



Why India Failed to Penalize those Responsible for the Circulation of Substandard Medicines and Vaccines while China Succeeded?



Singh BR*

Division of Epidemiology, ICAR-IVRI, India

Submission: May 26, 2017; **Published:** June 19, 2017

***Corresponding author:** Bhoj R Singh, Division of Epidemiology, ICAR-IVRI, India; Email: brs1762@gmail.com

Keywords: World customs organization; Foot and mouth disease; Central drugs laboratory; Not of standard quality; Central drug agency's

Abbreviations: WCO: World Customs Organization; FMD: Foot and Mouth Disease; CDL: Central Drugs Laboratory; NSQ: Not of Standard Quality

Introduction

The fake drug market is estimated at \$200 billion by the World Customs Organization (WCO). The World Health Organization estimates that as many as 30% of all medicines sold in some areas of Asia are fake. Of those surveyed, as many as 67% considered counterfeit medicines were labeled dangerous [1]. Indian pharmaceutical companies suggested that in India's major cities, one in every five strips of medicines sold is a fake leading to an annual revenue loss of 4-5%. It is also estimated that spurious drugs market growth are faster than the real drug market; it has grown from 10% to 20% of the total market.

Recent surveys revealed that Asia is the single largest counterfeit drug producing region. Within Asia, India is the leader followed by Egypt and China. About 75% of counterfeit drugs supplied in the world originate in India, followed by 7% in Egypt and 6% in China [2]. Fake drug and vaccines are responsible for more than million deaths across the globe every year [3]. Indian health ministry estimated that 5% of drugs in India are counterfeit, while 0.3% are spurious. In India 'Bhagirath Palace' Chandni Chowk, New Delhi is said to be the hub for counterfeit and spurious drugs. In Indian Pharma market of 40,000 crore, 20% is of fake drugs.

Drug counterfeiting is booming in India, why?

In India, large pharmaceutical companies supply medicines and vaccines of the highest quality to every country in the world, but why not in India? In a personal interaction CEOs of a few

big companies expressed that quality comes with a cost and cost is a big bar in India, probably due to meager budget for human and still less for animal health. The important reasons behind flourishing of fake medicine business in India are cancerous growth of pharmaceutical industry, poor pharmaceutical regulation and inconsistent regulatory checks on production, high drug prices, value added tax, prescription of drugs without registration, sale of drugs without prescription, lack of public awareness, weak enforcement of legislations and flexibility in the current legal framework (delayed justice and never ending judicial procedures), biased legislation skewed in favor of powerful, communities, sects and many more .

And over all of these, the lame democracy, giving freedom to do all the wrong but not a single right thing, is responsible for all illegalities. Another important fact is meager public expenditure on health by Indian Government, indirectly helping to the counterfeiters and fake drug producers to flourish. The purchasing system in the Government sector to favor L-1 instead of quality is another route through which fake and counterfeited drug producers keep on supplying the medicines even to the Government hospitals. Inconsistent interpretation and enforcement of relevant national legislation like that embodied in the Drug and Cosmetic Act has led to a degree of fragmentation and has been regarded as a root cause of inadequate control and prevention of medicines falsification [4].

Penalization of sub-standard and fake drug producers in India: A remarkable achievement

Recently Foot and Mouth Disease (FMD) vaccine of a renowned company in India failed in quality. The action taken was: A state cancelled its order. A few years ago, vaccines of all the three FMD Vaccine suppliers at that time were found substandard [5]. Action taken was: A few veterinary associations called for a boycott of FMD vaccine (the failed effort) but no action by Government against the producers of substandard vaccines but stern against those found the vaccine substandard.

An anti-rabies vaccine used in government hospitals in Kannur district, Kerala in 2002-3 was found to be sub-standard by Central Drugs Laboratory (CDL), HP but no action ever has been reported either against the producer, supplier or the users, why? In 2013, in India, 8,000 patients died over a five-year period in a remote Himalayan hospital because an antibiotic used to prevent infection after surgery had no active ingredient [6,7]. The action taken: Nobody knows.

In India, 33 drugs supplied to various government hospitals and stores in Arunachal Pradesh were found to be of sub-standard quality during laboratory tests. Madhya Pradesh has also been purchasing sub-standard or spurious drugs worth several million for distribution in government hospitals [8]. What was the action against those involved in all of this?

CDSO in July 2016 showed that six major pharmaceutical companies, including Cipla, Ipca Labs, Alkem Labs, Morepen Labs, Abbott and Sanofi were found manufacturing sub-standard drugs in 2015-16, of the 181 drug alerts during the period. Most of the companies have recalled their affected batches [9]. It is good that companies have recalled the substandard drugs but what was the penalty? Does anybody get penalized? In past one-decade, several firms were reported to supply substandard medicines and vaccines in India. Action taken was: Banned supply in the specific area for short time or of a particular name for a year or two.

