

LEGISLATION NEWS

Banking & Finance

- Verkhovna Rada Adopted the Law “On Realization of Social Initiatives of the President of Ukraine Regarding Cheapening of the Cost of Mortgage Loans”
- Amendments to the Order on Cheapening of the Cost of Mortgage Loans for Providing with Affordable Housing Citizens, in Need of Housing Conditions Improvement
- The Law “On Introduction of Amendments to Certain Legislative Acts of Ukraine (Regarding Functioning of Payment Systems and Development of Cashless Settlements)” Adopted in the First Reading

Capital Markets / Investment

- The Law “On the Institutes of Joint Investments” Adopted in the New Edition
- The Law “On Introduction of Amendments to Article 11 of the Law of Ukraine “On Securities and Stock Market” Adopted

Corporate Law / M&A

- Draft Laws on Simplification of the Procedure for Termination of Activity of Private Entrepreneurs with No Employees

Labour Law

- Law of Ukraine “On Employment of Population” Passed in Second Reading

Healthcare and Pharmaceuticals

- Promotion of Medicinal Products Restricted
- Medicinal Products Import Licensing
- Determining Wholesale Prices of Medicinal Products to Treat Hypertension
- Combating Counterfeit Medical Products
- New Bill to Ban Medicinal Products Advertising
- State Regulation of Medical Waste Introduced
- Restrictions on the Movement of Goods across the Border

- Import of Medicinal Products and Baby Food
- Law of Ukraine “On Prices and Pricing” Adopted
- Measures against Counterfeit Medicines Toughened
- Changes in State Registration Procedure for Medical Devices
- Clinical Trials of Medical Equipment and Medical Devices
- Toxicological Aid System
- Electronic Patient Registry
- Changes in the Regulation of Trade in Narcotic Drugs and Precursors
- Agreement on Procedure for Transferring Samples of Narcotic Drugs, Psychotropic Substances and Their Precursors Ratified

Food & Drinks

- Procedure for Processing or Disposal of Confiscated Ethyl Alcohol, Alcoholic Beverages and Tobacco Products
- Changes in the Excise Tax on Cognac and Cognac Drinks
- Changes in Food Labeling
- Changes in the Payment Transactions Registration Procedure

Customs Law

- New Customs Document Has Entered into Force
- Ukrainian Transport Inspection to Strengthen State Control over Motorists and Truck Carriers
- Clarification on Customs Clearance of the Commodity “Roasted Coffee”

Arzinger Success Stories

- Scientific-Practical Edition “Competition Law: Protection against Unfair Competition” to Be Published
- Lana Sinichkina Included into the Working Group to Finalize the Law on Domestic Trade

Verkhovna Rada Adopted the Law “On Realization of Social Initiatives of the President of Ukraine Regarding Cheapening of the Cost of Mortgage Loans”

- On July 05, 2012, the Verkhovna Rada of Ukraine on the basis of Draft Law No. 10557 adopted the Law “On Realization of Social Initiatives of the President of Ukraine Regarding Cheapening of the Cost of Mortgage Loans” (hereinafter – the “Law”).

The Law, in particular, established that in the State budget of Ukraine for 2013 and subsequent years shall be foreseen expenses for compensation of interest, paid out to banks and/or other financial institutions under loans, granted to citizens for construction (reconstruction) or purchase of residential housing. The compensation of interest shall be effected in order set forth by the regulation on cheapening of the cost of mortgage loans, established by the Cabinet of Ministers of Ukraine.

The Law also determines that the financing of objects of uncompleted construction, at the expense of the state budget programs, can be executed by way of concluding of agreements on sale purchase of property rights between the project owners of construction (owners, managers) and citizens.

The Law “On Mortgage” was supplemented with a provision, in accordance with which the person, who based on the agreement on satisfaction of claims of the mortgagee or a corresponding stipulation in the mortgage agreement on satisfaction of claims of the mortgagee, acquired ownership right to the mortgage property, based on the land plot, which is leased by the mortgagor, acquires the right to lease such land plot.

The indicated agreement on satisfaction of claims of the mortgagee or a corresponding stipulation in the mortgage agreement on satisfaction of claims of the mortgagee shall be deemed to be a document, confirming the transfer of the lease right of the land plot to the new owner of the mortgage property and the change of the lessee in the land lease agreement and shall be subject to state registration in order established by law.

If signed by the President of Ukraine, this Law will become effective on the day following its official publication.

Amendments to the Order on Cheapening of the Cost of Mortgage Loans for Providing with Affordable Housing Citizens, in Need of Housing Conditions Improvement

- On June 27, 2012 the Cabinet of Ministers of Ukraine introduced amendments to the Order on Cheapening of the Cost of Mortgage Loans for Providing with Affordable Housing Citizens, in Need of Housing Conditions Improvement, approved with the Cabinet of Ministers of Ukraine Resolution No. 343 dated April 25, 2012.

In particular, the amendments foresee the possibility to decrease the amount of the first payment in case of granting of additional collateral under the loan agreement in accordance with the internal rules of banks. In addition, now the borrower can conclude suretyship agreements not only with every legally capable family member, residing together with the borrower, but also with other guarantors, as well as provide additional pledges under the loan agreement.

The partial compensation of interest is granted to borrowers provided that the monthly payment under the loan agreement (excluding partial compensation of interest) does not exceed 50 % of the aggregate average family income. At that, the sum, which is left after all monthly payments under the loan agreement, must not be less than one living wage for the borrower and each member of his/her family, for whom the calculation of partial compensation of interest was carried out.

Also, the CMU eliminated requirements as to the upper income level of the borrower and his/her family members for receiving partial compensation of interest, as well as the necessity to annually submit the family income declaration to the tax service bodies.

The amendments took effect on July 07, 2012.

The Law “On Introduction of Amendments to Certain Legislative Acts of Ukraine (Regarding Functioning of Payment Systems and Development of Cashless Settlements)” Adopted in the First Reading

- On July 04, 2012, the Verkhovna Rada of Ukraine on the basis of Draft Law No. 10656, introduced by the National Bank of Ukraine (hereinafter – the “NBU”), adopted in the first reading the Law “On Introduction of Amendments to Certain Legislative Acts of Ukraine (Regarding Functioning of Payment Systems and Development of Cashless Settlements)” (hereinafter – the “Draft Law”).

