



# SPURIOUS DRUGS AND THEIR IMPACTS

## Abstract:

The quality of Drug formulations has been a prime concern at National as well as International level. Circulation of spurious drug can lead to grave & adverse consequences on both consumers (patients) and genuine manufacturers. According to the report received from various State Drug Controllers, the extent of circulation of spurious drug in Indian retail market is about **0.3%**. However, media often magnifies it, in a sensational manner, between 10-25% which is mostly unverified. Indian Pharma Industry expressed displeasure over the repeated projection of Indian Pharma Industry as major producers of spurious drugs in the world. Due to dire consequences on public health in view of various projections regarding circulation of spurious drug, a systematic study was necessary to assess the actual extent of spurious drug circulation in the community at large. Report on Countrywide Survey for Spurious Drugs SALA (Sound Alike and Look Alike) would, no doubt, provide relevant information about the flow of Spurious drugs in National market and bring awareness among the community. Perhaps this is the first time in world history such a scientific study has been carried out by collecting huge number of samples involving consumer associations and other NGOs. It is expected that people at large will be immensely benefited through this report and their belief in availability of quality medicines in India will be assured & strengthened.

**Keywords:** Spurious Drugs, SALA (Sound Alike and Look Alike), Drug Controllers, NGOs.

## Meanings & Definitions:

**Spurious** – false, counterfeit, not genuine

**Adulterate** – to corrupt, debase, or make impure by adding a poor or improper substance; as to adulterate liquors, to adulterate drugs.

**Sub-standard** – below standard, below a standard established to law.

*Spurious Drugs are mainly the products which are deliberately and fraudulently mislabeled and manufactured to mislead and misrepresent the patients by concealing their identity, source of manufacture and its content to profiteer on the popularity of fast moving branded or generic medicines. It may or may not contain the active ingredients in the manner mentioned on the label.*

## Introduction

The drugs and food are essential components of the health care of the public. The recovery of ailing patients from illness is directly related to the quality of drugs they consume. The proliferation of spurious drug in India is a serious problem for the health of the people and there is an urgent need to curb it.

a drug shall deemed to be spurious –

- (a) If it is imported under a name which belongs to another drug; or
- (b) If it is an 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
- (c) If the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or
- (d) If it has been substituted wholly or in part by another drug or substance; or
- (e) If it purports to be the product of a manufacturer of whom it is not truly a product

### **Extent of problem**

SFFC medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a SFFC medicine is unknown and its content unreliable. SFFC medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge.

About 5-8% of total drug imported in USA is either counterfeit or substandard. Counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest. In most industrialized countries with effective regulatory systems and market control (i.e. Australia, Canada, Japan, New Zealand, the United States of America, and most of the European Union), incidence of SFFC medicines is extremely low – less than 1% of market value according to the estimates of the countries concerned. But in many African countries, and in parts of Asia, Latin America, and countries in transition, a much higher percentage of the medicines on sale may be SFFC.

### **The Effect of Spurious Drugs on Health of People:**

- Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source.
- Use of SFFC medicines can result in treatment failure or even death.
- SFFC medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.

It is difficult to ascertain a precise effect of a spurious drug on health of a person for the following reasons:

**a.** It is not known at the time of consumption of medicine that it is a spurious drug. Therefore, if the drug is not effective a patient usually thinks that the diagnosis is wrong and either he consults another physician or ends up having a series of diagnostic tests including x-rays, ultra sound, MRI etc resulting in an increased medical expenses, mental agony and absence from work or studies.

**b.** If there are certain toxic effects of the medicine then it is usually assigned to an allergic reaction of the medicine and the physician might change the medicine. The toxic medicine is then completely forgotten and is not pursued any further.

**c.** If the medicine is fatal then usually the death is assigned to the disease or the negligence of a doctor or the hospital.

Even when spurious drugs do not endanger life they can leave the patient seriously ill and those with inadequate potency can induce drug resistant bacteria i.e, they will not respond even when right medicine in right dosage is given.

### **Preventive measures to be taken to control Spurious Drugs**

Adopted model guidelines by the State Drug Control Organizations are

1. In the case of detection of manufacture and/or sale etc. of spurious or imitation drug products by the unlicensed manufacturers or sellers, the case shall be investigated on top priority and provisions of section 36 AC of the Act invoked under which these offences are considered cognizable and non-bailable. Necessary help from the enforcement agencies like police etc. should also be obtained, wherever required, so that the

rackets are busted and culprits booked in time for taking legal action.

2. In the case of detection of a case of manufacture and/or sale etc. of spurious drugs by a licensed manufacturer i.e. use of licensed premises for manufacture of spurious drugs and the criminal intent is apparent, the case is required to be pursued with equal vigour as in the case of unlicensed manufacturer.

3. The Patent and Proprietary formulations should be tested by the Government analysts as provided under Rule 46 of the Drugs and Cosmetics Rules.

4. Co-ordination between regulatory authorities is key to success in taking timely action in cases of violation of the provisions of the Drugs and Cosmetics Rules.

5. The State Drug Control Organizations shall create a rapid alert system so that any vital information in the cases of spurious/adulterated drugs is passed on to the appropriate authorities quickly for taking further action in the matter.

### Examples of Spurious Medicines and their effects

| S. No. | SFFC medicine   | Country/ Year                     | Report  |
|--------|---|-----------------------------------|---|
| 1.     | Avastin<br>BEVACIZUMAB<br>(for cancer treatment)                                | USA, 2012                         | Affected 19 medical practices in the USA. The drug lacked active ingredient.                                      |
| 2.     | Viagra and Cialis<br>SELDINAFIL & TADALAFIL<br>(for erectile dysfunction)       | UK, 2012                          | Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer. |
| 3.     | Truvada and Viread<br>EMTRICITABINE 200mg +<br>TENOFVIR 300mg<br>(for HIV/AIDS) | UK, 2011                          | Seized before reaching patients. Diverted authentic product in falsified packaging                                |
| 4.     | Zidolam-N<br>LAMIVUDINE+ZIDOVUDINE<br>(for HIV/AIDS)                            | Kenya, 2011                       | Nearly 3000 patients affected by falsified batch of their anti retroviral therapy                                 |
| 5.     | Alli<br>ORLISTAT 60 mg<br>(weight-loss medicines)                               | USA, 2010                         | Smuggled into the USA. Contained undeclared active ingredients with possible serious health risks to the consumer |
| 6.     | Anti-diabetic traditional medicine<br>(used to lower blood sugar)               | China, 2009                       | Contained six times the normal dose of glibenclamide. Two people died, nine people were hospitalized              |
| 7.     | Metakelfin<br>(antimalarial)  | United Republic of Tanzania, 2009 | Discovered in 40 pharmacies. The drug lacked sufficient active ingredient.  |
| 8.     | Rhoclon (Human Anti D Immunoglobulin)   | India, 1999                       | Imitation of drug filling in empty vials  |
| 9.     | Anti rabies vaccine   | India, 2012                       |   |
| 10.    | Fortwin injection<br>PENTAZOSIN   | India, 2013                       |   |

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|-----|-------------------------------------|-------------|--|
| 11. | Veptoin tabs<br>PHENYTOIN SODIUM    | India, 2013 |  |
| 12. | Duphaston Tabs<br>DIHYDRO ZESTIMINE | India, 2013 |  |
| 13. | Zifi 200<br>CEFIXIME                | India, 2013 |  |

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