

How to Cite:

Rajesh, S., Dhamotharan, J., Kumar, P. S., Babu, M. A., Jagadeesan, M., & Reddy, K. T. K. (2022). Eradication of spurious adulterated and under standard quality drugs, a regulatory pertaining in Indian regulatory system. *International Journal of Health Sciences*, 6(S8), 1611–1627. <https://doi.org/10.53730/ijhs.v6nS8.11647>

Eradication of spurious adulterated and under standard quality drugs, a regulatory pertaining in Indian regulatory system

Rajesh S

Department of Pharmacy Practice, SRM College of Pharmacy, SRM Institute of Science and Technology, kattankulathur, Tamil Nadu- 603203, India

Jothieswari Dhamotharan

Department of Pharmaceutical Analysis, Sri Venkateswara College of Pharmacy, RVS Nagar, Chittoor, Andhra Pradesh – 517127

Dr. P. Suresh Kumar

Department of pharmaceuticals, The Erode College of pharmacy, Perundurai Main Road, Veppampalayam, Vallipurathanpalayam post, Erode-638112

M. Arockia Babu

School of Pharmacy Sharda University Greater Noida, UP -201310

Jagadeesan M

Department of Pharmacy Practice, SRM College of Pharmacy, SRM Institute of Science and Technology, kattankulathur, Tamil Nadu- 603203, India

Konatham Teja Kumar Reddy

Department of Pharmaceutical Analysis, Anurag university Venkatapur, Ghatkesar Rd, Hyderabad, Telangana 500088
Corresponding author email: teja.konatham1704@gmail.com

Abstract---Drugs and pharmaceuticals have become an integral part of the lives of human beings as well as animals. They play an important role in saving lives, restoring health, preventing ailments, avoiding epidemics, and maintaining general well-being. In order to achieve this objective, they are required to be safe, efficacious, and of desired quality. As a deterrent and challenge in achieving this objective, the menace of Spurious, Adulterated, and Not of Standard Quality drugs have emerged as the biggest hurdles globally. Though Spurious and Adulterated drugs have attracted concerns of the society and Government agencies, the issue of Not of Standard Quality drugs has not been addressed satisfactorily. If a drug is not of desired quality, it shall not deliver the required benefits to the patient and

thereby fails to achieve the basic objective of consuming the drug leading to dire consequences or even death.

Keywords---eradication spurious adulterated, standard quality drugs, regulatory pertaining, Indian regulatory system.

Introduction

Drugs and pharmaceuticals have become an integral part of the lives of human beings as well as animals. They play an important role in saving lives, restoring health, preventing ailments, avoiding epidemics, and maintaining general well-being. In order to achieve this objective, they are required to be safe, efficacious, and of desired quality. As a deterrent and challenge in achieving this objective, the menace of Spurious, Adulterated, and Not of Standard Quality drugs have emerged as the biggest hurdles globally. Though Spurious and Adulterated drugs have attracted concerns of the society and Government agencies, the issue of Not of Standard Quality drugs has not been addressed satisfactorily. If a drug is not of desired quality, it shall not deliver the required benefits to the patient and thereby fails to achieve the basic objective of consuming the drug leading to dire consequences or even death.

In India, the control is executed by the Central Drugs Standards Control Organisation (CDSCO) under the Central Government and the State Drugs Control Departments (SDCD) under each State Government by implementing the provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945. Due to the parallel setup of the drug regulatory mechanism in India, the inherent drawbacks and overlapping functions of such a system added by the shortage of officers have crippled the system leading to failure in achieving the objective of providing quality drugs to the patients. The provisions of the Drugs and Cosmetics Act, 1940 and Rules, 1945 are of the pre-independence era and have not been reviewed in a comprehensive manner. Only a few needs-based amendments have been made and implemented from time to time.

The issue of Not of Standard Quality drugs in India has acquired pandemic proportions; hence, there is a desperate need to address this issue on top priority. A strong drug enforcement system with the primary responsibility of ensuring the availability of standard quality drugs to the public is a need of the hour. Reports published in the newspaper quote, [Deccan herald newspaper] "The country has 12000 manufacturing units & only 1500 regulatory staff" clearly shows the inadequacy of the drug regulatory system. Various committees have highlighted the need for strengthening the drug regulatory system and recommended ways for its implementation but, not much has been achieved. Though the government has made attempts to strengthen the regulatory system, it appears to be very slow and inadequate

The present Indian Regulatory setup is a parallel type of setup, wherein the Central Drugs Standards Control Organization (CDSCO) and State Drugs Control Departments (SDCD) function parallel to each other with obvious inherent disadvantages and demerits. The important issue to be tackled is *non-uniformity*

in the implementation of the Drugs and Cosmetics Act, 1940 and Rules, 1945. At present, both SDCD and CDSCO are functioning with inadequate manpower and infrastructure, which has brought down their efficiency in the implementation of the said Act and Rules.

Need for study

The primary responsibility of the Central and State Drug Regulatory Authorities is to ensure the availability of Standard Quality Drugs to the public. In order to achieve this objective, the officers, during their day-to-day inspections of premises that import, manufacture, or distribute drugs (wholesale or retail), draw samples of the drugs as per the procedure laid down in the Drugs and Cosmetics Act, 1940 and send them to the Government Drugs Testing Laboratories. The Drugs Testing Laboratories play a key role in ascertaining the quality of the drugs sampled by the officers. The test report is issued by the Government Analyst in Form-13 declaring a drug sample as Standard Quality or Not of Standard Quality by specifying the parameters tested and reason for declaring the drug sample as Not of Standard Quality. The time consumed from the point of sampling to the point at which the report is received by the regulatory officer varies from state to state and from drug to drug. In the present-day Indian scenario, the drug testing laboratories take anywhere between six months to one year or even more to test the drug sample and issue the report in Form-13. Relatively, states like Karnataka, Maharashtra, and Gujarat take about three to six months, which is also not desirable.

