WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.084
Volume 12, Issue 2, 564-574. Review Article ISSN 2277– 7105

SPURIOUS DRUGS (A BRIEF REVIEW)

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Article Received on
29 Nov. 2022,

Revised on 19 Dec. 2022,
Accepted on 09 Jan. 2023

DOI: 10.20959/wjpr20232-26960

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ABSTRACT

Today's worldwide community has recognized the spread of spurious medications as a threat, particularly in developing nations. The sale of spurious drugs is a specialized form of white-collar crime. These medications can have various negative effects, including therapeutic failure, severe adverse events, and even death. Steps taken for the prevention of spurious drugs are drug quality monitoring, monitoring of drugs through the supply chain, technological innovation, enforcement of laws and legislation, awareness and vigilance, international cooperation and generic medicine promoting strategies.

KEYWORDS: Spurious drugs, Therapeutic failure, Awareness, Vigilance.

INTRODUCTION

In India with a population of more than 1.24 billion, there is fundamental right to health and has been recognized in the national constitution and statutory laws as well as in international laws.[1-2] Globally, one third of the global population about 2 billion people lack access to essential medicines.[3] However, people accept, prefer and buy counterfeit or substandard products over genuine or branded products due their cheap price, easy accessibility and availability in the market.[4] The spurious drugs/falsely labelled/falsified /counterfeit (SFFC) are poor quality drugs that can cause treatment failure or even death.[5] Accordingly, 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".[6] The global

prevalence of spurious and counterfeit drugs ranges from 1–50%.[7] It is more severe in the developing countries; the World Health Organization estimates that about 25% of the medicines are spurious drug that consumed in developing countries.[8] The vast majority of spurious and counterfeit medicines are currently thought to be produced in China, India and Russia, although significant numbers of illegal factories have also been reported in Nigeria and the Philippines.[9]

In India, The Drug and Cosmetic Act 1940 and Rules 1945, regulating the manufacture, sale, and quality of drugs and formulations, provides a definition of ‘‘spurious drugs’’ under section 17-B these are:

1. If it is manufactured under a name which belongs to another drug.
2. If it is imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or.
3. if the name of an individual or company claiming to be the drug's producer appears on the label or container and that person or company is fake or not exist.
4. It has been replaced entirely or partially with another medicine or substance.
5. If it claims to be a product of some one's manufacturer.

Both spurious and Counterfeit are sometimes used synonymously but there are certain differences between these two terms which are as differentiated as below:

Difference between Spurious and Counterfeit drugs are[10]

Sl. No	Spurious drugs	Counterfeit drugs
1	The drug product/formulation is without any active ingredient/salt	The drug product/formulation contains labelled drug
2	Sample will fail when tested in the laboratory	Sample may pass when tested in the laboratory
3	It may or may not resemble in packing, design, look, etc with popular original brand	It will resemble in packing, design, look with popular brand. The batch number, manufacturing date, expiry date, labels on the product may be from the original pack. Even the physician/pharmacist may not be able to detect it
4.	Injurious to health; may cause problems even death of the patient.	May not be injurious to health.
5.	There is criminal intent behind producing and supplying these drugs.	Criminal intent may or may not be there.

6.	Normally the medicines are sold without Bill.	Medicines may be sold on valid invoices by licensed chemists.

Historical aspect of spurious drugs

In the past, there were often very few written laws., and much less regulations governing the practise of pharmacy because earlier then, drugs were not produced, kept, sold, or used in specialised ways. Most of these medications had to be imported at first, but over time they started to be produced in India, which marked the beginning of the massive pharmaceutical industry we know today. A number of laws were passed after the Poisons Act of 1919, which was primarily passed to control drug importation, and they currently control the area of pharmaceutics. In India, the manufacture, distribution, and sale of medications are all governed by the 1940 Drugs Act. This Act, currently known as the Drugs and Cosmetics Act of 1940, was revised in 1964 to bring cosmetics within its limits. Ayurvedic and Unani medicines were included to the Act's. The establishment of the Drugs Technical Advisory Board, Ayurvedic and Unani Drugs Technical Advisory Board, and Drugs Consultative Committee is required under the Drugs Act. The several Drugs Technical Advisory Boards provide guidance to the Federal and State Governments on a variety of technical issues pertaining to the implementation of the Act. Representatives from the Central Government and other State Governments make up the Drugs Consultative Committee. This Committee provides recommendations to the National, State, and Drug Technical Advisory Boards regarding the enforcement of consistency in the application of the various provisions of the Act throughout the Nation. Established in 1962, the Central Drug Laboratory examines imported and domestically produced medicines for their components, purity, and potency. Additionally, this Act mandates that a patent or proprietary drug's formula be displayed on the medication's label or container. A regulation known as the Drugs and Cosmetics Rule of 1945 went into force in 1945 in line with the requirements of the Drugs and Cosmetics Act of 1940 (formerly known as the Drugs Act of 1940). The manufacture, distribution, and sale of pharmaceuticals in India are all governed by this rule. The retailer's process for selling medicines is prescribed by this rule. Along with the serial number and the date of the sale, the retailer should keep records of the following information in a record.

