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DRUG PROCUREMENT POLICY IN UKRAINE: IS THERE A «WINDOW OF OPPORTUNITY»?

ПОЛІТИКА ЩОДО ЗАКУПІВЛІ ЛІКІВ В УКРАЇНІ: ЧИ Є «ВІКНО МОЖЛИВОСТЕЙ»?

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Abstract

Using documentary analysis and other qualitative methods we analysed current policies on state procurement, pricing, and health technology assessment, as well as historical aspects of drug reimbursement in Ukraine. The analysis was done through a prism of the Multiple Streams Framework or Kingdon's model.

Ukraine currently has a generic-oriented market of drugs (medicines, vaccines, and supplements for diagnostics), characterized by insecure patent protection, bureaucratic and unstable procurement regulations, corrupt practices and an unstable economic background.

The research shows that over the past 15 years Ukraine has made multiple attempts to develop and implement health insurance and a drug reimbursement system, while the main mechanisms for drug procurement remained in the form of centralized and regional tenders. Health technology assessment is being considered, but not used formally. Incremental policy changes initiated by the Ministry of Health in 2014-2016, have not yet reshaped the post-Soviet system of healthcare financing. The implementation of the modern approaches recommended by the international organisations and the fight against corruption were doomed to failure by disagreements among multiple stakeholders, many of whom with vested interest. Similar challenges to health policy elaboration and implementation are observed in other Central European and former Soviet states.

Key words: *Kingdon's model, health policy, procurement system, policy entrepreneurs, policy coherence.*

Анотація

Використовуючи аналіз документів та інші якісні методи ми проаналізували поточну політику щодо державної закупівлі ліків, їх ціноутворення та оцінки медичних технологій, а також історичні аспекти відшкодування вартості ліків в Україні.

Дослідження засвідчує, що за останні 15 років Україна зробила кілька спроб з розробки та впровадження медичного страхування та системи компенсації вартості ліків, однак централізовані і регіональні тендери залишаються основними механізмами закупівель лікарських засобів. Оцінка медичних технологій обговорюється, але офіційно не використовується. Поступові політичні зміни, ініційовані Міністерством охорони здоров'я в 2014-2016 роках, досі не змінили пострадянську систему фінансування охорони здоров'я. Реалізація сучасних підходів, рекомендованих міжнародними організаціями, та боротьба з корупцією стримуються розбіжностями між кількома зацікавленими сторонами, багато з яких має корисливі інтереси. Схожі проблеми в розробці і здійсненні політики в галузі охорони здоров'я спостерігаються в інших країнах Центральної Європи і колишнього Радянського Союзу.

Ключові слова: *модель Кінгдона, політика охорони здоров'я, система закупівель, політичні ділки, узгодженість політики.*

Introduction Since its independence in 1991, Ukraine has been claiming the implementation of health care reforms. Some authors noted the failure of the undertaken measures and a lack of systemic or large-scale transformations (Lekhan et al., 2015; Semigina, 2013). Thus, the hierarchically structured system of healthcare, its outdated governance (World Bank, 2015), as well as the political, economic and social principles of health policy have remained mainly unchanged from Soviet times. At the same time, marketization of all areas of life in Ukraine resulted in new formal and informal economic practices within the system of healthcare and pharmaceuticals (Stepurko, Pavlova, Gryga, Murauskiene & Groot, 2015).

In 2015-2016, the civil society pushed the Ukrainian government to introduce a number of institutional changes into the current drug procurement policy. The issue of drug provision is perceived as one of the most challenging areas of health policy (Patients of Ukraine, 2016). However, these temporary innovations have not yet embedded into a broader healthcare financing reform, nor into the strategic revision of health policy goals.

This paper analyzes the drug procurement policy in Ukraine through a prism of the Multiple Streams Framework or Kingdon's model (Kingdon, 1995). Focusing on the problems, policy and politics streams, the authors look at the societal and institutional dimensions of the drug procurement policy and examines why health policy decision-making failed to introduce the approaches recommended by the World Health Organisation (WHO) – universal health insurance, health technology assessment and other instruments to ensure equity in health and avoidable deaths (WHO, 2012). The paper is based on desk-review that included analysis of legislative acts, draft laws, political and other documents, as well as non-structured interviews with health policy stakeholders, including discussions during the Summer School «Transformations of Healthcare System: Eastern Europe» (Ukraine, L'viv, 18-23 July 2016).

Thematic analysis (Ryan&Bernard, 2003) was applied to process the data. Specific considerations were given to: (a) historical and current state purchasing mechanisms and regulations, pricing policies; (b) attempts to implement reimbursement for drugs and other health policy changes; (c) policy options for further changes in drug procurement policy. The results of the research are presented in the descriptive analysis. We are aware of the limitations of this analysis based on the qualitative methods of research, yet we hope it will add another layer into the picture of understanding the challenges and realities of the public policy within a post-socialist society.

