



Newsletter №6  
June 26, 2010

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Dear Madam /Sir:

We are happy to introduce you the following Information Digest from Legal Alliance Company, member of Eurojuris Ukraine Association.

## Theme: Revision of the Ukrainian Pharmaceutical Law

### Hot Topics

#### Order of Labeling of Pharmaceutical Products with a Braille Type

On May 19th, 2010 the draft order of the Ministry of Health of Ukraine (MOH) "On approval of an Order of labeling of pharmaceutical products with a Braille type" was posted on the official web-site of the MOH of Ukraine for public hearings. The Draft aiming to regulate the procedure of conduction of expertise of registration materials for pharmaceutical products, which are submitted for the state registration (reregistration), and also expertise of materials concerning modification of registration materials during the term of validity of a registration certificate.

The draft foresees that labeling with a Braille type shall be printed on the secondary package of pharmaceutical product, which is used in ambulatory conditions irrespective of a type of packaging, pharmaceutical form, pre-packing and dozing of pharmaceutical product.

Labeling of packages with a Braille type shall be provided in Ukrainian and/or Russian language depending on a language of labeling. It does not exclude a possibility to provide with information in several languages, one of which is a language of a producer, upon condition that provided information is identical in different languages.

Labeling shall be provided with full (not abbreviated) Braille system, where each Braille sign means a separate letter of alphabet, sign of punctuation, number, etc. Abbreviated Braille system with letter combination is applicable to packages of small volume (up to 10 ml).

Labeling with a Braille type is not obligatory for pharmaceutical products, which are used only by accredited specialists (usually, products-orphanants, pharmaceutical products for parenteral infusion, radiopharmaceutical products, etc.).

Additionally, the Draft approves a List of abbreviated names of pharmaceutical products for labeling with a Braille type.

### New Regulatory Acts

#### Control over production of pharmaceutical products which are subjected to state registration

On May 25<sup>th</sup>, 2010 the new Order of provision of control over production of pharmaceutical products, which are submitted for state registration, approved by the order of the MOH of 17.03.2010 No 236, is entered into force. The order determines such definitions as "control of production of pharmaceutical products during its state registration", "requalification" of pharmaceutical product. The Order defines criteria and procedure of provision of control over production of pharmaceutical products, which are submitted for state registration.

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## Personal Data Protection

On June 6th, 2010 the Supreme Council of Ukraine adopted the Law of Ukraine “On protection of personal data”. The Law regulates relations, connected with protection of personal data during its processing. The Law defines any information concerning a person as the personal data. Meanwhile, personal database is defined as the combination of structured personal data in electronic form and/or in form of card-registers of personal data.

In this regard, to the personal database may be referred any systemized data concerning physical persons, belonging to the legal entity, or physical person (upon condition that they are used without personal aim). The Law foresees obligatory receipt of consent from a physical person for processing of her personal data, and also registration of all personal databases in the special register. The Law essentially complicates work with personal data, requiring additional notification of a physical person concerning actions, connected with change, transfer and elimination of data.

In case of its signing by the President, the Law shall enter into force from January 01st, 2011.

## Drafts of Regulatory Acts

### Certificate of Compliance of Material and Technical Base

On May 18th, 2010, the draft order of the MOH of Ukraine “On approval of a form of a Certificate on condition of material and technical base of subjects of entrepreneurship, existence of regulatory acts, including regulations on standartization, necessary for provision of commercial activity on medical practice, reworking of donor blood and its components, production of products from them” was posted on the official web-site of the MOH of Ukraine for public hearings. The Draft aiming to improve the procedure of licensing of commercial activity on medical practice, reworking of donor blood and its components, production of products from them, provision of disinfection, desinsection, and deratisation works (except works on veterinary control).

The draft proposes to approve forms of the following certificates on condition of material and technical base of subjects of entrepreneurship, existence of regulatory acts, including regulations on standartization, necessary for:

- provision of commercial activity on medical practice;
- provision of commercial activity on reworking of donor blood and its components, production of products from them;
- provision of commercial activity on provision of disinfection, desinsection, and deratisation works (except works on veterinary control).

