

## **Ukraine: Recent Developments in Legal Regulation of Medicine and Healthcare**

*Authors: Yaroslav Petrov, Tetyana Buchko, associates with Asters*

The medicine and healthcare legal environment in Ukraine still suffers from after-effect of the Soviet healthcare system. The attempts to reform this sphere so far have been largely unsystematic and inconsistent.

As regards further healthcare reform, a key issue for Ukraine is to select a more efficient healthcare financing model. Today, the healthcare system is financed through general taxes and is based on contractual state purchases of healthcare services. There have been suggestions to introduce compulsory medical insurance which would attract funds to medicine from private sector. However, the legislative proposals in this regard have failed to muster enough support among the general public, as well as in the Parliament.

In 2010-2011, the Ukrainian Parliament and Government adopted several important legislative acts in the sphere of medicine and healthcare, *inter alia*, relevant to registration of prices for medical products, tax incentives, clinical trials, fighting with counterfeit products; as well as initiated legislative changes in the sphere of medicine import substitution and others.

Below is a summary of recent trends in this sphere.

### ***Competition Issues***

Over the past few years, the Antimonopoly Committee of Ukraine (the AMC) has tightened its grip over the pharmaceutical sector. In particular, the AMC carried out a large number of investigations in this sphere and imposed penalties for overpricing and misleading advertisements.

AMC's actions with regard to overpricing. Starting from 2009, when the swine flu pandemic caused buying fever in Ukraine, and as a result suppliers were in a position to charge unjustifiably high prices for medications, the AMC every year issues a number of orders/recommendations to pharmaceutical businesses to cut down prices of medicines used to treat colds and related diseases to a reasonable level.

The most recent recommendations binding for consideration were issued on 13 October 2011, when the AMC requested 10 largest Ukrainian producers and 10 major distributors to refrain from economically unjustified increase of prices for pharmaceuticals and creation of artificial shortage of pharmaceuticals. In particular the recommendations were addressed to Borschahivka Chemical and Pharmaceutical Plant, Kyivmedpreparat, Kyiv Vitamin Plant, InterChim, Farmak, Pharmaceutical Company Zdorovia, Lekhim-Kharkiv, Halychpharm, DKP Pharmaceutical Plant, Pilot Plant GNTSLS, Optima-Pharm Ltd, ABC LOGISTICS PARK, BaDM, Yuria-Pharm, Venta Ltd, Pharmplanet, Gladpharm Ltd, Edelveis, Alba Ukraine, and Fra-M. The recommendations are aimed at ensuring price stability in the market during seasonal exacerbation of infectious diseases among the population. Simultaneously the AMC and its territorial divisions are planning to carry out inspections of wholesale suppliers and retail pharmacies which may result in imposition of a fine in amount of up to 10% of the company's turnover for omission to comply with the recommendations.

Also, the AMC is concerned about overpricing for certain products claiming that the prices for such products are significantly lower in the jurisdictions where they are produced if compared with the level of prices in Ukraine. The products in question are Furadonin, Mucosan, Heparin, Ceregene, as well as diapers and condoms. In this respect the AMC has carried out numerous inspections and is planning to create a working group consisting of the representatives of the AMC and other state authorities, the pharmaceutical manufacturers, distributors, and associations in order to prevent overpricing in pharmaceuticals sector.

AMC's actions with regard to misleading advertisements. One of the most headline-making cases was imposition on Boehringer Ingelheim GmbH & Co KG (Austria) of the fine of UAH 1 million

(approx. USD 125 thousand) for placing advertisement of its cough medicine (Lasolvan) in 2010. The AMC asserted that the advertisement in question had the potential to mislead consumers as regards therapeutic effect of the drug. Besides, numerous other pharmaceutical companies, such as Rainbow Ltd. (Ukraine), Sandoz Pharmaceuticals d.d. (Slovenia), Herbion Private Limited (Pakistan), Silverhorst Ltd (Ukraine), etc. were recently fined for false/misleading advertisement. The AMC also imposed fines on a number of pharmacies for advertising low "wholesale" prices and thus misinforming consumers.

### ***Pricing***

In 2009, the Government introduced harsh control over pricing in the pharmaceutical sphere. This step provoked active response from the pharmaceutical community that resulted in introduction of price regulation only for a limited list of medical products.

Further, aiming to regulate wholesale prices, in 2011 the Government imposed an obligation on pharmaceutical market players to undertake state registration of wholesale prices for medical and medical-purpose products. Medical institutions, which are partially or fully financed from state or municipal budgets, shall purchase medical and medical-purpose products at the prices, which do not exceed registered wholesale prices increased by statutory defined surcharges. Such institutions cannot purchase goods that are not registered in the state register of wholesale prices.

