



Pharmaceutical system in Ukraine: current and prospective issues

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Abstract

Introduction: To review the current pharmaceutical system in the private and public sectors in Ukraine in terms of the availability and affordability of medicines, to explore and analyze national health system reforms started to be introduced in 2015.

Methods: The captured data was analyzed using the predetermined themes of financing, pricing, reimbursement, reforms and market analysis in Ukraine. We also examined the prices and volumes of medicines in 2013-2015.

Results: This analysis showed the dynamics of key indicators of the pharmaceutical market of Ukraine for 2013-2015. We used data from the MOH, market research analytical system “PharmXplorer”, “Pharmstandard” company “Proxima Research”.

Conclusions: The analysis of retail sales of drugs on the pharmaceutical market of Ukraine for the last 3 years indicates a decreasing sales trend in number of packages and dollar values. The current structure of market is characterized by the inadequate consumption of drugs, a high use of medicines for symptomatic treatment, increasing the average drug cost, medical devices, generic drugs dominance and lack of legislative regulation of pricing for the original drugs. Importantly, positive results of reimbursement of medicines for hypertension indicated an urgent need to introduce mechanisms for reimbursement of other medicines for the treatment of diabetes and some socially important diseases.

In Ukraine the capacity building and educational programs on HTA for pharmacists have already started. That is necessary to implement the requirements to health technology assessment to prioritize the procurements of medicines and their financing by government according to the developed scientific methodology.

Introduction

In Ukraine have been introduced requirements to Good Pharmacy Practice – GPP, approved by the Decree of Ministry of Health (MOH) of Ukraine No. 455 dated 30.05.2013. According to this Decree, GPP captures pharmaceutical care, practice and services, that are focused on the improvement of health, rational use of medicines and achievement of good outcomes from treatment.

Financing

In 2014, Ukraine had a population of about 45,36 mln and a gross domestic product (GDP) of about \$ 3082,5 per capita. The country’s health system consists of a public and private sectors. Total health expenditure was about 7,8% of GDP and in US \$ per capita it was accounted for \$313 in 2013^[1,2].

However, only a little over half (54,5%) of this total health expenditure was from public sector sources in 2013. Out-of-pocket were 42,8 % of total health expenditure in 2013. This indicator is high on account of the expensive medicines, which are generally purchased at full cost price by patients^[1,2].

In fact, the government health expenditure makes 80% for salaries and maintenance of health facilities. In 2014 only 13% of total market sales of medicines were public, financed through tenders of MOH, regional tenders and hospital procurements. In 2014 retail pharmacy sales were 3 mlrd US \$ for 1,1 mlrd packs^[3,4].

Officially, Ukraine has a comprehensive guaranteed package of health care services provided free of charge at the point of use as a constitutional right; nevertheless, so-called charitable donations are widely levied. Most health financing comes from general government revenues raised through taxation (value added taxes, business income taxes, international trade and excise taxes). Officially the system is financed by general taxation and declaratively provides universal access to unlimited care that is free at the point of use in publicly owned health care facilities^[5].

The key players in the Ukrainian health system are the central government (Cabinet of Ministers), the Ministry of Finance, the Ministry of Health (MOH) and local governments. The Verkhovna Rada (Parliament) sets the goals, major objectives, priorities, budget guidelines and regulatory framework for the health sector, and approves the targeted national health programs. The Cabinet of Ministers coordinates the development and implementation of national programs and creates legal, economic and management mechanisms to support the health system^[5].

The Ministry of Finance prepares the draft state budget, which is then submitted to the Parliament for approval. This sets out the public resources to be allocated to the health sector at each level of administration: central, regional, municipal and district or community level budgets in any given year. The Ministry of Finance is also the body that establishes the requirements for state institutions (including health care facilities) in formulating and implementing budgets^[5].

The national MOH coordinates and governs the core statutory health system. The MOH is the leading body within the executive responsible for implementing health policy, including policies on specific state health programmes, including the most significant health-related problems in Ukraine: communicable diseases (infants vaccination), HIV, tuberculosis, cancer, diabetes, cardio-vascular diseases and administration of publicly owned health care facilities. Regional health care authorities are presented by regional and city state health care departments^[4,5].

