ОРГАНІЗАЦІЯ ОХОРОНИ ЗДОРОВ'Я

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ORGANIZATION OF THE HEALTH SYSTEM IN BULGARIA - FOCUS ON PAYMENT AND AFFORDABILITY OF MEDICINES

Aim. To conduct a retrospective review and analysis of measures taken to improve the patients' access to therapy in Bulgaria.

Materials and methods. The study is based on data from officially published regulations and laws, as well as publications on measures to control spending in healthcare and their impact on patients and government spending. Regulatory mechanisms introduced through laws and regulations are also mentioned in the analysis.

Results and discussion. The measures taken are divided into several groups in order to examine all aspects of drug affordability – cost control mechanisms affecting access to medicines, patients' co-payment, and physical drug availability. It has been determined that the external reference pricing, Health Technology Assessment (HTA), discounts and negotiations, a regressive scale for price calculation, limiting prices for generics, budget cap and payback mechanism, therapeutic effect monitoring are used to set and control drug prices. It has been found that despite the decrease in drug prices, there is a noticeable increase in government spending, as well as in household spending. Retail pharmacies established in the country are mainly in cities. About 32 municipalities cannot provide patients with access to medicines. The financial implications are significant, and the burden for patients is growing/

Conclusion. Efforts in recent years have focused on reducing costs for both patients and the population as a whole. Based on the results of the study, it has been found that the introduction of reference pricing (internal and external), health technology assessment, budget constraints, negotiations, as well as generic drug policies do not contribute to patient's access to therapy. The cost control measures implemented at this stage are not as effective as expected. In addition, it has been determined that the household expenditure on medicines has been increasing recently, and all policy measures taken do not contribute to supporting patients financially.

Key words: healthcare costs; measures for cost control; affordability of medicines; access to medicines; co-payment

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ОРГАНІЗАЦІЯ СИСТЕМИ ОХОРОНИ ЗДОРОВ'Я В БОЛГАРІЇ – ФОКУС НА ОПЛАТУ ТА ДОСТУПНІСТЬ ЛІКІВ

Мета — ретроспективний огляд та аналіз запроваджених заходів для поліпшення доступу пацієнтів до терапії в Болгарії.

Матеріали та методи. Дослідження базується на даних офіційно опублікованих постанов та законів, а також на публікаціях щодо заходів контролю витрат в охороні здоров'я та їхнього впливу на пацієнтів і державні витрати. Механізми регуляторних установ, запроваджені через закони та нормативні акти, також згадуються в аналізі.

Результати та їхнє обговорення. Вжиті заходи поділено на кілька груп, щоб дослідити всі аспекти доступності ліків – механізми контролю витрат, що впливають на доступ до ліків, співоплату пацієнтів та фізичну доступність ліків. Визначено, що для встановлення та контролю цін на ліки використовуються зовнішнє референтне ціноутворення, оцінка медичних технологій, знижки та переговори, регресивна шкала для розрахунку цін, обмеження цін на генерики, обмеження бюджету та механізм окупності, моніторинг терапевтичного ефекту. Визначено, що попри зниження цін на ліки помітно зростання державних витрат та витрат домогосподарств. Роздрібні аптеки, створені в країні, розташовані переважно у великих містах. Близько 32 муніципалітетів не можуть забезпечити пацієнтам доступ до ліків. Фінансові наслідки є значними, а тягар для пацієнтів зростає.

Висновок. Зусилля останніх років були зосереджені на скороченні витрат як для пацієнтів, так і для населення в цілому. За результатами дослідження визначено, що запровадження референтного ціноутворення (внутрішнього та зовнішнього), оцінка медичних технологій, обмеження бюджету, переговори, а також політика щодо генеричних препаратів не сприяють доступу пацієнтів до терапії. Заходи з контролю витрат, що запроваджуються на цьому етапі, не мають очікуваної ефективності. Окрім того, визначено, що останнім часом витрати домогосподарств на ліки зростають, а усі вжиті політичні заходи фінансово не сприяють підтримці пацієнтів.

