Bratisl Lek Listy 2008; 109 (7)
324 – 328

CLINICAL STUDY

Patients attitudes towards experience with use of generics in Slovakia, performance of generic substitution

Palagyi M[1], Lassanova M[2]

The Slovak Generic Association (GENAS), Bratislava, Slovakia. **michaela.palagyi@sandoz.com**

Abstract: *Background:* Generic substitution of branded pharmaceuticals is a widely adopted tool among payers to achieve cost savings. The adoption and safe use of generics among consumers is predicated upon their knowledge of and attitudes toward these products.
Objectives: The aims of this study were to assess patients' attitudes towards generic drugs and their experience with using generics, identify factors associated with differences in attitudes and/or experience, and discern the rate of generic substitution in Slovakia.
Methods: Two thousand questionnaires were distributed to patients via pharmacies throughout Slovakia by eleven pharmaceutical companies representing GENAS (the Slovak Generic Association). Responses were received from 1,777 persons (88.85 % response rate). Demographic information of respondents was also acquired.
Results: Only 33.8 % (600/1773) of respondents care to know about the product which they are using. Over one half (61.1 %, 1084/1774) of respondents indicated no distrust in using generics, with many of them indicating a preference for a product with a lower co-payment.
Conclusion: About 1/3 of patients care to know whether they are using generic or branded pharmaceuticals. If there is a lack of information about generics, this could inhibit the use of generics by patients and discern a rate of generic substitution *(Tab. 3, Fig. 1, Ref. 18)*. Full Text (Free, PDF) *www.bmj.sk.*
Key words: generic association, GENAS, generic drug, information about generics.

Impact on practice

– In general, patients may need more information about generics in order to avoid any further distrust to use generics

– The limited factor in performance of generic substitution is the approach of physicians and/or pharmacists.

In general, there are 2 groups of drugs – brand-named and generics: "Brand-name drug" can be placed on the market after granting the marketing authorisation by a competent authority based on confirmed safety, efficacy and quality of medicinal product. As soon as a data exclusivity of brand-name drug expired, a generic drug is allowed to be submitted for registration. The competent authority evaluates a bioavailability study and a marketing authorisation for generic could be granted only based on confirmed bioequivalence.

"Generic drug" shall mean a drug which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies (1).

Relevant criteria for bioequivalence study are defined in the appropriate detailed guidelines.

Two drugs are bioequivalent if they are pharmaceutically equivalent or pharmaceutical alternatives and if their bioavailabilities after administration in the same molar dose are similar to such degree that their effects, with respect to both efficacy and safety, will be essentially the same. The EMEA standards consider 2 products bioequivalent if 90 % confidence interval for measure (i.e. AUC, Cmax) of relative bioavailability lies within an acceptance interval of 0.80–1.25 (2).

The objective of one of the published studies was to estimate the use of multisource drugs, specifically generic formulations, among a nationally representative sample of adults (3).

Generics are typically less expensive than brand-name drugs, and prices for generics have historically increased less than those for brand-name drugs (4).

Use of a generic formulation instead of brand name for ?multisource drugs (that is, those with 1 generic available) could be one mechanism for limiting drug expenditures. Since 1980s, almost every state has enacted laws to allow and in some cases mandate generic substitution (5). The introduction of generic substitution was associated with a shift in trend from an increase into decrease both for patients' and society's expenditures. This

The Slovak Generic Association (GENAS), Bratislava, Slovakia, [1]Sandoz d.d., Bratislava, Slovakia, and [2]Department of Pharmacology, Faculty of Medicine, Comenius University, Bratislava, Slovakia

Address for correspondence: M. Palagyi, PharmDr, The Slovak Generic Association (GENAS), Ruzinovska 42, SK-821 01 Bratislava, Slovakia.
Phone: +421.903501133

suggests that generic substitution has contributed to a reduction in the growth of pharmaceuticals expenditure (6). Generic substitution was also introduced in Slovak legislation in December 2004. Ministry of Health of the Slovak Republic issued a list of active substances which could be a part of generic substitution (7). Physicians and pharmacists are legally obliged to inform patients about all alternatives to prescribed drug with lower co-payment. Then it is up to the patient to decide whether she/he will prefer a generic substitution. However, three years after the introduction of generic substitution in Slovakia the rate of generic substitution is still poor. On the other hand, market share of brand-name drugs is still growing – 85.2 % in value and 49.6 % in units (8). It seems to be that there is a lack of information about generics in Slovakia causing distrust in using generics. In order to increase patients' trust in using generics, GENAS (The Slovak Generic Association) decided to focus its activities to public education.