Current pharmaceutical policies. Public sector

Moreover, the Center has the task of standardizing medical services, including pharmaceutical services. The national treatment protocols are developed by the Department of Standardization for medical services of the State Expert Center of the MOH. The evidence search for the protocols development is conducted by the expert group of the Department of Standardization and usually involves international and national clinical protocols from the other countries. The development and approval of the protocols is proceeded by the group of clinical experts, who are appointed separately for each discipline by the Orders of the MOH. The committees may consider economic evidence in their decision, while no requirements for methodology and input parameters are officially or publicly available. The meantime in the developed countries economic evaluation seeks to inform the range of very practical and unavoidable decisions in health care, which will be made or not they are based on evidence, analysis and explicit social values^[5,6].

Medicines may be used in Ukraine only after their official state registration by the MOH (i.e., marketing authorization). The above rule exempts from the mandatory registration regime those medicines that are prepared in pharmacies in accordance with medical prescriptions for individual patients or in accordance with orders placed by healthcare institutions, provided that such drugs are prepared from active and auxiliary substances allowed for use in Ukraine. Official state registration involves a three-step procedure consisting of pre-clinical research, clinical trials, and the filling of an application in the form of a “registration dossier” for the state registration with the MOH^[5,7].

HTA introduction

Since 2010 the articles on HTA introduction were published by Ukrainian scientists (K. Kosyachenko, A. Nemchenko, O. Zalis’ka, O. Mandrik, O. Piniashko). Since 2012 me-

thodical recommendations for postgraduate studies on Pharmacoeconomics and HTA at Danylo Halytsky Lviv National Medical University are used in the educational process (published by O. Zalis’ka, O. Mandrik). Currently the Commission of implementation of HTA system in Ukraine of the MoH works and considers the introduction of HTA into practice since 2014. In 2015 the 1st scientific-practical open online-course of lectures in the most popular Ukrainian medical journal Apte-ka.ua was launched (O. Piniashko, O. Zalis’ka)^[14-16, 18]. The key issues of HTA in Ukraine have been discussing during the ISPOR Annual Meetings and Congresses, HTA roundtables and are published in the following reports and articles^[9,14-18].

Reimbursement policy

This first Pilot project introduced state price regulation for essential antihypertensive medicines. All medicines registered as antihypertensives were divided into three groups: those reimbursed at 90% of the reference price; those reimbursed at up to 90%; and those that are not reimbursed. Positive results of Pilot project were: the decrease of incidence of stroke on 6,4% and frequency of calls to emergency on 16%.

Meanwhile the Cabinet of Ministers decided to initiate Pilot project on insulin and its analogues reimbursement in 2016. The patient will receive insulins free of charge with the prescription. Nowadays over 200,000 citizens of Ukraine need insulin for the everyday treatment. The MOH started the implementation of a registry of insulin-dependent patients, providing a unique electronic code for drug’s prescription and allowing to determine an amount of funds regions need for insulins reimbursement. The register is a needed tool for insulins reimbursement system implementation. The registry will contain information about patient’s health condition and insulins prescribed, while the prescription code will allow a patient to get the drug in pharmacy. The registry is already being tested in 6 regions and by the year end all the regions are expected to be attached to the system^[4].

According to the Decree of Cabinet of Ministers of Ukraine No. 759 dated 26.08.2015 there were approved the list of diseases and special groups of patients to whom medicines are dispensed free of charge and at 50% price.

Price regulation for medicines in Ukraine is based on the Decree of Cabinet of Ministers No. 333 dated 25.03.2009 “Some issues for state pricing of medicines and medical products”. And this Decree approves the National List of Essential medicines, medical products and pricing.

Reference pricing in Ukraine is regulated by the Decree of the Cabinet of Ministers No. 240 dated 02.07.2014 "About reference pricing on medicines and medical products, which are purchased by the means of state budgets". The reference countries are Bulgaria, Moldova, Poland, Slovakia, Czech Republic, Latvia, Hungary and Serbia.