After the report is received by the regulatory officer, a procedure has to be followed for informing the person/ licensee from where the sample was drawn with directions to stop further distribution of the drug and to recall whatever has already been distributed under information to the officer. Upon receipt of this information, the officer has to inform the officers of other areas where the drug in question has been distributed. They, in turn, will follow up with such other distributors and retailers, and if stocks are found, they will freeze the same. This procedure is time-consuming and will take at least a month or 2 in the normal course depending upon the workload of the individual officer and his diligence in the matter. This is within a particular state. If the drug has been distributed to more than one state, which is common in the Indian scenario, the time taken is more than six months, within which time the drug is likely to be consumed in total, and all efforts for its recall fail.

Depending on the parameter in which the drug has failed and its severity, further action is contemplated, and guidelines issued in this regard by the Drugs Controller General India (DCG(I)) will be taken into consideration, and punitive action in terms of departmental action or filing of a complaint in the jurisdictional court will be taken up. In case the guidelines, in a particular case, recommend for departmental action, the action is taken reports of Licensing Authority reach the concerned state where a sample was drawn after a long time, sometimes few years or may not be received at all.

In case, filing of a complaint is contemplated, then the investigation has to be carried at the place of manufacture, which could be anywhere in India. This

means the concerned state investigating officer who does not have jurisdiction in any other state will have to entirely depend on the regulatory officers of the state where it has been manufactured. In order to investigate at the place of manufacture, the concerned jurisdictional officer has to accompany the investigating officer. Getting cooperation in such a situation has been an uphill task, as has been proved in many cases, and in many instances, investigating officer comes back without conducting an investigation. In such a situation, filing a complaint is not possible.

The delay in tracing a Not of Standard Quality drug and further delay in its recall defeats the very purpose of the existence of drug regulatory agencies. Apart from the above issues, the biggest problem is that of non-uniformity in the implementation of the Drugs and Cosmetics Act, 1940 and Rules, 1945. Irrational Drug Combinations and Fixed-Dose Combinations (FDC's) not approved by (DCG(I)) have flooded the Indian market due to the high-headed approach by the State Licensing Authorities. Nonuniform implementation of guidelines issued by DCGI with respect to dealing with NSQ drugs is also a major concern. Delays in grant and renewal of certificates such as certificate of Pharmaceutical product (COPP) and Free sale Certificate (FSC) have hampered exports, as the issue involves inspection of manufacturing facilities jointly by SDCD as well as CDSCO officers.

Grant and renewal of licenses of Blood Banks take years due to lack of coordination between these two regulatory agencies. The reason being the inspection of blood banks has to be carried out jointly by SDCD and CDSCO officers. Newer areas such as New Drug approval, licensing of Medical Device manufacturing facilities, Pharmacovigilance has not received the importance that these areas deserve due to lack of manpower, both regulatory and ministerial. Import of drugs requires a stringent audit of facilities that register for approval of their products, which is not being done contrary to other countries who import drugs manufactured in India only after satisfying that Indian manufacturing facilities are as per their requirements.

Further,

1. The present regulatory system is functioning with an average of 63.6% of the sanctioned strength. It is much lower in some states. The sanctioned posts are just 20 to 30 % of the actual strength required considering the present workload. Hence, the in-effectiveness of the present regulatory system is obvious.
2. As such, the problem of jurisdiction faced by officers during the inter-state investigation of poor-quality drugs is creating hurdles to book the culprits. The parallel setup of CDSCO and SDCD always tries to shift the responsibilities to the other side.
3. Effective from 10-08-2009, the penalty for the manufacture of Spurious or Adulterated drugs has been enhanced to imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times the value of the dug confiscated, whichever is more.

But, punishment for the manufacture and sale of Not Standard quality drugs has not been revised.

4. According to the guidelines framed for taking action on drugs declared as Spurious and Not of Standard Quality, it is recommended that the state Drugs Control Departments shall constitute Screening Committees comprising of at least three senior officers, not below the rank of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are desired to be launched. There is no uniformity between the states for deciding to grant approvals where prosecution is warranted, and departmental actions are taken.
5. The report of the working group on Drugs & Food Regulations for the formulation of the 12th Five Year Plan (2012-2017) has listed the problems in the drug regulatory system in our country:
 - Inadequate manpower at the state and central level
 - Inadequate or weak drug control infrastructure at the state and central level
 - Inadequate testing facilities
 - Non-uniformity of enforcement of law and regulation
 - Lack of training to regulatory officers.
 - Lack of database.
 - Inadequate IT services
6. The 51st Drugs Consultative Committee (DCC) meeting, which was held on 9th June 2017 in New Delhi, has clearly indicated that there is a crying need to revamp/transform the Indian Regulatory System into a robust Regulatory System.
7. The Drugs Technical Advisory Board (DTAB) held its 77th meeting on 16-06-2017. Under Agenda No. S-3 it is mentioned that "Measures for Uniform Implementation of Provisions of Drugs & Cosmetics Act and Rules throughout the Country" and states that "The DTAB agreed following recommendations of the DCC for strengthening Drug Regulatory System in the Country to ensure effective and uniform implementation of the provisions of the said Act."

