Prevalence of the use and social acceptance of generic drugs

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ABSTRACT

The objective of this study was to point out the prevalence of generic drug use and popular acceptance in the municipality of Itumbiara-GO, besides presenting the relationship between cost and benefit, efficacy and factors that influence user acceptance. The study consisted of a bibliographic and field study, through the application of a quantitative methodology, through a structured questionnaire that was applied and a group of 50 randomly selected people. It was verified that most of the group of interviewees has knowledge about generic drugs, as well as their low costs; but reported that they receive information from unreliable sources, which state that the generic medication does not have the same efficacy as a

reference drug. The research also related that public policy actions development lives by the Ministry of Health and health professionals are mental foundations for the popularization of generic products. It was possible to conclude that the actions of dissemination and education by health agencies should be continuous, since they have the purpose of informing the community and thus, contributing to the promotion of health, especially, of the low-income population.

Keywords: drugs, health, population, low income.

1 INTRODUCTION

The drugs, para be considered generic, it is necessary that they are identical with those of reference. In addition, as far as the appearance is, the generic product needs to present the same form, the same excipients, packaging, label and shelf life. It is recommended that this drug be identified by the name of the molecule of the active ingredient, that is, by its chemical formula; and its difference from the reference medicine is by the name fantasy. The fancy name of the reference medicine is chosen by the laboratory that developed it and is therefore protected by patent laws. In addition, the reference products come from research and development and undergo clinical studies to prove their safety and efficacy, which must be documented by the supervisory body (Vieira & Zucchi, 2006).

According to Hasenclever (2004), in the mid-1990s, the questioning of putting on the agenda a legislation specifically for generic drugs, concomitant with the discussion of the new patent code, came into discussion in Brazil. Where measures were created that determined that changes in the packaging of medicines were necessary. Decree No. 793 of 1993 began to impose that all drugs marketed would need to contain the chemical name on their packaging, so it would help to increase the level of information for physicians, especially, so that they could be aware of the most appropriate medication at the time of prescription.

Through Law 9,787, sanctioned in the national congress, generic drugs began to be officially legalized, and can then be produced and marketed. At the same time, the National Health Surveillance Agency (ANVISA) was also created, which is a government agency, under special regime, whose activities cover all sectors of the economy related to products and services that can directly affect the health of the Brazilian people (ANVISA, 2012).

Since then, the federal government has started to promote policies for the implementation of generic drugs, due to the acceptance of the population, in order to facilitate access to low-cost drugs with proven quality. The federal government begins to adhere to a national generic drug policy mainly following a guideline aimed at promoting the rational use of medicines, which involves the prescription, production, dispensing, use of generic drugs and the guarantee of good quality; with the objective that the entire population had access and that health professionals, as well as those responsible for dispensing,

which are pharmacists, were actively participatory in disseminating the subject (Utzig cited by Oliveira, 2009).

Since the creation of the generic drugs law in Brazil, a certain prejudgment is observed, which may have originated at the time of approval, when part of the legislative assembly was against the creation of the law. The subject was treated with prejudice, which may have contributed to the one that nowadays, a portion of the population that has no information and understanding about it, has some fear in acquiring the generic drug for therapeutic purposes. Other influences that may impair the image of the generic drug are also discussed. Therefore, it is of paramount importance to inform the benefits of the generic product as well as its effectiveness (Hasenclever, 2004). Thus, this study is justified by the need to clarify the factors that influence the lack of knowledge about generic drugs, as well as their resistance to their use. It is likely that the low cost of generic drugs and federal government campaigns influence the acceptance of the population for generic drugs, to the detriment of reference drugs.

The present study aimed at pointing out the prevalence of generic drug use and popular acceptance in the municipality of Itumbiara-GO, besides presenting the relationship between cost and benefit, efficacy and factors that influence user acceptance. Specifically, the objective was to verify the popular knowledge about the quality of generic drugs, identify difficulties in accepting generic drugs and point out what are the main advantages of generic medication.

2 METHODOLOGY

2.1 BIBLIOGRAPHIC SURVEY

First, a descriptive bibliographic research was carried out, of qualitative and exploratory nature before scientific databases Scielo, Google Scholar, Medline and Lilacs, with the purpose of obtaining greater knowledge about generic drugs, that is, to determine when they were implanted, to raise what are their benefits for the population and verify if the population is aware of its effectiveness. For the search, the time frame of publication was performed from the 2000s, using the following keywords: drugs, generics, prescription, health, public and legislation. Articles addressing the theme of the use of generic drugs and their social acceptance were included in the study.