A more indirect method of price regulation was the introduction of certain tax privileges. For example, sales of medicines and medical devices registered in Ukraine used to be exempt from value added tax (VAT). However, in 2014, with the worsening economic situation in Ukraine, emergency measures introducing 7% VAT on medicines and medical products were brought in (The Law No. 1166-VII on preventing financial catastrophe and preparing the foundations for economic growth in Ukraine, dated 27.03.2014)^[5].

Reforms of MOH

Currently the strategic goals of the MOH of Ukraine, that were published on December 7, 2015, are: the providing of high quality, affordable and financial accessible medicines and vaccines for patients, effective healthcare services of higher quality and patient-oriented, a fair financing system, new system of public health^[4].

In 2015 the main achievement of the MOH in the providing of transparency in state procurement and tendering processes is 60% transmission of the function of state medicines' procurements to the international organizations such as UNICEF, UNDP, Crown Agents (UK). This is approved for 12 national programs for approximately \$ 88 mln by the Law No. 269-VIII dated 19.03.2015 and the Decree of Cabinet of Ministers of Ukraine No. 787 dated 8.10.2015. This national programs cover vaccines, medicines for the TB, HIV, hemophilia, hepatitis B/C and cancer treatment, orphan drugs, TB and HIV diagnostics. In 2016 it is planned by the MOH to transmit 100% of all the state procurements to the international organizations^[4].

Pharmacy sector

The Conception of development of pharmaceutical sector of health care system is set by the Decree of MoH No. 769 dated 13.09.2010 and regulates the use of pharmacoeconomics, step by step implementation of National Formulary System and pricing.

According to the official data the State register of medicines in Ukraine includes 12356 drugs, among them 3667 domestic and 6869 foreign^[19].

In 2015 retail segment consists of about 20 000 points of retail sales, which include traditional pharmacies and pharmacy units – smaller retail establishments with less technical requirements regarding their size, location and interior design specifics^[7].

The pharmacy price of a drug includes the pharmacist's mark-up and a value added tax of 7%. The mark-up is determined by the wholesale price of the drug pack and is set depending on the category of medicine. For example, when a medicine by INN is included in the National list of Essential Medicines, then the mark-up must be set at no more 25% (Decree of the Cabinet of Ministers of Ukraine No. 333 dated 25.03.2009 and No. 449 dated 7.07.2015). There is no special regulation for selling prices for the other medicines^[5,7].

The total market (hospital and retails sales) is predominantly an out-of-pocket market with about 87% of the total market share in values and 89% in volumes paid by the patient/final consumer from his pocket (retail). The hospital segment is very insignificant (about 13% in values) and unstable due to lack of public finances and absence of efficient reforms in provision of pharmaceutical and health care in the country^[7,21].

The **table 1** summarizes the 2013-2014 expenditures in the retail. The total volume of retail decreased in values in USD for 27% in 2015, in volumes for 3,3%, but in values in UAH it showed growth for 22,4% in 2015 comparing to 2013-2014^[3,20,21].

Year	Medicines		Medical products		Cosmetics		Dietary supplements		Total market
	\$Mln/packs	Share in pharm.cort	\$Mln/packs	Share in pharm.cort	\$Mln/packs	Share in pharm.cort	\$Mln/packs	Share in pharm.cort	
Monetary units									
2013	3804,0	84,9	356	7,9	182,7	4,1	138,1	3,1	4480
2014	2920,7	85,2	272,5	8,0	131,4	3,8	104,5	3,0	3429
Natural units									
2013	1274,1	64,0	612,4	30,7	59,6	3,0	46,2	2,3	1992
2014	1116,8	63,3	552,3	31,3	52,1	2,9	43,4	2,5	1764

Table 1. Analysis of retail sales for medicines, medical products, cosmetics, dietary supplements in Ukraine in the period 2013-2014

In 2015, the segment experiences drastic changes: the segment is growing in the local currency, but decreasing in USD/ EUR and in units. In 2015 retail pharmacy sales for the first nine months were 1,3 mlrd US \$ for 741 mln packs. Hospital sales for the same period were 0,2 mlrd US \$^[3,7,21].

