

COUNTERFEITING LIFE-SAVING DRUGS: HOW INDIAN LAW TACKLES THE DILEMMA?****NAMRATA CHAKRABORTY & SOMNATH BANERJEE****INTRODUCTION**

Year - 2010; a Report was published by Rama Lakshmi in the Washington Post specifying the impact of the destructive vice 'Counterfeit' on 12-25% of every Indian Drugs.¹ The Next year 2011 was not an exception also from exhibiting the similar waves as Sri Lanka debarred a flock of drugs made and imported from Indian Pharma Industry at that time. The ground was the predictable heinous business with the same phenomenon – 'Counterfeit'. What is it as a whole? In the form of a literal interpretation, Counterfeit denotes the simple rivalry against Genuinity. But shaping it from a Pharmaceutical Viewpoint risks estimated 1.2 billion lives of Indians, because Counterfeiting with health extends to Counterfeiting with Life in realm. Delving deeper into Indian Scenario, what extracts out is the essence of Constitutionalism and efficacy of fundamental rights intrinsic in such essence. Right to Life being Article 21 of the Constitution of India thus forms the foundation behind the dignified existence of Indian Citizens while recognizing right to health as a branch of its multi-faceted tree. India hence regards its Constitution as the King of all other Indian Kings. But question may pertain - do the Indian Evils abide by such notion?

The wording 'Counterfeit' itself represents an evil face in Contemporary Pharmaceutical Sector which drastically violates the Right to Health of the innocent citizens in the name of business with life-saving medicines. The World Health Organization (W.H.O) rightly explicated the menace as the profit-oriented illicit business of selling unlicensed and fabricated drugs at higher cost under the cover of genuine life-saving medicines. Not only a falsified drug, even a substandard drug which fails to qualify the standards as fixed by the authority (National Medicines Regulatory Authority) also belongs to the regime of "Counterfeited" Drugs.² Measuring its drastic impact, FICCI (Federation of Indian Chambers of Commerce & Industry) discovered enormous loss incurred in the big-shot Indian Companies in lieu of

¹ The alternative (2011), "Pharma secure: Fighting fake drugs in India", available at: <http://thealternative.in/social-business/pharma-secure-fightingfake-drugs-in-india/>

² Counterfeit Drugs In India: A Malady Much Deeper; October 24, 2016 ; <http://www.tapanray.in/counterfeit-drugs-in-india-a-malady-much-deeper/>

taxes estimated around 1000 crores rupees per year. The sole reason is the loss of credibility of those popular entities as the forged medicines are usually sold by misusing the veil of a branded manufacturer in order to deceive a consumer loyal to such brand. Thus Counterfeiting does not only cause massive loss to the instrumentalities of State; such greed of reigning competitive economy subsequently incurs huge losses of innocent lives also. It has already been passed several decades since the malady is wide-spreading towards the entire India and victimizing its gigantic populi in a steadfast way. Today along with the small and local manufacturers, the big Pharma enterprises are discovered to be liable for manufacturing and selling the counterfeited life-threatening drugs instead of saving the lives. But who will measure their liability? Like other nations, India shows its efficacy to combat the pressing hazards through enactments, amendments and their successful implementation. But what is happening today in the Indian Pharma Sector compels us to believe the deficiency of legislative weapons for safeguarding the billions lives from the epidemic threat. Hence, to defeat the spurious and penalize the offenders, an effective antidote should be laid down and subjected to critical analysis which must qualify the test of time and essence rather than the lack of enforceability.

COUNTERFEITING OF DRUGS : HOW IT ESCALATES IN INDIA?

