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COMPARATIVE ANALYSIS OF APPROACHES TO PHARMACOTHERAPY FOR THE TREATMENT OF EPILEPSY IN UKRAINE AND THE UNITED KINGDOM

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ІНФОРМАЦІЯ

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Ключові слова:
epilepsy;
drug;
British National Formulary;
National Medicines Formulary;
Unified Clinical Protocol.

АНОТАЦІЯ

The aim of the work. To carry out a comparative analysis of the range of medicines used for the treatment of epilepsy in accordance with the provisions of regulatory documents in Ukraine and the United Kingdom.

Materials and Methods. The study used official data on the regulatory regulation of epilepsy pharmacotherapy, in particular, the recommendation of the British National Form (updated April 2018), the State Medicines Form (Issue 11, Ministry of Health, Order No. 892 of 18.04.2019), Unified Clinical protocol of primary, emergency, secondary (specialized) and tertiary (highly specialized) medical care for epilepsy in adults "(Order of the Ministry of Health of Ukraine of April 27, 2014 No. 276). The following methods were used: logical, system-analytical, comparative analysis and generalization of information.

Results and Discussion. According to the results of the analysis of the data of the British National Form, it is determined that 19 anti-epileptic drugs under the international non-proprietary name are recommended for the treatment of epilepsy patients. When comparing antieptic drugs with drugs that are included in the domestic regulatory provisions governing the provision of quality medical and pharmaceutical care to patients, a number of differences were identified. These differences include both the absence of certain medicines under the international non-proprietary name and different approaches to the formation of patients' pharmacotherapy lines. According to the results of a comparative analysis of the composition of the range of recommended anti-epileptic drugs, the British National Form with the State Form of Medicines found that only nine drugs of international non-proprietary name were included in the national composition. Studies of anti-epileptic drugs, according to the State Medicines Form, give grounds for claiming the dominance of foreign-made drugs (68 % of the total number of anti-epileptic drugs presented). Manufacturers of anti-epileptic drugs have been analyzed, leaders in foreign and domestic companies have been established.

Conclusions. A number of differences have been identified between the recommendations of the British National Form and the National Medicines Form and the standardized clinical protocol for the treatment of epilepsy patients. Thus, there are only 9 antiepileptic drugs in the National Medicines Form, out of the 19 medicines listed in the British National Form. The national protocol of treatment includes 12 drugs under the international non-proprietary name. Analysis of the data of the State form of medicines for anti-epileptic drugs, showed that the total number of medicines represented was 315 trade names, taking into account the forms of issue, the main share of this range was formed by drugs of foreign companies, the ratio was 68 % to 32 %.

Introduction. In order to ensure the rights of citizens to receive quality and affordable medical and pharmaceutical assistance from the state, it is necessary to introduce a comprehensive approach that should be based on the implementation of international legal standards and their adaptation to the realities of functioning of the national health care system. The socio-economic significance of the problem of neurology, in particular, epilepsy, is due to the negative trend in the prevalence of this pathology in Ukraine and around the world.

According to WHO, the total number of officially registered epilepsy patients in the world is around 50 million. In this case, at least one attack during the life of 5 % of the population, and 20–30 % of patients are life-long diseases [1]. About 100,000 patients with epilepsy are registered in Ukraine. It should be noted that experts estimate that this figure is low because many cases are still undiagnosed.

Epilepsy is included in the heading of nerve diseases according to MKH-10. Important socio-economic consequences of this disease are disability, high risk of complications, decreased quality of life of patients, social disadaptation of the population [2]. In the pharmacotherapy of epilepsy, the main purpose of the use of anti-epileptic drugs (PEPs) is to control unexpected seizures, while minimizing the relevant side effects resulting from treatment. In the context of the need to raise the level of social standards in society, the issues of organizing the provision of effective medical and pharmaceutical care for epilepsy patients are emerging as urgent.