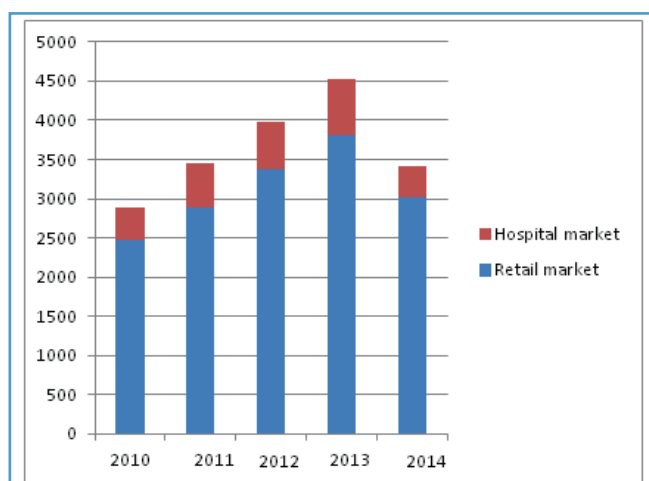


Figure 1. Retail and hospital sales dynamics in values 2010-2014, mln, USD

Ukraine has already lost certain territories and consumers which caused a redistribution of the largest retail players' market shares, there is shift of consumers consumption to cheaper products and overall decrease of consumption in physical terms. According to apteka.ua, the total retail turnover in 2014 has lost about 4% of the market in values on the east of Ukraine due to the recent military crisis^[7].

The market share in volumes for foreign manufacturers is 24,3% in 2015 and 28,2% in 2014, for domestic – 75,7% and 71,8% in accordance. The market share in values for foreign manufacturers is 58,6% in 2015 and 62,9% in 2014, for domestic – 41,4% and 37,1% respectively^[7,20].

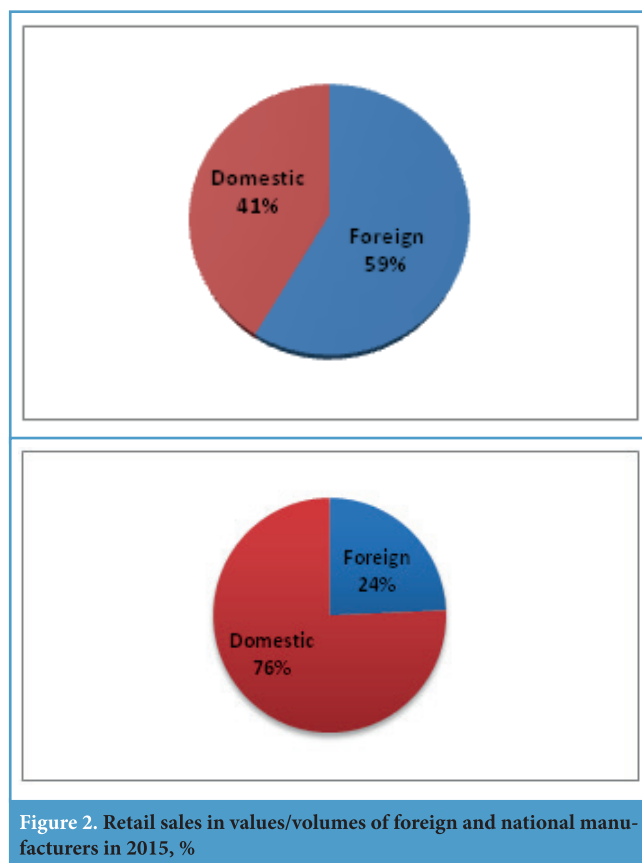


Figure 2. Retail sales in values/volumes of foreign and national manufacturers in 2015, %

Prescription medicines (Rx) cover 35,9% in volume units and 55,8% in values (UAH) in 2015. While OTC drugs compose 64,1% in volume units and 44,2% in values (UAH) of the market respectively^[7,20].

According to Proxima Research there were composed top sales of drugs that were the most frequently used in 2013-2015. Consumption of medicines is not quite appropriate to the structure of morbidity in Ukraine. Top-10 selling drugs in values are presented in table 2^[3,7,20].

