



Combating Counterfeit and Substandard Medicines In India: Legal Framework and The Way Ahead

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Abstract

India has witnessed an exponential rise in markets of counterfeit medicines. Public health and well-being have suffered drastically due to these nefarious enterprises that are engaged in the trade of fake and substandard drugs for making illegal profits. As per WHO, the global market of fake drugs amount to 200 billion USD and 67% of these counterfeit drugs were categorized as dangerous to human health. Perpetrators have targeted Indian markets because it is a lucrative avenue for them and India doesn't have a stringent regime or legal framework to tackle the menace of counterfeit drugs. India is the fourth largest export-import market for counterfeit and substandard medicines. In addition to people, ethical companies manufacturing genuine medicines have also endured heavy losses due to the booming counterfeit medicine market. Though India has certain administrative bodies in place to combat the challenge, criminals keep coming up with new methods to defraud the public as well as the government. The authors, in this article, have attempted to conduct a comprehensive analysis of the contemporary trends and challenges pertaining to counterfeit and substandard drugs racket. The author has also analyzed the legislative and policy framework and its efficacy against the menace of fake and substandard drugs.



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Introduction

The menace of fake and counterfeit medicines has evolved over the years. These fake drugs are one of the gravest dangers posed to the society. An estimate of the World Customs Organization (WCO) revealed a 200 billion USD market of counterfeit drugs. In addition, 67% of these counterfeit medicines were labelled as dangerous to human health.¹ (WHO, 2006)

To understand, "a counterfeit medicine is defined as one that either contains the wrong active ingredient, none of the specified active ingredient, or the correct active ingredient at the wrong dose."² (U.S Food and Drug Administration, 2022)

According to the WHO, counterfeit in relation to pharmaceutical products implies the intentional and fraudulent mislabelling in relation to the identity,

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composition and /or source of a final and market-ready product, or any ingredient for the preparation or composition of a pharmaceutical product. The act of counterfeiting may be applicable to both classes of products i.e. generic and branded, as well as conventional remedies.³ (Sagar *et al.*, 2006)

Counterfeit products may include the following:

- Products with appropriate ingredients but having inadequate quantities of active or effective ingredients, or even expired active ingredients; or
- Products with incorrect ingredients (which may possibly be toxic in nature and directly pernicious to patients); without active ingredients (harmful if patients do not get their disease treated correctly); or
- Products with false or misleading packaging.

In general terms, these defective drugs have generally been understood as spurious/false-labelled/falsified/counterfeit (SFFC) drugs. These drugs may prove fatal. A definition of SFFC drugs has been given by the International Medical Products Anti-counterfeiting Taskforce (IMPACT) of the World Health Organization (WHO): "medicines which are deliberately and fraudulently mislabelled with respect to identity and/or source, and also which may include products with correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging."⁴ (World Health Organization, 2022)

However, in 2017, to remove any potential confusion, the World Health Assembly had adopted the term substandard and falsified (SF) drugs.

Menace of Counterfeit and Substandard Medicines: Indian Scenario

Pharmaceutical industry of India has grown exponentially (at the rate of over 10%) in the past few decades. It has a huge domestic turnover amounting to around INR 20,000 crores and exports over INR 10,000 crores.⁵ (Sagar *et al.*, 2006) By volume, it is believed to be the fourth in the world. But, consumers in India are concerned about the quality of medicines. The issue of counterfeit and substandard medicines in India is rampant.

Pharmaceutical companies based in India have asserted that in major cities one in every five strips of medicines is counterfeited. This consequently results in revenue loss of about 4-5%.⁶ (Verma *et al.*, 2014) Moreover, it is estimated that the market of counterfeit drugs is growing at an extremely rapid pace and is posing a serious threat to the genuine drug market.