Theoretical Framework Current debates about the processes of health policy decision-making (Bartlett, Bozikov & Rechel, 2012; Figueras &McKee, 2012; Marmor & Wendt, 2012; Rachel &McKee, 2014) demonstrate the limitations of applying rational, evidence-based approaches, which are so valued by health scientists and political analysts (Lomas & Brown, 2009; Lomas et al., 2005;Platt et al., 2013). Some researchers (Cacace et al., 2013) suggest that in many instances health policy is an irrational and dynamic process dealing with entities of substantial complexity. At the same time, it may be framed by societal expectations and political legacies (Etiaba et al., 2015;Reising et al., 2015). Monaghan (2011) and Ruger (2010) pointed out that ideas of equity and social justice, as well as traditional level of commodification and state intervention, economic visions and legal frameworks matter in political decisions on health issues. Thus, Multiple Streams Framework (MSF) can be used for health policy analysis, as it takes into account the complex nature of such policy.

The MSF was first proposed by John Kingdon in 1984 as an explanation of a policy change (Kingdon, 1995).The main underlying assumption of the MSF concept is the belief that policymaking is unpredictable. The framework centres on three different streams – problem stream, the policy stream, and the politics stream that are floating in constant parallel within the policymaking environment. The problem stream refers to those issues or situations that capture public attention, including that of the government. They may come to government's attention through feedback on existing policy programmes, with a focus on events like crisis, or via indicators, such as statistics. The policy stream is conceptualized as a «policy primeval soup», in which policy ideas and solutions are developed, selected or rejected. Policies can be developed independently from problems. The politics stream refers to public opinion, election results, and demands of interest groups. The politics stream also includes such factors as the national mood, administrative or legislative turnover, and pressure group campaigns (Kingdon, 1995).

When the three streams join at critical moments, they constitute a «policy window». When this window opens, the issue becomes a part of the policy agenda and subsequent policy-making steps will ensue. The coupling of streams is determined by the

presence of policy windows and the actions of the so-called policy entrepreneurs (or policy actors) who introduce and promote their ideas on many occasions, investing time and energy into increasing their chances of getting an idea placed on the decision-making agenda (Kingdon, 1995). They are active in both the problem stream and the policy stream, and they must act quickly when the policy window opens, or the opportunity will pass by them (Zahariadis & Exadaktylos, 2016).

It should be noted that Kingdon's MSF is empirically based, with data generated from 247 interviews with transportation and health policy-makers in the US (Kingdon, 1995). It is still actively used in health policy analysis (see: Black, 2001; Guldbrandsson, & Fossum, 2009).

Kingdon was criticized for making no attempts to test the framework outside the US (Sabatier, 1999). Winkel and Leipold (2016) doubt the ability of the MSF to generate insights useful in comparative research. However, other sources describe how the model was applied in policy analysis outside the US and not only for health policymaking, but for educational, infrastructural and other policies (see: Ackrill, & Kay, 2011; Chow, 2014; Ma & Wenfa, 2012; Sager & Thomann, 2016). Knaggård (2015) regarded the MSF as a powerful tool for understanding the policy process and, in particular, agenda-setting in policy, while Béland and Howlett (2016) pointed out advantages of the MSF application to the policy analysis.

Thus, the applicability of the MSF has always been a debated topic in the literature, but this framework addresses ambiguity of policy-making and many ways of thinking about the same problem evoking confusion and stress. The MSF allows to investigate problem framing as a separate process and enables a study of actors that frame problems without making policy suggestions. Health policy with its multifarious approaches to solve the same problem is an area that captures interest of different groups, but it mainly has incremental models of policy formation. Such peculiarities of health policy require a special analytical framework, and for the purposes of our research the MSF providing theoretical ground for the debate on different dimensions of the drug procurement policy in Ukraine without making assumptions of reasons.

Research Findings

Policy stream: current system of health financing, drug procurement and (over)regulation tools

State Health Financing in Ukraine

Until now, Ukraine's healthcare financing mechanism was based on a general taxation system in which expenditures were split between state (national) and regional budgets. In 2015, financing of the healthcare system reached 71 billion UAH (around 3.2 billion USD). In 2005-2015, total volume of financing increased by more than five times. However, such boost may be explained mostly by currency devaluation: the mean annual exchange rate for one USD rose from 5.13UAH in 2005 to 21.85UAH in 2015. The share of state and regional budgets spent on drugs and medical devices varied in each year; in 2014 centralized procurement and regional procurement reached 2.1 billion UAH and 3.9 billion UAH, respectively (State Statistical Service of Ukraine, 2015).

The communication with experts and discussions with health care insiders demonstrate that currently the central state budget is directed towards financing targeted therapeutic programmes and several hospitals of national subordination. In 2015, the national state budget covered the following costs: diagnostic equipment, pediatric vaccination, treatment of HIV, hepatitis B and C, tuberculosis, adult and childhood oncology, cardio-vascular diseases, childhood haemodialysis and phenylketonuria, neonatal screening for genetic diseases, adult nephrology assistance, implants and endo-prosthesis, organ transplantation, blood donations, orphan children and severe diseases, reproductive health, fertility treatment, multiple sclerosis and haemophilia. The regional budget aims to finance healthcare in the regions, districts, cities and other territorial units. Through the preceding years, the regional budgets either co-financed the targeted programmes in the regions (for example, ambulance medical help, oncology, HIV, cardio-vascular disease, and nephrology) or fully covered expenses for specified treatment (for example, insulin for patients with diabetes mellitus).

Regulations on supply of pharmaceuticals

Coverage of the population by «free» pharmaceuticals is a populistic issue within Ukrainian policy. It is rooted historically in Soviet times – free, yet limited pharmaceutical were available for the inpatient care at the hospitals, while outpatient pharmaceuticals were excluded from benefits package of free healthcare. At the same time, patients from many

dispensary groups – e.g. diabetes, asthma – received free medication for life.