Who does not want to win in competition? But when such winning is achieved in a deceitful way, a big NO must stand as a barrier to appreciate the winner. Subsequently the Competition does not only limit itself to a healthy business strategy; rather it ends with turning towards the illicit trade practices. Such climax somehow converges with the Contemporary Indian Scenario while probing the protagonist terror of Pharmaceutical Industry. Today, the Indian Pharmaceutical Sector globally stands 4th in terms of the volume and rate of production of quality drugs as more than 55% drugs are exported from India to the global regulatory markets. In the financial year 2011-2012, the drugs exported by India amounted to a sum of 82,730 Crores in Indian Currency. But it is worthy to mention herein that higher the competition, more the greed tends to rule the market and the path of greed ultimately constructs where the forgery begins. Hence, the several reports published within the period of 2007 and 2015 (including the aforementioned reports) expressly designates our Economy as one of the largest spurious drugs manufacturer along with having a gigantic marketplace of the counterfeited drugs. The surveys conducted by various agencies dreadfully point out the states like New Delhi, Gujarat, West Bengal,

Uttar Pradesh as the famous epicenters for such speciousness. Besides being the biggest manufacturer and dealer of generic drugs; India has also enlisted as the hub of counterfeited drugs in Global eye. What was once limited to exotic and sensual pills only; has now protracted its scope towards the painkillers, cancer medicines, slimming products and other prescription life-saving drugs also. The *status quo* went into worse when chronic diseases like Diabetes, HIV, and Cancer were spotlighted as the victim of counterfeit plagued by the Indian Pharmaceutical Sector.

In the era of Globalization, while advancing the trade and commerce sector for paving towards a developed nation, the vice like drugs counterfeiting weakens the bone marrow of Indian Economy with an aim to earn raw money by risking public lives, economic development and escaping from the hike of drugs pricing and taxes at large. This is why today amongst the worldwide counterfeited products; drugs gained the top position with a sum of \$200 billion market value. Tragically, 75% drugs sold over the World were found by OECD to be rooted from India and as the time flies, today the figure is tirelessly increasing its range by no stretch of imagination. Like Indian Currency, even the trademarks or logos engraved by the branded Pharma Manufacturers like Wockhardt, Cipla, Aventis, Novartis India, Novo Nordisk India, Pfizer India, Ranbaxy etc. have been preys of this global threat.

Although the Health Ministry attempted to strengthen the drug laws in order to protect IP regime from the hands of destructive infection; but till date the victory of counterfeiting is persistent at its own pace. It is well-evident from a recent survey conducted by ASSOCHAM (Associated Chambers of Commerce and Industry) indicating that the counterfeited drugs may cross the range of \$10 billion by the year 2017 itself.³ Therefore, it is not too hard to envision that the illicit counterfeit tactics including stuffing the low-quality ingredients with the real drugs, selling the expired drugs in licensed brand packages etc. would rule the domestic and international empire of regular drugs such as Betadine, Calcium Injections, Syrups etc. in near future. What will be left as residue are the scattered marks of death toll across the corners of Globe.

³ IIFL MUMBAI, http://www.indiaonline.com/article/news/assocham-5971406133_1.html

A GLIMPSE OF COUNTERFEITING CASES IN PHARMA ZONE

The pace of corruption is at high acceleration in India as the safeguards so laid down fail to qualify the test of time and so as the safeguard-provider does. Corruption flourishes not only in drugs dealers; but in the fringe of societal system itself. Instead of strengthening the penalty clauses, Indian legislature and bureaucrats are busy in stiffening the noose of corruptive trade tricks. Hence, only a few arrests for drugs counterfeiting have been limelighted till date in India, amongst which a glimpse is presented below.

1. The case⁴ came up for hearing in the Washington Court. According to the facts of the case, the charge was instituted in 2002 against 7 people and 5 Companies who used to manufacture and sell Counterfeited Viagra pills over the Internet. The entire process of arrest was subjected to a 17 month's Investigation process under which the Investigating authorities purchased more than 28000 spurious Viagra pills from India and China as the concerned wholesalers used to operate openly in these two nations. The instant case also faced far-reaching impact in India as an Indian Pharma Company named Benzo Chemical Industry was involved herein for the purpose of covering the operators and selling a tablet-punching instrument to manufacture spurious Viagra tablets.
2. September, 2000⁵ - One Indian named Chander P. Marwah and 4 other Uzbek women were arrested for smuggling out 800 kg counterfeited drugs having market value of 2 Million rupees. Such huge quantity of counterfeited drugs was originated and supplied from Unisul Private Ltd., Sonapat as traced out by the Investigators. It was found that Indian Customs were also engaged in smuggling the packaging. Further, the four women came from Uzbek for selling the China Silk in India and this was their 23rd trip to India in past 1.5 years. After tracing out the hub in Sonapat, the Delhi Police along with FDA raided the bases and seized numerous spurious drugs from those bases which were almost to ship.

