

Electronic solutions for combating counterfeit drugs

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Abstract

Pharmaceutical crime, often surfacing in the form of spurious, refilling, relabeling, imitation, and counterfeiting of drugs[1] poses a grave danger to public health. These crimes undermine the health care system besides jeopardizing the lives of sick and frail. As per US Food and Drug Administration, “counterfeit medicine is fake medicine. It may be contaminated or contain the wrong or no active ingredient. They could have the right active ingredient but at the wrong dose.”

Starting from manufacturing to distribution, criminal activities are evident all along the system, of counterfeit medicines primarily driven by financial gain. The recent trends[2] involve:

- Increased use of internet
- Prevalence of erectile-dysfunction medication
- Prevalence of doping substances
- Illicit (opioid-based analgesic) medicines and narcotics
- Tenuous ties to terrorism
- Increased trafficking of tramadol.

Besides, the prevalence of some licensed manufacturers producing unlicensed drugs, perforations in the distribution network is the important factor in the counterfeiting of drugs. Considering the distribution network, wholesalers (both primary and secondary) play a major role in drug distribution. Manufacturers sell most of their drugs to wholesalers, who then resell them either directly to retailers or a secondary wholesaler. Secondary wholesalers usually base their business on a rapid turnover of discounted drugs. Secondary wholesalers buy discounted drugs from manufacturers who are selling these drugs for a short time at a discounted price, perhaps to meet sales goals or to reduce inventory overstock. Who then resell them to the wholesalers for a margin but still less than what the manufacturer is offering at that moment.[3] This is where the scope for the introduction of counterfeit drugs into the system increases.

Available Technologies

At present, many systems are being used by manufacturers to fight the problem of drug counterfeiting. They include using blister packaging, using taggants, barcodes, two-dimensional encryption, holograms, etc. Besides, many countries, have mandated the use of track and trace systems to plug the gaps in the distribution systems such as radio frequency identification (RFID), e-pedigree.[4]

However, holograms and bar codes are being easily duplicated making them ineffective.[5] Lack of a common standard is restricting the growth of track and trace solutions, besides there are concerns regarding security as they contain sensitive information.[6]

The main impediment for track and trace solutions is that with the different manufacturers adopting different systems, wholesalers and resellers have to maintain many types of solutions across their systems. The resellers are not interested in having several types of solutions across their facilities.[5] Furthermore, pharmaceutical companies are reluctant to adopt RFID solutions because they can be replicated, also due to the concern that the imposition or introduction of RFID tags has a negative impact on slowing down the production processes. Another impediment being deployment costs for RFID solutions being still relatively high.

Some countries have tried m-Pedigree for authentication of drug that a consumer buys by dialing a code on their mobile and message received back through short message service (SMS) authenticating the product.[7] However, this also has the problem of not having a common standard, with users some mobile service providers not providing interoperability across the spectrum.

The Way Forward

Since counterfeiting is a serious national problem with international ramifications and jeopardizes the health care system,[8] the national governments need to take this problem in its stride. Since the government is spending a lot on the health care, the governments cannot leave the problem of counterfeiting to the individual manufacturers to combat.

A comprehensive solution is needed to combat the problem combining the manufacturers, wholesalers and resellers. The proposed solution should be able to support multi-factor authentication. It should also support multiple protocols (unstructured supplementary service data, SMS, hypertext transfer protocol secure over global system for mobiles [GSM], and general packet radio services) and devices such as personal computers, mobiles, point of sale terminals, besides working with assisted and self-service applications. In India, where the government has a unique biometric-based identification system called “Aadhar”, a similar system can be extended to include the drug distribution system right from the manufacturer to the final consumer, providing biometric-based authentication at every step. A road map to a comprehensive electronic solution using the GSM/code division multiple access technology and internet is proposed here which is shown in [Figure 1](#) which will be able to remove the gaps in the supply chain and a bio-metric based solution at each step the drug changes hand will pinpoint the source of crime, if any.

Conclusions

Counterfeiting and related pharmaceutical crimes are on the rise and have the potential of eroding the public confidence on the health care system. At present, the 40 billion dollar global counterfeit drug trafficking continues to be fought by central and state regulators, pharmaceutical companies, wholesalers/distributors, and pharmacies.

As competition from lower cost products is squeezing profits and the internet is undermining the price differentiation across markets, many manufacturers are unable to spend large amounts on R and D which is the lifeline of the pharmaceutical sector. It is, therefore, imperative that governments should consider as a national problem and factor in this problem in their health care policies. With India being touted as a major source of counterfeit drugs, it's time that the government adopt a zero-tolerance policy and implement a comprehensive solution taking advantage of infrastructure created for unique identification system by suitably supplementing the system.

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Conflicts of interest

There are no conflicts of interest.

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Figures and Tables

Figure 1