Currently, only a few population groups are entitled to free pharmaceuticals, and even fewer people receive «free drugs» in reality. The widest coverage is often allocated to «war veterans», followed by children (of various ages), pregnant and post-partum women, people with disabilities, etc. Also, the state covers outpatient treatment for certain conditions, such as HIV infection, TB, epilepsy, certain psychiatric conditions, asthma and diabetes. Meanwhile, as pharmacies provide only limited availability of free medicines, even these prioritized groups may need to cover these costs out-of-pocket. However, often not all drugs are available at all times at the pharmacies that are allowed to dispense them under government regulation, in which case even those who are formally eligible for free or subsidized medicines, have to purchase them out-of-pocket. Together with out-of-pocket payments, drugs accounted for nearly 40% of total health expenditures in Ukraine (WHO, 2016).

In early 1990s, the pharmaceutical market across the former Soviet Union, including Ukraine, was liberalized, and prices were freed from regulation. While it may have helped to address the existing supply problems, access to treatment was determined by a patient's ability to pay the market-based prices for drugs (RPR, 2016).

It should be also mentioned that in Ukraine, with liberalized drug markets, most drugs can simply be purchased without a prescription over the counter and thus self-treatment is common. Experts speaking out at the conference, pointed out that pharmaceutical manufacturing, distribution and retail are now almost universally based and run for profit by private enterprises.

Current pricing policies in Ukraine limit retail and wholesale margins for the list of essential medicines (Cabinet of Ministers of Ukraine, 2009), and require price declaration for state procurement (Cabinet of Ministers of Ukraine, 2014). Existing state regulation of wholesalers and pharmacy retail prices for a specified list of essential medicines aims to improve affordability and access to these essential drugs to the population. Meanwhile, price declaration mechanisms were established to control state spending on treatment for tender purchases and later for reimbursement.

Despite the price control of the list of essential medicines set at both the national and regional levels, retail prices at pharmacies in different Ukrainian regions can vary by a factor of three (Ministry of Health of Ukraine, 2016b). It is worth to stress that the Ministry of Health (MOH) does not promote and support self-regulation of the pharmaceutical market.

The history of Procurement System and Mechanisms

Until 2015, procurement system in Ukraine included mainly of (1) centralized tenders operated by the MOH and procuring from the state budget and (2) regional tenders operated by regional health authorities, procuring from the regional budgets.

The drugs' registration (Ministry of Health of Ukraine, 2015b) and inclusion into the «List of drugs that can be purchased by healthcare establishments, financed from state and local budgets» – the so-called «list #1071» (Cabinet of Ministers of Ukraine, 2009) – were the first mandatory steps for any drug procurement from state budget. The central state nomenclature committee issued an annual list of products for state procurement and finalized it after regional health authorities submitted requests for their annual quantities. The healthcare authorities can purchase only the products included into the list #1071 (there were 784 positions in 2015), the nomenclature list and based on the wholesaler prices determined by the MOH. The state formulary adopted in line with the WHO Model Formulary (Ministry of Health of Ukraine, 2015a) and unified clinical protocols are recommendatory to follow and may be considered during the review of the list #1071 and tender nomenclature.

Despite similarities, the state drug register, unified protocols, state formulary, and the list #1071 are all independent documents, with each of them falling under separate review processes (Table 1). The drug register is a regularly updated system which includes all of the medical products with approval for realization in Ukraine.

The Ukrainian multi-step tender system lacked a unified approach to evidence review. Such complexity may create corruption risks and effectiveness in the tender system.

The following complementary mechanisms for drug coverage have existed in parallel with the tender system in Ukraine:

1) Private insurance – the sector that is underdeveloped in Ukraine, contributing less than 1% of the total health expenditures (Lekhan et al., 2015). And while the medical insurance market sees positive developments in Ukraine, it involves mainly corporate clients in large cities and private hospitals

2) Single-acting regional sickness funds acting in Ukraine as non-profit or civil organisations collecting financial contributions from their members and providing basic medical and pharmaceutical treatment within the state healthcare system. In contrast to private insurance, members' contributions to sickness funds are small (around 3% of the minimum wage), and so the package of proposed services is limited mostly to the basic treatment of specific diseases within the state hospitals. Such sickness funds can either group their members by residence (sickness funds in Zhytomyr, Poltava, Rivne, and Ternopil regions) or by employer – sickness fund of the police in the capital city, sickness fund of the corporation «Asovstal», etc. (Association of the employees of the sickness funds in Ukraine, 2014).;

Table 1. Characteristic of the documents regulating state procurement

	National drug register	**National formulary**	**Unified clinical protocols**	**List of drugs permitted for state purchases**
Initiator	State	Any stakeholder	Any stakeholder	Any stakeholder
Inclusion criteria	All registered drugs	Dossier is assessed by experts' committee	Dossier is assessed by experts' committee	Dossier is assessed by experts' committee
Fees for the review / evaluation	None	Payment is required if initiator is a producer	No payment is required voluntary sponsorship exists	No payment
Submission requirements	Submission not needed	Dossier includes label, clinical and economic evidence	No structured submission	Dossier includes label, clinical, economic evidence and proof of use on local population
Drug presentation	Generic and brand name, registration certification, content, producer	Generic and brand names, labeling information, daily defined dose and price per daily defined dose	Generic names, doses and schemes	Generic names by Anatomical Therapeutic Chemical Classification System
Review periodicity	Regularly	Annually	Once in four years [a]	Annually

[a] *Legal norm, frequently not followed.*

Source: Composed by authors based on communications and documentary analysis (Ministry of Health of Ukraine, 2015a; Ministry of Health of Ukraine, 2015b).

