

Determination of social and economic accessibility of drugs for treatment of Parkinson's disease on the basis of modern approaches

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Abstract

In the context of the economic crisis, the availability of medicines for the population is one of the key issues facing pharmaceutical sector of healthcare system. Due to the fact of that, the purpose of the work was to study the social and economic accessibility of medicines, since such studies in the future may provide an opportunity for effective input of medicines costs reimbursement system, which will increase their availability, especially for socially vulnerable groups of population. The data analysis of the clinical protocols of Great Britain, Kazakhstan and Ukraine was conducted, and the indicators of social and economic availability within 2014–2018 were calculated. The obtained results indicate an adequate level of availability of medicines for the able-bodied population and, unfortunately, a low level of accessibility of medicines for people of retirement age with a tendency to further descension. These results point the necessity of the further research and development of government control systems and provision of pharmaceutical care for the population.

Keywords

clinical protocol, medicines, index of retail prices, neurological diseases

Introduction

In Ukraine, the reform of the pharmaceutical sector in healthcare system has been identified as one of the main areas of state policy aimed for developing of effective mechanisms for providing population with medicines besides affordable and effective pharmacotherapy, as well as people's illness prevention. At the same time, in the context of economic crisis, the problem of social and economic accessibility of medicines remains relevant, as well as the problem of provision of effective medical and pharmaceutical care by the use of medicines in accord-

ance with the protocols and standards of treatment based on international documents, for instance WHO Guideline on Country Pharmaceutical Pricing Policies (2013), considering state regulations of pricing and monitoring of medicines prices.

It should be noted that such national health policy is inherent not only in Ukraine. For example, the 72nd World Health Assembly (WHA-72), which was recently held in Switzerland (May 20–28, 2019) and was devoted to the problem of the search for new ways of providing effective and affordable medical and pharmaceutical care. Also, special attention was paid to the issues of social and

economic accessibility of drugs, which were reviewed at a fundamentally new level. During the Assembly, the “Road Map for Access to Medicines, Vaccines and Medical Products 2019–2023” was approved, which is based, above all, on the social and economic approaches. The approved 5-year Roadmap program is based on three strategic priorities, namely: achieving progress towards overall coverage of health services; introduction of effective measures to overcome the crisis in health care, and improvement of health and quality of life of population.

At the same time, an important part of the National health policy implementation is the state support for patients with severe illnesses, among which Parkinson's disease (PD) has a special place, according to Pringsheim T et al. (2014), and is second to the prevalence of neurodegenerative disorders among the elderly people. According to the experts, there are 6.9 million patients in the world and, according to the forecasts, their number could reach 14.2 million by 2040, due to the rapid aging of population. Today, the average age of the onset of the disease is 60–65 years, but it was noted by Rizek P et al (2016) that every 20 cases occur among people aged over 40 years old, and every 10 cases – among people aged 50. Therefore, the special concern of health care professionals is the fact of an increasing in the prevalence of the PD of the very able-bodied population, which forms social and economic potential of the country. It should be noted, that PD is also being considered as an incurable disease, so patients are forced to take medicines throughout their lives. Therefore, the issue of social and economic accessibility of antiparkinson drugs remains relevant.

Materials and methods

The main goal of the study was to determine the social and economic affordability of medicines for the treatment of PD based on modern approaches. To achieve the goal, the research algorithm was developed. It consists out of four stages (Fig. 1).

An important stage of the research was the choice of comparative countries for the analysis of the pharmaceutical component of clinical protocols for PD treatment. For more disclosure, the following data was used: Clinical protocol for the provision of medical care for patients with PD, approved by the Ministry of Health of Ukraine №317 (2008); Clinical protocol for diagnosis and treatment of PD (Kazakhstan) (2016); National Institute for Health and Care Excellence guideline – PD in adults (UK) (2017). The aforementioned choice of countries is substantiated, above all, by the focus of the national health reform on building a socially oriented model of Beveridge Medical Insurance (UK) and a historical affinity for the development of national health systems (Kazakhstan).