Comparable situation occurred in Norway. The rationale behind the introduction of generic substitution in Norway was primarily cost containment. The patient and/or physician can refuse generic substitution, but the patient may as a result pay a higher price in some cases (9).

The aims of the study

The aims of the study were to assess patients' attitudes towards generic drugs and their experience with using generics, identify factors associated with differences in attitudes and/or experience, and discern the rate of generic substitution in Slovakia.

Methods

The rationale behind the survey in March–May 2007 of the Slovak Generic Association was not very well performing generic substitution.

Two thousand questionnaires were distributed to patients via pharmacies throughout Slovakia by eleven pharmaceutical companies representing GENAS. Each GENAS representative received a map describing all regions of the country were questionnaires and educational brochures had to be distributed. Patients were randomly selected. Each patient was handed the questionnaire by a GENAS representative directly in a pharmacy. After distribution and collection of questionnaires, each patient received a brochure about generics as a part of further educational process. Statistical analysis was based on demography (specific regions) – Eastern, Middle and Western Slovakia. The patient's experience depended on: gender, age, educational background. Questionnaire was created by GENAS members and consisted of 5 questions: patient's interest to know whether a medicinal product is generic or brand-name drug; common understanding of generic medicinal products; any distrust to use generics; a relevant parameter for patients to decide in favour of using generics or brand-name drugs; verification if pharmacist or physician proposed a generic substitution to the patient.

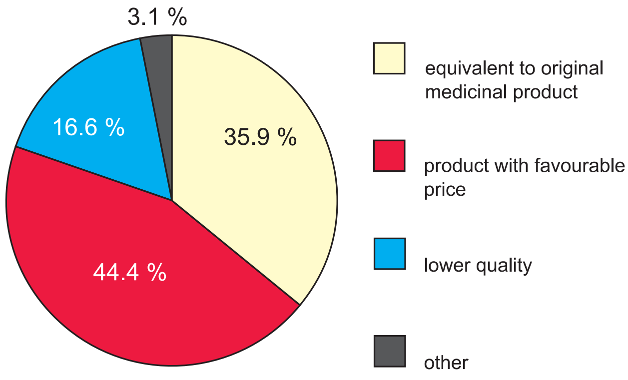

Fig. 1. Understanding the term "generic medicinal product" by patients.

All monitored variables were qualitative. Tables of frequency were used in descriptive statistics. In order to identify relations between monitored variables, Chi-Square Tests in contingency tables were used. SPSS (Statistical Package for Social Sciences, version 13) was used for the analysis and all tests were performed on significance level=0.05.

Results

The response rate was 88.85 % (1777/2000). 1,776 respondents provided the information about gender – 58.2 % (1033/ /1776) women and 41.8 % (743/1776) men and their age – 88 (5 %) up to 18 years, 436 (24.5 %) up to 30 years, 585 (32.9 %) up to 45 years, 459 (25.8 %) up to 60 years and 208 (11.7 %) above 60 years. There was a significant difference in age between groups of women and men ($p<0.001$). 1,775 respondents provided the information about educational background – 14.3 % (253/1775) grammar school, 8.8 % (156/1775) secondary healthcare education, 47.1 % (836/1775) other secondary education, 7.1 % (126/1775) university healthcare education and 22.8 % (404/1775) other university education.

The most of the respondents were from Eastern Slovakia (ES) – 672 (38 %), followed by Western Slovakia (WS) – 576 (32.6 %) and finally Middle part of Slovakia (MS) – 520 (29.4 %).

Information about generic interest

Only 33.8 % (600/1773) of respondents care to know which product they are using e.g. generic or brand-name drug. There was no significant difference between positive answers on the question and regions.