2.2 FIELD STUDY

The study was conducted through a quantitative methodology, through a structured questionnaire to verify the degree of information of the population about the generic drug, the cost-benefit ratio of use, the therapeutic efficacy and the popular acceptance of generic medications. According to Godoy cited by Neves (1996), quantitative research, instead of decoding complex themes of meanings, is efficient to

measure objective data, such as the information that the population has regarding generic drugs. These factors can only be studied by means of scales, that is, by quantification.

The research was carried out in the city of Itumbiara-GO, located in the southern region of the State of Goiás. To implement the application of the questionnaire, a contact was made with 50 people before the application of the questionnaire in order to inform them about the objective of the research.

The study population consisted of 50 participants and aged over 18 years, being of any gender, schooling, monthly income and social class. The research was carried out at the participant's residence, according to their availability of time and through a previous contact to schedule the interview. The interviews were conducted in an environment restricted to noise sands and interventions, so that there was minimal interference in the results of the research.

For data collection, a structured questionnaire was developed with 10 questions and with only one alternative as an answer. A Free and Informed Consent Form was elaborated, containing explanations about the research objectives. The participants were presented with the Free and Informed Consent Form, and after the participant's agreement and the signing of the term, the questionnaire was applied and the information collection was then analyzed and the research was completed. The structured questionnaire was used to investigate whether the participant had knowledge about the importance of the generic drug, its efficacy and its benefits. The interview was conducted using a table, two chairs, pen and questionnaire. The materials were prepared before the application of the questionnaire, making the participation of the importance of the research to obtain consistent data.

The participants were presented with a Free and Informed Consent Form to demonstrate all ethical aspects. The data of the questionnaire were submitted to total confidentiality, not citing names in the final result of the research, preserving the image of the participants. The questionnaire was applied individually in the residence of each participant, being present only the participant and the interviewer.

3 RESULTS AND DISCUSSION

3.1 BIBLIOGRAPHIC SURVEY

Generic medicines are identical to those of reference, which can be proven through studies of pharmaceutical equivalence *in vitro* and bioequivalence *in vivo*, by matching the results of clinical trials of safety and efficacy of the referenced product (Rumel et al., 2006).

According to Dighe quoted by Storpirstis et al. (2004), pharmaceutical technical development is the manufacturer's sector that has the function of formulating products with patent expiration, thus needing to follow and comply with the pharmaceutical equivalence specifications of the reference product. It is acceptable that the formulation and manufacturing process are not identical with respect to the innovative medicinal product, as it should be considered that the equipment and suppliers of raw

materials used do not necessarily need to be the same among manufacturers, but such differences cannot influence the bioequivalence between the products.

> "Generic Medicine" should be written on the generic packaging on the packaging of generics on a yellow stripe. In addition, it must be included in Law No. 9.787/99. As generics have no brand, what you read on the packaging is the active ingredient of the drug. The price of the generic drug is lower, because manufacturers of generic drugs do not need to make investments in research for its development, since the formulations are already defined by the reference drugs. Another reason for the reduced prices of generics concerns marketing. Its manufacturers do not need to advertise, because there is no brand to be disclosed (De Paula et al., 2009, p. 01).

The legal period of patent protection is twenty years, counting from the date of issuance of the research deposited to the competent body responsible for making it valid. The process of developing the study is added to the patent time, that is, they are years of research initially going through the phase of pre-clinical, clinical and government approval tests, with this leading companies running against time for their innovative products to enter the market as soon as possible, so that they can obtain financial return, because once the patent protection period has expired , will be exposed to competition from generic and similar medicines (Capanema & Son, 2007).

According to Rosenberg (2010), reference drugs require major investments, because they are unique and derived from research and development, are protected by patents, and necessarily legalized by the responsible and regulatory body that carry out a strict control to verify their quality, bioavailability, safety and efficacy, that in Brazil the body responsible for this function is ANVISA (National Agency of Sanitary Surveillance). This agency has issued a series of decrees and ordinances to enable the production, dispensing of generic drugs, registration and prescription, directing the course of implementation of drug policies in Brazil (Carvalho et al., 2006).

For ANVISA (2012), line medicines go through a process that goes from when they are considered R&D products, later introduced to the market, being able to emerge because it is an innovation and then may suffer a fall in income due to the emergence of new technologies. All these steps are supervised and regulated by ANVISA, The National Agency for Supplementary Health (ASN) and the National Commission for the Incorporation of Technologies in SUS (CONITEC), all of which are government agencies linked to the Brazilian Ministry of Health.

