

# ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

*Recommended by Doctor of Pharmacy, Professor M. M. Slobodianiuk*

UDC 615.22:616.1

<https://doi.org/10.24959/nphj.18.2205>

A. S. Nemchenko, Yu. Ye. Kurylenko

National University of Pharmacy

## Analysis of approaches to pharmacotherapy of patients with cardiovascular diseases according to the data of the Ukrainian and British Formularies

**Aim.** To analyze the approaches to pharmacotherapy of patients with cardiovascular diseases (CVD) indicated in the State Formulary of Medicines of Ukraine (SFMU) and the British National Formulary (BNF), as well as the reimbursement systems of drug cost in Ukraine and Great Britain.

**Materials and methods.** In the course of the study materials from the on-line version of BNF No. 70 2015 and materials of SFMU No. 9 of 2017; official sites of the Ministry of Health of Ukraine and the National Health Service of Great Britain (NHS) were used. The methods of system analysis, logical generalization of information and the analytical method were also chosen.

**Results and discussion.** A rapid growth of diseases of the cardiovascular system requires introduction of more effective, safe and affordable pharmacotherapy, which, in turn, can not be carried out without the availability of formularies of drugs and the formulary system as a whole. Approaches to pharmacotherapy of CVD patients indicated in SFMU and BNF, as well as the reimbursement systems of drug cost in Ukraine and Great Britain under conditions of social health insurance (SHI) have been analyzed.

**Conclusions.** It has been found that not all drugs recommended for the treatment of CVD used in the UK are registered in the territory of Ukraine; moreover, most of the registered drugs do not have the appropriate dosing. Due to the limited number of drugs included in the reimbursement system the costs of therapy are incumbent upon the patient himself/herself in Ukraine, while in Britain with its SHI system a significant number of drugs under insurance prescriptions is compensable. Therefore, one of the ways to increase the availability of pharmacotherapy in Ukraine is development of the concept of the rational use of drugs and implementation of SHI.

**Key words:** pharmacotherapy; cardiovascular diseases; formulary system; reimbursation; social health insurance

A. С. Немченко, Ю. Є. Куриленко

### Аналіз підходів до фармакотерапії хворих на серцево-судинні захворювання за даними Українського та Британського формулярів

**Метою** дослідження є аналіз підходів до фармакотерапії хворих на серцево-судинні захворювання (ССЗ), зазначених у Державному формулярі лікарських засобів (ЛЗ) України (ДФУ) та Національному Британському формулярі (British National Formulary (BNF)), а також систем реімбурсації вартості ЛЗ в Україні та Великобританії.

**Матеріали та методи.** У ході дослідження використовувалися матеріали он-лайн версії BNF № 70 2015 р. та матеріали ДФУ № 9 2017 р.; офіційні сайти МОЗ України та Національної служби здоров'я Великобританії (The National Health Service (NHS)). А також були обрані методи системного аналізу, логічного узагальнення інформації та аналітичний.

**Результати та їх обговорення.** Стрімке зростання хвороб серцево-судинної системи вимагає впровадження більш ефективної, безпечної та доступної фармакотерапії, яка, у свою чергу, не може бути проведена без наявності формулярів ЛЗ та формулярної системи в цілому. Проаналізовані підходи до фармакотерапії хворих на ССЗ, які зазначені у ДФУ та BNF, а також система реімбурсації вартості ЛЗ в Україні та Великобританії за умов соціального медичного страхування (СМС).

**Висновки.** Встановлено, що не всі ЛЗ, рекомендовані для лікування ССЗ, які використовуються у Великобританії, зареєстровані на території України, а більшість зареєстрованих не має відповідного дозування. У зв'язку з обмеженою кількістю ЛЗ, які включені у систему реімбурсації, в Україні витрати за терапію покладаються на самого хворого на відміну від Великобританії, де діє система СМС, та значна кількість ЛЗ за страховими рецептами підлягає компенсації. Тому одним з напрямків підвищення доступності фармакотерапії в Україні є розробка концепції раціонального використання ЛЗ та впровадження СМС.