Understanding of the term "generic"

The most common understanding of the term "generic medicinal product" was product with favourable price (786 responses out of 1,772), then 637 respondents considered generic medici-

Tab. 1. Relations between understanding of term "generic medicinal product" by patients and region.

			understanding				Total
			equivalent to original	favourable price	lower quality	other	
region	WS	Count	230	243	80	20	573
		% within region	40,1%	42,4%	14,0%	3,5%	100,0%
		% within understanding	36,3%	31,1%	27,2%	37,0%	32,5%
	MS	Count	153	241	96	30	520
		% within region	29,4%	46,3%	18,5%	5,8%	100,0%
		% within understanding	24,1%	30,9%	32,7%	55,6%	29,5%
	ES	Count	251	297	118	4	670
		% within region	37,5%	44,3%	17,6%	,6%	100,0%
		% within understanding	39,6%	38,0%	40,1%	7,4%	38,0%
Total		Count	634	781	294	54	1763
		% within region	36,0%	44,3%	16,7%	3,1%	100,0%
		% within understanding	100,0%	100,0%	100,0%	100,0%	100,0%

Legend: WS – Western Slovakia, MS – Middle Slovakia, ES – Eastern Slovakia

Tab. 2. Relations between understanding of term "generic medicinal product" by patients and patients´ doubts to use generics.

			doubts				Total
			I don't have any reason	I don't know what is a difference	I do have doubts without concrete reason	I do have doubts	
understanding	equivalent	Count	500	67	56	13	636
		% within understanding	78,6%	10,5%	8,8%	2,0%	100,0%
		% within dbts	46,3%	20,2%	19,0%	20,6%	36,0%
	favourable price	Count	492	179	101	13	785
		% within understanding	62,7%	22,8%	12,9%	1,7%	100,0%
		% within dbts	45,5%	54,1%	34,4%	20,6%	44,4%
	lower quality	Count	64	68	128	33	293
		% within understanding	21,8%	23,2%	43,7%	11,3%	100,0%
		% within dbts	5,9%	20,5%	43,5%	52,4%	16,6%
	other	Count	25	17	9	4	55
		% within understanding	45,5%	30,9%	16,4%	7,3%	100,0%
		% within dbts	2,3%	5,1%	3,1%	6,3%	3,1%
Total		Count	1081	331	294	63	1769
		% within understanding	61,1%	18,7%	16,6%	3,6%	100,0%
		% within dbts	100,0%	100,0%	100,0%	100,0%	100,0%

Legend: dbts – doubts

nal product equivalent to brand-name drug and only 294 respondents considered generic as a product with lower quality. People with different educational background differ statistically significantly in understanding of term "what does it mean generic medicinal product" (Fig. 1). The highest number of respondents who considered generics as equivalent to brand-name drugs was in group of people with secondary healthcare education (47.1 %) and the lowest in group of people with grammar school (27.9 %). There was a significant difference in understanding of the term "generic medicinal product" by respondents from different regions ($p<0.001$). For instance, 40.1 % respondents from Western Slovakia considered generic medicinal product equivalent to brand-name drug and in the middle part of Slovakia only 29.4 % of respondents had the same opinion (Tab. 1).

Tab. 3. Relations between regions and proposal from physician or pharmacist side for generic substitution.

			options		
			yes	no	Total
region	WS	Count	342	232	574
		% within region	59,6%	40,4%	100,0%
		% within options	30,6%	36,0%	32,6%
	MS	Count	333	187	520
		% within region	64,0%	36,0%	100,0%
		% within options	29,8%	29,0%	29,5%
	ES	Count	443	226	669
		% within region	66,2%	33,8%	100,0%
		% within options	39,6%	35,0%	37,9%
Total		Count	1118	645	1763
		% within region	63,4%	36,6%	100,0%
		% within options	100,0%	100,0%	100,0%

Legend: WS – Western Slovakia, MS – Middle Slovakia, ES – Eastern Slovakia

Attitude towards generics

61.1 % (1084/1774) of respondents had not any distrust to use generics. 78.6 % of respondents who considered generics as equivalent to brand-name drugs had no doubts to use generics. Only 21.8 % of respondents who considered generic as a medicinal product with lower quality had no doubts to use generics (Tab. 2). There was a significant difference in doubts to use generic medicinal product by patients from different age categories ($p<0.001$). The highest score of people who did not have any distrust to use generics were from age category up to 30 years (65.7 %). There was also a significant difference between respondents from different regions of country ($p<0.001$). No doubts had 68.8 % respondents from Western Slovakia and only 54.8 % from Eastern Slovakia.

