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A Descriptive Study on Medications Brought by Pilgrims During Hajj Seasons 2005 and 2006 in Saudi Arabia

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Abstract: Counterfeiting is generally perceived by society as a victimless crime. Counterfeiting of medicines is a particularly dangerous practice. This is not only illegal but constitutes a serious warning to public health as these drugs are not subject to safety checks. In recent years, the business level of the counterfeit medications has increased excessively worldwide. For the same reason, Saudi Arabia has assigned representatives from the Saudi Arabian Department of Customs (SADC), the Ministry of Health and Saudi Food and Drug Authority (SFDA) to inspect pharmaceuticals and herbal compounds brought by pilgrims in order to save the country from the risks of prohibited and counterfeit medication. This was a prospective descriptive observational study conducted in the pilgrim's arrival terminals of the pilgrimage city at King Abdul Aziz international airport, Jeddah for two weeks each during Hajj of 1426H (2005) and 1427H (2006). The outcome of the study indicates that most of the drugs brought were from South East Asia, India, Pakistan and African countries. About 20% of the medications inspected by the pharmacists have been rejected. Overall, results of 1426H Hajj study indicated that out of 29 samples of medications subjected to analysis, 34.4% were counterfeited however during 1427H Hajj study, out of 148 laboratory analyzed samples, 49.3% of samples were found to be counterfeited or did not meet with the specification of different international pharmacopeias.

Key words: Counterfeit medications · Hajj · Low quality medications · Pilgrim

INTRODUCTION

Every year, millions of Muslim pilgrims visit Makkah, the Muslims holy city in Saudi Arabia to perform Umrah and Hajj. In order to protect the country from prohibited medicines and health products brought by pilgrims and those who exploit the Hajj season to smuggle numerous prohibited medications, the Saudi Arabian Department of Customs (SADC) has employed number of trained staff to protect the country from such risks. The SADC in cooperation with the Ministry of Health and Saudi Food and Drug Authority (SFDA) has hired number of skilled pharmacists to work together with the customs officers. The role of the pharmacist was to identify herbal and healing medications and compounds brought by pilgrims and to ensure it safety and to prevent counterfeit medications from entering the Kingdom of Saudi Arabia. Counterfeit medications and associated risks had gained great concern since long time. The problem of counterfeit medicines was first addressed at the international level in 1985 at the Conference of Experts on the rational use of Drugs in Nairobi [1]. The first international meeting on counterfeit drugs, a workshop organized jointly by the World Health Organization (WHO) and the international Federation of Pharmaceutical Manufacturers Associations (IFPMA), was held in April 1992 in Geneva. The participants agreed on the following definition: "A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include product with the correct or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging" [2]. It is estimated that as many as 20 percent of the annual deaths from malaria worldwide may be the result of taking ineffective drugs.

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A 2001 study in the Lancet concluded that up to 40 percent of artesunate (the best medicine to combat resistant malaria today) products contained no active ingredients [3, 4]. The World Health Organization (WHO) estimates that counterfeit drugs account for more than 10 percent of the global medicines market. They are present in all regions but developing countries bear the burden of the problem. An estimated 25 percent of the medicines consumed in developing countries are believed to be counterfeited [5]. Counterfeit medicines constitute between 40 and 50 percent of total supply in Nigeria and Pakistan [6]. In China, authorities have found that some products have a counterfeit prevalence ranging between 50 and 85 percent [7]. About 36.5 percent of antibiotics and anti-malarial on WHO essential drugs list in Thailand and Nigeria are substandard [8]. A total of 192,000 Chinese patients are reported to have died in 2001 from fake drugs and in the same year Chinese authorities closed 1,300 factories while investigating 480,000 cases of counterfeit drugs worth US $57 million. In 2004, Chinese authorities arrested 22 manufacturers of grossly substandard infant milk powder and closed three factories after the death of over 50 infants [3]. Counterfeit Viagra is a worldwide problem. The University of London reported in September 2004 that half the men from England buying Viagra online are getting a counterfeit drug [3, 9]. European Federation of Pharmaceutical Industries and Associations has reported in a recent position paper that European markets have potential risk at penetration of fake drugs mainly from outside Europe [10]. Based on the above findings it was clear that significant number of the pilgrims and visitors are traveling to the Kingdom of Saudi Arabia are from different Islamic countries in which counterfeit medications are widely spread. The matter requires close control on the arrivals from such countries to ensure that counterfeit medications would not be entered into the Kingdom during Hajj season. In order to identify the capacity of the problem, this study was conducted with the pilgrims arriving through city of Jeddah to perform Hajj of 1426H and 1427H.