Rank 2015	Rank 2013	Brand trade name	ATC	INN	Company
1	1	Actovegin®	A16AX10	Deproteinized calf blood extract	Takeda
2	7	Pharmacitron®	N02BE51	Comb drug	Pharmascience
3	8	Sodium chloride	B05XA03	Sodium chloride	Others
4	4	No-spa®	A03AD02	Drotaverine	Sanofi
5	19	Nurofen®	B05XA03	Ibuprofen	Reckitt Benckiser
6	13	Nimesyl®	B05XA03	Nimesulid	Berlin-Chemie/Menarini
7	5	Essentiale®	B05XA03	Essential Phospholipids/ Others	Sanofi
8	6	Citramonum	N02BA51	Comb drug	Others
9	26	Sinupret®	R05X	Comb drug	Bionorica
10	25	Amixin	L03AX21	Tiloronum	Interchim, Ukraine

Table 2. Top-10 brands of retail sales in values in the analogous period of 2013 and 2015

According to Proxima Research, results of 2014 full year showed that the distribution of sales shares between ATC-1 classes remained unchanged. The largest share in values is controlled by “A - Alimentary tract and metabolism” (17%), “C - Cardiovascular system” (12%), “R - Respiratory system”, “N - Nervous system” (11%) and “M - Musculoskeletal system”. This distribution did not change significantly in recent years^[7].

Price volatility and decreased purchasing power of the population caused changes among best selling products on the market. Ukrainian market is experiencing the same world trend regarding marketing status of pharmaceuticals: share of Gx products has been increasing in the market. Since 2013 it rose from 38% to 42,2% in 2015 in values. Share of original (innovative) medicines decreased within the same period from 18,8% to 17,2%. The average cost of a Gx pack in Ukraine is about \$1,8 whilst original drugs cost four times more: about \$7 per pack (2015, apteka.ua). The weighted average cost of 1 pack of original drug and Gx drugs in the period under review compared to the same period last year increased by 65,1% and 47,8% respectively. The average cost of one pack in the pharmacy cart for the first 9 months of 2015 amounted to 1,37 \$ and it increased by 44,7% compared to the same period of 2014^[7,20,21].

The only type of promotion of pharmaceuticals and medical devices that is currently specifically regulated by Ukrainian law is “advertising”. Ukrainian legislation contains few provisions that specifically regulate practices (other than simple advertising) aimed at the promotion or marketing of pharmaceuticals and medical devices^[7].

Conclusions

In 2015, the Ukrainian pharmaceutical segment experiences drastic changes: the segment is growing in the local currency, but decreasing in USD/ EUR and in units. In summary, among number of current challenges, inefficiency of health care financing, inequitable access to resources, generic-oriented drugs market without mandatory prescription, high prevalence of out-of-pocket payments can be named in Ukraine.

Pharmaceutical policies should reflect national priorities for health and industrial policy, including cost containment, employment, innovation and trade promotion^[22]. In next few years there is a need to update and harmonize the legislative and institutional framework in Ukraine regarding to the European requirements and practice. Implementation of public health insurance and wider reimbursement policies will decrease the high indicator of out-of-pocket spending on medicines. While currently we estimate a significant share of treatment costs from patient's perspective.

However, reimbursement and policy decisions are still not fully transparent, and as a consequence of the economic crisis. The most critical question for decision-makers is whether they really want to improve the rationale of health care decision making or they should just concentrate on reducing the public health care spending, as experienced in recent years.

The analysis of retail sales of drugs on the pharmaceutical market of Ukraine for the last 3 years indicates a decreasing sales trend in number of packages and dollar values.

The current structure of market is characterized by the inadequate consumption of drugs, a high use of medicines for symptomatic treatment, increasing the average drug cost, medical devices, generic drugs dominance and lack of legislative regulation of pricing for the original drugs. Importantly, positive results of reimbursement of antihypertensive medicines indicated an urgent need to introduce mechanisms for reimbursement of other medicines for the treatment of diabetes and some socially important diseases.

That is necessary to implement the requirements to health technology assessment to prioritize the procurements of medicines and their financing by government in order to improve the market access, medicines prescription and patients' health outcomes according to the developed scientific methodology. ■

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