Some recent surveys show that Asia is the largest region where these counterfeit medicines are manufactured. Following information is pertinent in this regard:

- 75% of counterfeit medicines supplied across the world originate in India;⁷ (Singh, 2017)
- As per the estimate of Indian Health Ministry, 5% of medicines in India are counterfeit and 0.3% are spurious; and spurious;⁸ (Singh, 2017) and
- Indian Pharmaceutical market has an estimate value of INR 40,000 crore and 20% of the market is of counterfeit medicines⁹ (Singh, 2017)

Factors like high domestic demand and low manufacturing costs have made India one of the leading global producers of low-cost generic medicines. India's pharmaceutical industry stands third in the world in terms of volume. It is the 13th largest market in terms of value.¹⁰ (Indian Brand Equity Foundation, 2022) This has given rise to the counterfeit market as well. According to a study conducted in 2013, 20% of India's pharmaceutical market comprises of counterfeit drugs which rough amounts to 4.3 billion USD.¹¹ (The Centre for Safe Internet Pharmacies, 2022) The issue of counterfeit medicines is majorly prevalent in low-income and middle-income countries. It is striking that only 1% of medicines in high countries are fake as opposed to 10-30% in low-income and middle-income countries.¹² (Centres for Disease Control and Prevention, 2012)

It has been globally accepted that India is the biggest market of generic medicines. This has resulted in India becoming a centre of counterfeit and substandard medicines. Major fake drug markets are found in Bihar, Gujarat, Uttar Pradesh and West Bengal. In 2006, India, along with China and UAE,

was one of the countries that were a major source of counterfeit drugs seized by European Union.¹³ (Reynolds *et al.*, 2013)

Pharmaceutical industry of India is growing at a steady growth and plays a major role in economic development. As of March 31, 2012, India is estimated to have exported drugs worth 14.6 billion USD (~INR 82,730 crores). A report has revealed that around 12-25% of all medicines that are sold within the territory of India are fake or counterfeit. India has emerged as one of the biggest producers of counterfeit and substandard drugs. It has also become an attractive market for the same.¹⁴ (Verma *et al.*, 2014)

On the other hand, in 2013, estimates of the Ministry of Health estimated that around 5% of medicines in India are counterfeit while 0.3% is substandard. Bhagirath Palace at Chandni Chowk in New Delhi is widely recognized as the hub for such kind of medicines. Earlier, the threat of fake drugs was limited to costly pills like Viagra.¹⁵ (The Alternative, 2015) But now, the fake drug market in India has spread to all kinds of pharmaceuticals including cough syrups, multivitamins, mineral supplements, painkillers, etc.

It has proved to be extremely difficult to monitor the rise of counterfeit drug market around the world, and especially in India. The market has expanded multi-folds in the past few decades.

Reasons Behind the Rise of Counterfeit Medicines Market in India

Following are some of the major reasons which have contributed in the exponential growth of counterfeit drug market:

- Little or no access to healthcare facilities in rural and semi-urban areas;
- Irregular and fragmented supply chain of medicines
- Lack of consumer awareness
- Traditional practices relating self-treatment and self-medication
- Lack of an effective enforcement machinery
- Online pharmacies
- Growth in technology related to counterfeiting of medicines

One major issue of concern is that these counterfeit medicines are almost unidentifiable even by trained healthcare professionals and physicians.

Challenges Posed by Counterfeit Medicines

Several challenges have been posed by the burgeoning fake drug industry in India:

- It has resulted in considerable loss of business opportunities for genuine manufacturers of medicines. The estimated loss of pharmaceutical companies worldwide due to fake medicines is around 46 billion USD.¹⁶ (Pharmafile, 2017)
- To extend maximum healthcare benefits to the needy, government promotes the manufacture of cheap unbranded generic drugs.¹⁷ (Galani, 2017) It is noteworthy that almost 90% of the value of India's pharmaceutical market is dominated by generic drugs. But, the widespread availability of counterfeit drugs makes things difficult.
- Existence of counterfeit drugs unreasonably increases economic and social burden on the healthcare system because more measures are required to deal with these drugs.
- It has also increased the resourcing liabilities of the government. Indian government has taken various anti-counterfeiting initiatives but it is still lagging behind. India's Central Drugs Standard Control Organization had only 323 employees in 2014 (~2% of the size of the FDA in the United States).¹⁸ (BBC News, 2011)

