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Abstract

Background: Counterfeit medicines are a threat to public health and the national economy in Egypt. The many community pharmacists in the country could help prevent counterfeit medicines reaching the patient. Information on community pharmacists’ perceptions of counterfeit medicines is lacking.

Aims: This study assessed the awareness, practices and perceptions of community pharmacists in Alexandria, Egypt with regard to counterfeit medicines. The aim was to identify gaps and inadequacies in pharmacy practice that might allow infiltration of counterfeit medicines in the legitimate medicine supply chain.

Methods: A cross-sectional study was conducted of 175 community pharmacists in Alexandria in 2014–2015. A semi-structured interview questionnaire was used to assess their perceptions, awareness and practices. The chi-squared test was used to assess the relationships between selected pharmacists’ characteristics and their awareness, purchasing practice and training related to counterfeit medicines.

Results: Most pharmacists thought medicine counterfeiting was widespread in Egypt and that they could contribute to combatting the problem. However, most also lacked a clear perception of counterfeit medicines, an awareness of their danger to patients or the legislation to reduce them. Their procurement practices and detection of counterfeit medicines and handling of incidents of counterfeit medicines were inadequate. Pharmacists who thought counterfeit medicines were widespread or a health threat were significantly more likely to purchase
medicines from certified sources (P < 0.05).

Conclusion: Pharmacists should be developed as a frontline resource to combat counterfeit medicines. To enhance their role, the pharmacy curriculum needs to be updated and continuing professional development activities mandated.

Keywords: pharmacist, counterfeit drugs, perception, Egypt

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**Introduction**

As initially defined by the World Health Organization (WHO), a counterfeit medicine is “one which is deliberately and fraudulently mislabelled with respect to identity and/or source” (1). More recently, new definitions have been introduced where medical products that deliberately or fraudulently misrepresent their identity, composition or source are termed falsified products (2). Despite efforts by international and national agencies to combat counterfeiting and falsification of medicines, this problem is still a serious threat to global health (3–5). Counterfeit medicines are widespread and varied, and encompass all types of therapeutic classes, ranging from life-saving to lifestyle products (6,7). Estimates indicate that up to 15% of drugs are counterfeit and, in parts of Africa and Asia, this figure exceeds 50% (5,8).

In Egypt, powerful factors both on the supply and demand side drive counterfeiting of medicines and are threat to the health care system and patient safety. The supply of counterfeit medicines
is driven by the large market size, huge profits, and the availability of sophisticated counterfeiting technology. At the same time, drug shortages and the demand for inexpensive medicines by an ever-increasing population encourage the spread of counterfeit medicines, making Egypt a target for illegal local manufacturing, and smuggling and trafficking of counterfeit medicines (9,10). The situation is made worse by a lack of awareness of the problem of counterfeit medicines and limited resources to combat it. Moreover, the Egyptian pharmacy practice law, number 127 dates back to 1955 and lacks provision for dealing with the spread of counterfeit medicines. This complex situation undermines efforts to reduce counterfeit medicines, leaving the patient the victim of ineffective or harmful medicines (9).

In such an environment, pharmacists could be enlisted to help safeguard patient safety if supported by the necessary professional development and partnership. The views and attitudes of pharmacists about counterfeit medicines have been surveyed in several developing countries and they suggest improvements could be made (11–14). Indeed, the involvement of pharmacists could be influential in Egypt because of their large number (15,16), which is higher than average in the Middle East and is one of the highest in the world (17). Furthermore, community pharmacies are often the first point of access to affordable health care and clinical services for patients in Egypt (18). However, studies to assess the practices in community pharmacy in Egypt in relation to the spread of counterfeit medicines and efforts to limit the spread are lacking.

In this study, we explored the perceptions, awareness, and practices of community pharmacists in Alexandria, Egypt with regard to counterfeit medicines. We aimed to identify specific gaps and inadequacies in the educational, regulatory and professional components of pharmacy practice that facilitate infiltration of counterfeit medicines into the legitimate medicine supply chain and affect pharmacists’ involvement in efforts to control the spread of counterfeit medicines.

**Methods**

**Study design and sample**

This was a cross-sectional study of 175 randomly selected private community pharmacies in Alexandria, Egypt in 2014–2015. Epi Info, version 6 was used to calculate the sample size based on an expected awareness of counterfeit medicines of 50% of pharmacists, 95% confidence level, 5% level of significance, a permissible error of 5% around the expected prevalence, and a type one error of 0.05. The sample was selected using a two-stage cluster technique that involved random selection of two of the seven health administrative zones in Alexandria, Eastern and Borg Al-Arab zones. Then the number of listed private community pharmacies in each zone was selected proportionately to population size. Pharmacies received an invitation letter delivered by hand explaining the purpose of the study and importance of its outcomes. Working in a private community pharmacy (one pharmacist from each pharmacy)
and at least one year of experience were the inclusion criteria.

