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Study on the availability of medicines in the context of regional healthcare system development (case study of the Sverdlovsk Region)

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Subject. Increasing the availability of modern effective and safe medicines is one of the key objectives for the development of regional health systems in pursuit of the goals of the national Healthcare project. As a complex process, the modernisation of the pharmaceutical provision system is an important issue for the economy, the state, and society. The availability of medicines for cardiovascular diseases has a special place among the issues of reforming the system of pharmaceutical provision for citizens. The high prevalence of cardiovascular disease among people causes a negative economic impact and a significant cost to public healthcare systems around the world. The cause of this economic loss is the cardiovascular disease mortality and morbidity rate in the working-age population, which results in a substantial loss of human capital.
Objectives. The aim of the study was to analyse and assess the assortment, financial, and logistical availability of medicines for cardiovascular diseases at all levels of medical care in the context of the development of the regional healthcare system, based on materials from the Sverdlovsk Region for 2011-2019.
Methodology. The study was based on data from the Monitoring of Assortment and Prices for Vital and Essential Drugs (VED) in the Sverdlovsk Region for the period of 2011-2019. A comparative and structural analysis of the availability of medicines for the treatment of cardiovascular diseases was carried out using the WHO and Health Action International (WHO/HAI) methodology. It was based on the calculation of the median ratios of local prices to international reference prices of medicines for groups of domestic and foreign drugs, original brands, and generics. We also considered price groups for the outpatient and inpatient market segments.
Conclusions. A study of the availability of medicines for cardiovascular diseases in the Sverdlovsk Region revealed that medicines at the outpatient level are provided predominantly for socially disadvantaged groups at the expense of public funds. At the inpatient level, the medicines are funded by the Territorial Fund of Compulsory Medical Insurance, the range of medicines provided is limited to the VED list. The list of medicines for the treatment of cardiovascular diseases for the inpatient and outpatient levels of medical care has virtually no continuity, which reduces the overall level of availability of medicines. To improve the quality of pharmaceutical provision for the development of the regional healthcare system, additional research on price dynamics and pharmacoeconomic analysis is required. It should consider the trends in the Russian pharmaceutical market.

Keywords: medicine prices, availability of medicines, regional healthcare system, WHO/HAI, reference prices.

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Introduction

Increasing the availability of modern effective and safe medicines is one of the key objectives of the national Healthcare project[1]. As a complex process, the modernisation of the pharmaceutical provision system for citizens is an important issue for the economy, the state, and society, as it ensures the sustainable development of the national healthcare system.

As Cameron et al. [8] and Günther et al. [10] point out, the availability of medicines for the treatment of cardiovascular diseases has a special place among the issues of reforming the system of pharmaceutical provision for citizens due to a number of factors.

The high prevalence of cardiovascular disease among people causes a negative economic impact and a significant cost to public healthcare systems around the world. The cause of this economic loss is the cardiovascular disease mortality and morbidity rate in the working-age population, which results in a substantial loss of human capital. Experts estimate that the cumulative economic damage caused by cardiovascular disease in Russia could reach more than 2% of its gross domestic product[2].

In addition, it is obvious that cardiovascular diseases are of extreme social concern, as they are considered to be the leading cause of mortality. Therefore, close attention to the treatment of cardiovascular diseases is justified and relevant.

It is known that the system of medical care for the treatment of cardiovascular diseases is represented by several interconnected stages: the outpatient level (via polyclinics, consultation and diagnostic centres, etc.), the emergency level, the inpatient level (including the day hospital phase), and the rehabilitation level. At each level, based on the diagnosis and medical indications, the necessary pharmaceutical therapy is administered. It is funded in accordance with the structure of the state pharmaceutical provision system at both the federal and regional levels.

The financial burden of treating cardiovascular diseases is borne by the regions of the Russian Federation. The treatment is provided within the framework of the regional programmes for state guarantees of free medical care for citizens. In addition to the allocated state funds, the programmes include additional forms and conditions for such treatment, as well as additional volumes. However, so far there are no clear criteria for the formation of regional systems for the provision of medicines for patients with cardiovascular diseases.