**Ключові слова:** фармакотерапія; серцево-судинні захворювання; формулярна система; реімбурсація; соціальне медичне страхування

А. С. Немченко, Ю. Е. Куриленко

## Анализ подходов к фармакотерапии больных на сердечно-сосудистые заболевания по данным Украинского и Британского формуляров

**Целью** исследования является анализ подходов к фармакотерапии больных сердечно-сосудистыми заболеваниями (ССЗ), указанных в Государственном формуляре лекарственных средств (ЛС) Украины (ГФУ) и Национальном Британском формуляре (British National Formulary (BNF)), а также систем реимбурсации стоимости ЛС в Украине и Великобритании.

**Материалы и методы.** В ходе исследования использовались материалы он-лайн версии BNF № 70 2015 г. и материалы ГФУ № 9 2017 г.; официальные сайты МОЗ Украины и Национальной службы здоровья Великобритании (The National Health Service (NHS)). А также были выбраны методы системного анализа, логического обобщения информации и аналитический.

**Результаты и их обсуждение.** Стремительный рост болезней сердечно-сосудистой системы требует внедрения более эффективной, безопасной и доступной фармакотерапии, которая, в свою очередь, не может быть проведена без наличия формуляров ЛС и формулярной системы в целом. Проанализированы подходы к фармакотерапии больных ССЗ, указанные в ГФУ и BNF, а также система реимбурсации стоимости ЛС в Украине и Великобритании в условиях социального медицинского страхования (СМС).

**Выводы.** Установлено, что не все ЛС, рекомендованные для лечения ССЗ, которые используются в Великобритании, зарегистрированы на территории Украины, а большинство зарегистрированных не имеет соответствующего дозирования. В связи с ограниченным количеством ЛС, включенных в систему реимбурсации, в Украине затраты на терапию полагаются на самого больного в отличие от Великобритании, где действует система СМС, и значительное количество ЛС по страховым рецептам подлежит компенсации. Поэтому одним из направлений повышения доступности фармакотерапии в Украине является разработка концепции рационального использования ЛС и внедрения СМС.

**Ключевые слова:** фармакотерапия; сердечно-сосудистые заболевания; формулярная система; реимбурсация; социальное медицинское страхование

Cardiovascular diseases (CVD) are the whole complex of diseases of the circulatory system. According to statistics annually in Ukraine almost 50 thousand cases of myocardial infarction (MI), 110 thousand cases of coronary heart disease (CHD), and more than 3500 cases of congenital heart diseases are registered. Patients with CVD are at high risk; therefore, they require effective medical and pharmaceutical care [1].

**The aim** of our study is to analyze the approaches to pharmacotherapy of patients with CVD indicated in the State Formulary of Medicines of Ukraine (SFMU) and the British National Formulary (BNF), as well as the reimbursement systems of drug cost in Ukraine and Great Britain.

### Materials and methods

In the course of the study materials from the on-line version of BNF No. 70 2015 and materials of SFMU No. 9 of 2017; official sites of the Ministry of Health of Ukraine (MOH) and the National Health Service of Great Britain (NHS) were used. The methods of system analysis, logical generalization of information and the analytical method were also chosen.

### Results and discussion

In connection with constant growth of diseases of cardiovascular system (CVS) the information on the effective prescription and rational use of drugs should be constantly updated. In turn, BNF is a model for many international and national organizations and plays a significant role in informing the medical and pharmaceutical professionals concerning implementation of the rational pharmacotherapy.

One of the main differences of the formularies studied is that in BNF the sections are structurized by the name of diseases and provide information for specialists

in the field, whereas in SFMU the sections are structurized by the groups of drugs in accordance with each nosology included [2,3].