The explanatory note to the Draft Law reads that the aim of the document is to ensure constant, reliable and efficient functioning of payment systems, mass implementation of cashless settlements and development of the national payment infrastructure.

One of the main novelties of the Draft Law is the empowering of the NBU to establish maximum limits of cash payments at settlement for goods and services. At that, the state tax service, according to the suggested amendments, will execute control over adherence to the order of cash settlements for goods (services), the order of acceptance of cash for its further transfer by bank and over compliance with the legislative requirements regarding mandatory ensuring by economic entities of the possibility for payment for goods (services) with electronic payment means.

Thus, in accordance with the proposed changes to the Code on Administrative Violations, the refusal to accept a payment card will be subject to a fine in amount of 500 non-taxable minimum incomes (UAH 8,500 as of today). Also, pursuant to the suggested changes to the Criminal Code of Ukraine, criminal liability will be introduced for forgery of electronic money, their illegal issue and use.

The Draft Law also envisages introduction of amendments to the Law “On the National Bank of Ukraine”, namely by broadening the authorities of the regulator, in particular, by foreseeing that the NBU:

- Coordinates and controls the creation of payment instruments;
- Keeps the register of payment systems, settlement systems, participants of such systems and operators of services of payment infrastructure;

- Executes supervision (oversight) over payment systems and settlement systems;
- Determines the order of execution in Ukraine of routing, clearing and settlements between the participants of the payment systems under operations, executed within the territory of Ukraine with the use of payment cards, issued by banks-residents;
- Keeps the register of commercial agents of banks;
- Determines the order of application of digital signature, including the electronic digital signature, for verification of electronic documents for transfer of funds; and
- Issues licenses to non-banking financial institutions, which aim at becoming members of payment systems, for money transfer without opening of accounts, and withdraws such licenses in accordance with legislation.

The proposed changes to the Law “On Payment Systems and Transfer of Monies in Ukraine” relate to definitions, in particular, new definitions are introduced (e.g., system of settlements, processing, routing, payment means, mobile payment instrument etc.) while certain existing definitions (e.g. acquiring, electronic payment means, payment organization etc.) are amended.

Amendments to the Law “On Payment Systems and Transfer of Monies in Ukraine” also foresee that the NBU maintains the Register of payment systems, settlement systems, participants of such systems and operators of services of payment infrastructure (hereinafter – the “Register”). Inclusion of information to the Register is a necessary pre-condition for activity of payment organizations of payment systems, participants of payment systems and operators of services of payment infrastructure. The Draft Law also sets forth the volume of such information.

The proposed amendments also envisage that banks, which have concluded agency agreements with legal entities (commercial agents), bear responsibility to the payer and the receiver, connected with the transfer execution, in accordance with the law and agreements, concluded between them.

In accordance with the Draft Law banks will be obliged to introduce SMS-banking service (notification on every operation on the client’s cell phone) for all cardholders without exception. If the bank fails to do so, it shall reimburse to the client all losses, in case of funds disappearance.

Pursuant to the Draft Law, the NBU will acquire full control over all payment systems, which are active or represented in Ukraine, including those which operate through payment terminals and accept money for mobile connection, housing utilities, etc. In order to continue their

activity, the owners of the networks of terminals will be required to obtain a corresponding license from the NBU. Currently such payment systems carry out their activity based on licenses issued by the National Commission for Regulation of Markets of Financial Services.

The Draft Law provides additional requirements for international payment systems (such as VISA and MasterCard), which operate in Ukraine. In particular, they will be required to register with the NBU their rules of work in Ukraine. Following this, they will be required to transfer their guarantee deposits of Ukrainian banks-issuers of payment cards to UAH and to Ukrainian banks, and the processing of payments inside Ukraine – to the processing centers in Ukraine.

The Draft Law also grants to the NBU the right to establish the order of execution in Ukraine of routing, clearing and settlements among the participants of payments systems under operations, executed in Ukraine with the use of payment cards issued by banks-residents, and to ensure the formation and placement of guarantee deposits of members of payment systems under operations, executed within the borders of Ukraine with the use of payment cards in national currency of Ukraine, on the accounts of the NBU and other banks of Ukraine.

In addition, the Draft Law grants the right to banks to place on the payment card two or more payment system's trademarks.

If adopted in its current wording, the Draft Law will become effective immediately after its official publication.

CAPITAL MARKETS / INVESTMENT

The Law “On the Institutes of Joint Investments” Adopted in the New Edition

- On July 05, 2012, the Verkhovna Rada of Ukraine on the basis of Draft Law No. 9615 adopted the Law “On the Institutes of Joint Investments” in the new edition (hereinafter – the “IJI Law”).

The IJI Law significantly expands the possibilities of the institutes of joint investments (hereinafter – the “IJI”), in particular, by providing a detailed list of assets, which can be acquired by a particular IJI. The IJI Law also regulates the activity of specialized investment funds.

One of the most important changes is the return of the right for IJI to act as shareholders of commercial banks. Some time ago the legislators restricted such right of IJI, which caused critic among the market participants.

In accordance with the IJI Law the requirement regarding mandatory rating does not apply to venture funds. Also, a new article was introduced regarding conversion of securities of IJI, which is a withdrawal from circulation of securities of a particular IJI with simultaneous exchange for the securities of another IJI, given that both IJIs are managed by the same asset management company.

The IJI Law also introduced the definition of qualified IJI, which will in fact have almost no requirements to the assets structure. Individuals could become participants of such IJIs only in case of acquisition of securities for the sum of no less than 100 minimal salaries.

The IJI Law will become effective one year following the termination of the year, in which it was published, save for certain provisions, which will become effective simultaneously with the Law “On Derivatives”.

The Law “On Introduction of Amendments to Article 11 of the Law of Ukraine “On Securities and Stock Market” Adopted

- On July 04, 2012, the Verkhovna Rada of Ukraine on the basis of Draft Law No. 10630 adopted the Law “On Introduction of Amendments to Article 11 of the Law of Ukraine “On Securities and Stock Market”.

The adopted Law sets forth the possibility of denomination of the nominal value of treasury bonds of Ukraine in

national currency or foreign currency.