Self-acclaimed Gujarat Model for fighting against producers and distributors of sub-standard drugs

It is advocated that Gujarat Model has been a successful one in reducing the growth of fake drug industry in India. In Gujarat, during 2015-16, of the 13,540 drug samples collected, only 448 samples tested not of standard quality (NSQ), while in 2014-15, from the 11,300 samples tested, 516 were found NSQ. In 2013-14, out of 9,317 samples collected, 567 samples were tested NSQ. Now the question is out of >1500 NSQ producers, suppliers, and prescribers how many were punished?

Why India fail in penalizing the wrong doers?

Is it a low level of deterrence? In an effort to increase the level of deterrence in India, the death penalty has been introduced for the manufacture and/or sale of counterfeit medicines that cause grievous harm or death. Alongside this, the minimum prison

term for related crimes has been increased from 5 to 10 years. However, there have been recent criticisms of the Central Drug Agency's performance. In reality, it is hard to find any case where any of producers of counterfeit drugs has ever been penalized.

Even the Indian Parliament has accepted it that we are not handling corruption properly. All nations need to guard against corruption of all types but it appears that India faces particular challenges, including which exist in the pharmaceutical sector regulation [10]. We know who, where and how the market of fake drugs and vaccine is operating in India and its hub is in Delhi, who is stopping the Government from the action? Probably the elements of Government, from top to bottom are involved. Why was Action not taken even in proven cases? Probably every one responsible for taking action has got its share. Is there nobody honest in India? It may not be true but truthful are unorganized, more egoist and less cooperative, that is why they get isolated and their voice get easily silenced in the system.

Why China succeeded in penalizing the wrong doers?

Last year, China penalizes 357 officials over substandard vaccines and 202 suspects arrested over illegal trade of vaccines [11]. In history of Independent India, it will be difficult to find a case of any official who has ever been penalized for clearing the substandard drug or vaccine; rather examples are there when those revealing the name of producers of substandard vaccine in India were penalized [12].

In July 2007, China's top food and health official, Zheng Xiaoyu, was executed on corruption charges in connection of approving untested drugs. He was executed within a few weeks of when a court handed down his death sentence. The swift move was largely seen as both an effort to reassure the international community that China was serious about tackling safety issues and an example of "slaughtering the chicken to warn the monkey" to keep other officials in line [13]. Even then, Yasgenh Huang, a professor at MIT's Sloan Business School told that there are plenty of adequate laws and regulations, the problem is enforcement. The issue is that the regulators are unable to be impartial in the enforcement of the laws. On the other hand, thousands of batches of substandard or standard quality vaccine have been passed by Indian regulatory authorities even without testing or proper testing consistently since last several decades but instead of penalization Government has rewarded almost all those involved in the pious game of cheating India and Indians [14].

References

1. Counterfeit Medicines: an update on estimates (2006) WHO, Geneva, Switzerland.
2. Verma S, Kumar R, Philip PJ (2014) The Business of Counterfeit Drugs in India: A Critical Evaluation. *International Journal of Management and International Business Studies* 4(2): 141-148.
3. Southwick N (2013) Counterfeit Drugs Kill 1 Mn People Annually: Interpol.

4. A Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs (2003) Indian Ministry of Health and Family Welfare (Government of India).
5. Singh BR , Singh AK, Sharma S, Khan R (2014) Testing of FMD Vaccine (intended to be used under FMD-CP of Govt of India) at CCS NIAH, Baghpat (UP) India.
6. Anti-rabies vaccine substandard: KGPA (2003) PTI.
7. Ossola A (2015) The fake drug industry is exploding, and we can't do anything about it.
8. Pharmaletter (2008) Largest Fake Drug Haul in Europe from India. PSI.
9. The Pharma Letter (2016) Indian government moves to tackle substandard drugs.
10. Parliament of India (2012) The Functioning of the Central Drugs Standard Control Organisation (CDSCO).
11. Atanur M (2016) China penalizes 357 officials over substandard vaccines.
12. Sharma DC (2016) How India punishes those who exposes corruption.
13. Hays J (2012) Drug Makers, Vaccines, Fake Drugs and Drug Safety in China.
14. Singh BR (2016) Treachery with India: vaccine testing at ICAR-IVRI.



This work is licensed under Creative Commons Attribution 4.0 License
DOI: [10.19080/GJPPS.2017.02.555599](https://doi.org/10.19080/GJPPS.2017.02.555599)

Your next submission with Juniper Publishers will reach you the below assets

- Quality Editorial service
- Swift Peer Review
- Reprints availability
- E-prints Service
- Manuscript Podcast for convenient understanding
- Global attainment for your research
- Manuscript accessibility in different formats
(Pdf, E-pub, Full Text, Audio)
- Unceasing customer service

Track the below URL for one-step submission

<https://juniperpublishers.com/online-submission.php>