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Research article

The switch from patented medicine to the generic one: an option or a necessity?

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Abstract

This paper assesses the influence of a number of factors taken into account when a brand name drug is replaced by a generic one. It also evaluates responses of health professionals – physicians and pharmacist—and patients regarding the issue of switching. We compared and contrasted their responses in order to identify new points of cooperation for the intended benefit of the patient. Thus, the sample drew from all three groups, consisting of 50 doctors, 50 pharmacists, and 50 patients. We collected information regarding the age, residence, income level, and education level for the patients, and age and experience for the specialists. Based on responses to the survey, replacing the original medication with a generic one raises many issues, such as lack of information for the patient and specialist, lack of collaboration between physician and pharmacist, ineffective communication between specialist and patient, and the influence of the overall profit motive.

Keywords : health professionals, pharmacists, brand drugs, generic drugs, patented medicine

Highlights

- ✓ This paper concludes that the switch between original medication with a generic one is rather a necessity than an option.
- ✓ The pharmaceutical market is currently confronted with some deficiencies related to information and/ or collaboration between physicians, pharmacists and patients.

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Introduction

The prescribing, dispensing, and purchasing of drugs are influenced by many factors, and sometimes attempts to find the best approach can affect the relationship between physician/pharmacist and patient, the one who should be the primary beneficiary of health services (1).

The switch from brand name to generic medication is increasingly encountered in the current, fluctuating pharmaceutical environment, one that is continuously changing due to changing economic and social conditions. At the same time, many original medications have lost their patent/license, with a consequential disappearance of the original medication and increased reliance upon generic drugs (2).

The original formulation is initially discovered and developed by a pharmaceutical company, and once approved for marketing, the company can market and sell the "original" product exclusively under patent to recoup funds for research and development and to net profit.(3). Current studies estimate that bringing a new drug to market incurs an average cost of 802 million US dollars over a period of 10 to 15 years (2, 3).

Once the license for a particular product expires, it is eligible for conversion into a "generic medicine." Because the generic drug may differ in color, taste, shape, inactive ingredients, preservatives, and/ or packaging, generic manufacturers are usually required to submit additional documents to the regulating authority to demonstrate that their drug is manufactured in compliance with good manufacturing practice, that it is as pure and stable as the original drug, and that bioequivalence tests show the same pharmacokinetic parameters within the body, that is, it must dissolve and be absorbed at the same rate and to the same extent as the original product. Specifically, the generic form must act the same as the patented drug via the same mechanism, and it must also follow the same pattern of absorption, distribution, metabolism, and elimination from the body (3, 4).

However, replacing the original drug with a generic form is a difficult choice, in some cases, for both the physician and patient, on the assumption that the generic drug may not offer the same quality as the original preparation, as reflected by its lower price. The lower price, of course, is explained by the fact that the manufacturer of the generic drug requires no investment in clinical research and marketing of the new product. In addition, the fact that many pharmaceutical companies produce generics leads to competition and lower prices (3). At times, patients complain of increased incidence of side effects when switching to a generic drug, and therapeutic ineffectiveness is often reported by patients to the physician or the pharmacist. However, the lack of pharmacovigilance reports and an increased number of research studies demonstrate no significant differences in the effectiveness of generic medicines (5, 6).

Ongoing information regarding the comparison of original and generic drugs is essential for physicians when choosing to prescribe either the generic vs the brand name medication, as the physician can take into account the therapeutic effectiveness/ineffectiveness and safety profile of each (6). A better understanding of issues facing the pharmaceutical market, including the unavailability of the original brand name medications, and ongoing collaboration between physician and pharmacist could mitigate patient concern about acquiring the recommended drug. Other issues such as stabilizing the patient with a particular treatment, ensuring adherence to the prescribed medication, and consideration of the patient's financial situation should not be neglected. However, campaigns conducted to promote various generic drugs, along with close relationships between the physician/pharmacist and medical representative, could result in the use of medications that are not optimal for treating the patient's needs (7, 8).

Pharmacists are the final link in the chain requiring well-regulated drug dispensing rules, but the current financial problems (delayed payments by the National Health Insurance House or the pharmacy economic profit) may compromise ethics (1). For example, patients' access to information about medicines through media and their financial limitations may lead them to pressure their pharmacist, frequently requesting certain drugs without first consulting with their physician or health specialist (9).

The aim of this study was the quantitative analysis of the responses of health professionals—physicians and pharmacists—and patients on factors that influence the switch from an original medication to a generic one. We also conducted a comparative analysis of the responses of patients, physicians, and pharmacists with the hope of improving the relationships among these three groups so as to obtain greater benefit for the patient.