The Law also envisages that the terms of placement of treasury bonds of Ukraine shall be adopted by the Ministry of Finance of Ukraine in accordance with the legislation. Further, the Law stipulates that the sale, payment of

cash income under and redemption of treasury bonds of Ukraine shall be executed in national or foreign currency in accordance with the terms of their placement.

This Law will become effective on the day following its official publication.

CORPORATE LAW / M&A

Draft Laws on Simplification of the Procedure for Termination of Activity of Private Entrepreneurs with No Employees

- In July 2012 there were 2 draft laws on simplification of the procedure for termination of activity of private entrepreneurs with no employees.

Thus, Draft Law No. 11005 submitted to Ukrainian Parliament envisages a simplified procedure for conduction of unscheduled inspections and reduction of their periods (up to 3 business days) concerning private entrepreneurs with no employees if they declared no economic activity income, are no VAT payers, if tax authorities have no information that they have employees or opened accounts in banks of other financial institutions.

Moreover, the web-site of the Ministry of Justice of Ukraine published another bill on so called “application” principle for termination of activity of private entrepreneurs who have no employees. If this draft law is passed

into the law, an application to the state registration will be sufficient and termination will be registered not later than on the next business day, provided, of course, that there are no grounds for refusal (in particular, if Unified State Register contains no information on employees, outstanding taxes or other compulsory payments).

In general, these changes would be welcomed, if it was not for the ultimate Ukrainian problem when a law is passed but is impossible to be enforced on practice. Thus, first of all, a lot of work shall be done in order to implement full-scaled information exchange between different governmental agencies in Ukraine that could make the practical use this supposed “application” principle possible. The actual enforcement of this law can only happen if the state begins to work persistently on this problem. But currently it is rather a declaration than reality.

LABOUR LAW

Law of Ukraine “On Employment of Population” Passed in Second Reading

- On July 5, 2012 Ukrainian Parliament has passed in second reading the Draft Law No. 10497-1 dd. 22.05.2012 into Law of Ukraine “On Employment of Population”.

The law was presented for public discussion on the website of the Ministry of Social Policy as early as in April this year.

According to demand of the modern employment market the Law introduces new terms, such as employee’s competitiveness, young employee, voucher (document for re-qualification, upgrade of qualifications of a person etc.) and implements new effective mechanisms in order to stimulate employment of the population.

Positive novelties for employees are employment quotas for certain categories of employees, including:

- 1) a parent or a parent substitute supporting children under 6 years of age; a single parent with a child under 14 years of age or a disabled child; or a person supporting on his/her own a person disabled from childhood (irrespectively of age) or a I group disabled person;
- 2) orphans and children without parental care;
- 3) persons of 15 years of age who, as an exception, may be employed provided consent of parents or a person substituting them;
- 4) ex-convicts or persons after compulsory treatment;
- 5) young adults after graduation or termination of education in general educational, vocational training and higher educational establishments, after obligated military or alternative service (within 6 months after end of the training or the service) employed for the first time;
- 6) persons having less than 10 years till retirement.

For employment of foregoing categories of persons pursuant to paragraph 2 article 14 of the Law companies with less than 20 staff employees shall provide 5 per cent of jobs.

The Law also provides different bonuses for employers if they create new jobs. If a company creates new jobs for such employee categories for at least two years, it will

receive reimbursement of single social security contributions for such persons. If an employer creates new jobs, employees such persons and pays them a monthly salary of at least three minimal wages for a year, and if the salary remains unchanged during this period, it will receive 50 per cent of the single social contribution accrued for such persons during the year. Small entrepreneurs who create new jobs and employ unemployed persons for at least two years will receive monthly reimbursement of the single social contribution.

The initiators of the law have introduced an effective mechanism for stimulation of self-employment. Young professionals agreeing to work in rural regions for at least 3 years will be provided with housing and one-time payment of 10 minimal wages.

An employer performing works (implementing an infrastructure project) at the expense of the state or local budgets will be obliged to give jobs under such projects to unemployed persons.

For full-time students in higher educational or vocational training establishments the Law provides a possibility of paid or unpaid internship with opening of a work book.

Persons of 45 years of age with at least 15 years of insurance record will be entitled to a voucher for professional re-training.

In order to create jobs for unemployed persons the territorial bodies will provide paid community jobs for up to 180 calendar days.

Professional training for unemployed persons will be carried out upon order of an employer for a specified job position or for self-employment, and there will be a possibility to confirm professional qualification obtained through informal education.

At this, for the first time the Law regulates activity of private requirement agencies, including employment by such agencies of employees for work by another employer. It is also envisaged to stimulate employment market intermediaries towards consolidation and to give them a status of self-regulating organizations in order to delegate them certain powers as to making propositions on formation and implementation of the state employment policy.

The Law specifies conditions of employment of foreigners and circumstances when no work permit is required.

Moreover, status of an unemployed person will be given from the first day of registration with the State Employment Service, and not from the 7th lacking appropriate job offers. If working times are cut by more than 50% em-

ployees are entitled to apply for partial unemployment aid. Employees of pre-retirement age having less than 1.5 years till retirement are entitled to early retirement in case of staff reduction.

Currently, the Law is being prepared to be submitted to the President of Ukraine for signing.

HEALTHCARE AND PHARMACEUTICALS

License for Import of Medications

- On July 26, 2012 the President of Ukraine signed the Law of Ukraine “On Amendments to Certain Legislative Acts of Ukraine (on licensing import of medications and definition of the term “active pharmaceutical ingredient”)” as adopted by the Ukrainian Parliament in the second reading on July 4, 2012 based on draft law No.10562.

This Law changes the definition “medication” and legislative stipulation of the definition “active pharmaceutical ingredient”.

Moreover, the law sets forth a procedure for licensing import of medications according to which import of medications to Ukraine is allowed only provided their registration in Ukraine accompanied with series quality certificate issued by the manufacture and a license for import of medications issued to the importer (a manufacturer or a person representing the manufacturer) according to the procedure as required by law.

The annex to the license shall contain a list of medications which the licensee is allowed to import and special conditions for conduction of the activity. At this, an import license is issued if there is sufficient material and technical basis, qualified personnel and quality control conditions for medications to be imported to Ukraine.