To determine the dynamics of social and economic affordability of medicines during 2014–2018, the following indicators were calculated and analyzed: group index of retail prices for medicines, and their availability. Retail

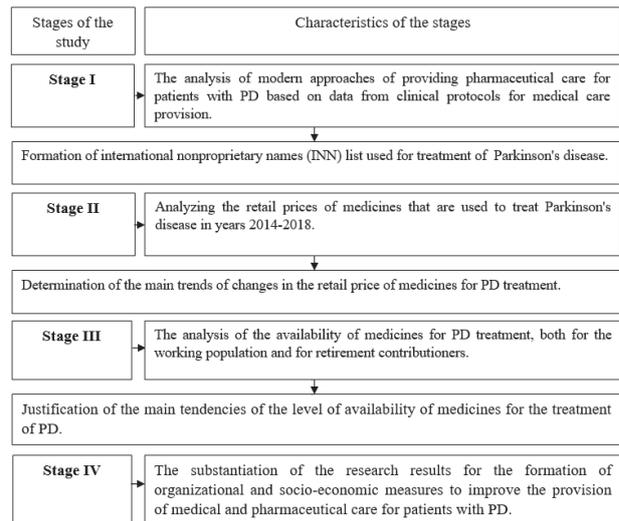


Figure 1. Algorithm for conducting studies to determine the social and economic affordability of medicines for the treatment of PD.

prices for medicines used for the treatment of PD were determined using analytical tool for the pharmaceutical market researches “Pharmstandard” of Morion Company (Ukraine). Group index of retail prices for medicines was calculated by the formula:

$$I_g = \frac{1}{n} \sum_{i=1}^n I_i, I_p = \frac{\bar{P}_i}{\bar{P}_{io}}$$

where: I_p – chain price index;

\bar{P}_i – the arithmetic average weighted retail price of the i -th drug in the current period;

\bar{P}_{io} – the arithmetic average weighted retail price of the i -th drug in the previous period;

n – amount of medicines in the investigated group.

To calculate the affordability index (D) of the medicines, the following formula, that was proposed by Kubareva I (2010) was used:

$$D = \frac{I_r}{I_g}$$

where, I_r – index of average wage/retirement contribution changes relative to the previous reporting period;

I_g – index of retail price change for medicines in relation to the previous reporting period.

Affordability is a complex concept that shows the affordability of drugs, depending on price growth index, the minimum wage and the consumer basket.

Nowadays, it is widely accepted that improving the affordability of medicines only means reducing drug prices. It is proposed to use the same scheme to improve the affordability of medicines, without thinking about where cheap drugs can come from if prices for raw materials, substances, electricity, etc. are rising. State regulation of only retail drug prices will not solve the problem of their affordability. Problems of drugs affordability for Ukrainian population are not related only to their value or availa-

Table 1. Indicators of the dynamics of the nominal average salary and average retirement contribution during 2014–2018.

Indexes	Year				
	2014	2015	2016	2017	2018
Nominal average salary, USD	292.66	192.87	202.72	267.10	316.19
Average retirement contribution, USD	128.53	72.50	66.42	68.73	91.09

bility on the pharmaceutical market. The real reasons concerning this problem are social stratification and the lack of a fair distribution of material goods among the population of the country. The inaccessibility of most drugs to many social groups is a consequence of their low solvency.

According to the WHO recommendations, aimed at protecting patients' rights and allowing them to prioritize health care, the basis of the concept is to use a limited number of medicines that are reasonably selected according to clinical and economic indicators, helping to improve the supply of medicines and their more rational use.

Pharmaceutical assistance to citizens of the country is being treated in hospitals in accordance with the rules of the current legislation and is provided free of charge at the expense of budgets (state and local), so its availability should be determined by the adequacy of budget financing.

The above-mentioned formula for calculating the accessibility index was developed by the scientists of the Department of Organization and Economics of Pharmacy at the National Pharmaceutical University (Kharkiv, Ukraine) under the direction of Professor Alla S. Nemchenko according to the data of literary sources. It was found that in order to achieve the state-guaranteed level of medicines accessibility, the indicator should be greater or equal to one ($D \geq 1$). When conducting D calculations, the official data from the State Statistics Service of Ukraine was used, regarding the dynamics of the nominal average salary and the average retirement contribution in years 2014–2018 (Table 1).