CVD in SFMU and BNF are in a separate second subsection. In SFMU this subsection includes such diseases as hypertension and essential hypertension, ischemic heart disease, arrhythmia, and ventricular arrhythmia, tachyarrhythmia, and supraventricular tachyarrhythmia, sinus tachycardia, heart failure, MI, stenocardia and Prinzmetal's angina, hypercholesterolemia, mixed dyslipidemia, swelling of veins, Buerger's disease, atherosclerotic and discirculatory encephalopathy, ischemic cerebral stroke, peripheral circulatory disorders, acute coronary syndromes, vascular disease.

In BNF such diseases as deficiency of coagulation factors, subarachnoid hemorrhage, blood clots (blocked catheters and lines, pulmonary embolism), hypertension associated with pheochromocytoma, pulmonary hypertension and cardiac arrest are included to the second subsection.

In turn, ischemic heart disease and hypertension are the most common among CVS diseases in the world. Recommendations for the treatment of hypertension and ischemic heart disease in BNF are given in sections 4 and 7, respectively. Similar recommendations in SFMU are specified in subsections 2.1; 2.3; 2.4; 2.5; 2.6; 2.8; 2.11; 2.19. The therapy CVD for BNF was approved by the National Institute for Health and Care Excellence (NICE), namely recommendations – "Hypertension in adults: diagnosis and management" CG127 and "Stable angina: management" CG126 [4]. For pharmacotherapy of hypertension and ischemic heart disease in Ukraine it is recommended to use the unified Clinical Protocols of the primary, secondary (specialized) and tertiary (highly

specialized) medical care: “Arterial hypertension” and “Stable coronary heart disease” (orders of MOH No. 384 dated 24.05.2012 and No. 152 dated 02.03.2016 with amendments No. 994 dated 23.09.2016), as well as and adapted evidence-based clinical guidelines [5].

In SFMU and BNF inhibitors of angiotensin converting enzyme (ACE) are used for pharmacotherapy of patients with hypertension; in the case of their intolerance, patients are offered antagonists of AT1-receptors of angiotensin II or the combination of a beta-blocker and hydrochlorothiazide or a diuretic associated with thiazide. In the case of high risk of cardiac insufficiency development or when it is impossible to take calcium channel antagonists, the patient should administer chlortalidone or indapamide. Additionally, in BNF the therapy is performed with bendroflumethiazide, levobunolol hydrochloride, which are not registered on the territory of Ukraine.

Compared to the UK the registration for 42 international nonproprietary names of drugs for treating CVD is absent in Ukraine, among them 38.09 % of drugs are for the treatment of hypertension, 2.38 % – the treatment of ischemic heart disease and 59.53 % – for pharmacotherapy of other diseases of CVS.

In BNF it is recommended to prescribe beta-blockers or calcium channel antagonists for patients with stable angina, which is a type of ischemic heart disease. In patients with left ventricular dysfunction the treatment with beta blockers should be started with a low dose, this dose is slowly increased within several weeks or months. If beta-blockers or calcium channel antagonists can not adequately control the symptoms, then a combination of beta-blockers and calcium channel antagonists of dihydropyridine (e.g., amlodipine, felodipine, nifedipine with a modified release) should be used. In the case of intolerance or contraindications to these drugs it is recommended to take combined drug with long-acting nitrates (ivabradine, nicorandil or ranolazine). It is also recommended in BNF to include tirofiban as an effective antiplatelet drug in the treatment regimen.

It should be noted that providing medical and pharmaceutical care in the UK is one of the key areas of NHS; it is implemented by the regular assessment of all services provided to the population. First of all, the presence of the appropriate formularies in BNF guarantees prescription of a drug with the proven efficacy, safety and economic benefits to a patient. One of the significant differences between the healthcare systems of UK and Ukraine is the presence of social health insurance (SHI), which greatly saves the cost of patients on pharmacotherapy. In the UK the SHI model of William Beveridge – budget insurance medicine – is used. The determinant principle of this model is the common availability of medical and pharmaceutical services for all citizens. The main feature of this model is financing of medical and pharmaceutical care provided to the population from the state budget funds and partially at the expense of the social tax share paid by employers and employees.