The main objective of the study was to create a database of medicines and health products that was being brought into the Kingdom of Saudi Arabia by the pilgrims in quantities more than their personal uses. The secondary objective was to identify the types and reasons of medicines brought by pilgrims and conduct pharmaceutical analysis on certain samples of medications to ensure their conformity with standards and specifications.

METHODS AND MATERIALS

This was a prospective descriptive observational study conducted in the pilgrim's arrival terminals of the pilgrimage City at King Abdul Aziz international airport in the city of Jeddah, Saudi Arabia for two weeks during Hajj of 1426H (2005) and Hajj of 1427H (2006). The study sample included all pilgrims arriving through the pilgrimage city and having medications or compounds in excess of their personal use. Pilgrims were initially inspected by Saudi Arabian Department of Customs (SADC) official. In case if a pilgrim brought medicines and compounds in large quantities or were suspicious then only on duty pharmacists were called to interview the pilgrims.

A special form was designed to collect information on medicines and health products including demographics information of the pilgrim, name of the medicines, strength, dosage form, quantity of the medicines, packaging, expiration date, manufacturing country and the reason to bring the medicines or health products during the Hajj. A digital camera was used to document the different types of medicines. A liaison has been made between the Saudi Food and Drug Authority (SFDA) and the Saudi Arabian Department of Customs (SADC) to give the researchers and their assistants pass tags to allow them to enter to the pilgrim's city and pilgrim's arrival terminals. Also, a liaison has been made between customs officers at the pilgrim's city and medicines clearance department of the Ministry of Health, who was in charge of clearing medications entering the country before moving its responsibility to SFDA to work jointly and use their telephones and work stations to receive notifications on the medicines and compounds requiring clearance. A sample of medicines and compounds brought in large quantities or were suspicious have been taken for analysis. The samples were stored and forwarded to the laboratories of the Ministry of Health at Riyadh for analysis to ensure its contents and agreement of the underlying specifications with the pharmacopeia. The samples have been analyzed using authentic methods reported in USP and BP. The concentrations were determined by appropriate spectroscopic and chromatographic methods. All methods were valid using reference sample provided from company to Ministry of Health laboratory. All results were entered and analyzed using SPSS.

RESULTS AND DISCUSSION

During the research period in 1426H and 1427H which lasted 14 days each year, the total number of the medicines subjected to inspection were (n=1,475) in 1426H and (n=1,468) in 1427H . The number of pilgrim's campaigns of which the medicines were subjected to inspection was 322 in 1426H. The number of medication items in each pilgrim campaign ranged from 1 to 56 with an average 4.6 medication in each campaign in 1426H.

It was observed that during 1426H Hajj, 49% of the medications were brought by male's pilgrims and 10% of the medications were brought by female's pilgrims. It was also observed that 34% of the medications were brought by pilgrims between the ages of 30 to 39 years old (Table 1).

The study also identified that during the Hajj of 1426H, 70% of the pilgrims provided the reason for bringing medicines was for the Hajj campaign, 22% explained that reason was for personal use and 8% stated that the purpose was for business. On the other hand during the Hajj of 1427H, 75% of the pilgrims explained the reason for him to bring medicines were for the Hajj campaign, while 14.5% provided reason as a personal use and 9% indicated that the purpose was for business

A list of the number of medicines or health products inspected during Hajj of 1426H and 1427H based on the pilgrim country of arrival is shown in table 2 in which Indonesia represented around 15.6%, followed by Iran (11%) and Nigeria with 9% of the total inspected medicines or health products during the Hajj of 1426H while on the other hand during the Hajj of 1427H, for the total inspected medicines or health products, Iran represented about (12.8%), followed by Nigeria (11.3%) and Indonesia (10.9%) and during Hajj of 1427H it was also found that out of 1460 items 94.6% was medicines, 3.3% were herbal products, 0.8% were sedatives, 0.4% were cosmetics and 0.3% were unknown.

