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ORIGINAL PAPER

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Pharmacoeconomic Analysis of Antiepileptic Reimbursement for Neuropathic Pain in Bosnia and Herzegovina – Budget Impact Analysis of Pregabalin

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ABSTRACT

Introduction: Neuropathic pain resulting from injury to the nervous system. Up to 7% to 8% of the European population is affected. A number of different treatments for neuropathic pain have been studied including antiepileptic. Pregabalin and gabapentin are often considered first-line treatments. Pregabalin provides equivalent efficacy to gabapentin, showing greater potency at much lower doses and is considered as cost-effective intervention. In Federation of Bosnia and Herzegovina (FB&H), gabapentin is fully reimbursed, while pregabalin is enlisted on list B with copayment. **Aim:** To develop simple budget impact (BI) model and assess BI of introducing pregabalin into full reimbursement in FB&H. **Material and methods:** Budget impact model was developed using Microsoft Excel 2010. Local epidemiology data and data on drug consumption from government reports in 2016 were used. Two scenarios with three-year time horizon have been developed: 1) without and 2) with pregabalin reimbursed at the same level as gabapentin. Two developed scenarios have been compared from health insurance fund (HIF) perspective. **Results:** In scenario 1 consider both drugs fully reimbursement and without patient switch among alternatives the total cost would be increased for 780,025 KM; 852,027 KM and 943,830 KM over a 3-year period. In scenario 2 considering both drugs fully reimbursed but with patient switch topregabalin total annual cost would be increased for 732,241 KM; 742,395 KM and 751,761 KM. Comparing scenario 1 and 2 it is found that scenario 2 is more favorable from HIF perspective. **Conclusion:** Implementation of

pharmacoeconomic principles in reimbursement decisions in Bosnia and Herzegovina would improve access to medicines and contribute rationale resource consumption.

Keywords: economics, pharmaceutical, neuralgia, health policy, decision making.

1. INTRODUCTION

Neuropathic pain is pain caused by damage or disease affecting the somatosensory nervous system (1). Neuropathic pain may result from disorders of the peripheral nervous system or the central nervous system (brain and spinal cord). Thus, neuropathic pain may be divided into peripheral neuropathic pain, central neuropathic pain, or mixed (peripheral and central) neuropathic pain. Up to 7% to 8% of the European population is affected, and in 5% of persons it may be severe (2).

Applying this prevalence we can estimate that in Bosnia and Herzegovina (BH), based on the latest published population census from 2013 (3), there are 284,375 patients in the BH population of which 177,870 in the Federation of BH and 99,524 in the Republic of Srpska.

A number of different treatments for neuropathic pain have been studied, but the literature is sizable, rapidly evolving, and lacks important information about practical aspects of patient management. On the basis of randomized clinical trials, medications recommended as first-line treatments for neuropathic pain included certain antidepressants (i.e., tricyclic antidepressants and dual reuptake inhibitors of both serotonin and norepinephrine), calcium channel α_2 - δ

ligands (i.e., gabapentin and pregabalin), and topical lidocaine. Opioid analgesics and tramadol were recommended as second-line treatments that can be considered for first-line use in selected clinical circumstances. Other medications that generally would be used as third-line treatments include certain other antidepressant and antiepileptic medications, topical capsaicin, mexiletine, and N-methyl-D-aspartate receptor antagonists (4).

Pregabalin and gabapentin are often considered first-line treatments for various neuropathic pain syndromes, generally irrespective of cause (5).

One cohort study reviewed the utility of switching patients with neuropathic pain due to peripheral neuropathy from gabapentin to pregabalin (5). The authors found that those who responded well to gabapentin and those who did not show additional benefit with decreased pain when they were switched to pregabalin. Patients taking pregabalin also had improved pain control compared with those who remained on gabapentin. Patients who experienced adverse events with gabapentin were more likely to also experience adverse events with pregabalin. These patients were also more likely to discontinue use of pregabalin than those who responded well to both gabapentin and pregabalin.

