



High Cost of Medicines in Ukraine: Factors and Price Components

February 2015



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Systems for Improved Access
to Pharmaceuticals and Services

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Simon Conesa

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ACRONYMS AND ABBREVIATIONS

BSG	Bacillus Calmette-Guerin TB vaccine
CSO	civil society organization
DoEF	Department of Economics and Finance
GDP	gross domestic product
GMP	Good Manufacturing Practice
HAI	Health Action International
HIV and AIDS	human immunodeficiency virus and acquired immunodeficiency syndrome
Hrv	hyrvnia (Ukrainian currency)
MOH	Ministry of Health
SAUMP	State Administration of Ukraine in Medical Products
SEC	State Expert Centre
USD	US dollars
VAT	value added tax
WHO	World Health Organization

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EXECUTIVE SUMMARY

Medicine prices are a contentious issue, with many products arguably unaffordable, even in developed countries,¹ where, on average, approximately 10% of the health budget is spent on medicines. But in low- and middle-income countries, that figure is usually substantially higher, and a sizable proportion of the population usually pays for medicines out of pocket, thereby reflecting both limited resources and generally inefficient public health systems. High out-of-pocket costs disproportionately affect the economically disadvantaged and are more likely to impair patient access to effective treatments in poorer communities.²

The effectiveness and transparency of implementing regulations, as well as of procurement and related activities, have a decisive effect on medicine prices. The final price for the paying customer—whether the patient, the public health service, or an insurer—is affected by the various elements that contribute to the development, production, procurement, and distribution of a medicine. This report examines the elements (procurement and distribution) that, through regulation, fall within the control of the Government of Ukraine. In the case of Ukraine, those elements, together with the retail markup, officially add 37.5% to acquisition costs. That percentage is generally in line with other countries, but it is high in absolute terms, because procurement prices are higher in Ukraine.²

Corruption in Ukraine is perceived to be a major obstacle to upholding the rule of law. In 2013, Ukraine was ranked 142 (of 175) by Transparency International’s Corruption Perceptions Index.³ Although reports indicate that corruption permeates all spheres of life in Ukraine, health care is the sector in which it is perceived to have the greatest effect. A 2012 survey on price and availability of medicines in Ukraine, which was undertaken by the State Expert Centre of the Ministry of Health, found poor availability for about one-third of originator brands and less than two-thirds for the most sold generics. It also found high prices (approximately 14 times higher for originator brands and 4–5 times higher for the most sold generics) in the public sector, when compared with international reference prices. That study recommended an in-depth analysis of the price components of essential medicines and an investigation of the reasons for variations in prices and availability among the various regions (oblasts). The analysis should take into account that each facility procures medicines independently.

Context and Market

This section describes the supply-and-demand characteristics of the pharmaceutical market, together with other economic and external factors. All of those factors influence the “free

¹ “Hard Pills to Swallow,” *The Economist*, January 4, 2014, <http://www.economist.com/news/international/21592655-drug-firms-have-new-medicines-and-patients-are-desperate-them-arguments-over>.

² Medicines prices, availability, affordability and price components, Ukraine. Health Action International (HAI) and World Health Organization (WHO), 2012.

http://www.haiweb.org/medicineprices/surveys/201203UAE/sdocs/Summary_report_ukraine_mar2012.pdf

³ Transparency International, 2014. <http://www.transparency.org/cpi2014/results>

market” price of commodities, that is, prices in absence of regulation. In a perfectly competitive market, prices reflect the equilibrium of available supply with existing demand. Pharmaceutical markets are vastly more complex, however, and although supply and demand still affect prices, several other factors are particularly influential in Ukraine.

With Ukraine’s population of approximately 45 million and its universal-coverage public health service, one would expect medicine prices to be competitive, but that is not the case. One reason is that most government health care expenditures go to inpatient medical care, with only a relatively small proportion (13%) going to outpatient services.⁴ Moreover, in 2012, total health care expenditures accounted for approximately 7.6% of gross domestic product (GDP), of which public funds contributed 55% (or 4% of GDP), which is low compared with regional standards. Although prepaid schemes such as private insurance funds have recently grown in importance, out-of-pocket spending represents approximately 42%, with donors providing less than 1%.⁵

As is the case in many well-developed and competitive markets, the Ukrainian market is dominated by a small number of wholesaler-importers. However, serious concerns have been raised regarding the fairness of the market in Ukraine, and this concentration is thought to be one of the primary avenues for artificially inflating prices.⁶

Economic and External Factors

Ukraine is now considered a lower-middle-income country, despite political instability that led to a contraction in GDP of 8.2% in 2014 and to a currency devaluation of nearly 50%.⁷ Regardless, the total value of the Ukrainian medicines market is still attractive for pharmaceutical companies. In fact, because of the 2014 GDP contraction and the accompanying exchange rate decline, the market’s value increased in the first half of 2014, even if its volume decreased.

In 2010, medicines were tax-exempt, but since April 1, 2014, a reduced 7% value added tax (VAT) rate has been imposed on them. From interviews with the supplier and manufacturer associations, the author found that a lack of clarity in drafting the law results in medicines being charged the regular 20% VAT at customs. Although in theory, the VAT should be reimbursed after the filing of a VAT return, such compensation almost never occurs.⁸

⁴ Ukraine Health Systems Review. Lekhan V, Rudi V, Richardson E. Health Systems in Transition 12(8):1–183.

⁵ World Health Development Indicators 2015, The World Bank. <http://wdi.worldbank.org/table/2.15>

⁶ Who makes money on epidemics of HIV/AIDS in Ukraine Anticorruption Action Centre, 2013.

http://network.org.ua/upload/novosti/zvit_Who%20makes%20money_eng.pdf.

⁷ “World Bank: Ukraine’s GDP to Decrease by 2.3% in 2015,” Mirror Weekly, January 13, 2015,

http://mw.ua/ECONOMICS/world-bank-downgrades-its-gdp-growth-expectation-for-ukraine-in-2015-914_.html.

⁸ “Introduction of VAT on Medicines and Medical Products,” KPMG International, April 8, 2014,

www.kpmg.com/ua/en/issuesandinsights/articlespublications/industries/pharmaceutical-bulletin/pages/pharma-alert-08-04-2014.aspx.

Regulatory Framework

The State Expert Centre (SEC) has primary responsibility for market authorization of medicines and is funded through fees and charges for services, with no contribution from the state budget. Since 2000, a separate agency, the State Administration of Ukraine on Medicinal Products (SAUMP), has been responsible for licensing wholesalers, manufacturers, and retail pharmacies, as well as post-market quality control. SAUMP is fully funded by the Ministry of Health (MOH) through the state budget.⁹

Although both agencies appear effective, there is a lack of coordination between them and to some extent a duplication of efforts. Some stakeholders have also expressed concern that both agencies do not have a sufficient number of well-trained personnel and that SAUMP has an insufficient number of adequately equipped and supplied labs, especially for investigating the post-market quality issues.

Procurement

This section covers all processes related to procurement, including distribution and management of medicines and medical supplies. Procurement is conducted by using tenders. The terms set in the government's request for tenders shape the conditions that selected suppliers must meet when executing contracts, including (a) financial conditions before and after award; (b) quantities, which may or may not be flexible; (c) quality; and (d) logistics expenses, which in Ukraine include customs and distribution. All those conditions will directly affect the costs faced by suppliers and, consequently, the prices that are likely to be offered under those conditions.

Transparency and accountability of public procurement in Ukraine are lacking, resulting in collusion and monopolistic practices.¹⁰ In fact, for several years, public procurement has been underperforming in two major areas: (a) procurement prices tend to be much higher than those obtained by other countries or international agencies, such as the United Nations Children's Fund or the International Development Association,¹¹ and (b) product availability and delivery to facilities are both unpredictable.