Information about generic substitution

56.5 % (1003/1775) respondents preferred medicinal products with lower co-payment. Only 17.5 % (311/1775) of respondents preferred brand-name drug even with higher co-payment. The study showed a significant difference in choosing of generics or brand-name drugs by patients with some distrust to use generics and patients without any doubts to use generics ($p<0.001$). Patients who are not familiar with the difference between generics and brand-name drugs preferred products with lower co-payment (68.1 %). Only 15.9 % patients who had doubts to use generics preferred products with lower price.

With regard to generic substitution, the study showed a significant difference between patients who were informed by pharmacists or physicians about generic substitution and patients' doubts to use generics ($p<0.001$). Also there was a significant difference between giving the information about generic substitution to patients by pharmacists or physicians in regions – Eastern, Middle part and Western Slovakia ($p=0.050$) (Tab. 3).

Discussion

One of the important factors for successful generic substitution is patients' understanding of the term generics and trust that generics are products with the same quality as brand-name drugs and not only cheaper alternatives to brand-name drugs. Our study showed that quite a high number of patients are focusing on pricing parameters, approximately 1/3 of patients defined generic as a product with favourable price.

Another study showed that only 1/3 of patients with grammar school education thought that generics are equivalent to brand-name drugs due to various reasons. Some patients may believe that a brand-name formulation is superior perhaps because direct-to-consumer advertising influences patient beliefs about medications (10, 11).

Similar study performed in Germany has evaluated the attitude of patients towards generic drugs and prescriptions containing generic drugs an alternative to brand-name products, with a special focus on information on patient's attitude to generics provided by their general practitioners (GPs). Nearly two thirds of patients stated that they knew of the difference between brand-name drugs and generics, one third were not satisfied with the information given by their GPs (12).

Different research has shown that physician and pharmacists play an important role in decision to choose a brand-name or generic formulation of a medicinal product (13). Choosing a brand-name drug when a generic is available may be influenced by a variety of factors. While most states permit pharmacists to substitute a generic unless directed by the physician or patient, a minority of states mandate that a pharmacist substitutes a generic unless overridden by a physicians' order (5). Physicians and pharmacists in Slovakia are also required to substitute by a generic (14). Quite a high number of patients who consider generic as a product with lower quality have distrust to use generics. Even though, in reality the standards and regulations for manufacturing generics are the same as for brand-name drugs (15). Historically, the debate has focused on the issue of bioequivalence, and clinical practice has identified a number of drug classes for which generic substitution should be approached with caution (16).

Nevertheless, there is still some reluctancy to use generics as shown in a study performed in Germany in which 13 % of patients were unwilling to switch to generic drug. Variables associated with non acceptance were old age, having a low educational level and being retired – which means not having to pay for drugs. Also non acceptance was also higher if the patient did not know what a generic drug was. The percentage of patients that did not accept switching to generic drugs is very low. To increase the substitution for generics there is a necessity to better inform and educate the population (17). On the other hand, a study in Spain showed a high acceptance of replacement by generic drugs in community pharmacies (90.8 %) (18).

Our study showed that quite often there is a lack of information about generic substitution provided to patients in our country. The level of education is one of the limiting factors for successful generic substitution.

Conclusion

Only 33.8 % of patients care to know about drug which they are using, e.g. generic or brand-name drug. Consequently, if there is still lack of information about generics in Slovakia, this could create some distrust to use generics by patients. Definitely, further educational activities for patients are necessary. Although the national legislation is requesting a generic substitution, not all physicians and/or pharmacists are performing it properly.

References

1. Directive 2004/27/EC of The European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Article 10., Official Journal of the European Union L 136/34. Available at: http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/dir_2004_27/dir_27_en-pdf. Accessed September 23, 2007.

