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ARTICLE

Factors influencing generics and fixed dose combinations recommendation by pharmacists for cardiology patients	1020
Zornitza Emilova Mitkova, Konstantin Tihomirov Tachkov, Guenka Ivanova Petrova and Manoela Metodieva Manova	

Full Length Research Paper

Factors influencing generics and fixed dose combinations recommendation by pharmacists for cardiology patients

Zornitza Emilova Mitkova, Konstantin Tihomirov Tachkov, Guenka Ivanova Petrova* and Manoela Metodieva Manova

Department of Organization and Economics, Faculty of Pharmacy, Medical University of Sofia, Bulgaria.

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The goal of this study is to evaluate the knowledge and factors influencing generic medicines and fixed dose combination recommended by pharmacists for patients with cardiovascular diseases. The research is an inquiry among pharmacists working in community pharmacies. A questionnaire with 14 questions was distributed among 600 pharmacies and after the revision, 144 answers were proceeded. The questionnaire contains 8 questions which aim to reveal the degree of acceptance of generic and fixed dose combination products in a 5 point Likert scale. Six questions clarify the reasons and frequency of generics and fixed dose combinations recommendation. Z-test and t-test analysis was applied to evaluate the statistical significance among the proportions and answers. Pharmacists have a negative opinion towards the country's generic medicines policy. Factors influencing the positive mindset include NHF's politics to reimburse the lowest costing equivalent (62.5%), the presence of generic medicines on the market (58.9%). The fact that the public does not have sufficient knowledge about generic medicines is listed as a factor impacting the opinion negatively, whereby there are a large number of indifferent opinions (41%). Pharmacists indicate that on average of 56.6% of their patients are being treated by a generic product, whereas 78% use combination drugs acting on the cardiovascular system in the last two questions. Factors that positively influence generic medicines recommendation by pharmacists are the regulatory measures and reimbursement policy, while patients' knowledge and pharmacists' incentives are negatively influencing the process. The fixed dose combinations are very positively evaluated by the pharmacists.

Key words: Generic medicines, cardiovascular medicines, fixed dose combinations, pharmacist's perception.

INTRODUCTION

Generic (off patented) medicines are bioequivalent to the first patented product with the same international nonproprietary name but are sold at a lower price on the

market (Dylst et al., 2013; EGA, 2010; Kesselheim et al., 2008). For example, the first Enalapril was marketed under the trade name Ramipril. When the patent of the

*Corresponding author. E-mail: guenka.petrova@gmail.com.

King and Kanavos, 2002; Sheppard, 2010; Simoens, 2013). Many generic medicines are used in cardiology, which later became part of newly developed fixed dose combination products to better suit the complex therapy of cardiovascular diseases (Dimopoulos et al., 2004; Wald et al., 1999). Combination drug therapy is defined as the use of 2 or more pharmacologic agents administered separately or in a fixed-dose combination of 2 or more active ingredients in a single-dosage formulation (Terrie, 2010). Fixed dose combinations improve patients' compliance and concordance with therapy especially when patient polymorbidity is an issue (Bangalore et al., 2007).

Therapeutic guidelines recommend combination therapy in the area of hypertension, cardiac insufficiency, myocardial infarction etc. (Limbert and Lamb, 2002). Some authors even consider that the future belongs to combination products (O'Riordan, 2012). The degree of acceptance and factors influencing generic medicines and fixed dose products recommendation by pharmacists for patients with cardiovascular diseases is not well studied (Mott and Richard, 2002).

The goal of this study is to evaluate the knowledge and factors influencing generic medicines, and fixed dose combination recommended by pharmacists for patients with cardiovascular diseases.

METHODOLOGY

The research is an inquiry among pharmacists working in community pharmacies. A questionnaire with 14 questions was distributed among 600 Bulgarian pharmacies. The questionnaire contains 8 questions which aim to reveal the degree of acceptance of generic and fixed dose combination products in a 5 point Likert scale where 1 is strongly disagree and 5 is strongly agree. Six questions clarify the reasons and frequency of generics and fixed dose combinations recommendation. Validating the questionnaire required first discussing it with the association of cardiologists in the country, after which it was tested in 3 pharmacies. After corrections, it was distributed to 600 pharmacies. The rate of return of the fulfilled questionnaires is 27%. Z-test and t-test analysis was applied to evaluate the statistical significance among the proportions of answers. What was compared was the proportions of those considered with positive perception (answer 4 and 5 on Likert scale) and those with negative perception (answer 1 and 2 on a Likert scale). The medium point was used when there was lacking statements in the positive or negative group.

