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Review Article

COUNTERFEIT DRUGS: PROBLEMS AND SOLUTIONS

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ABSTRACT
The pharmaceutical industry is under extraordinary strain. Facing the wrath of consumers because of the cost of products, constantly answering the questions of state and federal legislators looking to control health care costs, and losing value in the marketplace, the industry's hands are more than full. A less discussed but substantial problem impacts all of pharmaceutical industry's other problems, counterfeiting. The World Health Organization estimates that counterfeit drugs make up about 10 percent of the global medicine market, and more than 25 percent in developing countries. With counterfeit drugs increasingly finding their way into global distribution chains and ultimately into patients' mouths, it is essential that pharmaceutical companies have effective enforcement strategies to combat the manufacture and distribution of counterfeit drugs.

KEYWORDS: Counterfiet drugs, brand protection, mass encryption, RFID technology

INTRODUCTION

Counterfeit Drugs are defined as any brand name or generic product sold under a product name without proper authorization. This definition also includes products that have been relabeled or repackaged without authorization; most significant to patient health are counterfeits that contain incorrect drug, no drug, improper dose, and/or contaminants. Risks involved with taking a counterfeit drug include unexpected side effects, allergic reactions, and the worsening of medical condition. Counterfeit drug products pose a potentially serious public health concern and can jeopardize the credibility of the entire industry.

The problem of counterfeit drugs is well recognized by most pharmaceutical companies, government authorities, and the general public in India and abroad. The World Health Organization estimates that counterfeit drugs make up about 10 percent of the global medicine market, and more than 25 percent in developing countries. With counterfeit drugs increasingly finding their way into global distribution chains and ultimately into patients' mouths, it is essential that pharmaceutical companies have effective enforcement strategies to combat the manufacture and distribution of counterfeit drugs.

The present article aims to review the extant information on this problem, discuss a number of critical issues, and explore the implications for the Indian pharmaceutical sector. The second part of this article will focus the potential solutions available to the pharmaceutical industry to combat this problem.

The first step in solving any problem is identifying it. This requires recognizing it for what it is. Counterfeiting, whether drugs or any other product is a crime. Though every civilized jurisdiction in the world recognizes this and has criminal sanctions for such conduct, brand owners are reluctant to treat counterfeiting as a crime. It is time for the pharmaceutical industry to recognize counterfeiting for what it is, an attack on its product[1].

THE PROBLEM AREAS

1) National reputation at stake: India a major producer of counterfeit drugs

The production of counterfeit drugs in India has led to significant negative publicity around the world. A simple internet search yields many articles in the mainstream media about the abundance of counterfeit drug production in India and its harmful effects. Although much attention has been placed on specific examples where a particular counterfeit product has produced harm and even death, the recent trend in newspaper and television reports in the Western media point to the general and pervasive problem of counterfeit drug production in India. A recent report by the European Commission has singled out India in this regard; the 2006 EC report was based on data gathered from actual customs seizures at European borders and stated that "in the medicines sector, India is the number one source, followed by the United Arab Emirates and China". The EC report goes on to state that the flourishing pharmaceutical industry in India along with lax export oversight was primarily responsible for this problem[2].

One of the key problems that counterfeit medicines pose, therefore, is the damaging national reputation that is emerging for India and its pharmaceutical industry. It is for this reason that the DCGI and other Indian authorities have become engaged in this issue with a stated resolve to combat the scourge of counterfeit drug production in India.

2) Brand protection

Besides tarnishing the National image, Counterfeit drugs pose significant financial loss for the brand owner, a fact that has led some major companies to introduce measures that make it more difficult to introduce counterfeit variants of their products. Pharmaceutical companies make substantial investments in R&D, clinical trials, manufacturing, and marketing. And yet, the moment a batch of products leaves the manufacturing facility, it enters a vast supply chain where it is vulnerable to the entry of knock-offs made by companies that did not have to bear the massive cost in introducing that brand. Most pharmaceutical companies are now grappling with this problem and searching for cost-effective solutions. It is therefore vital that supply chain security is implemented at all stages of the product's life-cycle down to the final consumer so that product safety is not lost on the way to the consumer.