During the Hajj of 1426H, it was observed that 4.13% of total inspected medicines or health products were manufactured in India, 3.25% in Indonesia, 2.77% in Pakistan, 2.16% in Iran and 0.94% in Nigeria. While during the Hajj of 1427H, it was noted that out of total inspected medicines or health products, 11.7% were manufactured in India, 9.2% in Iran, 8.2% in Indonesia, 4.8% in Nigeria and for 7.4% it was not specified (Table 3).

A list of the top 10 medicines brought by pilgrims during Hajj of 1426H is listed in table 4, out of 1475 medicines, Paracetamol (n=32), Amoxicillin (n=17), Metoclopramide (n=16), Metronidazole (n=15), Diclofenac (n=14) and Ciprofloxacin (n=12) being high in the list.

Table 1: Demographic characteristics for pilgrims with medications subjected to inspection.

Pilgrim Characteristics	Number (%)
Gender	
Male	726 (49)
Female	145 (10)
Not specified (Hajj Campaign)	604 (41)
Age	
24 – 29	16 (1)
30 – 39	504 (34)
40 – 49	265 (18)
50 – 59	68 (5)
60 – 69	10 (0.7)
Not specified	612 (41)

Table 2: The number of medicines or health products inspected based on the country of origin

Arrival Country	1426H Number (%) (N=1475)	1427H Number (%) (N=1468)
Indonesia	231 (15.6)	160 (10.9)
Iran	164 (11.11)	188 (12.8)
Nigeria	137 (9.3)	166 (11.3)
Pakistan	83 (5.6)	58 (4)
Guinea	77 (5.2)	--
India	69 (4.7)	--
Bangladesh	57 (3.9)	--
Morocco	56 (3.8)	--
Iraq	--	79 (5.4)
Kuwait	--	69 (4.7)
United Arab Emirates	--	62 (4.2)
Syria	--	54 (3.7)

Note: countries with less than 3.5% of items inspected were not included in the table

Table 3: Country of manufacture of inspected medicines

Country	1426H Number (%) (n=1475)	1427H Number (%) (n =1465)
India	61 (4.13)	172 (11.7)
Indonesia	48 (3.25)	121 (8.25)
Pakistan	41 (2.77)	33 (2.25)
Iran	32 (2.16)	135 (9.21)
Nigeria	14 (0.94)	70 (4.77)
Syria	13 (0.88)	53 (3.61)
Ghana	13 (0.88)	--
Bangladesh	7 (0.47)	17 (1.16)
Germany	7 (0.47)	24 (1.63)
France	6 (0.20)	55 (3.75)
China	5 (0.33)	37 (2.52)
Egypt	5 (0.33)	18 (1.22)
Not specified	--	549 (37.4)

Table 4: Top 10 inspected medications brought by pilgrims (1426H)

Name of medicines	Number (%) (n =1475)
Paracetamol	32 (2.16)
Amoxicillin	17 (1.15)
Metoclopromide	16 (1.08)
Metronidazole	15 (1.01)
Diclofenac	14 (0.94)
Ranitidine	14 (0.94)
Ciprofloxacin	12 (0.81)
Betamethasone	11 (0.74)
Ibuprofen	11 (0.74)
Salbutamol	11 (0.74)

Table 5: Therapeutic class of medicines brought by pilgrims

Name of therapeutic class	1426H Number (%) (n =1475)	1427H Number (%) (n =1452)
Antibiotics/Anti-infective	207 (14.03)	314 (21.62)
Analgesics and antipyretics	189 (12.81)	193 (13.29)
Antacids/Antiulcer Agents and Acid Suppressants	61 (4.13)	49 (3.37)
Anti-inflammatory	53 (3.59)	73 (5.02)
Anti-histamine	45 (3.05)	42 (2.89)
Anti-hypertensives	45 (3.05)	--
Vitamins and Minerals	38 (2.57)	50 (3.44)
Anti-diabetics	35 (2.37)	39 (2.68)
Pain killers	24 (1.62)	--
Anti-asthma	22 (1.49)	--
Unknown	--	116 (7.98)

The list of the therapeutic class of the medicines is shown in table 5 and it shows that during the Hajj of 1426H, out of 1475 medicines, antibiotics (n=207), analgesics (n=189) and antacids (n=61) were the most common therapeutic classes brought by the pilgrims. On the other hand during the hajj of 1427H, out of 1452 medicines anti-infective agents (n=314), analgesics and antipyretics (n=193), unknown (n=116), anti-inflammatory agents (n=73) and vitamins (n=50) were the most common therapeutic class of medicines.