Another small trial compared the degree of pain relief with gabapentin to pregabalin in patients with postherpetic neuralgia in order to more closely determine equivalent dosing between the 2 medications. Patients were switched from gabapentin to pregabalin using one-sixth the dose of gabapentin with unchanged dosage frequency. After switching medications, patients reported similar pain relief and side effects, with the exception of an increased incidence of peripheral edema in the pregabalin group. The authors concluded that the analgesic effect of pregabalin was about 6 times that of gabapentin (6).

In Federation of BH there are two reimbursement lists on a Federal level; List A which is fully reimbursed and obligatory to be implemented in the whole territory by cantonal health insurance funds (HIF) gabapentin and pregabalin, and List B which defines different level of copayment and its implementation at cantonal level depends on local decision and budget availability. Gabapentin is fully reimbursed and enlisted on List A, while pregabalin is enlisted on List B and not available at the whole territory of Federation of BH (7).

In our study we present pharmacoeconomic approach in reimbursement decision making in Federation of BH by applying simple budget impact model for assessment of pregabalin budget impact in case it is introduced into List A.

2. AIM

The aim of this study is to develop simple budget impact (BI) model and assess BI of introducing pregabalin into reimbursement list A in Federation of B&H. By this example, our aim is to show importance of pharmacoeconomic evaluations into reimbursement decision making in order to proper allocation of available resources based on exact measures

3. MATERIALS AND METHODS

Budget impact model (BIM) was developed using Microsoft Excel (Microsoft Corp., Redmond, WA) version 2010. The model was used to assess the financial impact to health

insurance funds (institutes) of introducing pregabalin into reimbursement lists of Federation of BH. The model has been built according to the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) guidelines (8) and existing legislation.

This analysis was conducted with a 3-year time horizon considering year 2017 as baseline. Using real market data we have calculated number of patients and corresponding consumption in packs on a yearly basis according to defined daily drug dose (DDD) (9). Two scenarios for 3-years period after introduction of pregabalin into List A:

Scenario 1: Base case scenario based on a forecast of market consumption using current trends and the assumption that pregabalin is introduced into reimbursement list A, same as gabapentin

Scenario 2: An alternative scenario where pregabalin is introduced into reimbursement list A and its market share consequently increased.

In the base case scenario 1, the evolution of the market within three-year period was observed with overall growth in consumption of these two drugs at an annual rate of 10% in terms of number of patients, as a direct result of increased prescription and availability of treatment in terms of inclusion in the positive list.

Alternative scenario 2 considers the same criteria as a base case scenario plus introduction of the pregabalin into reimbursement list A and annual increase of patient treated with pregabalin of 20%, 30% and 40% respectively. The assumption is that pregabalin will be more prescribed than gabapentin due to its effectiveness and hence some of patients currently treated with gabapentin will be switched to this therapy.

Model calculates only direct costs of drugs that are included into reimbursement calculated per pack and annual consumption according to DDD. The drug costs on the basis of cost per pack of each drug, the number of days of therapy and the annual cost associated to each drug regimen was calculated.

For both scenarios number of patients treated by antiepileptic has been calculated as 3% based on study published by Leong C et al. (10). Prices of both comparators taken into the calculation are those announced by Federal Ministry of health and aligned with maximal wholesaler prices set by the Agency for medicines and medical devices of BH (ALIMSBH) (11). All prices and costs are presented in Bosnian convertible marks (KM).

4. RESULTS

Overview of the consumption trends expressed in convertible marks of gabapentin and pregabalin in BH in year 2016 and share of consumption in Federation of BH according to the Report on drug utilization issued by ALIMSBH is presented in Table 1. It is apparent that there has been an increase in the consumption of both drugs, which is a confirmation that there is a need for these therapies within the approved indications, and most often in the treatment of neuropathic pain. According to some studies, the proportion of new antiepileptic in neuropathic pain therapy ranges from 29% - 40%.

