

ОРГАНІЗАЦІЯ ОХОРОНИ ЗДОРОВ'Я

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THE ANALYSIS OF DYNAMICS OF CHANGES IN THE AVAILABILITY INDEXES OF BETA-BLOCKERS IN UKRAINE

Aim. To study the dynamics of changes in the availability indexes of beta-blockers within 2013-2016.

Materials and methods. In the study the data of the legislative normative base, "Morion" information retrieval system for 2012-2016 and special literature were used. The coefficients of adequacy of solvency (C.a.s.) and the availability indexes (A) were calculated. The historical, logical, graphical, mathematical and statistical research methods were used.

Results. It has been found that in the second year (2013) of implementation of the Pilot Project concerning the state price control on drugs used in the treatment of hypertension the increase of the availability is characteristic for all names of beta-blockers. In 2014-2015 there was a negative tendency to the drug availability decrease, and in 2016 on the contrary the drug availability increased. Thus, according to the data of 2016 the availability indexes of beta-blockers did not reach the "pre-crisis" values of 2013. By the average value of the availability indexes the imported drugs became more accessible than drugs of the domestic production.

Conclusions. The impact of implementation of the Pilot Project (2012-2014) and the financial and economic crisis (2015-2016) on the availability indexes of beta-blockers determines the need for further research in this area and emphasize the socio-economic relevance of introduction of effective mechanisms of reimbursement of drug consumption.

Key words: beta-blockers; cardiovascular diseases; availability of drugs; coefficient of adequacy of solvency

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АНАЛІЗ ДИНАМІКИ ЗМІН ПОКАЗНИКІВ ДОСТУПНОСТІ ПРЕПАРАТІВ БЕТА-АДРЕНОБЛОКАТОРІВ В УКРАЇНІ

Мета: дослідження динаміки змін показників доступності бета-адреноблокаторів упродовж 2013-2016 років.

Матеріали та методи. У дослідженнях нами використовувалися дані законодавчо-нормативної бази, інформаційно-пошукової системи «Моріон» за 2012-2016 рр. та спеціальної літератури. Розраховувалися коефіцієнти адекватності платоспроможності (C.a.s.) та показники доступності (D). Застосовувалися історичний, логічний, графічний та математико-статистичні методи досліджень.

Результати досліджень. Встановлено, що на другий рік (2013 р.) проведення Пілотного проекту з державного регулювання цін на ліки, які використовуються у лікуванні артеріальної гіпертензії, всі найменування бета-адреноблокаторів характеризувалися збільшенням їх доступності. У 2014-2015 рр. окреслилася негативна тенденція до зниження доступності препаратів, а у 2016 р., навпаки, до збільшення. При цьому, за даними 2016 р., показники доступності бета-адреноблокаторів так і не досягли своїх значень «докризового» 2013 р., а за середнім значенням показника доступності імпортовані препарати стали доступнішими, ніж ліки вітчизняного виробництва.

Висновки. Доведено авторами неоднозначність впливу реалізації Пілотного проекту (2012-2014 рр.) та фінансово-економічної кризи (2015-2016 рр.) на показники доступності бета-адреноблокаторів обумовлює необхідність проведення подальших досліджень у зазначеному напрямку та підкреслює соціально-економічну актуальність упровадження дієвих механізмів компенсації вартості споживання ліків.

Ключові слова: бета-адреноблокатори; серцево-судинні захворювання; доступність препаратів; коефіцієнт адекватності платоспроможності.

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АНАЛИЗ ДИНАМИКИ ИЗМЕНЕНИЙ ПОКАЗАТЕЛЕЙ ДОСТУПНОСТИ ПРЕПАРАТОВ БЕТА-АДРЕНОБЛОКАТОРОВ В УКРАИНЕ

Цель: исследование динамики изменений показателей доступности бета-адреноблокаторов в течение 2013-2016 гг.

Материалы и методы. В исследовании нами использовались данные законодательно-нормативной базы, информационно-поисковой системы «Морион» за 2012-2016 гг. и специальной литературы. Рассчитывались коэффициенты адекватности платежеспособности (Ca.s.) и показатели доступности (D). Использовались исторический, логический, графический и математико-статистические методы исследований.

