

**Curbing Counterfeit Drug Production
in India**



By

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CURBING COUNTERFEIT DRUG PRODUCTION IN INDIA

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Abstract

This paper presents policy recommendations on curbing counterfeit drug production in the Indian domestic market. Interviews, surveys, or focus groups were conducted with the following stakeholders in Delhi: consumers, doctors, NGOs, medicine authentication service providers, medicine wholesalers, and medicine retailers. This research along with the existing literature revealed a high degree of variability in the level of counterfeiting across drugs and regions in India, low levels of consumer awareness of counterfeit medicines, and low barriers of entry into counterfeit production. Based on these findings the following recommendations are made: government mandate use of SMS authentication technology on certain drugs, the National Pharmaceutical Pricing Authority reduce price controls, the Central Drugs Standard Control Organization (CDSCO) implement more targeted and effective consumer awareness campaigns, and CDSCO regulate the sale of medicine manufacturing equipment. These findings are only tentative and further research in rural areas with greater sample sizes will be required in the future.

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1.0. Introduction

The pharmaceutical industry in India was among the five largest in the world (by volume) in 2012, with 64% of the companies operating in India servicing the domestic market (Dun and Bradstreet, 2012; India Brand Equity Foundation, 2013). The industry is plagued with counterfeit drugs¹; some studies have estimated the level of counterfeiting in the domestic Indian market as high as 15% (Bate, Jin, & Mathur, 2011; Chaudhry & Stumpf, 2013). Consumption of counterfeit medicines may lead to adverse health effects. These may include increased resistance to medicines, illness, and sometimes even death (Bate, Jin, & Mathur, 2011; Brhlikova, et al., 2011; Chaudhry & Stumpf, 2013). The greatest impetus for action in addressing this issue is the adverse health effects on the consumer. However, there are also secondary effects caused by the prevalence of counterfeit medicine which are of great concern including the lower productivity of the workforce which may result in lower economic growth (if counterfeiting is widespread), and secondly, increased public health care costs (Bate, Jin, & Mathur, 2011; Brhlikova, et al., 2011; Chaudhry & Stumpf, 2013). This paper presents policy recommendations on curbing counterfeit drug production in the Indian domestic market.

According to the Central Drugs Standard Control Organization (CDSCO) counterfeit medicines can be categorized into three types: drugs with minor defects, spurious and adulterated drugs, and grossly sub-standard drugs (CDSCO, 2008). Spurious and adulterated drugs are misrepresented to resemble the product of another company; these drugs are also sometime described as “misbranded drugs.” They may or may not have the active ingredient; hence they actually *may* be beneficial to the consumer. Grossly sub-standard drugs do not perform the function they claim to, and may have an opposite and undesirable effect. These drugs would have a missing active ingredient up to a certain percentage threshold which would vary depending on the specific type of medicine (vaccine, tablet, etc.). This paper is concerned with the potentially most harmful drugs: spurious and adulterated drugs that lack an active ingredient, and grossly sub-standard drugs.

Previous studies of counterfeit medicines in India have focused on the prevalence of these medicines (Bate, Jin, & Mathur, 2011; CDSCO, 2009). There have also been studies that explored solutions to counterfeit production, but they have had a global focus, or they have focused on one specific solution to a problem that requires a combination of initiatives (Brhlikova, et al., 2011; Chaudhry & Stumpf, 2013; Sproxil, 2012; Stevens, 2013). This study focuses specifically on the solutions to the medicine counterfeiting issue in India and investigates solutions to this issue by speaking to the sometimes, neglected stakeholders.

Interviews, surveys, or focus groups were conducted with the following stakeholders: consumers, NGOs, SMS medicine authentication service providers, pharmacists, medicine distributors, and

¹ ‘Medicines’ and ‘drugs’ are used interchangeably in this paper.

doctors. This research along with the existing literature revealed a high degree of variability in the level of counterfeiting across drugs and regions in India, low levels of consumer awareness of counterfeit medicines, and low barriers to entry to medicine counterfeiting. Based on these findings the following recommendations are made: government mandate use of SMS authentication technology on certain drugs, the National Pharmaceutical Pricing Authority (NPPA) reduce price controls, the CDSCO implement more targeted and effective consumer awareness campaigns, and CDSCO regulate sale of medicine manufacturing equipment. Some of these recommendations have been made before or are currently in place, but this paper suggests what modifications they require and how specific elements of these initiatives should be implemented.

However, these findings are only tentative. The samples in this study were restricted to urban areas and research must be done in rural areas to understand if the distribution systems and consumer buying habits differ. I was also unable to speak to CDSCO and drug manufacturers. It is important to speak to manufacturers and understand what they believe the best solutions to the issue area. The CDSCO has a limited amount of publicly available information on their current initiatives and past findings; therefore it may be insightful to interview them.