Approximately 18 % of the income taxes of physical persons are sent to NHS fund, this is about 4.5 % of the average income of citizens. The SHI system is called the National Insurance (NI), and it is subordinated to HM Revenue and Customs (HMRC). From its fund NHS, social assistance and pension payments are financed. Every citizen need to obtain the National Insurance number (NIN) to make it possible for NHS and NI to save the data regarding all payments to citizens received concerning medical or pharmaceutical care. Prescription drugs are dispensed free of charge or by different systems of reimbursement; however, there is a special fee for a prescription (about 8 pounds). This fee is not charged from invalids, children, the elderly, pregnant women, unemployed or people with a low income, students, patients with certain chronic diseases (diseases of CVS, diabetes mellitus type II, etc.). Patients have the opportunity to get approximately 85 % of the prescribed drugs free of charge with preferential status based on the group of diseases, their income level and age. NHS provides reimbursement of drug cost for pharmacies. The existence of the formulary system is an integral part of the effective functioning of SHI in Great Britain.

In Ukraine the formulary system was introduced according to the order of MOH No. 529 “On creation of the formulary system of providing drugs to the healthcare institutions” dated 22.07.2009. Thanks to the creation of formularies of different levels providing medical and pharmaceutical care to patients becomes more effective. However, the available formularies of drugs require constant update (for example, creation of modern mobile applications to the electronic form).

Unlike the UK, Ukraine is only at the initial stage of SHI introduction into the healthcare system. In 19.10.2017 the Verkhovna Rada of Ukraine adopted the bill No. 4981 “On compulsory state social health insurance” dated 14.07.2016 [6]. According to this bill the sources of formation of the SHI fund are income insurance payments (1 %); income from investment of costs of the insurance fund; funds of insurance reserves of insurers who lost their license for SHI implementation and other sources that are not prohibited by law. As in the UK, to receive payments by the health insurance card it is necessary to have a certificate of insurance that exists in the form of a card with the information carrier in electronic format providing storage and transfer of the patient’s data to the information system.

Currently, the reimbursement system of drug cost in Ukraine is out of SHI. Unlike the UK, reimbursement is only available for particular diseases, for example CVD, bronchial asthma, diabetes mellitus type II according to the state program “Affordable medicines” [7]. Now, according to our calculations, among drugs registered and prescribed by doctors only 1.52 % of them are to be reimbursed, while only 0.15 % are fully refundable, and 0.85% are partially reimbursed.

Summing up, it should be noted that currently the proportion of patients of the working age is increasing in

Ukraine; therefore, improving the system of providing medical and pharmaceutical care requires implementation of SHI and the use of modern socio-economic systems of the drug cost reimbursement.

#### CONCLUSIONS

1. It has been found that the main difference in the approaches to pharmacotherapy listed in SFMU and BNF is that 42 drugs by the international non-proprietary name used in the UK have not been registered in the territory of Ukraine. Along with this, those drugs that have registration are not always presented in drug forms and doses in BNF.

2. In the UK there is SHI, namely the model of budget insurance medicine. Most drugs by insurance pre-

scriptions are included in the reimbursement system for pharmacotherapy of patients with CVD, the more expensive and innovative drugs are used.

3. In Ukraine the cost of therapy is incumbent upon the patient himself/herself; therefore, when including a drug to SFMU their affordability should be taken into account. In this regard, the important issue of improving the quality, efficiency and availability of medical and pharmaceutical care is introduction of SHI, the reimbursement system of the drug cost and the regulatory support of these processes in Ukraine.