**Data collection tool**

Data were collected using a semi-structured interview questionnaire. After arranging an appointment with the community pharmacies, face-to-face interviews were conducted at the pharmacies by an investigator trained in the interview process. The questionnaire was developed in English, then translated to Arabic and back-translated to English. The final version was checked against the original version and validated by five pharmacists representing different stakeholders (community pharmacists, syndicate of pharmacists, academia, pharmaceutical industry and health ministry). Questions were divided into sections including demographic information and pharmacists' perceptions, awareness and practices with regard to counterfeit medicines. A pilot study was conducted among 25 randomly selected community pharmacists included in the main study and the reliability of the questionnaire assessed using the Cronbach alpha test. The questionnaire was slightly modified following the pilot study. Differently worded questions were used to reduce social desirability bias in responses that suggested undesirable behaviour. The Cronbach alpha was 0.73 indicating reliability of the questionnaire.

**Statistical analysis**

Data were analysed using SPSS, version 16.0. For knowledge- and practice-related questions, responses were scored poor, fair and good, while for attitude-related questions, responses were scored negative, neutral and positive. Frequencies, percentages, means and standard deviations (SDs) were used to describe numerical variables. The chi-squared test was used to test the statistical significance of relationships between selected personal and professional characteristics of the pharmacists and their awareness, purchasing practice and training related to counterfeit medicines. P ≤ 0.05 was considered statistically significant.

**Ethical issues**

The study protocol was approved by the Research Ethics Committee of the Faculty of Pharmacy, Alexandria University (AU-PREC-8113). Informed written consent was obtained from the participating pharmacists. Participants were assured of the confidentiality of personal data, voluntary participation, and the absence of conflicts of interest.

**Results**

A total of 270 pharmacies were invited to participate in the survey; of these, 95 declined to participate (response rate 65%). The average interview lasted 40 minutes. Demographic characteristics of the pharmacists are given in Table 1. The mean age of the pharmacists was 36.3 (SD 13.9) years, 60.6% were male, and 61.1% were pharmacist managers.
Perception of counterfeit medicines

In a series of questions with multiple responses allowed, of the 175 pharmacists, 66.8% perceived counterfeit medicines as inactive, 61.7% as harmful and 28.6% as less effective/less expensive medicines. Only 98 of the 175 respondents (56.0%) were familiar with the different counterfeiting methods. As shown in Table 2, most pharmacists (87 of 98) thought counterfeit medicines were products not containing an active pharmaceutical ingredient and 37 considered they were medicines with altered expiry date or label information. Based on their practice, the respondents indicated that the drug classes most likely to be counterfeited were erectile dysfunction medicines (74.9% of the 175 pharmacists), weight control medicines (43.4%), dietary supplements (39.4%) and narcotic products (29.1%) and, to a lesser extent, antibiotics, anticoagulants, cardiovascular medicines and antihistamines.

As regards medicine counterfeiting in Egypt, 96% of the 175 respondents believed that the problem existed with 50% of them considering it widespread. Inadequate legislation and regulatory control by the Egyptian Drug Authority and large profits for counterfeiters were considered the main driving factors of the spread of counterfeit medicines (Figure 1). Most of the 175 respondents perceived counterfeit medicines as harmful to the national drug industry (82.9%) and public health (71.4%) while the rest (38.3%) did not perceive a threat.

Awareness of methods to detect counterfeit medicines

Most of the 175 respondents (70.3%) said that they could visually distinguish a counterfeit medicine much or some of the time. Package characteristics and appearance of the medicine were the main elements of product authenticity noted by these pharmacists. Of these 123 pharmacists, 14.6% mentioned seals and package quality, 53.6% shape, 17.1% colour, 24.4% embossing, and 69.9% product-specific authentication marks as the elements of product authenticity they recognized. Most of the pharmacists who said they could distinguish counterfeit medicines (84.6%) had developed their awareness and ability to detect counterfeit medicines through personal experience. About a third (35.0%) also relied on information provided by pharmaceutical inspectors, other pharmacists (4.9%), the Syndicate of Pharmacists (3.2%), medical representatives (2.4%) and their undergraduate education (2.4%). Only 53.1% of the 175 respondents were aware of common anti-counterfeit medicine authentication techniques; digital watermarks were the most well-known. Most of the respondents were not aware of legislation to control medicine distribution (85.1%) or reduce counterfeit medicines (88.0%). However, they identified inadequate legislation and regulatory control by the Egyptian Drug Authority as the main factor driving the spread of counterfeit medicines, and expressed the need for specific legislation on drugs with heavier penalties for counterfeiting.