The paper is organized into the following sections. Section 2 reviews the relevant literature. Then Section 3 describes the research methodology. Section 4 presents the findings and recommendations. Finally, Section 5 concludes and Section 6 discusses possible extensions for future research.

2.0. Literature Review

2.1. Counterfeiting in India

Counterfeiting in India is reported to be less sophisticated than in China, the other large source of counterfeit medicines (Wertheimer & Norris, 2009). In India the counterfeiters are comprised of “unlicensed manufacturers who operate out of small cottage factories, licensed manufacturers who secretly make fake drugs alongside their legitimate products and importers who bring in drugs from China and then fraudulently repackage them” (Chaudhry & Stumpf, 2013, p.4). The small cottage operations can also be described as “fly by night” operations where the counterfeiter can shut down and move production immediately if tipped off about a raid (Jain, 2013). These operations are more likely to exist in areas where there are lower levels of law enforcement and/or higher levels of corruption (Jain, 2013; Misra, 2013).

There are no precise estimates available on the magnitude of drug counterfeiting in India. A few studies are discussed below to illustrate the great range in the estimates. The following studies are based on medicines samples for sale in the domestic market. Bate, Jin, and Mathur (2011) took samples from Calcutta, Delhi, and Chennai from 2008 to 2010. They found that 14% of the

drugs failed at least one of the following tests: visual inspection, the minilab test², or the spectrometry test³. In addition to India, samples were taken from 16 other countries in their study. In this aggregate sample, 3% of the drugs failed the visual appearance test, 11% failed the minilab test, and 15% failed the spectrometry test. This means, that at least for this entire sample, a significant number of medicines were lacking the active ingredient, they were either spurious and adulterated drugs, or grossly sub-standard drugs. A larger nationwide study conducted by the CDSCO in 2008 found only .046% drugs were counterfeit in a sample of 24,780 (CDSCO, 2009). Other experts in the field have pegged the state estimates of counterfeiting at 5% to 10%, while manufacturing companies have reported counterfeiting of 20% to 25% in their specific brands (Jain, 2013; Misra, 2013). There are also statistics on the level of counterfeiting in Indian produced drugs for export. Some studies have reported that up to 35% of counterfeit medicine sales worldwide are from drugs manufactured in India (Wertheimer & Norris, 2009). The United States had reported India as one of the top three exporters of counterfeit medicines in 2011 (Brhlikova, et al., 2011; Chaudhry & Stumpf, 2013). Evidently, it is difficult to understand what percentage of production is or has been counterfeit in the past. Conflicts of interest in the reporting of these numbers may make this issue even more severe (Brhlikova, et al., 2011). The assumption made in this paper is that the level and type of counterfeiting is significant enough to warrant immediate government and public attention.

2.2. Solutions to Counterfeiting

According to the World Health Organization (WHO), the fundamental first step towards fighting counterfeit drug production is the establishment of a drug regulatory body (WHO, 2013). Other recommendations by WHO and other initiatives undertaken by countries have included: increased random inspection of drugs, consumer awareness campaigns, use of more sophisticated technology for inspection, increased regulation of the pharmaceutical supply chain, and increased punishments for counterfeiters (Chaudhry & Stumpf, 2013; Wadman, 2008). These initiatives are usually led by the government through the drug regulatory body of a country (Chaudhry & Stumpf, 2013; Wadman, 2008; World Health Professions Alliance, 2011). Inspection of drugs has been an easier task for net medicine importers relative to exporting nations like India. Countries importing the drug are able to conduct inspection at the port of entry, and they have been able to restrict entry of medicines to a few manufacturers (Wertheimer & Norris, 2009). Some countries, in collaboration with the government and manufacturers in the exporting nation, have been able to do random checking in the source country before allowing the entry of medicines from that country or a specific manufacturer (Wertheimer & Norris, 2009).

India had taken its first steps towards tackling this issue with the establishment of its drug regulatory in 2008, the CDSCO. It has a number of goals that are aligned with the solutions discussed above including: increased capacity (number of employees and equipment) of CDSCO

² This includes a disintegration test for basic solubility and semi-quantitative thin layer chromatography (TLC) for presence of and relative concentration of active ingredients (Bate et al, 2011 p. 4)

³ "This provides a spectra of the entire treatment, including active ingredients, binding agents, dyes and other "excipients" (Bate, 2011, p. 4).

to perform its duties, large scale surveys of counterfeit medicines, greater checks on imports, and consumer awareness campaigns initiatives (CDSCO, 2013). Many of these initiatives are ongoing, and some implementation timelines extend to 2020. Therefore, it is difficult to measure the success of the CDSCO in these areas thus far. More recently, in 2008, India had increased its penalties for counterfeiters. Convicted counterfeiters are now fined a minimum of USD \$22, 550 or three times the value of drugs confiscated, and the minimum jail sentence for counterfeiting is now ten years (Bate, Jin, & Mathur, 2011). Future studies on the prevalence of counterfeit medicines may be an indicator of the CDSCO's success.

