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RESEARCH OF THE RANGE OF BRONCHODILATORS USED IN THE TREATMENT OF OBSTRUCTIVE RESPIRATORY DISEASES AND ANALYSIS OF THEIR AVAILABILITY WITHIN THE FRAMEWORK OF THE "AFFORDABLE MEDICINES" PROGRAM

Actuality. *The product policy of manufacturers of medicines used for obstructive respiratory diseases is based on studying the pharmaceutical market of Ukraine, conducting an analysis of the assortment of medicines with the aim of updating it, ensuring profitability, and searching for new effective medicines.*

The aim of the study is to investigate the range of bronchodilators used in the treatment of obstructive respiratory diseases and to analyze their availability within the framework of the "Affordable Medicines" program.

Material and methods. *The objects of the study were the State Formulary of Medicines (sixteenth edition), the directory of medicines Compendium online, the Regulatory and directive documents of the Ministry of health of Ukraine, the State register of medicines of Ukraine, online resources – Apteki.ua. and Tabletki.ua. Marketing, graphical, logical generalization, and mathematical-statistical methods were used in the study.*

Research results. *As of early 2025, 37 trade names of bronchodilators used for the treatment of obstructive respiratory diseases were registered in Ukraine. Among the studied medicines, imported produced drugs predominate, accounting for 59,46%. Germany ranks first among the importing countries in terms of the nomenclature of the studied medicines (22,73%) supplied to the domestic pharmaceutical market. The leading domestic manufacturers of bronchodilators are PJSC "Farmak" (20%) and LLC "Multispray" (20%). Among the studied medicines, 83,78% of the assortment consists of monocomponent medicines, while the rest are two-component medicines. Among the dosage forms of bronchodilators used for the treatment of obstructive respiratory diseases on the domestic pharmaceutical market, aerosol for inhalation predominate, accounting for 26,32%. These include both imported (6 trade names) and domestically produced (4 trade names) medicines. Currently, only four bronchodilators used for the treatment of obstructive respiratory diseases are included in the "Affordable Medicines" program: Salbutamol, Salbutamol-Neo, Spiriva®, and EasyFree®.*

Conclusion. *The domestic pharmaceutical market of bronchodilators used in the treatment of obstructive respiratory diseases was studied. The results of the analysis support the feasibility of developing and introducing domestically produced bronchodilators into the pharmaceutical market of Ukraine.*

Key words: *obstructive respiratory diseases, bronchodilators, assortment research, "Affordable Medicines" program, reimbursement of cost of medicines.*

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ДОСЛІДЖЕННЯ АСОРТИМЕНТУ БРОНХОДИЛАТАТОРІВ, ЩО ЗАСТОСОВУЮТЬ ПРИ ОБСТРУКТИВНИХ ЗАХВОРЮВАННЯХ ДИХАЛЬНИХ ШЛЯХІВ, І АНАЛІЗ ЇХ ДОСТУПНОСТІ ЗА УМОВ РЕАЛІЗАЦІЇ ПРОГРАМИ «ДОСТУПНІ ЛІКИ»

Актуальність. *Товарна політика виробників лікарських засобів, які застосовують у лікуванні обструктивних захворювань дихальних шляхів, базується на вивченні фармацевтичного ринку України, проведенні аналізу асортименту лікарських засобів із метою його оновлення, забезпечення рентабельності та пошуку нових ефективних лікарських засобів.*

Мета дослідження *полягає у вивченні асортименту бронходилататорів, які застосовують за обструктивних захворювань дихальних шляхів, і проведенні аналізу їхньої доступності за умов реалізації програми «Доступні ліки».*

Матеріал і методи. *Об'єктами дослідження були Державний формуляр лікарських засобів (шістнадцяте видання), довідник лікарських засобів «Компендіум-online", нормативні та директивні документи Міністерства охорони здоров'я України, Державний реєстр лікарських засобів України, інтернет-ресурси – Apteki.ua й Tabletki.ua. У дослідженні були використані маркетингові, графічні, логічного узагальнення та математико-статистичні методи.*