Ключові слова: витрати на охорону здоров'я; доступність ліків; доступ до ліків; заходи щодо контролю

Introduction. The rising public expenditure in healthcare, especially due to medicines, is a significant burden for countries worldwide. Laws and regulations to control pharmaceutical spending are often introduced, although sometimes there is no evidence to support their effectiveness. Therefore, monitoring the success of the policies introduced is crucial and very important.[1] Changes in GDP have a positive impact on public spending, as a study in Bulgaria has shown. Economic growth and rising GDP are directly connected to increases in spending [2]. Researching and tracking the effectiveness of the measures introduced is a key to achieving real control of public spending reductions.

On the other side, examining the patients' co-payment is important to evaluate established measures from the perspective of patients [3] Out-of-pocket payments or co-payments include fees, whereas the direct payments for healthcare services are not covered by the National Health Insurance Fund (NHIF). It is significant financial burden for outpatient therapy, especially in lower-income countries.[4] In 2018, an average of 94% of households reported payments that were not reimbursed by the NHIF. Data from the 2019 show 73% co-payment for outpatient medicines in Bulgaria compared to an average 40% in the EU. [5]

Health systems have several main goals - universality, equity, sustainability and high quality of health services. Accessibility includes the prices of services and products, which should be within the financial capabilities (of the payer and/or the patient). [6] Universal Health Coverage (UHC) is a key priority in many European Union (EU) countries responsible for health policy, encompassing population coverage, service coverage and cost recovery. By improving the availability of data, policymakers will be able to take more targeted policy actions and support the goals of both universal health coverage and the European Health Union [7].

Many European countries use the Managed Entry Agreements (MEAs) to control market entry and medicines prices. MEAs are agreements between a manufacturer and a payer that allow coverage/reimbursement of new therapies under certain conditions. These agreements can use various mechanisms to address uncertainty about new technologies and to make decisions about the adoption of new drugs, taking into account their economic impact. [8, 9] The models in EU are mainly focused on pricing measures, reimbursement measures, and measures directly affecting the patients [10]. Research on the effectiveness could contribute to further policies development or amendments of the established those.

A small number of studies discussed the consistency of all the measures introduced in recent years in Bulgaria. They are described in several publications, but changes in legislation are constantly, which requires regular monitoring and discussion.

Aim. The aim of the study is retrospective review and analysis of implemented measures for improving access to therapy in Bulgaria. The officially published Ordinances and Law for medicines payment as well as publications revealing the cost controlling and evaluation was considered for the study conduction in order to find their impact on access to medicines and patients affordability to therapy.

Materials and methods. The study is a retrospective review of published data examining the measures implemented and their impact on patients and public spending. Publications since the last 5 years are considered relevant due to continuous changes in legislation and innovations. The mechanisms described and defined by regulatory institutions introduced through law and regulations are also included in the analysis.

The search for publications covers the databases Google scholar and Pub med. The keywords used are "measures for health care costs controlling in Bulgaria", "public and household expenditure in Bulgaria", "healthcare costs control in Bulgaria". The publications after 2020 are considered as relevant. The manuscript languages are not limited. All measures leading to the monitoring and control of medicine prices and their impact on patient access were

considered potentially significant.

The first part of the study discusses the policy effects in place and the results that may have been achieved from the payer's perspective. The second part of the study explores the actual physical and financial access to therapy in Bulgaria if the differences in household costs are considered.

Results and Discussion. The actions adopted are divided into several groups in order to examine all aspects of medicines affordability - mechanisms for cost control affecting access to medicines, patients' physical and financial availability of medicines. On total 8 publications relevant to the topic are extracted and the results are discussed below. Public expenditure measures from National Health Insurance Fund (NHIF) perspective [11].

Efficacy of implemented mechanisms is under review at the current moment as the medicines costs continue to rise latest years. The payment institution costs are sustainable in some degree, but new medicines, inflation, aging population, and disease epidemiology are the main reasons leading to increasing spending and affecting annual NHIF budget.

The first part of the study listed some of the implemented policy measures considering the medicines reimbursement and therapy costs [12].

› The Positive Drug List (PDL) was introduced to select the medicines paid by public costs and to define the reimbursement value. It has 4 Annexes, depending on the source of funding: [13]

› Annex №1 Medicinal products for outpatient therapy paid by NHIF;

› Annex №2 Medicinal products paid for from the budget of hospitals (reimbursed by NHIF within the clinical pathways);

› Annex №3 Medicinal products paid for from the budget of the Ministry of Health;

› Annex №4 Limit price of medicinal products included in the PDL.

