



Generic Medicines

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Abstract

Introduction: Generally, a drug is any chemical substance capable of affecting the functioning of the organism of each living being or micro-organism when penetrates the living organism.

Purpose: The purpose of this review study focuses on the characteristics, properties and contribution of generic drugs to modern therapeutics.

Methodology: The study material consisted of articles on the topic found in Greek and international databases such as: Google Scholar, Med net, PubMed, Medline and the Hellenic Academic Libraries Association (HEAL-Link). The exclusion criterion for the articles was the language, except for Greek and English.

Results: Every new "original" drug for marketing has been protected for some time with rights after its final approval such as banning its production by another company or banning the production of the active substance and patent, etc. During this period, the cost of research and development is proportionally included in the price of the drug, from the discovery of its active substance to its circulation. Upon the expiry of this period, as always determined by national and international law, all such expenses are considered to have been amortized. Other drug companies are then granted the right to produce it. So, it is then considered a generic drug.

Conclusions: Generic medicines play an important role in the pharmaceutical market because they offer effective treatment at low cost. According to both National Medicines Agency (EOF) and the Panhellenic Association of Pharmacists, generics are bio-equivalent formulations and safe for human use.

Keywords: Medication, Original medicines, Generic medicines, Herbs, Analgesics, Antispasmodic, Antimicrobial, Anesthetic Drugs, Antidepressants, Antimalarials, Anxiolytics

Introduction

The word medicine has been practiced in all languages in one way or another, as pharmacology, pharmacy, etc. The word is Homeric and means "herbal substance", meaning a plant with some biological action. Homer's epic poems contain many prescriptive adjectives for medicines, such as beneficial, soothing, and euphoric [1,2]. Herbs already known since antiquity are the original stock of medicines in European medicine. Some of them are used in therapeutics up to modern times [1]. According to World Health Organization (WHO) a drug is defined as any substance or mixture of substances produced, offered for sale, or presented for use in

the diagnosis, treatment, mitigation or prevention of the disease, abnormal fitness, or its symptoms in human beings or animals.

Moreover, any substance used for the restoration, correction, or alteration of biological functions in humans or animals [3]. Generally, a drug is referred to any chemical substance capable of affecting the function of the organism of any living being or micro-organism when it penetrates it. To put it briefly, any substance or mixture that relieves, or cures from diseases or pains of the human body and generally restores human health [4,5]. The classification of the various medicinal products is generally as follows [4].

Chemical Classification

They derive from the chemical group to which they may belong, such as alkaloids.

Pharmacological Classification

They derive from their pharmacological action such as analgesics, antispasmodic, antimicrobial, and anesthetic drugs.

Therapeutic Classification

They derive from their therapeutic effects such as antidepressants, antimalarials or anxiolytics.

Complex Classification

They derive from the disease of the functional system or organ for which they are administered and of the intended purpose, such as antiseptics, anticholinergics, laxatives, expectorants or mucolytic agents.

Secondary classification

They derive from their form of making them available for use depending on age and capabilities of the recipient such as tablets, powder medicine, tablets, drops, suppositories, injectables, serums or vaccines.

It is noteworthy that pharmacological and therapeutic classification of the drug differ significantly, given that some drugs with different mechanism of action may have the same therapeutic effect [6]. In Greece, classification of medicinal products, as defined by EOF (National Organization for Medicines), is based on the diseases of the various systems and organs through which they are administered and their action. This complex classification method is adapted to that of the European Pharmacopoeia and World Health Organization (WHO) [5].

In addition, in Greece the competent body responsible for the Greek Pharmacopoeia and the protection of Public Health throughout the production, distribution, promotion, marketing and advertising of medicinal products is EOF (National Organization for Medicines), which was established in 1983 as a Public Entity / legal entity of public law which is a specialized public authority under the "Ministry of Health and Welfare" or as it is renamed [7]. Subsidiaries assisting the work of EOF are the Institute for Pharmaceutical Research and Technology (IFET) and the International Biological Material Research Center (EKEVIL). The most important issue of EOF that is periodical is the National Drug Code Directory [8]. As regards the field of pharmaceuticals, there is another classification of medicines and refers to original medicines and generics [4].

A. Original medicines are considered medicines manufactured by a company to which the rights have been assigned by the beneficiaries.

B. Generic medicines are considered medicines of the same composition of active substances as original medicines, the

same formulation as the original medicinal product. Their bioequivalence has been proved by appropriate bioavailability studies.

The purpose of this review study focuses on the characteristics, properties and contribution of generic drugs to modern therapeutics.

Methodology

The study material consisted of articles on the topic found in Greek and international databases such as: Google Scholar, Mednet, Pubmed, Medline and the Hellenic Academic Libraries Association (HEAL-Link), using keywords: medicine, original medicines and generic medicines. The exclusion criterion for the articles was the language, except for Greek and English. Mostly, only articles and studies that were accessible by the authors of this study were used.

Talking About Generic Medicines

Any new "original" medicinal product after its final marketing authorization has been protected under rights for some time such as a ban on its production by another company or a ban on the production of the active substance, the patent etc. During this period, the cost of research and development is proportionally included in the price of the drug, from the discovery of its active substance until its release. [9]. Upon the expiry of this period, as always determined by national and international law, it is considered all such expenses to have been amortized. Other drug companies are then granted the right to produce the drug, which is then considered a generic drug. Therefore, generic medicine is considered any drug whose active substance is no longer covered by a patent and patent rights therein. The term is purely commercial. Generic medicines have a lower price than their patents [10].