- The name and address of the patient.
- The name and address of the prescribing doctor.
- The name of the drug or name of the ingredients used in a mixture with quantity of each.

- While selling drugs enlisted in certain schedules of this rule (Schedule C, H and L), the name of manufacturer, the batch number of the product, and the expiry date of the potency of the drug should be recorded.
- The signature of the person under whose supervision the medicine is compounded and sold should be there.

The Drugs Control Act of 1950 governs the manufacture, sale, and distribution of drugs and gives manufacturers and/or dealers instructions on how to set the maximum price for each substance. The Drugs and Magic Remedies (Objectionable Advertisements) Act of 1954 was created to make sure that drug makers sell their products in a morally upstanding manner. (Under this Act, advertisements that violate morality or decency are restricted, as are claims that certain drugs have magical properties, such as increasing potency or cure diseases). The Delhi Quackery Prohibition Bill, 1997, which allows jail for operating the medical profession without an authorized permit, was passed by the Delhi government to prevent this type of unethical advertising.[11]

Categories of spurious drugs[12]

1. **Category A (Spurious and Adulterated drugs):** This group of formulations includes those whose true nature is concealed and those are deliberately created to look like a particular brand of medication with the objective to confuse. Active substances may or may not present. Most often, these medications are made by unlicensed manufacturers in violation of the law. These goods can be contaminated with dangerous chemicals.
2. **Category B (Grossly sub-standard drugs):** Licensed businesses produce these medicines. These medications can include vaccinations that failed potency tests, tablets that failed tests for tablet disintegration, or liquid preparation which had microbial contamination.
3. **Category C (Minor defects):** These medications are manufactured by companies with legal authorization and may have minor issues that do not seriously hurt the patient.

Consequences of spurious drugs

The effects of using fake and fraudulent medications might range from therapeutic failure to the incidence of major side events and even fatalities. The main danger facing infectious diseases is the emergence of medication resistance. Poor-quality medications run the danger of causing the spread of resistance in diseases that are treated with combination therapy, such as HIV, tuberculosis, and falciparum malaria.[13] In 1998, the use of a cough syrup containing

diethylene glycol resulted in the deaths of more than 30 children.[14] At JJ Hospital Bombay in 1986, doses of impure glycerine resulted in the deaths of more than ten patients.[15,16] The businesses making the actual product suffer a significant financial loss in such a situation.[17] In numerous nations, diethylene glycol has been substituted for or contaminated with pharmaceuticals . In such a scenario there is huge financial loss for the companies producing the genuine product.[18] Contamination of, or substitution in, medicines of diethylene glycol has occurred in many countries including Argentina, Bangladesh and Nigeria, Therapeutic failure or adverse events result in loss of confidence in the health system and the systems of drug control and enforcement.[19] The reputation of the original product is damaged and the pharmaceutical companies which invest huge resources in developing innovative products suffer financially. The state also loses revenue from the taxes and duties that would be payable on the legitimate product.[20] Developing countries with lax regulatory environments for drugs are also disadvantaged in their ability to attract direct foreign investment.[21]

Economic effects of counterfeit drugs

The subsequently causing a rise in morbidity, adverse drug responses, and drug resistance, spurious drugs also put a financial strain on society. Along with an increase in sickness, mortality is also rising, and this might result in lost economic potential. Sales of fake medications will hurt sales of real medications, which will hurt businesses that have made quality, research, and development investments in medications. Additionally, this can discourage businesses from doing foreign investments. The government also suffers a large loss in tax revenue. Along with this, a sizable sum must be spent on the development of technologies that can identify fake medications and protecting the drug supply chain. Indian imports may be barred due to spurious drugs pharmaceuticals.[22]

Prevention of spurious drugs

At the Broad level, the fight against spurious medications necessitates multifaceted, multisectoral, cross-border partnership, while at the micro level, it requires restrictive rules, enforcement, awareness, and vigilance. To be successful, it needs the involvement of all parties. From the viewpoint of developing nations, it is important that this dispute does not result in an increase in medicine prices or the removal of low-cost sources of bulk medications.[23]

Following steps may be taken

Drug quality monitoring

The state is responsible for ensuring that the general population has access to high-quality medications through its regulating organisations. Maintaining surveillance over potential movements of fake or counterfeit pharmaceuticals and swiftly investigating such cases are important components of drug regulatory agencies' careful and thorough oversight of the drug supply. Compare the printing, shape, embossing, taste, smell, and consistency of a suspect sample with a genuine product is the quickest, cheapest, and simplest method. To enable thorough and widespread surveillance and drug monitoring, the state should ensure that testing facilities are widely accessible. According to the 2003, Meanings of the term Committee report, only 15 states in India had functional testing laboratories, and only seven of those were complete. Eleven states lacked drug testing facilities.[24]

Monitoring of drugs through the supply chain: Drugs should be monitored by regulatory agencies and producers through the supply chain, to the consumers. In this aspect, every package has been marked with a quality stamp that includes a batch number that provides product tracing.[24]

