ОРГАНІЗАЦІЯ ТА ЕКОНОМІКА ФАРМАЦІЇ

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Substantiation of the model of pricing for essential drugs in the context of the Health Technology Assessments

The problem of availability of drugs can be solved by implementation of effective social and economic mechanisms.

Aim. To substantiate theoretically the effective management model of pricing for drugs.

Materials and methods. The analysis of drug availability has been conducted; the model of pharmaceutical pricing has been proposed.

Results and discussion. The effective social pricing model for drugs has been proposed. This model is based on the use of a consolidated list of essential drugs, the method of forming the cost of drugs, scientifically based methods of the state regulation of prices and the results of the Health Technology Assessments .

Conclusions. Implementation of effective social pricing model allows improving drug availability and pharmaceutical care for the population.

Key words: *pricing; essential drugs; National list of drugs; Health Technology Assessments*

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Обґрунтування моделі формування цін на основні лікарські засоби в контексті оцінки технологій охорони здоров'я

Проблему доступності лікарських засобів (ЛЗ) можна вирішити через впровадження дієвих соціально-економічних механізмів.

Мета роботи – теоретичне обґрунтування ефективної моделі управління ціноутворенням на ЛЗ.

Матеріали та методи. Проведено аналіз цінової доступності ЛЗ, запропоновано модель фармацевтичного ціноутворення.

Результати та їх обговорення. Запропоновано соціально ефективну модель ціноутворення на ЛЗ. Вказана модель базується на використанні єдиного переліку ОЛЗ, методики формування собівартості ЛЗ, науково обґрунтованих методів державного регулювання цін та результатів оцінки технологій охорони здоров'я.

Висновки. Впровадження соціально ефективної моделі ціноутворення дозволить підвищити доступність ліків та фармацевтичної допомоги для населення.

Ключові слова*: ціноутворення; основні лікарські засоби; регулюючі переліки; Національний перелік ОЛЗ; оцінка технологій охорони здоров'я*

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Обоснование модели формирования цен на основные лекарственные средства в контексте оценки технологий здравоохранения

Проблему доступности лекарственных средств (ЛС) можно решить путем внедрения действенных социально-экономических механизмов.

Цель работы – теоретическое обоснование эффективной модели управления ценообразованием на ЛС.

Материалы и методы. Проведен анализ ценовой доступности ЛС, предложена модель фармацевтического ценообразования.

Результаты и их обсуждение. Предложена социально эффективная модель ценообразования на ЛС. Указанная модель основана на использовании единого перечня ОЛС, методики формирования себестоимости ЛС, научно обоснованных методов государственного регулирования цен и результатов оценки технологий здравоохранения.

Выводы. Внедрение социально эффективной модели ценообразования позволит повысить доступность лекарств и фармацевтической помощи для населения.

Ключевые слова*: ценообразование; основные лекарственные средства; регулирующие перечни; Национальный перечень ОЛС; оценка технологий здравоохранения*

The main priorities of the European strategy "Health 2020" is the focus on the high quality and availability of medical and pharmaceutical care, universal coverage of the population. According to the National Drug Policy the state must ensure the overall access to essential drugs based on the rational choice, affordable prices and appropriate financing. In this context, there is a formulary system in Ukraine; the elements of Health Technology Assessments (HTA), medical insurance and reimbursement are implemented.

Currently, the national healthcare system can not fully meet the needs of the population in high-quality and effective medical and pharmaceutical care. Unfortunately, effective mechanisms to provide availability of drugs have not been implemented. The Ukrainian patients pay 95 % of the treatment cost from their own pockets.

The issues of the rational use of drugs do not lose their topicality over the years both from the pharmacotherapeutic and economic point of view. The works of such famous domestic and foreign authors as A. S. Nemchenko, A. A. Kotvitska, K. L. Kosyachenko, L. V. Galiy, I. V. Kubareva, D. Yu. Belousov, T. Bazargani, J. Carone, K. Ruggeri, N. Pinson, J. Vernon, P. A. Danzon deal with improvement of the state regulation of prices, the rational selection and use of essential drugs, efficiency of the formulary system and HTA. The government of Ukraine initiates new healthcare reforms, including the regulation of drug prices. The previous reforms have been unsuccessful since the process is not scientifically based, correctly organized, transparent and controllable. Therefore, creation of the effective pricing model, which would take into account the results of HTA, appears to be important and necessary at present. This was the aim of this article.

Materials and Methods

The analysis of drug availability was conducted; the efficiency of price regulation mechanisms was assessed; the model of pharmaceutical pricing was developed.