In 2014, however, the most significant problem has been the failure of the public tenders at both the central and decentralized levels. So by late August, only approximately one-quarter of the centrally procured medicines, for which the forecasted amounts were already adjusted to reflect availability of funds, were actually purchased, thus forcing most patients to pay for their medications out of pocket. That figure improved to approximately three-quarters but not until the end of the year.

⁹ Ukraine Health Systems Review. Lekhan V, Rudi V, Richardson E. Health Systems in Transition 12(8):1–183. 2010

¹⁰ As above

¹¹ International Drug Price Guide. Management Sciences for Health. <http://erc.msh.org/priceguide/>

Such failures are related to fluctuations in exchange rates arising from the devaluation of the Ukrainian hryvnia (Hrv), which lost 50% of its value during 2014. In Ukraine, tenders must specify the precise quantities and expenditure amounts reflected in the detailed budget approved by the Parliament, which at the time the requests for tenders were published no longer reflected current market prices. When tenders failed, Ukrainian legislation forced the government to republish the request for tenders but without making any adjustments, which—given the economic situation—resulted in a chain of failed tenders. At the end of the year, however, the Cabinet of Ministers adopted a resolution allowing the MOH to recalculate quantities according to available funding, even if the long delays would have a negative impact on medicine availability.¹² It is uncertain whether that resolution will be maintained after this currency crisis.

Pricing

Ukraine has minimal supply-side regulation in place that establishes maximum wholesale and retail markups for pharmaceuticals and medical devices. Those markups are applied to the procurement prices.

Procurement prices are based on registered prices, which are calculated from supporting documentation provided to the MOH by manufacturers or importers. According to some stakeholders, those supporting documents are not checked for accuracy and have been cited as a source of inflated prices.

Given the limitations encountered by the supply-side regulations, the government has also become interested in testing demand-side interventions, starting with a pilot project on price regulation and reimbursement of hypertensive medicines and insulin. The pilot was not widely regarded as successful, and there are concerns that this attempt may have created a negative market perception of reimbursement schemes, which are currently being considered by the Government of Ukraine as a potential approach to trying to improve its service to the Ukrainian population.

¹² “Public Procurement of Medicines: Formation of the Expected Price or MoH Ukraine Finds All the Possible Ways to Overcome the Crisis Tender,” Apteka, August 18, 2014, www.apteka.ua/article/302993.

BACKGROUND

Medicine prices are a contentious issue, with many products arguably unaffordable, even in developed countries,¹³ where, on average, approximately 10% of the health budget is spent on medicines. But in low- and middle-income countries, that figure is usually substantially higher, reflecting both limited resources and generally inefficient public health systems. Given that a sizable proportion of the population usually pays for medicines out of pocket, high medicine costs disproportionately affect the economically disadvantaged and are more likely to impair patient access to effective treatments in poorer communities.¹⁴

The final price for the paying customer—whether the patient, the public health service, or an insurance company—is compounded by all activities involved in the development, production, procurement, and distribution of the medicine. This report will focus on only those activities that are under the control of the Government of Ukraine, that is, procurement and distribution. However, it is worth mentioning that development and production costs—activities that are undertaken by private companies and that are often used to justify high prices—are currently under international scrutiny, with recent studies showing that pharmaceutical companies spend more on marketing than on research and development.¹⁵

Thus, this study does not consider manufacturing costs but focuses instead on the manufacturers' selling prices and the cumulative effects of all activities from procurement through distribution and dispensing. Each activity involves a cost that may be lightly or heavily regulated in various countries. The latter is the case in Ukraine, because those activities officially add 37.5% to procurement prices. That effect is generally in line with other countries, but it should be noted that in absolute monetary terms, the effect depends on the base procurement prices.¹⁶ In addition, the effectiveness and transparency in implementing those regulations, plus in procurement and related activities, have a decisive effect on medicine prices.

Corruption in Ukraine is perceived to be a major obstacle to establishing and maintaining the rule of law. In 2013, Ukraine was ranked 142 (of 175) on Transparency International's Corruption Perceptions Index. Ukraine has had a consistent index ranking of 25 out of 100, where 100 represents an ideal corruption-free environment, with more than 84% of Ukrainians perceiving the health care sector as widely or extremely corrupt.¹⁷

An interim report prepared by the Anticorruption Action Centre with funding from the All-Ukrainian Network of People Living with HIV is the latest in a series of reports to identify

¹³ "Hard Pills to Swallow."

¹⁴ Medicines prices, availability, affordability and price components, Ukraine. Health Action International (HAI) and World Health Organization (WHO), 2012.

¹⁵ Richard Anderson, "Pharmaceutical Industry Gets High on Fat Profits," BBC News, November 6, 2014, www.bbc.com/news/business-28212223.

¹⁶ Medicines prices, availability, affordability and price components, Ukraine. Health Action International (HAI) and World Health Organization (WHO), 2012.

¹⁷ Transparency International, 2014. <http://www.transparency.org/cpi2014/results>

problems related to weak governance and corrupt practices in the pharmaceutical supply chain.¹⁸ Key areas identified in the report include (a) staging tenders among multiple companies controlled by one beneficial owner, (b) staging cartel agreements, (c) converting state companies into shell companies to purchase pharmaceuticals offshore and to sell them to the Ministry of Health (MOH) at inflated prices, and (d) using a local register as a reference to justify overestimated tender prices. For example, in 2010, more than 600,000 doses of a tuberculosis prevention vaccine (Bacillus Calmette-Guerin, or BCG) were procured by the MOH through a Cypress-based importer at prices ranging between hryvnia (Hrv) 14.63 and Hrv 16.15 per dose (approximately 1 US dollar [USD]), whereas just one year earlier, the vaccine was procured directly from a manufacturer (Ganza Company) at one-tenth the 2010 price (Hrv 1.53).¹⁹

The National Strategic Research Institute has also conducted a study.²⁰ Moreover, the Ukrainian Ministry of Internal Affairs has been investigating a reported procurement of drugs at high prices resulting in an overpayment of Hrv 20 million just in 2012.²¹ Finally, in the same year, a survey on price and availability of medicines in Ukraine—conducted by the State Expert Centre of the MOH, following the methodology developed by the World Health Organization and Health Action International²²—found low availability (29.5% of originator brands and 58.3% of most sold generics) and high prices (approximately 14 times for the originator brands and approximately 4–5 times for the most sold generics) in the public sector when compared with international reference prices. That survey recommended an in-depth study of the price components of essential medicines and an investigation into the causes of the differences in prices and availability among the various regions (oblasts), taking into account that each facility procures commodities separately.²³

¹⁸ Who makes money on epidemics of HIV/AIDS in Ukraine Anticorruption Action Centre, 2013. http://network.org.ua/upload/novosti/zvit_Who%20makes%20money_eng.pdf

¹⁹ Interfax-Ukraine, 2011. <http://www.kyivpost.com/content/business/prices-of-medicine-in-ukraine-ten-times-higher-due-111355.html>

²⁰ National Institute for Strategic Studies. October 2014; On combating corruption in the public administration of regional development <http://www.niss.gov.ua/articles/908/>; Public participation in governance: the role of non-governmental think tanks <http://www.niss.gov.ua/articles/260/>.

²¹ “Health Ministry Officials Suspected of Abuse in the Procurement of Medicines,” 2013.

²² Medicines prices, availability, affordability and price components, Ukraine. Health Action International (HAI) and World Health Organization (WHO), 2012.

²³ Ibid.

CONTEXT AND MARKET FACTORS

In a perfectly competitive market, which is composed of a large number of equally powerful (influential) suppliers and a large number of equally powerful purchasers, prices arise from the equilibrium of available supply with existing demand. However, pharmaceutical markets are vastly more complex for a number of reasons, including, among others, (a) the monopolistic control of certain molecules under patent law, (b) the differential price setting by the manufacturers, (c) the numerous intermediary players, and (d) the regulated nature of the market.