In addition to these government initiatives there have been some notable private sector solutions. Counterfeiting is of importance to manufacturers as counterfeit medicines reduce their market share. To counter this issue they have introduced innovative technologies into the market. One method implemented by manufacturers in the past has been the labeling of drugs with high-tech holograms. Unfortunately, this method has failed in many regions as the counterfeiters have been able to replicate these holograms (Stevens, 2013). Another more promising technology that manufacturers have employed is SMS verification of codes on medicines that allow the consumer to authenticate the medicines they buy (Sproxiil, 2012; Stevens, 2013). This has allowed for the tracking of medicines throughout the supply chain, and has empowered consumers by allowing them to verify the genuineness of their medicines. This solution has been implemented in many countries including Nigeria, Ghana, and the United States (Sproxiil, 2012).

In Section 4, I will identify how these approaches can be applied in India. The recommendations are driven by interviews and surveys conducted with stakeholders, and secondary research. The next section describes the research methodology employed.

3.0. Research Methodology

This section will discuss the primary research methodology for this study. Unfortunately, literature on the nature and extent of counterfeiting in India is sparse and inconclusive. There is a lack of information on: how the medicine supply chain operates in India, levels of counterfeiting, levels of consumer awareness of counterfeit medicines, and on consumer medicine purchasing behaviour. Therefore, to better understand the counterfeit drug issue, an attempt was made to understand the challenges and constraints that each stakeholder faces, and the strategies they utilize in regards to this issue. These stakeholders included: consumers, drug manufacturers, NGOs, CDSCO, and those in the distribution system including pharmacists, doctors, wholesalers, and authentication service providers. This research was conducted in June, 2013. All primary research was done in Delhi.

There were 97 surveys conducted in South Delhi and a focus group session was completed. The surveys ascertained information about the purchasing habits of consumers and their awareness of counterfeit medicines; the majority of the questions were close-ended. Some of the characteristics of the sample in the survey are provided in Figures 1 to 4 below. As shown in

Figure 1, one major limitations of the survey was the low female participation. This was an issue because most surveys were done during working hours in the market. Females are less likely to work in open spaces. Secondly, as a male researcher, women may have been reluctant to speak to me, the sole researcher for this project. The different education, age, and income levels, however, are equally represented in the sample, although far from perfect, as can be seen from Figure 2 to 4.