It should be mentioned that the differentiated approach to determination of the accessibility indicators for certain segments of the population depending on their level of incomes, or social status will allow to calculate the most vulnerable segments of society and, accordingly, to implement the most effective measures for improvement of the level of medical and pharmaceutical care provision for population.

Results and discussion

Considering lack of compulsory health insurance in Ukraine, economical availability of pharmaceutical care for people is ensured through the state regulation of drug prices and reimbursement system.

In accordance with the provisions of the CMU Resolution No. 955 from 17.10.2008 "Measures to stabilize the prices of medicines and medical products" concerning drugs included in the National List of Essential Medicines (approved by CMU Resolution No. 333 from 25.03.2009 "Some issues of state regulation of prices for medicines and medical products"), their retail allowance for the pop-

ulation should not exceed 10% from wholesale price. At the same time, retail prices are formed on the basis of purchase price. For those medicines, the wholesale price of which does not exceed 4 USD, trading allowance can be up to 25%. If the wholesale price is 4–20 USD, trade allowance can be up to 20%. If wholesale price is 20–40 USD, allowance may be up to 15%, and if the wholesale price of the medicine is more than 40 USD, then allowance cannot be more than 10%.

It should be noted that the National List of Essential Medicines includes only drugs of the group N04BA02 Levodopa with decarboxylase inhibitors. Therefore, all other drugs that are used in PD treatment are not under the state regulation. The amount of the supply and trade allowance is arbitrary and is determined independently by the entity.

In Ukraine, according to the CMU Resolution No. 1303 of 17.08.1998 "About regulation of free and preferential dispensing of the prescribed medicines in the case of outpatient treatment of certain populations and for certain categories of diseases", in case of outpatient PD treatment it should be free of charge. Medicines that are registered in Ukraine and are included in the health care industry standards are also free of charge. Dispensing of free medicines in the case of outpatient treatment for PD patients is carried out by pharmacies according to the prescriptions prescribed at district hospitals. It is worth mentioning that from April 2017 The Available Medicine program is introduced in Ukraine. The reimbursement mechanism under this program applies to cardiovascular disease, type II diabetes and bronchial asthma.

At the same time, in Ukraine for drugs that are purchased in whole or in part at the expense of the state and local budgets, the maximum wholesale allowances cannot be higher than 10%, and retail allowances cannot be higher than 10% charged to the purchase price (CMU Resolution dated October 17, 2008 No. 955 "About the measures for stabilization of the prices of medicines and medical products").

In accordance with the developed algorithm, at the first stage of the research, pharmaceutical component of the clinical protocols of medical and pharmaceutical care provision to patients with PD in the UK, Kazakhstan, and Ukraine were analyzed.

According to the National Institute for Health and Care Excellence guideline – Parkinson's disease in adults (Great Britain), for the disease in first manifestation and its onset agonists of dopamine receptors (DA) should be used in people with minor motor defects, namely: rotigotine, pramipexole, ropinirole, MAO-B inhibitors (selegiline, rasagiline). Levodopa derivatives in the early stages of the disease should be prescribed to people whose motor symptoms affect the quality of life.

Table 2. Dynamics of the group indexes of retail prices for medicines during 2014–2018.

ATC classification groups	I_g				
	2015/2014	2016/2015	2017/2016	2018/2017	2014–2018
N04AA01 Trihexyphenidyl	1.40	1.09	1.03	1.05	1.14
N04BA02 Levodopa and decarboxylase inhibitor	1.34	1.25	1.10	1.15	1.21
N04BA03 levodopa, decarboxylase inhibitor and COMT inhibitor	1.52	1.12	0.98	0.89	1.13
N04BB01 Amantadine	1.53	1.19	1.10	1.10	1.23
N04BC04 Ropinirole	1.96	1.01	0.80	–	1.26
N04BC05 Pramipexole	1.43	0.99	1.01	1.23	1.17
N04BC08 Piribedil	1.19	1.03	1.10	1.28	1.15
N04BC09 Rotigotine	1.28	–	–	–	1.28
N04BD01 Selegiline	1.60	1.02	1.05	1.31	1.25
N04BD02 Rasagiline	–	1.03	0.98	0.94	0.98
N06DA03 Rivastigmine	1.75	1.12	1.07	1.27	1.30
Average value I_g	1.50	1.09	1.02	1.14	1.19

In case of development of fluctuations and dyskinesia to levodopa, it is recommended to add DA (rotigotine, pyribedil, pramipexole, ropinirole), MAO-B inhibitors (selegiline, rasagiline), or COMT inhibitors (levodopa, decarboxylase inhibitor and COMT inhibitor) in the treatment scheme.