In recent years, extensive research has been conducted by national scientists on organizational, economic, marketing and pharmacoeconomic trends to improve the provision of medical and pharmaceutical care for patients with epilepsy. At the same time, the last analysis was conducted in 2017 [3–5].

In view of the above, the aim of our study was to analyze approaches to pharmacotherapy of epilepsy in Ukraine and the United Kingdom.

Materials and Methods. The study used data from the British National Formulary (BNF) (update April 2018), the State Formulary of Medicines (Issue 11, Ministry of Health of Ukraine from 18.04.2019 No. 892), a unified clinical protocol of primary, emergency, secondary (specialized) and tertiary (highly specialized) medical care "Epilepsy in adults" (Order of the Ministry of Health of Ukraine dated 27.04.2014, No. 276) [6–9]. During the research, the following methods were used: logical, system-analytical, comparative analysis and generalization of information.

Results and Discussion. Part of the system of standardization of medical care is the National Formulary, whose purpose is to systematize information on medicines and features of their clinical application. The UK is one of the first countries in the world to develop and implement a formulary system (since 1949) that is constantly being updated and improved. The development of the BNF is carried out by the British Medical Association and the Royal Pharmaceutical Society of Great Britain. The structure of the BNF consists of sections that are intended for medical specialists by specialization. Medicines are indicated by international non-proprietary names (INN), and specifies their clinical application. BNF included in have clinically proven efficiency and safety. It should be noted that in the European countries of the world, BNF data are used as a standard to improve approaches to the provision of medical and pharmaceutical care for various diseases [6].

Given the above-mentioned comparative analysis of the range of drugs for epilepsy pharmacotherapy in Ukraine with BNF is relevant. As a result of the analysis of the BNF content, it is determined that the recommended form contains 19 anti-epileptic drugs (AEDs) for INN, the use of which is aimed at blocking attacks by individual types. The National Medicines Formulary contains 9 anti-epileptic drugs with 19 medicaments, which are listed in the British National Formulary. In the national state form there is no such drugs as: oxcarbazepine, levetiracetam, piracetam, ethosuximide, rufinamide, vigabatrin, tiagabine, eslicarbazepine acetate, zonisamide, lacosamide. These anti-epileptic drugs are drugs of the new generation. Based on systematic analysis, as well as clinical benefit, side effects, and cost-effectiveness, NICE and the American Academy of Neurology's updated guidance supports the onset of old-generation AEDs [10]. It should be also noted that the provision of pharmaceutical and medical care to patients with different etiologies in the UK is funded by the National Insurance Fund and the AEDs registry is much wider than in Ukraine. In any case, in the treatment of epilepsy, the main criterion for the choice of drugs is the individual characteristics of the patient.

Unified clinical protocol of specialized medical care for patients with epilepsy, where pharmacotherapy is also ranked by type of seizures and treatment lines, revealed a number of differences (Table 1).

The domestic Unified Clinical Protocol for Treatment does not contain certain drugs for INN, namely: *ethosuximide, rufinamide, vigabatrin, tiagabine, eslicarbazepine acetate, lacosamide, zonisamide*. In our opinion, a deeper study of the feasibility of their application in Ukraine in providing medical and pharmaceutical assistance is possible. It should be noted that according to the BPF, ethosuximide is prescribed to patients with absent attack types, both in the first and second line of therapy. The BNF contains sodium valproate, which is a salt of valproic acid, which is included in the national unified clinical protocol. It should be noted that since 2013, the FDA has considered the above-mentioned medicines contraindicated in

Table 1
Comparative analysis of AEDs that are part of the BNF, the State Drug Formulary, the unified clinical protocol