Rising Threat of Substandard, Spurious and Low-Quality Medicines

In three Government-sponsored studies over a period of 15 years it was shown that 3% of medicines in the Indian market are either counterfeit or of substandard quality. There have been certain unverified reports that claim the same figure to be around 25 to 30 per cent. In a 2015 report released by the Associated Chambers of Commerce and Industry (ASSOCHAM), it was revealed that 25% of medicines marketed in India are either fake or of substandard quality. It further stated that majority of these counterfeit drugs are sold under generic names such as Betadine and Crocine. However, the results provided by ASSOCHAM have been denounced by Prafull D. Shah, the former Vice President of Indian Pharmaceutical Federation.

He asserted that projecting higher numbers of substandard drugs in India works in favour of foreign pharmaceutical companies which are always under threat by the booming pharmaceutical sector of India.

Manufacturing and marketing of substandard drugs is a threat to public health and life. It is a fraudulent activity that has been carried out in the Indian markets for a long time. As per a study conducted in 2008 in two key cities of India i.e., Delhi and Chennai, an estimate of 12% of samples in Delhi and 5% of samples in Chennai were discovered to be substandard.¹⁹ (Bate *et al.*, 2009) Instances of these substandard medicines have also been discovered in Kerala and Maharashtra. In 2007, four deaths in Maharashtra were attributed to these substandard drugs.²⁰ (PIB.NIC, 2020) In 2012, 300 infant deaths were reported due to a substandard medicine used to treat pneumonia.²¹ (The Health Site.com, 2020)

Back in 2003, an expert committee was appointed to inspect and examine all dimensions of the regulatory framework relating to medicinal products and issues relating to spurious/substandard medicines in India. The committee was chaired by Dr. R.A. Mashelkar. Data and reports were examined at length by the selected panel before asserting the absence of a specific, scientific and statistically designed investigation model which could provide with a realistic and accurate estimate.

The Mashelkar Report²² (cdsco.nic.in, 2020) cited some reasons behind the existence of substandard medicines in India. They can be summarized as follows:

- Weak drug control infrastructure at both Centre and State levels;
- Paucity of drug inspectors;
- Inadequately equipped laboratories and testing facilities;
- Non-uniform nature of enforcement mechanism;
- Lack of trained cadres in specific regulatory areas;
- Absence of a well-managed data bank;
- Lack of accurate information; and
- Inefficient of labour division between Central and State regulatory bodies which created inconsistencies in policies and regulatory requirements.

As per the recommendation by the Mashelkar Committee, three countrywide studies were conducted which were as follows:

First Study

It was supported by WHO wherein, from across India, more than 7,000 samples were collected and tested. Out of those samples only 3.12% were found to be of substandard quality;

Second Study

It was carried out by the Central Drug Standards Control Organisation (CDSCO) wherein, from around 40,000 medical stores of India, more than 24,500 samples were collected and tested. Out of these samples, 644 were put in the "SALA" (sound-alike and look-alike) category. The survey report also stated that only 11 of these samples were not accepted by pharmaceutical manufacturers as genuine products through actual physical examination; and

Third Study

This is the latest survey that was conducted between 2016 and 2018 wherein 48,000 samples were collected and tested. The survey revealed that only 16 of those samples were spurious while 3.1% were kept in the poor-quality category.

Post 2010, no individual or organization including CDSCO has released any absolute or complete data pertaining to substandard and spurious drugs. However, between 2009 and 2013, government has observed some cases of importation of spurious and substandard medicines. To cite an instance, in 2009, CDSCO officials seized 3 cases of unregistered drugs originating from China.²³ (pib.nic.in, 2020) These drugs were caught at the sea port at Chennai. The cases relating to importation of substandard drugs were reported for a continuous period of three years i.e. 2009-10, 2010-11 and 2011-12. A surprise inspection was also carried out by CDSCO officials in Delhi and Bhiwandi. It was revealed that 85 out of 130 sales outlets were engaged in business of banned drugs.²⁴ (pib.nic.in, 2020) The problem of marketing of substandard and spurious drugs has been mounting year by year.