Technological innovations: Other authentication technologies, like as barcoding, blister packaging, complex holograms and logos, colour-shifting ink, and taggants or chemical markers embedded in a drug or its label are also applied by manufacturers in addition to track-and-trace technology.[25] Another method known as spatially offset spectroscopy may be useful in surveillance since it enables handheld devices to verify the chemical makeup of pharmaceuticals in sealed blister packs and bottles.[20]

Enforcement of Laws and Legislation: It is well known that the majority of nations have passed laws that are sufficiently strict to punish forgers; there are still implementation gaps.[26] The application of laws requires a strong political will, particularly in emerging nations with weak judicial, administrative, managerial, and policing systems. In nations where they don't already exist, central drug regulating authorities need to be established. These regulating bodies should have sufficient personnel and material resources as well as legal and administrative authority to take action against counterfeiters if they are to be effective. In order for efficient investigation and prosecution to occur, enforcement also necessitates good coordination between the many governmental bodies, including the drug regulating agencies, police, court, customs, and intelligence. In India, the government

constituted an expert committee under the chairmanship of Dr RA Mashelkar to examine all aspects of regulatory infrastructure and the extent and problem of spurious/counterfeit drugs in the country.[27,28]

Awareness and Vigilance: It is crucial to inform all parties involved doctors, pharmacists, traders, marketing staff, manufacturers, as well as the general public about the issue of fake medications. Some non-governmental organisations in India have created strategies to address the issue of fake pharmaceuticals. The Organization of pharmaceutical producers of India (OPPI) is a collection of pharmaceutical manufacturers engaging with the Pharmaceutical Security Institute (Geneva, Switzerland) and the International Federation of Pharmaceutical Manufacturers Association to establish an intelligence network to combat the trafficking in fake medicines. Similar to this, two important former police officers have been hired by the Indian Pharmaceutical Alliance (IPA), a grouping of several pharmaceutical makers, to assist in solving the issue. The pharmaceutical business has to understand that sharing data on the incidence of fake pharmaceuticals is in both the consumers' and their own interests. All parties manufacturers, authorities, or individuals should be required by law to notify the relevant authorities immediately if they have any suspicions that pharmaceuticals are being sold illegally so that action can be taken.[29]

International cooperation: Due to the fact that the trade in spurious medications crosses international borders, international cooperation is essential to fight this threat. The necessity for cooperation[30] is driven by the contribution of criminal organizations and the potential usage of free trade zones for the sale in fake drugs. The ability to pinpoint the true origin of exported medications is a requirement for both importing and exporting nations. It is only feasible if there are established legal and administrative agreements, as well as methods for cross-border information exchange. Interpol, the Organization for Economic Cooperation and Development, the World Customs Organization, the World Intellectual Property Organization, the World Trade Organization, and the WHO should be deemed important stakeholders in this system.[31]

Generic medicine promoting strategies: The $20 billion Indian pharmaceutical business ranks third in terms of volume and thirteenth in terms of value. India excels as the "pharmacy of the developing world," focusing on the accessibility and affordability of the pharmaceutical items in the nation. All Central Government hospitals and Central Government Health Scheme (CGHS) dispensaries in India have been ordered to prescribe

generic medications as frequently as feasible. The state government also gives doctors instructions on how to administer generic medications. The Department of Pharmaceutical, Ministry of Chemical and Fertilizers, launched the "Jan Aushdhi Campaign" (Medicines for Public Campaign) nationwide in collaboration with the State Government by opening "Jan Aushdhi" generic drug stores in government hospitals and supplying generic medications through Central Pharma Public Sector Undertaking.[32]

DISCUSSION

It is time for the authentic pharmaceutical industry to work with law enforcement to stop the trafficking in spurious drugs pharmaceuticals because these products may also be accountable for eating away at the financial shares of the industry. The day does not seem far off when such fraudulent drug producers or sellers would be required to pay significant damages under the guidelines of India's rapidly growing consumer activism under the Consumer Protection Act's jurisdiction. The media can play a crucial role in this regard. The general public has to take a part in the decision about these recent trend. They must take the medications that their doctors have advised them to take and never consent to the pharmacist obtaining a substitute. To ensure the validity of the medications, one should carefully examine the blister package or the medicine container, and rarely they may need to be rechecked by the prescribing physician.

The major effect upon the pharmaceutical company is total loss of sales and loss of protecting the brands and they have lost their goodwill among the public which it leads to loss of revenue. They will have to take many safety measures and high-cost packing in order to gain trust from the consumers, to repair the damages done to the brands and its name. Governments will have to put in lots of efforts to take many measures such as enforcement measures to be taken in the pharmaceutical and inspection to be taken in laboratories. Loss of confidence or trust in governments and public health programmes, so more of therapeutic failures destroy the credibility and success of health programmes. Politicians must create stricter regulations, and those enforcing the law must punish individuals who spread fake medications. Any fatality brought on by fake drugs may be looked into and tried as murder, under Section 302 of the Indian Penal Code.

CONCLUSION

The introduction of conflict pharmaceuticals in India has caused issues all around the world. To tackle the problem of fake medicines, governments must band together and settle on a

unified definition. Conducting reliable, objective studies on the incidence of spurious drugs pharmaceuticals in India is necessary in order to advance the healthcare system.

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