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Role of the Pharmacist in Preventing Distribution of Counterfeit Medications

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Abstract and Introduction

Abstract

Objective: To provide an overview of the counterfeit medication problem and recommendations of a joint American Pharmacists Association (APhA) Academy of Pharmaceutical Research and Science and APhA Academy of Pharmacy Practice and Management taskforce.
Date sources: SciFinder and PubMed were searched from 1980 to March 2011 using the following keywords: counterfeit drug product, counterfeit medications, drug product authentication, drug product verification, and track-and-trace. Publications, presentations, and websites of organizations that research the counterfeit medication problem in the United States and other countries were reviewed. A representative from the security division of a pharmaceutical manufacturer and a representative from a supplier of anticounterfeiting technologies gave presentations to the taskforce.
Summary: The taskforce recommends that pharmacists (1) purchase medications from known, reliable sources; (2) warn patients of the dangers of purchasing medications over the Internet; (3) confirm with distributors that products were purchased from manufacturers or other reliable sources; (4) monitor counterfeit product alerts; (5) examine products for suspicious appearance; (6) work with the pharmaceutical industry, distributors, and the Food and Drug Administration (FDA) to close gaps in the supply chain, especially for drugs in short supply; (7) use scanning technology in the pharmacy as part of a prescription verification process; (8) educate themselves, coworkers, and patients about the risks of counterfeit medications; and (9) report suspicious medications to FDA, the distributor, and the manufacturer.
Conclusion: The consequence of a patient receiving a counterfeit medication in the United States could be catastrophic, and pharmacists must play an active role in preventing such an event from occurring.

Introduction

The American Pharmacists Association (APhA) established a taskforce consisting of members of the APhA Academy of Pharmaceutical Research and Science and the APhA Academy of Pharmacy Practice and Management to assess pharmacists' roles in preventing patients from receiving counterfeit medications. Members of the taskforce included practitioners in academia, hospital, and industry, as well as an advisor from the Food and Drug Administration (FDA). Sci-Finder and PubMed were searched from 1980 to March 2011 using the following keywords: *counterfeit drug product*, *counterfeitmedications*, *drug product authentication*, *drug productverification*, and *track-and-trace*. Publications, presentations, and websites of organizations that research the counterfeit medication problem in the United States and other countries were reviewed. A representative from the security division of a pharmaceutical manufacturer and a representative from a supplier of anticounterfeiting technologies gave presentations to the taskforce.

Statement of the Problem

Imagine that a patient is prescribed chemotherapy to treat a life-threatening tumor. A pharmacist dispenses the prescribed medication and counsels the patient without realizing that the tablets did not contain an active ingredient. In this scenario, not only is the patient not receiving the prescribed medication, but the physician and pharmacist are evaluating treatment outcomes based on the patient's response to a placebo.

Counterfeit medications have been defined as "products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product."[1] Examples include

medications that contain no active ingredient, an incorrect amount of active ingredient, an inferior-quality active ingredient, a wrong active ingredient, contaminants, and repackaged expired products.[2]

The impact of counterfeit medications on the legitimate global pharmaceutical market has been estimated to reach $75 billion, and the profit margin is reportedly greater than illicit drug trafficking.[3] Counterfeit medications have been distributed via complex global networks that have been traced to terrorists and organized crime.[4] Estimates indicate that less than 1% of prescription medications sold in the United States and Europe and 30% sold in developing nations are counterfeit,[5] and the problem is likely growing rather than receding. Although 1% may seem low, if a pharmacy dispenses 200 to 300 prescriptions per day, that means that two or three of them could be counterfeit. Pfizer reported discovering 14 counterfeit Pfizer products in at least 36 countries, including the United States, in the first 9 months of 2009[3] and reportedly seized more than 11 million counterfeit tablets, capsules, and vials in 2009.[5] A U.S. Immigration and Customs Enforcement official reported at least weekly seizures of counterfeit medications on the U.S. border.[3] Placebo products initially dominated, but a recent trend is for counterfeiters to substitute less expensive active ingredients in hopes of securing repeat business.[5]

Ensure Procurement From Reliable Sources

Internet Suppliers

Although any product can be counterfeited, economics and an increased ability to enter the supply chain drive counterfeiters to target high-demand, high-priced medications. Medications sold via nontraditional distribution channels such as the Internet, the gray market, and clinics have a higher risk of being counterfeit.