It shall be stressed out that the law shall come into force on the next day after its publishing save for single provisions as provided by transitional provisions of the law. Thus, the requirement regarding the license for import of medications to Ukraine will come into force as of 01.03.2013, and the procedure for licensing the import of active pharmaceutical ingredients (substances) will be implemented beginning with 01.01.2015.

Strengthening of the Liability for Falsification of Medications

- On July 26, 2012 the President of Ukraine signed the Law of Ukraine “On Amendments to Certain Legislative Acts of Ukraine on Strengthening Liability for Falsification or Turnover of Falsified Medications” as adopted by Ukrainian Parliament in the second reading on July 4, 2012 based on draft law No. 10561.

This draft law amends article 442 of the Code of Ukraine on Administrative Violations pursuant to which violation of limitations set forth for healthcare and pharmaceutical professionals during exercise of their professional activity is an administrative violation and subject to a fine in amount of 300 tax-free allowances (currently, UAH 5 100), and in case of repeated violation to a fine in amount of 1200 tax-free allowances (currently, UAH 20 400).

It is important to highlight that consideration of cases connected with violation of limitations set forth for healthcare and pharmaceutical professionals during exercise of their professional activity will be delegated to the State Service of Ukraine for Medications which is envisaged by amendments introduced by this Law to article 2448 of the Code of Ukraine on Administrative Violations.

Besides, the law strengthens criminal liability for contraband of narcotics, psychotropic, their analogues and precursors or falsified medications (article 305 of the Criminal Code of Ukraine). In particular, the criminal liability has been increased and now constitutes 5 to 8 years by first offence, 8 to 10 years by repeated offence or in a conspiracy or 10 to 12 years if offense is committed by an organized group.

Moreover, criminal liability for falsification of medications is imprisonment for 3 to 5 years with confiscation of falsified medications; repeated violation or in a conspiracy results in imprisonment for 5 to 8 years; actions provided by part 1 or 2 of this article, if caused death or other grave consequences, are punished with imprisonment for 8 to 10 years or life imprisonment.

It shall be noted that the Criminal Code of Ukraine was amended with article 3212 which provides criminal liability for violation of established procedure for pre-clinical trial, clinical trial and state registration of medications. In particular, intended violation of the established procedure for pre-clinical trial, clinical trial and state registration of medications is punished with imprisonment for 3 to 5 years with revocation of the right to hold certain positions or exercise certain activity for 1 to 3 years, and repeated violation or violation committed in a conspiracy results in imprisonment for 5 to 8 years. Actions provided in part 1 or 2 of this article, if caused death or other grave consequences, are punished with imprisonment for 8 to 10 years with revocation of the right to hold certain positions or exercise certain activity for 2 to 3 years. This law shall come into force on the next day after its publishing.

6. Medication is designed for treatment of:

- TB
- STDs
- highly dangerous contagious diseases
- HIV/AIDS
- cancer and other tumors
- diabetes
- obesity (including medications used for reducing body weight)
- impotence (erectile dysfunction)

Besides, resolution of the Cabinet of Ministers of Ukraine dd.16.07.2012 No. 629 introduced changes to resolution of the CMU dd. 31.03.2004 No. 411 “On Approval of the Regulation on the State Medication Registry” according to which the State Medication Registry will now contain information about advertisement prohibition of a medication, pharmacopeia article or quality control measures for a medication. These amendments are effective since July 18, 2012.

Single Issues of Pharmaceutical Advertising

- On June 6, 2012 decree of the Ministry of Health of Ukraine No.422 “On Certain Issues of Prohibition of Medications Advertising” was adopted. This decree was revised by the Ministry of Health of Ukraine and was repeatedly submitted for state registration to the Ministry of Justice of Ukraine. On July 16, 2012 it was registered by the Ministry of Justice of Ukraine under No.1189/21501. This decree was officially published on July 30, 2012 and came into force.

This decree stipulates criteria for prohibition of pharmaceutical advertising. Such criteria include:

1. Medication is sold on prescription.
2. Medication contains narcotics, psychotropic substances and precursors.
3. Use of the medication could be addictive which is indicated in the instruction for medical use, except medications for external (local) application.
4. Medication is intended for treatment of women during pregnancy or breastfeeding only.
5. Medication is intended for treatment of children under 12 years of age only.

Procedure for Import to Ukraine of Unregistered Medical Equipment and Medicinal Products

- On July 2, 2012 draft order of the Ministry of Health of Ukraine “On Approval of the Procedure for Import to Ukraine of Unregistered Medical Equipment and Medicinal Products” was presented for public discussion. According to this draft the currently effective order of the State Medication Inspection of the Ministry of Health of Ukraine dd. 16.06.2010 No.112 “On Approval of the Procedure for Import of Unregistered Medicinal Products to the Customs Territory of Ukraine” shall cease to be in force. According to the new procedure there shall be no electronic notices-letters with which the State Medication Service sends to the State Customs Service permits or prohibits to import unregistered medicinal products. The new procedure does not apply to import of medicinal products for exhibition, fair, conference purposes provided their export from Ukraine after end of the event, for conduction of drug multicenter clinical trials and as humanitarian aid. At the same time, issuance of a permit for import of unregistered medicinal products will now take 5 business days instead of 30. An interesting point is that current procedure clearly stipulates that

customs clearance of unregistered medicinal products is carried out after customs authorities receive a written/electronic notice allowing import of unregistered medicinal products to Ukraine.

Moreover, on July 3, 2012 the Ukrainian Parliament registered draft law No. 10691 “On Amendments to the Tax Code of Ukraine (concerning cancellation of incentives for medicinal products)” which envisages cancellation of the special VAT-free import regime for medicinal products. Pursuant to the explanatory note to the draft law these amendments are motivated by a consideration that cancellation of the VAT-free regime for medicinal products has made the negative trends on the market even worse (dumping import of syringes, avoidance of anti-dumping payments), has reduced production volumes of these products in Ukraine and use of existing capacities (for example, one-way syringes – 40-45%), and has created unequal competition conditions for economic entities.

