Healthcare Reform: the Synergy of Power and Legal Advisers

Dmytro ALESHKO
is a partner at Legal Alliance Company

Nataliia SPIVAK
is an associate at Legal Alliance Company

The recent dynamic development of the legislation which regulates the healthcare sector and particularly the pharmaceutical market is due to the active process of its harmonization with the legislation of the European Union. It is these dynamics that distinguish this relatively young sphere from many others.

This year was full of really important events, which directly affected not only representatives of business, healthcare professionals, but also patients. Thus, the Affordable Medicines state program was introduced to reimburse the cost of certain categories of medicines, a system of selecting essential medicines to satisfy the basic needs of those people who receive treatment in healthcare facilities, and the system of public procurement through international specialized organizations were reformed. Furthermore, in the near future a long-term strategy will be adopted to provide the population of Ukraine with pharmaceutical products.

Legal Alliance Company was actively involved in the reform processes in many areas of the healthcare sector. In recent years we have implemented a lot of norm-setting projects related to the most urgent issues for the pharmaceutical market.

An example of this is the introduction of the Affordable Medicines state program, the goal of which is to reimburse the cost of drugs for outpatient treatment of people suffering from cardiovascular diseases, type II diabetes and bronchial asthma. The program was launched in early April 2017 and has already demonstrated its first positive results. Moreover, its funding for the subsequent period was increased by UAH 200 million. The plans include expanding the list of diseases and chronic conditions, in connection with which patients will be able to receive medicines for free or for partial payment.

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Thanks to this state program, patients who have a doctor's prescription can buy drugs at reduced prices (with patients paying 1%-75% of the retail price) or even receive some of them for free. The cost of medicines is reimbursed by pharmacies at the expense of targeted transfers from the state budget to local budgets. The interim results of the program demonstrated a decrease in the average weighted cost of reimbursable medicines. This became possible due to the introduction of an external and internal mechanism of reference pricing for drugs.

Our experts participated actively in this process at the stage of the regulatory framework development. The issue here is the Resolution of the Cabinet of Ministers of Ukraine *On State Regulation of Prices for Medicines, No. 862 of 9 November 2016* and Resolution *On Introducing Reimbursement for the Cost of Medicines, No. 863 of 9 November*, as well as on subsequent amendments to them.

We cannot say that the regulation-setting process is completely in line with the plan and corresponds to the stated timeframes. In practice, the mechanisms used to solve the set tasks can be radically changed following numerous meetings, brainstorming and round tables. Lawyers working on the regulatory framework participate, as a rule, in the discussion and development of a strategy for achieving the desired result, recommend possible ways to resolve issues that arise inevitably in the course of the work. Sometimes there is an urgent need to amend the recently approved regulations. Much depends on the quality of communications established between all participants of the process.

Any large-scale reform at the first stages of its implementation raises a lot of questions. Now it is happening to the National List of Essential Medicines. Since mid-2015 our company has, as a legal adviser, supported the process of reforming the model of formation and functioning of the National List, a list of drugs to satisfy the priority medical care needs of the population which are in healthcare facilities for treatment at the expense of state and local budgets.

One model of reform was the World Health Organization's international practice of creating its Model List of Essential Medicines. This list is the basis for many developing countries. The work on reform, amongst other things, included the formation of an expert body for the transparent selection of essential medicines, which are high-quality, effective and safe drugs of high economic feasibility, and the construction of a model for the selection of essential medicines. A total of more than 10 by-laws were developed and subsequently approved.

In 2018, healthcare institutions and facilities financed from state and local budgets will have to procure drugs in accordance with the new National List. From 1 January 2018, subject to satisfying 100% need of medi-

cines included in the National List, customers in the regions will be able to procure any other drugs registered in Ukraine, the need for which they will determine independently. In this case, preference should be given to medicines included in industry standards in the field of healthcare.

Let us note that today in Ukraine a significant share of medicines is procured centrally by the Ministry of Health through international specialized organizations. Such procurement is not limited to the National List, so patients will, as before, have access to the drugs they need, which are obtained through Government programs.