**Conflict of Interests:** authors have no conflict of interests to declare.

#### REFERENCES

1. Європейська база даних статистичної інформації «Здоров'я для всіх» [Електронний ресурс]. – Режим доступу : <http://medstat.gov.ua/ukr/normdoc.html>
2. Online version: «British National Formulary No. 70». – Available at : <https://www.pharm.reviews/images/statyi/british-national-formulary-2015.pdf>
3. Інформаційно-пошукова система «Електронний формуляр» 9 випуск [Електронний ресурс]. – Режим доступу : <http://www.dec.gov.ua/index.php/ua/informatsijno-poshukova-sistema-elektronnij-formulyar>
4. Official site “The National Institute for Health and Care Excellence”. – Available at : <https://www.nice.org.uk/>
5. Реєстр медико-технологічних документів «Кардіологія» [Електронний ресурс]. – Режим доступу : <http://mtd.dec.gov.ua/index.php/uk/reiestr-mtd/itemlist/category/17-kardiolohiia>
6. Офіційний сайт Верховної Ради України [Електронний ресурс]. – Режим доступу : [http://w1.c1.rada.gov.ua/pls/zweb2/webproc4\\_1?pf3511=59745](http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=59745)
7. Реєстр лікарських засобів, вартість яких підлягає відшкодуванню [Електронний ресурс]. – Режим доступу : <http://www.apteka.ua/article/420532>

#### REFERENCES

1. *Yevropeiska baza danykh statystychnoi informatsii “Zdorovia dlia vsikh”*. Available at: <http://medstat.gov.ua/ukr/normdoc.html>
2. *Online version: “British National Formulary № 70”*. Available at: <https://www.pharm.reviews/images/statyi/british-national-formulary-2015.pdf>
3. *Informatsijno-poshukova sistema «Elektronnyi formuliar» 9 vypusk*. Available at: <http://www.dec.gov.ua/index.php/ua/informatsijno-poshukova-sistema-elektronnij-formulyar>
4. *Official site “The National Institute for Health and Care Excellence”*. Available at: <https://www.nice.org.uk/>
5. *Reiestr medyko-tehnologichnykh dokumentiv “Kardiolohiia”*. Available at: <http://mtd.dec.gov.ua/index.php/uk/reiestr-mtd/itemlist/category/17-kardiolohiia>
6. *Ofitsiyni sait Verkhovnoi Rady Ukrainy*. Available at: [http://w1.c1.rada.gov.ua/pls/zweb2/webproc4\\_1?pf3511=59745](http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?pf3511=59745)
7. *Reiestr likarskykh zasobiv, vartist yakykh pidlihaie vidshkoduвання*. Available at: <http://www.apteka.ua/article/420532>

#### Information about authors:

Nemchenko A. S., Doctor of Pharmacy (Dr. habil.), head of the Organization and Economy of Pharmacy Department, National University of Pharmacy.

E-mail: [asnemchenko@ukr.net](mailto:asnemchenko@ukr.net). ORCID: <http://orcid.org/0000-0003-1601-8881>

Kurylenko Yu. Ye., PhD student of the Organization and Economy of Pharmacy Department, National University of Pharmacy. E-mail: [ulianikk@gmail.com](mailto:ulianikk@gmail.com).

ORCID: <http://orcid.org/0000-0002-5360-3185>

#### Відомості про авторів:

Немченко А. С., д-р фарм. наук, професор, завідувач кафедри організації та економіки фармацевції, Національний фармацевтичний університет.

E-mail: [asnemchenko@ukr.net](mailto:asnemchenko@ukr.net). ORCID: <http://orcid.org/0000-0003-1601-8881>

Куриленко Ю. Є., аспірант кафедри організації та економіки фармацевції, Національний фармацевтичний університет. E-mail: [ulianikk@gmail.com](mailto:ulianikk@gmail.com).

ORCID: <http://orcid.org/0000-0002-5360-3185>

#### Сведения об авторах:

Немченко А. С., д-р фарм. наук, заведующая кафедрой организации и экономики фармацевции, Национальный фармацевтический университет.

E-mail: [asnemchenko@ukr.net](mailto:asnemchenko@ukr.net). ORCID: <http://orcid.org/0000-0003-1601-8881>

Куриленко Ю. Е., аспирант кафедры организации и экономики фармацевции, Национальный фармацевтический университет. E-mail: [ulianikk@gmail.com](mailto:ulianikk@gmail.com).

ORCID: <http://orcid.org/0000-0002-5360-3185>

Надійшла до редакції 23.11.2017 р.