



Contemporary Scenario of SSFFC Medicines: A Systematic Review



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Abstract

Health care professionals (HCPs) play most significant role in health care system and provide medicines to cure and heal diseases, lessen symptoms, relieve pain, avoid disease or symptoms and slow down the disease process. Unfortunately, sometimes medicines not found to be potent due to the problem of substandard/spurious/falsely labeled/falsified/counterfeit medicines (SSFFC). The issue is widely spread globally and affects both developing and developed nations. In India every year several incidences of SSFFC medicines were reported, which tremendously affects the health of the public. SSFFC medicines not only affect public health but it also results in the economic crises. This concern cannot be neglected any more. A comprehensive study on the contemporary scenario of the problem, its recognition and detection with respect to locality, medication category, and drug form investigation is not present. Our purpose is to thoroughly explore and investigate the evidence available on SSFFC in the period of 2013-2016. Reports suggest the incidence occurrence in their region wise manner.

Keywords: SSFFC; Adulterated; WHO; CDSCO

Introduction

Globally every year dubious quality drugs affect a large number of populations. Drug safety, efficacy, and quality are the prior responsibilities of health care professionals [1]. However, substandard/spurious/falsely labeled/falsified/counterfeit medicines (SSFFC) make it hard for HCPs to provide trust worthy and resolute health care system [2,3]. Countries including developing and developed endure many health issues due to counterfeit/substandard/ spurious drugs. Victim of these drugs faces life threatening issues, financial crises and loss trust on the health system. SSFFC could be branded or generic drug. Weak regulatory guidelines and their enforcement in the manufacture, storage, importation, distribution, supply and sale of drugs result in the poor quality or NSQ (Not of Standard Quality) drugs [4]. Globally counterfeiting covers a large market and is complicated to distinguish, detect, inspect, enumerate and prevent them [5-7]. Thus this conundrum of the poor quality of drugs should be minimized by rigorous regulation and legal actions. The purpose of this review is to investigate the incidence of substandard/spurious/falsely labelled/falsified/counterfeit medicines for the duration of 2013-2016. Data from 2013 to 2016 were assembled and disclosed the actual status of poor quality drugs in India.

SSFFC Definition

WHO in 1992 describe counterfeit medicine as medicine which is intentionally and deceptively mislabelled with respect

to identity and/ or source [8]. WHO in 2011 define counterfeit and substandard medicines in new term 'substandard/spurious/falsely-labelled/falsified/counterfeit medical products' (SSFFC) [9-12]. SSFFC includes generic as well as branded drugs. SSFFC may be with the correct ingredients or with the incorrect ingredients, devoid of active ingredients, with inadequate active ingredients or with fake packaging [13]. Counterfeit products can be categorised as:

- Drug ingredients are wrong.
- Insufficient amount of ingredients present.
- Drug product with no drug ingredients.
- Drug ingredients differ from which it is mentioned on label.
- Drug products with fake and inappropriate packaging.
- Drug products which have been expired and which do not have expiry date.
- Drug products with high content of impurities.

Type of SSFFC

Drug and Cosmetic Act, 1940 states that counterfeit, misbranded, spurious, adulterated and fake drugs and not good quality drugs are of three types [14].

I. Type A: It includes spurious and adulterated drug product. The actual characteristics of drug product obscure and mislead it with several identified brand. Active ingredients may not be present in mislead products. Mostly the manufacturers of these products are unknown and unlicensed authorities. Type A consists of adulterated products with harmful ingredients [15].

II. Type B: It includes grossly substandard drug product. These products mainly fail in their various evaluatory parameters like disintegration or dissolution test in case of tablets and pyrogen/endotoxin test in case of parenteral preparation. Broadly it includes [16].

- a. Active ingredient: less than 70% and 5% for thermally labile and thermally stable products.
- b. Tablets/Capsules: disintegration/dissolution not passes.
- c. Liquid preparations: fungus occurrence.
- d. Parental preparations and Vaccines: sterility, pyrogen/endotoxin test not passes.
- e. Adulterant: present of any substance which is injurious to health.

III. Type C: It includes products with insignificant fault. These categories of products do not cause significant harm. The insignificant imperfection of dosage form includes like picking, cracking, change in formulation colour, smell, sedimentation, weight variation and errors in the label. Example includes [17].

- a. If tablets are broken or chipped,
- b. If the coating is uneven or spot is present.
- c. Cracking of emulsions.
- d. Presence of sedimentation in any clear liquid dosage form.
- e. Net content deviation.
- f. Drug products fail in weight variation, colour test and deviation in net content.
- g. Any labelling errors.

Preventive measures for SSFFC

Regulatory guidelines: There should be appropriate regulatory guidelines to prevent SSFFC, which should be followed rigorously. There should be penalties and imprisonment for felony related to manufacture, distribution and sale of spurious or adulterated drugs. There should be Standard Operative Procedures [SOP] in each region to observe if there is any violation of the provision of the Act [14,18].

Source integrity and Supply chain: The obtain source of medicine should be reliable. There should be possible regulatory guidelines to avoid counterfeit drugs. Particular measures should be taken for state licensed pharmacies. Some initiatives that devote reliable supply chain includes [16,19]:

- a. Tool and techniques to enable the traceability and localization of drug
- b. A limited number of intermediates in supply chain system while preserving free competition.
- c. Rapidly and successfully analyze the suspect drug
- d. Authenticate internet pharmacies and websites by awarding logo to the site. Presence of online official trustworthy sites.

By this step; one can get the medicine from a reputed source.

Pricing: Relatively cheaper price available drug product should be treated with extra cautions. Sometimes supplier trades the medicines at price more than its original one. The consumer should make sure to authenticate the price before the purchase [20].

Consumer awareness: Consumer should know the drug to be consumed. Any time when prescription refilled colour, odour, taste, the texture should be observed carefully. If there is any mystification then talk to the supplier. The appropriate campaign should be launched for the awareness of society against SSFFC [14,16].

Health care professionals' obligation: HCP should embrace entire stakeholders concerned with conception, making, regulation, allocation and sale of medicines. From the pharmaceutical laboratories that produce the medicines to the patients, all these professionals should be qualified and trained to identify and track SSFFC medicines [21].