The analysis of pharmaceuticals included in the regional subsidised pharmaceutical provision programmes in different regions of the Russian Federation (as of 2018) showed that the average number of medicines for cardiovascular diseases by region was 50. In particular, in the Sverdlovsk Region, the list included 25 medicines. At the same time, the Sverdlovsk Region ranked 23rd (from best to worst) in terms of the total morbidity rate of the population among the regions of the Russian Federation. In 2018, there was a 35.0 % increase in morbidity rate of the population compared to the average annual rate in recent years. Diseases of the circulatory system are the leading cause

[1] Russia's National Projects: Healthcare URL: https://clck.ru/RrbXN

[2] The state of health of the population and the performance of the healthcare system in the Sverdlovsk Region (based on the annual statistics reports for 2018). Information Bulletin. Moscow. State-Funded Healthcare Institution of the Sverdlovsk Region "Medical Information Analysis Centre", 2018.

of morbidity among the adult population in the Sverdlovsk Region, accounting for 11.4 % of the total morbidity in this group[3].

Thus, it is relevant to study the issue of assessing the availability of medicines for cardiovascular diseases at all levels of medical care for citizens for similar social groups in the regions of Russia.

We define the concept of *availability of medicines* as the ability of patients to obtain the necessary medicine at the right time and at a price they can afford or on preferential terms (see, e.g., Petrov et al. [1], Gong et al. [9], Sharma et al.[14], and Wirz et al. [15]).

Therefore, the key elements of the availability of medicines are:

– ***The assortment availability*** of medicines, as their availability in sufficient quantity and variety corresponding to the level and type of treatment.

– ***The financial availability*** of medicines, as the affordability of the prices and/or preferential terms for obtaining them.

– ***The logistical availability*** of medicines, as the timeliness of their receipt and delivery corresponding to the level and type of treatment.

The aim of the study was to analyse the availability of pharmaceuticals for the population in 2011 and 2019 using the example of cardiovascular disease treatment. We intended to assess the assortment, financial, and logistical availability of medicines as a determinant of sustainable development of the national healthcare system (based on the materials of VED range and price monitoring in the Sverdlovsk Region).

The objectives of the study included:

– An analytical assessment of the assortment availability of medicines based on changes in the range of medicines for cardiovascular diseases in the outpatient and inpatient segments of the pharmaceutical market in the Sverdlovsk Region for 2011-2019.

– An analytical assessment of the financial availability of medicines based on changes in the prices of medicines for cardiovascular diseases in the outpatient and inpatient segments of the pharmaceutical market in the Sverdlovsk Region for 2011-2019.

– An analytical assessment of the logistical availability based on the study of conditions and consequences of import substitution of medicines for cardiovascular diseases in the outpatient and inpatient segments of the pharmaceutical market in the Sverdlovsk Region for 2011-2019.

Materials and methods

To achieve the objectives, we conducted a statistical analysis of the average retail prices per package of medicines, of the range of medicines for cardiovascular diseases in the outpatient segment, and the average package prices per trade name in the inpatient segment for Sverdlovsk Region for 2011-2019. Moreover, we used the methodology of the World Health Organization and Health Action International (WHO/HAI) to analyse the availability of medicines[4].

The study was based on the data from the Monitoring of the Range and Prices of Vital and Essential Drugs (VED) in the Sverdlovsk Region for the period from 2011 to 2019 with a step of 2 years. The database contains more than 200,000 records entered by the regional institutions. The majority of them (80 to 88 %) refer to the outpatient segment, and between 20 % and 12 % refer to the inpatient segment.

The qualitative analysis was based on the results of in-depth and semi-structured interviews with experts: representatives of medical organisations and pharmacies, the Ministry of Health of the Sverdlovsk Region, and Roszdravnadzor of the Sverdlovsk Region.