There exists a huge lacuna with regards to the quality and security measures under which a medicine is manufactured and the protection of that product once it has left the manufacturing plant. Beyond this point, brands are exposed and extremely vulnerable in the supply chain—a problem that only seems to be growing. The US-based Center for Medicines in the Public Interest predicts that counterfeit drug sales will reach US$75 billion globally by 2010, an increase of more than 90% from 2005. Therefore, it is ultimately in the interest of the pharmaceutical industry to maximize efforts in combating this problem and ensuring that the safe delivery of their products is an integral part of the operational framework. After all, just as counterfeit drugs affect the reputation of the country of origin, they can also tarnish the reputation of the brand owner through negative publicity[3].

3) Export barriers

Another problem that Indian pharmaceutical companies face with growing concern is the impending export barriers that are appearing in Western markets. In light of the increasing incidence of counterfeit medicines, many governments are introducing strict measures to ensure the safety of drugs that come into their markets from abroad. Recently, the State of California has already passed a bill (SB 1476) that requires all drugs sold in that state to have passed through a secure supply chain system and to also have an electronically documented trace of that drug's movement, which is referred to as the electronic pedigree (e-pedigree). In other words, all prescription medicines must be electronically tracked and traced at all times throughout the complete supply chain, according to this law. Most importantly, the stringency of this law is such that even the smallest packaged medicine must adhere to this requirement and actually have an e-pedigree. The burden on pharmaceutical companies is that any anti-counterfeit measures must encompass medicines right down to the item level. In the heels of the California law, there are now 13 additional states in the USA that have introduced similar laws[3].

A similar level of alarm has been voiced by the European Federation of Pharmaceutical Industries and Associations (EFPIA). Thus, stringent laws for the importation of drugs from abroad into the

European Union also appear to be imminent. The question that arises is, what is the jeopardy for Indian pharmaceutical companies? Put simply, those companies that currently export medicines to the U.S. and E.U. markets must begin the process of securing their supply chain and implementing anti-counterfeit measures. If such measures are not in place, then their drugs will not be sold, for example, in California as of January 1, 2009 because importers, wholesalers, and retailers will require an e-pedigree to be produced by the Indian exporter. With the rest of the U.S. and E.U. in tow, the jeopardy is that Indian companies that currently export to those markets, or who wish to do so in the future, will face entry barriers until they are able to meet the legal requirements for drug importation. In addition to the immediate market loss, the vacuum created by such barriers will be filled by other vendors who have implemented e-pedigree systems in their supply chain[4].

4) Patient protection

The best-case scenario for a counterfeit drug is that it does not produce the desired therapeutic effect. The worst-case scenario is that it harms or kills the consumer. There is no dearth of examples in this regard from both India and abroad. Consumer groups have strongly advocated the position that it is ultimately the responsibility of the pharmaceutical company to protect their products and take all necessary measures for both clinicians and consumers to identify a bonafide drug. This point of view has resonated through government agencies that are empowered to protect the general public. Although there are no guarantees that a particular drug will not be faked and sold in the open marketplace, there certainly is a case to be made that pharmaceutical companies must make genuine efforts to protect their products.

Consumer protection also requires taking measures against manufacturing problems that may occur within the parent company. For example, ineffective recall measures can often be propagated through a complex supply chain such that a less than total recall leaves a segment of the consumer base exposed to a problematic situation. Although these are rare in these times of high manufacturing standards, it is safer to be prudent and ensure that the supply chain is capable of bi-directional information flow—i.e., real-time knowledge of the flow of goods from the plant to the pharmacy as well as the reverse.

THE SOLUTION

Counterfeiting of medicines not only lowers the pharmaceutical companies' revenues but also poses serious health hazards It is important to distinguish those measures that protect only against the problem of counterfeiting, those that provide the pharmaceutical company with supply chain tracking, and those that are effective in both regards. We'll focus on the possible solutions to the myriad of problems related to counterfeit drugs in this section.