Up to 60% of medications purchased online could be counterfeit or substandard,[5] and more than 50% of medications purchased online from sites that concealed their actual physical address were found to be counterfeit.[6] Congress passed the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 to prohibit the delivery, distribution, or dispensing of a controlled substance over the Internet without a prescription.[7] Nonetheless, thousands of websites sell unapproved and/or counterfeit medications, including the sale of prescription medications without requiring a prescription.[1] The Pharmaceutical Research and Manufacturers of America developed a website containing information for patients on the risk of buying prescription medications over the Internet.[8] The National Association of Boards of Pharmacy (NABP) created a database (i.e., Verified Internet Pharmacy Practice Sites) of online pharmacies that are legitimately licensed and operating on the Internet.[9] The White House announced the formation of a nonprofit organization to educate the public on the risks of purchasing medications on the Internet.[1]

Beware of Fraudulent Distributors

A "perfect storm" exists when legitimate suppliers of a highdemand, expensive medication are unable to supply the market needs and counterfeiters break into the supply chain because pharmacists are searching for alternative suppliers. Examples of documented counterfeited products include Tamiflu during influenza season [10] and Alli shortly after its introduction as an OTC product.[11]

Planning for product shortages minimizes the risk of buying counterfeit medications. Guidelines for managing medication shortages include recommendations for inventory management, use of therapeutic alternatives, and precautions against stockpiling.[12] Information is readily available on medications in short supply, the reason for the shortage, the status of future supply, and companies that can supply products previously in short supply.[13–16] New suppliers should be approved after conducting a background check, obtaining a credit history report, checking the licensing status of the firm as a wholesaler, checking to determine whether civil/criminal litigation exists against the company, and verifying the date and place of incorporation, years in business, and form of entity.[17]

NABP has a voluntary accreditation program for wholesale distributors: the Verified-Accredited Wholesale Distributors.[18] Criteria include review of operating procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every 3 years.

Monitor Counterfeit Product Alerts

FDA coordinates the Counterfeit Alert Network, a coalition of health profession and consumer groups, to disseminate alerts about specific counterfeit medication incidents in the United States. The American College of Clinical Pharmacy, Academy of Managed Care Pharmacy, APhA, American Society of Health-System Pharmacists, Healthcare Distribution Management Association, National Association of Chain Drug Stores, and National Community Pharmacists Association are among the organizations that receive notification from FDA in the event of a confirmed counterfeit case in the United States and instances outside the United States that could affect the U.S. marketplace.[19] Pharmacists should ensure that they receive notices of counterfeit medications from at least one of these organizations.

A total of 18 states have taken a legal/regulatory approach to prevent counterfeit prescription medications by using the "normal distribution" model for wholesale distribution. In this model, a wholesaler purchases prescription medications within an established customary supply chain (e.g., obtaining prescription medications solely from the manufacturer or designated agent of that manufacturer as defined by law). If not, the wholesaler is required to provide the buyer with documentation known as a pedigree. A pedigree documents the product's movement through the normal distribution system. Federal law defines pedigree as a statement that identifies each previous sale, purchase, or trade of a medication, including the dates of the transactions and the names and addresses of all parties.[20] Under the pedigree requirement, each person engaged in the wholesale distribution of a prescription medication in interstate commerce, who is not the manufacturer or an authorized distributor of record, must provide a pedigree to the person who receives the medication. Pharmacists should confirm that medications purchased from wholesaler(s) were obtained and distributed using the safeguards embedded in this model.

Pharmacists can help ensure the integrity of the supply chain by purchasing medications from known, reliable sources, warning patients of the dangers of purchasing medications over the Internet, affirming that distributors purchased the product from the manufacturer or another reliable source, and monitoring counterfeit product alerts.

Ensuring Product Integrity

Pharmaceutical industry, wholesaler, and FDA efforts to control the distribution of counterfeit medications have focused on two major fronts: packaging and dosage form authentication systems. The issue is complex because the detection technology must be simple to use and cost effective in the field but unable to be easily thwarted. In addition to these authentication systems, pharmacists and technicians should always closely examine products for suspicious appearance.