The above factors have necessitated the need for the present study so as to effectively resolve all the problems plaguing the present drug regulatory mechanism of India and suggest ways which will help in implementing the provisions of The Drugs & Cosmetics Act, 1940 and Rules, 1945 in an effective and uniform manner so that the menace of Not of Standard Quality drugs, Spurious and Adulterated drugs can be eliminated and the responsibility of ensuring quality drugs in the Indian market as well as exports that lie solely on the regulatory system, is achieved in an effective manner.

Review of literature

India is considered as the primary originator and merchant of spurious/falsely-labeled/falsified/counterfeit (SFFC) drugs. However, no authentic evidence exists against the country, according to the data provided by the government and non-government agencies of India. As of now, no enormous randomized investigations of drug quality have been done in India. [Spuriousdrugs.Availablefrom:<https://www.advocatekhaj.com>]

As per a report discharged by the World Health Organization in 2017, about 10.5% of medications sold in low and center-pay nations, including India, are unacceptable and misrepresented. Reviews in India as of late have pegged the extent of unsatisfactory medications at about 3% of the complete medications sold, while about 0.28% were seen as fake, demonstrating that India has a more concerning issue of inadequate medications instead of out and out phony or fake ones. [<https://www.economictimes.indiatimes.com/articleshow>] The issue of low quality is, as of now, intense and relentlessly developing and is probably going to cause significantly more harm soon. In that capacity, low-quality medication does not bear any widespread definition as it might differ from nation to nation. All in all, low-quality medication is the deceptive/dishonestly named/distorted/fake (SFFC) drugs that can cause treatment disappointment or even passing. [<https://www.researchgate.net/publication/273464064>]

The law in India does not discuss “counterfeit” drugs. According to the law (Section 17 of the Drugs and Cosmetics Act), a medication in India can be fake, defiled, or misbranded, and the assembling and closeout of such medications are precluded and pulls in punishments (Sections 18 and 27 read together). [<https://www.ijme.in/articles/the-spurious-drugs-gene-and-its-pervasiveness>]

With a population of more than 1.24 billion [<http://www.data.worldbank.org/country/India>], the right to health is a fundamental right in India and has been recognized in the national constitution and statutory laws as well as in international laws [WHO. The right to health. 2008]. Globally, about 2 billion people, one-third of the global population, lack access to essential medicines [<http://www.apps.who.int/medicinedocs/pdf/s5571e/s5571e.pdf>]. As medicine is a lifesaving entity and thus is necessary for the treatment, while they account for 20-60% of care cost and 50-90% of this cost is being paid by the patient, particularly in low- and middle-income countries [http://www.searo.who.int/LinkFiles/ReportsWorldMedicines_Situation.pdf].

India is a developing country where more than 40% of the population survives on less than US \$1 a day [Bate R, et.al], and if a patient needs medicines, he has to pay more than half of this. There are some schemes by the Indian government for the distribution of free generic medicines for certain categories of patients [<http://www.pib.nic.in/newsite/erelease.aspx?relid=89323>].

However, people accept, prefer, and buy counterfeit or substandard products over genuine or branded products due to their low price, easy accessibility, and availability in the market [Gentry JW et.al]. The consumer does not know about the manufacturer or the quality of the product, and many times they are unaware of expired, degraded, or substandard products which ultimately results in failure of the treatment and with antibiotics, this lead to antimicrobial resistance [Taylor R, et.al Newton PN et.al]. Substandard product arises correspondingly due to lack of expertise, unfair manufacturing practices or insubstantial infrastructure; whereas counterfeit is the product of black marketer

The problem of poor quality is already very serious and steadily growing and is likely to cause much more damage in the near future [Furnham A et.al] as such poor-quality drug does not bear any universal definition as it may vary from

country to country [Nayyar GML et.al]. In general, poor quality, drugs are the spurious/falsely-labeled/ falsified/counterfeit (SFFC) drugs that can cause treatment failure or even death. Accordingly, the International medical products anticounterfeiting taskforce (IMPACT) of World Health Organization (WHO) defines SFFC medicines as “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.”

In India, as per the Drug and Cosmetic (D and C) act, 1940, under section 17, 17A, and 17B, poor the quality drug comprises misbranded, spurious, and adulterated drugs, respectively. With the 2008 amendment of the D and C act, the Indian drug regulatory authority that is Central Drugs Standard Control Organization (CDSCO) has categorized not of standard quality (NSQ) products in three categories A, B, and C that is helpful in categorizing the products during quality evaluation. Category A incorporates spurious and adulterated drug products, which conceal the real identity of the product or formulation and be similar to some well-known brand. These products may or may not contain active ingredients and are generally manufactured by unlicensed antisocial people or sometimes by licensed manufacturers. Products that consist of adulterant/ substituted products or incorporate some filth materials are known as adulterated drugs. Category B includes grossly substandard drugs in which the product fails the disintegration or dissolution test and where active ingredient assay gets below 70% and 5% of the permitted limit for the thermolabile and thermostable product, respectively for tablets or capsules. In case of parenteral preparation, failing sterility, pyrogen/ endotoxin test or inappropriate toxicity, and fungus presence in any liquid preparation hold such products in this substandard category. Category C involved products with minor defects like emulsion cracking, change in formulation color, a small variation in net content, sedimentation in a clear liquid preparation, failing weight variation test, spot or discoloration on a product, uneven coating, presence of foreign matter, and labeling errors.

In this evaluative review, an attempt has been made to know the correct extent of the SFFC or NSQ drugs in India and to make awareness among the public, medical practitioners, and pharmacists. Data was acquired from governmental and non-governmental studies, literature, news, journals, and authentic websites. All the data was compared and interpreted to reveal the real story of poor-quality drugs in India.