For a generic drug to be pharmaceutical equivalent it is necessary that it presents the same active ingredient, in the same amount, the same pharmaceutical form, and may or may not contain the same excipients, fulfilling the specific actions described in the Brazilian pharmacopoeia. After bio availability, the evidence is made by comparing the test drug and the reference drug, being analyzed through a curve (ASC) of plasma concentration as a function of time. Thus, it is possible to evaluate whether the time and extent of the absorption of the products compared are equivalent (Araújo et al., 2010).

According to Dias (2006), the publication of Resolution No. 391 attributed the implementation of the generic law to the Ministry of Health and allowed interchangeability with the reference product, which directly contradicted the Brazilian Pharmaceutical Industry Association (ABIFARMA). ABIFARMA, in turn, immediately informed doctors and pharmacies that at no time the pharmacist could exchange a generic drug for reference under penalty of heinous crime, generating protest at that time by the Federal Council of Pharmacy and the Association of National Pharmaceutical Laboratories (ALANAC). Therefore, not stopping there, ABIFARMA ended up launching advertising campaign so that the population would not accept the improper replacement of medicines in pharmacies. In addition, it sent the prescribers stamps not to prescribe generic. After all this discussion, ANVISA responded to the outrage by reaffirming the proposal for the implementation of generic drugs in Brazil.

According to Araújo (2010), many physicians do not recommend this type of medication, which leads patients to acquire brand-name drugs, usually 50% more expensive. A survey conducted last year by the Brazilian Consumer Protection Association (Pro-Test) showed that 46% of the medical class have doubts about the efficacy of generics, and that 42% do not have the habit of prescribing this drug.

The interpretation of the generic word may be one of the barriers that negatively influences the image of the drug because the meaning it represents is of a parallel product without quality or with dubious quality and with low price. This leads consumers to suspect its quality, efficacy and safety (Carvalho et al., 2006).

It has been almost 14 years since the sanction of Law No. 9,782, of January 26, 1999, which creates and officializes or generic drugs. It is noticeable that part of the well-understood population knows and buys with conviction the generic drug. However, a large part of the population, especially those located in places where resources are remote, do not know the purpose of the generic drug. It is of paramount importance that health professionals clarify the population. Since the creation and regularization of generic medication, much has been discussed about it. However, the most important is to bring information necessary for the population to have access, raising awareness, what is the generic drug and how important it is for health promotion (ANVISA, 2012).

It can be seen that there has been an improvement since then, due to much work by the government, pharmaceuticals and the pharmaceutical industry. It is noticeable that there is a little more lack of the medical class for the promotion of generic medicine to be concrete, because if there was a union of health professionals, the answer to acceptance and understanding about the generic drug would achieve its goal, which is not only cost/benefit, but that awareness leads to improvement in quality of life improving the health of the population (Carvalho et al., 2006).

In so way that the population has been aware of the situation since Law No. 9,782 was sanctioned, the Government of Brazil has been working to bring information about generic drugs.

> Generic policy has been one of the main governmental tools to expand access to reliable medicines for the population as a choice. Once the patent has expired, the introduction of products based on the original but unbranded medicinal product contributes to increased competition and reduced information asymmetries in the medicinal product market. Moreover, as the associated laboratories, when performing bioequivalence and bioavailability tests and implementation of a campaign to clarify its meaning, the emergence of generics would serve to make doctors and patients informed and increase the demand for alternative products to the reference drug (Hasenclever, 2004, p. 04).

The stimulation of competition is a factor of great importance, since it generates an increase in the competitiveness of the market, thus benefits the consumer so much that will have extensive options for choosing interchangeable products with proven quality and effectiveness and affordable price. As for the manufacturer, although generic drugs have the name of the active ingredient as the standard, the consumer will show the reliability and reputation of the company (Carvalho et al., 2006).

According to Barros cited by Monteiro et al. (2005), the policy of generic drugs when it is proven to be installed, should be taken very seriously and professionally. In this way, it is possible to strictly respect quality control, enabling medicines with excellence in quality, with reliability in safety and efficacy. In to prove these characteristics, it is necessary to prove it through bioequivalence and pharmaceutical equivalence tests, adding all this at a price accessible to the consumer, being true the possibility of this sequence of events due to the fact that generic drugs do not require high investments in research and dissemination in the media.

In order for these policies to achieve the main objective of informing the consumer/patient that the generic drug is reliable, pharmacists to promote interchangeability and physicians who are prescribers, are the main informants to spread this guidance. The pharmaceutical professional is essential for these marketing and advertising policies promoted by the government to bring the expected results. Being able to raise awareness and clarify whatever the patient's doubt, with regard to policies to promote generic drugs, knowing that all this is for the benefit of the population and improvement in quality of life.