New Requirements to Professional Activities of Medical and Pharmaceutical Professionals

- On July 3, 2012 the Ministry of Justice registered the Order of the Ministry of Health dd. 14.06.2012 № 440 “On Amendments to the Procedure for Writing Prescriptions and Applications for Medical Products and Medical Devices”, the essence of which is reduced to the permission to prescribe medicines under their trade names. Also, the amendments provide that INN, if any, shall be indicated in the prescription. On 26 July 2012 the President signed the Law of Ukraine “On Amendments to the Basic Law of Ukraine on Healthcare Regarding the Establishment of Restrictions in the Exercise of Professional Activities by Medical and Pharmaceutical Professionals”. The law was passed by the Parliament of Ukraine based on the bill No.10560. According to this law significant restrictions are imposed on the promotion of medicinal products. It is important to note that the requirements of the Law will prevail over the order of the Ministry of Health of Ukraine. Therefore, the following restrictions will apply (Article 78-1)¹ from the date of its entry into force:

Medical and pharmaceutical professionals acting as such shall not have the right:

1. To obtain unlawful benefits from business entities that produce and/or sell medicinal products and medical devices, or from their representatives.

This rule does not introduce any novelties, since it is fully consistent with the Law of Ukraine “On the Principles of Preventing and Combating Corruption.”

2. To obtain samples of medicinal products or medical devices for using them in their occupational activities from business entities that produce and sell medicinal products or medical devices, or from their representatives (except for cases related to clinical trials of medicinal products or medical devices conducted under agreements).

In contrast to the previous restrictions, this rule will seriously affect the pharmaceutical market of Ukraine. Distribution of samples of medicinal products among medical and pharmaceutical professionals (sampling) was not regulated by any applicable laws and, while being in the “grey zone”, was often practiced by pharmaceutical companies. However, due to the adopted amendments medical and pharmaceutical professionals are directly prohibited from receiving samples of medicinal products or medical devices.

In fact, this rule reproduces the provisions of subparagraph 3), paragraph 1, article 74 of the Federal Law “On the Fundamentals of Public Healthcare in the Russian Federation” (RF), which states that, (medical professionals and heads of medical organizations are not entitled, inter alia, to receive samples of medicinal products or medical devices from a company or a company’s representative for their subsequent delivery to patients (except in cases related to the conduct of clinical trials of medicinal products or clinical trials of medical devices). This ban came into force on January 1, 2012.

It is important to note that in the European Union sampling is considered to be advertising according to the Directive 2001/83/EC of the European Parliament and of the Council, and thus can be legally practiced under certain conditions.

3. To advertise medicinal products or medical devices, including to write prescriptions on forms that contain advertising information and indicate the manufacturers of medicinal products (trademarks);

This restriction carries a lot of risks for the pharmaceutical business:

- implementation of the so-called “card” projects allowing patients to purchase medicines at reduced prices, which means that physicians (pharmacists) would provide information in respect of particular medicinal products under a TM to patients. In this case, physicians’ informing patients about special offers may be regarded as a violation of the said restriction and may

1 According to the wording of the bill prepared for the second reading. The Bill signed by the President has not been published at the time of this message.

entail the respective physician's liability, which in turn may lead to reputational risks for a pharmaceutical company and to potential non-routine inspections of pharmaceutical companies by supervisory authorities and law enforcement agencies;

- brand reminders (like medical staff clothing, medical devices, pens, notepads, calendars, etc.) that bear trade names of medicinal products, which actually advertise medicinal products, available in a doctor's consulting room may be considered a violation of the above restrictions. Therefore, physicians are likely to refuse to accept such "gifts" from pharmaceutical companies; this will make the latter to review their latest promotional policies and reallocate the budgets;
- there is a high risk that state authorities will interpret the wording "to advertise medicinal products or medical devices, including to write prescriptions on forms that contain advertising information and to indicate the manufacturers of medicinal products (trade-marks)" as a requirement to prescribe medicines under international non-proprietary names (INN), leaving the choice of a medicinal product (specific brand, trade name) to a patient. In this case, some questions arise: as we know, even medicines similar in the active substance and bearing the same international non-proprietary name may have a different composition of excipients that can significantly affect the patients' treatment and state. For instance, if a patient is allergic to some of the excipients a physician must prescribe exactly the medicinal products that contain no substances causing an allergic reaction, which may be considered as a violation under the Law.

It should be noted that the practice in Russia has taken a similar path. Thus, on July 24, 2012 the President of Russia signed the amendments to the Federal Law as of July 21, 2005 No.94-FZ "On Placing Orders for Supplies of Goods, Works and Services for State and Municipal Needs". According to the amendments, if the subject of an auction, including an auction in electronic form, is the supply of medicinal products, the auction documentation shall contain a reference to the international non-proprietary name (hereinafter the INN) of the medicinal product; if there is no INN, the chemical or grouping names of medicinal products should be indicated.

4. To refuse to provide a patient with information at the patient's request, or to provide incorrect information about the availability of medicinal products with the same active substance (according to its international non-proprietary name) in the respective pharmacy, its distribution form and dosing, in particular to con-

ceal the information about the availability of similar low-price medicines. The provisions of this paragraph apply to pharmaceutical professionals only.

According to this restriction, the right to choose a medicinal product is really left to the patient, whereas pharmaceutical companies are virtually deprived of such promotion channels as physicians or pharmacists.

The restrictions imposed on medical and pharmaceutical professionals actually restrict the promotional activities of the entire pharmaceutical business.

The law has entered into force on August 1, 2012.

Changes in Public Procurement Procedure

- On July 4, 2012 the bill No. 9634 substantially amending the Law of Ukraine "On Public Procurement" was passed into law. The bill fully exempts most of the state-owned enterprises, including utilities, state-owned companies and business companies with state ownership exceeding 50% from the bidding procedure for procurement of goods and services. The said law considerably **restricts the scope of application of the law on public procurement by extending the list of goods and services, the procurement of which is not regulated by this document. These are acquisition or lease of land, buildings, other real property or property rights to land; services provided by courts of arbitration for consideration and resolution of disputes in which the customer is involved; financial services provided in connection with issue, purchase, sale, transfer of securities or other financial instruments, etc.**

According to some experts, these changes make public procurement opaque, which might lead to cases of corruption and inefficient spending of budget funds. The Press Service of the Parliament reports that the purpose of the act is to improve the legislation on public procurement. Thus, **it clarifies the powers of the Ministry of Economic Development and Trade of Ukraine in monitoring public procurement; introduces the possibility to procure food products under a shortened procedure, and establishes cases of cancellation of the procurement procedure in one party by the customer, etc.** The law was signed by the President of Ukraine on 01.08.2012.