SFFC drugs: A pandemic threat

Poor quality drug or substandard product encounters a major stringent issue for the global health system and it cannot be ignored. In most streamlined regions of the globe like Japan, Canada, Australia, New Zealand, the United States of America, and most of the European Union, hardly 1% of the market value products are counterfeit, developing countries like Africa, Latin America, and many parts of Asia may markedly be the seller and producer of SFFC medicines. Russia, China, India, Brazil, Mexico, Pakistan, Southeast Asia, and Middle

Eastern countries are considered as the chief operators in the distribution and manufacturing of counterfeit drugs [Shepherd M et.al]. A decade ago, it was examined by WHO that 10% of the global medicines were counterfeit.

However, contrary to its previous communicated data WHO-IMPACT pointed out that data was not much authentic [McLaughlin KE et.al]. It means no absolute extent is reported. Now, it is questionable that what are the causes and influences of this problem. In turn, one reason is poverty, and the other is ignorance, and these could contribute to the demand for counterfeit and substandard drugs [Barnes K. et.al]. Moreover, ignorance of poor quality, unregistered medicines, lenient penalties, inadequate enforcement of laws are some of the significant causes which provoke the situation

Day by day, public trust in the health system may deteriorate as the consumption of substandard drugs by patients increase due to the availability and lack of detection of SFFC or NSQ medicine in the market. Consumption of SFFC medicines can be responsible for failure of treatment or even death. Unbelievably, 0.20 to 0.30 million people die every year in China just because of the counterfeit and substandard drug product. No such data is available in India, yet many patients are dying every year. According to a report revealed by International Policy Network, globally, 0.70 million deaths were reported for malaria and tuberculosis because of counterfeit drugs This data reveals the loopholes in the regulatory system and the cautions for avoiding poor-quality medicines.

SFFC or NSQ drugs in India

India is the largest manufacturer of generic drugs, and probably 12-25% of the medicines supplied globally are contaminated, substandard, and counterfeit. Being the world's largest manufacturers of active pharmaceutical ingredients and finished products, it is likely that India, along with China, could be the major contributor to spurious medications as per Patrick Lukulay, vice president of the US Pharmacopoeial Convention's global health programs. In a report, it has been declared by the European Commission that 75% of the global cases of SFFC medicines originate from India. Indian Government officials initiated an investigation to scrutinize the drugs product which is supplying by India to Nigeria when India was accused along with other 29 Asian countries as the main originator of counterfeit drugs [Raufu A. et.al]. On one side, India extensively interacts with the African countries in providing quality medicine at affordable prices, while on the other side, predictive blame is imposed on India and China for exporting the fake or substandard quality of antimalarial, antibiotics, and contraceptives drug product to Uganda and Tanzania. In turn, India and China deny such blames [Burke J. et.al].

However, no authentic shreds of evidence exist against the country according to the data provided by the government and non-government agencies of India. Many researchers have investigated only individual drugs or a narrow range of drug preparations and formulations. Currently, no large randomized studies of drug quality have been done in India. In the year 2000, it has been stated that around 35.0, 23.1, and 13.3% of global sales of counterfeit medicines come from India, Nigeria, and Pakistan, respectively, and counterfeiting includes all

therapeutic classes of drug and mainly antibiotics [Francis PA et.al]. A decade ago, Indian government officials estimated that 9% of the drug products were of substandard quality [Mudur G et.al].

Although according to Indian press media, 30-40% of the total marketed drugs are considered spurious, this data is without any scientific confirmation. Under laboratory analysis in a survey accomplished in 2007 by southeast Asia Region Pharmaceutical (SEARPharm) Forum, a group of Pharmaceutical Associations of International Pharmaceutical Federation (FIP) and WHO, 10 743 samples were collected from 234 retail outlets. About 3.1% were estimated as spurious, and 0.3% were out of pharmacopoeial standard. In 2007, 294 fixed drug combinations (FDCs) products were unlawfully available in the market since these were not approved by the Drugs Controller General of India (DCGI) [<http://www.pib.nic.in/newsite/erelease.aspx?relid=60818>].

In 2008, out of 1 83 020 chemist shops, 8418 chemist licenses were suspended or canceled by the State Drugs Control Organizations on behalf of their trade with spurious drugs. According to CDSCO, estimation of the data during 2003-2008 indicates 6.3-7.5% of the samples were of substandard quality, and 0.16-0.35% were encountered as spurious [31]. In 2009, CDSCO reported that in 1995-96, 10.64 and 0.30% tested samples out of 32 770 were substandard and spurious, respectively, while in 2007-2008, 6.42 and 0.16% tested samples out of 42 354 were substandard and spurious, respectively [http://www.cdsc.nic.in/report_book_13-7-10.pdf]. It was a good achievement by the drug authority.

Nevertheless, in 2009, 24,136 samples of 62 brands of drugs product were collected in a nationwide survey to find those products which are covertly manufactured and thus to explore the extent of a spurious drug in India. Samples were drawn from over 100 pharmacy outlets from various regions of India, which belonged to nine therapeutic categories of 30 manufacturers. The survey affirmed that only 11 products (0.046%) were spurious. Supplementary information revealed by the state Drugs Control Departments declared 1146 (4.75%) products were of substandard quality. Hereby, it can be observed from the government data that spurious drugs are at the same level while there is a great decline in the number of substandard drugs from 10.64% in 1995-96 to 5.75% in 2008-09 [Bate R, et.al]. These kinds of inspections and surveys by government officials are some driving steps for public safety. However, stringent actions are yet to be taken for the betterment of public health. Overlaying the effects of inferior manufacturing standards, deterioration with inactive or toxic fillers, relabeling of time-expired drugs, and degradation during storage is closely associated with drug quality [Newton PN et.al], which must be checked regularly by fast and efficient techniques.