ATC group AEDs	Presence AEDs		
	British national formulary	State drugs formulary (№11, 2019)	Unified clinical protocol
N03AG01 – valproate sodium	+	+	+
N03A X09 – lamotrigine	+	+	+
N03A F01 – carbamazepine	+	+	+
N03A A02 – phenobarbital	+	+	+
N03A B02 – phenytoin	+	+	+
N03A F02 – oxcarbazepine	+	-	+
N03A X14 – levitiracetam	+	-	+
N03A E01 – clonazepam	+	+	+
N06B X03 – piracetam	+	-	+
N03A X12 – gabacentine	+	+	+
N03A X11 – topiramate	+	+	+
N03A X16 – pregabaline	+	+	+
N03AD01 – ethosuximide	+	-	-
N03AF03 – rufinamide	+	-	-
N03AG04 – vigabatrin	+	-	-
N03AG06 – tiagabine	+	-	-
N03A F04 – eslicarbazepine acetate	+	-	-
N03AX15 – zonisamide	+	-	-
N03A X18 – lacosamide	+	-	-

women of childbearing age and pregnant, because of the presence of teratogenic properties and the ability to cause fetal defects.

Given the priority areas of treatment of patients, namely the rational prescribing of drugs and the use of drugs, taking into account the effectiveness, safety and economic feasibility, it is important to conduct a detailed analysis of the updated State form of drugs in the direction "Medicines for the treatment of epilepsy".

Analysis of the data of the State Drugs Formulary, shows that the major part of the pharmacotherapy of patients with epilepsy is formed by the N03A – anti-epileptic drugs at ATC classification system, namely the group N03AA – barbiturates and their derivatives, N03AB02 – anticonvulsants hydantoin, N03AE01 – anti-epileptic drugs; benzodiazepine derivatives, N03AF01 – antiepileptic drugs, carboxamide derivatives, N03AG01 – antiepileptic drugs, fatty acid derivatives and N03AX – other antiepileptic drugs.

It is established that the total number of AEDs per INN is 9 drugs or 174 trade names of drugs. The distribution of AEDs by ATC classification groups is given in Table. 2. The leaders in the number of represented drugs in the State Form are the group N03AX – other anti-epileptic drugs (77.14 % of the total number of trade names).

Analysis regarding AEDs showed the following dosage form (Fig. 1). Unconditional domination in the state forms are solid dosage forms of drugs AEDs. Thus, the time of the medicines in the form of capsules, tablets, lyophilized powders for oral administration was 98.36 %, which indicates the ease of use given the duration of treatment.

It should be noted that a small proportion of drugs in liquid form (solutions for injection, syrups).

According to the results of the analysis, in accordance with the manufacturing companies, it is established that 46 state-owned companies are represented in the State Formulary of the AEDs, the majority of which are foreign companies. The ratio of the share of foreign production to domestic production is 68 % to 32 %. The first place in the number of submitted AEDs belongs to the domestic company LLC Pharma Start – 28 LP (or 8.9 % of the total number of submitted medicines), the second place is occupied by a representative of foreign manufacturers, namely the company KRKA, Slovenia (24 LP or 7.6 %). Also, the leading manufacturers that are included in the State Pharmaceutical Formulary and have more than 10 AEDs offers were the companies of Darnitsa Pharmaceutical Firm and San Pharmaceutical Industries Ltd., India with 16 LPs, Pfizer Deutschland GmbH, Germany with 15 sales

Table 2
Analysis AEDs for epilepsy according to the National Formulary of drugs (Issue 11 update 04. 2019)

ATC-groupe	Quantity INN	Quantity trade names	Part, %	Number of trade names for the INN (including release forms)	Part, %
N03AA – barbiturates and their derivatives	1	3	1,72	6	1,90
N03AB – hydantoin derivatives	1	4	2,30	5	1,59
N03AF – carboxamide derivatives	1	23	13,22	30	9,52
N03AE – benzodiazepine derivatives	1	1	0,57	6	1,90
N03AG – fatty acid derivatives	1	23	13,22	25	7,94
N03AX – other anti-epileptic drugs	4	120	68,97	243	77,14
Total	9	174	100	315	100