### State Control Over the Pharmaceutical Products Imported to the Territory of Ukraine

On April 27th, 2010 the draft of Resolution of the Cabinet of Ministers of Ukraine “On modification of the Resolution of the Cabinet of Ministers of Ukraine from September 14th, 2005, No. 902” was posted on the official web-site of the Ministry of Health of Ukraine for the public hearings. The Draft foresees a new redaction of the Regulation of the state control over the pharmaceutical products, imported to the territory of Ukraine.

In particular, the Draft defines that the control over conformity of immunobiological products is conducted under a separate regulation.

The Draft modifies the terms of performing of a quality control, namely, increases the terms for submittal of an application for quality control from three to five working days after customs clearance, increases the term for visual control from three to five working days, and also shortens the term for performing of a laboratory analysis from 21 (twenty one) to 14 (fourteen) working days.

The Draft also obliges the owners of registration certificates or their official representatives to submit copies of the original layouts of the packages with a signature of a manager and a stamp, one-time for a period of validity of the registration certificates for the pharmaceutical products, and also copy of the GMP certificate, or a license for PIC/S countries.

Contrary to the current version, the Draft foresees that the absence of GMP certificate (or a license for PIC/S countries) is enough ground to perform a laboratory analysis. In accordance with the Draft, in case of repeated importation of a series of the pharmaceutical product by the one subject of entrepreneurship, a laboratory analysis is not required, unless other grounds for laboratory analysis will be identified during visual control.

The Draft modifies an approach concerning compensation of the cost of selected samples for analysis, namely, according to the Draft the cost of the samples is included into production expenses of the subjects, from which such samples were selected.

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## **Draft Law of Ukraine “On Pharmaceutical Products”**

On June 02nd, 2010, the draft Law of Ukraine «On pharmaceutical products» was posted on the official web-site of the MOH of Ukraine for public hearings. The Draft Law regulated relations, connected with turnover of pharmaceutical products, and also foresees the order of public control and pharmacological supervision, rights and obligations of physical persons and legal entities, competence of bodies of executive power in the sphere of turnover. The Draft Law proposes to extend terminology, envisages on the legislative level such terms as the “distributor”, “generic pharmaceutical product”, “original (innovative) pharmaceutical product”, “pharmaceutical production”, “post-marketing surveillance”, “reimbursement”, “formular system”, “pharmaceutical service”, “pharmaceutical assistance”, “pharmaceutical maintenance”, etc. The Draft Law regulates the process of creation (elaboration), manufacturing, state control, importation to Ukraine and exportation from Ukraine of the pharmaceutical products in more details. The Draft Law is enlarged with a new section concerning pharmaceutical practice, which regulates question of trade of the pharmaceutical products, order of providing the population with the pharmaceutical products in case of natural disasters, catastrophes, epidemic diseases, and the order of utilization of the pharmaceutical products.

## **Draft Law of Ukraine “On National System of Emergency Medical Treatment Provision”**

On June 02nd, 2010, the draft Law of Ukraine “On national system of emergency medical treatment provision” was posted on the official web-site of the MOH of Ukraine for public hearings. The Draft Law regulates legal relations in the sphere of organization of emergency medical treatment provision, foresees rights and obligations of company’s officials, medical workers, citizens of Ukraine, foreign citizens and persons without citizenship, which are situated on the territory of Ukraine and request for emergency medical treatment. According to the Draft Law national system of emergency medical treatment provision is a component part of the health protection sphere of Ukraine, which assures urgent organizational, diagnostic and treatment measures, aimed at provision of medical services to sick or injured persons, staying in emergency condition on pre-hospital and early hospital stages all over the territory of Ukraine under unified rules, extension and normative, either in daily conditions, or in emergency conditions, and unites in its structure the following services: emergency medical treatment, State service of medicinal catastrophes and department of emergency care of multi-field hospitals.