According to Clinical Diagnosis and Treatment Protocol for Parkinson's Disease (Kazakhstan), if the disease's first manifestation occurs in person who is under 50 years old and in case of mild motor defect, the treatment should start with inhibitors of MAO-B (selegiline, rasagiline); in case of moderate motor defect – with DA (rotigotine, pyribedil, pramipexole, ropinirole). When effectiveness of the prescribed treatment is reduced, combinations of MAO-B inhibitors with amantadine, DA, cholinolytics (bipyridine, trihexyphenidyl) (with evident tremor) should be added.

If person is 50–70 years old and in case of mild or moderate motor defect, treatment with MAO-B inhibitors (selegiline, rasagiline) or DA (rotigotine, pyribedil, pramipexole, ropinirole), respectively, is also used. However, if a patient experiences an evident motor or cognitive defect, his treatment begins immediately with levodopa.

If a patient is over 70 years old and has a light motor defect, MAO-B inhibitors (selegiline, rasagiline) are used, and in case of moderate and severe motor defect levodopa derivatives should be used.

In intermediate stages of disease patients with mild and moderate motor defects should obtain drug combinations, and in later stages small doses of levodopa are added. Patients taking levodopa will gradually increase their dose until the optimal level is obtained.

In Ukraine, according to the clinical protocol, the provision of medical care to PD patients is approved by the Order №317 from 13.06.2008 of the Ministry of Health of Ukraine. At the initial stages of the disease, groups of medicines such as selegiline (N04BD01), rasagiline (N04BD02) or amantadine (N04BB01) are used. In case of the further progression of the disease, medicines of the groups trihexyphenidyl (N04AA01), biperiden (N04AA02) or levodopa and decarboxylase inhibitor (N04BA02) should be added.

It has been found that according to the data of the protocols for the provision of medical care to the UK patients having the first PD manifestations, it is recommended to prescribe medicines such as ropinirole (N04BC04), pramipexole (N04BC05), piribedil (N04BC08), rotigotine (N04BC09), selegiline (N04BD01), rasagiline (N04BD02). In the process of further development of PD, levodopa or inhibitors of COMT can be added to the treatment scheme. At the same time, with evident tremor, it is necessary to prescribe such medicines as trihexyphenidyl (N04AA01), biperiden (N04AA02) or levodopa, as well as decarboxylase inhibitor (N04BA02).

The obtained results have shown that in Ukraine it is necessary to expand the list of medicines for PD treatment, taking into account the modern medical technologies of health care and the trends of the national pharmaceutical market development.

Based on the current list of medicines used to treat PD, social and economic indicators of medicines were analyzed. For the given purpose, the dynamics of retail prices for medicines for years 2014–2018 was determined, and the group price index of retail prices was calculated. The obtained results are presented in Table 2.

It was found that in the period 2015, the I_g index was 1.50; in 2016 – 1.09; 2017 – 1.02, and in 2018 – 1.14. The average I_g index within 2014–2018 years was 1.19. The obtained data have shown that in the pharmaceutical market of Ukraine there is a tendency of growth of average retail prices for medicines, which are used for PD treatment. This fact can be explained by a significant devaluation of the national currency and, consequently, a significant increase in the medicines prices, which is a negative phenomenon from the social and economic point of view that should be resolved at the state level.

The analysis of the mean indicator in accordance with the ATC classification has shown that the largest increase of the indicator within 2014–2018 years was characterized by medicines of the groups of rivastigmine ($I_g = 1.30$), rotigotine ($I_g = 1.28$) and ropinirole ($I_g = 1.26$). At the same time, the rasagiline derivatives characterized by a tendency

Table 3. The dynamics of the availability of medicines for the working population during 2014–2018.