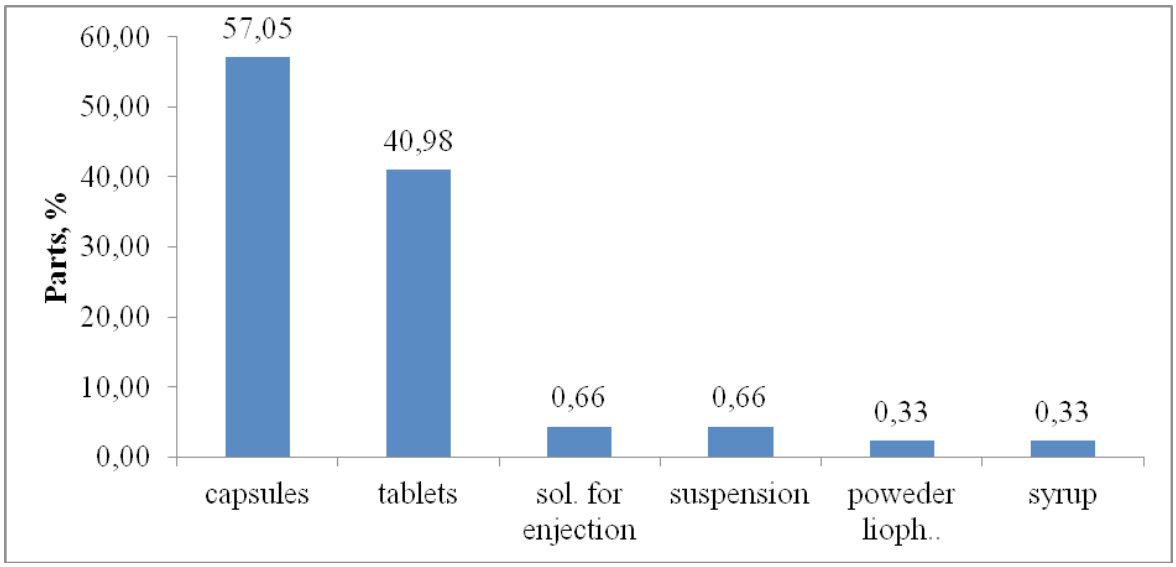

Fig. 1. Analysis AEDs for epilepsy recommended for dosage forms.

names PLIVA Croatia, Croatia – 14 LPs, Sandoz, Slovenia – 13 drugs, Pharmaceuticals Inc., Canada – 12 and Balkanpharma-Dupnica JSC, Bulgaria – 10 items. The analysis in the context of AEDs manufacturers represented by the number of AEDs in State Formulary of drugs shown in Fig. 2.

Based on the analysis range of medicines, used to treat patients with epilepsy can claim a significant dominance of foreign drugs, indicating the need to introduce additional ways to stimulate domestic producers of AEDs.

Summarizing data from a comparative analysis of the range of medicines included in the BNF, the State Pharmaceutical Formulary, the Unified Clinical Protocol for primary, emergency, specialized and highly specialized medical care for epilepsy patients, it is possible to state the need for improvement and review of the pharmacist approach European standards and evidence of clinical evidence. It should also be noted that in the UK there is a system of reimbursement of the value of medicines, which increases the availability of medicines for the population. Unfortunately, in Ukraine, the main payer is the patient. Therefore, the introduction of full or partial reimbursement of medical treatment will guarantee the receipt of quality, effective and timely pharmaceutical assistance to patients with epilepsy.