Results and Discussion

The results of the WHO studies indicate that the problem of providing the population with qualitative and affordable drugs is topical not only for the countries with low levels of economic development, but globally as well. Limitations of drug availability in Ukraine are caused by a complex of factors, namely the low level of innovation and investment development of domestic production of drugs and dependence on imports; the high cost of original medicines and the problem of generic bioequivalence verification; lobbying the of the applicants' interests and the complicated procedure of drug registration; irrational selection, drug prescribing and use in practice; the low income of the population; the absence of health insurance and reimbursement; inefficient pricing, etc.

As of 20.09.2016 there were 12839 names of drugs in the State Registry of Medicines of Ukraine, among of them drugs of domestic production – 30 %, and foreign drugs – 70 %. The volume of drug sales in 2015 was 47.1 billion USD (18 % more than in the previous period) per 1.3 billion packs. Retail sales of drugs in monetary terms increased by 18 % (up to 38.6 billion UAH), in natural units they reduced by 18 % (to 818.6 million packs). The weighted average price for pharmaceutical products increased by 43 % in 2015. According to the "Pharmstandard"/"PharmXplorer" market research analytical system of "Proxima Research" company the cost of one pack of a drug in 2015 was 42.5 UAH (domestic drugs – 22.7 UAH, imported drugs – 107.8 UAH, being almost 5 times more expensive). The share of domestic drugs in the structure of sales increased to 75 % (in packs); however, it was only 37 % in monetary terms. Most drugs at the Ukraine pharmaceutical market are generic – their share is over 94 %, while in the USA it is – 12 %, in Japan – 30 %, in Germany – 35 %, in France – 50 % [1]. Needs in original medicines are provided mostly by imports.

In recent years in Ukraine there was an uncontrollable growth of drug prices caused by devaluation of the national currency and introduction of VAT on drugs. Crisis phenomena in economy and social political life greatly affected the solvency of the population and the healthcare system as a whole. Managing the cost of drugs is crucial for the optimal use of the limited resources of the healthcare system. Trade margins restrictions, reference pricing, registration and monitoring of drug prices, mechanisms of partial reimbursement are used in order to stabilize the drug prices and improve their affordability [2]. To standardize the medical and pharmaceutical care and to provide the rational use of drugs the formulary system was created, the standards of Good Pharmacy Practice (GPP), Good Regulatory Practice (GRP) and Good Practice of pharmacovigilance (GPvP) were implemented. Unfortunately, it should be stated that selection and prescription of drugs are often determined by aggressive marketing policies of pharmaceutical companies, but not by the needs of the individual patient or the healthcare system. In view of the abovementioned, the Good Pharmacotherapeutic Practice was approved by the order of MOH of Ukraine No. 651 dated 26.07.2013. This assumes not only the rational use of drugs according to clinical indications by the minimum price, but also the appropriate use of funds and personal responsibility of the authorities of healthcare institutions for compliance with the requirements of medical normative documents.

It should be noted that the system of the state regulation for prices on drugs in Ukraine is very complicated and inefficient (Fig.).

This is primarily conditioned by the absence of clear methodological approaches to formation and control of prices for essential drugs. Thus, for the purpose of the price control some regulating lists are used in Ukraine. The National List (approved by the Resolution of the Cabinet of Ministers of Ukraine No. 333) includes 215 drugs by INN corresponding to 2682 trade names, including 940 domestic drugs (30 %). The budget list is intended for public procurements (approved by the Resolution of the Cabinet of Ministers of Ukraine No. 1071); it includes 784 drugs by INN or by common names, i. e. 8900 trade names, including 2912 domestic drugs (32.7 %), as well as drugs prepared in the pharmacy.

