demands a new mindset for drug manufacturers and regulators alike: they must recognize the need to treat pharmaceutical packaging like a valuable currency and secure it with robust security and authentication features.

Layers of Security

Uses a multi-technology approach, including layers of overt, covert, digital, and analytical technologies, to address counterfeiting, tampering, and diversion through a strategy of interdiction, authentication, and digital verification.

Overt Technologies

Overt technologies are designed to be easily recognizable but difficult for counterfeiters to replicate. They deliver unique visual features that a consumer can easily validate in a point-of-sale environment with the tools they carry with them every day—their eyes. These features include inks, holograms, labels, and tamper-evident seals and provide the first layer of protection against the fraudulent use of a product.

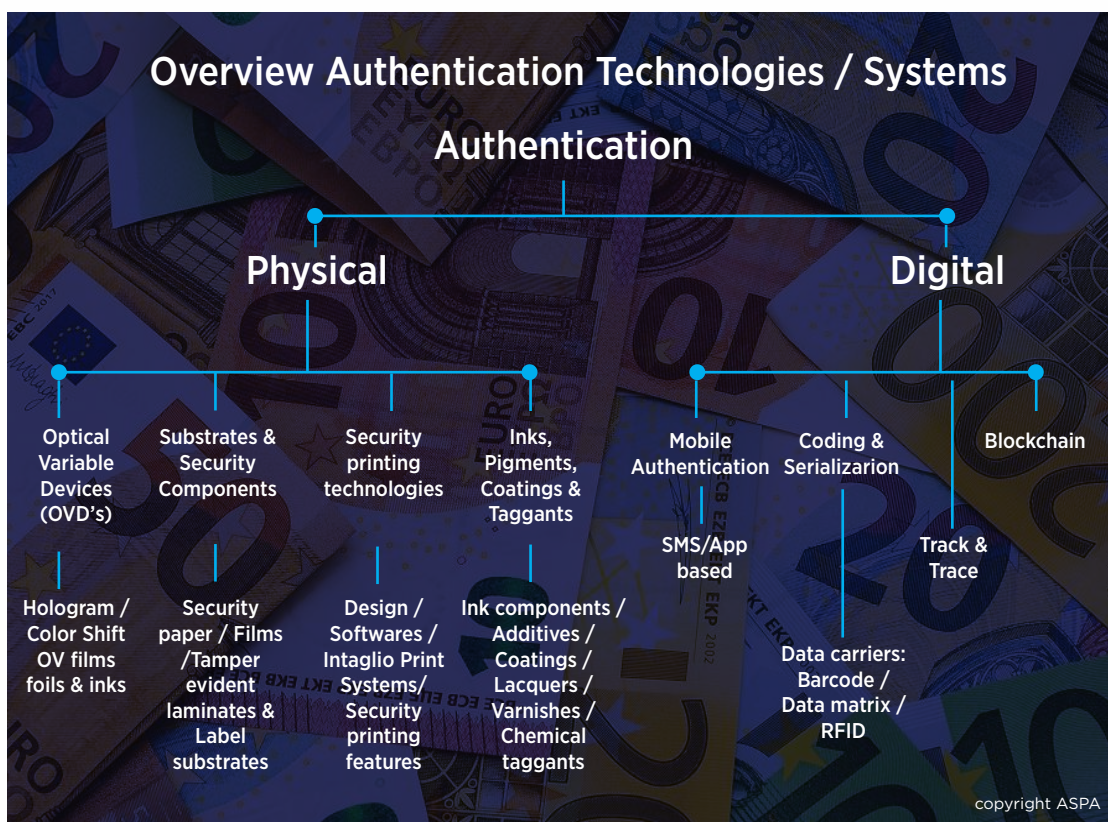
An overt mark gives caregivers something to look for before administering a drug to know that they have the right drug in hand and that it is authentic. At the same time, overt authentication technologies empower consumers to take part in the authentication process as well since little training and no equipment is required to identify a well-executed overt mark as authentic.