[3] Statistical information on the state of health and provision of medical care to the population of the Sverdlovsk Region. Open Government of the Sverdlovsk Region. URL: https://clck.ru/32mChE

[4] Health Action International. URL: http://haiweb.org/medicineprices

Results

Assortment availability

The assessment of the assortment availability of medicines was based on the structural and comparative analysis of the main groups of medicines from the List of Vital and Essential Drugs for cardiovascular diseases in the Sverdlovsk Region for the period from 2011 to 2019 for outpatient and inpatient segments, including international nonproprietary names (INN) and trade names, in monetary and physical terms.

An analysis of the breakdown of medicines by trade names and international nonproprietary names in the outpatient and inpatient segments over the studied period showed that the number of international nonproprietary names was increasing, while the number of trade names was decreasing. This indicated a decrease in the range of available medicines (Fig. 1).

The structural analysis of therapeutic groups of cardiovascular drugs in the Sverdlovsk Region in 2019 by outpatient and inpatient segment in physical terms reveals an increased share of generic drugs in the inpatient segment compared to the outpatient segment. A possible reason is the financial limitations of healthcare organisations.

In addition, it was found that the transition of the patient from the inpatient to the outpatient segment was accompanied by a structural shift in the consumption of medicines: the share of originator medicines increased, there was a shift towards more expensive generics, or medicines subsidised through the pharmaceutical provision programmes.

Financial availability

To access the financial availability, we carried out a *statistical* and *pharmacoeconomic analysis* of the direct costs of drug therapy for arterial hypertension in 2019. According to the clinical guidelines for the treatment of arterial hypertension by Kobalava [2], the initial pharmacotherapy includes five groups of drugs (diuretics, beta adrenoreceptor antagonists, calcium antagonists, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists). They can be used as a single therapy or in combination, depending on the disease's severity.

For the outpatient segment, a reference group was formed according to the WHO/HAI methodology, based on the List of Essential Drugs for arterial hypertension. End-user prices were recorded and presented as a median price ratio (MPR) of local prices to reference prices

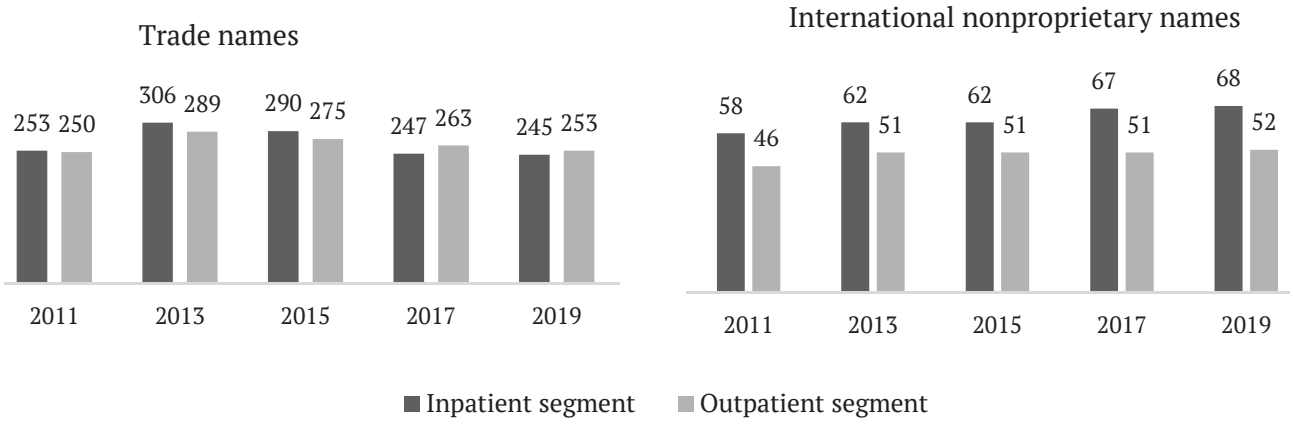

Figure 1. Changes in the number of VEDs by trade names and international nonproprietary names in the Sverdlovsk Region