At present, Ukraine has a population of approximately 45.5 million, with that number declining over the past few years.²⁴ Publicly owned facilities provide the majority of health care services. General government expenditures on health as a proportion of total health expenditures were 55.7% in 2007.²⁵ As mentioned in the executive summary, the bulk of government expenditures goes to inpatient medical services, with only a relatively small proportion (13%) funding outpatient services.²⁶ The MOH is responsible for health policy, but its influence is limited because it directly manages only so-called national programs, which include treatment for the following: HIV and AIDS, tuberculosis, oncological diseases, cardiovascular diseases, cerebrovascular diseases, viral hepatitis, hemophilia, autism, and Gaucher's disease.

A significant proportion of health services is delivered in facilities owned and managed at the oblast or district level. Those facilities are responsible for the procurement and management of all medicines and medical products that are not supplied within national programs, as previously described. That decentralized activity is funded partly by transfers from the national budget, but also from local sources. Therefore, the MOH's principal role is to set health and pharmaceutical policy and to offer guidance and norms for facilities at all levels. But its involvement in procurement and distribution is limited to only those medicines included in the national programs (figure 1).²⁷

²⁴ Ukraine country profile, World Bank, 2013. <http://www.worldbank.org/en/country/ukraine>

²⁵ World Health Organization, 2009; http://apps.who.int/nha/database/Country_Profile/Index/en.

²⁶ Ukraine Health Systems Review. Lekhan V, Rudy V, Richardson E. *Health Systems in Transition* 12(8):1–183. 2010.

²⁷ Health care systems in transition: Ukraine; Lekhan V, Rudy V, Nolte E. WHO Regional Office for Europe on behalf of the European Systems and Policies 2004.

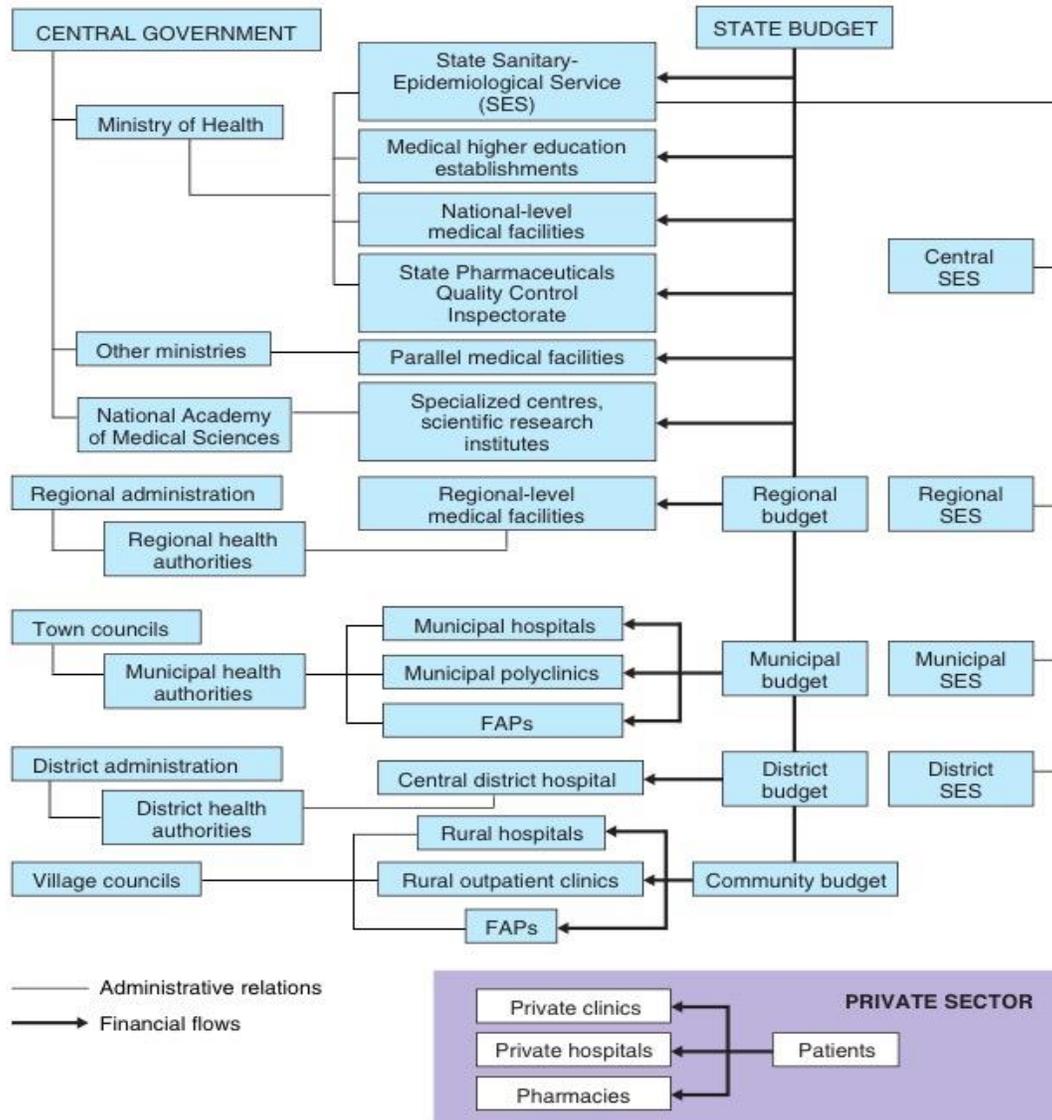


Figure 1. Overview of Ukrainian health care sector

Source: Reference 3; FAP, Feldsher and Midwife Post

Regardless of the country’s recent economic instability, the burden of disease in Ukraine is in line with that of fully developed economies, having thus shifted more toward noncommunicable diseases (table 1).²⁸

²⁸ Ukraine: ten health questions WHO Regional Office for Europe, 2005. http://www.euro.who.int/__data/assets/pdf_file/0003/103827/E88202_UKRAINE.pdf

Table 1. Health and Demographic Indicators

Cause	Share of burden of disease		
	Ukraine	EU 15	EU 10
Cardiovascular diseases	30%	17%	22%
Neuropsychiatric disorders	14%	27%	21%
Unintentional injuries	11%	6%	9%
Cancer/malignant neoplasms	10%	17%	16%
Infectious and parasitic diseases	5%	2%	2%
Intentional injuries	5%	2%	3%
Non-infectious respiratory diseases	4%	7%	3%
Sense organs disorders	4%	5%	5%
Respiratory infections	1%	1%	1%
Perinatal conditions	1%	1%	1%
Diabetes	1%	2%	2%
Total communicable diseases	9%	5%	4%
Total non-communicable diseases	74%	87%	83%
Total injuries	16%	8%	12%

Source: World Health Organization, *World Health Statistics 2006* (Geneva: WHO, 2006).

Note: EU-15 countries are Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, and United Kingdom. EU-10 countries are Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovak Republic, and Slovenia.