Covert Technologies

Covert technologies contain hidden features that are not visible to the human eye and can only be detected with commercially available microscopes or specialized readers, making them ideal for second-level field investigators looking for an added degree of certainty in the authentication process. Covert solutions can be incorporated into products along with overt authentication solutions or can function on a stand alone basis to protect against counterfeiting. A hospital worker concerned about a potential simulation of packaging may not have time to send a questioned drug out for third-party analysis. A covert feature can provide a field investigator (such as a hospital security officer) an additional level of assurance that a product is authentic (or verifiable cause for concern that it is not). Current technology features a broad spectrum of covert authentication solutions that varies from machine-readable technology and micro-text.

Track-and-Trace Digital Technologies

Digital-authentication solutions provide actionable intelligence to brand owners through electronic means so that they can pinpoint unauthorized sellers on the internet, track-and-trace products through the distribution chain, and remotely authenticate a product anywhere and anytime by scanning a product label with a smartphone or by entering a code into a web-platform. A robust digital-authentication program can help prevent fake drugs from entering the supply chain, providing a key complement to the benefits of overt and covert technologies.



Spectroscopic Analytical Technologies

Field instruments capable of characterizing and analyzing the unique light signature of organic materials can play an important role in the fight against counterfeiting by determining a product's authenticity (and safety) quickly and reliably. Once only available for lab use due to their size and cost, vendors have developed relatively low-cost and portable instruments that are suitable for non-destructive analysis in the field.

The ideal Solution

To generate the best solution, authentication solution providers should use ISO 12931 to consider all appropriate technologies and match the best features and techniques with their customers' particular challenges. In many cases, only a combination of technologies will meet customer requirements. While it is difficult to establish specific rules across various challenges and issues, strategies that incorporate an amalgamation of overt, covert, and forensic security technologies provide the most functionality to deliver the optimal level of authentication.

A robust digital-authentication program can help prevent fake drugs from entering the supply chain, providing a key complement to the benefits of overt and covert technologies.

8.

CONCLUSION:

No Country or Organization can tackle this international issue alone, collaboration and coordination of effort are critical to success. The counterfeiting, tampering, and diversion of pharmaceuticals are on the rise because of many reasons including the imbalance between supply and demand for the authentic product or its ingredients, poor practices along the supply chain, inadequate quality control at the manufacturing site, weak regulatory measures, non-adoption and right use of anti-counterfeiting technology, enforcement measures and above all awareness. As said by the experts, “Amid every crisis, lies great opportunity”. We are in the midst of one today, and we must ensure we take the opportunity to protect ourselves and our loved ones – protect them against the pandemic by taking the recommended precautions, but also protect them against the harm of these illegal, harmful, and counterfeit products.



9.

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As a nation, we now face a serious threat and challenge from the illicit economy.

Illegal activities slowed industrial growth, thus affecting producers, and stunted revenue, hitting job growth. Consumers were the ultimate victims of counterfeiting, smuggling, and piracy as they paid excessive prices for substandard products that also increased exposure to health and safety risks.

To fight the crime of the 21st Century, the involvement of all stakeholders is important and therefore, we must maintain all that we can do to prevent it. A hand is what is required to come out of the and this is where we prove our responsibility.

JOIN US IN FIGHT AGAINST FAKES!

About



The Authentication Solution Providers' Association (ASPA) is a self-regulated, non-profit organization of authentication solution providers.

Formed in 1998 with the objective to curb counterfeit products in various sectors, it is the only association of its type in the world primarily focused on the adoption and advancement of authentication technology and solutions for brand, revenue, and document protection. As an industry body of authentication solutions providers, ASPA encourages its members to adopt best practices, standards, and usage of advanced technology in providing cost-effective anti-counterfeiting solutions against counterfeiting. ASPA members protect over 15,000 brands worldwide through the identification of genuine products and documents. ASPA works closely with global authorities such as International Hologram Manufacturers Association (IHMA), Counterfeit Intelligence Bureau (CIB), FICCI-CASCADE, CSIR-NIIST, ACMA, CII & other industry bodies in India.

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