In the recent raids, some noteworthy locations where counterfeit medicines are produced and sold in wholesale include the following:

- Baddi (and industrial town) located in Himachal Pradesh;
- Agra, Aligarh, Bulandshahar, and Muradnagar districts situated in the state of Uttar Pradesh;
- Patna district in Bihar; and
- Some locations in West Bengal.²⁵ (Outlook, 2019)

The responsibility of licensing and monitoring the domestic drug manufacturers and initiating legal action against offenders is attributed to individual states. It is fair to contend that countries are mainly to be blamed for licensing and monitoring local drug manufacturers for quality, and pursuing punitive legal action against the perpetrators. This implies the absence of nationally uniform norm. Therefore, it means that a manufacturer of substandard drugs could receive approval in a state where the drug control mechanism is weak. Moreover, these manufactures drugs could also be sold across the country.

Though the India's pharmaceutical market is not hit extensively by substandard or spurious medicines but, as we have already observed that these statistics are extremely difficult to monitor and the market of these medicines is spreading quite fast, it is important for policy-makers and regulators to be on their toes to effectively face the menace. It is also asserted that absence of a scientific investigation model is one of the major reasons behind failure in accurate estimation of level of substandard drugs in the country.

In the light of continuously expanding pharmaceutical industry and rising degree of pernicious ailments, India cannot afford the presence of any quantity of substandard or spurious drugs. There is also paucity of data to show the actual impact of substandard drugs on public health in India. Therefore, in the interest of general public health and safety, immediate attention and protective measures are required to deal with the issue.

India has also faced a backlash on an international level. The United States has openly accused India for being a major source of counterfeit medicines in the world, but for pharmaceutical companies in the country, it is asserted that substandard medicines pose a more serious concern than what has been marked by their largest market overseas.

US Trade Representative office's annual report on intellectual property protection has claimed that in the pharmaceutical market in India, up to 20% medicines that are sold are counterfeit. It is further asserted that the same poses a grave threat to the general health and safety of the patients. However, Indian government has vehemently opposed the findings of the report by categorizing it as an attack on cheap and affordable generic drugs of which India is the largest exported in the world.

In its special report, the office of the United States Trade Representative has said that that the United States represents its specific concern with the large-scale marketing of counterfeit medicines that are manufactured, sold, and distributed among various trading allies majorly including countries like India, China, Indonesia and Thailand.

It is estimated by a Washington-based International Policy Network that over 7 lakh people lose their life every year around the world due to consumption of fake or spurious medicines.

In 2018, USTR released a report which stated that the entire value of counterfeit pharmaceutical products confiscated at the United States' border majorly consisted of products which were either shipped from or transhipped through India, China, Hong Kong and Vietnam. It was also asserted that these counterfeit drugs were emerging as a grave concern as they were being proliferated through illegal online sales, particularly in countries like India and China.²⁶ (Chandna, 2019)

The report further adduced that the production, supply and distribution of medicinal products and other active pharmaceutical ingredients bearing counterfeit or fake trademarks is an exponentially increasing concern that has pressing consequences for consumer health and safety, and is exaggerated by the rapid growth of unauthorized or illegal online sales.²⁷ (Chandna, 2019)

The Ministry of Health in India, however, has defended its stand by saying that the numbers are exaggerated and that Indian government is taking stern measures to combat the menace of counterfeit and substandard medicines.

It was asserted that though the Indian government has taken many effective measures to keep a check on the production and marketing of fake and spurious medicines such as stringent penalties, making certain offences non-bailable and cognizable, special courts for speedy disposal of matters and channelizing the expenditure towards strengthening the regulatory framework for pharmaceuticals and enhancing staff capacity, more steps need to be undertaken to raise quality benchmarks or standards.²⁸ (Somvanshi, 2019)

Counterfeit and Substandard Medicines: Intellectual Property Rights Perspective

Pharmaceutical sector across the world essentially overlaps with the IPR regime (particularly trade mark and patent). When look counterfeiting of medicines from the lens of IPR, we observe a different perspective and different manner in which the problem can be tackled. In India, there is a robust IPR regime in place pertaining to its participation in international instruments. However, how efficiently the menace of counterfeiting is dealt with is a subject of critical analysis.