Manufacturing of spurious and substandard quality drug products is fraudulent activity, and their availability in the market is a life-threatening issue for public health. In 2008, a pilot study performed in two major cities of India, Delhi, and Chennai to explore the extent of substandard and counterfeit drugs available in the market, under which it was estimated that 12 and 5% of samples from Delhi and Chennai, respectively, were of substandard quality. In 2007-08 maximum

instances were from Maharashtra, and in 2008-09 Kerala was the leading manufacturer of spurious and substandard drugs. In 2007 four deaths were reported in Maharashtra related to spurious drugs. While more serious results came in the news when it was reported that 300 infants died in 2012 in Kashmir because of ceftriaxone substandard quality product which was used to treat pneumonia [Dutta N.et.al]

No absolute and entire data is reported for substandard and spurious drugs after 2010 by CDSCO, non-government organizations, or any individual research. For the last three years, the government has noticed several cases of spurious and substandard drug importation. In 2009, at Chennai seaport, CDSCO officials caught 3 cases of unregistered bulk drugs originating from China. Cases related to the substandard quality drug product importation in India showed 35, 35, 34 cases for 3 consecutive years 2009-2010, 2010-2011 and 2011-2012, respectively [<http://www.pib.nic.in/newsite/erelease.aspx?relid=93258>]. On a surprise inspection by the CDSCO officials, 85 sales outlets out of 130 were trafficking with the banned drugs in Delhi and Bhiwandi city. It is highly recommended to investigate individually every drug product that is available in the domestic market.

Considering the expansion of the pharmaceutical industry and the degree of potentially fatal diseases, any amount of substandard or spurious medicines is unacceptable because it raises morbidity and mortality [Wondemagegnehu et.al]. Only a few published data admit the extent of the problem and its influence on public health. Thus, there is a requirement for immediate attention and research by the regulatory authority towards this public safety issue.

Generic medicine promoting strategies

Indian pharmaceutical industry exists at third rank in volume and thirteenth in terms of the value of worth US \$20 billion. Focusing on the accessibility and affordability of the drug products in the country, India excels as the 'pharmacy of the developing world'. Indian government instructed all Central Government hospitals and Central Government Health Scheme (CGHS) dispensaries to prescribe generic medicines in large extent as possible. Physicians are also instructed by State Government to prescribe generic medicines [Caudron JM et.al].

Department of Pharmaceutical, ministry of chemical and fertilizers, in collaboration with the State Government commenced nationwide "*Jan Aushadhi Campaign*" (Medicines for Public Campaign) by way of launching '*Jan Aushdhi*' generic drug stores in the Government hospitals and supply of generic medicine through Central Pharma Public Sector Undertaking. Till mid-2012, the government has already opened 122 *Jan Aushdhi* stores, where about 231 generic medicines are being marketed.

Preventive measures for SFFC or NSQ drugs

To scrutinize the complications of the SFFC or NSQ drug in India, Government has acquired numerous steps, which are [Available from:

[http://www.cdsc.nic.in/forms/list.aspx?lid=1825 and Id=33](http://www.cdsc.nic.in/forms/list.aspx?lid=1825&Id=33)], Amendment of Drug and Cosmetic act, 1940 in 2008 for making penal provisions and reset certain offenses as perceptible and non-bailable. When adulterated or spurious drug cause death, then imprisonment imposed for not less than ten years or for a lifetime with a penalty of not less than one million Indian Rupees (INR) or three times the value of the drugs confiscated, whichever is more; in order to make restraint for illegal practices.

1. Since 2008, on various levels, 216 additional posts generated to strengthen the regulatory mechanism. In 2008, there were 111 sanctioned posts and 64 officers in position, while in 2012, there were 310 posts and 121 officers in position, which included 65 drug inspectors.
2. For a trial of offenses related to adulterated and spurious drugs product, the Drug and Cosmetic (Amendment) Act, 2008, accredited establishment of specially designated courts, and nationally 14 states/Union territories already introduced such courts.
3. For effective regulatory surveillance throughout the country, Hyderabad and Ahmadabad have upgraded from sub-zone to full zone while Bangalore, Chandigarh, and Jammu have established as new subzones under the direction of CDSCO.
4. CDSCO publishes monthly a list of drugs, medical devices, and cosmetics that are evaluated and declared as not of standard quality/spurious/adulterated/misbranded.
5. Enhancement of Central Drug Laboratories with new sophisticated testing equipment set up and creation of a new testing laboratory at Hyderabad.
6. To ensure proper traceability of those manufacturing units, which are situated abroad, from where drugs product are imported in India, a new scheme for regular overseas inspection has been introduced. For instance, two such inspections have formerly done in China.
7. To encourage attentive public participation in exploring the detection of spurious drug products, a 'Whistle Blower' scheme is initiated. Under this scheme, if accurate information on the movement of spurious drugs product provided to the regulatory authorities, informers are suitably rewarded and
8. At the state level, Tamil Nadu and Kerala Government undertake drug quality evaluation services by Tamil Nadu Medical Service Corporation Limited and Kerala Medical Service Corporation Limited, respectively; and regularly report the NSQ products, which they fetched from government hospitals.

For minimizing SFFC or NSQ drugs at the national or states level, there is still an urgent requirement for more rigid and stringent regulations, policies, and legal actions against the problem.