Результаты исследований. Установлено, что на второй год (2013 г.) проведения Пилотного проекта по государственному регулированию цен на лекарства, которые используются в лечении артериальной гипертензии, для всех наименований бета-адреноблокаторов характерно увеличение их доступности. В 2014-2015 гг. наметилась негативная тенденция к снижению доступности препаратов, а в 2016 г., наоборот, к повышению. При этом, по данным 2016 г., показатели доступности бета-адреноблокаторов так и не достигли своих значений «докризисного» 2013 г., а по среднему значению показателей доступности импортные препараты стали более доступными, чем препараты отечественного производства.

Выводы. Установленная авторами неоднозначность влияния реализации Пилотного проекта (2012-2014 гг.) и финансово-экономического кризиса (2015-2016 гг.) на показатели доступности бета-адреноблокаторов обуславливает необходимость проведения дальнейших исследований в данном направлении и подчеркивает социально-экономическую актуальность введения действенных механизмов компенсации стоимости потребления лекарств.

Ключевые слова: бета-адреноблокаторы; сердечно-сосудистые заболевания; доступность препаратов; коэффициент адекватности платежеспособности.

Statement of the problem. On April 01, 2017, the government program "Available medicines" was started in Ukraine. The main purpose of this program is to provide available medicines for patients with cardiovascular pathology, bronchial asthma and type 2 diabetes. Literally, one can say that implementation of the program "Available medicines" is the most notable event in the social life of the country for the last decades. There are more than 157 medicines that take part in this program by the trade names of 35 (100.0 %) drug manufacturers, among them 18 companies from the EU countries (51.4 %), Ukraine (15 companies – 42.8 %), India and Israel (1 company each – 2.9 %, respectively). At the beginning, 2700 pharmacies were already involved in the implementation of the program "Available medicines" throughout the territory of Ukraine, which should provide a required range of medicines [1]. The priority for the implementation of this program is the fact that the cost of 23 medicines by the international nonproprietary names will be covered by the state. From June 01, 2017, according to the decree of the Cabinet of Ministers of Ukraine dated 17.03.2017 No.152 "On availability of medicines" the Ministry of Health must form a working group on evaluation of efficiency of the state regulation mechanism for medicines and according to the data analysis give scientifically-motivated recommendations

and proposals as to the improvement of these mechanisms before March 01, 2018 [2]. Therefore, the studies aimed at analyzing the availability indexes of medicines used for the treatment of cardiovascular diseases, particularly in pharmacotherapy of hypertension, have socio-economic and practical importance.

Analysis of recent research and publications. Recently the problem of availability of drugs used for the treatment of socially important diseases, which cardiovascular pathologies can be referred to, has been studied in various aspects in the works of domestic and foreign scientists [3-11]. Under the conditions of financial and economic crisis in Ukraine, catastrophic decrease in the purchasing power of the population and greater market influence on development of the domestic pharmaceutical market the problem of increasing drug availability is considered today by the scientists in the context of the national security of the country.

Identification of aspects of the problem unsolved previously. According to the analysis data of the special literature sources and periodicals containing the urgent problems of pharmaceutical provision of the Ukrainian population, including a weekly edition "Apteka" (Pharmacy) one can state the following facts. In the modern informational environment there are no works where authors analyze the changes

Table 1

**THE RESULTS OF ANALYSIS OF THE DYNAMICS OF CHANGES IN Ca.s.
AND A OF BETA-BLOCKERS AT THE DOMESTIC MARKET (2012–2016)**