RESULTS

Out of the 600 pharmacists, 160 returned the fulfilled blanks and after the revision 144 answers were proceeded. The mean work experience of all the pharmacists interviewed is 17 years (SD 11.15). Only one of the participants has reported having a specialty degree. The distribution of answers to generic medicines characteristics is depicted in Table 1. The question aims to explore their knowledge and capability of identifying the fundamental characteristics of generic medicines.

Pharmacists are not unified in their opinion (Table 1). It makes an immediate impression that the number of neutral pharmacists interviewed is relatively high, although nearly a quarter of them don't have an opinion regarding the equivalency of generic medicines, 20% do not believe the only difference between original and generic is in the excipient make-up, whereas 25% don't have an opinion regarding their substitution. The percentage of negative answers is disturbingly high. In those, 20% don't agree with the notion that generic and original drugs are equivalent; 22.3% don't agree with the notion that the only difference between them is in the excipient make-up of the dosage form; 18% don't feel that they are interchangeable.

The opinions in regards to safety are not so negative. 59.6% believe that generic medicines have the same safety as the original; 82% believe that they can be prescribed under the same therapeutic schemes; 58.4% believe that they cause the same adverse effects (Table 2). Table 3 presents the evaluation of the influence of drug prices on accessibility, whereby nearly 5% of pharmacists feel negatively on the subject; 18.8% believe that lower prices indicate lower quality; 16% feel that the difference in prices is not due to the lower production cost.

These results shed light on the fact that 32 (22%) of the interviewed pharmacists do not recommend generic medicines. The pharmacists, which do recommend generic medicines, cite their accessibility and lower prices as the key factors that influence them. 99 interviewees have registered complaints of adverse effects from generic medicines, whereby their frequency varies from 0.1 to 70%. If the patient is not satisfied, the prevailing opinion is that he should seek specialist consultations, along with a substitution of the therapy with another international nonproprietary name (INN) (81%). 64.6% will recommend returning to the original, whereas only 17.8% are willing to suggest another generic (Table 4).

The main determining factors when recommending another generic molecule is the patient's consent (81.9% positive answers), the lower price (81.3%), patient's income (72.8%), doctor's approval (63.3%), the comparable safety (59.7%), and last, but not least the comparable efficacy (47.2%) (Table 5). The results obtained from the questionnaire indicate also, that the indifferent group is significant and varies between 13 and 37%. The opinion towards combination therapy and fixed doses combinations is significantly more positive. The main reasons behind the acceptance of combination therapy, as believed by pharmacists, are: it is easier for the patients (87.5%), simpler when patients are taking a multitude of medicines (78.5%), (reducing?) the risk of incorrect usage (74.2%), improving patient approval (66%), in elderly on a poly-therapy (59.4%) (Table 6).

Pharmacists, who refrain from recommending a combination therapy (n=24), believe that responsibility

Table 1. Distribution of answers for generic medicines characteristics.

The generic and original medicines	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
Are equivalent as therapeutic effectiveness	3 (2)	26 (18)	34 (23)	55 (39)	26 (18)	6.5 (<0.0001)
Differs only in excipients content	10 (6.9)	22 (15.4)	30 (20,8)	51 (35.4)	31 (21.5)	6.0 (< 0.0001)
Have the same INN, and are completely interchangeable	11 (7.6)	15 (10.4)	36 (25)	48 (33.4)	34 (23.6)	6.9 (< 0.0001)

Table 2. Distribution of answers for the generic medicines safety.

The generic and original medicines	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
Are equally safe	6 (4)	20 (13.8)	26 (18.7)	64 (44)	28 (19.5)	7.9 (<0.0001)
Could be prescribes in the same therapeutic schemes	2 (1.4)	4(2.8)	20 (13.8)	63 (43.8)	55 (38.2)	13.3 (= 0)
Have the same adverse events frequency	7 (4.9)	24 (16.7)	29 (20)	51 (35.5)	33 (22.9)	9.6 (= 0)

Table 3. Distribution of answers related to influence of the prices of generic medicines.