Table 1

Statistical analysis of prices of medicines for arterial hypertension in the outpatient segment

Parameter	2011		2019	
	Original brands	Generics	Original brands	Generics
MPR	***16.34*** [1.73–64.29]	***3.63*** [2.65–10.28]	***14.11*** [1.7–37.92]	***2.5*** [1.67–5.64]
Minimum	0.61 (furosemide 40 mg)	0.13 (furosemide 40 mg/ml)	***0.33*** (furosemide 40 mg)	0.13 (furosemide 40 mg/ml)
Maximum	140.04 (amlodipine 10 mg)	23.03 (simvastatin 20 mg)	***69.85*** (amlodipine 10 mg)	11.99 (simvastatin 20 mg)
Number of medicines	13	20	11	20

Table 2

Cost of annual pharmacotherapy for arterial hypertension in 2019, RUB

Therapeutic group	Name of the medicine	Generics	Original brands
Diuretics	Hydrochlorothiazide 25 mg	1,687	–
	Spironolactone 25 mg	3,787	–
	Furosemide 40 mg	***170***	431
Beta adrenoreceptor antagonists	Atenolol 50 mg	780	–
	Bisoprolol 5 mg	2,713	5,017
	Metoprolol 50 mg	4,305	***23,597***
Calcium antagonists	Amlodipine 5 mg	886	6,100
	Verapamil 40 mg	1,737	–
	Nifedipine 20 mg	1,680	–
Angiotensin-converting enzyme inhibitors	Lisinopril 10 mg	2,059	–
	Enalapril 5 mg	1,479	3,727
Angiotensin II receptor antagonists	Losartan 50 mg	1,359	3,607

from the International Drug Price Indicator Guide by Management Sciences for Health[5]. According to the WHO/HAI methodology, it is considered that if the MPR value is ⩽1, then prices are affordable.

During the study, there were price reductions for both generic and original medicines. The most affordable medicine throughout the study period was furosemide, which is a diuretic, and the most expensive was amlodipine. The price of the most expensive medicine (amlodipine 10 mg) in 2019 was 69.85 times the international reference price (Table 1).

In 2019, the cost of an annual course of pharmaceutical therapy for arterial hypertension ranged from RUB 170 to RUB 23,597 and depended not only on the type of medicine, but also on the choice of a particular medicine within one therapeutic group. For example, treatment with generic metoprolol was 5.5 times more expensive than treatment with other generic beta adrenoreceptor antagonists (Table 2).

According to the WHO/HAI methodology, a medicine is considered affordable if a month of treatment for a chronic disease requires less than one day's earnings of a low-wage, low-skilled worker.

Our analysis showed that the average affordability of generics was high, and a worker with the lowest wage could purchase a medicine for a month of therapy at less than one day's earnings. Among the original medicines, there

[5] International Drug Price Indicator Guide. URL: http://mshpriceguide.org/en/home/

were unaffordable ones (Metoprolol 50 mg), for which such a worker would spend more than five days' wages (Table 3).

Logistical availability

Logistical availability was assessed by comparative analysis of the volume of substitution of original medicines with generics, as well as the volume of substitution of medicines manufactured by Russian pharmaceutical companies with foreign-made medicines from 2011 to 2019.

When assessing the logistical availability, we analysed the continuity of pharmaceutical therapy for cardiovascular diseases in the inpatient and outpatient segments to determine the degree of substitution of original medicines with generics (Figure 3) and of foreign-made medicines with Russian-made ones (Figure 4).

When moving from the inpatient to the outpatient segment, the therapy continuity is disrupted: cheaper generic medicines are replaced by expensive original medicines produced by foreign manufacturers.

Results

It is worth noting that the issue of availability of medicines in the context of regional health system development has recently been addressed both locally by individual countries and territories and internationally.

