Chapter 82
Anti-Counterfeit Technologies for Spurious Drugs in India

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ABSTRACT

The problem of counterfeit drugs in India has led to significant negative publicity around the world. In this paper, the author discusses how mobile/radio based and other technologies are not only helping educate people on how to check counterfeit medicines and supply chain management, but also promoting disease surveillance and spurious drugs data collection.

INTRODUCTION

India is also looking at future growth as a leader in contract manufacturing of brand-name prescription drugs and host for clinical trials which cost about one-tenth of a clinical trial conducted in the United Sates (according to a Ministry of Commerce and Industry strategy report). The emergence of India in this sector (Pharma) reflects the developing industrial capacity of the nation and highlights the reality that counterfeiting is carried out on an industrial scale in all sectors where a potential profit is perceived (Figure 1). Stressing on the same, the EC report on counterfeit products, based on the figures given by the customs departments of all EU member states," India is the number one source in counterfeit medicines, followed by the United Arab Emirates and China (Singh & Prasad, 2007).

Together, these three sources are responsible for more than 80% of all counterfeit medicines (Singh & Prasad, 2007). In the year 2006, concerned over European Commission's (EC) allegations about large scale supply of 'counterfeit' Indian drugs to the region, India had sought clarifications from the EC (Singh & Prasad, 2007)

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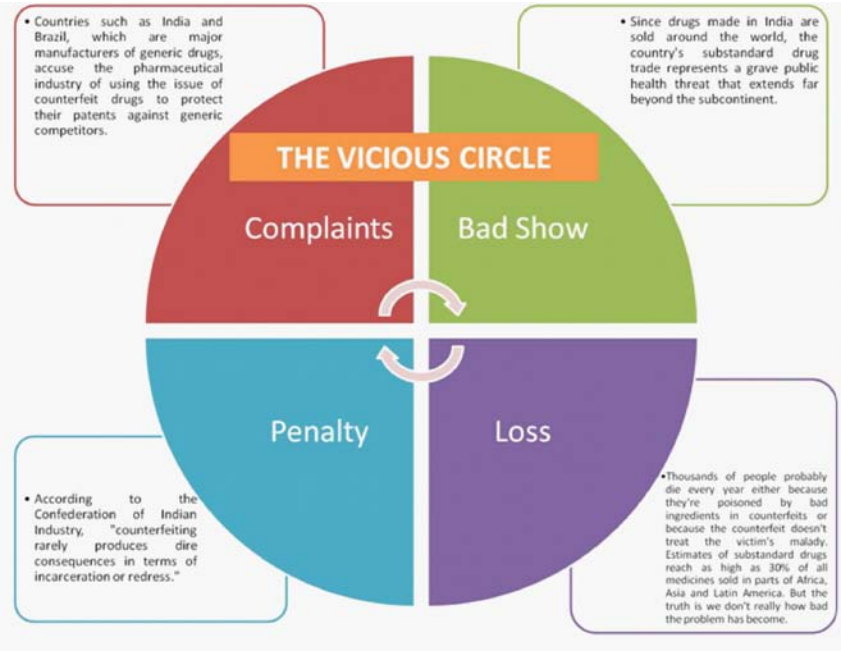
Figure 1. Counterfeit medicine: The vicious circle



on its claim and on its definition of counterfeit drugs. Terming the report as a "non-tariff barrier" (Singh & Prasad, 2007), the Indian pharmaceutical industry said such barriers will harm its global expansion. India is the fourth largest producer of pharmaceuticals by volume. According to latest reports, nearly half of its revenue is coming from exports, mainly from the EU and the US (Singh & Prasad, 2007). To this effect, Directorate General of Foreign Trade (a division of India's Ministry of Commerce and Industry) has made bar coding mandatory on all medicine packs meant for exports recently. This is going to come into effect from July 1, 2011, to trace and track the medicines to its source of origin (Stone, 2011). One of the few programs that aim to acquire accurate statistics of drug counterfeiting, at least in developing nations, is a Bill & Melinda Gates Foundation-funded project called the ACT consortium, which is currently tracking the malaria drug counterfeiting problem across the African continent.

Counterfeit Medicines Classification (Sheth, Siva Prasada Reddy, Narayana, Regal, Kaushal, & Sen, 2007)

1. Products that do not contain any of the specified active ingredients despite such declarations on their labels.
2. Products that contain active ingredients other than specified on their labels.
3. Products that contain the correct strength of the specified active ingredients but whose source is different to the one declared.
4. Products which contain the specified active ingredients but in strengths different to those declared; they may also contain different or different quantities of impurities.

Anti-Counterfeit Technology/ Applications (WHO & IMPACT, 2008)

Anti-counterfeit technologies can be broadly classified as follows (Figure 2):