ATC classification groups	D relative to average salaries by years			
	2015	2016	2017	2018
N04AA01 Trihexyphenidyl	0.87	1.13	1.33	1.19
N04BA02 Levodopa and decarboxylase inhibitor	0.9	0.99	1.24	1.08
N04BA03 levodopa, decarboxylase inhibitor and COMT inhibitor	0.8	1.1	1.4	1.4
N04BB01 Amantadine	0.79	1.04	1.25	1.13
N04BC04 Ropinirole	0.62	1.22	1.72	–
N04BC05 Pramipexole	0.85	1.25	1.36	1.02
N04BC08 Piribedil	1.01	1.2	1.24	0.98
N04BC09 Rotigotine	0.94	–	–	–
N04BD01 Selegiline	0.76	1.2	1.31	0.96
N04BD02 Rasagiline	–	1.2	1.39	1.32
N06DA03 Rivastigmine	–	1.1	1.28	0.98
Average value I_g	0.84	1.15	1.36	1.14

Table 4. Availability of medicines dynamics for pensioners within 2014–2018.

ATC classification groups	D relative to average salaries by years			
	2015	2016	2017	2018
N04AA01 Trihexyphenidyl	0.74	0.98	0.97	0.96
N04BA02 Levodopa and decarboxylase inhibitor	0.78	0.86	0.91	0.87
N04BA03 levodopa, decarboxylase inhibitor and COMT inhibitor	0.69	0.96	1.02	1.12
N04BB01 Amantadine	0.68	0.91	0.91	0.91
N04BC04 Ropinirole	0.53	1.07	1.25	–
N04BC05 Pramipexole	0.73	1.09	0.99	0.81
N04BC08 Piribedil	0.87	1.04	0.91	0.78
N04BC09 Rotigotine	0.81	–	–	–
N04BD01 Selegiline	0.65	1.05	0.95	0.77
N04BD02 Rasagiline	–	1.05	1.02	1.06
N06DA03 Rivastigmine	–	0.96	0.93	0.79
Average value D_a	0.72	1.00	0.99	0.91

to lower retail prices, which can be estimated as a positive social and economic trend. So, in general for the period of 2014–2018, the average value of the I_g index was 0.98.

The next stage of the research was to study the availability (D) of the medicines separately for the working population and the pensioners. The obtained results are presented in Table 3. According to the given results, in 2015 the level of accessibility of medicines was not optimal (i.e. under 1.0), excepting – Piribedil group (D – 1.01). In our opinion, this is primarily due to the fact that the country experienced a crisis situation, which led to a significant increase among medicines prices. At the same time, it has been found that during the period of 2016–2018 in Ukraine, almost all groups of medicines for PD treatment were available to the working population. Therefore, the average indicator D in 2016 was 1.15; in 2017 – 1.36, and 1.14 in 2018.

The results of the analysis of the availability of medicines for the pensioners indicate a rather low availability of medicines for PD treatment in the period of 2015–2018 (Table 4). The lowest level of medicines availability was determined in 2015. Thus, the average value of this indicator for this period was 0.72. This fact indicates that social protection, unfortunately, has not reached its optimal value for the entire period of the study. The established

fact proves, in our opinion, that there is a need of State measures for the mentioned group of patients.

The next stage of the study was to analyze the indicator dynamics of the availability of the foreign and the domestic production for the working population. It was found that during 2015–2017, the increase dynamics for this indicator was observed, indicating the stabilization of the social and economic situation in Ukraine. At the same time, in 2018 there was a decrease in the indicator of the availability of drugs for the working population for the both foreign and domestic drugs in comparison with 2017. It should be noted that during 2015–2018, the availability rate for the domestic medicines was significantly higher, comparing with the same indicator for the foreign medicines (Fig. 2).