Do you consider that the lower price of generic medicines	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
Does not mean low quality of the products	5 (3.5)	22 (15.3)	27 (18.7)	49 (34)	41 (28.5)	7.5 (<0.0001)
Is due to lower production cost	5 (3.5)	18 (12.5)	29 (20)	44 (30.6)	48 (33.4)	11.6 (= 0)
Allows affordable therapy to more patients	5 (3.5)	2 (1.4)	16 (11)	47 (32.6)	74 (51.4)	13.5 (= 0)

Table 4. Distribution of answers for possible measures in case of patients' complain.

If the patient is not satisfied with generic medicine	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
will recommend to continue with originator	22 (15.3)	11 (7.6)	18 (12.5)	33 (22.9)	60 (41.7)	7.2 (< 0.0001)
will recommend another generic with the same INN	38 (26.4)	41(28.5)	49 (34)	20 (13.8)	6 (4)	-6.5 (< 0.0001)
will recommend consultation with physician to change the therapy with different INN	8 (5.6)	1 (0.7)	19 (13.2)	38 (26.4)	78 (54.2)	12.7 (=0)

lies solely on the physician. Other colleagues, who responded positively to that question

(n=120), indicated that their decision is influenced by patient approval, minimizing the risk of

mistakes, patient comfort. However, they do admit that all decisions should be consulted with a

Table 5. Distribution of answers to generic substitution decision.

The main factor that influence your decision to recommend generic substitution is	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
Is equal quality	8 (5.6)	18 (12.5)	50 (34.7)	42(29.2)	26 (18%)	5.3 (<0.01)
Is equal safety	5 (3.5)	6 (4)	47 (32.6)	55 (38.2)	31 (21.5)	6.4 (< 0.0001)
Is lower price	2 (1.4)	5 (3.5)	20 (13.8)	44 (30.6)	73 (50.7)	13.1 (=0)
Is patients income	6 (4)	4 (2.7)	29 (20.1)	35 (24.3)	70 (48.5)	11.5 (< 0.0001)
Is patients acceptance	2 (1.4)	5 (3.5)	19 (13.2)	46 (31.9)	72 (50)	5.9 (< 0.0001)
Is physician agreement	5 (3.5)	12 (8.3)	33 (22.9)	39 (27.1)	55 (38.2)	9.3 (=0)

Table 6. Distribution of answers to advantages of fixed doses combination.

Does the therapy with fixed dose combination possess any advantages in comparison with mono products	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	z-test value (p-test value)
In case when combination therapy is necessary	2 (1.4)	5 (3.5)	24 (16.7)	43(29.9%)	70 (48.6)	12,7 (=0)
In case when there is a risk of inappropriate administration	1 (0.7)	4 (2.8)	35 (24.3)	38 (26.4)	66 (45.8)	12 (=0)
To facilitate patients	1 (0.7)	3 (2.1)	14 (9.7)	34 (23.6)	92 (63.9)	14. 4 (=0)
To improve compliance	-	6 (4.2)	43 (29.9)	37 (25.7)	58 (40.3)	11 (=0)
For elderly on polytherapy	1 (0.7)	3 (2.1)	30 (20.8)	34 (23.6)	76 (52.8)	13.2 (=0)

Table 7. Distribution of answers to patients' perception about the generic medicines.

Do you consider that your patients are agree with generic medicines?	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
Yes because they pay less	1 (0.7)	6 (4.2)	29 (20)	48 (33)	60 (41.1)	12 (=0)
Yes when they are well informed	4 (2.8)	6(4.2)	35 (24.3)	50 (34.7)	49 (34)	10.8 (=0)
No because they doubt in their effectiveness	14 (9.7)	22 (15.3)	61 (42.4)	33 (22.9)	14 (9.7)	1.1 (0.2889)

doctor. In response to the question “should generic medicines be recommended in a combination therapy” (Table 7), the distribution of answers is analogical. This means that 24 of the interviewed do not recommend it, whereas the rest base their decision on the before mentioned arguments, including also the following factors:

Medicine price and patients' financial capabilities.

The consent given by patients, when they are being recommended a generic product shows that the financial factor is the leading one (74.1%) influencing the decision, as well as their individual knowledge on the topic (68%). The doubts regarding efficacy are stated as a concern, but the

difference between the largely negative and largely positive opinion is not statistically significant. The industry's influence and the lack of incentives for pharmacists to recommend generics is an important factor, but the answers given did not offer a statistically significant difference between the negative and positive opinion (Table 8).