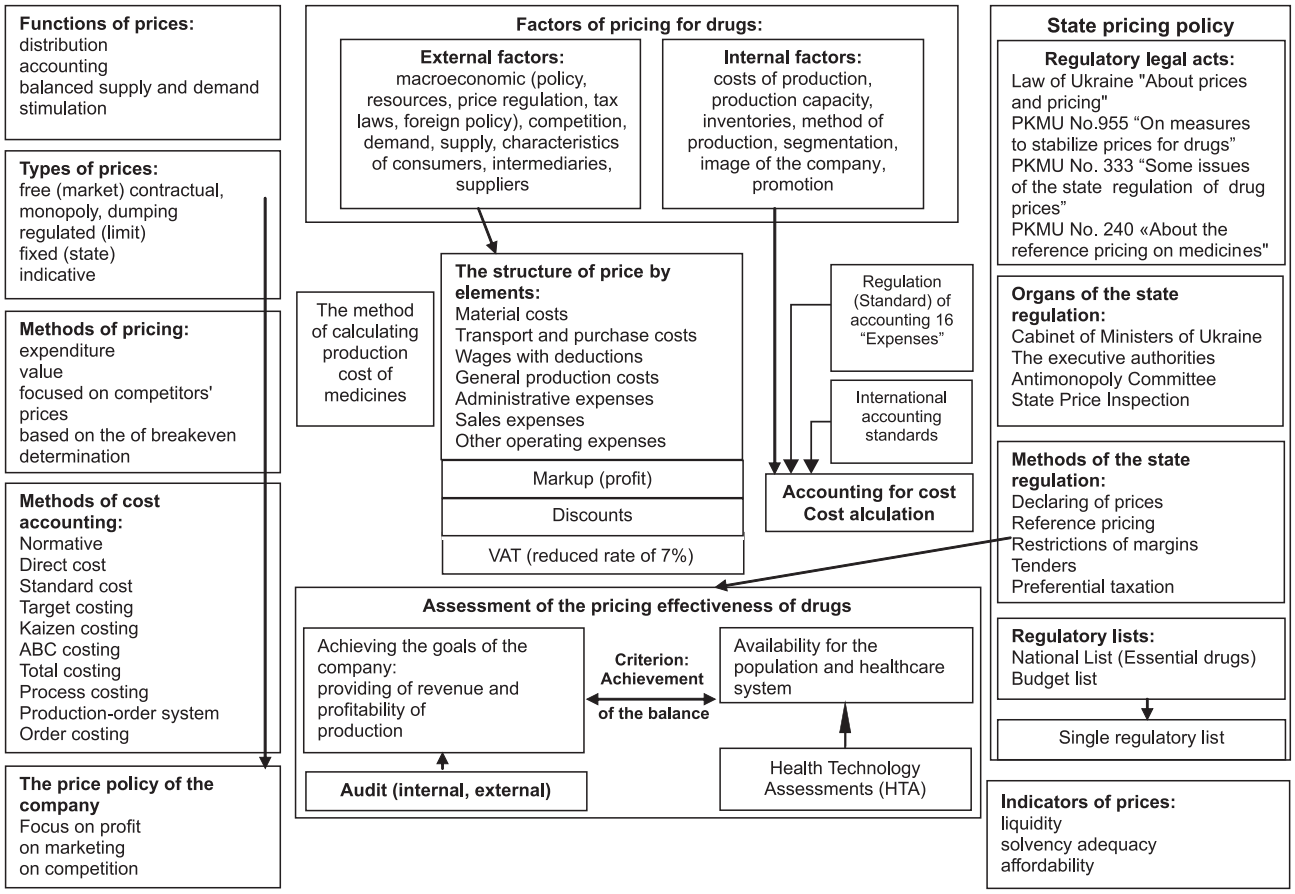

Fig. The model of pharmaceutical pricing in Ukraine

According to the current legislation there is the limitation of wholesale and retail margins on essential drugs, and declaring of wholesale selling prices for drugs purchased by budgetary funds. Thus, the main regulatory impacts are aimed at setting certain limitations in the wholesale and retail sector. Understanding that the manufacturer's price is a key element in the whole process of pricing it is appropriate to introduce effective mechanisms of the state regulation exactly in this sphere [3]. It is important to achieve a balance of interests between the healthcare system (in relation to cost containment and efficiency improvement, guarantees of drug availability), the population (in relation to safety, quality, availability of drugs and effective treatment) and pharmaceutical industry (in relation to profitability of the domestic industry, intellectual property protection, job retention, public support).

It should be noted that currently there is no approved sectorial method of calculating the cost of drugs. Because of the absence of a unified methodological approach to formation of the production cost of drugs purchased by budgetary funds, there is a groundless overpricing at every stage of the price formation and, an inefficient use of the budget.

Analysis of social economic regulatory lists allows identifying the main problems for their effective use. For example, azithromycin – an antimicrobial agent for systemic use – is presented in the National list and the Budget list under 87 trade names, 19 of them are domestic drugs (23%). As of 21/09/2016 only prices for 46 names of azithromycin (trade names) were declared in the register of wholesale drug prices. We analyzed the prices for azithromycin drugs in the form of tablets/capsules of 250 mg (6 pcs in a pack). The budget list comprises 40 names of these drugs (including 8 – of the Ukrainian production, 18 – manufactured in India, others – produced in Slovenia, Czech Republic, Poland, Canada, Great Britain, Belarus, Croatia, Serbia, Jordan and Egypt). Of these 40 drugs the wholesale prices were declared for 24 medicines (all of them – of foreign production) (Tab.).

