

BILCARE VIEWPOINT

Reducing the Impact of illegal counterfeits in Pharma sector

Secure Supply chain. Secured brand

This white paper focuses on challenges posed by illegal counterfeits which are difficult to be identified just by visual inspection in the market, by nature (lookalikes, pass offs, imitations or spurious products) to the brand owner.

These products are riding on the brand owners products. While they eat directly into the brand owners sales, these also have a potential to erode the brand recognition in the market since the patient community is likely to perceive some of them as the rightful product from the brand owner and associate related ineffectiveness to the brand.

This is a significant challenge for the brand owners. The solution is a combination of systemic controls and process controls that deter the counterfeit with ability to provide authentication of the original product in the market. The combination is bound to create the ecosystem that drives counterfeiters away from the brand owner's products, thus enhancing the brand protection.

Introduction

Indian Pharma sector is currently 4th largest in the Asia Pacific geography, behind Japan, China and South Korea. The \$14.2 billion industry (as per 2008 sales data) is expected to grow at an average CAGR of 14% to more than \$40 Billion by 2013.

India is gradually developing an undesirable reputation for producing sub-standard medicines. India is on Watch list of WHO, US, UK for counterfeits. The Mashelkar Committee, which studied the various aspects of the growing threat from spurious drugs, quoted figures which varied from 0.5% (from state authority figures) to a widely quoted 35%, taken from a report in the *Lancet* in 2001 based on WHO figures.

Counterfeits are products that are deliberately and fraudulently mislabeled with respect to Identity and /or source. It can be apply to both branded and generic products. It may include products with the correct ingredients but fake packaging, with wrong ingredients, without active ingredients or with insufficient active ingredients. Lookalikes and pass-offs are the counterfeits that are very close in looks to the original product and bank on the inability of the customer to note the slight variations.

The industry is highly fragmented, with around 20000 registered manufacturing sites and 250 pharma companies which hold more than 70% of the market; with Top 10 players holding about 17%. Majority of pharma production is with contract manufacturers or loan licensees (typically SMEs) for cost benefits.

The regular distribution channel consists of about 80 to 100 thousand stockists and more than 550 thousand retailers. A typical Drug manufacturer may connect with about 30 CFAs, 500 to 5000 stockists and about 200K Retailers.

The supply chain is very open by nature with very limited control mechanisms available with the brand owner over the activities within the supply chain. Counterfeit manufacturers take advantage of these factors to ride on the brand.

Growth Drivers for Counterfeits in Indian Market

Following factors proliferate counterfeits in the Pharma sector within India:-

1. Large distribution network that paves the way for parallel distribution for counterfeiters
2. Counterfeiters offer as high as two times or more the margin compared with what the legal chain offers
3. There exists no mechanism for an end user to confirm the authenticity of a drug
4. Lack of awareness and illiteracy compounds the problem
5. Inefficiency in the legal system including drug inspectors and police compounded by corrupt practices and lack of coordination among these agencies limit their effectiveness in controlling counterfeits
6. Investments in anti-counterfeit measures, without government support is dampened by the margin maximization pressure on BOs due to the controlled price regime (74 drugs under price control now)
7. Easy availability of supplies to manufacturers compounded with the absence of any monitoring mechanism of 'supply to legal consumption' make counterfeit undetected at the supply side

Necessary solution features

There are lots of packaging innovations that have come to the market in the past decade claiming to solve the counterfeit problem for the Pharma companies. The counterfeiters have proven to be smarter and faster than most of these solutions making investments in these products ineffective. The solution needs to provide different capabilities to the brand owner. Key feature required to deter counterfeits in the market is the ability of to authenticate the product. This ability can support the creation of mature ecosystem that will eventually prevent the counterfeiters

from targeting brand owners products by forming the secure supply chain.

It is important to address the unauthorized activities of legal supply chain partners before taking up the larger challenge of counterfeiters who are look alikes or pass offs. This will need capabilities for the solution to provide the systemic lock at the outsourced manufacturing locations, ability to closely track unauthorized activities and take corrective actions through alerts and reporting mechanisms and ability to plug the recycled expired product from getting into the distribution channel.

While brand owners have the option to build their own auditing teams to remove dependence on the government machinery, a focus on empowering the patient community by providing the ability to authenticate the product on ground will create a customer base that expects and demands original product thus pushing the counterfeits out of the market.

A combination of Bilcare's secure supply chain management solution with the demand side solution that ensures patient compliance has a great potential to addressing the drug counterfeits by building a matured ecosystem that discourages the counterfeiters from focusing on the Brand Owners products thus ensuring further growth in sales for the original product.