In 2012, total health care expenditures accounted for approximately 7.6% of GDP, from which public funds provide approximately 55% (approximately 4% of GDP) of national health financing. That amount is low when compared with regional standards, and it increased only approximately 1% during Ukraine's explosive economic growth during the 2000s, when GDP increased six-fold.²⁹ Although prepaid schemes such as private insurance funds have lately grown in importance, out-of-pocket spending represented approximately 42% of funds, and other donors provided less than 1%. That spending represented approximately USD 293 per capita, which amounted to approximately USD 562 when adjusted for purchasing power parity.³⁰

Moreover, on the demand side, the public sector's leverage is further diminished because approximately 80% of that limited budget is inexorably tied to salaries.³¹ As a legacy of the Soviet era, when number of beds was used as a proxy for measuring quality of service, the remaining approximately 20% has been traditionally focused on inpatient services. According to Article 45 of the Constitution of Ukrainian, health care services should be free of charge in the public sector. Despite that, a decree by the Cabinet of Ministers (Decree 1138, September 17, 1996) allows public hospitals and government-owned medical schools to charge patients for their services. Accordingly, in most cases, patients are asked to make a "voluntary" donation to a

²⁹ Trading Economics 2014 <http://www.tradingeconomics.com/ukraine/gdp>

³⁰ World Development Health Indicators; World Bank, 2012; <http://wdi.worldbank.org/table/2.15>

³¹ Private communications during interviews with local civil society organizations (CSOs).

specific charity and to purchase their own medications and health care products. Thus, private expenditure consists primarily of out-of-pocket payments, which are high because of the high cost of medicines, which patients purchase at full price (table 2).³²

Table 2. Government Health Expenditure by Service Program as a Percentage of Total Health Expenditure in 2003, 2005, and 2008

Type of Expenditure	Total Health Expenditure (%THE)			Public Health Expenditure (%THE)		
	2003	2004	2008	2003	2004	2008
Health systems administration	3.3	3.2	2.8	3.3	3.2	2.7
Education & training	2.1	2.1	-	2.1	1.9	-
Research & development in health	0.4	0.4	-	0.4	0.4	-
Investment in medical facilities	3.1	4.7	5.5	3.1	4.7	5.1
Public health & prevention	3.7	3.7	3.4	3.5	3.3	3.2
Medicines	32.7	32.7	32.7	1.0	1.2	0.5
Medical devices	-	-	-	-	-	-
Medical services	56.6	52.1	52.6	43.9	42.4	44.2
Inpatient care	24.5	23.6	27.1	24.2	23.2	22.2
Day care	0.4	0.3	0.4	0.4	0.3	0.4
Outpatient care (excl. dental)	12.7	12.7	14.3	10.8	10.8	13.0
Outpatient dental care	1.4	1.4	1.4	0.9	0.8	0.8
Ancillary services	4.5	4.5	4.6	1.1	1.1	1.2
Home care	-	-	-	-	-	-
Treatment in psychiatric & addition hospitals & care clinics	2.5	2.5	-	2.3	2.3	-
Long-term care	0.2	0.2	0.1	0.2	0.2	0.1
Rehabilitation	7.4	6.9	4.8	4.0	3.8	-
Other unclassified services	1.1	1.1	2.8	0.6	1.1	-

Source: State Statistics Committee of Ukraine, 2010.

A final defining factor is the fact that pharmaceutical companies advertise medicines directly to the public (in addition to professionals), which is compounded by the fact that pharmacies generally sell any medicine to any customer without requiring a written prescription. That situation gives a perverse incentive to the supply-side players to sell expensive medications. According to senior officials from the World Health Organization (WHO) and the MOH who were interviewed in December 2014, that translates to a severe mismatch between the prevalent burden of disease and the most sold medicines in both value and volume.

When one focuses on the demand side of the pharmaceutical market in Ukraine, the number of companies involved in retail distribution fluctuated during the past decade and stood at 22,072 in June 2011. Of those companies, approximately three-quarters are privately held, with chain pharmacies becoming a significant market force.

There are serious concerns regarding the processes of public procurement of medicines in Ukraine, with most of the attention directed first on the wholesalers and distributors and then on

³² “Kvitashvili Wants to Bring in \$10 Billion Ministry of Health,” BusinessUA.com, February 20, 2015, <http://businessua.com/medic/16370kvitashvili-hoche-povernuti-v-moz-10-mlrd.html>; Ukraine Health Systems Review. Lekhan V, Rudy V, Richardson E. Health Systems in Transition 12(8):1–183. 2010

the local manufacturers. A salient example of the latter would be Indar, a local manufacturer that managed to secure half of the allocated public budget for insulin (USD 21.7 million) immediately on entry to the market.³³

The wholesale market comprises 320 companies, with approximately 5% belonging to the state or community.³⁴ The structure of the private sector supply chain is shaped by five large wholesaler-importers that bring in 80% of the drugs from international manufacturers or suppliers and then sell them to private hospitals, retail pharmacies, or drug outlets. Apart from the horizontal consolidation following mergers and acquisitions, some vertical integration has occurred, with some wholesalers creating their own pharmacy chains. Wholesaler concentration has been a common trend in well-developed and competitive markets because of economies of scale. For instance, by 2004, the top three wholesalers in Europe accounted for approximately 55% of total sales in France, Germany, and the United Kingdom³⁵ and approximately 90% in the United States.³⁶ However, in Ukraine, the lack of oversight in the wholesale market raises serious concerns on its overall efficiency and transparency and has been pointed to as one of the major corruption-enabling areas.³⁷

Ukraine was a key site for the manufacture of medicines in the former Soviet Union. As a consequence, it has approximately 160 registered manufacturers today, even if most of them are basically repackaging instead of self-manufacturing. The production of more than 1,500 chemical entities has been declared, of which the vast majority are generics. The top four manufacturers—Pharmak, Arterium Corporation, Yuri Pharm, and Darnika—account for approximately 60% of domestic production.³⁸ There has been a strong drive by the State Administration of Ukraine in Medicinal Products (SAUMP) and market forces (focusing on exportation) to make all of them compliant with good manufacturing practices (GMPs). On its part, Ukraine GMP Inspection became a member of the Pharmaceutical Inspection Co-operation Scheme in January 2011.³⁹ The local manufacturing companies export pharmaceuticals valued at USD 234 million to 55 countries. As a result, according to the State Statistics Committee, Ukraine has a positive trade balance in pharmaceuticals.

³³ Who makes money on epidemics of HIV/AIDS in Ukraine Anticorruption Action Centre, 2013.

http://network.org.ua/upload/novosti/zvit_Who%20makes%20money_eng.pdf

³⁴ Ukraine Health Systems Review. Lekhan V, Rudi V, Richardson E. Health Systems in Transition 12(8):1–183. 2010.

³⁵ Werner Clement, M. T. (n.d.). Bundesverband des pharmazeutischen Großhandels. Retrieved January 09, 2015, from The European Pharmaceutical Wholesale Industry: Structure, Trends, and socio-economic importance: http://www.phagro.de/_phagro/upload/standpunkte/5f2908e7-2729-46a6-850f-b348243dbf77.pdf.

³⁶ Turner Investments. (2011, January 28). Turner Investments. Retrieved January 09, 2015, from Why the Big Three drug distributors could get bigger: <http://www.turnerinvestments.com/why-the-big-three-drug-distributors-could-get-bigger/>

³⁷ Who makes money on epidemics of HIV/AIDS in Ukraine Anticorruption Action Centre, 2013.

http://network.org.ua/upload/novosti/zvit_Who%20makes%20money_eng.pdf

³⁸ Ukraine Health Systems Review. Lekhan V, Rudi V, Richardson E. Health Systems in Transition 12(8):1–183. 2010.

³⁹ Pharmaceutical Inspection Co-operation Scheme, Accession Dates webpage, www.picscheme.org/accession-dates.php.

The number of pharmacy outlets in Ukraine has fluctuated over the past decade and stood at 22,072 in June 2011. That number included 13,655 pharmacies and pharmacy units (pharmacy subdivisions designed to provide ready-made pharmaceuticals), 5,420 drugstores, and 2,997 pharmacy kiosks, the latter being allowed to sell only over-the-counter medicines.

Approximately three-quarters of those retailers are privately owned, with chain pharmacies becoming a significant market force, only one-quarter of which are owned by the state or community. Consequently, retail outlets are concentrated in urban areas, with only approximately 15% of them in rural areas, which usually translates into higher prices in nonurban areas, which account for approximately 33% of the population.

ECONOMIC AND EXTERNAL FACTORS

Ukraine is now considered a lower-middle-income country, with political instability contributing to an 8.2% contraction in GDP in 2014 and a 2015 forecast for a further decline of 2.3%.⁴⁰

The total value of the Ukrainian pharmaceutical market during the first six months of 2014, including hospital procurement and retail sales, was approximately USD 18.5 billion for approximately 633 million units. That figure represents an approximate 12% increase in value compared with the same period in the previous year, but a decrease of approximately 5% in volume. The increase occurred entirely in the retail sector, because the hospital sector actually declined slightly in volume (by 3%) but decreased more in value (by approximately 17%).⁴¹ Taking into account the GDP contraction mentioned previously, which was accompanied by a currency devaluation of approximately 30% compared with hard currencies such as the US dollar or the euro, those figures are surprisingly good.