Table 2 shows the dosing regimen and it is apparent that the most commonly used dose in clinical practice for gaba-

ATC	Anatomy group	2015		2016		Increment	Federation of BH	
		KM	Share %	KM	Share %		2016	2017
N	NERVOUS SYSTEM	76.173.109,65	12,76%	81.644.003,53	13,15%	7%	/	/
N03	ANTIPILEPTICS	10.794.993,59	1,81%	12.106.250,94	1,95%	11%	/	/
N03AX12	gabapentin	734.927,52	0,12%	960.114,90	0,15%	23%	475.634	585.030
N03AX16	pregabalin	106.558,02	0,02%	170.061,33	0,03%	37%	95.666	138.645

Table 1. Overview of the consumption trends in year 2015 and 2016

Drug	Day 1	Day 2	Day 3 →	Day 7 →	Number of tablets/capsules per day		
					300 mg	75 mg	150 mg
Gabapentin (mg)	300	600	900	900	3		
Pregabalin (mg)				150		2	1
Pregabalin(mg) 50%*	150	150	150	300		3	2
Pregabalin(mg) 20%*				600			4

*dose increase after 7 day of therapy is needed for 50% or 20% of patients

Table 2. Recommended dosing and maintenance dose for gabapentin and pregabalin

Drug	Price per pack on RB list (KM)	Number of tablets/ capsules per pack	Price per tablet/ capsule (KM)	Number of tablets/ capsules per patient per month	Number of packs per patient	Monthly cost per patient (KM)	Annual cost per patient (KM)
Gabapentin 300 mg	19,00	50	0,38	3	2	34,20	410,40
Pregabalin 75 mg	27,44	56	0,49	2	1	29,40	352,80
Pregabalin 150 mg	39,76	56	0,71	1	1	21,30	255,60

Table 3. Monthly and annual cost of neuropathic pain treatment per patient for gabapentin and pregabalin

Variable	Literature source / Calculation	Absolute value	Year 2016		
			Annual treatment cost per patient (KM)	Total treatment cost (KM)	Cost for HIF (KM)
Number of patients in Federation of BH		177.870	/	/	/
Treated with antiepileptic (total)	35% (29-40%)	62.255	/	/	/
Treated with antiepileptic (Federation of BH)	3%	1.924	/	/	/
Treated with gabapentin (Federation of BH)	73%	1.404	410,40	576.202	576.202
Treated with pregabalin (Federation of BH)	37%	520	255,60	132.912	66.456

Table 4. Cost of neuropathic pain treatment cost paid by HIF in 2016 for gabapentin and pregabalin

pentin is 300 mg, and in the case of pregabalin, for the most optimal regimen of 75 mg and 150 mg, according to the individual needs of patients.

According to the dosing regimen, DDD and valid drug prices on the lists in the Federation of BH, in Table 3 the monthly cost per patient for gabapentin or pregabalin for the most optimal dosage regimen or dosage form are presented.

It is evident that treatment with any of the dosage forms of pregabalin is significantly cheaper than the therapy with gabapentin in the most common doses in this indication.

If we take epidemiological data on the number of patients in the Federation of BH and the literature data on the rate of patients who use antiepileptics in the examined indication, expected annual cost is calculated (total and cost for HIF depending on the status on the lists, gabapentin – list A or 100% of the costs are borne by health insurance institutions,

and for, pregabalin – list B with 50% paid by HIF), as shown in Table 4.

Scenario 1 based on the assumptions that the growth rate of prescribing gabapentin and pregabalin is 10% per year (increase in the number of patients), along with the constant dynamics and the share of drugs in prescribing practice in the Federation of BH, and the presumption that pregabalin is included in the A list of medicines as well as gabapentin had been developed and results are presented in Table 6.

In this scenario, in the first year after the pregabalin introduction on list A, the total cost for these drugs will be increased by 21%, while in the second and third year the increase will be 9%. In absolute terms, this means: 780,025 KM; 852,027 KM and 943,830 KM over a 3-year period respectively.