Figure 1: Sample by Sex

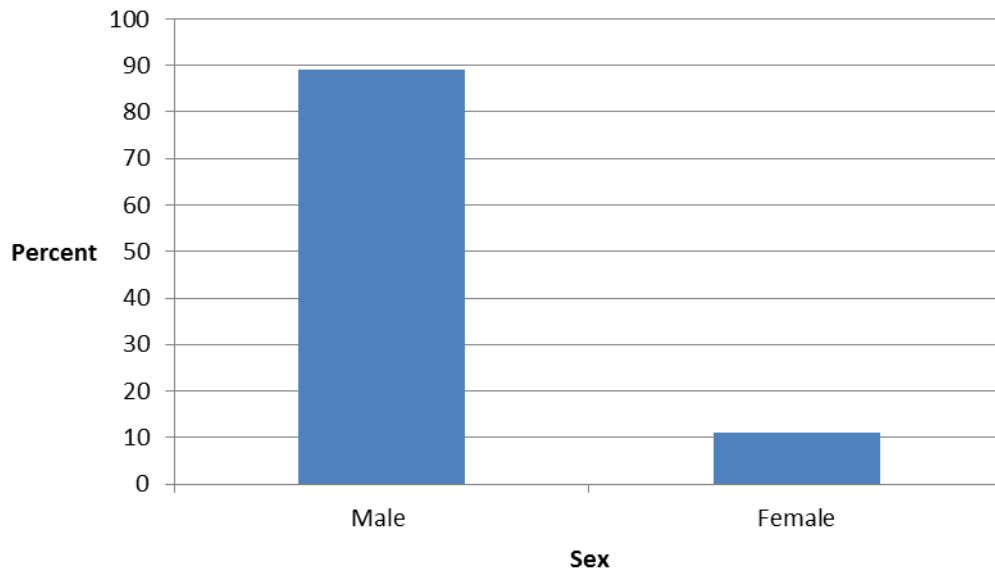


Figure 2: Sample by Income Level

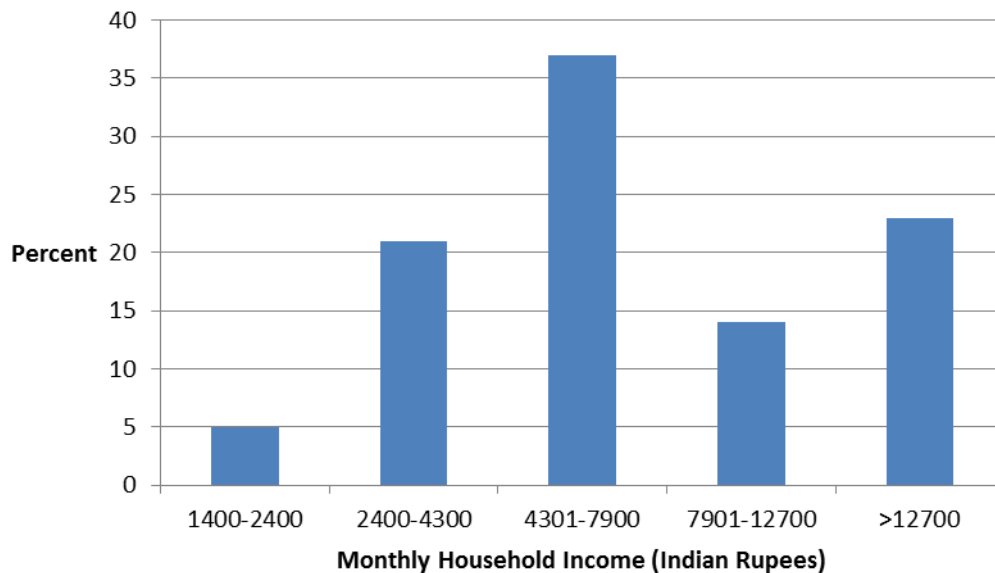


Figure 3: Sample by Education Level

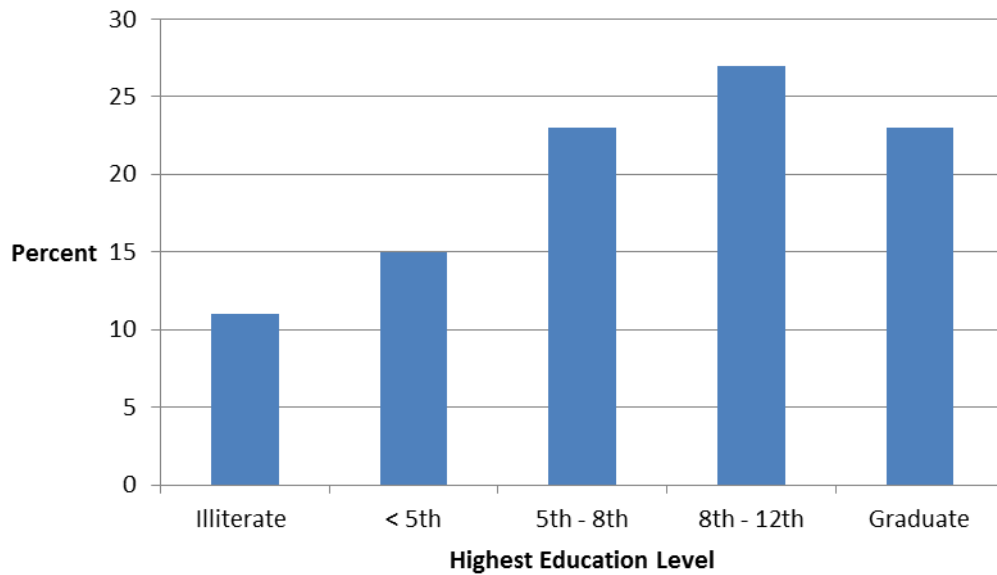
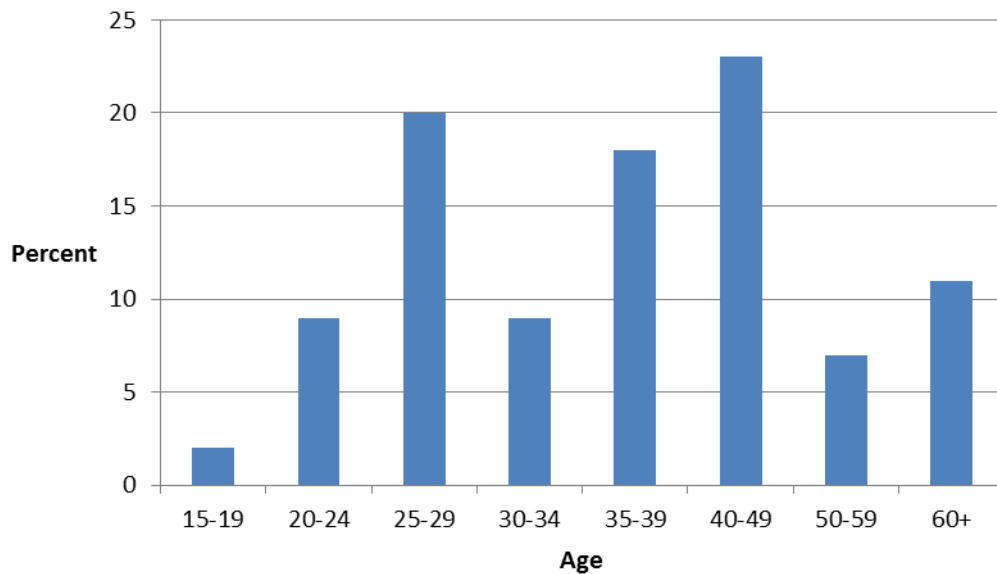