Результати дослідження. *Станом на початок 2025 року в Україні зареєстровано 37 торгових назв бронходилататорів, які застосовують за обструктивних захворювань дихальних шляхів. Серед досліджених лікарських засобів переважають імпортні препарати, частка яких становить 59,46%. Німеччина посідає перше місце серед країн-імпортерів за номенклатурою досліджуваних лікарських засобів (22,73%), які постачають на вітчизняний фармацевтичний ринок. Лідерами серед вітчизняних виробників бронходилататорів є Приватне акціонерне товариство «Фармак» (20%) та Товариство з обмеженою відповідальністю «Мультіспрей» (20%). Серед досліджених лікарських засобів 83,78% асортименту становлять монопрепарати, решта – двокомпонентні. Серед лікарських форм бронходилататорів, які застосовують за обструктивних захворювань дихальних шляхів, на вітчизняному фармацевтичному ринку переважають аерозолі для інгаляції, частка яких становить 26,32%. Це як імпортні (6 торгових назв), так і вітчизняні (4 торгові назви) лікарські засоби. Натепер у програму «Доступні ліки» включено лише чотири бронходилататори, які застосовують за обструктивних захворювань дихальних шляхів – Сальбутамол, Сальбутамол-Нео, Спіріва® й ІзіФрі®.*

Висновок. *Досліджено вітчизняний фармацевтичний ринок бронходилататорів, які застосовуються для лікування обструктивних захворювань дихальних шляхів. Результати аналізу вказують на доцільність розроблення та впровадження вітчизняних бронходилататорів на фармацевтичному ринку України.*

Ключові слова: *обструктивні захворювання дихальних шляхів, бронходилататори, дослідження асортименту, програма «Доступні ліки», відшкодування вартості лікарських засобів.*

Introduction. Actuality. Chronic obstructive respiratory diseases, namely chronic obstructive pulmonary disease (COPD), bronchial asthma, emphysema, and bronchiectatic disease, are chronic inflammatory disorders. They are characterized by airway obstruction and subsequent airflow limitation, which can vary in severity and clinical manifestations.

Chronic obstructive respiratory diseases, especially COPD and bronchial asthma, are major contributors to global morbidity and mortality, necessitating significant and continuously rising healthcare costs. Over the past decades, these conditions have emerged as a critical public health issue worldwide. Research indicates that asthma affects between 1 and 18% of the population across various countries (Global Initiative for Asthma, https://ginasthma.org/; Ley-Zaporozhan, 2008). Additionally, COPD ranks among the leading causes of death in many nations (Minov, 2015).

Given current trends, including a growing and aging population, COPD will continue to be a significant burden worldwide, with a relative increase of 23% in the number of COPD cases, approaching 600 million, with a growing and unequal burden among women and low- and middle-income countries. Globally, projections indicate that the overall prevalence of COPD may decrease slightly from 10,6% in 2020 to 9,5% by 2050. Factors contributing to this decrease may include urbanization and technological modernization (Cho, 2020; Boers, 2023; COPD worldwide – Statistics & Facts, https://www.statista.com/statistics/1493739/copd-prev-

alence-forecasts-worldwide/; Prevalence of chronic obstructive pulmonary disease (COPD) worldwide in 2020 and projections to 2050, https://www.statista.com/statistics/1493739/copd-prevalence-forecasts-worldwide/). In Ukraine approximately 3 million people, or at least 7% of the population, are affected by COPD.

The high prevalence and mortality rate of COPD can be attributed to a lack of public awareness regarding its causes, symptoms, and consequences, as well as the late diagnosis by healthcare professionals and insufficient availability of spirometric equipment in hospitals and clinics. Experts from the European Respiratory Society (ERS) estimate that 30% of people in Europe who actually suffer from COPD may be unaware of their condition. This is particularly concerning since preventive measures at early stages are the most effective in slowing disease progression (Prykhodko, 2016).

Pharmacological therapy for COPD is used to reduce the severity of symptoms, decrease the frequency and intensity of exacerbations, improve overall condition, and enhance exercise tolerance. The choice of drug class for COPD treatment depends on the availability and cost of medicines, as well as on the clinical response balanced against side effects. Any treatment regimen must be individualized, since there is a relationship between symptom severity, airway obstruction, and exacerbation frequency.