Product reliability: SSFFC easily averts from the society if the medicinal products are reliable to consume. One should observe the medicine cautiously and evaluate it on following basis [14,22]

- a. **Label:** Commonly original label removed and replace with a counterfeit label. Always look for holograms, sealing tape tears and seal. Observe the label carefully.
- b. **Expiry date:** Be active to view expiry date. Mainly expiry date was altered in label to sell expired drugs.
- c. **Packaging:** Packaging of the product should be observed meticulously. Several advanced packaging technologies proved helpful in combating this issue. Some of them are:
 - i. Acous to magnetic identification (AMID)
 - ii. Bar code
 - iii. Electro-magnetic identification (EMID)
 - iv. Holograms
 - v. Pedigree system of labelling
 - vi. Pilfer-proof packing
 - vii. Pharma code
 - viii. Radio Frequency Identification (RFID)
 - ix. Security label
 - x. Verification Systems

Vigilance and feedbacks: To assure the safety and efficacy of the drug there should be organized vigilance, monitor incidents and systematize feedback of the patients. The pharmaceutical company should [23].

- Make and update the list of most likely medicines to be forged.
- Thoroughly report the concern authorities regarding the entire incidence related to the product.
- Systematically recall suspect batches and maintain the product transparency.
- For rapid analysis of suspect drug, permanent all time available hotlines should be present in pharmaceutical companies.

Reports on SSFFC Drugs in India

(Table 1-5)

Table 1: SSFFC in year 2016.

Region	Report
Agra	On Tuesday the FDA officers of UP investigate various drug store in Agra. These stores were seized for selling fake drugs. At Saiya near the border one person was detained for selling fake drugs. The owner selling the drugs illegally [24].
Ahmadabad	The low potency antibiotic drugs in Ahmadabad were reported to be adulterated by paracetamol, flour, factory starch and white powders, said by the officers of food and drugs department [25].
Ahmadabad	The regulatory drug officers found that the calcium tablet 'Shelcal 500' whose makers was Torrent Pharmaceuticals were of low standard quality. The batch was recalled. These calcium tablets formulated by Akums Drugs & Pharmaceuticals subsidiary Pure and Cure Healthcare [26].
Ahmadabad	The Eltroxin manufactured by Glaxo Smithkline was found to be counterfeited by Pharma Hub in Mehsana and Heaven Medical Agency in New Vadaj of Ahmadabad. These wholesaler companies alter the labels of the drug and further sell the drug [27].
Arunachal Pradesh	A report by CDSCO states that sub-standard drugs in Arunachal Pradesh were supplied in hospitals. These low standard quality drugs were manufactured by Ipca Labs, Alkem Labs, Morepen Labs, Abbott and Sanofi. T-Citra and levocetirizine montelukast were also of sub standard quality [28].
Delhi	It can be assumed that India's biggest fake drug scam was ruined by the officers of Revenue Intelligence. Worth 4700 crore, 23500 kg mandrax tablets was seized [29].
Delhi	The government generate a report according to which many drugs were found to be adulterated. CIP-ZOX of Cipla's, Macleods Pharmaceutical Orcerin, Indian Drugs & Pharmaceuticals Ltd's Pantoprazole, Ipca Laboratories Zerodol SP and Karnataka Antibiotics & Pharmaceutical Ltd's Norfloxacin. Macleods Pharmaceutical's Orcerin were found to spurious and substandard [30].
Delhi	The capital region generic drugs manufacturer found to be a hub of SSFFC. Shockingly, the Delhi national capital region surrounded by spurious drugs. In an investigation it was found that one third of all procured drug in Delhi NCR region was either fake or spurious [31].
Gujarat	The food and drugs department of Gujarat found fake antibiotic tablets. These tablets include amoxicillin, ciprofloxacin, ofloxacin and cefixime. These antibiotics seized from SR Enterprise in Sarkhej and Shradha [32].
Gujarat	The manufacturing units' licenses of 336 companies have been suspended by the Food and Drug Control Administration (FDCA) of Gujarat. While 2 manufacturing licenses cancelled and noticed have been generated for stop manufacturing of drugs by FDCA. When 370 samples have been drawn by Central Drugs Standard Control Organisation then 8 among them found to be not of standard quality [33].
Gujarat	When Food and Drug Control Administration of Gujarat execute a survey on medical stores, hospital and manufacturing units than 535 drugs were found not-of- standard quality out of 11071 drugs [34].
Himachal Pradesh	In H.P a closed pharmaceutical company named as Vardhman Pharma found to manufacture the spurious drugs. The license of the company has been cancelled earlier and still found to manufacture the drugs [35].
Hyderabad	Hindustan Uniliver cosmetics' were found to be fake and 5 persons were under arrest while the trade of these cosmetics in Laad Bazaar [36].

The coordinated use of these technologies within the official and parallel trade distribution channels increase the chance to identify and eliminate forged drugs before they reach to the patient.

Method

This report is prepared from published materials collected over the internet and on web portals in the India. Further Google web hunt was conducted using seven keywords viz. 'spurious drug, spurious medicine, counterfeit drug, counterfeit medicine, fake drug, fake medicine, fake cosmetic' in combination with the year 2013, 2014, 2015, 2016 and country name India. Up to 50 pages were searched under 'web' and 'news' section of Google. The search covered a period of four years data (2013-2016). This review contains SSFFC drugs incidence found in India as well as Indian SSFFC drugs which have been reported worldwide during four years (2013-2016).