In scenario 2, the growth rate of gabapentin and pregabalin prescription is assumed to be 10% annually (an increase in

Variable	2016			Year 1		Year 2		Year 3	
	Number of patients	Annual cost of treatment per patient (KM)	Total cost (KM)	Number of patients	Total cost (KM)	Number of patients	Total cost (KM)	Number of patients	Total cost (KM)
Treated with antiepileptic (FBH)	1.924	/	/	2.116	/	2.328	/	2.561	/
Treated with gabapentin (FBH)	1.404	410,40	576.202	1.544	633.822	1.699	697.204	1.869	766.924
Treated with pregabalin (FBH)	520	255,60	132.912	572	146.203	629	160.824	692	176.906
Total annual cost for HIF (KM)	/	/	642.658	/	780.025	/	858.027	/	943.830
Annual cost increment (%)					21%		10%		10%

Table 6. Scenario 1 - both alternatives (gabapentin and pregabalin) introduced to reimbursement list A without change in prescribing pattern (no-switch)

Variable	2016			Year 1		Year 2		Year 3	
	Number of patients	Annual cost of treatment per patient (KM)	Total cost (KM)	Number of patients	Total cost (KM)	Number of patients	Total cost (KM)	Number of patients	Total cost (KM)
Treated with antiepileptic (FBH)	1.924	/	/	2.117	/	2.328	/	2.561	/
Treated with gabapentin (FBH)	1.404	410,40	576.202	1.236	507.057	951	390.434	628	257.687
Treated with pregabalin (FBH)	520	255,60	132.912	881	225.184	1.377	351.961	1.933	494.075
Total annual cost for HIF (KM)	/	/	642.658	/	732.241	/	742.395	/	751.761
Annual cost increment (%)					14%		1%		1%

Table 7. Scenario 2 - both alternatives (gabapentin and pregabalin) introduced to reimbursement list A with change in prescribing pattern (switch)

Compared scenario	2016	Year 1	Year2	Year 2
Scenario 1 (KM)	642.658	780.025	858.027	943.830
Scenario 2 (KM)	642.658	732.241	742.395	751.761
Difference(KM)	0	-47.784	-115.632	-192.069

Table 8. Comparison between Scenario 1 and Scenario 2

the number of patients), but with a reduction in the number of patients treated with gabapentin due to switch on pregabalin because of its better efficacy in this indication and at annual rates of 20%, 30% and 40% respectively. The three-year budget impact for Health Insurance fund in Federation of BH is presented in the Table 7.

Due to the lower cost of annual treatment with pregabalin, and the better efficacy of therapy with this drug, in the first year, it is expected that the total cost paid by HIF for this therapy will also be increased but significantly less than in scenario 1, meaning 13.8% increase (86,583 KM), but in the second and third year the increase will be only 1% annually. In absolute terms, this would mean: 732,241 KM; 742,395 KM and 751,761 KM in the first, second and third year after the introduction of pregabalin into the reimbursement list A, respectively.

By comparing the two proposed scenarios, it can be concluded that in the case of the realization of scenario 2, even savings would occur, and as shown in Table 8

5. DISCUSSION

As with many chronic pain conditions, patients with neuropathic pain are high consumers of health care resources, such as visits to medical professionals and use of prescription medications (12). Findings from observational studies in the

USA and Europe suggest that between 70.0% and 96.0% of NeP subjects seeking care experience moderate to severe pain (13) It is associated with worse health and quality of life than non-neuropathic pain, and its incidence, prevalence, and impact are likely to increase with the aging population (14).

Diverse pharmacological treatments of NP have become available, and interpreting the data on their efficacy and safety involves substantial complexities and ambiguities (15). Antiepileptic drugs are used for treating epilepsy, but have also been used for treating neuropathic pain. Antiepileptic drugs work in different ways, and there is no expectation that they are equally effective. Cochrane reviews on antiepileptic published in 2013 found that only for gabapentin and pregabalin was there some evidence that they worked in long-term nerve pain with diabetes (painful diabetic neuropathy) and pain after shingles (postherpetic neuralgia). Pregabalin also had evidence of efficacy in central neuropathic pain (typically pain after stroke) and in fibromyalgia (16). Both agents have been shown to be effective for neuropathic pain disorders, however, only pregabalin has been FDA approved for both the management of diabetic peripheral neuropathy and post herpetic neuralgia (17).