2. Note for guidance on the investigation of bioavailability and bioequivalence. CPMP/EWP/QWP/1401/98. London: EMEA, 2001: 3-11. Available at: http://.emea.europa.eu/pdfs/human/ewp/140198en-pdf. Accessed September 23, 2007.

3. Haas JS, Phillips KA, Gerstenberger EP, Seger AC. Potential savings from substituting generic drugs for brand-name drugs: Medical Expenditure Panel Survey, 1997—2000. Ann Intern Med. 2005; 142: 891—897.

4. Kreling DH, Mott DA, Wiederholt JB. Prescription Drug Trends: A Chartbook Update. Menlo Park, California: Henry J. Kaiser Family Foundation, 2001. Available at: http://www.kff.org/rxdrugs/loader-cfm?url=/commonspot/security/getfile.cfmPagel D=13796. Accessed September 11, 2007.

5. Primer A. Generic drugs, patents and the pharmaceutical marketplace [document on the internet]. National Institute for Health Care Management Foundation; 2002. Available at: http://www.nihem.org/-nihcmor/pdf/GenericsPrimer.pdf. Accessed September 23, 2007.

6. Andersson K, Bergström G, Petzold MG, Carlsten A. Impact of a generic substitution reform on patients• and society's expenditure for pharmaceuticals. Health Policy 2007; 81: 376—384.

7. Vyhláška Ministerstva zdravotníctva Slovenskej republiky č. 559/2005 Z.z., ktorou sa ustanovuje zoznam ATC skupín liekov, pri ktorých je možný výdaj náhradného generického lieku, účinnosť 15 Dec 2005. [Decree of Ministry of Health in The Slovak republic No. 559/2005 laying down the list of medicinal products in ATC groups, where a generic substitution could be performed, came into force 15 Dec 2005]. Available at: . Accessed September 23, 2007.

8. IMS dataview 6.7 — Slovak combined DataView Database June 2007, YTD/05/07. 2003 IMS Health Incorporated.

9. Kjoenniksen I, Lindbaek M, Granas AG. Patients' attitudes towards and experiences of generic drug substitution in Norway. Pharm World Sci 2006; 28: 284—289.

10. Brennan TA, Lee TH. Allergic to generics. Ann Intern Med 2004; 141: 126—130.

11. Robinson AR, Hohmann KB, Rifkin JI, Topp D, Gilroy CM, Pickard JA et al. Direct-to-consumer pharmaceutical advertising: physician and public opinion and potential effects on the physician-patient relationship. Arch Intern Med 2004; 164: 427—432.

12. Himmel W, Simmenroth-Nayda A, Niebling W et al. What do primary care patients think about generic drugs? Int J Clin Pharmacol Ther 2005; 43: 472—479.

13. Mott DA, Cline RR. Exploring generic drug use behaviour: the role of prescribers and pharmacists in the opportunity for generic drug use and generic substitution. Med Care 2002; 40: 662—674.

14. Zákon NR SR č. 140/1998 Z.z. o liekoch a zdravotníckych pomôckach, §38b [Act of The National Council of The Slovak republic No. 140/1998 relating to medicinal products and medical devices, paragraph 38b]. Available at: http://www.zbierka.sk/zz/predpisy/default.spx?PredpisID=14397FileName=98-z140Rocnik=1998. Accessed September 23, 2007.

15. Murphy JE. Generic substitution and optimal patient care (Editorial). Arch Intern Med 1999; 159: 429—433.

16. Meredith P. Bioequivalence and other unresolved issues in generic drug substitution. Clin Ther 2003; 25: 2875—2890.

17. Sagardui-Villamor JK, Lacalle Rodríguez-Labajo M, Casado-Buendía S. Substitution of generic for brand medicines in primary care. Factors associated to refuse change. Aten Primaria. 2005; 36: 489—493.

18. Honrubia AF, Carbajal de Lara JA, Cebrian Picazo C et al. Acceptance of replacement by generic medicines at community pharmacies. Aten Primaria 2007; 39: 81—85.

Received November 6, 2007.
Accepted May 15, 2008.