Group of medicines	Ca.s.					D			
	2012	2013	2014	2015	2016	2013/ 2012	2014/ 2013	2015/ 2014	2016/ 2015
C07AB02 – Metoprolol	1.14	0.97	1.06	1.75	1.61	1.22	0.92	0.73	1.08
Domestic medicines	0.19	0.16	0.16	0.23	0.25	1.22	0.97	0.73	0.93
Foreign medicines	1.54	1.34	1.52	2.29	2.07	1.22	0.90	0.73	1.14
C07AB07 – Bisoprolol	1.31	1.07	1.11	1.22	1.00	1.26	1.01	1.02	1.23
Domestic medicines	0.63	0.51	0.5	0.60	0.47	1.24	1.03	1.05	1.21
Foreign medicines	1.6	1.36	1.35	1.56	1.32	1.27	1.00	1.02	1.22
C07AB12 – Nebivolol	2.6	1.73	2.03	2.57	1.95	1.22	1.00	0.88	1.38
Domestic medicines	1.95	1.42	1.86	1.30	1.07	1.38	1.05	1.05	1.23
Foreign medicines	2.76	2.03	2.08	2.75	2.06	1.18	0.99	0.85	1.40

of the availability indexes of the socially important medicines included to the state programs during their functioning and after their completion in time. Under the conditions of the operative data absence concerning the efficiency of implementation of the government program “Available medicines” in 2017 the data of changes in the availability indexes of beta-blockers involved in implementation of the Pilot Project in Ukraine during 2012-2014 and after its completion in 2015-2016 (Decree of the Cabinet of Ministers of Ukraine dated 25.04.2012 No. 340 “On implementation of the Pilot Project concerning the state regulation of prices for medicines used for the treatment of people with hypertension”) were used in our studies. In the studies the data of “Morion” information retrieval system for 2012-2016 were used, and the individual and group indexes (Igp) of the average purchase and retail prices were calculated. To assess the availability of beta-blockers the coefficients of adequacy of solvency (Ca.s.) and the availability indexes (A) were used [12-13]. As it is known, the abovementioned indicators characterize social and economic availability of medicines considering the minimum salary, the index of its changes during a certain period of time and the cost of the consumer basket, and as well as the total index of retail prices for medicines presented in the National List of Basic Medicines and Products for Medical Purposes [13-14]. The average purchase and retail prices for beta-blockers (C07AB02 – Metoprolol, C07AB07 – Bisoprolol, C07AB12 – Nebivolol) were calculated according to the data of price monitoring for

medicines conducted by the appropriate method proposed by domestic scientists [13]. It should be noted that when calculating Ca.s. the average retail prices for medicines were taken without considering the cost of their compensation within 2012-2014. Therefore, one can state that taking into account the compensation of medicines the indicators of Ca.s. might have lower values and be more available for the population. Considering a significant dependence of the domestic pharmaceutical market upon import the analysis of the availability indexes was conducted by the “domestic medicine – foreign medicine” parameter.

Objective statement of the article. The aim of the study was to analyze changes in the availability indexes of beta-blockers during implementation of the Pilot Project (2012–2014) and after its completion (2015–2016). As it is known, the completion of the abovementioned project was connected with the lack of further financing of the appropriate measures of reimbursement of cardiovascular medicines from the state budget.

Presentation of the main material of the research. The results of analysis of the dynamics of changes in the average purchase and retail prices for beta-blockers included in the Pilot Project were considered in the previous publications [15]. Therefore, without going into the characterization of the dynamics of their changes the availability of beta-blockers was analyzed. The results of the data obtained are given in Tab. 1 and 2.

As can be seen from Tab. 1, in the second year (2013) of the Pilot Project the Ca.s. indicator

Table 2

THE RESULTS OF ANALYSIS OF CHANGES OF THE Ca.s. AND A INDICATORS ON BETA-BLOCKERS PRESENTED AT THE DOMESTIC PHARMACEUTICAL MARKET WITHIN 2012-2016