### ***VAT***

The newly enacted Tax Code provides for VAT exemption for sale of medical products allowed for production and use in Ukraine and registered in the state register of medical products, as well as medical-purpose products defined by the Government.

Consequently, drug stores registered as VAT payers should charge VAT on sales of medical and medical-purpose products, which are not VAT exempt. Non VAT payers can sell such products without charging VAT until their turnover reaches UAH 300 thousand (approx. USD 37 thousand), which triggers a statutory requirement for registration as a VAT payer.

### ***Clinical Trials***

Recently, the Ukrainian Healthcare Ministry approved new rules that govern clinical trials of drugs, medical devices and products and are substantially in line with the European and international practices.

Additionally, in May 2011 the Parliament adopted legislative changes aiming at improvement of legal mechanism for holding clinical trials with participation of minors or persons with limited capacity.

Nevertheless, some local peculiarities remain, such as the need for those parties involved in a clinical trial (sponsors, the site and investigators) to enter into separate agreements instead of just one agreement. Also, foreign pharmaceutical companies may face problems related to implementation of their liability insurance policy while performing clinical trials in Ukraine. Ukrainian insurance companies often lack experience in indemnity insurance in the sphere of clinical trials, and unclear insurance regulations add confusion in this respect.

Customs clearance of medicinal products intended for clinical trial may also present a problem as customs authorities often insist on additional evaluation and increase of the customs value of such products.

### ***Ban on Advertising***

In August 2010, the AMC announced that it would approach the Government to initiate legislative prohibition to advertise drugs and biologically active additives. In response to the AMC's initiative, a draft law proposing to ban advertisement of medical products in Ukraine has been submitted to the Parliament.

This is not the first proposal in this respect. Over the past few years, the Government and the Ukrainian Healthcare Ministry have repeatedly announced their support to the ban on drug

advertisement. Their principal argument in favor of prohibition to advertise drugs is that this step should bring down prices for medications as promotional costs represent a substantial portion of the price. However, recently the Parliament turned down the draft law.

### ***Medicine Import Substitution***

Statistics demonstrate that the share of imported medical products in the Ukrainian market is increasing considerably year-on-year. In 2011, the Government has started implementing certain initiatives to reduce the increased influence of imported medical products on the pharmaceutical market of Ukraine. In particular, the Ukrainian Healthcare Ministry developed the draft Concept of the State Target Program for the Development of Import Substitution Production in Ukraine and Substitution of Imported Products by National, Including Biotechnological Products and Vaccines for 2011-2021.

The main idea of the initiative is to set up clear legal mechanisms for protection of national producers by limiting registration and purchase of imported medical products, substitutes of which are produced by national manufacturers, by creating various fiscal incentives for national producers, and by supporting foreign investors to develop Ukrainian domestic manufacturing.

### ***Fighting Counterfeit Products***

Ukraine is considered to be one of the largest markets for counterfeit medical products, which may reach up to 50% of the Ukrainian market share according to some estimates.

The Government takes serious measures in fighting counterfeit medical products. In November 2011, fundamental legislative changes to the Ukrainian Law on Medical Products, the Criminal Code and the Code of Administrative Offences came into force. These changes have introduced a definition of counterfeit medical products and defined the criminal liability for production and/or smuggling of such products. These legislative changes are considered as a positive step.

Moreover, it should be noted that Ukraine intends to accede to the Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes, which provides for obligation of the parties to the Convention to introduce criminal responsibility for production and supply of counterfeit medical products. The Convention establishes a framework for national and transnational cooperation between the competent healthcare authorities, police, and customs both at the domestic and international level.

### ***Priorities for Reformation of Medicine and Healthcare***

Various professional organizations, which unite the Ukrainian pharmaceutical community, take an active role in analyzing the problems that the industry is facing and the ways of improving the situation. For example, in the recent Report of the American Chamber of Commerce "Partnership for Successfully Competing in the Global Economy (2011/2012)", industry players have identified the action plan of policy, legal and regulatory reforms in the healthcare sector for the next couple of years, which includes necessity to:

- adopt the new law on medical products;
- improve the procedure for state quality control over medical products;
- improve public procurement of medical products (including unification of requirements for local and foreign manufacturers);
- improve regulations concerning clinical trials in Ukraine; and
- cancel VAT on imported drugs for clinical trials by means of changing relevant legislation.

This report has been distributed to relevant stakeholders so that they can take these recommendations into consideration while implementing reforms in the healthcare sector.