

BILCARE VIEWPOINT

Perils of an uncontrolled open-ended supply chain

Secure supply chain. Secured brand

This white paper focuses on some of the unique counterfeiting challenges experienced by the Indian pharma industry due to an open-ended and uncontrolled supply chain.

Brand owners are in need of a solution that can help prevent uncontrolled activities within the designed legal supply chain, thereby creating a secure supply chain. Key features required for such a solution are the ability to first establish the authenticity of the product in the market place and then to provide actionizable pointers towards such occurrences that enable the brand owner to initiate the appropriate corrective or preventative action.

Introduction

The Indian pharma sector is currently the 4th largest in the Asia Pacific geography, behind Japan, China and South Korea. The industry is expected to grow at an average CAGR of 14% to more than \$40 Billion by 2013.⁽¹⁾

The Indian pharma industry is highly fragmented, with around 20000 registered manufacturing sites and 250 pharma companies holding more than 70% of the market and the Top 10 players holding about 17%. The Majority of pharma production is with contract manufacturers or loan licensees for cost benefits.⁽²⁾

Institutional sales constitute about 18% of the pharma sales while the sales through the regular distribution channel are about 82%.⁽¹⁾

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 with limited brand owner control over the activities within the supply chain. This presents multiple challenges to the brand owner.

Challenges

1. **Product overruns at the contract manufacturer (CM):-** The contract manufacturers can typically manufacture 8-10% extra drugs compared to the batch sizes agreed with the brand owner as per contract. This is referred to as the "product overrun" by the contract manufacturer. This is currently possible for the contract manufacturer since there is no systemic way for the brand owner to track the manufacturing activities at the outsourced location. The contract manufacturer gets considerably higher margins by selling this product overrun directly to the distribution channel, compared to what the brand owner

offers as a transfer price. This results in loss of direct sales for the brand owner.

2. **Drug diversions by institutions:-** Institutional sales in an Indian context include sales to government hospitals, the military and private hospitals. Traditionally, the military is mandated to buy the drug stocks through tenders in quantities twice as large as the projected demand for those drugs for the following year. Pharma companies are required to sell the drugs to institutions at discounted prices. The surplus available at the institutions is at times pushed to regular channels by leveraging the price discounts. This results in lost sales for the brand owner's product through the regular distribution channel. This loss is estimated at about 20-30% of the institutional sales.
3. **Drug diversions within distribution channel:-** Pharma companies run geography-focused promotional offers as part of their marketing strategies, estimated at about 5-7% of the sales in the regular distribution channel. The promotional products are routed through the regular distribution channel to the retailers/patients. Within the distribution channel, there is no mechanism for the brand owner to ensure that these promotional products reach the intended parties. The stockists can claim the discounts for routing these products to the intended parties and divert them to other geographies, where the product may be priced higher intentionally by the brand owner. This results in a payout to stockists against false claims, lost sales at higher price in unintended geographies and ineffective promotional strategies.
4. **Recirculation of expired products:-** Ideally, expired drugs are supposed to be routed back to the drug destruction facilities

approved by the brand owner through a reverse supply chain. While the reverse route is defined in principle for the regular distribution channel, no mechanism currently exists to track the return of expired drugs and the actual destruction by the destruction agency. There is a lack of drive from brand owners for funding this activity since they don't view this as a value adding activity, having already booked the sales when the product left the forwarding agent's facilities in the forward supply chain.

The institutional sales even lack a specific returns route, since these are mostly executed as tendered sales.

In this way, an opportunity arises for the counterfeiters to recycle and repackage the expired drugs and push them back into the distribution channel. While this results in lost sales for the original product, as well as a loss of brand value in turn for the brand owner, there is an even more serious consequence for patients who may be administered these drugs, resulting in ineffective or at times fatal medication.

While there are significant efforts being made by the pharma industry to address these counterfeits from illegal sources, very few steps have been taken to address the unauthorized activities of legal supply chain partner. This may partly be because the brand owners do not realize the extent of the potential sales loss and the impact this has on the brand recognition within the supply chain.

The combined effect of all such unauthorized activities could be a loss of anywhere between 15-20% of net sales for the brand owner.

There are lots of packaging innovations that have entered the market in the past decade, claiming to solve the pharma companies' counterfeiting problems. To a certain extent, these solutions will provide the brand owner with track and trace capabilities.

However, the counterfeiters have proven to be smarter and faster than most of these solutions and the majority of packaging innovations frequently lack one key feature for assessing the origin of the product conclusively; the ability to authenticate the product in the market. The effectiveness of the solution is thereby drastically reduced, rendering the brand owner's investment significantly less effective.

Necessary solution features

For preventing product overruns, drug diversions and recycling of expired drugs, an effective solution needs to provide the brand owner with the following capabilities:-

- a. A systemic lock at the outsourced manufacturing locations to control product overrun scenarios, so that all drug production gets recognized as the brand owner's sales.
- b. The ability to closely track unauthorized activities and provide alerts and reports for the brand owners to take corrective and preventive action.
- c. The ability to plug the recycled expired product from getting into the distribution channel.
- d. Engender confidence in the authenticity of the product in the market place.

Bilcare's secure supply chain management solution for pharma scores where other technology solutions fail. Using its unique combination of nonClonable™ secure technology and an accompanying authentication mechanism, it provides a foolproof solution to key business problems, with the core value proposition of assuring product authenticity in the field, ably supported by a four- dimensional track and trace solution.