INN of medicines	Ca.s.					A		
	2013/ 2012	2014/ 2013	2015/ 2014	2016/ 2015	2016/ 2012	2014/ 2013	2015/ 2014	2016 /2015
C07AB02 – Metoprolol	0.85	1.09	1.65	0.92	1.41	0.75	0.79	1.48
Domestic medicines	0.84	1.00	1.44	1.09	1.32	0.80	0.75	1.27
Foreign medicines	0.87	1.13	1.51	0.90	1.34	0.74	0.81	1.56
C07AB07 – Bisoprolol	0.82	1.04	1.10	0.82	0.76	0.80	1.01	1.21
Domestic medicines	0.81	0.98	1.20	0.78	0.75	0.83	1.02	1.15
Foreign medicines	0.85	0.99	1.16	0.85	0.83	0.79	1.02	1.20
C07AB12 – Nebivolol	0.67	1.17	1.27	0.76	0.75	0.82	0.88	1.57
Domestic medicines	0.73	1.31	0.70	0.82	0.55	0.76	1.00	1.17
Foreign medicines	0.74	1.02	1.32	0.75	0.75	0.84	0.86	1.65

decreased for all names of beta-blockers. It indicates the increase of their availability for patients. The greatest decrease of data was observed in the group of C07AB12 – Nebivolol medicines in the whole (by 33.0 % compared to 2012), and the least decrease was in foreign names of C07AB07 – Bisoprolol (by 13.0 %, respectively). In 2014, which was the last period when the state allocated finances for reimbursement of cardiovascular medicines within the Pilot Project by all names of beta-blockers, the Ca.s. indicator increased. For C07AB12 – Nebivolol medicines in the whole the above-mentioned indicator increased by 17.0 %, for C07AB07 – Bisoprolol by 4.0 % and for C07AB02 – Metoprolol by 9.0 %. In terms of “domestic medicine – foreign medicine” the greatest increase was observed in the domestic medicines from the group of C07AB12 – Nebivolol (+31.0 %), and the least decrease was in foreign medicines from this group (+2.0 %). The increase of the Ca.s. indicator and, as a result, the decrease of drug availability in 2014 was connected with a rapid depreciation of the national currency practically by 4 times on the background of socio-economic and political crises, as well as the dependence of the domestic pharmaceutical market on import.

A negative tendency of increasing Ca.s. indicators was observed in 2015. Thus, the greatest increase of data regarding domestic C07AB02 – Metoprolol medicines (the increase by 65.0 %), and the least increase was for medicines from C07AB07 – Bisoprolol group (10.0 %). It is interesting that after a significant growth of the Ca.s. indicator in 2014 (the increase by 31.0 %)

for domestic C07AB12 – Nebivolol medicines (Ca.s.=1.86) in 2015 they decreased by 30.0 % up to Ca.s.=1.30.

After stormy years (2013-2015) of development of the domestic system of pharmaceutical provision of the population in 2016 the domestic market was relatively stabilized. Thus, according to the data of the last year of the study, in general, there was the decrease of the Ca.s. indicator up to 1.61 for C07AB02 – Metoprolol medicines (-8.0 %), Ca.s.=1.0 for C07AB07 – Bisoprolol (-18.0 %) and Ca.s.=1.95 – C07AB12 – Nebivolol (-24.0 %) for all names of beta-blockers. Then the average Ca.s. indicators for all medicines during the period of 2012-2014 (the existence of the Pilot Project – conventionally “the first period”) and 2015-2016 (after its completion – “the second period”) were calculated. It was determined that for C07AB02 – Metoprolol medicines the above-mentioned indicator was equal to 1.06 for the first period, and for the second period – 1.68, indicating the decrease of availability. There was a decrease in the availability of domestic (0.17 vs. 0.24), as well as foreign medicines (1.47 vs. 2.18). For C07AB07 – Bisoprolol medicines the Ca.s. indicator was equal to 1.16 for the first period, and for the second period – 1.11 (the conventional increase of availability). For C07AB12 – Nebivolol medicines the above-mentioned indicators were equal to 1.44 and 2.26 (the decrease of availability). Thus, for domestic medicines of C07AB12 – Nebivolol group the Ca.s. indicator decreased from 1.74 up to 1.19. It is explained by the increase of availability, and regarding foreign medicines the increase is from 2.29 up