Figure 4: Sample by Age



The focus group consisted of ten men. Seven of them were greater than 60 years old, and three were between 40 and 50 years old. Nine of them were college graduates, while one was a high school graduate. The focus group session was conducted to better understand what the consumer's awareness of counterfeit medicines was and to supplement the survey results. A

focus group with different demographic groups would have been ideal, but time constraints did not allow for this.

Interviews were conducted with those along the distribution chain. This group included: six pharmacists in South Delhi; eight medicine wholesalers in Bhagirath Palace; and three doctors. Finally, an interview was conducted with Faguni Jain, the regional sales director of Sporilix, a private firm providing medicine authentication services in India. There was an attempt made to contact 15 drug manufacturers, including Ranbaxy and Pfizer. There was no response from these manufacturers.

An interview was also conducted with Bejon Misra, the founder of the Partnership for Safe Medicines India (PSM-India), an organization that focuses specifically on patient safety. There was an attempt made to interview the CDSCO. Although they did show an interest in sharing their viewpoints on this issue, they became unavailable when an attempt to schedule an interview was made.

The lack of a response from manufacturers and the CDSCO may be due the stringent time constraints set for this project. The time constraint also limited the sample area and sample size. The sample area for this project was primarily in an urban area, South Delhi. In the future it will be important to look at the distribution chain and consumer purchasing habits in rural areas.

4.0. Findings and Recommendations

4.1. Recommendation 1: Government Mandate use of SMS Authentication Technology

There should be government mandated use of SMS medicine authentication technology by manufactures of certain medicines to help consumers identify and consume only genuine medicines, and provide a disincentive for the production of counterfeit drugs. A large scale study must be done on counterfeit medicines and past studies need to be used to identify where counterfeiting is most rampant. It is important to know if counterfeiting is being concentrated in specific brands, markets, or medicine types (e.g. anti-malarial, infection).

Manufactures of drugs that meet the following criteria should be required to use this technology.

1. Drugs that are sold in bulk, in whole blisters or bottles for example.
2. Drugs used to cure or prevent severe illnesses.
3. Drugs with the highest levels of dangerous counterfeiting (spurious and adulterated drugs that lack an active ingredient, and grossly sub-standard drugs).

The manufacturers of such medicines then should be required by law to implement a scratch off panel on these medicines or a scratch off panel on a separate card within the packaging. The manufacturer or another private firm (authenticator service provider) would store information for all these medicines in a database. The consumer will then buy these medicines, scratch off the

label for the medicine code, and SMS this information to the authenticator (manufacturer or another contracted firm). The authenticator will then match this information to their database and respond with information about the genuineness of the medicine. The authenticator will then send reports of all counterfeit medicines to the CDSCO.

4.1.1. Findings: SMS Authentication Technology

PSM-India founder Misra described his experience interacting with a working group commissioned by the Indian government where companies made presentations of the technologies they are employing to deal with counterfeiting issues. According to Misra (2013) many large companies have already piloted SMS medicine authentication technology or some variant of it in India, or in their export markets. They are not willing to come forward with these technologies because they are concerned that the public will associate their medicine with counterfeits, which would lead to a decrease in sales. This may particularly be a concern in India, where the counterfeiting issue is not as widespread as in other countries where this technology has been employed, such as Nigeria. In 2001, counterfeiting in Nigeria was known to exceed 40%, and was as high as 90% in some medicine types (Jain, 2013; Wadman, 2008). Therefore, in a country like Nigeria, the public may be more aware of counterfeit medicines since it is so widespread and because of the importance of the medicine in which the counterfeit is occurring, primarily malaria medicine (Ross, 2013).