Practices related to counterfeit medicines
A large percentage of the 175 pharmacists (70.9%) verified the credibility of the supply source for medicines purchased; 20.0% did not seek verification and 9.1% did not know about it. However, most of the pharmacists (84.6%) did not regularly check the batch number of received medicines against that in purchasing invoices. Almost half of the respondents (83; 47.4%) admitted stocking counterfeit medicines unintentionally. Of these 83, 50.6% reported detecting counterfeit medicines during purchase, 20.5% after stocking, 1.2% during dispensing and 21.7% after dispensing (multiple answers were allowed). Detection was based on a personal check (51.8%), customer complaints (22.9%), alerts from the Egyptian Drug Authority (16.9 %) and other pharmacists (12%) or other sources (4.8%). When encountering an incident of counterfeit medicines, 77.7% of all respondents said they returned the suspect medicine to the supplier; only 23.4% reported the incident to the Egyptian Drug Authority. Furthermore, 75.4% of all respondents said they had accepted products with modified/unusual package characteristics.

Figure 2 shows the respondents' views on the effectiveness of stakeholders’ contributions to the national effort to combat counterfeit medicines. Most of the pharmacists considered the contributions of the Egyptian Drug Authority, the media, customs office, and nongovernmental organizations generally ineffective. Most did not know what role law enforcement agencies played and if they were effective. As regards pharmacists’ potential contribution to combating counterfeit medicines, 78.3% believed they could make a substantial contribution while 21.7% thought that combating counterfeit medicines was not part of their job. In addition, respondents considered that their current knowledge and skills were inadequate (quality of information they have) (56.6%) or limited (amount of information they have) (26.3%) for effective contribution to reducing counterfeit medicines and they highlighted a need for educational and continuing professional development activities.

Neither the pharmacists’ age nor length of practice significantly affected their awareness of counterfeit medicines (Table 3). However, awareness of female pharmacists was significantly lower than that of their male counterparts (P = 0.020). Pharmacists who thought the problem of counterfeit medicines was widespread (P = 0.035) or was a health threat (P = 0.023) and those who had unintentionally purchased counterfeit medicines (P = 0.013) were significantly more likely to purchase medicines from sources certified by the Egyptian Drug Authority. The small number of pharmacists who attended a training course on counterfeit medicines reported a slightly greater ability to differentiate between authentic and counterfeit medicines and to report suspicious offers to the Egyptian Drug Authority; however this association was not statically significant. Furthermore, training significantly increased the pharmacists’ eagerness to verify the drug supply source and purchase medicines from sources certified by the Egyptian Drug Authority.

Discussion
Pharmacists’ perceptions of counterfeit medicines revealed deficiencies in professional knowledge and awareness of some aspects of medicine counterfeiting. Perceptions were not based on a clear definition of counterfeit medicines and an inability to distinguish counterfeit medicines from substandard products was reported. An unclear perception of counterfeit medicines has also been reported by pharmacists elsewhere (19). In fact, lack of a worldwide consensus on a definition of counterfeit medicines and variation in the term from one country to another (1,20,21) may contribute to an imprecise understanding among health professionals. Pharmacists’ awareness of methods of medicine counterfeiting was limited, which is worrying. Nonetheless, their perception that erectile dysfunction products were the most likely to be counterfeited is in line with the high demand for such products in Egypt (22) and worldwide. In addition, most of the pharmacists considered that inadequate legislation and large profits were the main reasons for the spread of counterfeit medicines, which is consistent with global views (1,23–25). That most pharmacists recognized that counterfeit medicines existed in Egypt and half considered it a widespread problem could be a first step towards their effective involvement in combatting this problem.

Responses in the second section of the questionnaire revealed that pharmacists relied mainly on their personal experience to develop awareness and skills to detect counterfeit medicines in the pharmacy. As expected, pharmacists’ ways to detect counterfeit medicines were limited to common packaging/labelling authentication features, which implies they lack sufficient skills and funds to improve their capability to detect counterfeit medicines in the pharmacy. Similar responses have been reported by pharmacists in both developing and developed countries (26,27). Furthermore, inadequate awareness of the pharmacists of current legislation in Egypt on anti-counterfeiting of medicines and medicine distribution is disturbing as this lack of knowledge may greatly affect their attitudes and practices. However, respondents stressed the urgent need for specific drug legislation with heavier anti-counterfeiting penalties. In fact, the current law in Egypt does not address the underlying public health threat of counterfeit medicines and has lenient penalties such as small fines (the equivalent of US$ 1100 to 2780) and a two-year prison sentence. The adoption of a specific law on counterfeit medicines with heavy penalties was the recommendation of a study in Hong Kong that reviewed regulations and court cases related to counterfeit drugs and conducted in-depth interviews with stakeholders (23).