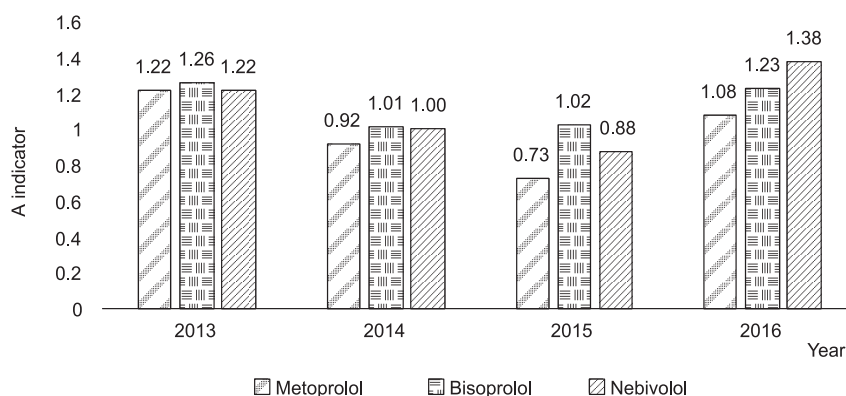


Fig. The analysis of the dynamics of changes in the A indicators during 2012-2016

to 2.41, which allows expanding the range of their socio-economic availability for the community.

Considering ambiguity of the results obtained by the Ca.s. indicators and complexity of their interpretation the next stage of our study was to analyze the dynamics of changes in the A indicator, which compared to the Ca.s. indicator should be determined taking into account the following important socio-economic indicators:

- the total index of prices for basic medicines;
- the minimum salary in the country;
- the cost of the consumer basket for the period under study [13].

The conventional group of “available” medicines for ordinary citizens included INN of medicines with the A indicator ≥ 1.0 , in other case ($A < 1.0$) medicines of beta-blockers were referred to the group of “unavailable” medicines [14]. Fig. shows the dynamics of changes in the A indicators for all names of beta-blockers during 2013-2016.

During 2013 all names of beta-blockers could be conventionally classified as “available”. The availability index fluctuated in the range from 1.8 (foreign names of C07AB12 – Nebivolol) to 1.38 (domestic medicines from C07AB12 – Nebivolol group). The last year of implementation of the Pilot Project, as well as the financial and economic crisis in the country caused the decrease in the availability indexes for all medicines studied. Thus, C07AB02 – Metoprolol medicines transferred from the conventional group of “available” medicines to the group of “unavailable” medicines, as well as foreign C07AB12 – Nebivolol medicines.

The greatest decrease of the A indicator was observed for C07AB02 – Metoprolol medicines

(–25.0 %), and the lowest decrease was for the foreign names of C07AB12 – Nebivolol (–16.0 %).

The following year (2015) after the completion of the Pilot Project brought negative tendencies towards drug availability in the pharmaceutical market segment under research. Thus, the availability of C07AB02 – Metoprolol medicines, including drugs of the domestic and foreign production, continued to decrease, as well as medicines from C07AB12 – Nebivolol group, including those of the foreign production. In 2015 C07AB07 – Bisoprolol medicines and the domestic names of C07AB12 – Nebivolol saved their positions as “available” medicines ($A \geq 1.0$).

Interesting tendencies at the market were observed in 2016. C07AB02 – Metoprolol medicines moved from the group of “unavailable” medicines to the group of “available” ones ($A = 1.08$); the availability of C07AB07 – Bisoprolol medicines increased significantly ($A = 1.23$, the increase of 21.0 %), a significant growth of the availability indexes was observed for C07AB12 – Nebivolol medicines (from 0.88 in 2015 to 1.38 according to the data of 2016, the increase of 57.0 %).

In general, it is worth mentioning that during 2013–2015 the availability indexes gradually decreased for all names of medicines from the group of beta-blockers, the exception was the data for C07AB07 – Bisoprolol medicines (a minor increase of the data in 2015 up to 1.02 vs 1.01 in 2014). Improvement of financial and economic indicators of the country development in 2016 and a relative stability at the pharmaceutical market led to increase of the availability indexes for all names of beta-blockers. It gives a slight hope for an optimistic development of the government program

“Available medicines”. Thus, availability of C07AB02 – Metoprolol medicines in the whole increased up to 1.08 vs 0.73 according to the data of the previous year (2015), for C07AB07 – Bisoprolol medicines up to 1.23 vs 1.02 (2015) and C07AB12 – Nebivolol up to 1.38 vs 0.88 according to the data of 2015.