In situations where the level of counterfeiting is high and the consumer is aware, the consumer would demand various authentication technologies from companies. In this scenario, the manufacturer would not be at risk of losing sales from introducing these technologies. In fact, the company would have an incentive to introduce an authentication technology as consumers would prefer these medicines. However, in India where the consumer is less aware of the issue (discussed in Section 4.2.1.) and where the medicine counterfeiting is much lower than in a country such as Nigeria, the introduction of this technology can lead to a decrease in sales. For this reason no company has an incentive to use this SMS technology unless they are mandated to which is why the government must take an active role in incentivising the use of this technology. This step was taken by the Nigerian government for all anti-malarial drugs in 2012 (Ross, 2013).

Manufacturers of drugs that have high levels of counterfeiting and those drugs which the consumer critically needs for their well-being should be the drugs that require use of this technology because consumers would be willing to pay a premium for the authentication service for these drugs and therefore, these would be the drugs where the manufacturers would be able to capture the most profit.

The drug manufacturers that should be required to use such technology should be manufacturers of drugs in which not only the level of counterfeiting is high, but where the authentication technology is feasible. A major challenge for authentication companies in India is that people

tend to buy individual tablets rather than the whole blister pack, which makes the use of the authentication technology unfeasible (Jain, 2013). This technology can be labour and capital intensive, therefore is not practical at the pill level (Jain, 2013). The purchase of individual pills may be a result of lower incomes in India, where people only have enough money to purchase a few tablets at a time. Another contributing factor to the purchase of individual pills in lower quantities may be incorrectly prescribed by pharmacists. Medicines such as antibiotics should be consumed until the full course is completed to avoid resistance to the medicine in the future or relapse of the illness (Sahoo, 2008). However, because of poverty or incorrectly prescribed by pharmacists or medicine retailers, people may only be consuming them at a quantity that allows them to be initially cured (Sahoo, 2008).

The use of SMS verification does not require significant local or state government intervention, which, as mentioned in Section 2, may be corrupt or inadequate. Since states with the highest level of corruption are more likely to have greater levels of counterfeiting, a private sector solution such as this is desirable. There are also additional steps that the government will need to take.

4.1.3. Recommendation 1B: NPPA Reduce Price Controls

The NPPA must allow manufacturers using the authentication technology to increase prices to incorporate the added cost of using this labour intensive and sometimes capital intensive technology (Jain, 2013).

4.1.3.1. Findings: Price Controls

The NPPA is the body responsible “to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country” (NPPA). The organization imposes a price ceiling on drugs and dictates how much drug manufacturers can increase prices in a given year (Jain, 2013; NPPA). If manufacturers that begin to use this technology are not allowed to increase prices then low volume and low margin manufacturers would go out of business. This decreased level of competition in the industry would not be good for consumers.

4.2. Recommendation 2: Implement More Effective Consumer Awareness Campaigns

The CDSCO should implement more effective consumer awareness campaigns so people understand medicine counterfeiting issues. The campaigns should focus on educating people on how to inspect their medicines, mainly the following aspects: packaging, labeling, pill appearance, pill taste, and side effects. These are similar to some of the campaigns undertaken in the United States by both NGOs and government agencies (Chaudhry & Stumpf, 2013). The public should also be given information about the CDSCO, appropriate drug purchasing habits (e.g. buying only from a pharmacist, asking for a receipt after your purchase), and contact information of agencies they can report adverse reactions and suspicious drugs to. The

authentication technologies should also be promoted by the government. This information must be communicated through a variety of mediums to ensure all demographic groups are included, especially those in rural areas. These mediums may include: social media, TV, radio, newspapers, and posters in pharmacies.

4.2.1. Findings: Consumer Awareness

The CDSCO has listed the implementation of consumer awareness campaigns as one of its goals for the 2013 to 2020 period, and states that it had in the past done various consumer awareness campaigns between 2000 and 2005 (CDSCO, 2012). According to my primary research previous campaigns have not been effective, as will be discussed below. Future campaigns should incorporate the recommendations mentioned in the previous section.

The surveys and focus groups revealed a lack of awareness regarding counterfeit medicines among consumers. Below, Figure 5 shows that only 61% of the sample was aware of counterfeit medicines. The focus group results however lay suspicions on this figure. Although, the highly educated focus group was aware of counterfeit medicines they believed these medicines were of a lower potency, and were unaware that these medicines may have adverse effects. The negative relationship between awareness and education was strong, as those with lower education levels were less likely to be aware of these medicines. This is demonstrated in Figure 6 on page 13. This relationship would particularly be of concern in rural areas, given the low levels of education (United Nations, 2013). Therefore, a focus on rural areas is warranted.

