

Attention! Legal Alliance newsletter is a monthly corporate publication that is distributed in order to inform our clients, business partners and other interested persons about the latest changes in legislation, and recent news about the company. Any information presented in the digest, is not a legal advice and does not constitute an agreement between the attorney and client..

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HOT TOPIC. Collision in the procedure of medicinal product registration

On February 9, 2012, the Minister of Health of Ukraine Mr. Anischenko signed the order of the MOH of Ukraine № 98 [On cooperation of the Department of the development of pharmaceutical sector of the MOH of Ukraine and the State Expert Center of the MOH of Ukraine](#), SE (hereinafter the "Order of the MOH of Ukraine № 98").

As provided by the Order of the MOH of Ukraine № 98, the previous order of the MOH of Ukraine of 15.02.2010 № 113 On certain issues of cooperation of the Department of the development of pharmaceutical sector of the MOH of Ukraine and the State Pharmacological Center of the MOH of Ukraine, SE became null and void. The nullified order of the MOH regulated the following issues:

- A procedure of cooperation of the Department of the development of pharmaceutical sector of the MOH of Ukraine (hereinafter the "Department") with the State Pharmacological Center of the MOH of Ukraine, SE (hereinafter referred to as the "SPC") concerning preparing the orders of the MOH of Ukraine on state registration (re-registration) of medicinal products and amending registration materials, and preparing and issuance of registration certificates;
- A procedure of cooperation of the Department with the SPC aiming at approval of the SPC's conclusions concerning clinical trials of medicinal products and substantial amendments.

Last year we provided [a critical legal analysis](#) of implementation of a procedure of "Unified Window" with respect to the state registration of medicinal products, which was introduced by the draft decree of the Cabinet of Ministers of Ukraine On amendments to the Decree of the Cabinet of Ministers of Ukraine of 26.05.2005 № 376 On Approval of the Procedure for State Registration (Re-registration) of Medicinal Products and Amounts of Fees for Their State Registration (Re-Registration).

At this point we shall again analyze the proposed changes in the procedure of cooperation of the Department with the SPC concerning preparing the orders of the MOH of Ukraine on state registration (re-registration) of medicinal products and amending registration materials, and preparing and issuance of registration certificates.

Expect soon the respective legal analysis of novels and risks for pharmaceutical business.

DRAFTS OF REGULATORY ACTS

A meeting with domestic pharmaceutical producers concerning price regulation for medicinal products was held in the State Service of medicinal products of Ministry of Health of Ukraine

A meeting with domestic pharmaceutical producers concerning price regulation for medicinal products was held in the State Service of medicinal products of Ministry of Health of Ukraine (hereinafter the "State Service").

According to the Head of the State Service Mr. Olexiy Solovyov, aiming at improvement of price regulation for medicinal products included to the obligatory minimal assortment for pharmacies the respective draft Decree of the Cabinet of Ministers of Ukraine *On certain issues concerning ensuring the availability of medicinal products and medical devices* was elaborated. At the present moment the said draft is not officially published.

The draft foresees amending of certain regulations of the government. In particular, amendments to the Decree of the Cabinet of Ministers of Ukraine of 8.08.2011 N932 *On improvement of the state regulation of prices for medicinal products and medical devices which are bought for the costs of the state and local budgets* foresee that the wholesale prices for medicinal products included to the obligatory minimal assortment for pharmacies, are subject to obligatory registration.

The amendments to [the Decree of the Cabinet of Ministers of Ukraine of 17.10.2008 N955 On stabilization of prices for medicinal products and medical devices](#) foresee the following limits of sale increases for medicinal products included to the obligatory minimal assortment for pharmacies: not more than 12% of the registered wholesale prices and not more than 25% of the purchase price. The participants of the meeting generally supported the new regulatory initiatives.

The MOH proposed the draft order *On introducing the Code of Ethics for pharmaceutical workers in Ukraine*

The draft order *On introducing the Code of Ethics for pharmaceutical workers in Ukraine* foresees the following: to establish a Commission of the MOH on compliance of the Code; to familiarize the personnel of institutions and establishments with the Code; to establish Ethics commissions at state services, pharmacies, higher educational institutions, scientific and research institutions, professional public organizations, which would be responsible for supporting and monitoring the implementation of the Code by pharmacists and chemists of the above institutions, and organizations, central methodological department of higher medical education of the MOH of Ukraine, heads of pharmaceutical (medical) institutions and post-graduate educational institutions to make appropriate amendments to programs and curricula for students of pharmaceutical faculties, pharmacist interns and students in order to study the Code of Ethics for pharmaceutical workers in Ukraine.

Control over the implementation of this order is assigned to the First Deputy Minister Moiseenko R.O.