Table 8. Distribution of answers to country generic medicines policy.

According to you is there a policy that stimulates the generic medicines utilization in the country	Strongly disagree (%)	Rather disagree (%)	Neither agree nor disagree (%)	Rather agree (%)	Completely agree (%)	Z-test value (p-test value)
Yes because more patients are agree with generic medicines prescribing	9 (6.3)	20 (13.9)	39 (27)	45 (31.3)	31 (21.5)	5.7 (<0.0001)
No because companies informed physicians for originator products	17 (11.8)	26 (18)	63 (43.8)	25(17.4)	13 (9)	0.6 (0.521)
No because patients are not well informed	14 (9.7)	14 (9.7)	59 (41)	35 (24.3)	22 (15.3)	2 (0.0488)
No because there are no incentives for physicians	20 (13.8)	21 (14.6)	59 (41)	38 (24.6)	16 (11)	1.3 (0.1903)
No because there are no incentives for pharmacists to substitute with generics	16 (11)	18 (12.5)	42 (29.2)	29 (20)	39 (27)	0.7 (0.4942)
Yes because the lowest generic is reimbursed	7 (4.9)	10 (6.9)	37 (25.7)	43 (29.9)	47 (32.6)	6.9 (= 0)
Yes because there are many generics on the market	9 (6.3)	11 (7.6)	39 (27)	46 (31.9)	39 (27)	7.9 (< 0.0001)

Factors influencing the positive mindset include National Health Insurance Fund's (NHIF) politics to reimburse the lowest costing equivalent (62.5%), the presence of generic medicines on the market (58.9%). The fact that the public does not have sufficient knowledge about generic medicines is listed as a factor impacting the opinion negatively, whereby there are a large number of indifferent opinions (41%). Pharmacists indicate that on average 56.6% of their patients are being treated by a generic product, whereas 78% use combination drugs acting on the cardiovascular system in the last two questions.

DISCUSSION

This result on the familiarity with generics medicines' characteristics leads us to believe that there is limited knowledge regarding generic medicines. Obviously, pharmacists have a more positive outlook on generics safety, as opposed to a negative outlook on the generic medicines as a whole. The fact that a limited number of pharmacists recommend generic medicines shows their skepticism and lack of confidence in the generics' properties.

Most European countries allow pharmacists to substitute medicines with other essentially similar products. The legal argument behind this is to provide patients with the least expensive option. Bulgaria, however, requires the patient's consent before substituting a medicine, which largely influences a pharmacist's decision. A possibility to consider as having an extremely negative effect on pharmacists' decision on drug substitution is the fact that it is forbidden to substitute prescription medication; especially medicines, which are reimbursed by the National Health Insurance Fund (NHIF).

Pharmacists have a negative opinion towards the country's generic medicines policy. According to local legislation, the pharmacists are not allowed to directly substitute the prescribed products with a generic equivalent. They have to either consult with the physician or ask for the patient's consent. This in fact makes any substitution almost impossible. The results prove other authors' conclusion that pharmacists are vital component of any successful generic medicines policy (Bhosle et al., 2003; Dunne et al., 2014). If they are not actively included in generic medicines recommendation other regulatory measures might appear inefficient

(Simoens, 2013; Quintal, 2012).

This study adds some more knowledge for fixed dose combinations preferences for patients with cardiovascular diseases. They became an important part of cardiology patients' therapy and preference towards them is strongly positive (Donovan, 1995; Bangalore et al., 2007).

The study chose cardiology patients to measure the knowledge and recommendation of generic medicines fixed dose combination because, cardiovascular diseases are complex ones, and very often require poly therapy (O'Riordan, 2012; Wald et al., 1999). Therefore studying the knowledge and attitudes towards fixed dose products in cardiology is important for the betterment of patient therapy (Figueiras et al., 2008; Heikkilä et al., 2011).

Conclusion

Factors that positively influence generic medicines recommendation by pharmacists are the regulatory measures and reimbursement policy, while patients' knowledge and pharmacists' incentives are negatively influencing the process. The fixed dose combinations are positively

evaluated by the pharmacists.

Conflict of interest

The authors have none to declare.

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