For Carvalho et al. (2006), the main focus and the impact that generic drug policy has addressed, should not be taken into account only the influence of price in the pharmaceutical sector, but of being a timely way to outline a plan for an innovation in pharmaceutical care and care, assuming that the role of the pharmacist is crucial in promoting drug policy mainly in the social sphere.

According to Blatt et al. (2012), the Brazilian Association of Generic Drug Industries clarifies that generics are 35% cheaper compared to innovators and the research results can be observed in different studies, thus reinforcing the importance of the implementation of generic drugs in Brazil and attesting that it provides an average reduction in drug costs.

> According to Ordinance No. 3,916/GM (Brazil, 1998), the Brazilian consumer profile consists of three classes: the first represents 15% of the population, has an income above 10 minimum wages and consumes 48% of the total drug market; the second is made up of 34% of the population, has incomes around 4 to 10 minimum wages and consumes 36% of the market and the third is made up of 51% of the population with income from zero to 4 minimum wages and consumes only 16% of the market (Carvalho et al., 2006 p. 05).

To Lisbon et al. (2001), it is likely that the government's proposed generic drug promotion policy will have a plausible effect on consumers due to the information provided and, consequently, reflect on the market by reducing price fluctuations.

3.2 FIELD STUDY

The quantitative analysis proved to be enriching, because it complemented the research and contributed to achieve the objectives proposed in this work. To reach the objective of the research, the information obtained through the structured questionnaire was analyzed, and the same one consisted of fourteen questions.

From the questionnaire applied with 50 randomly selected individuals, it was possible to verify that the majority of the population surveyed know what the generic drug is, what its importance is and the low cost it has, but they report having obtained information from third parties that the generic drug does not have the same effect as the reference drug.

Table 1: Distribution, according to gender, age, education, salary range, sample (n=50).

Attributes	Absolute Frequency (f)	Relative Frequency (%)
Sex		
Male	10	20%
Female	40	80%
Age		
From 18 to 36 years old	29	58%
From 37 to 49 years old	12	24%
From 50 to 78 years	09	18%
Schooling		
Elementary School	11	22%
High School	14	28%
Higher Education	25	50%
Salary range		
0 to 3 minimum wages	32	64%
4 to 6 minimum wages	16	32%
7 to 10 minimum wages	02	04%

The total number of participants in this regard was 50, and the majority of the interviewees were female (80%) and with the average age between 18 and 36 years. The interviewees had schooling at different levels, most of which attended higher education and the salary range prevailed between zero and three minimum monthly wages.

Table 2: Generic drug consumption.

Category	Absolute Frequency (f)	Relative Frequency (%)
They report having used generic drugs.	50	100%
They report that they did not use generic drugs.	0	0%

All participants interviewed stated that they had already used generic drugs. Although the research has shown that all participants have already made or used the generic drug, it is still not as significant in the population, because some people still had doubts about its effectiveness.

According to Carvalho et al. (2006), despite the strategies implemented by the government in order to stimulate the population to make the use of the generic drug, statistics show that, in 2005, the generic still represented 11.9% of the national market, when equal to the drugs for sale.

Table 3: Fear of using generic drugs

Category	Absolute Frequency (f)	Relative Frequency (%)
Doubt in making use of the generic drug.	11	22%
Have no doubt in making the use generic drug.	39	78%

The majority of respondents (78%) said they did not have their lives and did not fear when using generic drugs. Although the majority of the population surveyed has no doubts about using generic drugs, there is still a minority of 22% who show their lives in relation to use. According to Rocha et al. (2007), poorer countries are not supported by government as developed countries, so they need health care.

Table 4: Efficacy compared to the generic product to the reference product.

Category	Absolute Frequency (f)	Relative Frequency (%)
It believes in the same effectiveness of the effect.	39	78%
You don't believe in the same effectiveness of the effect.	11	22%

Most respondents (78%) believed in the proven efficacy of the generic drug, so they stated that they had no doubts about its consumption. Although the results presented in the research were satisfactory regarding the acceptance of the efficacy of generic drugs, there are still beliefs regarding the safety and efficacy related to the consumption of generic drugs, which may influence the choice of purchase (Figueiras et al., 2007).

Table 5: Knowledge about what is generic medicine.