It was not our aim in the study to compare the effectiveness of these drugs. However, it is quite clear that the ratio of price and quality for all these drugs will be significantly different.

As seen from Table, there are significant differences in the values of the declared prices (from 35.20 to 101.77 UAH per a pack) and retail prices (from 28.49 to 161.11 UAH), while the wholesale price for domestic drugs ranges from 32.55 to 72.66 UAH. In conditions of instability manufacturers/applicants lay financial risks to the declared price. It is of interest that some declared prices are significantly higher than the weighted average retail prices. Naturally, it is better for consumers if the choice of products is available, but in this case the quality-safety-price relationship is not evident. Moreover, it is impossible to neutralize the impact of asymmetric information.

The inefficiency of approaches to the state price control on drugs to be procured for the budget was demonstrated on the example of the antimicrobial agent for

Table

A comparative analysis of prices for azithromycin drugs

Trade name of a drug, dosage form	Manufacturer, country	Declared wholesale price, UAH*	Weighted average retail price, UAH
Azibiot® tab., 250 mg, No. 6	KRKA, Slovenia	–	59.85*
Azicin ® cap., 250 mg, No. 6	Darnitsa, Ukraine	61.20	66.84
Azimed® cap., 250 mg, No. 6	Kyivmedpreparat, Ukraine	52.36	63.59
Azinom cap., 250 mg, No. 6	Genom Biotech Pvt. Ltd., India	–	–
Azipol tab., 250 mg, No. 6	Polfa, Poland	49.67	64.01
Azit 250 tab., 250 mg, No. 6	Ind-Swift Limited, India	–	–
Azithral 250 tab., 250 mg, No. 6	Alembic Pharm. Limited, India	65.00	86.93
Azitrom tab., 250 mg, No. 6	Avant, Ukraine (in bulk)	–	–
Azithromax tab., 250 mg, No. 6	Pharmascience, Canada	95.88	44.65
Azithromycin-Apo tab., 250 mg, No. 6	Apotex Inc.,Canada	–	–
Azithromycinum-Astrapharm cap., 250 mg, No. 6	Astrapharm, Ukraine	32.55	29.58
Azithromycinum-BCHFZ cap., 250 mg, No. 6	Borschagovsky CPP , Ukraine	35.20	28.98
Azithromycinum-KR cap., 250 mg, No. 6	Chervona Zirka, Ukraine	54.22	29.30
Azithromycinum-Zdorovje cap., 250 mg, No. 6	Zdorovya, Ukraine	60.89	46.54
Azithromycinum tab., 250 mg, No.6	Alembic Pharm. Ltd, India	25.74	30.17
Azithromycinum-250 tab., 250 mg, No. 6	FDC Limited, India	47.31	–
Azithromycinum 250 tab., 250 mg, No. 6	Euro Lifecare (United Kingdom)	–	31.57
Azithromycin-Zentiva tab., 250 mg, No. 6	Zentiva (Czech Republic)	–	–
Azithromycinum cap., 250 mg, No. 6	Borisov plant medicines, Rep. Belarus	–	29.45
Azithromycin tab., 250 mg, No.6	Jubilant Life Sciences Ltd India	–	–
Azithromycin 250 tab., 250 mg, No. 6	Flamingo Pharm. Ltd. India	–	–
Azithromycin-Credopharm cap., 250 mg, No. 6	Unimax Lab./Mepro Pharm. Pvt. Ltd. India	–	–
Azithromycin-Norton cap., 250 mg, No. 6	Unimax Lab./Mepro Pharm. Pvt. Ltd. India	–	–
Azithromycin cap., 250 mg, No. 6	Kniss Laboratories Pvt. Ltd India	–	–
Azithro Sandoz® ® tab., 250 mg, No. 6	Sandoz Pharm. (Slovenia)	70.57	131.69
Azitro tab., 250 mg, No. 6	Cooper Pharma, India		
Azitrox® 250 tab., 250 mg, No. 6	Zentiva (Czech Republic)	–	128.71
Azivok cap., 250 mg, No. 6	Wockhardt Limited, India	–	–
Aziagio tab., 250 mg, No. 6	Agio Pharmaceuticals Ltd India	–	–
Defenz tab., 250 mg, No. 6	Biotavia Pharm Limited, India	–	–
Hemomicyn® cap., 250 mg, No. 6	Hemofarm, Serbia	101.77	126.63
Ormax cap., 250 mg, No. 6	Sperco Ukraine, Ukraine	72.26	81.90
Sumamed® tab., 250 mg, No. 6	PLIVA Hrvatska d.o.o Croatia	–	161.11
Zatrin -250 tab., 250 mg, No. 6	FDC Limited, India	–	–
Zitrox tab., 250 mg, No. 6	Macleods Pharm. Ltd, India	76.15	65.82
Zithrocin tab., 250 mg, No. 6	Unique Pharm. Lab. India	–	53.75*
Zithrolex® cap., 250 mg, No. 6	October Pharma S.A.E Egypt	–	–
Zitrolid® cap., 250 mg, No. 6	Scholkiv vitamin. Plant, Russia	–	–
Zomax® капс., 250 mg, No. 6	Al-Hikma Pharm. Jordan	–	–
Zyomicin® tab., 250 mg, No. 6	Kusum Healthcare, India	72.01	68.38