Jammu and Kashmir	Spurious drugs were caught in medical store and government hospital of J&K a survey done by government organization revealed that Amoxicillin Trihydrate IP 500 mg, Sterile Ceftriaxone Inj IP 1000 mg and Steile Ceftriaxone Inj IP 500 mg from JKMSCL does not pass the test and are of substandard quality [37].
Jammu and Kashmir	In the Kupwara markets the legal authorities check the run of spurious drugs. The local residential people have the concern about the quality of the drug. The sale of expired and lowered quality drug was found in medical shops. At Sub-district hospital Kupwara the expired injections sale was exposed [38].
Karnataka	The factories in Gauribidanur and Doddaballapur have been seized for the illegal supply of the drug. Among this 170 kg of Alprazolam and 13.8 kg of ketamine was found to be manufactured illegally [39].
Kerala	During the operation 'Henna' in Kerala many spurious cosmetics has been seized from the wholesale distributor outlets [40].
Maharashtra	In the Sholapur area of Maharashtra, Cops arrested four people from the chemical firm. From this firm banned Ephedrine 18.5 tonnes worth of Rs 2,000 has been seized [41].
Mumbai	The Allied Air Express has been raided by the official authorities of Mumbai, and seized 16 lakh tablets of psychotropic drug worth of 57 lakh. The drug smuggling was exposed from Mumbai to the US and UK [42].
Mumbai	In Mumbai the FDA officers arrest Munir Khan for selling spurious drugs of Rs 3.3 crore. Body revival drug was sold as miracle cure drug which heals several diseases in a pill. Sold drug was sub standard quality, mislabelled and spurious which was confirmed by the authorities [43].
Mumbai	Mumbai high court exposed a firm dealing with the spurious cancer drug. Taj Pharma was raided for selling counterfeited BICNU-branded drugs. It is an anticancerous agent which was made by Emcure [44].
Punjab	A big counterfeit drug scandal was exposed by the Punjab regulatory authorities. The operation raided 884 drug store among them 68 were caught for the procurement of counterfeit drug. Approximately 13 medical shop owners were detained and 2.6 million fines were charged [45].
Punjab	In Punjab some hospital was raided and it was found that the lab technicians were producing fake blood. They were caught for manufacturing and delivering 21,752 fake blood plasma packs [46].
Uttarakhand	In a joint action conducted by Rajasthan and Uttarakhand, two people were detained in Bhagwanpur in Uttarakhand for allegation of manufacturing and distributing antibiotics which are spurious and of substandard quality [47].
Globally*	The official authority globally in a survey found that the renowned pharma companies like Pfizer, Dr Reddy's Laboratories, Cipla, DRL and 63 other companies' drugs failed in a quality test. Under investigation, it was found that the Pfizer 25 sample, 9 sample from Dr Reddy's and Alembic, 7 sample from Cipla and 6 sample from Zydus Healthcare were found to be spurious and of substandard quality [48].
Globally*	The regulatory authorities of Maharashtra, Goa, Karnataka, Gujarat, Kerala, West Bengal and Andhra Pradesh carried out the quality test and found that 27 medicines failed in several tests. These drugs were sold by Abbott India, Sun Pharma, GSK India, Glenmark Pharma & Cipla. The drugs found to be of low quality, falsely labeled, incorrect ingredients, formulation issues and failed in dissolution and disintegration test [49].
Globally*	According to the survey conducted by National Institute of Biologicals, 47954 samples were collected by various hospitals, dispensaries and drug stores. Among this 3% substandard and lower quality drug were caught from drug stores, while 10% were caught from hospital [50].
Globally*	The drug regulatory authority from 7 states notified 18 pharma companies for the procurement of fake and sub standard quality drugs. During the survey it was found that 27 drugs manufactured by 18 pharmaceuticals failed in various tests. After the notification, only 1 from 18 companies had recalled the failed drug from the market and 2 withdraw the distribution of these batches drugs [51].

Table 2: SSFFC in year 2015.

Region	Report
Andhra Pradesh	The drug controller authorities of Andhra Pradesh seized 58 drugs from three districts. Four distributors across these three districts found to sell spurious and counterfeit drugs various pharmacological categories like non steroidal anti-inflammatory drugs, anti bacterial, anti-emetics and supplements [52].
Bangalore	Two held for selling spurious drugs to the elderly. In Bangalore, two people are selling spurious drugs, which are held by police [53].
Bangalore	An Ayurvedic store was raided by officers of crime branch. Two people were detained for selling fake drugs. Worth of crores fake drug was caught by the officers [54].
Bangalore	State testing 2,000 drug samples for quality: So far, 58 manufacturers have been prosecuted in the State for producing spurious drugs. He said rumours of a large number of spurious drugs circulating in the market were doing the rounds, but statistics were not available to substantiate it [55].
Bhubaneswar	Spurious drug racket exposed the medicinal condition of Puri district. During the inspection, it reveals that T Citra syrup sold at Kakatpur failed the quality test and found to be substandard in quality [56].

Bhubaneswar	Under the random inspection by official authorities in Bhubaneswar the tested drug sample was found to be of substandard quality. The antihistamine syrup levocetirizine montelukast (Montul brand) which was marketed by dubious enterprise was found to be spurious and of substandard quality. Another drug TFlox-OZÁ and tablets Montul were also not of standard quality [57].
Delhi	At Sadar bazaar a wholesale cosmetic store was raided by the Delhi police officers. The cops trapped worth of 50 lakh spurious and fake cosmetics from the store [58].
Delhi	Kingpin a fake drug gang was caught by Delhi police. The gang sell the fake medicines abroad. Police caught the gang near Kanhaiya Nagar metro and seized a carton of the fake drug worth Rs 50-60 lakh [59].
Delhi	India a rising counterfeiting centre reported by Delhi police. Huge stock of fake, counterfeited and spurious cosmetics of big brands name Revlon, Ponds, and Dove seized by the Delhi police [60].
Delhi	In Zirakpur a pharma factory have been seized by Delhi police. Police recovered a big quantity of fake medicines manufactured there. Three people have been detained and fake medicine of Rs 50 lakh have been seized [61].
Delhi	After raid also Sarojini Nagar Dirt is the centre of fake cosmetics. By the use of fake cosmetic people suffer from swollen eyes and rashes [62].
Delhi	On Saturday cops arrested two people for delivering spurious and substandard quality Buprenorphine Hydrochloride (Norphene) in Delhi [63].
Delhi	In the capital region three people were detained by the cops. Several cartons of fake drugs of Rs 50 lakh were seized by the officers. It includes 3 cartons of Zerodol SP tablets, 2 of Pantop-D capsules, and 5 of Pantop DSR. All carton were flooded by fake and spurious medicines [64].
Delhi	Fake herbal trade racket busted, 4 arrested. Four people, including a woman, have been arrested for duping several people by promising them profits from trading in Biognes, an herb seed used in medicines meant for treating HIV positive patients and other incurable diseases [65].
Delhi	Fake pharmacist held with drugs worth 50 lakh. In Delhi, a self-taught pharmacist was detained for the supply of various fake drugs including viagra and anti-depressants. The caught stock of fake drugs was estimated worth Rs 50 lakh [66].
Delhi	PAC raps Health Sec. on spurious drug supply for central scheme: The Public Accounts Committee of Parliament today chided the Ministry of Health for "misleading" it on spurious drug supply and non-transparent procurement of medicines under the Central Government Health Scheme asked it to return [67].
Delhi	In an investigational operation it was found that the Delhi medical shops were dealing the drugs sell without the government consent. It was found that 70% of non-steroidal drugs, 20% of antidiabetic drugs, 81% of antidepressants, 70% of antidepressants were marketed without approval of the government. It was also observed that some antibiotics, gastric medicines, paracetamol, , chlorpheniramine maleate, caffeine, sinarest and phenylephrine HCl were spurious and of substandard quality [68].
Gujarat	An organization based in Surat was caught while selling spurious and counterfeit medicines. The caught drugs value of Rs 7 lakhs [69].
Hardwar	The cops of Hardwar bust a gang for manufacturing fake cosmetics. Special operation group of Hardwar police detained some people for involving in the manufacturing duplicate and fake cosmetics of well known brands [70].
Hyderabad	The Drug control organization found that on random survey some drugs found to fail in quality test. 21 drugs have been recalled from the market as they are of sub standard quality. These drugs have been selected on a random basis from many drug stores from the city [71].
Hyderabad	For selling fake cosmetic products three people were in prison. The cops have detained three persons for selling fake Lakme cosmetic products of Hindustan Unilever Limited (HUL). The fake products were seized and in custody worth of Rs 18,000 [72].
Hyderabad	11 hospitals have been raided by Telangana drug controller. The officer found that the city medical stores have been flooded with spurious drugs. The drugs stores caught while selling expired and sub standard drugs to the local public of the city [73].
Jaipur	In Jaipur a firm was raided for manufacturing counterfeit drugs. The cops caught the drugs worth of Rs 50 lakhs. The officers say that many drug stores in the city were found to sell theses counterfeits drugs [74].
Jaipur	In a raid in Jaipur 50 lakh counterfeit drug was seized. The seized drugs are very commonly used pain killer, antibiotics, vitamins and many other supplements. It was also found that the caught drugs were manufactured from Uttarakhand [75].
Jamshedpur	In a survey it was found that fake cosmetics circulating in India. It was found that in Jamshedpur fake cosmetics is bursting. The fake cosmetics were manufactured in Kolkata. The fake cosmetics of very big brands were seized from the local market of the city [76].
Karnataka	The Karnataka drugs control department in a survey seized 27 non standard quality drugs. These drugs were caught from several medical and drugs stores of the city [77].