In our opinion, the obtained results of the indicator analysis of the availability of foreign and domestic production for the pensioners (Fig. 3) require special attention. According to the given results, it was determined that the availability index in 2016 increased in 1.3 times in comparison to 2015 for the domestic medicines and in 1.4 times for the foreign medicines. At the same time, in 2018 a tendency for a significant reduction of this indicator was observed. Thus, compared to 2017, the availability of the

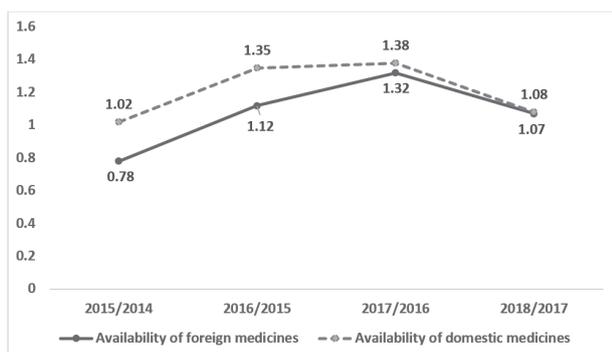


Figure 2. The dynamics of the indicator of the availability of foreign and domestic medicines for the working population.

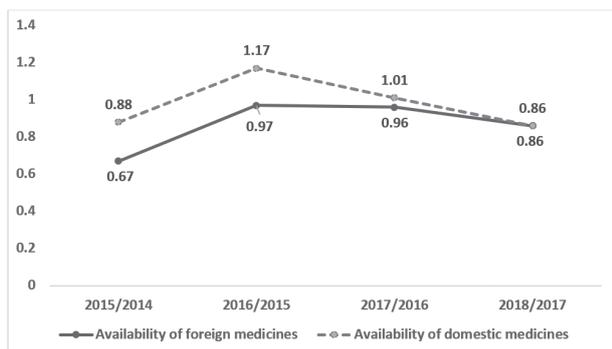


Figure 3. The dynamics of the indicator of the availability of foreign and domestic medicines for the pensioners.

domestic medicines has decreased from 1.01 to 0.86, i.e. in 1.17 times, and for the foreign medicines in 1.12 times. During the period of 2015–2018 years, the level of availability of the foreign medicines did not reach the optimal limit, which is equal to one. Of course, this fact must be defined as a negative characteristic of the studied process.

Therefore, the obtained results of the study suggest that there is a need to develop and implement state programs aimed at reducing the incidence and prevalence rates, increasing the duration and quality of life of PD patients through introduction of effective models of providing medical and pharmaceutical care for patients with the use of effective and accessible medicines.

Nowadays, in the vast majority of countries, the cost of pharmaceutical care for patients with socially dangerous and incurable illnesses is a subject for reimbursement system which is controlled by certain state programs. In

order to optimize budget expenditures and increase the availability of medicines included in these programs, most countries apply rather strict methods of state regulation of their pricing. According to the data of WHO main list for the provision of medical and pharmaceutical care for PD patients, combination of levodopa and carbidopa, as well as biperiden, is recommended.

There is no doubt that the social and economic availability of drugs is an important indicator of the efficiency of medical and pharmaceutical care for the population. However, the use of the results of the analysis of indicators of social and economic availability of drugs can optimize procurement of drugs, especially for patients who need long-term treatment.

Effective implementation of social and economic measures, in our opinion, will allow forming rational financial policy in the pharmaceutical sector of the healthcare, considering indicators of PD incidence and macroeconomic indicators of the country's progress.

Conclusions

The results of the study indicate the necessity for optimization and modernization of clinical protocols for PD patients. The main pharmacotherapy, since the use of modern medicines provides an opportunity to improve the quality of life of PD patients.

The analysis of the dynamics of retail prices for medicines within 2014–2018 years has shown that in the pharmaceutical market of Ukraine there is a tendency of growth of average retail prices for medicines that are used in PD treatment. So, the average value of I_g was 1.19.

It has been found that in Ukraine during 2016–2018 almost all medicine groups for PD treatment were available for the working population. At the same time, the results of the analysis of the availability of medicines for the pensioners during 2015–2018 years indicated low indexes.

International and national studies point to the fact that PD affects the great amount of elderly people. Taking into account low indicators of social and economic accessibility of medicines, for this particular category of Ukrainian population, in our opinion, it is necessary to introduce mechanisms for reimbursing the cost of medicines, which will provide an opportunity to increase the level of provision of medical and pharmaceutical assistance for PD patients.

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