In the early 2010s, medicines were tax-exempt.⁴² But since April 1, 2014, they have been subject to a VAT at a reduced rate of 7% (usually 20%) on the “supply of medicines and medical products allowed for production and consumption in Ukraine, and included on the State Register of Medicines and on supply of medical products according to the list approved by the Cabinet of Ministers of Ukraine.”⁴³ However, from interviews with supplier and manufacturer associations, and in the opinion of other experts,⁴⁴ a lack of clarity in the drafting of the law resulted in medicines being charged the regular 20% VAT at customs during the first few months. Even if in principle that VAT differential should have been reimbursed after a VAT return was filed, the reimbursement did not happen. Later, the situation was corrected, and the 7% VAT supported by the final buyer is now being applied to registered medicines (20% for those unregistered and used for clinical trials).

Another factor affecting medicine prices in Ukraine is related to external price referencing, which can be described as “the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country.”⁴⁵ Ukraine uses this tool, which will be further discussed under the “Pricing” section. For the moment, it should be noted that Ukraine is one of the benchmark countries used to calculate medicine prices in Russia, which itself is a reference country for China. The fact that both Russia and China represent large potential

⁴⁰ “Ukraine’s GDP to Decrease by 2.3% in 2015.”

⁴¹ Apteka online. (2014, 11 03). Hospital purchases in Ukraine in the I half of 2014. Retrieved 11 21, 2014, from <http://www.apteka.ua/article/311629>

⁴² According to the Revenue Code of Ukraine, sp. 197.1.27, p. 197.1 art. 197, p. V, as of December 2, 2010, no. 2755-V.

⁴³ As below

⁴⁴ “Introduction of VAT on Medicines and Medical Products,” KPMG International.

⁴⁵ WHO and HAI, Project on Medicine Prices and Availability, Working Paper 1, “External Reference Pricing.” May 2011

markets could negatively influence the prices that manufacturers will be willing to register in Ukraine, and examples of such behavior have been described in the literature.⁴⁶

However, some mechanisms may be used to avoid that situation, thus reducing price transparency by introducing either confidential rebates or some kind of discount or rebate under no-disclosure conditions. Hence, there is no way to ascertain whether that fact has a negative effect in Ukraine, but it is still worth mentioning. However, those mechanisms introduce a loss in accountability together with the reduction in price transparency, and that situation would pose an additional challenge in the Ukrainian context.

⁴⁶ P. M. Danzon and A. J. Epstein, “Effects of Regulation on Drug Launch and Pricing in Interdependent Markets,” NBER Working Paper 14041, National Bureau of Economic Research, Cambridge, MA, 2008; A. Richter, “Assessing the Impact of Global Price Interdependencies,” *Pharmacoeconomics*, 26 (2008): 649-59.

REGULATORY ISSUES

As briefly discussed earlier, the laws of supply and demand are the dominant factors in determining the price of a commodity in an ideal, perfectly competitive market. One of the characteristics that differentiates real markets from ideal ones is that the number of players is not “infinite,” and some may be large enough to apply unfair influence in price setting. When the commodity in question is a public good, such as water, energy, or medicines, governments impose regulations to help moderate prices at reasonable levels. What constitutes a “reasonable” price for medicines is contentious, but most professionals in the field will agree that fair prices should generate sufficient profits to sustain a healthy number of both manufacturers (both originator and generic) and suppliers, while ensuring that access to treatment is within reach for most patients.

This section will describe the regulations in place in Ukraine (excluding price regulation, which will be covered in the following section) and will investigate how they affect prices.

The State Expert Centre (SEC) has the primary responsibility for market authorization, that is, the registration and licensing of medicines and premarket assessment and quality control, as well as responsibilities for clinical trial oversight, pharmacovigilance, and rational use of medicines, including development of the National Drug Formulary. The SEC is completely funded through fees and charges for services, with no contribution from the state budget. Conversely, SAUMP—which has been responsible since 2009 for licensing wholesalers, manufacturers, and retail pharmacies, as well as post-market quality control—is fully funded by the MOH through the state budget. To fulfill its mandate, SAUMP has a network of laboratories across the country. GMP inspection, as well as the inspection of pharmacies and distributors, is also the responsibility of SAUMP.⁴⁷

Even though both agencies have solid reputations for the most part, there is a lack of coordination between them and no sense of a coherent national strategy. Another area of concern mentioned by some stakeholders interviewed for this report was the paucity of well-trained personnel and adequately equipped and supplied laboratories, particularly for on-market quality assurance and pharmacovigilance.

Medicine price registration is one of the processes that, although ensuring that only efficacious and safe medicines enter the pharmaceutical market, is supported by the medicine sale price. In Ukraine, a complete registration dossier for a new medicine is evaluated by the SEC within 210 calendar days. However, the SEC may request additional information, in which case the evaluation period may be extended for another 90 days. After the expert evaluation phase has been completed, the results are submitted to the MOH, and it takes another 30 days for a marketing authorization to be issued. The fee for the expert evaluation of the registration dossier is approximately USD 2,200 (Hrv 60.480) for a new chemical entity and approximately USD 1,500 (Hrv 41.760) for a generic compound.

⁴⁷ Ukraine Health Systems Review. Lekhan V, Rudyi V, Richardson E. Health Systems in Transition 12(8):1–183. 2010.

Contractual penalties resulting from inspection delays are borne by suppliers. Those costs are all built into their markups so that there is no transparency regarding the cost of those penalties or of additional warehousing costs in their quoted prices. An interview with Pharmak, the largest local manufacturer at the time of this writing, revealed some anecdotal evidence that inspections are frequent, with the figure of approximately 70 inspections during 2014 having been mentioned.

PROCUREMENT AND PRICING

The following section will cover the procurement processes, including a description of distribution and management; in the case of Ukraine, the costs of those activities are incorporated in the tendered medicine prices. The terms set out in the request for tenders shape the conditions that selected suppliers must meet when executing their contracts, including (a) financial conditions before and after award; (b) quantities, which may or not be flexible; (c) quality; and (d) logistics expenses, which may include customs and distribution to multiple points according to specified scheduled deliveries. All of those factors will directly affect the costs faced by the supplier and, consequently, the price that may be offered under those conditions.

Processes

Procurement of medicines and medical supplies is centralized for all products relevant to the national programs, which include treatment for the following: HIV and AIDS, tuberculosis, oncological diseases, cardiovascular diseases, cerebrovascular diseases, viral hepatitis, hemophilia, autism, and Gaucher's disease. Some of these programs receive financial support from donors, as HIV and AIDS and tuberculosis from the Global Fund, which is depicted in Figure 2.