Materials and Methods

The study was conducted in Bucharest and the surrounding vicinity between January 2016 and May 2016 by distributing questionnaires about generic and brand name drugs to healthcare professionals and the non-healthcare general public. The sample included

three groups: 50 doctors, 50 pharmacists, and 50 patients, taking into account various inclusion and exclusion criteria (Table I).

Patients	Healthcare professionals
Inclusion criteria	**Inclusion criteria**
- Age over 18 - Romanian citizen - People who wanted to take part in this study	- People that are practicing their job (physicians and pharmacists) - People who are practicing medicine in Bucharest or the counties/ cities/towns nearby - People who wanted to take part in this study
Exclusion criteria	**Exclusion criteria**
- Psychiatric disorders that do not allow the proper filling of the questionnaire - Illiteracy - People who did not want to take part in this research	- People who did not want to take part in this research - People who do not practice their profession even if they have specialized studies

Table I. Criteria for inclusion and exclusion for the sample in this research

The instruments were three different questionnaires, one for each type of participant: physician, pharmacist, and patient.

Fifty patients completed a questionnaire which collected information about age, residence, education level, and income level, along with 8 additional items used to assess patient behavior. These included:

1. The difference between original and generic drug (if they did not know, they were informed when given the questionnaire).

2. The observed differences in health status after switching from the original drug to the generic one.

3. The effective use of generic drugs in their treatment.

4. The primary source of information to be taken into account when purchasing medication.

5. The importance of medical advice when buying medicine.

6. The influence of the drug's cost when choosing between an original and generic medication.

7. The problem of failing to purchase a specific drug that the patient is using in their treatment.

8. Whether the switch from the original prescription to the generic one is based on the recommendation of the specialists or on other sources of information.

Fifty physicians were included in this research. In addition to information about age, experience, and type of speciality (medical or surgical), eight items were used to assess their behavior:

1. The differences between an original drug and a generic one.

2. The therapeutic efficacy and incidence of adverse reactions of the original vs. generic drug.

3. The safety profile of a generic drug.

4. The previous medicines given to their patients and their efficacy.

5. The financial situation of the patient and guidance to use generic drugs.

6. The relationship with the medical representative and its influence when choosing to prescribe a certain medication.

7. The cooperation with the pharmacist when specifying or switching from the original drug to the generic one and their knowledge about the lack of medicines in the market.

8. The previous experience concerning patient attitudes regarding the use of the generic drug.

Finally, 50 pharmacists completed a questionnaire. In addition to age and experience, seven items were taken into account to assess their attitudes.

1. The differences between an original drug and a generic one.

2. The therapeutic efficacy and incidence of adverse reactions of the original vs. generic drug.

3. Previous experience concerning the patient's preferences regarding the use of an original vs. generic drug.

4. The importance of the physician's recommendation when dispensing the medical prescription and the previous treatment received by the patient and its efficacy.

5. The influence of the patient's financial situation when administering the original medicine and their counseling on alternatives to original medicines.

6. The relationship between the medical representative and the pharmacy's financial profit, and influence of these factors on drug release.

7. The lack of original drugs in the pharmaceutical market, the impact of this lack, and how the relationship between the pharmacist and the patient is affected.

Results

The quantitative analysis of the answers given by the evaluated people

The patients who answered this questionnaire were 24 to 73 years old (average = 38 years), predominantly living in an urban environment (84.3%), with a monthly income between 1000-2000 lei (51%). 64.7% were university graduates, 17.6% high school graduates, 15.7% postgraduate degree holders, and only 2% college graduates. Of the total patients, 83.7% knew the difference between original and generic drugs, and 60% considered that significant differences appear after switching from the original drug. 65.3% of patients found that the generic drug was not as effective as the brand name drug. 83.7% believed the physician to be the most important source of information, 51% the pharmacist, 8.2% other people's recommendations, whereas only 2% were influenced by media. Most patients heeded the guidance the physician's orders much (50%) to very much (48%), and only 2% of them less. Patients also considered that the cost of the original drug was an essential factor when choosing between original drug and generic drug (58.3%), 54% had experienced at least once a problem with the purchase of an original drug and 46% had ever encountered such a situation. 64.3% indicated that the switch from the original drug to a generic one was influenced by pharmacists, 25% by physicians, and 10.7% by other factors not related to specialists.