According to the Regulation on rules of prices of medicinal products [14, 15] and the Health Insurance Act [16] the following measures are introduced:

✓ **External reference pricing** - the manufacturer's price cannot be higher than the BGN equivalent of the lowest manufacturer's price for the same medicinal product in Belgium, Greece, Spain, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and France;

✓ **Regressive mark-up scale,** under which the price of medicinal products is formed:
(Manufacturer's price + VAT) + (Wholesale mark-up + VAT) + Retail mark-up based on the manufacturer's price + VAT, where VAT is 20 %.

✓ **Reimbursement based on a reference price per DDD**- to determine the payment value of the medicinal products included in the PDL, a reference price per DDD or therapeutic course, concentration, or volume by INN and dosage form is calculated. The lowest price per DDD is used as a reference for all medicines within the group (25%, 50%, 75% or 100% of the reference price per DDD per package).

✓ **Generic policy** - implemented rules for reimbursement per reference price per DDD (internal reference pricing) and price cap for generic medicines [17].

In the PDL are included generic medicinal products if the declared manufacturer's price does not exceed 70 percent, and for biosimilar medicinal products does not exceed 80 percent of the manufacturer's price of a medicinal product with the same international nonproprietary name, form, dosage (INN).

✓ **HTA for innovation products** - if the positive assessments of the health technology by a regulatory institution from UK, France, Germany and Sweden are available. [10]

✓ **Budget cap and payback mechanism** for reimbursement of funds in case of exceeding the predicted annual budget, due to the NHIF. Reimbursed medicines are divided into three groups: Group A - medicines for outpatient treatment, prescribed after approval by a committee of three specialists; Group B - all other medicines outside group A; Group C - oncological and life-saving medicines.

The exceeding amount per year for each group is published by NHIF. The data for the exceeding amount which is attributable to

Table 1

THE EXCEEDING AMOUNT FOR EACH GROUP, EURO

Group of medicines	2020	2021	2022	2023	2024
Group A	22559466.48	15800907.72	39825165.6	66230706.3	58169577.45
Group B	4245 937.68	3482 188.2	4260 530.82	1802 552.16	27508664.07
Group C	46829660.64	39805 921.26	62246388.93	121842165.6	149968195.9

the marketing authorization holders (MAH) is presented (table 1) [18].

The following group of medicines contributes significantly for high healthcare costs as reveals the results till 2021 (tabl.2).

The access to therapy from patients' point of view

The second part of the study reveals the differences in patients' access to therapy.

Table 2

GROUPS WITH THE HIGHEST YEARLY NHIF SPENDING DURING 2019-2021, EURO

Pharmaco -therapeutic group		Yearly NHIF spending, euro		
		2019	2020	2021
Group A	Antineoplastic and immune modulating agents	92 618 969.22	100 352 463.87	105 163 926.78
	Medicines used in diabetes	52 561 598.07	60 354 025.26	62 061 145.20
	Nervous system acting medicines	-	31 718 183.67	33 065 438.43
Group B	Respiratory system acting medicines	38 670 312.42	39 505 463.43	38 492 289.27
	Cardiovascular system acting medicines	36 646 981.26	54 430 917.39	35 725 513.26
Group C	Antineoplastic medicines	247 092 784.05	312 641 611.68	352 789 198.26
	Blood and blood forming organs	6 365 626.20	7 029 557.46	8 200 311.42

The data presented covers the period 2019-2021 due to limited officially published information on pharmacotherapeutic groups. However, the trend is visible as increasing costs reimbursed by the NHIF and returned by the MAH are identified:

✓ the NHIF conducts negotiation of discounts for reimbursed medicinal products. The negotiated discounts no less than 10% for single entry products with marketing authorization holders, entirely in favor of the NHIF. The discounts are different between the therapeutic indications.

✓ monitoring of therapeutic effect is introduced by National Council on Prices and Reimbursement of Medicinal Products (NCPRMP). The contract includes specified clinical parameters in accordance with the criteria for monitoring set by the NCPRMP and the reimbursement after the achieved results could be discussed.