3 Reimbursement project' the pilot project of state health financing mechanism. For example, the pilot project on prophylaxis of hypertension started in Ukraine at the beginning of June 2012, involving price regulation and partial reimbursement of medicines through specially contracted pharmacies. With frequent breaks during the implementation period, this project was financed up to 2015. In 2016 the Cabinet of Ministers approved another reimbursement project covering insulin for patients with diabetes mellitus. The project, assigned to be financed from the regional budgets, defines eleven categories of diabetes treatment recipients who receive full or partial coverage of insulin and insulin analogues depending on the drug form, age, previous treatment, and compensation levels.

This, Ukraine continues to use the Soviet state-run model of health financing Since the declaration of independence, Ukraine has introduced only incremental changes into the mechanisms of health financing policies, including on drug procurement. The legacy of budgetary system co-exists with liberal pro-market approaches characteristic of pharmacies and other complimentary financial mechanisms. The range of coverage by free pharmaceuticals remains very narrow, and most of the time even vulnerable population groups have to pay for their medications by themselves.

Problem stream: challenges of current health situation and drug procurement in Ukraine

Ukraine, a former Soviet republic with current population of 45.5mln people, lies at the bottom threshold of middle-income jurisdictions (World Bank, 2011). Non-communicable diseases are the leading cause of death, and prevalence rates of human immunodeficiency virus (HIV), hepatitis C virus and tuberculosis are higher than in Western Europe (Strategic Advisory Group on Healthcare Reforms in Ukraine, 2014).

Experts outlined the following among the multiple healthcare challenges: inequitable access, an underdeveloped primary care system, high levels of prescription drug abuse, inefficient financing of health services, etc.

State Statistical Committee of Ukraine (2013) provides data that the majority of those who needed in-patient treatment refused hospitalization due to the high cost of drugs that the patients had to buy for the treatment and the high cost of medical services. Practice of out-of-pocket expenditures for health services contradicts the Ukraine's official «free-of-charge» health policy. The absence of healthcare reforms is quite convenient for medical doctors and healthcare managers who serve in this isomorphic system that formally is still (post)socialist, but in reality is market-driven and non-transparent.

In communication, Ukrainian stakeholders pointed out the problems with the quality of available drugs. While there are nominal policies for ensuring the quality of pharmaceuticals, fake or poor quality pharmaceutical products are a concern for patients across Ukraine. There are incentives for doctors to over-prescribe and there is a preference among both doctors and pharmacists for newer, more expensive, but rarely more effective drugs.

Formally, there is a strict delineation between over-the-counter pharmaceuticals and those that are available by prescription only. In practice this distinction is only strictly enforced for narcotics, psychotropics and their precursors. Easy access to the first and second-line antibiotics for the treatment of TB, for example, has been identified as a serious obstacle for controlling multiple drug resistance (Mosneaga et al., 2008).Experts believe that over-the-counter access (at a price) to almost all pharmaceuticals means that, potentially, a significant proportion of household resources is spent on ineffective and possibly dangerous use of pharmaceuticals.

Centralized procurement has also been associated with challenges. In Ukraine, it has been criticized because prices are still high, despite the use of tendering in procurement (RPR, 2016). Corruption and informal economy have strong influence on the state procurement system (National Council of Reforms, 2015). Stakeholders shared their view of the Ukrainian drug market divided among a handful of companies that have exclusive rights to supply, and of the state procurement based on «backroom agreements».

According to the State Service for HIV/AIDS and Other Socially Dangerous Diseases (2013), procurement and supply-management have been found to be inadequate and cause disrupted supply that hinders service intensity, quality and coverage of those who need medical treatment, while the Commissioner of Human Rights (2013) pointed out the violation of a right to free medical care.

The existing price declaration system has not been constant in Ukraine and, in fact, has experienced several changes during the last few years. In 2014, a new reference pricing scheme, widely used in European countries, was introduced to replace free-price declaration in Ukraine. However, ineffective policy processes (absence of the transferring period and preliminarily developed mechanisms, low stakeholders' involvement and dialogues) and defects in the policy content led to stagnation of the price declaration system in the first three months after its implementation. By our observation, the main content barriers in this policy were unclear or ambiguous procedures, inability to address in a timely manner the currency fluctuations for imported medical products, an unjustified mechanism of reference price determination for both original and generic medicines, and the absence of price reassessment because of the changes in the reference countries.

To reach transparent, objective and rational reimbursement decisions, most Western and Central European countries apply health technology assessment (HTA) as the multi-dimensional analysis of clinical, economic and social evidence. In Ukraine, several non-governmental – mainly patients' – organisations continuously articulate the need for setting up a central agency responsible for health technology assessment (HTA). In 2014, Ukraine's Ministry of Health created a working group for the elaboration of HTA. However, no effective policy has been developed so far.