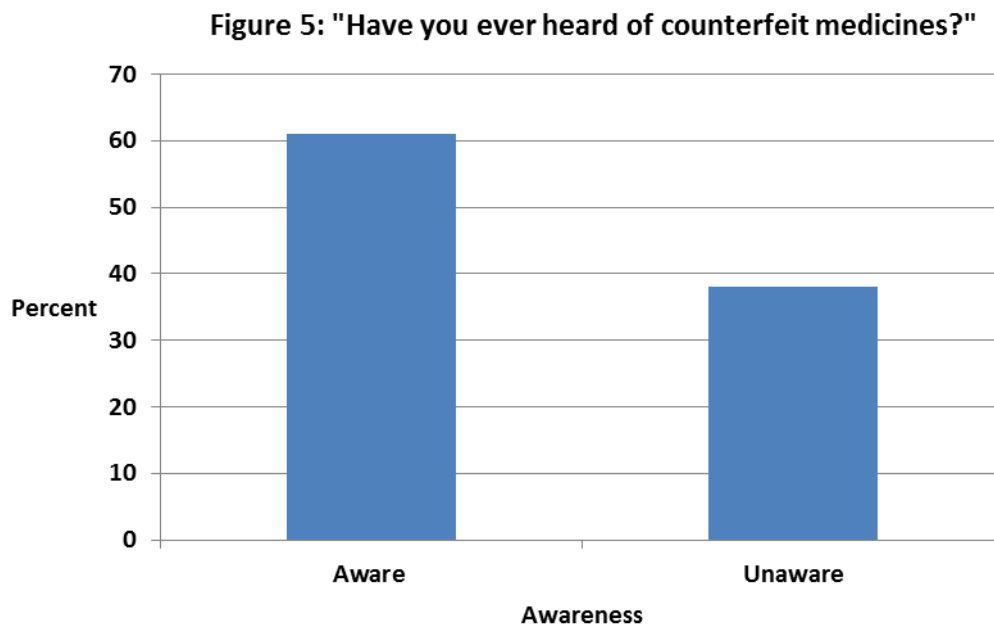
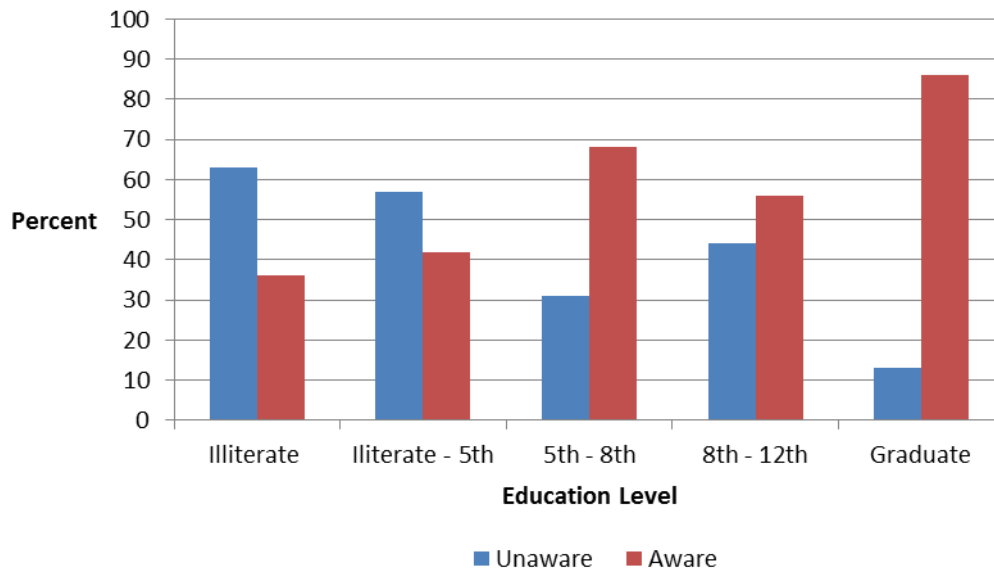


Figure 6: Awareness by Education Level



The lack of awareness may explain the lower level of scrutiny in the choice of pharmacies by consumers. When people were asked, “What factors are important for you in a pharmacy?” only 51% of those who were unaware of counterfeiting stated “Safety/trust factor” as an important factor, while 78% of those who were aware of counterfeiting stated it as an important factor.

4.3. Recommendation 3: Regulate Access to Medicine Manufacturing Machinery

The sale of medicine manufacturing equipment must be regulated. In the domestic market this machinery must be tracked all the way from the manufacturer to the retailer. Those who buy equipment must have the appropriate licenses from the CDSO and every machine should be accounted for. There should be fines for both the seller and buyer if regulations are not followed. Ownership information then can be used by the government to conduct annual audits on these manufacturers. If someone would like to sell their equipment they would do this through the appropriate government department. This would be similar to the monitoring of car owners through ownership slips by the Ministry of Transportation, for example.