Procedure for Monitoring Medical Care Quality

- On July 6, 2012, the draft of the order of the Ministry of Health of Ukraine “On Procedure for Monitoring Medical Care Quality” was submitted for public consultation. The Procedure provides for the implementation of measures to monitor the quality of medical care in health facilities. In particular, it is provided that the quality management and control of medical care shall be the responsibility of the Ministry of Health of Ukraine. Coordination, advice and functional assistance in health facilities will be provided by Coordinating Councils to manage quality of medical care and medical advice in health facilities, established by order of the Ministry of Health of Ukraine dated 24.02.2010 No. 163 “On Medical Care Quality Management”.

The purpose of medical care quality management is to ensure that the patients receive proper quality medical care in the required amount. It suggested that medical care quality control should be based on self-assessment, peer review, clinical audit, monitoring indicators of the quality attestation/certification, etc.

Changes in the Procedure of Supervising Business Operations in Sales of Medicines

- On July 13, 2012 the bill of Ukraine “On Amendments to article 2 of the Law of Ukraine “On Basic Principles of State Control (Supervision) in the Sphere of Business Activities” was submitted for public consultation. The bill provides for amendments to article 2 of the Law of Ukraine “On Basic Principles of State Control (Supervision) in the Sphere of Business Activities” (hereinafter the Law). In particular, it is proposed to exclude the state quality control of medicines from the scope of the Law. The ultimate goal of these amendments is the possibility to conduct inspections of business entities without notifying them of the date and time of inspection. This is impossible to date, due to the operation of part 3, article 4 of the Law, which states that the scheduled and unscheduled inspections shall be carried out during working hours of an economic entity, which shall be set the internal labour regulations. Also, paragraph 1 part 4 article 5 of the Law provides that state control agencies shall conduct scheduled inspections subject to a prior written notice, which shall be delivered to a business entity no later than ten days prior to the inspection.

Changes in the License Terms for Business Activities in Sales of Medicines

- On July 13, 2012 the bill of Ukraine “On Amendments to Article 21 of the Law of Ukraine “On Licensing the Certain Types of Business Activities” was submitted for public consultation. The bill provides the amending of the article 21 of the Law of Ukraine “On Licensing the Certain Types of Business Activities” by the part, according to which a licensee that has filed a complaint with the Expertise and Appeal Board against a decision passed by the licensing agency on revocation of a license for business activities in the production of medicines, wholesale and retail in medicines shall suspend the above type of business activities 30 days from the date of that decision, until an appropriate decision is passed by the special licensing authority. In fact that, this provision obliges business entities to suspend their operations after the decision to revoke the license has come into force, since the decision to revoke the license comes into force 30 days after its adoption. Thus, the business entity is not able to apply for a license again, which creates a nuisance for the regulator.

Changes in Public Procurement and Pricing Procedure

- On July 17, 2012 the bill amending the resolution of the CMU No. 955 dd. 17.10.2008 “On Measures to Stabilize the Prices of Medicinal Products and Medical Devices” was submitted for public consultation. The amendments shall provide for delivery and sales margins not exceeding 12 percent of the wholesale selling price and trade (retail) margins not exceeding 25 percent of the purchase price must be established for medicinal products and medical devices that are included in the National List of Essential Medicinal Products and Medical Devices (except narcotics, psychotropic drugs and precursors and medical gases) and the mandatory minimum range (socially-oriented) medicinal products and medical devices for pharmacies determine by the Ministry of Health. Thus, it is proposed to strengthen state regulation of medicinal products sales in pharmacies.

The List that sets the minimum range of medicinal products and medical devices for pharmacies has been approved by the order of the Ministry of Health of

Ukraine No. 1000 dd. 29.12.2011 “On approval of the mandatory minimum range of (socially-oriented) domestic medicinal products and of medical devices to pharmacies”. It contains a considerable share of OTC medicinal products that are not in the National List of Essential Medicinal Products and Medical Devices. Thus, pricing regulation is introduced for this group of medicinal products.

control of food products (imported into Ukraine, except for transit) and preliminary documentary control of goods the carrier or freight forwarder shall provide an international sanitary certificate issued by the expert country (the original) to the customs, if such certificate is required for sanitary measures.

To date, international sanitary certificates for sanitary measures are provided for in none of the exporting countries. Should this procedure be introduced, the State Sanitary and Epidemiological Service will notify thereof and provide an additional sample of the international sanitary certificate.

Introduction of the Electronic Registry of Patients

- On July 16, 2012, the order of the Ministry of Health No. 532 approving the Interim Procedure for Electronic Registry of Patients in Vinnytsia, Dnipropetrovsk and Donetsk regions and Kyiv was signed.

The document provides the establishing research centres to implement an electronic registry of patients on the basis of information and analytical centres of medical statistics till 1 September 2012, and for submitting proposals to the State Enterprise “National Center for Health Statistics of the Ministry of Health of Ukraine” concerning the improvement of the order of Interim Procedure for Electronic Registry of Patients in Vinnytsia, Dnipropetrovsk and Donetsk regions and Kyiv till October 1, 2012.

Two application programs have been chosen to operate the electronic registry. It is important to note that patients shall be included in the electronic registry of patients on the basis of their application to a health facility for treatment and subject to their written consent for processing their personal data. The sources of formation of the registry shall be the documents that identify a person – passport (birth certificate, residence permit, etc.) and information about the individual (patient), which is contained in medical records.

Changes in the Waste Management Procedure

- On July 6, 2012, the President of Ukraine signed the Law of Ukraine “On amendments to Article 31 of the Law of Ukraine “On Waste”, which was passed by the Parliament of Ukraine on July 6, 2012 based on the bill No. 10555.

According to the Law, the Cabinet of Ministers, ministries and other central and local authorities are entrusted, with within their competence, with the development and implementation of the system for collection, removal, disposal, and recycling of waste generated in the process of medical care provision, veterinary practice and related research.

In addition, a range of measures is introduced to prevent or reduce the volumes of medical waste. It is important to note that, under Article 23 of the Law of Ukraine “On Medicinal Products”, the procedure for recycling and disposal of medicinal products shall be set by the central executive body in the health care industry. Indeed, this procedure is established by Order of the Ministry of Health of Ukraine No. 349 dd. 08.07.2004.