## **Draft Law of Ukraine “On Establishments of the Health Care”**

On June 02nd, 2010, the draft Law of Ukraine «On establishments of the health care» was posted on the official web-site of the MOH of Ukraine for public hearings. The Draft Law foresees particularities of legal status, order of creation and activity of establishments of the health care, stipulates requirements concerning activity of physical persons-entrepreneurs in the sphere of the health care. Besides, the Draft Law defines particularities of activity of establishments of the health care in the following forms: budget institution, state unitary enterprise, municipal noncommercial (unprofitable) enterprise, university hospital, commercial entity, private enterprise, and also stipulates particularities of activity of physical persons-entrepreneurs in this sphere. Moreover, the Draft Law regulates activity of the establishments of health care under agreements on public procurement of medical services and agreements on provision of medical services.

## **Draft Law of Ukraine “On Medical Products”**

On June 09th, 2010, the draft Law of Ukraine «On medical products» was posted on the official web-site of the MOH of Ukraine for public hearings. The Draft Law aims at regulation of legal relations connected with development, manufacturing, operation, exploitation, control over security of medical products, their transfer throughout customs control of Ukraine, and determine rights and obligations of the producers and producer’s authorized persons, and persons, responsible for putting medical products into operation or exploitation in Ukraine, and also competence of state bodies and company’s officials in the sphere of operation of medical products. The Draft Law foresees classification of medical products depending on classes of their safety. Referring a medical product to the concrete class determines its further particularities of putting into operation and usage, namely, according to the Draft Law, clinical trials are not conducted concerning: medical products belonging to I class of potential usage risk, which during its usage does not contact with patient’s body; and medical products for diagnostic in vitro. Besides, the Draft Law establishes legal grounds of maintenance of the State register of medical products, monitoring medical incidents with medical products, foresees liability for violation of safety requirements for medical products.

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## The Company News

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### Legal Alliance Company held an online conference related to Unfair Competition: the Antimonopoly Committee as a Tool of Competition Wars

On 3, an online conference was held on [www.ligazakon.ua](http://www.ligazakon.ua) portal, arranged by Legal Alliance Company in the theme Unfair Competition: the Antimonopoly Committee as a Tool of Competition Wars.

Andrey Gorbatenko, Senior Attorney of Legal Alliance Company, and Natalia Lavrenova, Attorney, answered the online conference participants' questions.

Such issues as violations of trademark title as signs of unfair competition, coordination of operations economic entities, as well as deception of consumers by means of advertising, and consequences of such actions were discussed within the framework of the event.

You may find the whole text of the online conference at: <http://conf.ligazakon.ua/conference/competition-amku.htm>

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### Legal Alliance Company discussed admissible promotional methods with top managers of foreign pharmaceutical companies

On 18 May 2010, the Legal Alliance Company participated in the meeting held by the Association of International Pharmaceuticals Manufacturers (AIPM Ukraine); the subject was Acceptable Promotion Methods in Pharmaceutical Business.

The topicality of event participated by senior managers, representing the foreign producer of pharmaceuticals having operations in Ukraine, was explained by the change in the legislator's approach to the definition of unfair advertising of pharmaceuticals. It should be noted that the existing approaches have resulted in imposition of considerable fines on the key players at the pharmaceutical market in this country, and may result in a high risk of response on the part of supervising authorities to violations occurring in the industry.

Two panel meetings were planned at the event. The first part of the meeting was a closed round table discussion with the subject Protection of Interests of Foreign Pharmaceutical Companies in Ukraine. New Competition Rules. Executive Director of AIPM Ukraine Vladimir Ignatov and Senior Partner of Legal Alliance Company Ilya Kostin acted as moderators. At the second panel meeting the Partner of Legal Alliance Company Aleksey Bezhevets held a practical training Acceptable Promotion Methods in Pharmaceutical Business, where the attention of participants was focused on the hidden risks for advertising and marketing that may occur for pharmaceutical companies. The participants became aware of the recent court practice in the said area, heard analytical presentations, and were given an opportunity to ask questions of concern for them to practicing lawyers.