Notes: * – According to data of the Register of wholesale selling prices for drugs as of 21/09/2016; ** – According to Morion database as of September, 2016.

azithromycin systemic use included in the National list of essential drugs and the Budget List.

Analysis of the international experience shows that the problem of increasing availability of drugs is solved in different ways: the state registration of wholesale prices, limiting trade margins, fixed prices, limitations of the profitability when manufacturing and preferential taxation are used. In all countries analyzed the price of prescription medicines included in reimbursement is regulated. The prices for OTC drugs are usually not regulated by the state. In most countries there are the so-called positive and negative lists of medicines, ac-

cording to which the preferential supply and reimbursement are carried out [4-7].

Objectively growing needs of the healthcare system on the background of limited resources cause the necessity of assessment of the existing and innovative technologies in healthcare in regards to clinical efficiency, economic expediency and safety both for an individual patient and the healthcare system as a whole.

Medical and pharmaceutical care in each country has special features due to the political situation, the socio-economic level, development of technologies. Thus, a key factor for introduction of innovations in healthcare is availability of resources. "To achieve the best possible health services within the existing resources, implementation of the most efficient technologies should be supported taking into account the institutional, social and ethical issues" [8].

Within the framework of formation and implementation of national healthcare policies the authorized state bodies make decisions on licensing of certain activities related to the application of healthcare technologies, licensing of drugs and medicinal products for placing them at the market, reimbursement, etc. Regulatory authorities base on the information that comes from producers (applicants) within the legal terms during the licensing, decision making concerning drug registration, and tendering. However, the procedure does not provide comparison of the individual healthcare technology with the existing alternatives to determine the additional advantages from the point of view of the results for a particular patient or society in general. Therefore, the essential influence of information asymmetry on the decision to use HTA should be noted. Fair and reasonable scientific HTA enables to neutralize disadvantages caused by information asymmetry and reduce the risks of making responsible decisions concerning the application of a certain technology [9, 10].

Decision-making on specific aspects of the healthcare public policy (funding, compensation, investing, planning, etc.) are taken at the macro- or mesolevel by relevant competent authorities/persons. Analysis of the international experience shows that decision-making by politicians and scientists is carried on fundamentally different platforms, according to different criteria. For example, researchers rely on specific scientific data characterized by reliability, evidence, consistency. For politicians the main criteria are relevance, consistency, laconicism and timeliness of information with possible approximate estimates and assumptions, the preference is given to generalized data. Consequently, political decisions are often situational, conditioned by political expediency and not scientifically based [8].

The main values of the healthcare policy in EU are concentrated around evidential medicine, HTA and analysis of the economic effectiveness [11]. Experts estimate that the main objects of HTA should be as follows: the patient's safety, clinical efficiency, assessment of the cost/benefit ratio, economic efficiency, needs and problems of patients, the impact on the quality of life, availability of medical services, as well as ethical issues in healthcare [6].

One key element of HTA is comparative effectiveness research (CER). There are two types of CER – rapid assessment and full assessment [1]. The rapid assessment is evaluation of one HTA compared with one or more significant alternative types of intervention for a short period of time (e. g., launching a drug into production). The full assessment by pharmacoeconomic parameters taking into account the impact of HTA on the healthcare system is usually done in a few years after implementation of the technology to the market. At the same time as the reference technology different variants can be used, the "existing practice" or other alternatives are the most common, cheapest, most effective technologies meeting the standards and clinical practice guidelines.

CONCLUSIONS

The analysis of prices on essential drugs has shown their low availability and inefficiency of regulation mechanisms. The effective social model of pharmaceutical pricing has been developed. In conditions of limited resources of the healthcare system it is considered to be appropriate to introduce a consolidated list of drugs – the National list formed according to the WHO concept. This list will serve as a basis for public procurement, reimbursement schemes, preferential provision of drugs, as well as management of local production of drugs in development of import substitution. To identify the optimal drugs for their inclusion in the National list is important to use the results of HTA.

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

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