⁴ Centre for Science and Environment – Health Environment Newsletter, Sept – Oct, 2002
http://www.cseindia.org/html/healthnews/2002sept/oct/lead_story4.htm

⁵ The Tribune, September 10, 2000; <http://www.tribuneindia.com/2000/20000911/nation.htm#5>

3. Another arrest the Delhi Police made in 2003⁶ against Deva Singh in Jahngirpuri, a manufacturing hub of counterfeited drugs. The Police seized spurious drugs consignment having market value of 5 Lakhs Rupees which was smuggling out to Varanasi. Ampoxin- 500mg and Sporidex-500mg were found as counterfeited which were manufactured at Solan (Himachal Pradesh) and Okhla (New Delhi) under the embossed logos of Unichem Laboratories and Trademark of Ranboxy respectively. The information received from the arrestee stands as – the Arrestee was a commission as well as conduit agent under the racket which was operated in Delhi, H.P. and Haryana. Their mode of operation mainly confined to the possessing of false details and counterfeiting medicines under the trademarks of reputed Pharmaceutical manufacturers. The seized medicines were comprised of the chalk powder mainly as assessed from the Chemical Lab Test. Earlier; the arrestee was engaged with another counterfeiting hub at Rajasthan. After the Unit shut down by the Police Raid; the Arrestee again joined in the instant hub at Sonapat as a commission and conduit agent.

Apart from the above arrests, the maxim '*Justice delayed is justice denied*' rightly suits the scenario as approximately 1300 cases of drugs counterfeiting are still in pendency before the Bombay High Court only from 1997 onwards. Hence, measuring the pendency of justice in Indian Judiciary undeniably portrays the tragedy of such malfeasance hike in the periphery of Indian Society.

LEGISLATIVE WEAPONS GOVERNING THE DILEMMA⁷

It would be a mistake to deny the existence of legislative instruments to repair the dilemma. A bunch of tools Indian Legislature provided to uncover the veil of counterfeiters although the efficacy of those tools itself is a jigsaw puzzle. While building a legal framework around the terror, tools like Trademark Act (1999), Drugs and Cosmetics Act (1940), Patents Act 1970, Customs Act 1962, Copyright Act (1957), Consumer Protection Act (1986) etc. form the strong base of the framework to combat against the terror.

⁶ Hindustan Times, March 25,2003;

[http://www.healthlibrary.com/news/March2003/24-29 March 2003 /Spurious.htm](http://www.healthlibrary.com/news/March2003/24-29%20March%202003/Spurious.htm)

⁷ Anti-counterfeiting Committee Report (2011) , 59th Council Meeting, Manila, Philippines, Asian Patent Attorney Association India.