Effective Packaging

Several Indian pharmaceutical companies have implemented changes in their packaging formats as a way of reducing the impact of counterfeit activity. Among the more proactive options that have been employed are those based on holographic technologies, which provide a simplified means for consumers to deduce the authenticity of a drug. The reasoning is that a blister pack or vial that contains a hologram will be seen to be a genuine product that is resistive to tampering. Other more technologically sophisticated measures include nano tagging or chemical/physical forensic measures. These are far more expensive and have not yet been used by the pharmaceutical industry in an appreciable extent. These approaches offer an advantage as they can be applied at the item level, such as a blister pack. The major problem, however, is that they are generally costly and not effective over the long term. For example, holograms can cost as much as 10–25 paisa, depending upon their level of sophistication. This can add significantly to the MRP of low-end medicines that are the staple of the indigenous pharmaceutical market. Another problem is that the holograms themselves can also be eventually duplicated by the counterfeiters, making the initial investment by the brand owner ineffective when such knock-offs enter the marketplace. And finally, hologram technology does not provide the brand owner with an implementable protocol for supply chain management, track-and-trace ability (e-pedigree), or with the intelligence that is required in the event that counterfeiting occurs. For example, an expertly produced counterfeit medicine with a hologram cannot be distinguished from the genuine product, nor can the

brand owner trace the origin of the fake products. Given that pharmaceutical companies themselves can face such problems with these technologies, the ability of the consumer to distinguish authentic products becomes even more tenuous[6].

Radio-frequency identification (RFID)

There has been a major effort by several RFID companies to promote this technology as the magic potion to the pharmaceutical industry. The technology is based on an electronic chip that emits radio frequency waves encoding a specific ID or code. This information is then captured by a specialized chip reader as the products proceed through the supply chain. The major advantage of RFID technology is that no line of sight is required. The chip can be embedded in cartons or pallets in a hidden manner that resists tampering. RFID vendors have made major marketing efforts over the past few years to promote this technology and develop back-end software that empowers the brand owner with supply chain management. However, the major problems with RFID technology are cost, readability, and lack of item-level protection. The cost of RFID chips remains very high and actually is prohibitive for many uses. Cost estimates vary in India but each chip is typically in the range of 5 to 15 rupees. Although this is a manageable cost if the chips are only applied to product batches (e.g., cartons or pallets), the price becomes simply unacceptable at the item level. For example, it is inconceivable that a single blister pack or vial that costs mere rupees can be saddled with a further overhead for the RFID chip. The readability problem has a technical origin and constrains the use of this technology due to high error rates. Although estimates vary from study to study, error rates of 2.5% and above have been reported. This is simply not acceptable in any large-scale operation. The problem with error rates comes down to physics. Radio waves are easily deflected or impeded by metals and liquids. It is therefore difficult to predict how radio signals will be bounced around inside a pallet or carton of goods. Several major pharmaceutical and FMCG companies have evaluated RFID technology and concluded that it was still immature for their supply chain operation. It has been suggested that this technology is still 5-10 years away from full industrial implementation. The final impediment to use of RFID is that it is not yet possible to implement it at the item level, for two reasons. The first is the cost of each electronic tag which, as discussed above, would make the MRP of most medicines prohibitively expensive and place them outside the boundaries of established price ceilings, both government and market imposed. But perhaps the greatest impediment to item-level tagging is that the consumer does not carry RFID readers, which are electronic devices that decode the radio signal. As such, RFID simply cannot be implemented at the item level and thereby fails to include the consumer in the authentication process[5,6].

Mass encryption technology

The third category of solutions is the software-based mass encryption technology. Recent advances in computing machinery along with sophisticated algorithms for data encryption have propelled this field to the point where it is now commercially available to the pharmaceutical industry as a highly-effective tool for combating counterfeit activity. Every product is given a unique digital identity that is generated by a computer based encryption engine. The same software is able to decrypt the digital code. The codes themselves should not be confused with serial numbers, which are predictable sequences and require a database. Digital encryption requires no database and is therefore much more secure. In short, every product from the item to the pallet level can be given its own unique code. The encrypted code itself is usually a 16-digit alphanumeric code that can be displayed in scripted format and by way of a linear or 2-D Data Matrix barcode. 2-D barcodes, which are now becoming the industry standard, are printed on packaging during manufacture and therefore provide each medicine with the identity before it enters the supply chain. Significant quantities of encrypted information can be stored in this way to support a complex supply chain operation and permit authentication and tracing of individual medicines. The European Federation of Pharmaceutical Industries and Associations (EFPIA) has announced “its support for 2D Data Matrix Bar Coding, instead of the less reliable and more expensive RFID”[7].