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### Legal Alliance Company provides advice to patients associations within the framework of Social Partnership Day

On April 21, 2010 a press conference was held in Kyiv related to Social Partnership Day. The event was organized by the Union of Non-Profit Organizations "All-Ukrainian Association for Protection of Patients' Rights "Health of the Nation" with assistance from Novartis Pharma Services AG.

At the event the participants (most of them - representatives of Ukrainian patients' associations) had an opportunity to learn more about the role played by non-profit organizations, their possible cooperation with pharmaceutical companies, and share their expertise as to such cooperation during lively discussions.

At the event the Legal Alliance Company was represented by its Senior Associate Andrey Horbatenko who made a presentation dedicated to the legal aspects of non-profit organizations' activities. Mr. Horbatenko said the patients' associations are dealing with charitable activities as a rule: acceptance and provision of charitable assistance in the form of property or funds. Therefore, it is important to understand what is deemed to be a charitable activity from the legal point of view. The speaker focused on the tax issues related to the non-profit organizations established for rehabilitation purposes, he gave a detailed account when an organization may be exempt from taxes and in what instances it has to pay taxes. The audience demonstrated special interest in the part highlighting the financial activities and tax inspections.

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### Legal Alliance Company developed a scheme of interaction between pharmaceutical companies and drug store networks

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April 16, the Legal Alliance Company developed the scheme of interaction between pharmaceutical companies and drug store networks.

Despite particular legal restrictions limiting the interaction between the above players operating at the pharmaceutical market, the new scheme provides with an opportunity to establish cooperation between a specific pharmaceutical company and some drug store network without the need to violate the effective provisions of the applicable Ukrainian laws.

Andrey Horbatenko, Counsel, Legal Alliance Company said “Application of the scheme allows pharmaceutical company to efficiently organize and control the actions of drug store networks connected with merchandizing, as well as keep track of fulfillment by drug store of its contractual obligations.”

The Project is supervised by Senior Partner, Legal Alliance Company, Ilya Kostin, Partner Aleksey Bezhevets, Counsel Andrey Horbatenko and associate Yana Kartseva.

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### Legal Alliance included in the rankings of Legal 500

The rankings of the International Directory Legal 500 for 2010 again included the Legal Alliance Company into the list of best Ukrainian law firms to recommend it in several practice areas.

In the Ukrainian jurisdiction “Legal Alliance” got a high ranking for its corporate practice, mergers and acquisitions and real estate and construction.

With respect to the corporate law practice and mergers and acquisitions special credits were given to the partners Aleksey Bezhevets and Anatoliy Menshikov. The key company expert as to the real estate and construction practice was the partner, Irina Pustovitenko.

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### Legal Alliance Company - Legal Adviser for ADONIS DATA AS

Legal Alliance Company acted as a legal advisor for Norwegian ADONIS DATA AS with respect to its Ukrainian representative office operation.

The services comprised advise on hot tax-related issued and also issues related to day-to-day operation of the above representative office.

The Project was supervised by the Partners Anatoliy Menshikov and Aleksey Bezhevets.

*\* ADONIS DATA AS was incorporated in 1988, it is one of the oldest developers of software for maritime navigation.*

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### Legal Alliance Company succeeded in dispute resolution as a mediator

On March 18, 2010 Legal Alliance Company resolved successfully through mediation the settlement procedure for enforcement of debt and penalties under a medical equipment supply agreement.

The conflict between the parties was based on ambiguous interpretation of the equipment supply agreement’s terms and conditions as a result of which the Supplier intended to enforce payment of the debt and penalties under the agreement, and the Customer was trying to terminate the Agreement and obtain repayment of the funds earlier paid.

Initial legal claim amount was UAH 1,421,628.28.

In the course of the mediation procedure which took 3 days the Parties managed to find common ground that resulted in mutual compromise.

Legal assistance to the dispute was provided by Legal Alliance Company Senior Partner Ilya Kostin and Associate Natalia Lavrenova.

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For more detail please refer to Legal Alliance Company web site, [www.legalalliance.com.ua](http://www.legalalliance.com.ua)

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