Trade Mark Infringement and Counterfeit Drugs

In this context, the courts have taken stringent measures against pharmaceutical organizations that are engaged in the production of counterfeit or fake drugs by infringing the trade mark of popular pharmaceutical products.

In *Shalina Laboratories Pvt. Ltd. & Anr. v. Twin Impex & Anr.*,²⁹ (COMIP, 2018) the plaintiff pharmaceutical company had lodged a complaint against the defendants claiming that they had copied substantial features of plaintiffs' trademarks of their drug.

After thorough investigation, it was found out that the defendants had in fact lifted all the essential features of the plaintiffs' trademarks/packet labels. The similarity was of such a nature that it was nearly impossible for an ordinary person to distinguish one from the other.

Relying on the available data, the Bombay High Court came to the conclusion that use by any individual or organization of any word, colour scheme, font scheme, art work, mark, or trade dress used in ordinary course by business by the plaintiffs was a fraudulent practice and must be kept in check.

The Court's assertion can be summarized in the following manner:

- consumers purchase medicines from well-known pharmaceutical companies in good faith;
- frauds who manufacture and market fake drugs of poor standards play with that trust at the cost of their health and safety; and
- the court is left with no option but to deal with such perpetrators in a harsh and unsparing manner

To reach the above conclusion, the High Court of Bombay made reference to its earlier decision in *Glenmark Pharmaceuticals Ltd. v. Galpha Laboratories Ltd.*³⁰ (COMIP, 2018)

In this case the court held: "Drugs are not sweets. Pharmaceutical companies which provide medicines for health of the consumers have a special duty of care towards them. These companies, in fact, have a greater responsibility towards the general public. However, nowadays, the corporate and financial goals of such companies cloud the decision of its executives whose decisions are incentivized by profits, more often than not, at the cost of public health. This case is a perfect example of just that."³¹ (vakil no. 1, 2020)

The Bombay High Court took into account the malicious conduct of the defendants, and ordered them to pay costs to the tune of INR 1.5 crore. The court also instructed them to give personal undertakings to the Court to the effect that they would immediately take off the market *all* the products that contained the impugned marks "INASOL", "TANZOL", "SUPER PEPTI", "BON APETIT", "BIG APETITE", "IBUCAB" and "IBUSAP" and their variants. The court further instructed them to destroy those products.

The above stance of Bombay High Court can act as a guiding principle for the judiciary regarding the scandalous market of counterfeit and spurious medicines.

Pharmaceutical Patenting and Counterfeiting of Medicines

During the period of 1970 to 2005, India has emerged into significant player in the pharmaceutical industry in terms of production,

distribution and marketing. Relatively liberal process patent setup contributed further to the growth of generic drug market.³² (Nair, 2010) It resulted into two main scenarios:

- Local Indian firms developed their own manufacturing process and started producing generic versions and getting them patented; and
- Indian companies started exporting generic versions to countries recognizing patents.

This resulted in increased cases of fake and substandard drugs being manufactured and sold in the market. The menace of generic drugs had to be tackled and renowned pharmaceutical companies including various governments took initiatives to contain the same.

India's pharmaceutical industry underwent a drastic change after India accepted TRIPS standards. In India, product patent was recognized under the patent system from 1 January 2005, pursuant to India's treaty obligation to implement TRIPS standards. As a result, pharmaceutical companies were now restricted to produce or sell patented pharmaceuticals without obtaining a licence from the patent holder. Thus, the generic pharmaceutical industry that once flourished in India was stifled in the new regime. Moreover, this opened up the Indian pharmaceutical market to greater investment on pharmaceutical R&D. It ultimately resulted in enhanced public participation and awareness, swift patenting process and efficient patent enforcement in the Indian pharmaceutical industry.