Pregabalin has been shown in studies to provide equivalent efficacy to gabapentin, however, at much lower doses showing greater potency than gabapentin in pain and seizure disorders (18).

In a study conducted in China, it has been showed that pregabalin is an effective treatment for neuropathic, but at increased cost (19), which is opposite to our findings. Cost effectiveness model base study conducted in Greece showed that treatment of pain associated with Diabetic Peripheral Neuropathy (DPN) and Post-Herpetic Neuralgia (PHN) with

pregabalin is a cost-effective intervention for the social security in Greece compared to gabapentin (20).

The increase in expenditure of health care has prompted many governments, health insurance companies, and health providers throughout the world to adopt strategies to manage the high cost of medication, including formulary management and the use of pharmacoeconomics. Formulary management uses pharmacoeconomics as a means to reduce these costs by allowing efficient use of the available resources.

Obtaining value for money and ensuring the long-term sustainability of healthcare systems is a priority in all European countries and beyond. Achieving these objectives becomes even more important for countries with comparatively less resources available to spend on healthcare like Central and Eastern European (CEE) countries (21).

Current legislation regulating introduction and assessment of medicines that should be introduced into B&H Federation Cantonal reimbursement list across Federation of B&H proposes different criteria, and one of them is budget impact analysis. Unfortunately, there is no implementation of such rules causing lack of transparency in decision making process.

Significant funds are spent on drugs that do not have adequate therapeutic value, and this is in addition to losses occurring as a result of a jurisdiction conflict and overlaps in all regions of the country (22).

In previous studies it has been shown that in Federation of BH there are huge discrepancies in decision making during introduction of medicines into reimbursement lists which is based on WHO essential medicines list (EML) and that independent, unbiased, high-quality evidence such as WHO EML, Cochrane Database of Systematic Reviews (CSR) and HTA reports (national or international with local adaptations) should be used when deciding on medicine reimbursement (23).

Pharmacoeconomic and health technology assessment (HTA) in the Federation of Bosnia and Herzegovina, but also in the Republic of Srpska, has a short history because of a huge political impact in the decision-making process, decentralized system, and multiple decision makers in these regions. Challenges remain in assessments, in development of more transparent approaches in different areas of the health system in these regions, and in consistent application of appropriate standards especially in education of professionals who will provide establishment of HTA in the health system of The Federation of Bosnia and Herzegovina and the Republic of Srpska (24).

In our study we aimed to show how pharmacoeconomic approach can contribute better decision making process when selecting medicines to be introduced into the reimbursement list in a simple manner.

Even we are aware of limitations of our study, our finding suggest that deeper understanding and implementation of already introduced legislation could assure better decision making and access to medicines in Federation of Bosnia and Herzegovina as well as contribute to rational allocation of available scarce resources.

6. CONCLUSION

Budget impact model comparing two antiepileptic drugs, gabapentin and pregabalin currently with different reim-

bursement status has been developed. In two scenarios it has been calculated that introduction of pregabalin into reimbursement list A, meaning full reimbursement like gabapentin would contribute to budget increase. Due to potential patient using gabapentin switch to pregabalin based on better efficacy in neuropathic pain this impact would be decreased, so proposed scenario 2 seems more favorable.

Implementation of pharmacoeconomic principles in reimbursement decisions in Bosnia and Herzegovina would improve access to medicines and contribute rationale resource consumption.

- **Conflict of Interest:** The authors declare that they have no conflict of interest.
- **Author contribution:** T.C., R.J. and V.T. developed design and concept of the study. V.T. contributed to data acquisition. T.C. developed BIA model, performed data interpretation and drafting the article. T.C., R.J. and V.T. critically revised the article and final approval of the version to be published.

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