Generics have been a taboo issue since the turn of the century because of their association with the risk of side effects, malformations and genetic abnormalities due to the low level of control that was carried out until 1970. However, they have gradually become largely deactivated and begin to disseminate their use [11]. These medicines have been in use for the last century and their use and disposal is not a compulsory measure which is mandatory for all citizens. On the contrary, generic administration is considered a good and enough complementary measure to reduce costs and maximize health benefits [12]. In the United States of America and Western Europe, the landmark was the 1980s when the health market was liberalized and competition increased [11]. In the EU, in many countries such as Germany and France, generics have been widely sold for decades.

Since 1990, the above-mentioned systems have implemented a generic voluntary choice model, with patients always able to choose, in consultation with their attending physician [13]. In Greece, generics were introduced into the market as an additional measure in the context of austerity policies to reduce the cost of the

healthcare provided by the state to citizens. This measure, in other words, the introduction of generic medicines on the market, seems to be achieving its objective of helping the economic transition and reform of countries with many problems in their internal and external environment [14]. Pharmaceutical industries operating on the European market follow strict rules for the control of generic medicines, including the following [15]:

- A. Full product composition
- B. Description of the production method
- C. Description of the production process control methods
- D. Results of pharmaceutical studies
- E. Factory production license
- F. Certificate of Good Practice

In “an endless quest of maximum quality at minimum cost” a number of new methods and tools have been developed and used by health care professionals in order to assess and evaluate past or current clinical practice in relation to the practice of peers or established standards [16]. The Certificate of Good Practice certifies that the pharmaceutical industry maintains appropriate facilities and equipment, trained personnel and applies acceptable manufacturing processes. Specifically, it maintains detailed records of manufacturing processes and follows appropriate storage and transportation standards for used materials and products [17].

In terms of safety and efficacy, generic medicines can be licensed after the expiry of the “exclusivity” period of the original drug, which usually lasts 10 years. Generic authorization is carried out in accordance with the European Medicine Agency and provides for evaluation of scientific data including a bioequivalence study or an exemption study from a bioequivalence study as appropriate for the generic drug to be examined [18]. The National Medicines Agency evaluates the bioequivalence studies of the generics, which are clinical trials approved by the EOF and are carried out on behalf of pharmaceutical companies in collaboration with State Hospitals or Private Clinics in Greece. The procedure followed ensures the efficiency, safety, and quality of generics in all EU countries [7].

Regarding the use of generic medicines in daily therapeutic practice, the main reasons for their use and acceptance are their lower cost and confidence in health professionals, while product safety and efficacy appear to play a role in the final decision [19]. Clinical efficacy is considered the most important factor for possible replacement, but other criteria such as the formulation of the drug, the daily dose and the patient’s preferences are taken into account [20,21]. Patients’ acceptance for generic medicines is a prerequisite for the dissemination of generic medicines, as patients express a critical attitude and want to be informed about health issues, including generic ones. The patient’s confidence in the doctor who

will prescribe generic medication and previous experience with generic medicines plays a decisive role, of course [22].

In the international literature, there are studies related to the attitude of doctors towards generic medicines, in particular their knowledge of generics and their sources of information, their views, the quality and safety of generics, their confidence in the institutions which have a supervisory role in the production and distribution of generic drugs [22]. The National Organization for Medicines (EOF) and their respective Member States’ Medicines Organizations evaluate the bioequivalence studies, which are clinical trials carried out on behalf of pharmaceutical companies. The pre-approval process ensures the effectiveness, safety and quality of generic medicines in all EU countries [8,18]. Generic medicines marketed on the Greek market are about 3,000 in packing level, totaling about 7,300 medicines. Nowadays, generic medicines occupy 18% of the market.

Their pricing is at the level of 40% of the prototypes and as a consequence public spending on pharmaceuticals will have to be significantly reduced, with great benefits for social security [23]. According to the provisions of paragraph 5 of article 21 of Law 4052/2012 (Government Gazette 545/B /1-3-2012) and case 11 of sub-paragraph IB.2 of Law 4093/2012 (Government Gazette 3057/B/18-11- 2012), physicians are required to prescribe only active substances and not the brand names of medicines, so patients are informed by pharmacists of generic medicines [24]. Although the AEO has already approved and proposed appropriate generics in the Greek pharmaceutical market, however, patients’ ability to choose the medication themselves does not promote the purchase of generic medicines [25,26].

The rise in generic medicines has changed countries perceptions of pharmaceutical care.

The use of generic medicines is a more economical option in the context of efforts to control and reduce the cost of pharmaceutical care. The reduced price of generic medicines compared to the original medicines significantly contributes to the reduction of pharmaceutical costs. Since the introduction of generic medicines on the market, the prices of the original medicines have significantly dropped [27]. Thus, generic medicines safely and effectively represent a key strategy used by governments to reduce healthcare costs [28].

Conclusion

Generic medicines play an important role in the pharmaceutical market because they offer effective treatment at low cost. According to both the National Organization for Medicines (EOF) and the PanHellenic Association of Pharmacists, generics are bio-equivalent formulations and absolutely safe for human use. They also have about the same composition and method of administration, and also similar absorption by the human organism [29,30]. Undoubtedly,

the use of generic drugs could increase significantly if negative beliefs about the effectiveness of generic drugs are reduced [31]. These beliefs can be a personal bias for health professionals such as doctors, or pharmacists, but also patients. Nevertheless, these beliefs can be overthrown with the right information and education [32].

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