Rules of Spurious Drugs

1. On account of the discovery of production as well as deal and so forth of misleading or impersonation tranquilize items by the unlicensed makers or merchants, the case will be explored on top need and arrangements of area 36 AC of the Act summoned under which these offenses are viewed as cognizable and non-bailable. Important assistance from the implementation

offices like police and so forth ought to likewise be gotten, any place required, with the goal that the rackets are busted and guilty parties booked in time for making the legitimate move. The examinations in such cases ought to be facilitated, and indictments propelled at the most punctual. The speedy and convenient examinations would have an impediment impact on the corrupt people associated with the loathsome exchange of false medications.

2. On account of the recognition of an instance of assembling as well as deal and so forth of false medications by an authorized producer, for example, utilization of authorized premises for the production of false medications and the criminal purpose is evident, the case is required to be sought after with equivalent power as on account of an unlicensed maker. The examinations ought to likewise incorporate different exercises did by the producer on the premises.
3. On account of medications fabricated by an authorized producer under a legitimate assembling permit has been found horribly unacceptable, the issue might be examined at the maker's end, and where the criminal aim or gross carelessness has been set up and if the benefits of the case so request, and where it is felt that authoritative measures would not be adequate to meet the parts of the bargains, re-course to indictment ought to be turned to.
4. On account of medications produced by an authorized producer under a substantial assembling permit and discovered terribly unsatisfactory and where a criminal plan or gross carelessness is not set up, the weapon of arraignment ought to be utilized reasonably, where it is felt that authoritative estimates such as suspension or scratch-off of licenses or aggravating of offenses would not meet the parts of the bargains.
5. On account of not of standard quality (NSQ) reports in light of minor deformities emerging out of varieties from the endorsed norms or negations of different arrangements of section IV of the Act, managerial measures including suspension/wiping out or exacerbating of offenses might be depended on. Arraignment may just be propelled where it is legitimately felt that the above measures would not meet the parts of the bargains.
6. Area 36 AC, which makes certain offenses under the Act cognizable and non-bailable, has been embedded to encourage the capture of against social components engaged with the production of deceptive or defiled medications. The area ought to, in this way, be conjured with the most extreme consideration and just in situations where it is legitimately felt that it is basic to book the offenders for appropriate examinations for the situation.
7. The State Drug Control Department will establish screening boards of trustees containing at any rate three senior officials not underneath the degree of Assistant Drugs Controllers or identical to inspect the examination reports of the situations where arraignments are proposed to be propelled. The council may submit a composed assessment on the examination reports in regards to their achievability of making a legitimate move. The criminal aim or gross carelessness ought to be mulled over while suggesting activities such as indictment and so forth. Care ought to be taken that charges surrounded are not founded on unseemly arrangements, which might be hard to demonstrate in the official courtroom without appropriate

- support or proof. Instances of flopping in the test, brand name questions, and non-reestablishment of assembling permit in time ought to be inspected on their benefits before prescribing indictment in such cases.
8. Arraignments by the inspectors will be propelled based on composed consents of the controlling power, and this expert thus will think about the proposals of the screening advisory group while taking the ultimate conclusion on the issue.
 9. The patent and proprietary plans ought to be tried by the government investigators as gave under standard 46 of the drugs and cosmetics rules. On account of non-pharmacopeial or changed definitions, the examples might be tried according to the method given by the producer, which has been properly endorsed by the permitting authority. If there should be an occurrence of nonreceipt of such technique on demand, the example might be tried according to strategy for investigation accessible with the government examiner.
 10. The drugs consultative committee had before in 1993 affirmed nitty-gritty rules for making a move in explicit cases on reports of NSQ medications. These proposals, yet for the above, will likewise be taken into contemplations while allowing consent for indictment or regulatory activity against the guilty parties (Annexure A)
 11. Coappointment between administrative specialists is vital to achievement in making an auspicious move-in instance of infringement of the arrangements of the drugs and cosmetics rules. The state drug control organizations will, in this way, advise a nodal official with phone and fax number at the headquarter just as circle levels, which could be reached by other administrative experts for the trade of data and appointment in search/seizures/attack or examinations in the instances of false and debased medications. The detail of these officials will likewise be sent to the workplace of the Drug Controller General of India (DCGI) with the goal that this data is put on the site of the Central Drugs Standard Control Organization (CDSCO) for the data of administrative specialists just as the overall population.

Nation Wide Spurious Drugs Survey In India

About 3% of drugs in India are unsatisfactory, show well-being service overview. Over 3% of all medications sold crosswise over India are of unsatisfactory quality. As indicated by the first since forever overview led by the association service of well-being and family welfare. In the biggest at any point, experimentally planned medication review embraced on the planet for deciding the nature of medications. Service authorities said 0.0245% of the 47,012 examples were misleading.

The service had endowed the work identifying with doing a study of the degree of issues of fake and NSQ medications to the national foundation of organic (NIB). Noida. The NIB has since presented the report to the legislature. The study included upward of 224 medication atoms having a place with the 15 distinctive helpful classifications of the national rundown of fundamental drugs (National List of Essential Medicines) 2011. As a piece of this review, 47,954 medication focal and state medication testing labs have been licensed by NABL. "In general, out of the 47,012 examples tried, 13 examples were seen as false, and 1850

samples were seen as NSQ, said the discharge." All things considered, the level of NSQ medicates in India has been seen as 3.16%, and that of deceptive medications is 0.0245%. Tests identifying 23 dosage forms were drawn from 654 locales of 36 states and association domains from the stock chains, including retail outlets, government sources, and from eight air terminals and ocean ports. [Available from: <http://www.timesofindia.indiatimes.com/articles>]

