Substitution of Foreign Prescribed Medicines by Community Pharmacies in Palestine: A Legal and Pharmaco-Economic Analysis

تبديل وصفات الأدوية الأجنبية في صيدليات المجتمع في فلسطين در اسة قانونية صيدلانية اقتصادية

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Abstract

The purpose of this study was to asses the rate and the trend of foreign drug substitution by community pharmacies in Palestine, and to analyze the legal issues influencing prescription substitution such as physicians' acceptance. The study was made on a randomly selected list of foreign drugs. A total of 1425 prescriptions from twenty community pharmacies were analyzed for foreign drug substitution. The substitution rate was 25.8%. More than 58% of these substitutions were agreed by the prescribing physician. The most commonly substituted drugs were those that have a price difference compared with the local product equivalents. This study shows that foreign drug substitution in Palestine is common and mostly encouraged by patients to reduce prescription costs. This study also, shows that there is a need to modify the existing pharmacy practice law regarding brand name substitution.

ملخص

هدف هذه الدراسة هو تحديد وقياس معدل تبديل الأدوية الأجنبية في صيدليات المجتمع في فلسطين وتحليل النواحي القانونية والإقتصادية لعملية تبديل الأدوية، لقد تمت هذه الدراسة على قائمة عشوائية من الأدوية الأجنبية حيث تم تحليل ١٤٢٥ وصفة تم جمعها من ٢٠ صيدلية مجتمع وتمت دراستها من حيث تبديل الأدوية الأجنبية الموصوفة. النتائج أشارت الى أن معدل التبديل للأدوية الأجنبية هو ٢٠٠% حيث كانت أكثر من ٨٥% من عملية التبديل تتم بموافقة الطبيب الذي وصف الدواء. أكثر الأدوية الأجنبية هو ٢٠٠ التي يكون فارق السعر بينها وبين البديل المحلي كبير جداً. هذه الدراسة تشير الى أن عملية تبديل الوصفات التي يكون فارق السعر بينها وبين البديل المحلي كبير جداً. هذه الدراسة تشير الى أن عملية تبديل الوصفات المجنبية شائعة في صيدليات المجتمع في فلسطين وأن هذه العملية مقبوله للمريض حيث أنها تخفف من أعباء اسعار الدواء. كما أن هذه الدراسة تشير الى الحاجة لتعديل قانون مزاولة المهنة الفلسطيني بحيث يسمع ويشجع

Introduction and Aims

According to the Palestinian pharmacy practice legislation, community pharmacists are not permitted to change or substitute prescribed medicines without the written consent of the prescribing physician ^[1]. In Palestine, there several pharmaceutical companies producing a wide range of are pharmaceuticals. In addition, the local market is open to many foreign pharmaceutical companies that were functioning before the Oslo accord. An extensive comparison of the prices of pharmaceutical products in the Palestinian market showed two things. First, the locally produced pharmaceuticals are cheaper than their foreign counterparts. For example, Glucocare® (Glibenclamide) tablets produced by Pharmacare is sold to the customers at a price of 1.5 USD per 30 tablets, while Daonil® (Glibenclamide) tablets produced by Hoechst is sold at 3.5 USD per 30 tablets. This is due to several reasons. Among which is the cheap labor in West-Bank. Second, the profitability margin of locally produced pharmaceuticals is higher than that of their foreign counterparts in most of the cases. This might be attributed to the bonus policy given to community pharmacies by local drug companies. These two factors make the substitution of foreign pharmaceutical products with local counterparts good for the patient, the community pharmacists, the local drug companies and thus the national economy if quality is assumed to be the same for both products. Studies in other countries like USA have shown that drug substitution reduce prescription costs up to 9.9% ^[2]. However, substitution increases the legal liabilities of the dispensing pharmacist and might increase the doctor's dissatisfaction ^[3]. A study conducted in Canada indicated that for some drugs, particularly those with a narrow therapeutic index, the possible increased side effects and morbidity could partially offset the cost savings^[4]. In some European countries like Norway, substitution is allowed by law, but only for drugs imported from other countries i.e. parallel substitution.