- To protect the trademarks of the branded Pharmaceutical Companies from the gangs of counterfeiters, Indian Legislature effectively laid down several remedies in the form of ‘Trademark Act (1999)’. The provisos in the said Statute not only combat with Infringement, but also cognize counterfeiting as a punishable offence. Hence, along with providing civil remedies for Trademark Infringement, the victims of counterfeiting are entitled to criminal reliefs. Those who counterfeit trademarks of the renowned Pharma Companies, strictly fall under the ambit of Section 102 of the Trademark Act recognizing the offence of Trademark Falsification. Section 103 thus expressly penalizes the offenders with a fine extending upto Rs. 2 Lakhs as well as a term of imprisonment extending upto 3 years. Apart from the criminal reliefs, the Trademark Act (1999) prescribes the procedure of Trademark Registration and its protection in accordance with Section 29 whereas Section 27 maintains the proceedings for both the Registered as well as the Unregistered Trademarks in an action of passing off the trademarks.
- The main intent behind the Drugs and Cosmetics Act (1940) was to cover the wide area of spurious and adulterated drugs and cosmetic products. By this Act, the Government Enforcement Agencies are authorized to seize the adulterated products along with inspection. Also, to impose heavy penalties and stipulate a speedy anti-counterfeiting process, the Government of India has introduced the Drugs and Cosmetics (Amendment) Act further in 2008 which was notified in 2009 via Official Gazette of Central Government. For purpose of conducting speedy trial of offences relating to drugs counterfeiting, special courts are suggested to be constituted under the 2008 Amendment Act and accordingly, 14 States have already constituted such special courts under the Act. Moreover, the Amendment enhanced the term of punishment for manufacturing adulterated or counterfeited drugs to 10 years imprisonment extending upto life imprisonment and fine of 10 Lakhs Rupees or 3 times of the confiscated drugs pricing; whichever is more.
- The Prevention of Food Adulteration Act (1954) although seems to preserve the food products as envisaged by its title, it in realm authorizes the enforcement agencies to confiscate the counterfeited or adulterated goods and the Courts to impose sentence on the offenders along with impounding their license to manufacture goods. Besides, to protect the consumers’ lives from being trapped by

counterfeiters, the Parliament has enforced the Consumer Protection Act (1986) and implemented The Standard of Weight and Measure (Packaged Commodities) Rules (1977) which ensure genuine goods and services and the use of exact packaging process, weight and quantity of goods sold to the consumers respectively with an object to preserve the fundamental rights and justice in our democracy.

- Further, the provisions of Customs Act (1962) prohibit the trade and export-import of counterfeited or adulterated goods which infringe the IP laws without the knowledge of Rights Holder or its representatives. The Statute acts in consonance with the IP Right (Imported Goods) Enforcement Rules of 2007 and empowers the Customs Officials to seize the counterfeited commodities and strengthen the framework through the steps of ARTS (Automated Recordation & Targeting of IP Protection System).

TESTING THE ESSENCE OF WEAPONS

A war demands both weapon and manpower in the first instance. So is the fight against corruption too. Having adequate enactments can hardly minimize the risk of drugs counterfeiting in India unless those legislative weapons are effectively enforced on the wrongdoers in collaboration with the Indian Populi. Along with a strong legal base, the manpower should have such efficacy to take responsibility of wiping away the vices of economy. In a country of 1.2 billion; such manpower can only be gained not by showing the physical strength, rather by spreading the general and legal awareness amongst the masses. But, who will conduct the awareness campaign if the politicians devote themselves in the hands of corruption? Generally, Legislature enacts the law and the executives enforce that law according to the Indian Legal System. But where the Executive Officials have already vested their awareness in securing the menace like Counterfeiting, how would they efficiently enforce the Anti-Counterfeiting laws to protect the fellow citizens in turn?

On the other hand, while assessing the Anti-Counterfeiting laws, the remedy lies in imposing simple fine or convicting the fake manufacturers. But conflicts are rampantly arising as an express penalty clause can never be an effective solution to maintain law and order in the Pharma Industry. Absence of any enforcement mechanism and enhancement of the penalties would strengthen the law only by paper. What necessitates for reinforcing it by essence is subjected to test whether the concerned disease or the drugs are liable for causing death or grievous hurt to Individuals. Else it may result to conviction of reputed manufacturers merely.

The laws enforced till date in the sphere of anti-counterfeiting suffer from lacunae in conceptualizing and differentiating between the terms “Substandard”, “Counterfeited” or “Spurious” in terms of drugs. Since the laws act as a bridge between the public and justice; absence of such phenomenon in the will of legislature heads towards pinpointing the conflict in misinterpretation of General Public. Hence, what hardens the bridge is to heed and stress on clarifying the facts and nomenclatures used in the portrait of Drugs Corruption in accordance with the WHO-prescribed method.