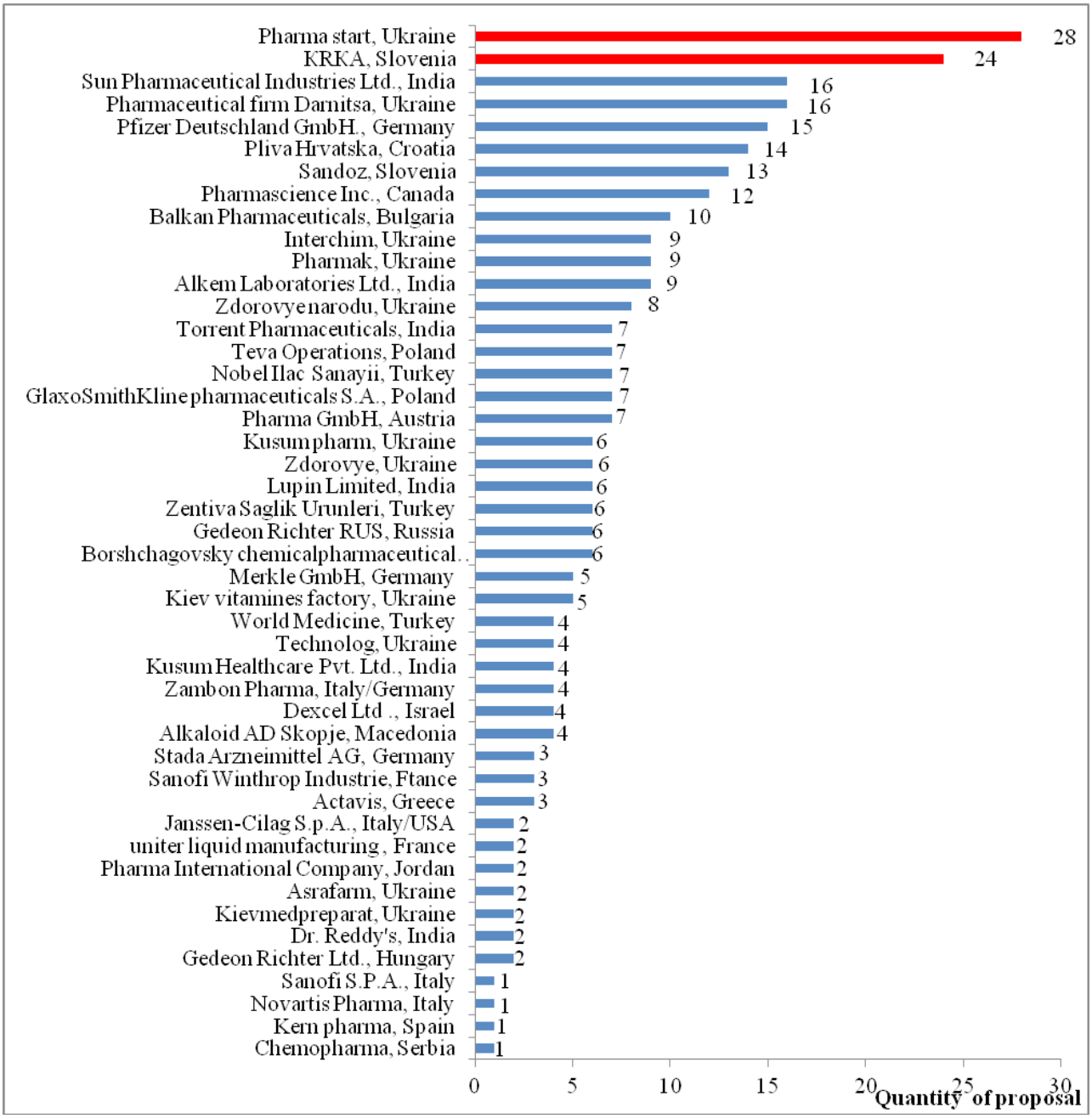

Fig. 2. Analysis manufacturers of AEDs by the number of forms submitted by the State drugs formulary.