Madhya Pradesh	In the Barwani district of Madhya Pradesh a drug known as 'eye wash' which is Ringer's lactate solution was found to be counterfeit. The drug was manufactured by Beryl Drugs pharma. This pharma industry also manufactures many IV fluids and ophthalmic preparation. The government banned the manufacture of these drugs [78].
Madhya Pradesh	As per the survey in Indian drugs one out of seven made known as substandard. In Madhya Pradesh Akpash Pharmaceuticals, metronidazole tablets failed a dissolution test and many drugs revealed as substandard [79].
Maharashtra	Interstate gang circulating spurious codeine syrup. A person named as Dalaram Chaudhary was detained by the FDA officer. Fake and spurious 14000 syrup bottles was seized by the officers [80].
Meerut	7 drug samples found to be fake in a survey. Raids conducted by the food and drug administration in Meerut over the past three months. The survey revealed that many medicine samples have failed in the quality and several tests. These drugs are of non standard quality [81].
Odisha's Puri	A racket has been busted by the government organization of Odisha. In an investigation, it was found that many drug stores are selling spurious drugs in the city [82].
Patna	In name of branded cosmetics, fake products were seized in Patna. In the Patna city 3 cosmetics store was raided by the officer's and substandard and low quality cosmetics worth of Rs 10 lakh were seized [83].
Punjab	A team of Punjab drug regulatory officers raided a chemist in Ludhiana and seized spurious medicines of more than Rs 2 crore from the medical shop [84].
Punjab	In Punjab, pregnancy spurious drugs had been seized in an investigation. The drugs have no active ingredients. Many capsules injection including hydroxyprogesterone caproate injection were caught in a survey [85].
Ranchi	In Ranchi Enforcement Directorate and Central Bureau of Investigations conduct an investigation a big medicine scam was busted. The medicine scam of 130 crore was apprehended [86].
Srinagar	Many spurious drugs have been caught from Srinagar. The Doctors Association of Kashmir has asked for capital punishment for those people who deal with spurious drugs [87].
West Bengal	The drug regulatory officers caught the contaminated sample of Phensedyl in a random survey. The West Bengal based firm caught the well known cough syrup Phensedyl which was mislabelled. The syrup contains more than double the active ingredient mentioned on the label. This active ingredient was found to be codeine [88].

Table 3: SSFFC in year 2014.

Region	Report
Agra	From Agra fake medicines racket was busted. In an enquiry done by the Drug Health Department, the fake medicines of a multinational brand were trapped. These medicines were caught from the local market of the Agra [89].
Amritsar	In an investigation the drug team detained the strips of counterfeit medicines from Bagga medical store. The store deals with many counterfeit and fake drugs. The drug store located in the local area outside Guru Nanak Dev hospital [90].
Bihar	Fake medicines racket was busted in Bihar. Officer ruined the fake drug racket in the state capital [91].
Chhattisgarh	Some medicines were excluded by the government of the Chhattisgarh. It was found that thirteen people were dead at the health camp of Takhatpur, Pendra and Marwahi. Hence some drugs including ibuprofen, ciprocin, lignocaine, xylocaine gel, absorbent cotton were banned by the government officers [92].
Chhattisgarh	Fake medicines supplied by the pharmaceutical firm known as Mahawar Pharma were seized by the Chhattisgarh government. The government also banned the use of these fake drugs. In various health camps, several people were died and have been affected crucially by the use of the drugs manufactured by Mahawar Pharma [93].
Cuttack	A fake vaccine racket ruined by the Directorate of Drug Control Administration and police commissioner of the state. In an investigation, it was found that at Bidanasi the combination of 5 vaccines commonly known as the pentavalent vaccine was fake and being sold to the people of Cuttack [94].
Delhi	Spurious and substandard drug were found to be sold in the government hospital of Delhi. A civil person report that 7 sample of medicines bought from the government hospital was not of standard quality. Regarding this, he also filed a complaint to RTI (right to information) [95].
Delhi	The famous wholesale market of medicines Bhagirath Palace in Chandni Chowk found to sell counterfeit and spurious medicines. The wholesale dealer supplies these drugs to several states all over the country. In an inspection, it was found that the insulin injections which are supposed to refrigerate and several precautions should be mind for its storage, found to be lying outside the medical shop. The investigation team ruined several medicines of Rs 6 lakh [96].
Greater Kashmir	An enquiry done by the state government of J&K revealed that the substandard quality drug being sold in the state. A survey done by the government uncovered the situation of the drug system in J&K. It was found 83 fresh samples, out of 3130, as substandard [97].
Greater Kashmir	Several substandard drugs were found to be sold by various pharmaceutical firms in J&K. Pharose Remedies Limited manufacture and sells Paracetamol of substandard quality. The drug found to fail in dissolution test. The Pharose Remedies pharma located in Bari Brahmana, Jammu, the drug controller suspend the license of the company [98].