This study aims at finding the categories of foreign medicines that are most commonly substituted and whether substitution was done by prescribing physician consent or not. The study will ultimately help the legislatures and MOH policy makers to appreciate the health, economical and legal impact of drug substitution on the patients and the Palestinian pharmaceutical practice.

Method and Design

Twenty community pharmacies in Palestine accepted to participate in this study, which took 5 months to finish. The participating pharmacies were:

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Al-Rahma, Ameed, Ayman and Modern, Hebron pharmacies in Qalqilia and Hebron. Saleh, Sufian, Rami, Saaed, Abu-Baker, Tubas, Raaft, Ebn Sena, Shefa and Al-Razi pharmacies in Nablus and Genin area. Samaer, Khaled, Modern, Ghazaleh, International and Raed in Ramallah and Jerusalem area.

All pharmacies contributed equally in the study. The patients were told and agreed to the substitution despite their doubts of un-equal quality between the two brands. Each community pharmacy was asked to collect and record data regarding substitution of prescribed medicines listed as in the Table one (table 1). For each substitution, the pharmacist was asked: (1) to record the number of prescriptions in which he made the substitution, (2) to record the total number of prescriptions of that particular drug he/she is dispensing per day, (3) to cite the reason(s) for substitution and (4) to cite whether he /she took the consent of the prescriptions physician or not. A total of 1425 prescriptions were reviewed from 20 community pharmacies that were selected at random. The collected data were analyzed using Excel program to obtain the results.

Results

1. Rate of substitution of prescribed medicines

The data collected from 1425 prescriptions showed that substitution of prescribed medicines do occur for all tested products. The substitution rate by pharmacies, which is the rate using the total number of prescriptions as the denominator was 25.8%. The data showed that substitution occur most frequently with Agiserc ® (Betahistine) and least frequently with Prozac ® (Table 1).

Drug	Total Number of Prescriptions in 5 months	Number of prescription that were substituted.	Percentage of Substitution.
- Actifed ® Syrup (Triprolidine, Pseudoephedrine and Dextromethorphan HBr)	164	46	28%
- Ventolin ® Syrup (Salbutamol)	198	67	34%
- Daktacort ® Cream (Miconazole HCl, Hydrocortisone)	201	32	16%

Table 1: Prescriptions collected and substituted with local pharmaceuticals at Al-Rahma Pharmacy

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			Continue table (1)
Drug	Total Number of Prescriptions in 5 months	Number of prescription that were substituted.	Percentage of Substitution.
- Zantac ® Tablet (Ranitidine)	43	11	26%
- Voltaren ® Tablet / Supp. / Amp. / Emulgel (Diclofenac Sodium)	289	59	20%
- Keflex ® Capsule (Cephalexin trihydrate)	82	28	34%
- Flagyl ® Tablet / Suspension. (Metronidazole)	79	13	16%
- Prozac ® Tablet. (flouxetine)	32	3	9%
- Convertin ® Tablet (Enalapril)	59	1	1.5%
- Gyno-Daktrin Vag. ® Cream / Ovules. (Miconazole)	147	42	29%
- Lacromycin Eye ® (Chloramphenicol)	77	18	23%
- Agiserc ® Tablet (Betahistine)	54	22	41%

Analysis of the data shows that 42% of these substitutions were made without consent of the prescribing physician. The community pharmacists claimed that they routinely substitute some drugs without the precriber's consent.

The prices of the foreign prescribed medicines and their local counterparts are seen in Table 2.

Table 2: Differences in prices between local and foreign prescribed medications as calculated at the Al-Rahma Pharmacy

Drug	Price in USD	Local Equivalent	Price in USD
- Actifed ® Syrup (Triprolidine, Pseudoephedrine and Dextromethorphan HBr)	2.5	Pulmadrin ®	1.3
- Ventolin ® Syrup (Salbutamol)	2.7	Ventocare ®	1.4
- Daktacort ® Cream (Miconazole HCl, Hydrocortisone)	8	Micocort ®	4
- Zantac ® Tablet (Ranitidine)	10	Dactazole ®	3