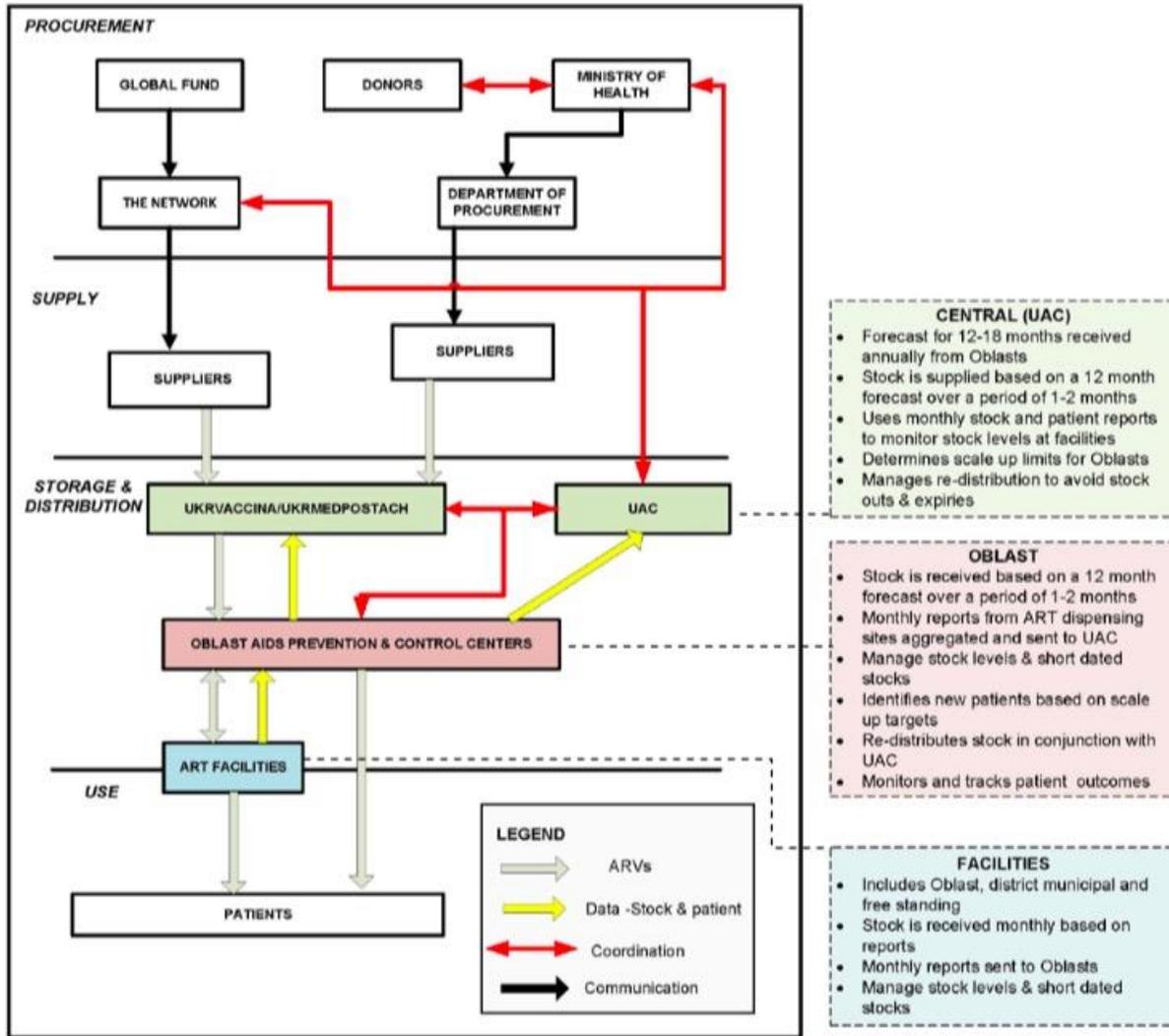


Figure 2. Characterizing the public-sector supply chain for ARV medicines in Ukraine⁴⁸

For all other commodities, a decentralized system is in place in which every oblast and government facility takes part, with varying levels of involvement depending on the oblast policies and type of facility. The following description covers only centralized procurement, because there is no consistency in the ways in which individual oblasts manage their pharmaceutical procurement.

The procurement process for the pharmaceuticals and supplies used in the national programs starts with a budgeting estimate by the MOH Department of Economics and Finance (DoEF) by spring, followed by an assessment of needs by the MOH by early summer of the previous year.

⁴⁸ Duarte, K., & Walkowiak, H. (2011, 09 20). Strengthening Pharmaceutical Management Information Systems for the HIV Program in Ukraine: Assessment and Identification of Areas for Technical Support. Retrieved December 7, 2014, from WHO: <http://apps.who.int/medicinedocs/documents/s21034en/s21034en.pdf>and.

The budget is established using the previous year's figures with adjustments for specific initiatives, which must be accompanied by reasonable justifications.

When the Ukrainian national budget is approved, the Ministry of Finance allocates a total budget figure for the MOH; that figure is converted to an itemized budget by a working group led by the deputy minister of health. The itemized budget must abide by all funds earmarked for specific programs and must incorporate those initiatives that have been determined worth funding, after factoring in the availability of funds and other requests from competing initiatives presented during that budgeting cycle.

The detailed budget is presented to the Cabinet of Ministers and upon approval is sent to the Parliament for official adoption. At that point, the Ministry of Finance communicates to the DoEF an anticipated monthly schedule for the release of funds. It should be noted, however, that those schedules do not materialize, and typically approximately 40% of the total funds are made available during the first two quarters of the year, with most of the remaining budget becoming available only during the fourth quarter, if at all. Taking that into account, the DoEF prioritizes funding for some programs during each quarter, at the expense of others.

Ukraine has legislation (Order 1071) that regulates which medicines may be procured using public funds, regardless of whether procurement is done at the national or decentralized level. The revision of that list of medicines is undertaken by the Therapeutics Department, which involves lead specialists. The list is extensive, and stakeholders have estimated that it probably covers approximately 80% of all registered medicines in the country. The length of the list is a problem, because it allows for the procurement of expensive medicines that may have significantly cheaper therapeutic equivalents, resulting in wasteful public spending and depletion of already-limited monetary resources.

The Procurement Department, nominally within the MOH, is an opaque entity, and it has proved difficult to obtain information regarding its structure, operating rules, or responsibilities. Thus, the system is founded on a desirable separation of the processes of selection and quantification on one hand and the tendering, procurement, and management of contracts on the other. Unfortunately, the general paucity of checks and balances undermines the department's proper, transparent, and efficient functioning.

For example, a particular cause for concern is the fact that the requirements or process for becoming a member of the Procurement Department could not be ascertained, but it is widely believed that some of its members have informal links with the Therapeutics Department,⁴⁹ causing a clear conflict of interest. As a consequence, according to all stakeholders consulted and in agreement with the reports consulted, public procurement does seem to be underperforming in two major areas: (a) product availability and delivery dates at the facilities are both unpredictable, and (b) procurement prices tend to be much higher than those procured in international markets⁵⁰ by other countries or international agencies, such as the United Nations Children's Fund or the International Development Association. Strongly related to those two

⁴⁹ Private communications during interviews with local CSOs.

⁵⁰ Management Sciences for Health, International Drug Price Indicator Guide (Medford, MA: MSH, 2014), <http://erc.msh.org/priceguide>.

areas, market oversight appears to be lacking, resulting in collusion and monopolistic practices, together with unnecessary public spending (figure 3).⁵¹