It is presented in two sections - physical and financial medicines affordability.

- **Access to medicines in place.** The access to pharmacies in Bulgaria is directly connected to the opportunities for providing the population with medicines. In 2019, there were 3814 pharmacies, and at the end of 2021 they decreased to 3355, with 17 municipalities without retail pharmacy. As a result, more than half of the pharmacies are concentrated in large cities, for example, in Sofia there are 750, in Plovdiv - over 200. In 2023, the number of municipalities without a pharmacy increases to 32 [19]. On total number of retail pharmacies dispensing medicines paid by public fund is 2732 at the beginning of 2025 in Bulgaria [20].

• **Access to medicines and patients' co-payment.** A significant part of the population in Bulgaria is currently uninsured and pays directly for medical services, unless they have access to free emergency medical care. The uninsured are mainly citizens living abroad, long-term unemployed people who choose not to pay into the healthcare system officially, and those without a valid ID card. 19% of households in Bulgaria experienced significant medical costs in 2018, and twothirds of these are concentrated among the poorest households.

A report by the Ministry of Finance, which examines the main characteristics of the healthcare system, states that Bulgaria ranks in 4th place among the EU considering the direct patients co-payments for healthcare costs [21].

The average healthcare costs of household in Bulgaria increased every year (tab. 3).

to 40.4 hours), but remains significantly high. Pharmaceutical companies have voluntarily agreed to cover the copayment of patients for therapy in order to ensure access and affordability due to expensive medicines and high co-payment [12].

The mechanism to improve access to treatment for patients with cardiovascular diseases with the introduction of 100% payment by the National Health Insurance Fund based on the reference price per DDD is implemented from April 2024. NHIF report a year later confirms the benefits for patients, including the difference in the number and cost of hospitalizations of patients with the relevant cardiovascular diseases before and after this regulatory change in the reimbursement level. The additional average number of patients treated is 29101 patients, the additional cost is 28981692 BGN, and the improved survival rate

Table 3

Household healthcare expenditure during 2015-2022 [22]

Average cost per household (euro)	2015	2016	2017	2018	2019	2020	2021	2022
Overall health expenditures	303	314	327	358	429	426	471	574
Medical products, appliances, and equipment	239	250	262	294	319	354	397	461
Pharmaceutical products	217	229	241	260	280	314	350	405
Outpatient services	43	39	39	39	44	45	45	68

The household spending on health grew substantially from 303 euro per household to 574 between 2015 and 2022. The costs for medicinal products and medical devices increased almost twice from 239 euro to 461 euro per household.

In 2021 current healthcare expenditure reached 8.6% of GDP, compared to 11.0% in the EU. The healthcare expenditure in Bulgaria amounted to EUR 1,708 per capita, which is the second lowest in the EU (average value is found EUR 4,028) [23].

The monthly income of pensioners required to co-payment for biological therapy varies between 10% and 280%, which cannot be covered by patients alone. The working hours per package for working patients vary between 7 and 137 working hours per month. The average treatment range decreases during 2019-2021 with a decrease in the range of working hours required for treatment (from 9

per patient is 5.25 years. The economic effect of additionally treated patients of working age to the economy as participants contributing to GDP is BGN is BGN 2627086399 [24].

Conclusions.

Efforts in recent years have focused on reducing both patient and public costs, and finding a balance is very difficult. The study confirms the following findings:

1. Introduction of reference pricing (internal and external), HTA, budget cap, negotiations, as well as generic policy do not favored patients' access to therapy. The cost control measures implemented at this stage do not have the expected effectiveness, and the public spending increase is significant. Sometimes this can affect pharmaceutical companies, possibly leading to withdrawals of medicines and further impairing physical access to therapy.

2. The household expenditure is rising in recent years and all policy measures in place do not support patients in a financial aspect. The costs for pharmaceuticals are significant and they increase twice for an eight years' period.

Prospects for further research. The further study on the impact of introduced policies on public spending is obligatory when discussing the rising cost for medicinal products and healthcare services. This type of economic, statistical, and medical review could support future political decisions.

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Z. Mitkova - research design; literature review; research methodology; data collection; data analysis and interpretation; writing the article – initial draft, revision and editing of the article.

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