Most studies assessing the availability of medicines were carried out in low- and middle-income countries, predominantly in pharmacy chains. It was observed that high prices and lack of adequate access to essential medicines is a global issue for healthcare systems (see, e.g., Abramov [1], Cameron et al. [8], Gong et al. [9], Meena et al. [12], and Moye Holz & Vogler [13]). Studies by Günther [10], Kalabina [11] were conducted in collaboration with pharmaceutical manufacturers with an a priori interest in increasing the consumption of medicines. These studies clearly shifted the estimates to justify an increase in the diversity and volume of medicines consumed.

As for the review of the results of empirical studies in the Russian Federation at the level of individual territories, the studies by Petrov,

Table 3

Ratio of monthly treatment costs to one day's wages of a low-wage, low-skilled worker in 2019 in the Sverdlovsk Region

Therapeutic group	Name of the medicine	Generics	Original brands
Diuretics	Hydrochlorothiazide 25 mg	0.39	–
	Spironolactone 25 mg	0.88	–
	Furosemide 40 mg	0.04	0.10
Beta adrenoreceptor antagonists	Atenolol 50 mg	0.18	-
	Bisoprolol 5 mg	0.63	***1.17***
	Metoprolol 50 mg	1.00	***5.50***
Calcium antagonists	Amlodipine 5 mg	0.21	***1.42***
	Verapamil 40 mg	0.41	–
	Nifedipine 20 mg	0.39	–
Angiotensin-converting enzyme inhibitors	Lisinopril 10 mg	0.48	–
	Enalapril 5 mg	0.34	0.87
Angiotensin II receptor antagonists	Losartan 50 mg	0.32	0.84

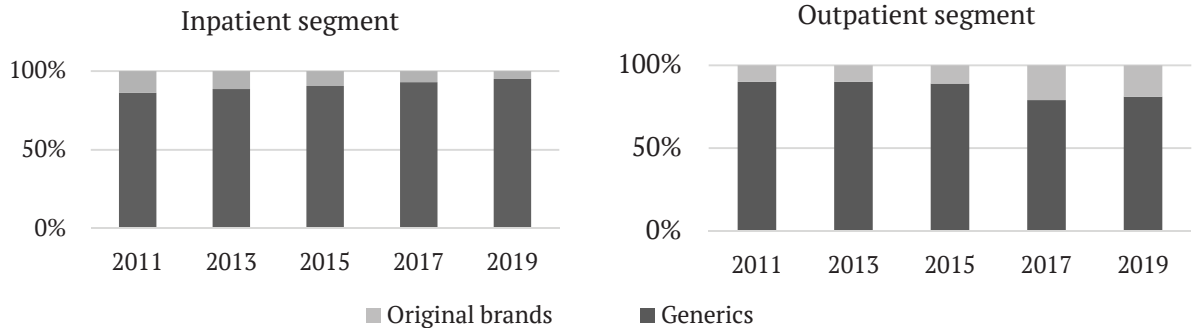

Figure 3. Dynamics of change in the consumption ratios of generic medicines and original brands in the inpatient and outpatient segments in the Sverdlovsk Region