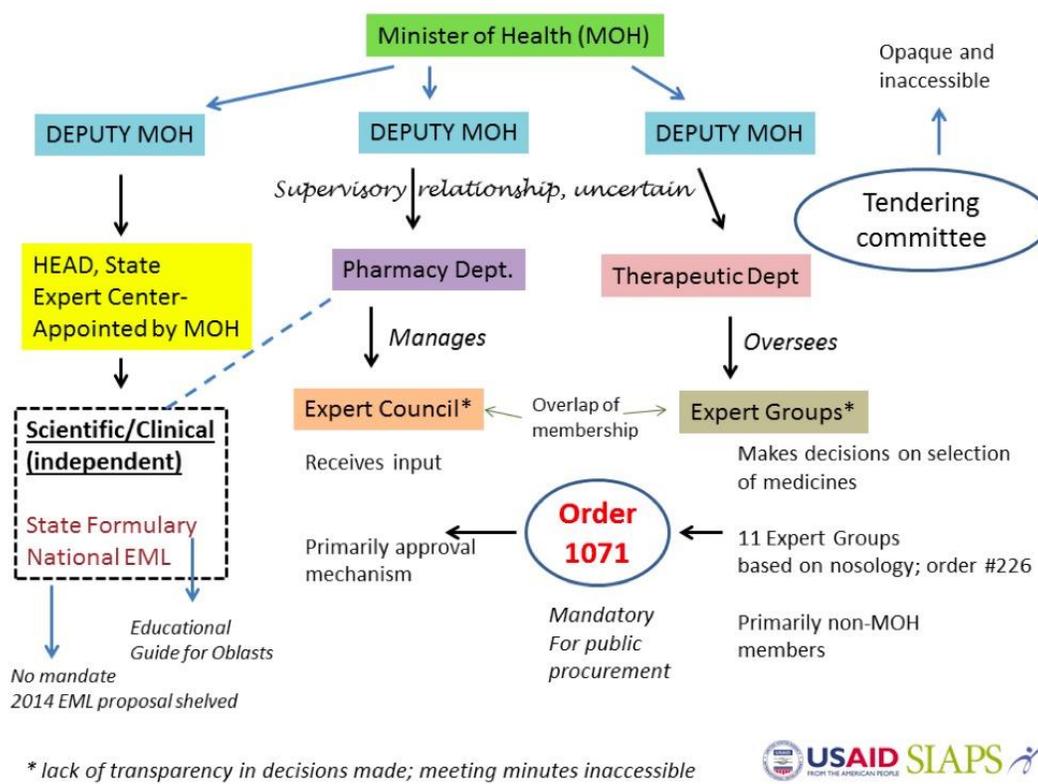


Figure 3. Selection and procurement of medicines for the public sector in Ukraine

Given the risk of their budgets being cut, facilities try to use all their funds as soon as they become available; therefore, they try to purchase all their medicines and medical supplies once a year. That approach is in line with Ukraine’s current scheduling for receiving medicines centrally procured by national programs once a year, thus creating logistics bottlenecks and associated problems.

However, in 2014, the biggest problem was the failure of the public tenders at both the central and decentralized levels. So by late August, only approximately 25% of the medicines that were centrally procured, whose needs were first forecast and later adjusted downward because of inadequate funds, were obtained, thus forcing patients to pay for them out of pocket. That figure improved to approximately 80%, but only at the end of the year. There are no data regarding the percentage of failed tenders at the oblast level, but anecdotal evidence indicates that, even if the situation is strongly dependent on the oblast, they have generally not been successful either.

⁵¹ Ukraine Health Systems Review. Lekhan V, Rudy V, Richardson E. Health Systems in Transition 12(8):1–183. 2010.

Those failures are related to the fluctuations of Ukraine's currency, which lost approximately 50% of its value in 2014, and an inherent inflexibility in the tendering. Typically, public tenders for medicines in other countries incorporate some flexibility in the quantities to be procured at the same unit price to cover for unexpected changes in demand. However, that flexibility was not legally possible in Ukraine until a cabinet resolution was adopted at the end of the year to tackle that particular issue. If such flexibility had been an option earlier in Ukraine, the currency exchange fluctuation would have translated into the government's being able to procure more limited quantities of most medicines, which ideally should have been done by prioritizing the medicines most needed to obtain the full, forecasted quantities and by cutting down on the others.

In Ukraine, however, the tenders had to include the exact quantities and prices reflected in the detailed budget approved by the Parliament; at the moment the tenders were floated, those medicines no longer reflected current market prices. When tenders fail, Ukrainian law forces the government entities to republish the tenders without making any adjustments, so that situation, given the current economic situation, translated into a chain of failed tenders. It appears that the tendering process should be redesigned to include more flexibility, by tendering for unit price instead of quantities or by using framework contract agreements. Finally, simplifying the process will attract more reputable international manufacturers and wholesalers, while increasing transparency as well.

Pricing

Medicine price regulations may have two distinct targets, depending on whether the intervention affects (a) the costs of the medicines for the suppliers (i.e., supply-side regulations), which include manufacturers, wholesaler-importers, and retailers; or (b) the price paid by the final consumer (i.e., demand-side regulation), which may be the patient, an insurance company, or the government in a publicly funded health system. The demand-side regulations focus on various types of price referencing that aim at increasing the market competition by using reimbursement mechanisms.⁵²

Ukraine has a supply-side decentralized regulation that establishes the maximum wholesale and retail markups for pharmaceuticals and medical devices. The activities carried out by wholesalers and retail pharmacies, together with the EU averages, are described in table 3.

⁵² Kurt Richard Brekke, Tor Helge Holmås, and Odd Rune Straume, "Comparing Pharmaceutical Prices in Europe: A Comparison of Prescription Drug Prices in Norway with Nine Western European Countries," SNF Report 11/11, Institute for Research in Economics and Business Administration, Bergen, October 2011.

Table 3. Activities of Wholesalers and Retail Pharmacies

Importer/wholesaler	Retail pharmacy
Forecast and consolidate orders from multiple pharmacies	Select wholesaler (when no fixed contract exists)
Negotiate prices with suppliers	Create marketing materials
Expedite product clearance at points of entry	Prescribe and dispense appropriate medicines; advise patients on how to take medicines
Provide warehousing at primary location	Inventory stocks, prevent losses
Distribute to secondary locations	Assume partial risk for overstocked and expired products
Manage stock	Provide credit between dispensing medicines and receiving payments from insurance companies or MOH
Pay suppliers before receiving payment from buyers (pre-financing)	
Perform quality control	
Assume partial risk for overstocked and expired products	

In Ukraine, depending on their perceived importance, medicines are classified using four separate lists—

- National list of essential medicines and medical devices, 2009 (2,682 medicines)
- State Formulary of Medicines, 2009 to 2012, 1st through 4th editions
- Mandatory minimum assortment (socially oriented) pharmaceuticals and medical products for pharmacies (approved by MOH Order 1000, December 29, 2011)
- Cabinet of Ministers Resolution 1071, September 5, 1996, “The procedure for pharmaceuticals purchased for health care institutions, financed from the budget” (last amended March 28, 2011)

For medicines included on those lists, the maximum allowable markup levels are detailed in table 4.

Table 4. Maximum Allowable Markups in Ukraine for Price-Regulated Medicines

Regulation under which the medicine falls	% Wholesale markup	% Retail markup
Regulation 1071	10.0	10.0
Regulation 333 (EML)	10.0	25.0
Regulation 1000 (100 < 300)	10.0	23.0
Regulation 1000 (300 < 500)	10.0	20.0
Regulation 1000 (500 < 1,000)	10.0	15.0
Regulation 1000 (> 1,000)	10.0	10.0

Those levels are applied to the procurement prices that are compared with the registered prices, which are used as a ceiling, since the MOH approved Order 705 on September 7, 2012: “On approval of the register of wholesale prices of medicines and medical devices, order modifications and dosage forms for declaration of change of wholesale prices for the medicine or the medical devices.” Table 5 illustrates how those markups compare with those across the European Union.⁵³

Table 5. Average Wholesaler and Retail Markups for Medicines in the European Union^a

EU country (data year)	% Wholesale markup	% Retail markup
Austria (2008)	6.5-13.4	19.2
Belgium (2007)	8.4	-
Bulgaria (2007; 2009)	7.0-10.0	18.0-22.0
Czech Republic (2007)	4.3	-
Denmark (2009)	6.0-7.0	19.3
Estonia (2009)	-	19.0
Finland (2008)	3.0	23.6
France (2007)	6.2	-
Germany (2004; 2007)	4.0-6.1	24.0
Greece (2007)	4.0	-
Hungary (2005; 2007)	6.0-6.4	19.5
Italy (2010)	3.0	-
Latvia (2008)	3.3	19.0
Lithuania (2005)	8.0-9.0	-
Luxemburg (2007)	-	46.7-50.2
Malta (2009)	15.0	20.0
Netherlands (2007)	13.0-24.0	-
Poland (2007)	9.8	-
Portugal (2007; 2008)	6.9	18.3
Romania (2007; 2008)	10.0-14.0	12.0-24.0
Slovenia (2007)	8.0-9.0	2.1 euros
Spain (2007)	3.5	-
Sweeden (2009; 2008)	2.0-3.0	21.3
UK (2007)	12.5	-

^aNo information is available for Cyprus, Ireland, and Slovakia.