Category	Absolute Frequency (f)	Relative Frequency (%)
They claim to have knowledge.	40	80%
They claim to have no knowledge.	10	20%

A total of 80% of the pair said they know what is generic medicine. Although the majority of respondents stated that they have knowledge about generic medications, the minority who stated ignorance were people between 50 and 78 years old and with education fundamental. According to Rocha et al. (2007), the education and age of individuals are associated with the knowledge of the population about what the generic drug is.

For better knowledge of the population in Brazil, people identify the generic drug through the external packaging, which has a yellow stripe and the letter "G" for identification. Thus, people recognize a generic drug by packaging, which is their main means of recognition (Blatt et al., 2012).

Table 6: Influence of third parties on the consumption of generic drugs.

Category	Absolute Frequency (f)	Relative Frequency (%)
They claimed to have received information from third parties about the non-efficacy of the medication.	30	60%
They stated that they had not received information from third parties about the non-efficacy of the medication.	20	40%

According to the results, 60% of participants reported that they have already accepted information from people without information about the effectiveness of the product. The population is aware of the medication and states that it has positive results when using the same one. However, according to Figueiras et al. (2007), the population suffers influences of common sense, because when the use of generic medicine is for chronic or serious diseases, the individual does not believe in its total effectiveness.

Table 7: Weight in the choice of generic drug use.

Category	Absolute Frequency (f)	Relative Frequency (%)
They had an influence on	13	26%
They had no influence	37	74%

In the results mentioned above, it can be stated that 74% of the population surveyed stated that they were not influenced in the choice of generic drug. According to Mosegui et al. (2000), there is a growth considered in the acceptance of the generic drug and a decrease in the perception of risk in relation to its use, but there is still some fear of the population in general.

Table 8: The medical prescription of generic drug.

Category	Absolute Frequency (f)	Relative Frequency (%)
Doctors prescribe the medicine.	37	74%
Doctors don't prescribe the medicine.	13	26%

According to the results of the research, 74% of the participants stated that the physicians who needed assistance prescribe the generic medication for use. Although research has shown that doctors prescribe generic drugs, most do not explain what the generic drug is for the patient. According to a survey conducted by (ANVISA), 46% of the population that uses generic drugs via prescription, 51% of consumers say they do not know about the generic drug through their doctor (Rocha et al., 2007).

Table 9: Interchangeability by the pharmacist.

Category	Absolute Frequency (f)	Relative Frequency (%)
Accept exchange for generic medicine	42	84%
Do not accept exchange for generic medicine	08	16%

From the surveyed participants, 84% of them accept the exchange of the reference drug with the generic suggested by the pharmacist. According to Castro (2000), the health professional has a fundamental role as an influencer and the best way to conduct the patient's treatment, because he acts proactively in the treatment of the patient. It is very important that a pharmaceutical professional should act in the treatment, because if the treatment is not conducted properly it may impair and compromise the effectiveness of the treatment.

Table 10: Price quotation of the generic drug in relation to the reference drug.

Category	Absolute Frequency (f)	Relative Frequency (%)
They claim that they have already made price comparisons	42	84%
They claim they didn't make a price comparison	08	16%

Of the population surveyed, 84% have already compared prices between generic drugs and reference drugs. According to the research conducted in the period from 2000 to 2004, based on values published in specialized journals, it can be confirmed that generic drugs are 40% cheaper compared to the reference, which is one of the factors that makes it more accessible to the user (Miranda et al., 2009).

Table 11: Influence of the price of medicines on purchase.

Category	Absolute Frequency (f)	Relative Frequency (%)
It's what influences the purchase	39	78%
It's not what influences the purchase	11	22%

According to the results of the survey, 78% of those surveyed stated that price is the main factor that influences the purchase of the drug. According to Nishijima (2008), the generic drug entered the market at a price well below that of reference medicine, being this major factor to reduce treatment costs.

4 CONCLUSION

The theme of generic drugs is an initiative of the Federal Government that brought unquestionable social benefits. The study showed that the population still needs further clarification on generic medication to clarify doubts about its efficacy. It is important to understand that these drugs were created for the benefit of the less favored population, making it accessible to pharmacological treatment with quality, efficacy and low cost as an alternative to promote health. The research also pointed out that most users are aware of the importance of generic drugs, which demonstrates that the actions developed by the government through the Ministry of Health and health professionals are managing to clarify and raise awareness among the population.

Although the study was carried out only in Itumbiara-GO, it is predictable that a large part of the Brazilian population living in remote places, where living conditions are still precarious and resources are scarce, do not have enough information about generic drugs and their benefits. It is important to highlight the role of health professionals and health agencies in continuing the policies for the implementation of generic drugs, to clarify and guide the population, with the purpose of promoting health, especially those of the less favored.

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