At the end of our studies the average A indicators in 2013 and 2016 in the whole for the full range of medicines and by the indicator “domestic medicine – foreign medicine” were calculated. It was determined that in 2013 the average A indicator for the names of beta-blockers was equal to 1.25 taking into account all forms of production, and in 2016 it was 1.20, i.e. the availability decreased in the whole. Regarding domestic medicines in 2013 $A=1.38$, and for foreign names of medicines $A=1.22$ (domestic medicines were more available). In 2016 a reverse tendency was observed, namely for the domestic range of beta-blockers $A=1.12$, while for foreign names $A=1.25$. It means that firstly in 2016 the level of availability for beta-blockers did not reach the values of the “pre-crisis” year (2013), and secondly, in 2016, as it sounds paradoxically, foreign medicines became more available for the population. The average availability index according to the domestic range of beta-blockers decreased by 23.21 % in 2016 compared to the year of 2013, while the foreign range increased by 2.4 %.

The study of the dynamics of changes in the Ca.s. and A indicators demonstrated a mixed effect of implementation of the Pilot Project within 2012–2014 and a powerful financial and economic crisis in 2014–2016 on the availability of beta-blockers. In our opinion, a promising direction for further studies is the analysis of factors affecting efficiency of reimbursement for socially important medicines under the conditions of a slow development of the domestic pharmaceutical market and implementation of direct mechanisms of the state regulation of prices for medicines.

Conclusions and prospects for further research

1. According to the research results it was determined that during the second year of the Pilot Project (2013) the Ca.s. indicator decreased for all names of beta-blockers, indicating the increase of their availability for patients.

2. In the last year of the Pilot Project (2014) the Ca.s. indicator increased for all names of beta-

blockers, which costs of consumption were supposed to be covered by the state, indicating further decrease in availability of drugs. A significant negative tendency was observed in 2015.

3. According to the analysis data of the A indicator it has been determined that in 2013 all names of beta-blockers included in the Pilot Project for reimbursement of medicines taken by hypertension patients referred to the conventional group of “available medicines”. According to the data of 2014 the availability decreased for all medicines. C07AB02 – Metoprolol medicines moved to the group of “unavailable” medicines, and groups of C07AB07 – Bisoprolol and C07AB12 – Nebivolol balanced were on the verge of availability.

4. It has been proven that further intensification of the financial and economic crisis and the lack of state programs in the system of pharmaceutical provision of the population in 2015 led to further decrease of drug availability from the group of beta-blockers. Thus, only C07AB07 – Bisoprolol medicines managed to save their positions of “available” medicines for ordinary citizens.

5. In 2016 the availability indexes of beta-blockers looked more optimistic. Thus, the growth in the A indicators for C07AB02 – Metoprolol medicines (in the whole by the range of products) was equal to 48.0 %, C07AB07 – Bisoprolol – 21.0 %, and for beta-blockers from C07AB12 – Nebivolol group – 57.0 %.

6. In general, it is worth mentioning that in 2016 availability of medicines did not reach their values of the “pre-crisis” year of 2013, during which the Pilot Project was implemented. Thus, in 2013 the average value of the A indicator for all names of medicines was $A=1.25$ taking into account medicines of all forms of production, while in 2016 it was 1.20. It is interesting that the availability index of foreign medicines in 2016 was higher ($A=1.25$) than the domestic range of medicines ($A=1.12$). Moreover, the availability index of domestic medicines in 2016 decreased from 1.38 to 1.20 compared to 2013.

7. Taking into account the abovementioned facts a promising direction for further studies will be the analysis of key factors affecting availability of beta-blockers as socially important medicines and mechanisms of reimbursement of medicines within the program “Available medicines”.

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