Packaging and Labeling Technologies

Packaging/labeling anticounterfeit features are primarily used for authentication, and they are difficult and/or expensive to copy. Among anticounterfeit features' limitations are that they provide no assurance as to the authenticity of the contents in the containers. However, pharmacists can check to see whether the tamper-evident feature is intact. An advantage of unit-of-use packaging is that each unit can be marked, thereby adding an additional layer of protection. Holograms, color-shifting inks, embedded codes, images, and dyes are currently being used by pharmaceutical manufacturers on packaging to create an additional layer of protection. The intaglio printing process used on currency was recently introduced for use on tamperevident seals and other pharmaceutical product labeling.[21] Intaglio printing produces a characteristic "raised" feel to the print and cannot be copied without the use of specialized printing equipment.

The White House's Counterfeit Pharmaceutical Inter-Agency Working Group recommended that Congress adopt a track-and-trace system for pharmaceuticals and related products.[1] "Track" refers to the identification of the product location in real time as it moves through the distribution chain, and "trace" provides a record of where a product has been.[22] Radiofrequency identification technology tags and barcodes carry product identification information for track-and-trace purposes. FDA also has issued a guidance document on the use of standardized numeric identifiers to create a unique "license plate" to track individual drug packages in the drug supply chain.[23]

Many of these anticounterfeiting technologies are being used by pharmaceutical companies to ensure distribution of the authentic product from the manufacturing site to the pharmacy. When these technologies are widely used for pharmaceutical packages, pharmacists will be able to quickly authenticate the unique identification number to determine whether the number is genuine and the product is legitimate. The Institute for Safe Medication Practices reports that pharmacies using imaging and/or scanning technologies as part of the prescription verification process make fewer medication errors and recommends adoption of a standardized prescription verification process in all pharmacies.[24] Use of imaging and/or scanning technologies coupled with software that prints a description of the medication's appearance on the pharmacy label or receipt also would reduce the chances of dispensing a counterfeit medication.

On-dosage Form Technologies

FDA provides guidance to pharmaceutical manufacturers on the use of physical–chemical identifiers (PCIDs) in solid oral dosage forms.[25] A PCID is "a substance or combination of substances possessing unique physical or chemical properties that unequivocally identifies and authenticates a drug product of dosage form."[25] Examples include inks, flavors, and chemical tags that are detectable analytically using techniques such as infrared, ultraviolet, and fluorescence detectors or visually using magnification.[25]

Importance of Education

Pharmacists, technicians, student pharmacists, and patients need to be educated about counterfeit medications. Professional materials are available from the Partnership for Safe Medicines.[26–28] Additional practical tips for identifying and preventing distribution of counterfeit medications are available from the World Health Organization,[7] the Royal Society of Great Britain,[29] and the International Pharmaceutical Federation.[30]

Reporting Suspicious Medications to Ensure Future Integrity

Pharmacists should report suspect counterfeit medications through Medwatch.[31] Some pharmaceutical companies will send an investigator to a pharmacy to examine suspicious products and conduct authentication tests if requested. Suspicious products should be removed from the dispensing area immediately until further instruction is given from FDA or other law enforcement officials.

Conclusion

Pharmacists play a critical role in preventing the distribution of counterfeit medications. By raising awareness, identifying education materials with practical suggestions, and implementing recommendations to ensure the integrity of the supply chain, pharmacists can help address the threat of counterfeit medications.

Sidebar

At a Glance

Synopsis: To help combat the threat of counterfeit medications, an American Pharmacists Association taskforce recommends that pharmacists purchase medications from known, reliable sources, warn patients of the dangers of purchasing medications over the Internet, determine whether distributors purchased the product from the manufacturer or another reliable source, and monitor counterfeit product alerts.

Analysis: *The issue of packaging and dosage form authentication systems is complicated by the fact that detection technology must be simple to use and cost effective in the field but unable to be easily thwarted by counterfeiters. The White House's Counterfeit Pharmaceutical Inter-Agency Working Group has recommended that Congress adopt a track-and-trace system for pharmaceuticals and related products, and the Food and Drug Administration has issued guidance on using standardized numeric identifiers to create a unique "license plate" to track individual drug packages in the supply chain. The Institute for Safe Medication Practices recommends adoption of a standardized prescription verification process in all pharmacies and has reported that pharmacies using imaging and/or scanning technologies as part of the prescription verification process make fewer medication errors.*

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