Interviews with the experts demonstrate the low technical feasibility of a prompt introduction of HTA as part of the drug procurement mechanism because of the data, manpower and financial con-

straints. HTA manpower is scarce in many low- and lower-middle-income jurisdictions, and so it is in Ukraine (Mandrik, 2015). Thus, educational HTA programmes must be not only profound, but also continuous because of the high levels of brain drain from the state regulatory committees to a private sector. Under conditions of the limited budget and manpower, the state either bears significant, frequently unaffordable costs of HTA review (long HTA when the full dossier is prepared by the authority) or risks low expertise to validate comprehensive economic models and dossier submissions from global producers with high research capacities (quick HTA when the dossier is only validated by the authorities). If the role of HTA in budget allocation is not defined, as is the case in many countries (Goeree er al, 2011; Mandrik, 2015), low HTA capacity leads to a limited added value of the submitted HTA reports in reimbursement decisions and demotivates investments into further HTA submissions.

So, in Ukraine, like in many former Soviet countries, the combination of the high drug prices and the increasing burden of chronic diseases means that access to outpatient pharmaceuticals and the related burden of out-of-pocket spending have now become some of the most pressing health policy issues. There is much waste in the purchase of pharmaceuticals in Ukraine, as many are bought directly by patients, and centralized purchasing is often abandoned or corrupted.

Politics stream: incoherency and populism in health decision-making

In the past 25 years, there have been 21 draft laws on health insurance or healthcare financing. For example, 6 draft laws on budgetary issues of healthcare were registered between October 2003 and June 2004, then three between September 2006 and December 2007, and two between March and June 2009. None of them were approved by the Ukrainian parliament. These draft laws addressing social health insurance were driven by the context and actors, drafted in a changeable political environment lacking a dominant political role and ultimately were revealed to be of low quality. The other issue is a long-standing political tradition of declarative policy oriented to keep (post)Soviet egalitarism and «free» healthcare as a package of social policies.

The political instability in the Cabinet of Ministers of Ukraine subverted introduction of any regulation by the Ministry of Health, which has had 12 different Ministers in the past ten years. These frequent turns in leadership complicate implementation of any long-term reformatory projects, such as social health insurance and reimbursement systems.

The year 2014 started in Ukraine with a takeover of power by pro-European political forces. The concept of social health insurance, so common in Europe, reappeared on the political agenda. Consequently, it was included into the Parliamentary coalition agreement (Verkhovna Rada of Ukraine, 2014), Presidential strategy «Ukraine-2020» (National Council of Reforms, 2015) and a Strategy of the Healthcare Sector Development (Strategic Advisory Group on Healthcare Reforms in Ukraine, 2014) that was initiated by the Ministry of Health and elaborated by the group on strategic reform. Despite this apparent breakthrough toward social insurance development, both political actors and their respective documents disagreed on its perspective. The Parliamentary coalition agreement directed the healthcare system toward public and private health insurance; the Presidential strategy mentioned optimization of the tender system and drug reimbursement; a strategy of the working group on strategic reform, initiated by the Ministry of Health, foresaw both social healthcare insurance and reimbursement implementation, but only in a long-term perspective. In 2014-2015, to provide a context for introduction of social insurance, the Cabinet of Ministers of Ukraine registered three new legislative acts concerning changes to Ukraine's taxation and budget codes, as well as declaring the autonomy of healthcare establishments. Meanwhile, just as the Cabinet of Ministers of Ukraine was announcing its support for medical insurance, the Ministry of Health of Ukraine declared health insurance to be a premature step. As such, the political and administrative feasibility of implementing social health insurance and drug reimbursement will depend much on reaching cooperation between the actors of background and insurance legislations.

In 2014-2016, a number of pressure group campaigns were launched in Ukraine by patients' organisations and civic groups. The goal of these activities was to push the government to provide financing and ensure supply of drugs necessary for treatment of childhood cancer, tuberculosis and HIV/AIDS. These campaigns, according to communication with the stakeholders, were successful in raising public attention to the issues of drug procurement and ill-reformed healthcare system as a whole.

Another policy entrepreneurattempting to merge the three streams and put forward an agenda of drug procurement to policymakers is the RPR («Reanimation Package of Reforms») civic platform.

It lobbies reforms in health policy to build a stronger Ukrainian state. Such reforms'according to RPR'should include legislative changes to guarantee «affordability of medical drugs for the citizens» (RPR, 2016).

So, while state actors are playing with words to preserve the old system, the civil society agents serve as policy entrepreneurs to change the drug procurement system.

Incremental changes in drug procurement in 2014-2016

With the political debate on social health insurance legislation ongoing, there are examples of public pressure empowering rapid changes in current procurement mechanisms. In 2015, the MOH transferred responsibility for drug procurement to international non-profit organisations for the following central health programmes: immunologic prophylaxis, diagnosis and treatment of hemophilia, chronic viral hepatitis, orphan and childhood oncology, anti-viral therapy and diagnostics, tuberculosis, viral hepatitis B and C, oncology, endo prosthesis and cardio-vascular diseases among adult patients. In 2015, purchases through international organisations (UNISEF, UNDP, and Crown Agents) constituted 60% of central state drug purchasing, with the remaining central tenders operated by the MOH. However, delays in signing necessary by-laws caused backlog in drug supplies. In 2016, the MOH reported that 800 million UAH were saved as a result of procurement by international organisations.