‘Prevention is better than Cure’ – the adage prevails everywhere and Pharma isn’t an exception also. When death toll increases due to consuming the counterfeited drugs by public at large, what is the benefit intrinsic in convicting the counterfeiter at all? Would it be able to decelerate the pace of death toll all on a sudden? Or whether the racket expanded throughout the Globe can be destructed instantly? In both cases, the graph of efficacy tends towards the negative axis leaving the positivity and evidences the reverse adage “Cure cannot be better than Prevention”.

Deficiency can be noticed in the technological advancement also. A negligible number of reputed pharmaceutical companies use advance technology today so as to alleviate their lead over the racket of counterfeiting scenario. Such minority in terms of technological upgradation ultimately encourages the spurious drugs dealers to copy the innovation, trademark as well as barcodes of the generic drugs manufacturers. Present Indian Scenario exhibits an ambiguity while probing the counterfeiting cases through inspection of the records and samples which are kept improperly by the generic drug dealers. Indian Pharma Sector thus lags behind in catching the real culprits in their grip due to absence of any immunity in the strips or codes.

Reaching to the climax of the proficiency test; what essentially matters are the mass of this diversity and their guaranteed Right to Health, Life and Justice at large. Where the Constitution, impliedly and expressly maintains democracy of Fundamental Rights; by any means of implementation the anti-counterfeiting weapons do not deserve to be an instance of conundrum in the first instance.

RECOMMENDATION & CONCLUSION

Socialist – as the word is uttered, the 1.2 billion populi demand a vice-free welfare-nation. Where the Great Constitution of India maintains unity and integrity of the nation and its citizens domestically as well as globally; gangs of dilemmas illegally obstruct the way in the shape of Counterfeiters. Although the legal framework in the Indian Anti-Counterfeiting domain forms a strong base, it still fails to collaborate with the enforcement agencies and deter the trade with counterfeiting drugs in the Global Pharma Market. Where Medical Professionals and Practitioners should play a major role to raise the level of awareness amongst the mass; the reality shows a different scenario due to the absence of coordination between the State Instrumentalities. Subsequently, the Anti-counterfeiting Statutes exhibit a flock of hidden conundrums which encourages the smoothening of counterfeiting process instead of tackling it. Hence, in the economy of corruption, The Recommendations of Mashelkar Committee can only act as fresh Oxygen and overpower such terror. It would be worth to mention that the Counterfeiting is not different from the terrorism from any viewpoint and thus the Counterfeiters should be treated and punished in line with the terrorists as in both cases, the business is dealt with the lives of common men ultimately. According to the Mashelkar Committee Report (2003)⁸, The CDSCO shall mandatorily advance the Drug Standardization procedure including the constitution of Central Drug Administration. The penalties prescribed in the statutes should be enhanced and the life imprisonment or death sentence should be implemented in order to secure the societal fringe from the grips of menace. Marks of ‘bailable’ or ‘non-cognizable’ should be substituted with ‘Nonbailable’ and ‘Cognizable’. Considering the counterfeiting of drugs as a criminal heinous offence, the trial court should be the lowest authority to try the concerned offences where the speedy and fair trial should act as a ‘Rule of Law’ of the Courts. Along with the Judiciary and Executive Officials, the Pharmaceutical Companies

⁸ MidDay, Aug 13, 2003; <http://www.chalomumbai.com/news/city/2003/august/61020.htm>

and NGOs should actively contribute their devotion and effort in sweeping the dust of the economy. In consonance with this, the Reputed Drug Manufacturers should engrave the upgraded technology like smart codes, RFID (Radio Frequency Identification) chips and secured trademarks to prevent the illicit trade and track the individual drug manufacturers. The advanced mechanism and appropriate regulatory process should necessarily be adopted with an aim to overtake the strength of criminals in the race of piercing the supply chain market. Moreover, it is the human lives whose interests at large are regarded as the inherent attribute of the consumerism and the globalization. Hence, the path which starts with a dream of competitive economy must end with effectively realizing it by moral means – this is the real essence of Constitutionalism.