Preventive Measures

1. These exercises ought to be driven by the government through the prescription managerial body of a country. Survey of meds is a less difficult task for net solution shippers near exchanging Nations like India. Countries getting the prescription should coordinate assessment at the port of entry and thusly reduce the segment of phony drug
2. India made its first walks toward taking care of this issue with the establishment of medicine regulatory in 2008, the CDSCO. It has different goals that are agreed with the courses of action discussed superior to an extended breaking point of CDSCO to play out its commitments, tremendous scale investigations of phony drugs, progressively unmistakable watches out for imports, and client care fights exercises. An impressive parcel of these exercises is ceaseless, and some execution courses of occasions loosen up to 2020
3. CDSCO distributes month to month a rundown of drugs, medicinal gadgets, and beauty care products that are assessed and announced as NSQ/spurious/ tainted/misbranded
4. Enhancement of Central Drug Laboratories with new refined testing hardware set up and making of another testing research center at Hyderabad
5. At the state level, Tamil Nadu and Kerala Government embrace sedate quality assessment benefits by Tamil Nadu Medical Service Corporation Limited and Kerala Medical Service Corporation Limited, separately and consistently report the NSQ items, which they brought from government clinics.

For limiting SFFC or NSQ drugs at the national or states level, still, there is an earnest necessity of increasingly inflexible and stringent guidelines, strategies, and lawful activities against the issue[.Jagadeesh K et.al]

References

1. Available from: http://www.timesofindia.indiatimes.com/articles/how/57318274.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst. [Last accessed on 2019 Sep 20].
2. Barnes K. New counterfeit report highlights worrying trends. Outsourcing Pharma 2007. Available from: <http://www.outsourcingpharma.com/Contract-Manufacturing/New-counterfeit-report-highlights-worrying-trends> [Last cited on 2013 Apr 4].
3. Bate R, Tren R, Mooney L, Hess K, Mitra B, Debroy B, *et al*. Pilot study of essential drug quality in two major cities in India. PLoS One 2009;4:e6003.

4. Bate R, Zhe Jin G, Mathur A. Does price reveal poor-quality drugs? Evidence from 17 countries. *J Health Econ* 2011;30:1150-63.
5. Burke J. India rejects claims it exported fake medicine to Africa. *The Guardian* 2013. Available from: [http://www.theguardian.com/world/2013/Jan/02/India-rejects-fake-medicine Africa](http://www.theguardian.com/world/2013/Jan/02/India-rejects-fake-medicine-Africa) [Last cited on 2013 2nd February].
6. Caudron JM, Ford N, Henkens M, Mace C, Kiddle-Monroe R, Pinel J. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. *Trop Med Int Health* 2008;13:1062-72.
7. CDSCO. Report on a countrywide survey for spurious drugs. New Delhi: Ministry of Health and Family Welfare, Government of India; 2009 p. 3-4. Available from: http://www.cdsc.nic.in/report_book_13-7-10.pdf [Last accessed on 2013 Nov 20].
8. Current Scenario of Spurious and Substandard Medicines in India: A Systematic Review. Available from: <https://www.researchgate.net/publication/273464064>. [Last accessed on 2019 20th September].
9. Deccan Herald newspaper dated 25/08/2015, heading- "India needs stronger drug enforcement system."
10. Estevez, A. G., Espinosa, A. H. R., Rodríguez, D. L., & Leyva, T. F. (2019). Current approaches and controversies: legalization and non-legalization of drugs. *International Journal of Health & Medical Sciences*, 2(1), 26-32. <https://doi.org/10.31295/ijhms.v2n1.85>
11. Francis PA. National Programme to Counter Fake Drugs. *Pharmabiz* 2000. Available from: <http://saffron.pharmabiz.com/article/detnews.asp?articleid=12328§ionid=47> [Last cited on 2013 Feb 12].
12. Furnham A, Valgeirsson H. The effect of life values and materialism on buying counterfeit products. *J Socio Econ* 2007;36:677-85.
13. Gentry JW, Putrevu S, Shultz C, Commuri S. How now Ralph Lauren? The separation of brand and product in a counterfeit culture. Lincoln, Nebraska; 2001. p. 258-65. Available from: <http://www.acrwebsite.org/search/view-conference-proceedings.aspx?Id=8485> [Last accessed on 2013 Nov 15].
14. Government of India, The Drugs and Cosmetics Act and Rules (Amendment) 2005. Ministry of Health and Family Welfare. Available from: <http://www.cdsc.nic.in/forms/contentpage1.aspx?lid=1888> [Last cited on 2014 14th October].
15. Guidelines for taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under The Drug and Cosmetic (Amendment) Act, 2008. New Delhi: CDSCO report; 2008 p. 1-13. Available from: [http://www.cdsc.nic.in/writereaddata/Guidelines under new penal provisions9.pdf](http://www.cdsc.nic.in/writereaddata/Guidelines%20under%20new%20penal%20provisions9.pdf) [Last accessed on 2013 Nov 13].
16. IMPACT. Counterfeit Medicines: an update on estimates. 2006. Available from: <http://www.who.int/medicines/services/counterfeit/impact/TheNewEstimatesCounterfeit.pdf> [Last accessed on 2013 Nov 18].
17. Jagadeesh K, Abhijith LM. Spurious Drugs: A Tragedy in Health System? Available from: <http://www.rjms.in/index.php/rjms/article/download/121001/83483>. [Last accessed on 2019 20th September].
18. McLaughlin KE. Counterfeit medicine from Asia threatens lives in Africa. *The Guardian* 2012. Available from: <http://www.theguardian.com/world/2012/dec/23/Africa-counterfeit-medicines-trade> [Last cited on 2013 Feb 2].