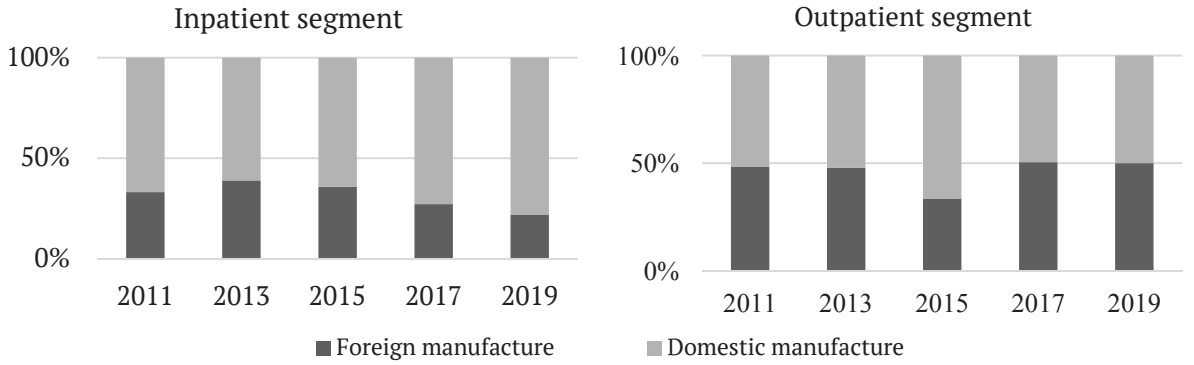

Figure 4. Dynamics of change in the consumption ratios of foreign and domestically produced medicines in the inpatient and outpatient segments in the Sverdlovsk Region

Abramov, and Kashtalap [1], Razzakova [3], Ziganshina [4], and Yagudina [5; 6] analyse the physical availability and affordability of cardiovascular medicines. These studies cover mainly the pharmacy chains based on sample studies of public and private pharmaceutical market sectors.

In contrast to previous studies on this issue, we attempted to analyse the assortment, financial, and logistical availability of medicines in aggregate, using cardiovascular disease treatment as an example. In our study, we used data from the Sverdlovsk Region Assortment and Price Monitoring for Vital and Essential Drugs for 2011 and 2019 (over 200 thousand records) to develop recommendations for sustainable development of the regional healthcare system.

As a result of the analysis of the assortment availability of medicines on the example of cardiovascular diseases, it was found that:

– For all therapeutic groups, the proportion of generic medicines in the inpatient segment is higher than in the outpatient segment.

– The transition of patients from the inpatient to the outpatient segment is accompanied by a noticeable structural shift in the range of medicines: the share of original medicines increases, there is a shift in favour of more expensive generics.

The analysis demonstrated a number of affordability barriers in the treatment of cardiovascular diseases:

– The affordability of original brands decreases compared to generics in the study period.

– The cost of an annual course of treatment varied significantly from RUB 170 to RUB 23,597 depending on the medicine (as of 2019).

– The average affordability of generics was increasing, and a worker with the lowest wage could purchase a medicine for a month's therapy, spending less than a day's wage. Among the original medicines, there were almost unaffordable ones, since such worker would spend more than five days' wages to purchase them.

Analysing the logistical availability of medicines for cardiovascular disease treatment, we determined that the increase in the availability of generic medicines reduced the burden of cost recovery for the state. However, the rational choice of medicines is important for patients to ensure the most effective, safest, and least costly pharmacotherapy.

Conclusions

Ensuring the availability of medicines for the development of the regional healthcare system is one of the key issues of the modern socio-economic policies of the regions.

According to an analytical review of the pharmaceutical market in Russia by DSM Group[6], the volume of the commercial market for pharmaceuticals was 112 billion roubles (in retail prices) in September 2022, up 14.7 % compared to August. The sales volume increased by 5.9 % as compared to September 2021. In physical terms, the sales volume of medicines in September increased by 13.9 % as compared to August and amounted to 376.4 million packs. However, this value was 9.1 % less than a year ago. Meanwhile, the average cost of a pack of a medicine in the Russian commercial market was 0.8 % higher in September than in August and reached 297.6 roubles. The market capacity in roubles in the first nine months of 2022 reached 1,009.9 billion roubles, with an increase of 20.1 % compared to the corresponding period of 2021. According to DSM Group estimates, the consumption of medicines through pharmacies reached 3.3 billion packs in the first nine months of 2022, which is 0.1 % higher than in the corresponding period of 2021.

Thus, the analytical evaluation of pharmaceutical provision in the regions in terms of the assortment, financial, and logistical availability of medicines provides an opportunity to understand the pricing processes for various categories of medicines in both the outpatient and inpatient segments of the market.