Conclusions. 1. The results of the BNF analysis showed that the recommendations for the treatment of epilepsy included 19 AEDs for INN, the effect of which is aimed at blocking seizures by individual. Medicines for INN. It has been proved that oxcarbazepine, levetiracetam, piracetam, etosuximide, rufinamide, vigabatrin, tiagabine, eslicarbazepine acetate, zonisamide, lacosamide are not available in the State Drugs Form. Analysis BNF comparison of antiepileptic drugs with drugs that are national uniform clinical protocol also made it possible to establish that AEDs such as ethosuximide, rufinamide, vigabatrin, tiagibine, eslicarbazepine acetate, lacosamide, zonisamide available.

2. Analysis of AEDs that are recommended by the State Drugs Formulary shows that the bulk of patients with epilepsy pharmacotherapy form the medicines group N03A – antiepileptic drugs. The total number of drugs per group was 315 trade names. Leaders in the number of proposals are N03AX – other anti-epileptic drugs (243 medicines).

3. An analysis of the dosage forms of anti-epileptic drugs recommended by the State Drug Formulary

showed that the bulk of the preparations is in solid forms (capsules, tablets, lyophilized powders) – 98.36 %, which indicates the convenience in the application with regard to the duration of treatment.

4. The analysis is relatively manufacturers demonstrated that AEDs are 46 manufacturers, the bulk of which are foreign companies. The ratio of the share of foreign production to domestic production is 68 % to 32 %.

Конфлікт інтересів: відсутній.

Conflicts of interest: authors have no conflict of interest to declare.

ПОРІВНЯЛЬНИЙ АНАЛІЗ ПІДХОДІВ ДО ФАРМАКОТЕРАПІЇ ЛІКУВАННЯ ЕПІЛЕПСІЇ В УКРАЇНІ ТА ВЕЛИКОБРИТАНІЇ

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Мета роботи. Проведення порівняльного аналізу асортименту лікарських препаратів, які застосовують для лікування епілепсії відповідно до положень нормативних документів в Україні та у Великій Британії.

Матеріали і методи. Під час дослідження використано офіційні дані нормативно-правового регулювання фармакотерапії епілепсії, зокрема, рекомендації Британського Національного Формуляру (оновлення квітень 2018 р.), Державного формуляру лікарських засобів (випуск 11, наказ МОЗ України від 18.04.2019 р. № 892), Уніфікованого клінічного протоколу первинної, екстреної, вторинної (спеціалізованої) та третинної (високоспеціалізованої) медичної допомоги епілепсії у дорослих (наказ МОЗ України від 17.04.2014 р. № 276). Були використані методи: логічний, системно-аналітичний, порівняльний аналіз та узагальнення інформації

Результати й обговлрення. За результатами аналізу даних Британського Національного Формуляру визначено, що для лікування хворих на епілепсію рекомендовано 19 протиепілептичних препаратів за міжнародною непатентованою назвою. При зіставленні протиепілептичних препаратів із препаратами, що увійшли до вітчизняних нормативно-правових положень, які регулюють надання якісної медичної та фармацевтичної допомоги хворим, встановлено ряд розбіжностей. Дані відмінності включають як відсутність певних лікарських препаратів за міжнародною непатентованою назвою, так і різні підходи до формування ліній фармакотерапії хворих. За результатами порівняльного аналізу складу асортименту рекомендованих протиепілептичних препаратів Британським Національним Формуляром з Державним формуляром лікарських засобів встановлено, що до складу вітчизняного увійшли лише 9 препаратів за міжнародною непатентованою назвою. Дослідження протиепілептичних препаратів, згідно з даними Державного формуляру лікарських засобів, дають підстави стверджувати про домінування лікарських препаратів іноземного виробництва (68 % від загальної кількості представлених протиепілептичних препаратів). Проаналізовано фірми-виробники лікарських препаратів, встановлено лідери серед іноземних та вітчизняних компаній.