19. Ministry of Health and Family Welfare. Report on Countrywide Survey for Spurious Drugs, Central Drugs Standard Control Organization. New Delhi: Ministry of Health and Family Welfare; 2009.
20. Morris J, Philip S. Counterfeit medicines in less developed countries. 2006. Available from: http://www.policynetwork.net/sites/default/files/IPN_Counterfeits.pdf [Last accessed on 2013 Nov 18].
21. Mudur G. India to introduce the death penalty for peddling fake drugs. *BMJ* 2003;327:414.
22. Nayyar GML, Breman JG, Newton PN, Herrington J. Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa. *Lancet Infect Dis* 2012;12:488-96. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22632187> [Last cited on 2014 May 24].
23. Newton PN, Amin A, Bird C, Passmore P, Dukes G, Tomson G, *et al.* The primacy of public health considerations in defining poor-quality medicines. *PLoS Med* 2011;8:e1001139.
24. Newton PN, Green MD, Fernandez FM, Day NP, White NJ. Counterfeit anti-infective drugs. *Lancet Infect Dis* 2006;6:602-13.
25. Newton PN, Green MD, Fernandez FM. Impact of poor-quality medicines in the “developing” world. *Trends Pharmacol Sci* 2010;31:99-101.
26. PIB. Generic Medicines. Press Information Bureau of India. 2012. Available from: <http://www.pib.nic.in/newsite/erelease.aspx?relid=89323> [Last cited on 2013 8th January].
27. PIB. Infrastructure for seizure and testing of spurious drugs. India: Press Information Bureau of India; 2009. Available from: <http://www.pib.nic.in/newsite/erelease.aspx?relid=55393> [Last cited on 2013 Jan 8].
28. PIB. Sale of Spurious Medicines in the Country. India: Press Information Bureau of India; 2010. Available from: <http://www.pib.nic.in/newsite/erelease.aspx?relid=60987> [Last cited on 2013 Jan 9].
29. PIB. Survey on Spurious/Sub-Standard Drugs. India: Press Information Bureau of India; 2013. Available from: <http://www.pib.nic.in/newsite/release.aspx?relid=92384> [Last cited on 2013 Jan 8].
30. PIB. Suspension of Drugs. Press Information Bureau of India. 2010. Available from: <http://www.pib.nic.in/newsite/erelease.aspx?relid=60818> [Last cited on 2013 8th January].
31. PSM. Counterfeit Drug Incident Encyclopedia. Partnership for Safe Medicines. 2013. Available from: <http://www.safemedicines.org/counterfeit-drug-incident-encyclopedia.html> [Last cited on 2013 19th March].
32. PSM. Proposed methodology to conduct a study on the extent of spurious drugs in the supply chain of the Indian market. India: ???; 2010. Available from: <http://www.safemedicinesindia.in/pdf/Methodology.pdf> [Last accessed on ???].
33. Raufu A. India agrees to help Nigeria tackle the import of fake drugs. *BMJ* 2003;326:1234.
34. See M. Pharmaceutical quality: an urgent and unresolved issue. *Lancet Infect Dis* 2012;12:428-9.
35. Shepherd M. Vulnerable points in the US drug-distribution system. *Manag Care* 2004;13(Suppl 3):25-9.
36. Spuriousdrugs. Available from: <https://www.advocatekhaj.com/library/bareacts/drugsandcosmetics/17b.php?title=Drugs%20>

- and%20Cosmetics%20Act,%201940&STitle=Spurious%20 drugs. [Last accessed on 2019 Sep 20].
37. Substandard Drugs are a Bigger Problem for India than Fake. Available from: https://www.economictimes.indiatimes.com/articleshow/69137983.cms?from=mdr&utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst. [Last accessed on 2019 Sep 20].
 38. Taylor RB, Shakoor O, Behrens RH. Drug quality, a contributor to drug resistance? *Lancet* 1995;346:122.
 39. The Spurious Drugs Gene and its Pervasiveness. Available from: <https://www.ijme.in/articles/the-spurious-drugs-gene-and-its-pervasiveness/?galley=html>. [Last accessed on 2019 20th September].
 40. WHO. Medicines: Spurious/falsely-labeled/falsified/counterfeit (SFFC) medicines. Geneva: World Health Organization; 2012. Available from: <http://www.who.int/mediacentre/factsheets/fs275/en/index.html> [Last cited on 2013 16th March].
 41. WHO. The right to health. 2008. Available from: http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf [Last accessed on 2013 Nov 29].
 42. WHO. The world medicines situation. World Health Organization. 2004. Available from: http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf [Last cited on 2010 Nov 30].
 43. WHO. WHO medicines strategy: countries at the core, 2004–2007. World Health Organization. 2008. Available from: <http://www.apps.who.int/medicinedocs/pdf/s5571e/s5571e.pdf> [Last cited on 2010 Nov 30].
 44. Widana, I.K., Sumetri, N.W., Sutapa, I.K., Suryasa, W. (2021). Anthropometric measures for better cardiovascular and musculoskeletal health. *Computer Applications in Engineering Education*, 29(3), 550–561. <https://doi.org/10.1002/cae.22202>
 45. Wondemagegnehu E. Counterfeit and substandard drugs in Myanmar and Viet Nam. World Health Organization: Geneva; 1999. Available from: <http://www.apps.who.int/medicinedocs/pdf/s2276e/s2276e.pdf> [Last accessed on 2013 Nov 11].
 46. World Bank. India. 2011. Available from: <http://www.data.worldbank.org/country/India> [Last cited on 2013 Mar 14].