The purchasing procedures for medicines of the pharmacists were worrying. Even though the Egyptian Drug Authority certifies drug sources, about a fifth of the respondents used uncertified sources, justifying their practice because of a greater profit margin, uninterrupted medicine supply and physician or patient satisfaction. A similar practice was reported by more than 50% of pharmacists in a study in the Islamic Republic of Iran (28). This practice, together with insufficient skills to detect counterfeit medicines, greatly increases the risk of bringing unsafe medicines into the pharmacy. Thus, pharmacists need to be educated in the dangers of counterfeit medicines and that they need to refer to, among other resources, guidance and drug purchasing guidelines of the Egyptian Drug Authority (29), WHO checklist (30) and other
guidance publications (31–33). At the same time, ensuring secure business practices, and establishing an accreditation system of wholesale distributors and an inventory management system to avoid drug shortages should minimize the perceived need to use uncertified sources (34).

Another alarming practice was the unintended stocking of counterfeit medicines by almost half of the respondents. A similar trend has been reported in other developing countries (26,28). In contrast, a survey of pharmacists in California, United States of America, indicated a much lower incidence stocking counterfeit medicines (27), which highlights the relationship between strong regulatory control and the extent of infiltration of counterfeit medicines into the legitimate supply system and good medicine purchasing practices.

Detection of the presence of counterfeit medicines after stocking and dispensing and the fact that pharmacists often lack the skills to identify counterfeit medicines and rely mostly on customer complaints implies that counterfeit medicines are reaching the patient. This presents a real threat particularly for life-saving drugs as well as drugs that do not produce a therapeutic response but where this lack of response cannot be easily perceived by the patient. Examples of the latter group of drugs include drugs used in prophylactic or preventive therapies or drugs with a delayed therapeutic effect such antidepressant drugs.

If pharmacists suspected a counterfeit medicine, about three quarters returned it to the supplier to avoid loss of the capital invested in the purchase. A similar trend was reported by 80% of pharmacists in a survey in Nigeria (26). Furthermore, the majority of respondents said that they had accepted products with modified/unusual packaging because they believed such modifications had been introduced by the manufacturer without notification. Such poor practices may prevent seizure of the suspect product and the issuance of a drug alert or recall notice and encourage further redistribution, which necessitates enhancement of partnership among stakeholders. Pharmacists must be urged to use relevant guidelines (35) for handling and reporting incidents of counterfeit medicines. In addition, pharmacists should educate patients about counterfeit medicines and identify and reach out to patients who might have received a product suspected to be counterfeit after being dispensed.

Although stakeholder partnership was generally considered ineffective by our pharmacists, it was encouraging that most of them believed that they could make a substantial contribution to the national effort to combat counterfeit medicines if they were partnered with and received relevant professional development. A small percentage of respondents thought that combating counterfeit medicines was not part of their job mainly because they would be unable to effectively detect counterfeit medicines. This was consistent with views expressed by 18% of
pharmacists surveyed in the Islamic Republic of Iran (28).

Increasing pharmacists' awareness of different aspects of counterfeit medicines and their involvement in continuing professional development activities would greatly enhance their contribution to combating efforts.

Our study has several strengths. The sample included pharmacists from two large health administrative zones in Alexandria. Pharmacists were addressed in their native language, Arabic. Furthermore, an interview-supported questionnaire allowed ambiguous or interesting responses to be transcribed and provided flexibility to explore relevant issues. The study limitations related to pharmacists' concerns of their rights, confidentiality of responses, the time spent to complete the interview and the nature of the study topic. Replication of the study in different parts of Egypt is recommended to test generalizability of our findings.

Conclusion

The perceptions, awareness, and practices of community pharmacists in Alexandria towards counterfeit medicines revealed deficiencies that make the current pharmacy system, legislation, and stakeholder partnership not well able to safeguard patient safety. In the current pharmacy practice environment, pharmacists need to be professionally developed as a frontline resource to actively combat counterfeit medicines. This is a responsibility most of our respondents were willing to assume. To enhance pharmacists' role in tackling counterfeit medicines, the pharmacy curriculum needs to be updated and continuing profession development activities mandated. At the same time, a national strategy to tackle counterfeit medicines is needed backed by strong legislation on drug distribution and counterfeiting. Furthermore, instituting a well-funded supreme drug authority responsible for establishing national standards for drug importation, manufacture, registration, distribution, tracking, inspection and recall would greatly contribute to preventing counterfeit medicines. Promotion of partnerships between stakeholders and collaboration with international organizations are also essential. More research should be undertaken to explore gaps in different components of the current pharmacy practice system and to document progress.

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