Public discussion of the draft Law of Ukraine *On amendments to certain legislative acts regulating the activities on implementation of medicinal products*

The draft Law of Ukraine *On amendments to certain legislative acts regulating the activities on implementation of medicinal products* proposes to introduce the following amendments:

1. To change clause 291.5 of Article 291 of the Tax code of Ukraine in order to exclude a possibility of being a single tax payer by a sole proprietor who owns more than a one pharmacy.
2. To add Article 74 of the *Basis of the legislation of Ukraine about health protection* with part 3 in the edition as follows: "sole proprietors may perform commercial activity on wholesale and retail trade of medicinal products upon the condition of compliance with the unified qualification requirements".
3. To add the Law of Ukraine *On medicines* with the provision that implementation of medicinal products shall be performed only upon a quality certificate, which is issued by a manufacturer, and a waybill under which a medicinal product was purchased.

The draft Decree of the Cabinet of Ministers of Ukraine *On amendments to the Procedure of state registration of medical equipment and medical devices*

In accordance with this Decree it is proposed to amend the Procedure of state registration of medical equipment and medical devices, approved by the Decree of the Cabinet of Ministers of Ukraine of 9.11.2004 N1497, which foresees a possibility of submittal of an application for registration and the accompanying list of documents in electronic form and being signed with an electronic digital signature of an applicant by means of telecommunication through the official website of the State Service of medicinal products of the Ministry of Health of Ukraine.

In the same time, the State Service of medicinal products of the Ministry of Health of Ukraine shall be obliged to approve the Instruction on preparing and submitting applications for state registration of medicinal devices in electronic form by means of telecommunication.

NEW REGULATORY ACTS

Standard of providing administrative services on the confirmation of the state registration of medical devices has been approved

As of now business entities, legal entities and individuals who duly submit applications with the respective annexes have a right to receive a free of charge confirmation from the State Service of medicinal products of the Ministry of Health of Ukraine about the state registration with a purpose to provide it to the customs authorities.

Terms of such administrative service are laid down in the Standard.

The Ministry of Health of Ukraine issued an informational letter concerning the state registration of medicinal products which contain medical devices

The MOH of Ukraine in his letter explained that during the provision of documents for registration (re- registration) of medicinal products the applicants should pay particular attention to the fact that if the medicinal product and medical device compose an integral unit, and medical device is a primary package of such product, and is unsuitable for reuse (as specified by the producer in the registration materials to the medicinal product), such product is subject to regulation by the Law of Ukraine *On medicines*, and does not require registration as a medical device.

If the finished form of the medicinal product comes with the medical device, which is a separate type of product, its technical and functional characteristics meet the definition of "medical device" and is intended to administration of the medicinal product into the body, such product is subject to regulation by the laws and regulations on medical products.

The list of domestic manufacturers of medicines, as of February 10, 2012.

The division of Licensing and Certification of the State Administration of Ukraine on Medicinal Products has published the list of domestic manufacturers of medicines, as of February 10, 2012.

In accordance with the list the production of pharmaceutical products in Ukraine is carried out by 116 business entities (as of January 1, 2011 - 137).

The list also mentioned that in 22 companies the production of medicines has been suspended for some or all forms.

Updated terms of registration of prices for medicines and medical products

The Cabinet of Ministers of Ukraine approved the Resolution № 74 "On Amendments to the Resolution of the Cabinet of Ministers of Ukraine from October 17, 2008 № 955 and from August 8, 2011 № 932" (hereinafter - Resolution № 74), which comes into effect from 14.02.2012.

According to the Resolution № 74 lifted a ban on the procurement of medicines and medical items at the expences of the budget, which was previously installed from September 1, 2011

According to the Resolution № 74, such a ban is to come into force again on April 1, 2012. However, domestic manufacturer instead of the 18 items calculation forms will fill only three:

- Cost;
- Profit;
- Price.

A new form has been introduced for foreign manufacturers. Henceforth it is necessary to specify:

- the customs value in national currency;
- the cost in foreign currency in accordance with the invoice;
- the exchange rate;
- wholesale selling price in local and foreign currencies.

Also, Resolution № 74 has expanded the list of documents required for registration of wholesale prices. According to the Resolution the list of medical products, wholesale and selling prices for which subject to registration, has been specified. Among them:

- dressings and suture materials;
- dental materials;
- sanitary and hygienic facilities;
- prosthetic and orthopedic devices and supplies;
- other materials and products, used in medicine and included into the State Register of medical equipment and medical supplies, that are purchased wholly or partly at the expense of the budgets.

It is also indicated that prices for medical equipment are not subject to registration. According to an updated procedure the registration of prices for products of medical appointment will require the information about the actual price of such products to be submitted in the country of origin and countries of the CIS and the EU, in which state regulation of prices for medical products is applicable.

Decree number 74 specifies record of customs duty and VAT in the calculation of wholesale and retail prices for medicines and medical supplies, purchased from the state budget funds. Limit supply and sales allowances must not exceed 10% of the registered wholesale selling price taking into account duty and VAT. Limit commercial (retail) allowances are set at a level no higher than 10% of the procurement price, including VAT.