In 2015, the Cabinet of Ministers of Ukraine approved a decree which allows free price declaration and price correction in case of currency fluctuation. Meanwhile, the mechanism of external reference pricing continues to exist under the pilot reimbursement projects for insulins. The register of insulins' reference prices based on the external refereeing of data from nine countries (Bulgaria, Moldova, Poland, Slovakia, Czech Republic, Latvia, Hungary and Serbia) is maintained by the MOH and is updated twice a year.

In 2016, the Cabinet of Ministers of Ukraine approved transferring of all central state purchases, the total value of 4.2 billion UAH, to international organisations. However, this reassignment of purchasing responsibilities from the MOH to the external agents was considered as a temporary action, in effect until March 2019 only.

In 2015, the ProZorro (https://prozorro.gov.ua/en), a public e-procurement system that has replaced old paper tenders, was launched. The system has a transparent nature, is based on the open procurement ideas and aims at fighting corruption during public tenders. Due to the fact that tender information can be seen by anyone who accesses the system, business and civil society can oversee the integrity of public procurement. At the beginning, the usage of a new system was not mandatory. Since 2016, the switch to the ProZorro system has become obligatory for central executive authorities and purchasers.

In early 2016, the MOH presented a new draft concept of healthcare financing for public discussion that included mechanisms for drug and medical device purchases (Ministry of Health of Ukraine, 2016a). It is based on a step-by-step approach to develop a National Purchasing Organisation projected to be up and running starting 2018. However, ongoing political debates and regularly occurring governmental crises put the stability of this approach at risk. Resignation of the Ukrainian Government in April 2016 and appointment of a new one (without a Minister of Health) diminish the hopes of quick reforms in public sphere, including health policy.

In spite of innovative ideas, not that many steps toward changes in health policy, or specifically drug procurement policy, have been done. The streams have not yet converged in full, while the window of opportunity opened after the Revolution of Dignity, as the bureaucratic and political systems are trying to re-establish themselves.

Prospective policy options

The conducted documentary analysis and communications provides the ground for sketching possible alternatives of the drug procurement policy development in Ukraine.

With regard to populistic political culture of Ukraine and the lack of visible influential political actors in the area of drug procurement policy, the first alternative may be sustaining of the current policy practices. It will mean minimum and quite formal following of the international guidelines, as well as preservation of the highly centralized, (state) paternalistic and corrupted system, including central tendering system of drug procurement for the selected groups of patients.

Taking into account the worsening of the economic situation, the second policy option may include further neo-liberalization of the whole health policy, including drug procurement policy. Austerity approach and market strategies may dominate effective price regulation strategies. Prospective de-

centralization in Ukraine may add new challenges to regional drug tenders.

As Ukraine is still claiming its European dimension of development, the third alternative can be based on liberal values and definition of the minimum healthcare package, including minimum drug provision and introduction of the societal health insurance as grounds for ensuring universal access to health services. This approach demands the wide-sector introduction of HTA and other WHO recommendations. This alternative demands cross-sectoral political consensus and coherence that are unlikely to be achieved in Ukraine with its controversial political culture.

Figure 1 presents a summative view of the streams, policy entrepreneurs and policy windows in Ukrainian drug procurement policy (2014-2016), within the MSF model. It takes into account WHO recommendations on universal health access and HTA serving as cornerstones for health policy reforms.

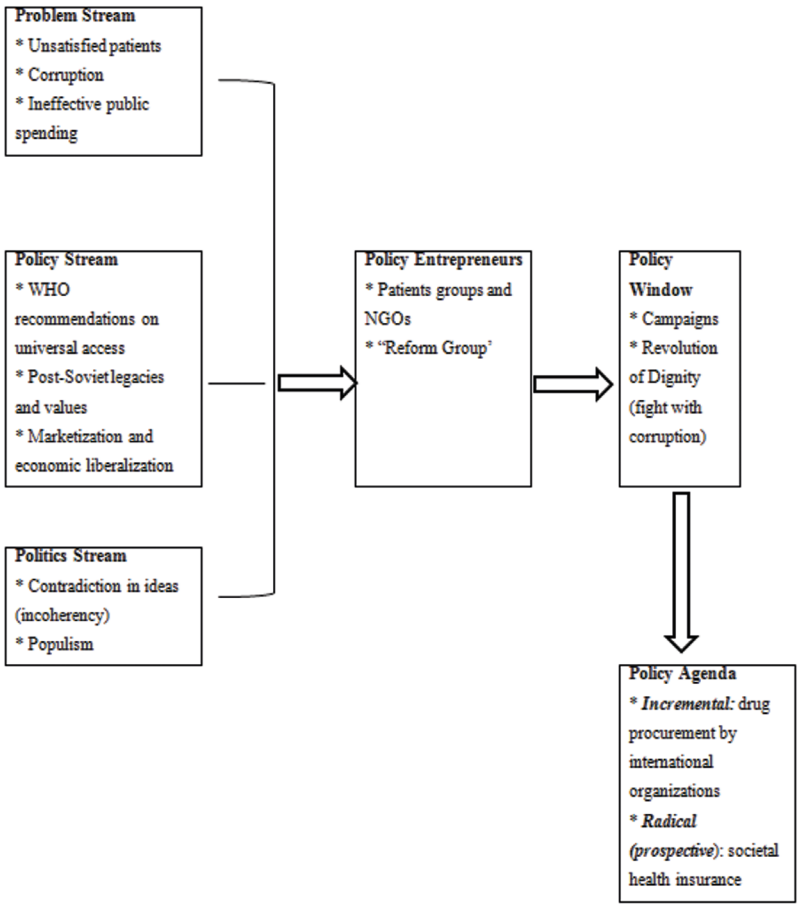

Figure 1. Multiple streams within drug procurement policy in Ukraine (2014-2016)
Source: composed by authors