Gurgaon	The spurious cosmetics caught by the food and drug administration. In Gurgaon, a car was detained and twenty cartons of spurious soap were seized by the officers. The manufacturer of these cosmetics was Kailash Khadi Gram Udyog, 503/13, Khasara No 909, Sadhrana, Gurgaon [99].
Himachal Pradesh	Central Drugs Standards Control Organization (CDSCO) reveals that many drugs from Himachal Pradesh were of substandard quality and fails in dissolution test. Tapentadol and Paracetamol tablets, Ofloxacin tablets, Amoxicillin & Dicloxacillin, Misoprostol, Amoxycillin & Potassium, Cefuroxime Axetil, Clavulanate, Salbutamol Sulphate Megarab, Albendazole, Cefixime dispersible, Trypsin Chymotrypsin, Ceftricolor, Ceftriaxone & Sulbactam and Gencin 80mg/2ml injection were found to fail in the test. CDSCO alerts the manufacturer of these medicines [100].
Himachal Pradesh	In a survey several drugs in the government hospital of Himachal Pradesh was found sub standard. The government detained the manufacturer of these spurious drugs. The drug includes Curecef, Vidin Ointment, Cefotaxime Injection and Ampicillin injection [101].
Jammu and Kashmir	The J&K government busted a spurious drug racket. Twenty five government officials of the different department were warned regarding the scam of spurious drugs. The purchase of drugs which were found to be spurious was banned by the officials [102].
Jammu and Kashmir	The racket of the fake drug sold by various medical stores had been busted by the J&K officers. According to the of Drug Control Act the drug store violates its rule and hence 123 drug store licenses had been cancelled. The stores were found to sell fake and spurious drugs [103].
Jammu and Kashmir	In a survey carried out by CDSCO, it was found that many government hospitals in J&K enclosed with substandard drugs. Substandard drugs include amoxicillin, potassium clavulenate injection and Zepoxin injection [104].
Jammu and Kashmir	A lot of fake medicines have been seized in Kashmir. In a survey a report reveals that 27 drugs were substandard. The substandard drugs were worth Rs 21.35 lakh [105].
Jammu and Kashmir	The sudden inspection done by the drug inspectors of Kashmir raided the medical shop near GB Pant hospital. The medical shop keepers were detained while selling the fake drugs to the patients [106].
Jammu and Kashmir	The S-K Institute of Medical Sciences was found with a substandard bandage. The manufacturer of these bandages trapped and regarding this warrant was issued against four people [107].
Jammu and Kashmir	The J&K ministers were found to involve in the fake drug scam. There were many allegations found against the state government for selling a fake and spurious drug to many hospitals and drug stores [108].
Jammu and Kashmir	The court of J&K passed an order to the government to seize all the fake, substandard and spurious drugs. The state and central drug standard control organization were asked to take in custody all chemists, medical stores, private and government hospitals to seized all medicines which were found to be fake and spurious [109].
Karnataka	According to the report 131 drug store were found to violets the drug & cosmetic act. The medical stores were found with large stock of fake, substandard and spurious medicines. Some stores were also seized while they are selling the medicines without legal licence and permission [110].
Madhya Pradesh	In Madhya Pradesh a big fake medicines scam was exposed. The government collect 3255 sample of medicines from various private and government medical shops. Out of this 147 sample were found to be spurious and of substandard quality. These samples were failed in various quality tests also [111].
Madhya Pradesh	Madhya Pradesh based pharma company known as Anupam Biotech was seized for the manufacturing and supply of the spurious and substandard drug. The company sell the drugs to Khanna, Ferozepur and Ludhiana [112].
Madhya Pradesh	Three pharmaceutical firms were seized and fined by the MP health officer for manufacturing and supply of spurious and substandard drug. Salbutamol 4mg (batch no. WB-14019) manufactured by Edrayad Pharmaceuticals Pvt Ltd, Multivitamin Tablet (batch no. WB- 14019) manufactured by Wilcure Pvt Ltd and Metronidazole tablet 200 mg (batch number MDT-1305) manufactured by La-Chemico Pvt Ltd (Kolkata) were revealed to be spurious and of lower quality [113].
Manipur	The Federation of Regional Indigenous Society (FREINDS) and Ayurvedic Doctor Association of Manipur detained 4 people for selling banned medicines to the patients [114].
Meerut	In Meerut a big drug racket has been busted by the government. Sri Hanuman Agency godown has been raided and big stocks of substandard, spurious and expired drugs have been caught. The company also used to tamper the label of the drugs. The seized drugs include antibiotics, anti diabetics, anti venom and several life saving drugs [115].
Mumbai	In Mumbai an online firm was caught while illegally selling sildenafil citrate. The wedged medicine was believed to sell in African and European countries. Seized drugs value of Rs 2 crore [116].
North east region	According to the report generated by the CDSCO the Northeast region become the hub of spurious, fake and substandard medicines. The survey revealed the actual medical condition of the region. In the month of September 45 drugs, medical devices and cosmetics were found of substandard quality and failed in many tests. These medicines were manufactured in Himachal Pradesh, Andhra Pradesh, Jammu, Goa, Punjab and Uttarakhand [117].
Patna	In Patna four people was detained while selling fake drugs. The raid in Sri Krishna Puri region ruined a big stock of fake medicines. The seized medicines were of several multinational brands and it is worth of Rs. 25 lakh [118].
Pune	The FDA filed a complaint and warrant against twenty three medical shops in Pune. These medical shops were caught for selling spurious and fake drugs. Many of them selling the drugs without any licence [119].
Tripura	Tripura assembly tumults over the substandard and spurious drugs supply in government and non government hospitals [120].

Globally*	According to the CDSCO report of January to March many drugs of government and private hospitals were found to be spurious and substandard.
	Sixty six samples were found to be substandard and spurious which was collected from various regions. The collected sample includes commonly used drugs like ranitidine, levocetirizine, paracetamol and amoxicillin and many more [121].

Table 4: SSFFC in year 2013.