In addition to the encryption and decryption of the codes, the software that supports this technology allows brand owners to fully manage their supply chain, i.e., track-and-trace. Thus, the technology is fully compliant with regulatory requirements being imposed by the U.S. and E.U. so that the needed e-pedigree is generated to conform to the new laws. Pharmaceutical companies are

empowered to track their shipments from the factory through all intermediate nodes right down to the retail level, in much the same way that courier companies track their shipments as they wind through the shipping chain. An additional advantage of such a powerful supply chain management tool is that pharmaceutical companies are better able to manage any recalls, should they be necessary. A major advantage that mass encryption enjoys over all other currently available technologies is that it empowers the consumer to authenticate a drug. Given that the codes can be printed on blister packs and vials in script form, the consumer can simply verify the authenticity of the drug by entering the code into an internet site or via SMS. The widespread use of mobile phones in India makes it possible to actually authenticate a product at the point of sale. Genuine drugs will pass authentication and the consumer will be sent a message to this effect. Counterfeit drugs will either contain no code or have an invalid code, which will not pass the authentication process. It is simply impossible for a counterfeiter to make up arbitrary codes because the combinatorial possibilities are astronomically large for a 16-digit alphanumeric format. Furthermore, the brand owner may choose to only allow a single authentication of any given code for maximum security. In this way, if a counterfeiter manufactures multiple fake products containing a single valid code, further authentications of that code will fail. The brand owner will have intelligence on where those failed authentications originated and can take measures to track down the source of the counterfeit drug. The recent decision by the Norwegian company Kezzler AS, a provider of mass encryption technology, to enter into India highlights both the market potential as well as the need for a cost effective solution to combating counterfeit drugs in India. The Kezzler technology has been widely hailed for its excellent features, leading the Maharashtra State FDA to recently adopt this technology for reducing fraudulent activity on their documents (e.g., permits, licenses, certificates, etc.). Although there are many notable features that set this technology apart from RFID and passive technologies, the two most appealing qualities that have attracted pharmaceutical companies are the scalability and cost of mass encryption. The codes can be generated at very high-speed, leading to efficient encoding of literally billions of medicines right down to the item level (blister pack, vial, etc.). Furthermore, because the technology is software based, it is extremely cost effective. For example, the cost of protecting all drugs in a high-volume setting is less than five paisa per code and can actually be reduced to even mere fractions of a paisa for ultra-high volumes. The features of mass encryption that are now getting substantial attention can be summarized to include its extremely low cost, supreme scalability, conformity to existing laws, superb track-and trace capability, and supply chain management that is bi-directional. Most importantly, mass encryption is a tool that empowers the end-user to verify the authenticity of a product. This last point can serve as a highly-effective marketing tool for pharmaceutical companies that implement technologies in which consumers are given the ability to undertake their own diligence. In doing so, consumers are not only protecting their own purchase but are actually helping the brand owner by serving as their detectives of counterfeit products in the marketplace[8].

CONCLUSION

In this article, we have highlighted some of the current problems that need to be addressed and provided an overview of the solutions that are readily at hand. Ultimately, the single most important mechanism for detecting a fake product is quite obvious but has been largely overlooked: you have to check it! Until recently the consumer had little or no realistic way of determining the authenticity of a drug. The recent arrival of mass encryption technology offers the pharmaceutical industry with a highly effective and low-cost solution for combating counterfeit drugs, ensuring a secure supply chain, and encompassing the consumer in the authentication process.

India now has a booming economy and an extremely bright future as a global player in many industries including pharmaceuticals. To propel the impression and global perception of India as a highly reputable supplier of medicines, the Indian pharmaceutical industry must take measures to combat the scourge of counterfeit medicines and take the lead in ensuring the safety of its supply chain. The efforts of Indian pharmaceutical companies in this regard will be rewarding to both key stakeholders—the brand owner and the consumer. Given the image that has been portrayed abroad of India as a major supplier of

counterfeit drugs, a genuine effort to combat this problem would likely be viewed as a highly welcome and needed measure.

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