Discussions

Diversity of approaches to drug procurement across the region

The analysis of streams within the Ukrainian drug procurement policy as a part of the health policy demonstrates the diversity of approaches that can be effective if properly applied.

Western European and many Central European countries – Poland, Slovakia, Hungary, Latvia, Estonia and Romania, among some of them – use reimbursement widely under the umbrella of social health insurance as a way to prioritize access to medicines. To reach transparent, objective and rational reimbursement decisions, most Western and Central European countries apply health technology assessment (HTA), as a multi-dimensional analysis of clinical, economic and social evidence (Levin et al., 2007; van Kammen et al., 2006). These countries also use price-control strategies to limit constantly growing healthcare expenses(Bouvy & Vogler, 2013).

Long-term effects of tendering are evident, as effective tendering may impact budgeting, payers' behavior, and market competition (Petrou, 2016).

In contrast to the above-mentioned countries, several former Soviet countries, such as Armenia, Azerbaijan, Georgia, Tajikistan, and Uzbekistan, experience frequent budget constraints, limit state treatment coverage, or avoid reimbursement of spending. Having limited budgets, they also develop procurement regulations, primarily to cover the highest needs of vulnerable population (Balabanova et al., 2012; Ibrahimov et al., 2010; Khodjamurodov & Rechel, 2010; Rykhadze, 2013; Rechel et al., 2013; WHO, 2011). Ukraine follows in the footsteps of this second group of countries.

While Ukrainian procurement and regulating policies are considered to be inefficient, the methods themselves are not unique and often see application in other countries. Tendering is a main procurement approach in a number of European countries, including Cyprus, Estonia, Italy, Latvia, Malta, Norway, Sweden and the United Kingdom, and may be done by individual hospitals or centrally by the Ministry of Health, social health insurance institutions or procurement bodies. External price referencing, used in Ukraine to define reimbursement prices for the piloted project on insulin coverage, is the predominant pricing policy in Europe. Many European countries also use HTA approach in reimbursement decision-making, including Belgium, Denmark, Sweden, the Netherlands, Finland, the United Kingdom, Ireland, Portugal, Germany and others (Bouvy & Vogler, 2013). Meanwhile, due to historical, economic and cultural differences, the effectiveness of strategies implemented in Western European countries cannot be transferred as an exemplar for Ukraine and other lower-income jurisdictions. Eastern European countries and, particularly, those of the former Soviet Union share similar historical and organisational backgrounds; and with minor exception they have followed similar trajectories in the development of healthcare systems and access to treatment processes (Maier & Martin-Moreno, 2011; Rechel, Richardson & McKee, 2014; Lekhan, Rudiy & Richardson, 2010). Because of their small market sizes, countries in this region require different approaches to drug procurement in order to ensure affordability of medical products and to remain attractive markets for international producers.

Defining the scale for state coverage, Ukraine and some other low-income countries of the former Soviet Union provide access to medicines referencing the WHO Model Lists of Essential Medicines (WHO, 2001). Recent pricing reforms in Armenia (Public TV of Armenia, 2015) and Azerbaijan (Ministry of Health of Azerbaijan, 2015) engage state control mechanisms, currently implemented in Ukraine, while, for example, Georgia uses an alternative – active generics promotion and free market competition (Transparency International Georgia, 2012). Reforms in Moldova are focused on implementing additional public procurement methods (also foreseen in Ukraine), including framework agreements, competitive dialogue, negotiation procedures and electronic tenders (Ferrario, 2014). HTA in Central European and former Soviet countries is frequently used more informally than formally with the new HTA agencies operating in Estonia, Lithuania, Romania, Turkey and Kazakhstan (Mandrik, 2015).

Despite the previously-mentioned failures of the Ukrainian state procurement system, tenders have been shown to decrease prices for off-patent drugs under conditions of transparency, high level of competition and large sales volumes (Petrou & Talias, 2015). On the other hand, in several other countries implementation of tenders has shown negative effects, such as decreased market attractiveness, drug shortages, reduced pharmacists' income and decreased patient compliance with treatment (Pauwels, 2014).

Value-based constrains on changes of the drug procurement policies

The situation in Ukraine with its highly corrupted, yet unreformed public sphere, including public procurement system of drugs, proves that the old-fashioned declarative policy and non-transparent practice are still dominating. Governmental structures, some political groups and the private sector prefer to keep the situation with drug procurement unchanged. Our findings fit statements of Minakov (2016) that a new power elite distance themselves fromthe agenda of the *Revolution of Dignity* and pursue their own public and private interests. According to Hale and Orrtung (2016), plutocratic «oligarchs,» and the economy patrimonialism have strong latent influence on the (lack of) reforms in Ukraine and constitute fundamental contextual challenges.