Patients with COPD are prescribed the following groups of drugs: short- and long-acting bronchodilators, glucocorticosteroids, xanthines, non-steroidal anti-inflammatory drugs, acetylcysteine, mucolytics, and antibacterial agents (Unified clinical protocol of primary, specialized, and emergency medical care: Chronic obstructive pulmonary disease, https://moz.gov.ua/storage/uploads/20b6a528-e940-4ca5-96fe-e99db7f1a59e/dn_1610_20092024_dod.pdf).

Recently, despite the substantial use of synthetic drugs for the treatment of various diseases, there has also been a growing tendency to prescribe plant-based drugs in modern medicine, which are well combined with synthetic drugs (for example, expectorant therapy for obstructive respiratory diseases) (Darzuli, 2019; Feshchenko, 2021; Budniak, 2022; Slobodianiuk, 2022).

The aim of the study is to investigate the range of bronchodilators used in the treatment of obstructive respiratory diseases and to analyze their availability within the framework of the "Affordable Medicines" program.

Materials and methods. The objects of the study were the State Formulary of Medicines (sixteenth edition) (State Formulary of Medicines (sixteenth edition), https://moz.gov.ua/uploads/10/54241-dn_418_12032024_dod.pdf), the Regulatory and directive documents of the Ministry of health of Ukraine (Regulatory and directive documents of the Ministry of health of Ukraine, https://mozdocs.kiev.ua/), the directory of medicines Compendium online, the ATC-classification (group R03 – medicines for the treatment of obstructive respiratory diseases) (Compendium, https://compendium.com.ua), the State register of medicines of Ukraine (State register of medicines of Ukraine, http://www.drlz.com.ua), the list of medicines whose cost is subject to reimbursement (Affordable Medicines, https://moz.gov.ua/uk/dev-dostupni-liki), online resources for searching medicines in Ukrainian pharmacies such as "Apteki.ua" and "Tabletki.ua" (Apteki.ua, https://apteki.ua/uk; Tabletki.ua, https://tabletki.ua/uk/).

The study used the following methods: marketing, mathematical-statistical, logical generalization, and graphical methods (Darzuli, 2020). The obtained data were systematized and presented in diagrams with explanations and conclusions (Budniak, 2024a; Budniak, 2024b).

Results and discussion. According to the ATC-classification, the analyzed bronchodilators use in bronchodilator therapy (BT) for obstructive respiratory diseases (OAD) belong to the main therapeutic group R03 – Medicines for the treatment of obstructive respiratory diseases, as well as to three subgroups: R03A – Adrenergic drugs for inhalation use, R03B – Other anti-asthmatic agents for inhalation use, R03D – Other agents for systemic use in obstructive respiratory diseases (Compendium, https://compendium.com.ua).

According to the State register of medicines of Ukraine (State register of medicines of Ukraine, http://www.drlz.com.ua), as of early 2025, there are 37 trade names (TN) of bronchodilators used for the treatment of obstructive respiratory diseases were registered in Ukraine (table 1).

On the Ukrainian pharmaceutical market of bronchodilators used in the treatment of obstructive respiratory diseases, there are domestic (40,54%; 15 TN) and imported (59,46%; 22 TN) medicines (fig. 1).

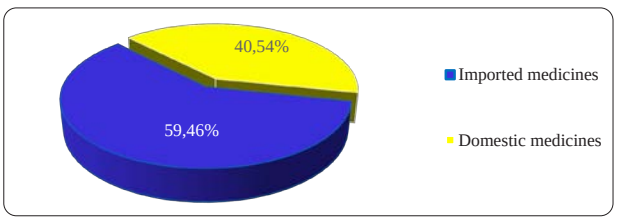

Fig. 1. The ratio of domestic and imported bronchodilators used in the treatment of obstructive respiratory diseases

Among domestic manufacturers, the leading positions in the nomenclature of medicines belong