Changes in the Application of Sanitary Measures at Checkpoints

- By the letter No. 03.07/2522/14 dd. 12.06.2012 the State Sanitary and Epidemiological Service informed about changes in the Procedure for preliminary documentary control at checkpoints across the state border (Decree of the Cabinet of Ministers of Ukraine No. 449 dd. 21.05.2012). Thus, for sanitary and epidemiological

FOOD & DRINKS

Procedure for Processing or Disposal of Confiscated Ethyl Alcohol, Alcoholic Beverages and Tobacco Products

- According to the Order of the Cabinet of Ministers of Ukraine No. 577 dd. 25.06.2012 “On Amendments to the Procedure for Registration, Storage, Evaluation of Confiscated and Other Property Transferred into State Ownership, and Disposal thereof, and Repeal of Certain Decisions of the Cabinet of Ministers of Ukraine”, the Procedure for disposal or destruction of expired or substandard or dangerous alcoholic drinks and tobacco products, approved by Decree of the Cabinet of Ministers No. 508 dd. 19.04.2004, has been repealed. In addition, changes have also been made in the Procedure for Registration, Storage, and Evaluation of Confiscated and Other Property Transferred into State Ownership, which is approved by the Resolution of the Cabinet of Ministers of Ukraine No. 1340 dd. 25.08.1998, according to which it is established that:
 - Ethyl alcohol, alcoholic beverages and tobacco products that are confiscated or pass into state ownership shall be stored in places records on which are included in the Unified State Register of Storage Places, whereas those placed under customs control may also be stored in warehouses of the customs;
 - Later, ethyl alcohol and alcoholic beverages are subject to industrial processing or destruction, and tobacco products are subject to destruction (to date, they are transferred for sale into the retail network or sold by the Ministry of Defense), respectively;
 - Recycling or destruction of ethyl alcohol, alcoholic beverages and destruction of tobacco products shall be carried out by decision of the commission formed by the agency that seized them, subject to the following requirements:
 - If required, the commissions may engage representatives of territorial agencies of the Ministry of Economic Development and Trade of Ukraine, State Veterinary and Phytosanitary Service and state-owned enterprises that produce alcohol. The decision is made with regard to economic feasibility of industrial processing, in terms of the seized volume, alcohol content, transportation costs, and, if necessary, on the basis of the conclusions prepared by these agencies and enterprises;
 - Industrial processing of ethyl alcohol and alcoholic beverages shall be made at the state-owned enterprises producing alcohol, the list of which shall be determined by the Ministry of Agriculture in coordination with the State Tax Service;
 - Enterprises that have processed ethyl alcohol and alcoholic beverages shall sell the ready products and transfer the funds to the appropriate budget or, in prescribed cases, to accounts of the customs;
 - Ethyl alcohol, alcoholic beverages and tobacco products shall be destroyed in coordination with State Sanitary and Epidemiological Service in enterprises certified to perform the corresponding operations in accordance with the Law “On Withdrawal, Recycling, Disposal, Destruction, or Continued Use of Defective or Dangerous Products”.

Changes in the Excise Tax on Cognac and Cognac Drinks

- On June 21, 2012 the Parliament of Ukraine registered the bill No. 10653 “On Amendments to Subsection 5 of Section XX “Transitional Provisions” of the Tax Code of Ukraine Concerning Peculiarities of the Application of Excise Tax Rates to Alcoholic Distillates and Alcoholic Beverages Produced by Distilling Grape Wine or Grape Marc” submitted by the Cabinet of Ministers. The bill shall establish a single excise tax rate for all alcoholic beverages referred to in commodity heading 2208 of the Ukrainian Commodity Classification for Foreign Economic Activity (UKT VED) starting from 01.09.2012 (to date from 01.01.2013). According to the currently applied rules the excise tax rate for cognac (coded according to UKT VED 2208 20 12 00, 2208 20 62 00) within the period from 01.01.2012 till 01.01.2013 shall be 27 UAH/1 liter of 100% alcohol. At the same time, other alcoholic beverages referred to in the commodity heading 2208, which are similar or directly compete with or substitute cognac products shall be taxed at the rate of 45.87 USD per 1 liter of 100% alcohol. This is contrary to

Article III of the General Agreement on Tariffs and Trade 1994 and the Rules of the intergovernmental bilateral free trade agreements providing for national treatment with respect to internal taxation of goods originating from other countries.

Rights”. Therefore, the provisions of the Law of Ukraine “On Protection of Consumers’ Rights” regulating the information about product properties, including product labeling, shall not apply to food product, unless otherwise expressly provided by this Law. In other words, the bill provides for separate regulation of food labeling.

Changes in Food Labeling

- On July 30, 2012 the bill of Ukraine “On Information for Food Consumers” was submitted to public consultation. The bill shall regulate the relations between executive authorities, market operators and consumers of food products and shall determine the legal procedure for providing information about food products intended for end consumers, including food products in public catering establishments, as well as foods that are delivered to catering facilities. The bill was drafted by the Ministry of Health pursuant to paragraph 103.1.1 of the National Action Plan for 2012 regarding implementation of the Economic Reforms Program in 2010 - 2014 “Rich Society, Competitive Economy and Effective State”. It is interesting to note that article 3 of the bill establishes a new section of legislation stating that legislation for information about food products consists of this Law and other regulations, which are issued in accordance with it and establish information requirements for certain types of food only. At the same time, article 15 of the Law of Ukraine “On Protection of Consumers’ Rights” states that consumers have the right to relevant, affordable, reliable and timely information about the products allowing conscious and informed choice. Thus, paragraph 2 part 1 of the same article regulates the list of information that must be contained in the product information. However, the final provisions of the bill include amendments to the Law of Ukraine “On Protection of Consumers’

Changes in the Payment Transactions Registration Procedure

- On July 16, 2012, the amendments to the Law of Ukraine “On the Application of Payment Transactions Registrars in Trade, Catering and Services” were submitted for public discussion. The bill envisages the introduction of mandatory compliance of payment transactions registers with the technical rules of payment transactions registrars after the entry into force of these regulations. Importantly, the bill shall cancel the obligations of business entities to daily print fiscal receipts, if no payment transactions took place. Also, the bill provides that compliance of business entities performing purchase and sale operations with foreign currencies shall be monitored by the National Bank of Ukraine and the State Tax Service of Ukraine by conducting actual tests. In addition, the use of payment transactions registrars is provided for non-bank financial institutions, which is a novelty. Non-bank financial institutions are credit unions, pawnshops, leasing companies, trust companies, insurance companies, pension funds savings institutions, investment funds and other legal entities, whose exclusive activity is the provision of financial services.