Concerning compulsory licensing of pharmaceutical patents which has been a raving issue in India, it has also been contended by the International Medical Humanitarian Organisation that compulsory licensing is a much required and statutorily permissible mechanism to curb patent barriers wherever necessary.³³ (Kohli, 2019) In current times, when prices of medicines are spiking exponentially making them more affordable in the domestic market is an essential endeavour that needs to be undertaken by the policy-makers.

It can fairly be contested that the transition in the Indian pharmaceutical patent regime allayed the threat of counterfeit and substandard drugs to some extent but still the menace looms. More aggressive

measures are required to effectively deal with the situation.

Counterfeit and Substandard Medicines: An Organized Crime

A systematic and well-organized act that endangers health and lives of millions of people cannot be taken casually. Pharmaceutical companies, around the world and in India, are engaged in the black business of producing and marketing fake and substandard medicines. It is extremely important to address this issue and deal with it as organized crime. The emergence of drug mafias in India has posed a grave threat to general public health. Innocent public that buys medicines owing to their trust in these pharmaceutical companies is being grossly manipulated and betrayed for money.

The trend that has followed in India pertaining to fake and substandard drugs has given rise to the assumption that the entire system has fallen prey to corruption. Many scholars believe that the market of counterfeit and substandard medicines in India is not only limited to a few isolated incidents but is organized. These drugs are manufactured and marketed in an organized and systematic manner in which government officials are also involved. This is the only reason behind inaction of the government. The incidents of production and marketing of fake and spurious medicines are continuously rising but are not dealt with in an effective manner. People who are responsible are silenced by bureaucratic forces.

To cite a few specific instances, drugs supplied to various government hospitals and stores in Arunachal Pradesh were found to be of sub-standard quality during laboratory tests. Madhya Pradesh has also been buying sub-standard or spurious medicines amounting to a large sum of money distribution in government hospitals. There was no action in any of the aforementioned cases.³⁴ (Supra Note p. 1-5)

Further, in 2016, a report by CDSCO revealed that six major pharmaceutical companies, including Cipla, Ipca Labs, Alkem Labs, Morepen Labs, Abbott and Sanofi were manufacturing sub-standard drugs in 2015-16, of the 181 drug alerts during the period. It was also showed that most of these companies recalled their batches.³⁵ (Supra Note p. 1-5) But, the fact that they were not penalized remains

contentious. In this series, many other companies in India were found to be engaged in supplying substandard medicines and vaccines. Maximum action that was taken against them was a short-time ban (a year or two) in some specific areas.

Counterfeiting of drugs is an attractive business endeavour because comparatively small quantities of counterfeit drugs can result in massive profits to the perpetrator. Also, the cost of production and marketing is much less than trafficking of addictive drugs and narcotics. The inception of counterfeiting can be traced to production of fake super-specialty medicines used to treat cancer and diabetes. Now, the business has also infiltrated the Ayurvedic, Unani and Homeopathic domains. The combination of high demand for affordable medicines and huge profit margins has made drug counterfeiting a booming business and an organized crime. To add, methods of counterfeiting are extremely sophisticated making it difficult to detect fake medicines.

Renowned pharmaceutical companies see a lucrative market in India due to several factors such as growing economy, rampant chronic diseases, ageing population and expanding middle-class. However, counterfeiting and substandard medicines market in India has spread so rapidly that it has put foreign investment at risk.

Legislative Framework to Combat Counterfeit and Substandard Medicines

India already has a Drugs and Cosmetics Act, 1940 (hereinafter referred to as the D&C Act) that deals with drugs of poor quality that may include misbranded,³⁶ (Section 17) adulterated³⁷ (Section 17A) or spurious³⁸ (Section 17B) drugs. The Act specifically bars the manufacture and commercialization of such drugs.³⁹

However, the D&C Act has certainly not been able to contain the pace at which the counterfeit and substandard medicine market in India is booming. Therefore, over the course of time, several amendments have been brought in the D&C Act. The amendment of 2008 has been specifically brought to deal with the issue of counterfeit medicines.