The physicians who participated were 25 to 50 years old (average = 32 years), with experience in the medical field of less than a year (23.1%), between 1 and 5 years (38.5%), 5-10 years (7.7%) and 10 years or more (30.8%). Their speciality was medical for 84.6% and surgical for 15.4%. All physicians were familiar with the concepts of original vs. generic drug and the differences between them. According to physicians, there are differences between therapeutic efficacy and incidence of side effects of the original vs. generic drug, 53.8% of them responding positively to this item. Also, 61.5% believed that the original medicine presents a better safety profile. All physicians took into account the treatment previously administered to the patient and its efficacy, but 53.8% did not take into account the patient's financial situation when prescribing a new medicine. Regarding previous experience, 69.2% answered that patients were reluctant to use the generic medicine. 76.9% responded that their relationship with a medical representative did not influence their prescribing, but 23.1% indicated this as very important. 38.5% of the physicians cooperated with the pharmacist when they prescribed a patented drug or a generic one, but a significant percentage of 61.5% did not have any connections with the pharmacist. 62.5% of the physicians were aware of the lack of original medicines in the pharmaceutical marketplace, but this did not influence them to prescribe generic drugs.

Pharmacists were 24 to 50 years old (average = 28 years), with experience in the pharmaceutical field mostly between 1 to 5 years (44.9%) or less than one year (40.8%). Pharmacists understood the concepts of original and generic drug and the differences between them. According to 89.9 % pharmacists, there are differences between the therapeutic efficacy and incidence of side effects for the original vs. generic drug. Regarding previous experience, 67.3% of pharmacists noted that patients prefer the original drug. All surveyed pharmacists advised patients on alternatives to the original drugs, but 20.4% did not consider the recommendations made by the patient's physician. 95.9% of pharmacists took into account the financial situation of the patient, and they guided them to alternatives that they could afford. The previous treatment used by the patient and its efficacy were important factors that 98% of the pharmacists considered when dispensing the medical prescription. The decision when choosing between an original or generic medicine was influenced by the relationship between the medical representative and the pharmacy's financial profit only for 18.8% of the pharmacists, while 81.2% ignored this aspect. 51% of pharmacists believed that the lack of original drugs in the pharmaceutical market affected their relationship with the patient, 20.4% very much, 20.4% little and 8.2% very little.

Discussions

Comparative analysis of the responses across the three groups

The surveyed patients lived predominantly in urban areas. Most were university graduates, a fact that reflects their knowledge about original vs. generic medications, as well as their better information about the available alternatives in the pharmaceutical market. Patients were concerned about the cost difference between original and generic medications, believing that generic drugs were less effective than patented medicine and leading to a higher frequency of complaints regarding side effects. This idea was further supported by physicians and pharmacists who were not always well informed about current bioequivalence studies, with both groups believing significant differences exist between the two types of drugs, with patented medicines having a better

safety profile than the generic equivalent. Such concerns by physicians and pharmacists resulted in patients' reluctance to use a generic drug. Patients were influenced by the price of drugs, leading them to choose a generic medicine even when not convinced their choice was the best option. While this factor was very important to patients, physicians did not take into account financial implications when prescribing medicine, as they, along with pharmacists, generally believe the original drug to be more effective (10). Although the main sources of information for the patient were the physician and the pharmacist, a significant percentage took into account recommendations made by other people or by the media (11, 12). Such information may be inaccurate and could result in pressure on the physician or pharmacist to presribe less appropriate medication for the patient's particular pathology (13, 14, 15). From our results, both physicians and pharmacists took into account the treatment previously used by the patient and their adherence to the treatment, the fact that brings a real benefit for the patient, especially since, as shown in this study, patients generally listen to the physician's advice (15).

Lack of original medicines in the current pharmaceutical market was a concern for all three groups evaluated (16, 17). Although physicians were informed about unavailable products, the lack of collaboration with the pharmacist may result in the physician's prescribing a less desired medication, and thus a significant number of patients face the problem of being able to afford their treatment. As difficulty acquiring their medication increases, the patients may become less confident in the services of the pharmacist. Pharmacists responded to this dilemma, indicating it can seriously affect their relationship and collaboration with the patient (18). Pharmacists advised their patients about alternatives to the original medicines, and a representative percentage took into account the recommendations of the physician (18, 19). Given that most surveyed patients reported that the switch from an original drug to a generic was made on the recommendation of the pharmacists, and given that pharmacists generally do not collaborate with physicians, the patient-physician relationship is likely to be affected (20, 21).

Conclusions

This study presents some of the factors that influence the substitution of an original medication with a generic one. This paper concludes that this switch is often not an option, but rather a necessity. The study also highlights the problems that the pharmaceutical market is now facing, such as a lack of information for both patient and specialists, the lack of collaboration between physician and pharmacist, ineffective communication between specialists and patients, and even sometimes the financial benefits to health care professionals that places the needs of the patients as secondary when in fact, they should be the primary beneficiaries of healthcare services.

Conflict of interest disclosure

The authors declare that there are no conflicts of interest to be disclosed for this article.

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