CUSTOMS LAW

New Customs Document Has Entered into Force

- On July 20, 2012 three new orders of the Ministry of Finance of Ukraine have entered into force pursuant to the Regulation on the Ministry of Finance of Ukraine approved by Presidential Order No. 446/2011dd. 08.04.2011. The orders regulate, inter alia, the customs sphere in the light of the New Customs Code of Ukraine, namely:
 - Order No. 599 On approval of the Customs Value Declaration Form and rules for its completion, which determines the procedure for completing the customs value declaration used by the declarant to determine and declare the customs value of goods crossing the customs border of Ukraine in accordance with the customs procedure for imports;
 - Order No. 607, which approves a typical settlement agreement to discontinue proceedings on violation of customs regulations and acts on their performance or nonperformance provided for by article 521 of the Customs Code of Ukraine;
 - Order No. 614 On approval of Procedure for filling customs declarations for a written declaration of goods moved across the customs border of Ukraine by individuals for personal, family or other needs not related to business activities, which determines the rules for filling, presentation and use of the declaration for goods moved across the customs border of Ukraine in hand luggage, accompanied and unaccompanied baggage or cargo shall be subject to written declaration in the manner provided for individuals.
- To introduce the European system of licensing, with a preliminary pre-licensing control;
- To increase the level of drivers training and retraining by introducing a new profession of a commercial vehicle driver. Obtaining a certificate of eligibility to this activity will require not only driving skills but also knowledge of transport legislation

As noted, the proposals developed by Ukrainian Transport Inspection require changes to the Laws of Ukraine “On Motor Transport”, “On Licensing Certain Types of Economic Activity” and the Code of Administrative Offences. The proposals are now reviewed by specialized departments of the Ministry of Infrastructure and interested non-governmental organizations, and then will be submitted to the Cabinet of Ministers, which has the right to initiate changes in legislation in accordance with Article 93 of the Constitution of Ukraine.

Clarification on Customs Clearance of the Commodity “Roasted Coffee”

- The State Customs Service of Ukraine has provided a clarification on customs clearance of the commodity “roasted coffee” by its Letter No. 11.1/3-16/8718-EII dd. 31.07.2012.

The letter notes that there is a discrepancy between the List of Commodities subject to state control (including in the form of preliminary documentary control) moved through the customs border of Ukraine (hereinafter the List of Goods) – Annex to the Resolution of the Cabinet of Ministers of Ukraine No. 1031 as of October 5, 2011, and the List of Objects of regulation in the sphere of plant quarantine (hereinafter the List of Objects) No. 705 as of 12.05.2007, approved by the Cabinet of Ministers of Ukraine.

The difference is as follows. According to the List of Goods, roasted coffee moved across the customs border of Ukraine is subject to sanitary-epidemiological and phytosanitary control. However, the List of Objects

Ukrainian Transport Inspection to Strengthen State Control over Motorists and Truck Carriers

- To improve the legislation in the sphere of motor transport, the State Inspection of Ukraine for Road Transport Safety (Ukrainian Transport Inspection) has taken the initiative to amend it, namely as follows:
 - To obtain the right to stop and detain a vehicle, to draw up protocols on administrative violations, as well as to introduce a system of levying fines as in the EU;

does not contain such an object of regulation as “roasted coffee”. Given the above, the State Customs Service of Ukraine notes in the letter that roasted coffee” may be moved through the customs border of Ukraine and undergo customs clearance (product codes according to the

UKT VED Code 0901 21 00 00 0901 22 00 00) without sanitary and epidemiological and phytosanitary control according to the decision of the Cabinet of Ministers of Ukraine No. 705 dd. 12.05.2007, until the List of Goods is amended appropriately.

ARZINGER

SUCCESS STORIES

Scientific-Practical Edition

“Competition Law: Protection against Unfair Competition” to Be Published

- Justinian Publishing House released the paper “Competition Law: Protection against Unfair Competition” co-authored by Head of the Legal Enforcement Laboratory of Science and Technology Development of the Institute of Intellectual Property of the National Academy of Legal Sciences of Ukraine Gennady Androshchuk and President of the Association for Resistance to Unfair Competition (ARUC), Senior Partner at Arzinger Law Office Sergiy Shklyar.

The work is based on the generalized international research of the World Intellectual Property Organization (WIPO), Organisation for Economic Cooperation and Development (OECD), the authors’ systemic analysis of laws and regulations and of foreign and domestic judicial and departmental practice. It deals with the theoretical and practical aspects of competition law related to protection against unfair competition. The authors provide a detailed analysis and classify unfair competition practices (mixing, misleading, discrediting competitors, misuse of others’ trademarks, imitation, comparative advertising, violation of trade secrets, etc.) and show the mechanism of protection as well as civil, criminal and administrative sanctions applied to infringers.

The publication provides an in-depth analysis of foreign competition law and describes the peculiarities of legal regulation of protection against unfair competition in industrialized and post-socialist countries. The authors cite the provisions of WIPO Standards on protection against unfair competition; foreign litigation and dispute resolution practice of the Antimonopoly Committee of Ukraine;

practical comments to the Laws of Ukraine “On Protection from Unfair Competition” and “On Advertising”.

The book is designed for researchers, teachers, graduate students of law and economics departments, law practitioners, and employees of public agencies, businesses and all those interested in economic and legal issues of protection against unfair competition.

To buy a book, please, contact Justinian Publishing House at:

Phone: **(044) 230-01-73, 230-01-74**
e-mail: info@justinian.com.ua

Lana Sinichkina Included into the Working Group to Finalize the Law on Domestic Trade

- Arzinger’s Counsel Lana Sinichkina joined the working group at the Ministry of Economic Development and Trade of Ukraine to finalize the provisions of the Law of Ukraine “On Domestic Trade” and prepare it for Parliamentary consideration. In particular, Lana actively advises team members on legislative regulation of legal relations that are affected by this bill.