Region	Report
Ahmadabad	Recently a racket of spurious drugs manufacture and sale was caught in Ahmadabad by the Gujrat FDA. A person named as Jayesh Mehta was detained for the supply of the spurious drug. A big stock of spurious drug worth of Rs 2 lakhs was caught by the officers. Jayesh selling the drugs without any legal documents [122].
Allahabad	A huge stock of fake cough syrup was caught at the railway junction of Allahabad. On Sunday cops seized 650 bottles of fake cough syrup which was planned to sell in West Bengal. 4 people were detained by the cops for this scam near railway station [123].
Ambala	The Vardhman pharmaceutical private limited owner was detained by the cops and warrant was issued against the duo. According to the kala amb cops the pharmaceutical company was manufacturing and supplying spurious drugs. The company also don't have any valid license [124].
Bangalore	Fake drug worth of Rs 12 lakh was caught by the police in Bangalore. A duo and 2 Nigerian were detained when they are selling the fake spurious drug to the citizen declaring that it will cure cancer [125].
Haryana	A big spurious drug scam was disclosed by the police. A renowned leader of BJP Pawan Bansal runs a pharmaceutical company. The company was alleged to manufacture and supply spurious and substandard drug [126].
Himachal Pradesh	According to the survey done by government, India now become a hub of spurious and fake medicines. Many pharmaceutical companies are alleged to manufacture and supply substandard quality drugs. In a survey, it was revealed that almost 45% Himachal Pradesh manufacturing pharma companies are involved in manufacturing and distribution of spurious drugs all over the country [127].
Himachal Pradesh	A pharmaceutical company located in Sirmaur was apprehended for illegal manufacturing and selling drugs. The drug controller officers sealed the company. The company was alleged to supply illegally drugs to the government hospital of many states of India including Chhattisgarh, Tripura and Uttar Pradesh [128].
Jammu and Kashmir	Fake medicines were wedged from the government hospital of Jammu and Kashmir. In an investigation, it was found that fake amoxicillin tablets being supplied to the patients in government hospital [129].
Jammu and Kashmir	Jammu and Kashmir CBI detained two brothers for the spurious drug scam. The duo caught for the procurement of spurious drugs from the state government [130].
Jammu and Kashmir	The pharmaceutical companies of Jammu were alleged for the distribution of spurious drugs. A warrant was issued against seventeen pharma campiness according to a source. As per the drug and cosmetic act, the companies were found to violet the drug act [131].
Jammu and Kashmir	Several hospitals of Jammu and Kashmir were found to supply fake medicines. As per the report, 7875 patients in Sher-Kashmiri institute of Medical Science were died due to the consumption of spurious drugs. These spurious drugs were believed to supply by the state government [132].
Jammu and Kashmir	In an investigation done by the drug controller of India it was found that the drug sample taken from the J&K government hospitals was spurious. On a random collection of 156 drugs from the various hospital of J&K two were found to be spurious [133].
Jammu and Kashmir	The spurious drug scam was busted by the J&K crime branch officers. The officers demand the detail of purchase and payment for the procurement of the drugs. The drug which was procured was believed to be spurious as per the report [134].
Jammu and Kashmir	In the drug analysis and testing done by doctor association Kashmir, it was found that twenty four samples which have been supplied to the hospitals were spurious and of substandard quality [135].
Jammu and Kashmir	The cost free distributed drug was found to be spurious by the drug controller officers. A major scandal comes to light when the government hospital was found to distribute cost free drug to the patients. Many substandard drugs were seized by the officers including Maximizen tablets manufactured by Himachal Pradesh based company [136].
Kanpur	Brijesh Pal was detained by the cops from Naubasta for illegal manufacturing and supplying fake oxytocin injections. A sack full of 100 and 60ml of 700 oxytocin injections were caught by the police. The injection was illegally manufactured by Brijesh in a small room in an illegal manner [137].
Mumbai	Fake and spurious drug racket were busted by the FDA officers. These spurious drugs were advertised openly on the television. The officers execute sting operation and order these drugs. Finally, the officers seized the big stock of spurious drug worth of Rs 12 lakh [138].
Nagpur	The parliament committee plead to seize spurious drug procurement. The committee notes the supply of the spurious drug to the patients in the city and hence plea all the stakeholders to hold the chain of the spurious drug [139].

Patna	Right from cosmetics to medicines almost everything was found to be fake, spurious and substandard in Patna. According to the report, Patna market becomes the central hub for the fake and spurious drug business. Many manufacturing units of counterfeit drugs were caught by the police in various region of Patna [140].
Patna	Substandard drugs become a major concern for the doctors. Huge stock of substandard quality drugs was trapped by the officers in Gandhi Maidan area. The officers seized thirty boxes of spurious drugs and detained the suspected person [141].
Tami Nadu	Many drugs and medical devices were ostracized by the medical services corporation of Tamil Nadu. In an investigation, it was found that from last 8 months the medical devices and drugs failed in quality and found to be contaminated. Commonly used drugs like aspirin, antibiotics and supplements as well needle; a syringe and other medical devices were found to be contaminated [142].
Globally*	A global investigation discloses that big quantity of spurious drugs has been supplied in different area globally. In investigation, the officers seized ninety lakh doses of spurious drugs in a year. Considering this many manufacturing unit and online pharmacies have been shutdown [143].

Table 5: SSFFC Indian report found world widely.

