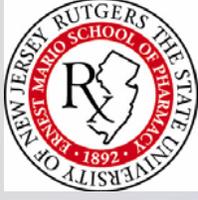




Evaluating Business Practices to Identify, Track, Report, and Respond to Counterfeit Medications: The ITRR Study



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Introduction

The World Health Organization (WHO) considers drugs to be counterfeit "if it has been deliberately and fraudulently mislabeled with respect to its identity and/or source." Studies by WHO estimate counterfeit drugs to be a \$32 billion-a-year business and that 8 to 10 percent of the global medicine supply chain is counterfeit. Despite the system of laws and regulations to deter counterfeiting, the United States remains a target for the distribution of counterfeit medications because it is the largest market for retail pharmaceutical sales in the world.

Counterfeit drugs pose serious threats to public safety and endanger the health and well-being of patients. To secure the U.S. drug supply chain, there are several areas that deserve attention, including the areas of technology, business practices, legislation, and international cooperation. Within the pharmaceutical industry, business practices for identifying, tracking, reporting, and responding to inquiries regarding counterfeit drugs vary. However, regardless of the company or product, it is essential that best practices are followed to ensure that prompt and accurate information is delivered in order to protect patient safety.

Objectives

To assess the business practices instituted by pharmaceutical companies to identify, track, report, and respond to counterfeit drugs, and to identify gaps in current practices for combating counterfeit drugs.

Study Design

Prospective analysis of pharmaceutical companies' practices for handling potential counterfeit reports at initial interface.

Data Collection

- Ten major industry-based medical information centers were contacted via phone.
- The phone numbers of the medical information centers were obtained from the 2006 PDR.
- Each company received one inquiry regarding a general concern due to a news report about counterfeit drugs.
- Standardized questions were placed by consumers to strategically evaluate each manufacturer's capability in identifying, tracking, reporting, and responding to counterfeit medications.
- Additional metrics of the calls were assessed such as call length and the number of transfers.

Target Population

The following ten pharmaceutical/biotech companies were included in the analysis:

- Abbott
- AstraZeneca
- Bristol-Myers Squibb
- Eli Lilly
- F.Hoffmann-La Roche
- GlaxoSmithKline
- Merck
- Novartis
- Pfizer
- sanofi aventis

Results – Identifying, Tracking, Reporting and Responding

Results were gathered from a telephone-based survey conducted with 10 major pharmaceutical companies. The calls were being asked as a consumer.

Figure 1. Total Length of Call

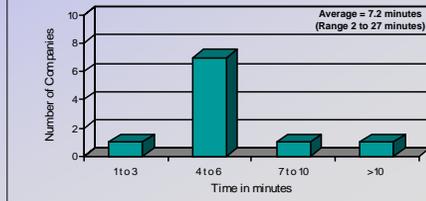


Figure 2. Number of Transfers During Call

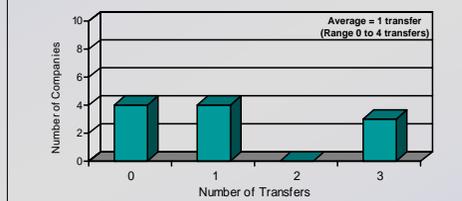


Figure 3. Company Practices to IDENTIFY Counterfeits

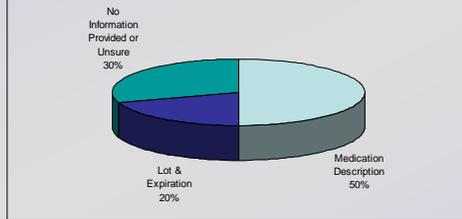


Figure 4. Procedures to TRACK Medications along the Supply Chain

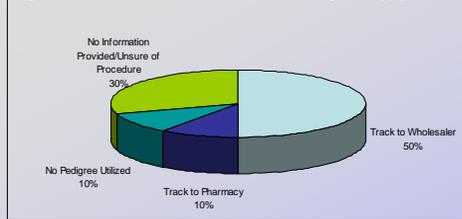


Figure 5. Measures to REPORT and RESPOND to Counterfeits

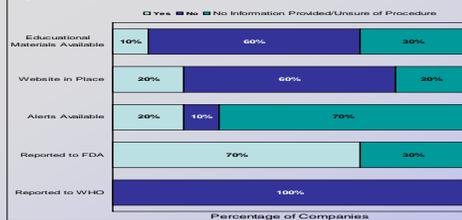
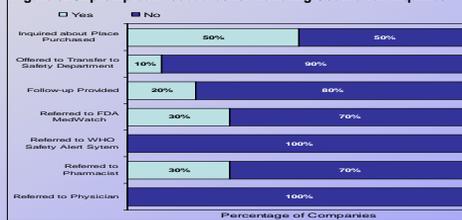


Figure 6. Unprompted Procedures for Handling Counterfeit Inquiries



Discussion

From the results, it is evident that the pharmaceutical industry do not have effective business practices in place for handling inquiries concerning counterfeiters nor are they fully utilizing resources provided by the FDA and WHO. All companies stated that it was unfeasible to IDENTIFY a counterfeit via phone. Only 50% questioned the source of the medication, and it was identified that companies do not use special packaging or routinely change packaging to deflect counterfeiting. Sixty percent of companies stated that pedigrees to TRACK the medications were utilized from manufacturer to the wholesaler but only one company utilized this system from manufacturer to pharmacy. Forty percent of companies identified that they would REPORT counterfeiters directly to the FDA, while another 30% would report suspected counterfeiters to the FDA via their safety department. No company identified that suspected counterfeiters would be reported to the WHO. Only 20% had business practices in place to RESPOND to counterfeit drugs such as alert networks, websites, and educational materials for consumers. Furthermore, when these resources were available through the manufacturer, company representatives did not disseminate this information.

Auxiliary business practices evaluated in addition to the assessment of primary endpoints included:

- The average call length of the inquiries was 7.2 minutes, with an average of one transfer per phone call.
- No company referred the caller to his/her physician.
- Thirty percent suggested that the caller follow-up with his/her pharmacist.
- Twenty percent provided follow-up, with one sending an educational letter about counterfeit drugs and drug importation.

Limitations

- The study consisted of only ten medical information centers within pharmaceutical and biotech companies.
- Responses were dependent on one company representative and his/her knowledge of the procedures surrounding counterfeit medications.
- Inquiries regarded hypothetical counterfeit medication.

Conclusions

The results of this study demonstrate that procedures in place for medical information departments to IDENTIFY, TRACK, REPORT, and RESPOND to counterfeit medications is inadequate. Therefore, in order to combat counterfeiting, the pharmaceutical industry in collaboration with federal agencies and international organizations should develop business practices to IDENTIFY, TRACK, REPORT, and RESPOND to counterfeit drugs and formulate specific approaches to assure that patients are educated and protected from counterfeit drugs.

This study may be used to further gauge medical information departments' abilities to identify, track, report, and respond to counterfeit medications so that best practice standards can be developed.

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