In Zaporizhzhya enterprise was fined 15 thousand UAH. for the false information about discounts on medicines

The Administrative Board of Zaporizhzhya regional territorial office of the Antimonopoly Committee of Ukraine imposed a fine of 15 thousand UAH on LLC "Vemafarm" for unfair competition in the form of dissemination of misleading information. LLC "Vemafarm" performing retail sale of pharmaceutical products, in August-November 2011 has placed information about discounts and preferential weekend time, which contained false statements, causing delusion of consumers.

Department has determined that the granting of discounts during these periods was provided only for certain categories of consumers. The actions of the Company, which consisted in distributing advertising materials containing incomplete information about the specific medicines and discounts on them, are in violation of legislation on economic competition protection. The society has recognized and stopped the breach.

COMPANY'S PRESS-RELEASES

- [Legal Alliance became a member of the Public Council for State Inspectorate of Ukraine on protection of consumer rights](#)
- [Legal Alliance Company advises pharmaceutical company in the course of antitrust investigation](#)
- [Oleksiy Bezhevets told pharmaceutical managers about the role of lawyers in the negotiation process](#)
- [Legal Alliance – associate of the 7th analytical conference “Ukrainian pharmaceutical market between crises”](#)
- [Legal Alliance Company has shared its experience of medicinal products prices registration](#)
- [Legal Alliance Company held a workshop on the promotion of RX medicines](#)
- [Illya Kostin took part in the meeting of the Ministry of Health Committee on pharmaceutical industry activities](#)

ANALYTICS

- [The search of representative offices in a new way](#) (Eugen Shcheglov)
- [Pharmaceutical advertising: Latest trends of Ukrainian legislation](#) (Alexander Bondar)
- [Features of personal data files registration through foreign representative offices](#) (Iana Kartseva, Lidiya Sangarovskaya-Gurlach)
- [Trends in the practice of antitrust and competition law of Ukraine for 2011](#) (Victoria Ptashnyk, Oksana Kondratieva)

- New Customs Code of Ukraine: the veto has been applied, yet no proposals are adopted (Iana Kartseva)
- Licence conditions for economic activity for the production of pharmaceuticals, wholesale and retail trade of medicinal products (Andriy Gorbatenko)
- Regular changes in the certification and implementation of technical regulations concerning medical devices (Mariia Baranovych)
- Criteria of necessity to obtain permission for the concentration in M & A transactions (Victoria Ptashnyk)

UPCOMING EVENTS

Date/time	Name / link	Price
28 February 2012 10:00:00	PRACTICAL TRAINING "FOREIGN REPRESENTATIVES: CURRENT ISSUES OF BUSINESS IN UKRAINE"	1350 грн.*
13 March 2012 16:00:00	MINI-WORKSHOP "INSIDER INFORMATION: RISKS AND CONSEQUENCES"	350 грн.
27 March 2012 16:00:00	MINI-WORKSHOP "THE LEGISLATION MODIFICATIONS IN MEDICAL PRODUCTS ADVERTISING. ANALYSIS OF ADVERTISING MATERIALS IN EXAMPLES"	350 грн.

Free admission of mini-workshops for regular customer card holders.

Should you need an assistance in registration, please, don't hesitate to contact Ms. Natalia Dokuchaeva tel.: +38 044 220 15 84 (85, 86), ext. 714, e-mail: dokuchaeva@l-a.com.ua.



Legal Alliance invites you to visit The European Pharma Law Convention 2012 with 10% discount

Dear Friends,

It is the pleasure, that we bring to you «**The European Pharma Law Convention 2012**».

Legal Alliance Company will partner and support the convention and will provide legal expertise and professional input to the convention's program:

- Pricing & Reimbursement
- Legal Compliance in Pharma
- Advertisement of Pharmaceutical products
- Competition

The convention will open doors on April 25-26 in Hotel Sheraton in Bratislava, Slovakia and will welcome participants from European pharmaceutical companies, leading legal experts and practitioners, as well as representatives of national and international regulatory bodies within the Pharmaceutical industry.

The Convention program will see names of key presenters like Richard Bergstrom – EFPIA, Christofer Fjellner – European Parliament, John Chave – EUPG, Blaz Visnar – DG Competition and many others.

Please, see the program on: <http://www.lawconvention.eu/files/documents/program-bratislava-2012.pdf>

Places for all business partners, clients and friends of **Legal Alliance Company are available with 10% discount** providing access for 450 EUR - Pharmaceutical / 900 EUR – Others.

In order to book your seat, please use the exclusively provided by Legal Alliance discount code (LAEPLC). For delegate bookings, please contact Mr. Peter Nemeč +421 914 22 82 36 pn@lawconvention.eu