Additional steps would need to be taken for imported machinery. All imported machinery can be monitored at the port of entry. Those who attempt to purchase this machinery without the appropriate licenses or without informing the government would then be fined. An alternative approach may be an international treaty that restricts the sale of this manufacturing technology. There would be agreement that all sellers of this equipment ensure that the potential buyer has the appropriate licenses with the respective drug regulatory body of their resident country. This information can be verified from the same regulatory body. Those companies and consumers that do not comply with these laws would then be fined.

4.3.1. Findings: Access to Manufacturing Machinery

There are very few restrictions on the purchase of various types of medicine manufacturing machinery, such as pill making machinery (Chaudhry & Stumpf, 2013; Wertheimer & Norris, 2009). This allows for counterfeiters without manufacturing licenses to purchase this machinery and manufacture medicines. The restricted sale of this equipment would prevent the counterfeiter from attaining the tools required to counterfeit.

On the other hand, the buyer of manufacturing machinery may be a licensed manufacturer. A medicine wholesaler that was interviewed claimed that counterfeiting is typically done by start-up operations, new manufacturers whose own brand of medicine fails. To recoup their investment these manufacturers turn to counterfeiting. The counterfeited drug may or may not contain the required level of active ingredient. The alternative to counterfeiting for these failed manufacturers is to sell their equipment. Tracking of equipment therefore would ensure that the equipment does not go to an unlicensed manufacturer, and previously licensed manufacturers with expired licenses are not using equipment to produce illegal medicine.

4.4. Checking and Monitoring of Counterfeit Medicines

This section does not contain a specific recommendation, but reiterates the importance of the inspection of counterfeit medicines. The CDSCO has done surprise inspections in the past at the wholesale and retail level (CDSCO, 2009; CDSCO, 2012). According to my interviews with wholesalers, the authenticator service providers, and pharmacies, counterfeit medicines often enter the supply chain at the wholesaler/distributor level. Increased checking at this level would allow for easier identification of the origin of these medicines, and potentially counterfeit medicine.

Increased and more efficient checking requires a greater number of inspectors with the latest technologies to perform inspection. These technologies include devices such as the hand-held Counterfeit Detection Device #3 which has been recently employed by the United States (Chaudhry & Stumpf, 2013). Devices such as these allow officials to verify the authenticity of medicine without taking the drug into the lab for testing, and only cost approximately \$1000 US. Finally, in addition to consumers, others in the distribution chain should be educated about counterfeit medicines and informed about the procedures to report suspicious drugs.

5.0 Conclusion

The production of counterfeit medicines is a serious public health concern. The key to curbing counterfeit medicine production will be in modified 'traditional solutions' that are applicable to the Indian context. This paper recommends: 1) government mandate use of SMS authentication technology on certain drugs, 1b) NPPA reduce price controls, 2) CDSCO implement more targeted and effective consumer awareness campaigns, and 3) CDSCO regulate the sale of

medicine manufacturing equipment. These will all require increased financial resources for the CDSCO to different extents, which is in line with the CDSCO's plans (CDSCO, 2012). Few countries have mandated SMS authentication technology into law. The implementation of such a technology is quite complicated and has many implications for manufacturers. Therefore, this step requires utmost prudence, which is why so many caveats have been placed on this recommendation in terms of which specific drug manufacturers should be required to employ this technology. If such a technology is to be implemented a significant amount of data must be gathered on where counterfeiting is occurring and the nature of counterfeiting. This will not only involve another large scale study, but regular random inspections of medicines. The differing estimates on the level of counterfeiting must be reconciled. Also, the NPPA must allow manufacturers employing authentication technologies to incorporate additional costs into prices of their drugs. Consumer awareness campaigns must be effective, and must exist on the ground, rather than just on paper. Finally, prevention must be emphasized by restricting access to manufacturing machinery. These steps should be taken with a true sense of urgency as this is an issue of the utmost importance to public health.

6.0. Limitations and Extensions

These findings should only be taken as tentative. The primary research for this project was undertaken in a time frame of less than three weeks as part of an internship program. Therefore, the samples were restricted to urban areas. There must be research done in rural areas to understand if the distribution system and consumer buying habits differ from urban areas. I was unable to speak to CDSCO and drug manufacturers. It is necessary to speak to manufacturers and understand what they believe are the best solutions to the counterfeiting issue. The CDSCO has a limited amount of publicly available information on their current initiatives and past findings; therefore, it may be insightful to interview them.

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