Table 1

Bronchodilators used for obstructive respiratory diseases

№	International Nonproprietary Name	Trade name	Dosage form	Country of manufacture
1.	Salbutamol	Astalin	aerosol for inhalation	India
		Ventolin Evohaler	aerosol for inhalation	Spain
		Ventolin Nebules	solution for inhalation	Germany
		Nebutamol®	solution for inhalation	Ukraine
		Salbutamol	aerosol for inhalation	France
		Salbutamol	pressurized inhalation, suspension	Ukraine
		Salbutamol-Inteli	pressurized inhalation, suspension	Spain
		Salbutamol-Neo	aerosol for inhalation	Ukraine
2.	Fenoterol	Berotec® N	aerosol for inhalation	Germany
		Bronchoterol	aerosol for inhalation	Ukraine
		Berovent-MF	aerosol for inhalation	Ukraine
3.	Salmeterol	Serobid®	pressurized inhalation, suspension	India
4	Formoterol	Zafiron	powder for inhalation, hard capsules	Poland
		Foratec	aerosol for inhalation	India
		Formoterol Easyhaler	powder for inhalation	Finland
		Fortiks	powder for inhalation, hard capsules	Spain
5	Indacaterol	Onbrez Breezhaler	powder for inhalation, hard capsules	Switzerland
6	Tiotropium bromide	Spiriva®	powder for inhalation, hard capsules	Germany
		Spiriva® Respimat®	inhalation solution	Germany
		EasyFree®	powder for inhalation	Greece
7	Glycopyrronium bromide	Sibriz Breezhaler	powder for inhalation, hard capsules	Switzerland
8	Fenoterol and Ipratropium bromide	Berodual®	inhalation solution	Italy
		Berodual® N	aerosol for inhalation	Germany
		Ipradual	inhalation solution / aerosol for inhalation	Ukraine
		Frivey® Combi	inhalation solution	Ukraine
		Frivey® Combi Nebula	inhalation solution	Ukraine
9	Theophylline	Eufilin-N 200	injection solution	Ukraine
		Euphylline-Zdorovye	injection solution	Ukraine
		Eufilin	injection solution	Ukraine
		Eufilin	injection solution	Ukraine
		Eufilin-Darnitsa	injection solution	Ukraine
		Neofilin	tablets	Ukraine
		Teopek	tablets	Ukraine
		Teotard	capsules	Slovenia
		Teotard	tablets	Bulgaria
10	Doxofylline	Aerofilin®	tablets	Italy
11	Umeclidinium bromide and Vilanterol	ANORO ELLIPTA	powder for inhalation	United Kingdom

to PJSC “Farmak”, Kyiv (20%; 3 TN), LLC “Multispray”, Kharkiv (20%; 3 TN), LLC “Yuria-Farm”, Kyiv (13,33%; 2 TN), PJSC “Pharmaceutical Company “Darnitsa””, Kyiv (13,33%; 2 TN), LLC “Microfarm”, Kharkiv (13,33%; 2 TN), with other manufacturers accounting for 6,67% each of the assortment of medicines (fig. 2).

Bronchodilators used in the treatment of obstructive respiratory diseases are supplied to the Ukrainian pharmaceutical market by manufacturers from 12 countries. By

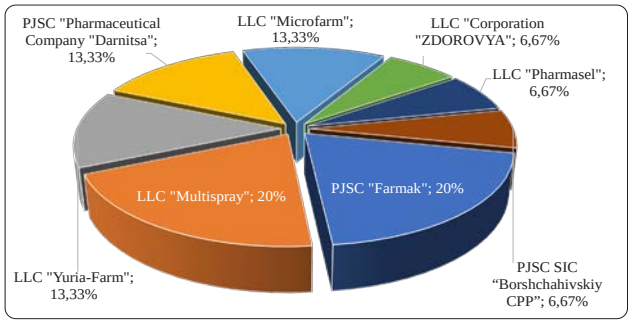

Fig. 2. The ratio of domestic manufacturers of bronchodilators used in the treatment of obstructive respiratory diseases