Region	Report
2016	
Nigeria	Quinine Sulphate manufactured by Indian manufacturing company CAD Pharma was found to be fake. This fake Quinine Sulphate was circulated to the various region of Nigeria. The Nigerian officers warn the local public regarding the supply of fake Quinine sulphate [144].
Scotland	Valium pills become the cause of death of several people in Glasgow. About more than hundred people died in Scotland by these fake pills. The fake pills are known as 'Blue plague'. These drugs are believed to manufactured and imported in India and another state of Asia [145].
Serbia	Big stocks of sexual enhancement pills which were counterfeited have been caught in Serbia while crossing the border. The officers seized 1134 shipment of these illegal and counterfeited medicines at custom. The fake and substandard erectile stimulants were manufactured in India [146].
South America	In a survey it was revealed that almost twenty five to thirty five percent of the drugs in South America are fake and of substandard quality which is not safe for the consumption. Many people consume these fake medicines and then suffered a lot. These fake medicines were believed to import from India [147].
Switzerland	Indian manufactured erectile dysfunction medicines were seized by the officers Diepoldsau border. The product belongs to well known pharma company 'Pfizer'. 1800 boxes were detained by the officers of border; the boxes were hidden in the vehicle. While crossing the border the officer caught the fake medicines. Later, again after few days, 1200 units of fake drugs were caught from vehicle [148].
UK	The well known erectile dysfunction medicine 'Viagra' was found to be fake in UK which was manufactured in India. The seized drugs fail in the quality test. It was found that the manufacturing plant was not hygienic and contaminated with toxic chemicals. Talcum powder, paint and detergent powder found to be the components of these fake pills with an unknown quantity of active pharmaceutical ingredients [149].
US	According to USTR after a survey in US it was found that almost ninety percent of the drugs which were counterfeited were imported by India, China and Singapore. In an investigation, it was revealed that 16% of 31,560 US government seizures of counterfeit goods involved pharmaceuticals were from the India and China [150].
2015	
US	On pharmaceutical and chemical evaluation of two generic drugs Cialis and Propecia which has been packed in India was found to be impure and counterfeit. The drugs contain an unknown form of impurities. The active pharmaceutical ingredients were mixed up with some other unidentified ingredients' [151].
US	Two persons named as Neil Russell in Pittsburgh & Manuel Pena in Houston was detained for the supply of misbranded online drugs which has been imported from India. CDR Marketing owner was an Indian named as Paridhi Sharma, was trapped to sell misbranded drugs from online pharmacy Another person Zhenya Nikolova who was the owner of online Alliance Pharmacy was also detained for selling substandard and misbranded drugs [152].
UK	During the secret investigation Pangea it was found that most of the drugs supplied by India and China to UK were fake. The officers of UK seized almost 2 million of fake doses of slimming drugs and erectile dysfunction drugs. These fake drugs may cause some serious problems to the consumers. Apart from drugs condoms and dental lab items was also found to be fake [153].
2014	
Kenya	Cipla an Indian drug manufacturer was under allegation for the supply of an unauthorized drug. Kenya public was under big health risk due to these drugs of substandard quality. According to a survey, almost thirty medical stores were selling counterfeit medicines in various regions of Kenya [154].
Myanmar	Myanmar was flooded with fake and illegally supplied drugs according to a report. The food and drug administration officer seized sixty sort of fake and illegal drugs. The source of these drugs was mainly India, Thailand and China [155].

2013	
Sri Lanka	The health minister of Sri Lanka Maithripala Sirisena debarred 4 Indian based generic pharmaceutical companies. In the quality test, the drug from these companies was found to be substandard. These lower quality drugs were seized by customs officers during their shipment. Laborate pharma, Bafna Pharmaceuticals, Vivek Pharma & Elysium Pharmaceuticals were found culpable for the supply of substandard drugs to Sri Lanka [156].
Ghana	The food and drug authority forbidden the import of an anti malarial drug Gsunate Plus in Ghana. The drug was found to be substandard in quality tests. An Indian based pharmaceutical firm Bliss GVS was culpable for the manufacturing and distribution of the substandard drug. As per the FDA report [157].

Overview

(Figure 1)

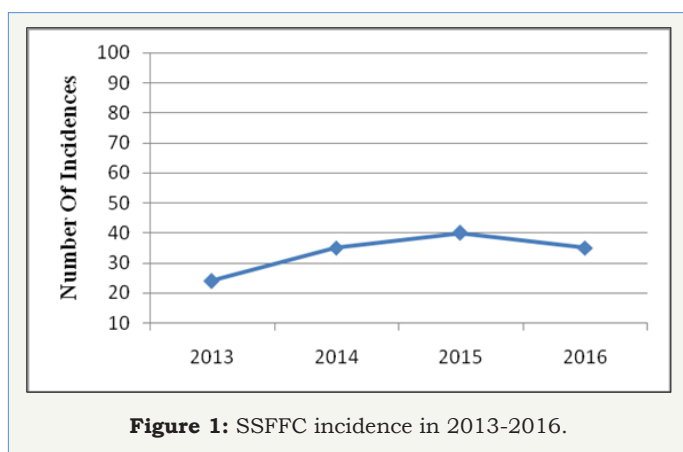


Figure 1: SSFFC incidence in 2013-2016.

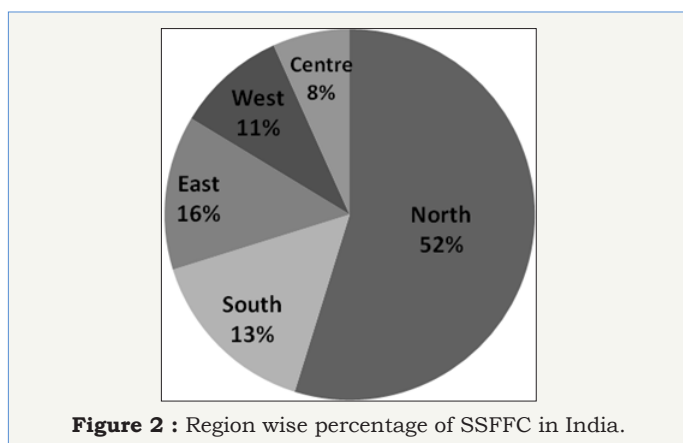


Figure 2 : Region wise percentage of SSFFC in India.

Consequences of SSFFC

SSFFC drugs have several numbers of adverse effects, which not only affects the health but also the economic aspects of the society. It results in various difficulties for patients like treatment failure, end organ damage, toxicity and sometimes death also. Adverse effects caused by SSFFC causes unfaithfulness in the health care system. The name of the original medicine was ruined up and the company bears the loss. Some time pharmaceutical company faces financial crises as the products are being counterfeited and sold at a relatively cheaper price [158]. In some cases counterfeit products neither have active ingredients nor harmful, then does it not harm the patient health but it overdue the treatment process [159]. Whereas if the product has no active ingredient and harmful ingredients were present then it may result in mortality and morbidity [160]. If an inappropriate quantity of active ingredients

were present then it either results into treatment failure or it may cause drug resistance. Consequential patient feel betray from the health care system. In return, it causes financial losses for patient, producers, traders and whole health care system. Eventually, it increases economic burden for the society [161].

Result

After observation of above data, it can be seen clearly that SSFFC has propagated all over the regions in India. Total 134 incidences have been reported from four years (2013-2016). In the year 2013, 22 and 2 reports within and outside India respectively have been observed. In the year 2014 within India 33 and outside India 2 report have been observed. Whereas the data enlarged in 2015 and 2016, includes 37; 28 reports in India and 3; 7 outside India respectively. Data revealed the alarming situation of SSFFC in India. In view of data, it is exposed that highest reports were from the North region (52%) which includes Himachal Pradesh, Haryana, Punjab, Delhi, Jammu & Kashmir and Uttar Pradesh. Further observed reports cover East region (16%) Jharkhand, Bihar, West Bengal and Odisha. Remaining reports cover South region (13%) Andhra Pradesh, Tamil Nadu, Karnataka and West region (11%) includes Rajasthan, Maharashtra and Gujarat. In central region (8%) that is Madhya Pradesh & Chhattisgarh show the least incidence as per the data (Figure 2).