⁵³ Panos Kanavos, W. S. (2011, March). The Pharmaceutical Distribution Chain in the European Union: Structure and Impact on Pharmaceutical Prices. Retrieved January 09, 2015, from EmiNet: http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/structimpact_pharmaprices_032011_en.pdf

A register of wholesale prices of medicines and medical devices is available on the MOH website.⁵⁴ The importer's registration supplies the "post-customs" price, together with the retail prices in the countries included in the reference country basket. A formula is applied, and the result obtained is the highest price at which the medicine or medical supply may be offered in a public tender.⁵⁵

Pricing formulas differ for domestic and imported medicines.⁵⁶ For those medicines that have no registered prices, the markups are applied to the prices declared in the custom forms, issued by the importers (e.g., wholesalers) at the border. Hindering transparency even more, the customs database is classified and is available only to the Ministry of Revenue and Duties.⁵⁷

Local manufacturers are required to submit a form to the State Register indicating the wholesale price to their customers.⁵⁸ No other supporting documentation is required by the MOH nor by the state pricing inspection, even if each has the right to do so. Consequently, domestic prices are easily inflated. This fact has been well documented, and the Antimonopoly Committee has publicly recognized that medicine prices in the State Register are overinflated.⁵⁹

To contain prices, the Cabinet of Ministers adopted Order 240 "on referential pricing on medicines and medical products, purchased with funds from the state and the local budgets." In accordance with that order of March 1, 2015, public health care facilities will no longer be able to procure any of the medicines included in Order 1071 for which a new wholesale price has been registered or reregistered, which currently stands at about one-third of those previously registered, potentially affecting the availability of important medicines in every therapeutic class.⁶⁰

Another supply-side price-regulating mechanism at play is a 2.5% distribution markup ceiling for medicines and medical supplies procured with public funds. That cost has to be absorbed by the supplier in its bid offer, which makes it difficult to ascertain the performance of the supplier in this particular field and which hinders the natural competition that would force those costs to decrease as the market matures.

It should be noted that several studies have found significant regional differences in medicine prices and in both wholesale and retail markups as a consequence of the decentralized implementation of the regulations. For instance, a study conducted in 2012 found that wholesaler

⁵⁴ Register of Bulk Release Prices, http://www.moz.gov.ua/ua/portal/register_prices_drugs/.

⁵⁵ Decree of the Cabinet of Ministers, "On Taking Measures for Stabilizing the Prices for Medical Remedies and Medical Products," <http://zakon2.rada.gov.ua/laws/show/955-2008-%D0%BF>.

⁵⁶ Decree of the Cabinet of Ministers, "On Certain Issues Regarding the State Regulation of Prices for Medical Remedies and Medical Products," <http://zakon2.rada.gov.ua/laws/show/333-2009-%D0%BF>.

⁵⁷ Article 56 of the Customs Code of Ukraine, <http://zakon1.rada.gov.ua/laws/show/4495-17/page3?text=%E4%E5%EA%EB%E0%F0%E0%F6%B3%FF>.

⁵⁸ Decree of the Cabinet of Ministers, "On Taking Measures for Stabilizing the Prices for Medical Remedies and Medical Products," <http://zakon2.rada.gov.ua/laws/show/955-2008-%D0%BF>.

⁵⁹ Who makes money on epidemics of HIV/AIDS in Ukraine Anticorruption Action Centre, 2013. http://network.org.ua/upload/novosti/zvit_Who%20makes%20money_eng.pdf

⁶⁰ "On March 1, 2015 Hospitals Will Not Be Able to Buy Most of the Drugs from the Range of 2014 Due to the Absence of the Declared Wholesale Prices," Apteka, March 2, 2015, <http://www.apteka.ua/article/325160>.

markups did not exceed 10%, and retail markups were also below their regulated maximums of 25%. In fact, the study found that some wholesalers were selling medicines at less than their registered procurement prices, which may have been due to volume discounts or rebates.⁶¹ However, large differences have been found not only between regions but also within regions.

A study conducted by the MOH has found that the application of those regulations has had a positive effect, which indicated that retail markups decreased from more than 23% to less than 14% of formerly unregulated medicines, once they were included on the corresponding list of regulated medicines. However, those supply-side interventions do not regulate final prices, and markups are applied to the prices paid for imported medicines (by a wholesaler) or imported active pharmaceutical principles used in the manufacture of generics, both of which were heavily affected by the severe currency exchange-rate fluctuations in 2014.⁶² Furthermore, as previously mentioned, offshore companies have been widely used to artificially inflate drug prices.⁶³ Currently, no mechanism exists for monitoring prices, which hampers evidence-based policy making in the area,⁶⁴ even though Ukraine joined the Pharmaceutical Pricing and Reimbursement Information Network in March 2013.⁶⁵

Given the limitations encountered by the supply-side regulations, the government has also become interested in testing demand-side interventions, starting with a pilot project on price regulation and reimbursement of hypertensive medicines and insulin (Decree 340 of the Cabinet of Ministers of April 25, 2012, “on the implementation of the pilot project on introduction of state regulation of prices for medicine for the patients with arterial hypertension treatment”). Information about the production price, on top of which the wholesaler and retailer markup are added, together with external referencing, is obligated for reimbursement.⁶⁶ This pilot project has been designed as a first demand-side approach for regulating medicine prices in Ukraine, thereby establishing a ceiling for the maximum reimbursement allowed and effectively capping the prices at which medicines should be sold.

Although insulin is still in the preparatory phase, the pilot project has begun in all oblasts with seven substances and two fixed-dose combinations for the treatment of hypertension—enalapril, lisinopril, bisoprolol, metoprolol, nebivolol, amlodipine, and nifedipine—with five major

⁶¹ Medicines prices, availability, affordability and price components, Ukraine. Health Action International (HAI) and World Health Organization (WHO), 2012.

⁶² “Ukraine Currency Hits Record Low against Dollar,” Yahoo! News, August 12, 2014, <http://news.yahoo.com/ukraine-currency-hits-record-low-against-dollar-140817457.html>.

⁶³ Addendum 1 d/d 07.10.2013 to the report of the Provisional Investigatory Commission of the Verkhovna Rada of Ukraine for investigating the facts of legislative violations during the realization of public procurement, inefficient application of budget funds and the abuse of office conducted by the officials of the Ministry of Health of Ukraine, other state enterprises, institutions, and organizations working in the field of health care and pharmaceuticals. http://w1.c1.rada.gov.ua/pls/zweb2/webproc4_1?id=&pf3511=48559.

⁶⁴ Ukraine Health Systems Review. Lekhan V, Rudiy V, Richardson E. *Health Systems in Transition* 12(8):1–183. 2010.

⁶⁵ Pharmaceutical Pricing and Reimbursement Information.

http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/national-systems/index_en.htm

⁶⁶ Apteka online. (2014, 11 03). Hospital purchases in Ukraine in the I half of 2014. Retrieved 11 21, 2014, from <http://www.apteka.ua/article/311629>.

reference countries (Bulgaria, the Czech Republic, Moldova, Poland, and the Slovak Republic) and three additional reference countries (Hungary, Latvia, and Serbia).⁶⁷ The pilot was not widely regarded as successful, and both the selection of medicines included in the program and slow government reimbursement were mentioned as major barriers to wider adoption. MOH officials associated with the pilot, however, maintain that the health outcomes were positive, citing a clear increase in the number of patients complying with their treatments.

The pilot project has been discontinued in 2015, on the grounds of budget cutting. There are concerns that this attempt may have created a negative market perception of reimbursements schemes, which are currently being actively considered by the Government of Ukraine as a potential approach to trying to improve its service to the Ukrainian population.

⁶⁷ Zalis'ka, O. (2013). Pricing of Pharmaceuticals in Emerging Countries of the Central & Eastern European Region: The Case of Ukraine. ISPOR 18th Annual International Meeting. New Orleans: ISPOR Central-Eastern European Network Forum.