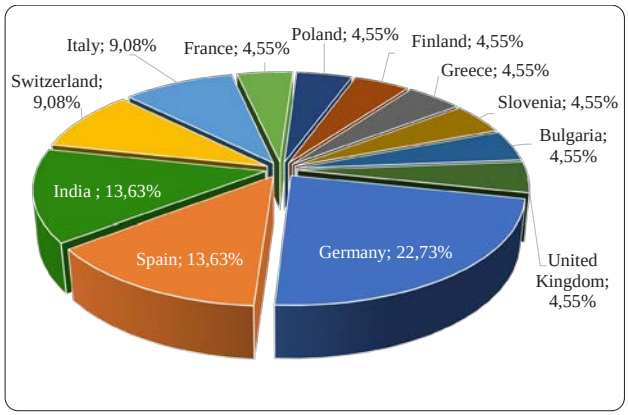

Fig. 3. The distribution of manufacturing countries by the number of registered bronchodilators used in the treatment of obstructive respiratory diseases on the pharmaceutical market of Ukraine

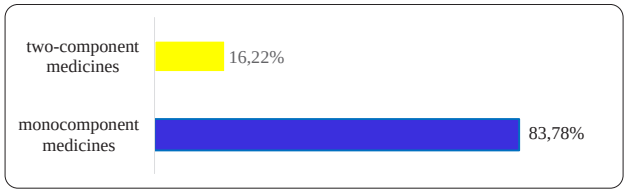

Fig. 4. Distribution of bronchodilators used in the treatment of obstructive respiratory diseases by component composition

analyzing the State Register of Medicines, the share of each manufacturing country in the product assortment was determined. The leaders are Germany (22,73%; 5 TN), Spain (13,64%; 3 TN), and India (13,64%; 3 TN). The remaining 50% of medicines are supplied by manufacturers from Switzerland, Italy, France, Poland, Finland, Greece, Slovenia, Bulgaria, and the United Kingdom (fig. 3).

Depending on the number of components included in the composition of medicines, they are classified as single-component, two-component, and multi-component medicines. Among the registered bronchodilators used in the treatment of obstructive respiratory diseases, 83,78% (31 TN) of the assortment consists of monocomponent medicines, with the share of two-component medicines being five times smaller (fig. 4).

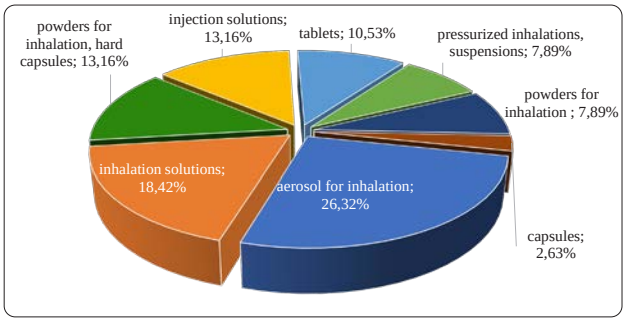

Fig. 5. Distribution of bronchodilators used in the treatment of obstructive respiratory diseases by dosage form

The studied group of medicines (table 1) is represented on the pharmaceutical market of Ukraine in various dosage forms (fig. 5). The most common are medicines in the form of aerosol for inhalation, accounting for 26,32% (10 TN). The second most common is inhalation solutions, which make up 18,42% (7 TN). The share of powders for inhalation, hard capsules, and injection solutions is 13,16% each (5 TN). A slightly smaller share of medicines used in BT for OAD is in the form of tablets, pressurized inhalations, suspensions, and powders for inhalation. The smallest share is made up of capsules.

Domestic bronchodilators used in the treatment of obstructive respiratory diseases are represented on the pharmaceutical market of Ukraine in the form of injection solutions (5 TN), aerosol for inhalation (4 TN), inhalation solutions (4 TN), tablets (2 TN), and pressurized inhalations, suspensions (1 TN). Among them, there are twelve monodrugs, represented in the form of injection solutions (5 TN), aerosol for inhalation (3 TN), tablets (2 TN), inhalation solutions (1 TN), pressurized inhalations, suspensions (1 TN); four two-component medicines in the form of inhalation solutions (3 TN), aerosol for inhalation (1 TN).