Висновки. Встановлено ряд відмінностей між рекомендаціями Британського Національного Формуляру та Державного формуляру лікарських засобів, а також уніфікованим клінічним протоколом лікування хворих на епілепсію. Так, у Державному формулярі лікарських засобів присутні лише 9 препаратів протиепілептичної дії з 19 лікарських препаратів, які зазначені у складі Британського Національного Формуляру. До вітчизняного протоколу лікування включено 12 препаратів за міжнародною непатентованою назвою.

Аналіз даних Державного формуляру протиепілептичних препаратів показав, що загальна кількість представлених лікарських препаратів складала 315 торгових найменуваннь з урахуванням форм випуску, основну частку даного асортименту формували препарати іноземних компаній, співвідношення становило 68 % до 32 %.

Ключові слова: епілепсія; лікарський препарат; Британський Національний Формуляр; Державний формуляр лікарських засобів; Уніфікований клінічний протокол.

СРАВНИТЕЛЬНЫЙ АНАЛИЗ ПОДХОДОВ К ФАРМАКОТЕРАПИИ ЛЕЧЕНИЯ ЭПИЛЕПСИИ В УКРАИНЕ И ВЕЛИКОБРИТАНИИ

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Цель работы. Проведение сравнительного анализа ассортимента лекарственных препаратов, применяемых для лечения эпилепсии в соответствии с положениями нормативных документов в Украине и в Великобритании.

Материалы и методы. В ходе исследования были использованы официальные данные нормативно-правового регулирования фармакотерапии эпилепсии, в частности, рекомендации Британского Национального Формуляра (обновление апрель 2018 г.), Государственного формуляра лекарственных средств (выпуск 11, приказ МОЗ Украины от 18.04.2019 г. № 892), Унифицированного клинического протокола первичной, экстренной, вторичной (специализированной) и третичной (высокоспециализированной) медицинской помощи при эпилепсии у взрослых (приказ МОЗ Украины от 17.04.2014 г. № 276). Были использованы методы: логический, системно-аналитический, сравнительный анализ и обобщение информации.

Результаты и обсуждение. По результатам анализа данных Британского Национального Формуляра определено, что для лечения больных эпилепсией рекомендуется 19 противоэпилептических препаратов по международным непатентованным названиям. При сопоставлении противоэпилептических препаратов с препаратами, которые вошли в отечественные нормативно-правовые положения, регулирующие предоставление качественной медицинской и фармацевтической помощи больным, был установлен ряд разногласий. Данные различия включают как отсутствие определенных лекарственных препаратов по международным непатентованным названиям, так и различные подходы к формированию направления фармакотерапии больных. По результатам сравнительного анализа состава ассортимента рекомендованных противоэпилептических препаратов Британским Национальным Формуляром с Государственным формуляром лекарственных средств установлено, что в состав отечественного вошли только 9 препаратов по международным непатентованным названиям. Исследование противоэпилептических препаратов согласно данным Государственного формуляра лекарственных средств дают основания утверждать о доминировании лекарственных препаратов иностранного производства (68 % от общего количества представленных противоэпилептических препаратов). Проанализированы фирмы-производители лекарственных препаратов, определены лидеры среди иностранных и отечественных компаний.

Выводы. Установлен ряд различий между рекомендациями Британского Национального Формуляра и Государственного формуляра лекарственных средств, а также унифицированным клиническим протоколом лечения больных эпилепсией. Так, в Государственном формуляре лекарственных средств присутствуют лишь 9 препаратов противоэпилептического действия из 19 лекарственных препаратов, которые указаны в составе Британского Национального Формуляра. В отечественный протокол лечения включены 12 препаратов по международным непатентованным названиям.

Анализ данных Государственного формуляра противоэпилептических препаратов показал, что общее количество представленных лекарственных препаратов составило 315 торговых наименований с учетом форм выпуска, основную долю данного ассортимента формировали препараты иностранных компаний, соотношение составляло 68 % к 32 %.

Ключевые слова: эпилепсия; лекарственный препарат; Британский Национальный Формуляр; Государственный формуляр лекарственных средств; Унифицированный клинический протокол.

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