Based on the monitoring and analysis of the availability of medicines for cardiovascular diseases in the Sverdlovsk Region, we made the following conclusions:

– In general, at the outpatient stage, medicines are provided for socially disadvantaged groups at the expense of the state. For other categories of citizens, the availability of pharmaceuticals is significantly lower and becomes a significant financial burden when treating cardiovascular diseases.

– At the inpatient level of cardiovascular disease treatment, medicines from the List of Vital and Essential Drugs are provided at the expense of the regional Compulsory Medical Insurance Fund. The availability of these medicines is relatively stable in terms of finance, assortment, and logistics.

– There is no continuity in the list of medicines for cardiovascular diseases for the inpatient and outpatient levels of medical care, which reduces the availability of medicines in the region as a whole, as exemplified by the Sverdlovsk Region.

Conflict of interests

The authors declare the absence of obvious and potential conflicts of interest related to the publication of this article.

[6] DSM Group. Analytical Report. Russian Pharmaceutical Market. Published: September 2022. – URL: https://clck.ru/FKjA3

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Исследование доступности лекарственного обеспечения населения в контексте развития региональной системы здравоохранения (кейс Свердловской области)

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Предмет. Повышение доступности современных эффективных и безопасных лекарственных препаратов является одной из ключевых задач развития региональных систем здравоохранения в рамках достижения целей национального проекта «Здравоохранение». Модернизация системы лекарственного обеспечения граждан как многогранный процесс находится в фокусе внимания экономики, государства и общества. Особое место среди вопросов реформирования системы лекарственного обеспечения граждан занимает проблема доступности лекарственных препаратов для лечения сердечно-сосудистых заболеваний. Распространенность сердечно-сосудистых заболеваний в популяции является причиной негативного экономического влияния и весомых затрат государственных систем здравоохранения на их лечение во всем мире. Основанием экономических потерь является смертность от сердечно-сосудистых болезней и заболеваемость ими населения в трудоспособном возрасте, что приводит к существенным потерям человеческого капитала.
Цели. Цель исследования состояла в проведении анализа и оценки ассортиментной, финансовой и логистической доступности лекарственных препаратов для лечения сердечно-сосудистых заболеваний на всех этапах оказания медицинской помощи в контексте развития региональной системы здравоохранения по материалам Свердловской области за 2011–2019 гг.
Методология. Информационной базой исследования стали данные мониторинга ассортимента и цен на жизненно необходимые и важнейшие лекарственные препараты (далее – ЖНВЛП) по Свердловской области за период 2011–2019 гг. Сравнительный и структурный анализ доступности лекарственных средств для лечения заболеваний сердечно-сосудистой системы был проведен с использованием методологии ВОЗ и Международной неправительственной организации «Программа действий за здоровье и здравоохранение» (WHO/HAI) на основе расчета медиан соотношений местных цен и международных референтных цен лекарств по группам отечественных и зарубежных препаратов, оригинальных и дженерических, а также с учетом ценовых групп для амбулаторного и госпитального сегментов рынка.
Выводы. В результате исследования доступности лекарственных препаратов для лечения сердечно-сосудистых заболеваний в Свердловской области было установлено, что лекарственное обеспечение на амбулаторном этапе осуществляется за счет преимущественно государственных средств для социально незащищенных групп населения, на госпитальном этапе – за счет средств территориального фонда ОМС из перечня ЖНВЛП. Практически отсутствует преемственность в формировании перечня лекарственных препаратов для лечения сердечно-сосудистых заболеваний для госпитального и амбулаторного этапов оказания медицинской помощи, что в целом снижает уровень доступности лекарственных средств. Для повышения эффективности лекарственного

обеспечения для развития региональной системы здравоохранения необходимы дополнительные исследования динамики цен и фармакоэкономический анализ с учетом тенденций фармацевтического рынка России.

Ключевые слова: цены на лекарственные препараты, доступность лекарственных препаратов, региональная система здравоохранения, WHO/HAI, референтные цены.

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Конфликт интересов

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