Imported bronchodilators used in the treatment of obstructive respiratory diseases are available on the pharmaceutical market of Ukraine in the form of aerosol for inhalation (6 TN), powder for inhalation, hard capsules (5 TN), inhalation solutions (3 TN), powder for inhalation (3 TN), pressurized inhalations, suspensions (2 TN), tablets (2 TN), and capsules (1 TN). Monodrugs are available in the form of powder for inhalation, hard capsules, and aerosol for inhalation, each with 5 TN, powder for inhalation, inhalation solution, tablets,

Table 2.

Bronchodilators used in the treatment of obstructive respiratory diseases and dispensed within the framework of the "Affordable Medicines" program

International Nonproprietary Name	Trade name	Dosage form	Country of manufacture	Co-payment amount for the consumer packaging, UAH
Salbutamol	Salbutamol	aerosol for inhalation	France	18,44
	Salbutamol-Neo	aerosol for inhalation	Ukraine	0,00
Tiotropium bromide	Spiriva®	powder for inhalation, hard capsules	Germany	0,00
	EasyFree®	powder for inhalation	Greece	0,00

pressurized inhalations, suspensions, each with 2 TN, and capsules with 1 TN. Two-component medicines are available in the form of aerosol for inhalation, powder for inhalation, and inhalation solution (1 TN each).

According to the "Affordable Medicines" program, reimbursement covers the cost of medicines or provides partial reimbursement for patients. The reimbursement within this program helps reduce the financial burden on patients by providing them access to essential medicines. This is especially important for individuals who require ongoing medication, such as patients with asthma and COPD, as the program helps them obtain life-saving medicines without significant treatment costs.

Starting from March 13, 2025, the Ministry of Health of Ukraine updated the list of medicines reimbursed under the state medical service guarantee program, in accordance with the Order of the Ministry of Health of Ukraine № 440 "On Approval of the Lists of Medicines and Medical Devices Eligible for Reimbursement under the State Medical Service Guarantee Program, as of February 26, 2025" (The Ministry of Health has updated the lists of medicines and medical devices under the "Affordable Medicines" reimbursement program, https://medplatforma.com.ua/news/91900-moz-onovylo-pereliky-likiv-i-medychnykh-vyrobiv-za-programoiu-reimbursatsii-dostupni-liky; Some issues regarding the availability of medicines subject to reimbursement in 2025, https://zakon.rada.gov.ua/laws/show/1380-2024-%D0%BF#n14). As of today, only four bronchodilators used in the treatment of obstructive respiratory diseases have been included in the "Affordable Medicine" program, which can only be obtained with a doctor's prescription.

Among the bronchodilators used in the treatment of obstructive respiratory diseases within the framework of the "Affordable Medicines" program, medicines with the international nonproprietary names salbutamol and tiotropium bromide are dispensed (table 2).

These bronchodilators are commonly used in the treatment of obstructive respiratory diseases, such as asthma and COPD, and may be dispensed within the framework of the "Affordable Medicines" program either for free of charge or with a small co-payment for patients.

Conclusions. 1. As of the beginning of 2025, there are 37 trade names of bronchodilators used in the treatment of obstructive respiratory diseases on the pharmaceutical market of Ukraine.

2. An analysis of the assortment of bronchodilators showed that imported medicines predominate, with a share of 59,46%. Among the countries importing bronchodilators used in the treatment of obstructive respiratory diseases, Germany leads in the nomenclature of medicines (22,73%). The leaders among domestic manufacturers of the studied medicines are PJSC "Farmak" and LLC "Multispray" (20% each). Monocomponent bronchodilators account for the largest share among those used in the treatment of obstructive respiratory diseases, totaling 83,78%. Among the domestic pharmaceutical market of the studied bronchodilators, aerosol for inhalation dominates among dosage forms, accounting for 26,32%. These include both foreign and domestically manufactured medicines. Among the dosage forms of the studied domestic-made medicines, injection solutions dominate. Among imported dosage forms, aerosol for inhalation predominates.

3. The results of the analysis indicate the feasibility of developing and implementing domestic bronchodilators used in the treatment of obstructive respiratory diseases on the pharmaceutical market of Ukraine.

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