At the same time, political culture in Ukraine is highly populistic (Semigina, 2013; Semigina, 2015). Health policy, and specifically drug procurement, serves undoubtedly as a stage where political actors play out the scenes about social justice, gambling with the issues of healthcare equity and affordability

of drugs. Soviet ideas of social justice are still implemented in the Ukrainian legislation and to some extend enhanced by the WHO suggestions on universal access to healthcare. However, the WHO does not push for definite political tools, while Ukrainian local policy-makers insist on keeping public ownership in healthcare and state-controlled practices. As White (2010) stressed many of the values of the Soviet period remain intact, as well as political ideas of the leftist parties. In the Ukrainian case, many of the political groups promoting free healthcare and opposing social health insurance are calling for the defense of entrepreneurship and tax reduction.

Institutional constraints on advancement of reforms in Ukraine

The events in the winter of 2014 showed Ukrainians' deep longing for a more transparent, citizen-responsive form of government. Ukraine's public sector remains affected by structural weaknesses left unaddressed from the time of its independence. Currently, unfinished, and in some aspects, non-initiated reform agenda is vast, as only incremental steps have been done. The example of Ukraine demonstrates the vital role of actors and policy entrepreneurs in procurement reforms. Change of state procurement system requires political stability for such transformation to be effectively implemented. This finding is in line with other researchers who discussed the institutional aspects of policy changes (Guldbrandsson & Fossum, 2009; Herweg, Huß& Zohlnhöfer, 2015; Hoppe, 2011; Tischuk, Kharazishvili & Ivanov, 2011).

In the context of the post-socialist countries, ability for radical changes can be linked to the authoritarian way of governance, strong leadership and tenacious pre-Soviet legacy of *paternalism* (described by Hale, 2016), while the wide-scale participatory policy making (politics stream) may represent institutional trap for quick changes in the long-established, yet ineffective systems, and for using the window of opportunity.

Roberts and Reich (2011) suggest three types of possible government failures related to the pharmaceutical sector: goals/priorities failure, policy design failure and implementation failure. We consider that in low- and middle-income countries without a strong political majority, actors focusing on personal interests and ambitions lead to failures of priorities (by selecting «populist calls» for the political agenda), failures of policy design and failures of implementation (by incomplete or absent political dialogue with opposition and strong focus on project «ownership»). While differences in healthcare structures and management between different jurisdictions are evident, the impact of politics on healthcare reforms, and the incapability of various political actors to reach a sound agreement, are observed in some countries, such as Ukraine, Armenia (Ghazaryan, 2013) and Hungary (Mihályi, 2007).

Concluding remarks. The current system of healthcare financing in Ukraine, including the state procurement mechanism, drug pricing policy and the absence of health technology assessment, can be considered as ineffective. It doesn't support one of the key health policy objectives of protecting patients from impoverishment.

During the last decade numerous attempts have been made to conduct reforms related to state drug procurement processes in Ukraine; all of them unsuccessful. The reforms aimed to introduce a universal health insurance, to amend the price declaration process, to implement HTA in healthcare decision-making, to pilot a reimbursement system for the outpatient drug segment, and to establish more transparent and efficient tender processes for hospital treatment. Despite such ambitious goals, by 2015 Ukraine has introduced only incremental changes into its drug procurement policies, burdened as it is by a corrupt and unstable political environment. Thus, several options may be foreseen of development of the procurement policy in Ukraine: (1) sustaining the current policy practices with a centralized corrupt tender system and the formal following of guidelines (no-change alternative); (2) significant cuts in state-financed drug coverage because of lack of government funding and unstable economic situation, following market-based advice strategies, price de-regulation and policies of austerity; or (3) defining the minimum package of guaranteed health services, including drug provision.

Ukraine currently has a generic-oriented market, characterized by insecure patent protection, bureaucratic and unstable procurement regulations, corrupt practices and an unstable economic background. In this context, central drug tendering for the wide list of state-covered medicines may result in a delay of innovation, decrease in market competition, worsening of investment climate, and drug supply problems without a concomitant positive impact on state expenses. Thus, it may be recommended to use the centralized procurement approach only for basic treatments purchased in bulk quantities and/or requiring medical control over consumption, such as for tuberculosis treatment, HIV treatment or vac-

cinations. Access to other state-guaranteed basic treatments can be provided using reimbursement schemes following a defined drug list, a unified document based on the WHO Model Lists of Essential Medicines. Considering the wide number of alternatives for these drugs on the Ukrainian market, we suggest a free pricing approach with the minimum reimbursed price established using internal referencing. Access to life-saving innovative treatments for vulnerable population groups may be defined using an HTA-based approach with obligatory budget impact assessment, risk-sharing schemes and price-negotiations.

To sum it up, our policy review suggests that while drug reimbursement is needed, its implementation has a higher probability to succeed if all relevant stakeholders, including patients' groups, professional networks and drug producers' associations are actively involved in the political dialogue during both the development of reforms and their implementation. Moreover, healthcare priorities, stakeholders, resources and barriers to implementation should be clarified prior to the drafting and initiation of policy. However, the case of Ukraine illustrates important implications of macro-level political stability and effective dialogue among stakeholders on initiation and successful implementation of healthcare reforms. Only under such conditions the window of opportunity will be opened for meaningful changes in the drug procurement system.

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