During the Hajj period 1426H, pharmacists cleared 80% of the medicines brought by the pilgrims whether for personal use or for the Hajj campaign purposes and around 20% of the medications were rejected for number of reasons including: 1) medications are prohibited, 2) the medications were in commercial quantities or in excess of the pilgrims need, 3) unidentified medications possible to be forfeited or has forbidden substances and 4) medications reported hidden in capsules or unfolded tapes. On the other hand during the Hajj of 1427H, 82.6% of the medicines were allowed to enter while 16% of medicines were rejected.

During study of 1426H Hajj, 29 medicines samples were subjected to analysis in the central pharmaceutical laboratory at the Ministry of Health which showed the following results: 1)10.3% of samples were mixed with a prohibited substance "phenylbutazone", a NSAID, which was used in the treatment of rheumatism. This substance was prohibited worldwide due to its high risk on the cerebrum and kidney and was associated with bleeding in the stomach and intestines. 2) compounds with high concentration of poisoning minerals such as leads and arsenic represent 13.8% and 3) herbal medications mixed with chemical medications such as sedatives represent 10.3% of the samples. Overall, 34.4% of all medications subjected to analysis were found to be counterfeited or did not meet the specification of different international pharmacopeias. On the other hand during the study of 1427H Hajj, 148 samples were analyzed at the central pharmaceutical laboratory of the Ministry of Health. Overall, results indicated that 49.3% of samples of drugs that have been analyzed were fake medicines or do not conform to the constitutions of medicine or toxic substances. It is also important to mention that this result doesn't reflect the personnel behavior of pilgrims from the countries under study.

DISCUSSION

The study is considered to be the first of its kind to be conducted in the Kingdom of Saudi Arabia on medications brought by pilgrims during the Hajj season. The study indicated that during the Hajj season, most medicines or health products were brought from Indonesia, Iran, Nigeria, Kenya, India and Pakistan. During the study it was also identified that most of the medicines or health products brought by the pilgrims during the Hajj season were manufactured in India, Iran, Indonesia, Nigeria and Pakistan. Reports have shown that the prevalence of substandard and counterfeit drugs is higher in countries where drug regulation is ineffective, for example in Asian and African countries [11]. The problem is more pronounced in countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement is weak [12]. India has been identified as one of the producers and distributors of counterfeit drugs worldwide along with other African and Asian countries [13].

In this study, it was noted that antibiotics, analgesics, antacids and vitamins were the most common therapeutic classes of medicines brought by the pilgrims during the Hajj season. A WHO survey of counterfeit medicines reports from 20 countries between January 1999 and October 2000 found that 60 percent of counterfeit medicines cases occurred in poor countries and 40 percent in industrialized countries. The largest numbers of reports are related to antibiotics, antiprotozoals, hormones and steroids [14].

In this study, 20% of the medicines and herbal products inspected by the pharmacists have been rejected for number of reasons included commercial quantities or in excess of the pilgrims need, or unidentified medications possible to be forfeited or has forbidden substances.

During this study, samples of medicines and herbal products have been subjected to laboratory testing in order to identify their real contents and validity for human use. Overall, results of 1426H Hajj study indicated that out of 29 samples of medications subjected to analysis, 34.4% were counterfeited however during 1427H Hajj study, out of 148 laboratory analyzed samples, 49.3% of samples were found to be counterfeited or did not meet with the specification of different international pharmacopeias.

The duration of the study was very limited, however, preliminary and significant information were provided. The information will enable the SFDA and other regulatory agencies to set out efficient control system to deal with the medications brought to the Kingdom during the Hajj season. The study clearly showed that based on a constructive and positive cooperation between the SFDA and the Customs Authority, the Kingdom could be protected from the risks of counterfeited and low quality medications.

CONCLUSION

Throughout the study, a database and a picture gallery was created on medications brought by pilgrims. This effort would assist the SFDA to trace the medications during the upcoming Hajj seasons and help to educate the staff by using pictures and statistics.

Based on the finding of this study, it was suggested to perform similar studies in the coming Hajj seasons. The duration of such studies should include the whole duration of Hajj and should cover all ports of entry. Future studies should increase the number of medications samples subject to analysis. The SFDA should set the policies and procedures that will help to prevent the entry of counterfeit medications into the Kingdom of Saudi Arabia. The SFDA should also educate the public and pilgrims from the risk of counterfeited and low quality medication.

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