Conclusion

SSFFC drugs exceedingly affect the health of the society. This problem is the primary concern for all the health care professionals' worldwide. Frequently SSFFC reports have been noticed in India every year. Several classes of drug found to be spurious, including antibiotics, anti depressant, anti-histamics, anti-emetics, anti-cough and cold, anti-protozoal, anti-ulcers, pain killers, CNS stimulants, vaccines, vitamins, supplements and cosmetics. This is the time to aware the society against SSFFC more vigorously. Furthermore, research is essential to report SSFFC incidence to evade it in future. Medicines quality surveys are encouraged to avoid this conundrum of society. Various physical/chemical analysis and all the key initiatives and preventive measures should be considered to avoid substandard & counterfeit medicines. Mutual collaboration of all stakeholders required to achieve success against SSFFC. Through this we can anticipate the SSFFC free world.

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25. From flour to starch, fake antibiotic drugs have them all.
26. Torrent pharmaceuticals.
27. Racket in spurious drug unearthed.
28. Indian government moves to tackle substandard drugs.
29. India's 'biggest' drug racket busted, Bollywood producer nabbed.
30. It's not only combiflam, more drugs under regulator's radar.
31. Need for policies and guidelines for diabetes management in public sector enterprises.
32. Fake antibiotics worth Rs 51 lakh seized.
33. Gujarat FDCA suspends licenses of 336 mfg units, cancels two mfg licenses for non-compliance to D&C Act.
34. Gujarat FDCA detects 535 NSQ drugs in state 2016-17 as against last year's 365.
35. Closed pharma unit found making drugs.
36. Five held for selling fake cosmetic products.
37. Vigilance raids in Jammu over sale of spurious drugs.
38. Spurious' drugs flood Kupwara markets.
39. City, outskirts becoming hub for manufacture of spurious drugs.
40. Spurious cosmetics wreck Kerala beauty parlours, state launches operation henna.
41. Banned drug Ephedrine worth Rs 2,000cr seized.
42. DRI unearths Rs 57lakh drug smuggling racket; 8 held.
43. FDA raids fake doctor's office, seized drugs worth Rs 3.3cr.
44. HC hauls up firm exporting spurious cancer drugs.
45. Counterfeit drugs: 884 medical stores raided in Punjab.
46. Not just drugs, fake blood also running through Punjab's veins.
47. Two arrested for making spurious drugs in Uttarakhand.
48. Medicine! Pfizer, Cipla, DRL, other 63 drug firms fail quality test
49. Drug regulation: 27 medicines sold by top firms 'fail' quality tests in seven states.
50. Majority of the drugs found in India are either fake or ineffective.
51. Official warns pharma units on spurious drugs.
52. APDCA seizes spurious drugs worth Rs.5 lakhs from 3 districts in AP.
53. Two held for selling spurious drugs to the elderly.
54. Duo selling fake ayurveda drugs to senior citizens.
55. State testing 2,000 drug samples for quality.
56. 340 Routine check unearths spurious drugs racket.
57. Drugs of fake firm found to be substandard, spurious.
58. Fake cosmetics worth Rs 50lakh seized from Sadar Bazar, two held.
59. Fake drug export racket busted; kingpin held.
60. India police bust counterfeit "factory" for Revlon, Ponds, and Dove labels.
61. Delhi cops raid Zirakpur factory, seize fake medicines, and arrest three.
62. Dirt cheap and fake cosmetics.
63. Two held for selling fake norphene injections in Delhi.
64. 3 held with fake drugs worth Rs. 50lakh.
65. Fake herbal trade racket busted, 4 arrested.

66. Fake pharmacist held with drugs worth 50L.
67. PAC raps Health Sec. on spurious drug supply for central scheme.
68. City chemists selling common drugs without government approval.
69. Spurious medicines worth Rs.7 lakhs were being sold.
70. Haridwar cops bust gang making fake cosmetics.
71. DCA recalls 21 spurious drugs.
72. Three arrested for selling fake cosmetic products.
73. Hyderabad: Telangana Drug Control Administration team raids 11 hospitals.
74. Rs. 50lakh worth fake drugs seized.
75. Counterfeit drugs worth Rs 50lakh seized in raid.
76. Fake cosmetics circulating in India.
77. Karnataka drugs control dept seizes 27 NSQ drugs.
78. Congress demands criminal case against drug manufacturers over botched cataract surgery.
79. 1 In 7 Indian drugs revealed as substandard.
80. Interstate gang circulating spurious codeine syrup: Girish Bapat.
81. 7 drug samples found to be fake.
82. Odisha's fake medicine bust leads to inter-state racket.
83. Fake cosmetics acting as top brands seized in India.
84. A team of Punjab drug regulatory officers today raided a chemist.
85. Spurious pregnancy drug being sold in state markets.
86. Two caught in medicine scam net.
87. Doctors seek death penalty for spurious drug dealers.
88. Drug police asks abbott pharma to explain tainted cough syrup sample.
89. Fake medicines supplied from Agra.
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91. Illegal, fake drug racket rocks Bihar assembly.
92. Chhattisgarh government bans 4 medicines.
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95. Keep an eye out for spurious medicines.
96. Business as usual after raid at Bhagirath Palace.
97. 83 more drugs found substandard.
98. 83 more drugs found substandard.
99. FDA intercept car, seize 20 cartons of spurious cosmetics soap.
100. 14 drugs made in Himachal Pradesh fail tests.
101. Government orders drugs from 'dubious' companies.
102. Spurious drugs: 25 government officials face action.
103. Licenses of 134 drug shops suspended, fake drug seized in Kashmir.
104. Drugs in JK's government hospitals substandard, says CDSCO report.
105. Kashmir's have consumed large stocks of fake medicines: DFCO.
106. Spurious drugs sold outside GB Pant.
107. SKIMS get sub-standard supply.
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111. Madhya Pradesh: 147 medicine samples in hospitals of inferior quality.
112. 7 booked for selling false drugs. MP health dept slaps fine on 3 firms for supplying substandard drugs.
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115. Drug racket had links with Meerut, Nepal.
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118. Fake drugs over Rs. 25lakh seized, four arrested.
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