Under the 2008 amendment, the Central Drugs Standard Control Organization (CDSCO) has tactically come up with three inclusive categories

containing different kinds of Not of Standard Quality (NSQ) drugs:⁴⁰ (cdsco.nic.in, 2020) :

- Category A: Includes spurious and adulterated drugs where the actual identity of the drug is concealed or is similar to a renowned brand;
- Category B: Includes substandard pharmaceuticals where the drug fails the test of dissolution or disintegration; and
- Category C: Includes products with minor or negligible defects (such as varying net content, failing the weight variation test, sedimentation, discolouration, uneven coating, labelling errors, etc.)

To deal with the complications posed by SFFC and NSQ drugs the Government has undertaken several measures which can be summarized as follows:⁴¹ (pib.nic.in, 2020)⁴² (cdsco.nic.in, 2020) :

- The D&C Act has been amended in 2008 to make offences non-bailable (where death is caused by adulterated or spurious drugs then punishment imposed is imprisonment for a term not less than ten years which may extend to life with a penalty of not less than INR 10 lakhs or thrice the market value of the confiscated drugs, whichever is more);
- 216 additional posts have been created to strengthen the regulatory mechanism (in 2008, total number of sanctioned posts were 111 and 64 officers were in position while in 2012, the number of sanctioned posts increased to 310 and 121 officers were in position out of which 65 were designated drug inspectors)
- Under the Drug and Cosmetic (Amendment) Act, 2008, special courts were sanctioned to be established for the trial of offences pertaining to fake and spurious. Across the nation, many States and Union territories have already established such courts;
- For augmenting the efficacy of regulatory surveillance across the nation, Hyderabad and Ahmadabad have upgraded from sub-zone category to full-zone category. Further, new sub-zones have been set up by Bangalore, Chandigarh and Jammu under the directions received from CDSCO;
- CDSCO monthly publishes a list of medicines, devices and cosmetics which contains products that are diligently examined and categorized

- as either NSQ, fake, mislabelled, spurious, adulterated or misbranded;
- Advancement of Central Drug Laboratories (CDLs) with state-of-the-art testing equipment and building a new advanced testing laboratory at Hyderabad;
 - To assure immaculate traceability of those manufacturing units, which are located outside India, from where pharmaceutical products are imported in India, new regulatory scheme for continuous overseas inspection has also been adopted. For instance, two such drug inspections have already been conducted in China;
 - To enhance proactive public participation in exploring the identification and detection of spurious/fake medicinal product, a 'Whistle Blower' scheme has been initiated. Under this scheme, if proper information regarding proliferation or movement of spurious pharmaceutical products is provided to the regulatory authorities, the informers are adequately or suitably rewarded; and
 - At the state level, Tamil Nadu and Kerala Governments have already undertaken certain active endeavours. Medicine quality evaluation services have been initiated by the medical service corporations of these two states that also forward regular reports regarding NSQ products retrieved by them from government infirmaries and hospitals

There is an urgent need to implement stringent regulations backed by sound policies and executive legal action in order to combat the widespread propagation of fake and substandard medicines (SFFC and NSQ drugs).

Conclusion

So far, the menace of counterfeit and substandard medicines in India seems quite difficult to contain

as it is spread both horizontally and vertically. The deep-rooted corruption in the pharmaceutical sector makes things extremely difficult. The ultimate victims are the people.

It is very necessary for the government to ensure robust implementation of stringent regulatory measures which it has already formulated. Further, proper regulation of the market of generic medicines has to be ensured as it is the main source of origin of spurious and substandard products and impacts heavily due to excessive reliance of the people.

Several measures such as formulating anti-counterfeiting measures including technological development, outsourcing of drug-vetting process to experts, adopting progressive methods of identifying fake and substandard drugs, etc. Further, raising public awareness in this domain would also prove extremely helpful.

In a country of around 1.5 billion people, health risk of working population is an extremely debilitating factor. Counterfeit and substandard drugs are a major contributor to this risk. It is high time for the government to strengthen its stance against this peril on both legislative and policy fronts.

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