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			Continue table (2)
Drug	Price in USD	Local equivalent	Price in USD
- Voltaren ® Tablet / Supp. / Amp. / Emulgel (Diclofenac Sodium)	10	Rufenal ®	2
- Keflex ® Capsule (Cephalexin trihydrate)	12.5	Cephacare ®	6
- Flagyl ® Tablet / Suspension. (Metronidazole)	5	Entogyl ®	3
- Prozac ® Tablet. (flouxetine)	16	Fluxicare ®	10
- Convertin ® Tablet (Enalapril)	20	Anapril ®	7
- Gyno-Daktrin Vag. ® Cream / Ovules. (Miconazole)	11	Gyno- Daktazole ®	8
- Lacromycin Eye ® (Gentamycin)	3.5	Genticin ®	1.5
- Agiserc ® Tablet (Betahistine)	17	Betastin ®	10.5

2. Reasons cited for substitution

The reasons cited for substitution were summarized in Table 3. The economical and patient factors were the driving force for most substitutions (>63% of the cases). The availability was also an important factor especially during the "Intefada" where the marketing activities of some foreign drug companies have been reduced.

 Table 3: Reasons cited for substitution

Cited Reason For Substitution	Percentage
The prescribed drug is not available.	31%
The patient is asking for a cheaper substitute.	43%
More profitable substitution.	20%
Other reasons.	6%

Discussion

Substitution of foreign prescribed medicines with locally produced ones is economically good for both the patient and the pharmacist. This assumption is made upon the price and margin of profitability of the local products compared to the foreign ones. For example, the price of Daonil® (Glibenclamide) tablet is 9 USD compared to 1.5 USD Glucocare® (Glibenclamide) tablet. Among the tested drugs, Agiserc ® (Betahistine) was the most commonly substituted. It

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might be the large price difference between the local product (Betastain ® (Betahistine); 5 USD per 20 tablet) and the foreign product (Agiserc ® (Betahistine); 10 USD per 20 tablets). Other products which are commonly substituted because of large price difference is the antibiotic Keflex ® (Cephalexin) (14 USD per 16 capsules compared with up to 6 USD for the local products). The least substituted drug product among the tested list was Prozac ® and Convertin ® (Enalapril). Both products are prescribed for serious illnesses and it sounds that product quality and therapeutic outcome is a big concern for both the prescribing physician and the pharmacist regardless of the price difference between the foreign and local counterpart product.

Substitution of prescribed medicines by community pharmacists is encouraged due to the political atmosphere in Palestine, which strongly supports local industry and calls for the boycott of some foreign products. Furthermore, the political instability makes it very hard to make available all the foreign drug products due to military interference in Palestine. Furthermore, the low income, the poor national economy and the lack of national health insurance coverage in Palestine encourages some patients to ask for less expensive substitutions which in most cases are encouraged by the practicing pharmacist. Substitution is certainly not the good way of solving the cost problem. A better communication and relationship between doctors and pharmacists and their common research of the most appropriate prescription should be a successful approach. It should increase the patient's compliance. Actually, the lack of prescription compliance according to all observers is a major issue ^[5]. An important drawback of substitution is the fact that some patients could find changes in appearance of their medication confusing and thereby resulting in a reduction of the compliance. Finally, although the bulks (58%) of substitutions were made by obtaining the consent of the prescribing physician, still there is a good percentage of substitution (42%) occurs without consent.

Generic instead of brand name of prescribing drugs might decrease the conflict between the prescribing physician and community pharmacies regarding substitution and thus cost reduction on the behalf of the patient. Unfortunately the share of generic medicines is very low in the Palestinian market. Palestinian legislatures need to modify the existing legislation regarding substitution of prescribed medicines. The suggested legislation is to achieve savings in the prescription costs and encouraging pharmacists to dispense less costly, generically equivalent products. For this legislation to be effective there have to be many substitutable products for a sufficient number of drugs; there has to be minimal interference with pharmacists' judgment; and pharmacists

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must be aware of the products available. This modification in pharmacy practice legislation should allow substitution of prescribed foreign medications without consent of the prescribing physician.

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