The introduction of the National List is not a question of the number of drugs on the list and the inclusion or non-inclusion of some specific positions in it. This is a matter of providing 100% of patients undergoing inpatient treatment with at least all the basic essential medicines. This applies to every Ukrainian. For citizens the introduction of the National List means that quality and safe key medicines of proven effectiveness that have been recognized as a priority for Ukraine should be provided free of charge from the beginning of 2018. This means reducing expenses from the "pockets" of consumers and improving the quality of medical care.

In unison with working on the National List, our company has long been providing legal support to prepare regulatory legal acts in the field of public procurement of medicines and medical devices with the involvement of international specialized organizations. Such activities are carried out in cooperation with the United Nations Development Program.

Thus, in 2015, Ukraine decided to delegate a part of the procurement from the Ministry of Health of Ukraine to UN agencies (the United Nations Development Program, the United Nations Children's Fund) and Crown Agents, which is the British procurement agency. This practice is applied in countries where a transparent and effective national procurement model has not yet been established. In our country, this step was the result of the long practice of non-transparent procurement procedures, high prices for goods, lobbying the interests of certain players on the pharmaceutical market and the absence of a separate special legislative regulation for the procurement of such socially important goods as pharmaceutical products. In addition, the existing system of public procurement did not allow the Ministry of Health to fully perform its functions to carry out systemic and comprehensive healthcare system reform,

S. Riabokon

the need for which has been long overdue in Ukraine.

It was not easy to launch international procurement of medicines and medical devices with the involvement of international specialized organizations. Lawyers of Legal Alliance were invited to cooperate from the very beginning of preparation of the regulations. Since Ukraine had no previous experience, it was necessary to form a model that would allow via legislation the procurement of high-quality medicines for Ukrainian patients at sensible prices from the outset.

Centralized procurement in accordance with the internal rules and procedures of specialist international organizations made it possible to reduce corruption risks significantly. Changes in the *Tax Code of Ukraine* and a number of by-laws allowed for such operations to be exempted from value added tax. Data available in open sources indicate that the procurement of medicines and medical devices through international specialized organizations has, as an interim mechanism, demonstrated significant savings of budget funds.

The mechanism introduced for the procurement of medicines and medical devices with the involvement of international specialized organizations is a temporary solution to urgent problems. Together with its implementation, Ukraine needs to develop and implement a local procurement mechanism that will be effective and lead to the achievement of set goals.

Moreover, with regard to regulation-setting practice, our work was quite fruitful within the framework of interaction with WHO experts in drafting the State Strategy for the Implementation of the State Policy in the Sphere of Provision of Population with Medicines for 2017-2025. In the near future it must be approved in Ukraine. Furthermore, in 2012-2014 within the framework of collaboration with the sectoral association for medical devices, Legal Alliance participated in the preparation of amendments to various resolutions of the Cabinet of Ministers of Ukraine and orders of the Ministry of Health of Ukraine regulating the activities of operators of the medical devices market.

In 2014-2015 our team also performed extensive work on drafting the Law of Ukraine *On Medicines*, which was registered in the Ukrainian Parliament. The European model for regulating the turnover of medicines was used as a basis for the draft law, particularly as stipulated in EU Directive 2001/83. Since this act does not cover the full range of necessary issues, separate sections of the draft law were developed taking into account the experience of European Union countries. Certainly, the peculiarities of the pharmaceutical market's functioning in Ukraine were considered too. The draft law was assessed by experts of the World Health Organization. Given the harmonization of Ukrainian legislation with EU legislation, we are confident that our country will again consider the issue of adapting one of the basic laws of the industry, and therefore the bill that we drafted will regain its relevance.

On the whole, norm-setting is a complex process and it requires that lawyers get fully involved in both technical and specialist issues. In the healthcare sector this means having medical and pharmaceutical knowledge, finding alternative ways to solving problems, often balancing between ensuring the rights of patients, interests of the state and business opportunities.

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