

The *Amended Law* provides that the description of special symbols used in labeling and the definition of a particular food product so as to cause it to belong to a certain category of special food products, such as dietetic or those designated for children, must be carried out in the manner provided by the Cabinet of Ministers.

15.4.5 Hazard Analysis and Critical Control Point System

Under the *Amended Law*, subjects of entrepreneurial activity (defined as individuals and legal entities which engage in the development, production, transportation, storage, import, sale, usage, and/or utilization of food products and food raw materials), are obliged to take measures with respect to the stage-by-stage implementation of the international system of food products quality assurance “Hazard Analysis and Critical Control Point” (the HACCP) at their respective enterprises. The terms and conditions of such stage-by-stage implementation will be governed by the Ukrainian legislation to be adopted in relation to particular categories of food products.

16. INDUSTRY REGULATION

16.1 Banking

16.1.1 The Ukrainian Banking Sector

The Ukrainian banking sector has a two-tier structure made up of the National bank of Ukraine (the “NBU”) and commercial banks of various types and forms of ownership. The banks act in accordance with the *Constitution of Ukraine*, the *Civil Code of Ukraine*; the *Commercial Code of Ukraine*, the *Law of Ukraine “On the National Bank of Ukraine”* dated 20 May 1999 (the *National Bank Law*), the *Law of Ukraine “On Banks and Banking Activity”* dated 7 December 2000 (the *Banking Law*), and the *Law of Ukraine “On Financial Services and the State Regulation of the Markets of Financial Services”* dated 12 July 2001, Ukrainian legislation on joint stock companies and other business entities, as well as the NBU regulations and their respective constituent documents.

16.1.2 The Role of the National Bank of Ukraine and Monetary Policy

The NBU is the central bank of Ukraine. Established in 1991 and governed by the *Constitution of Ukraine* and the *National Bank Law*, the NBU is a specialized state institution with the principal objective of ensuring the external and internal stability of the national currency and possessing broad regulatory and supervisory functions in the banking sector. The NBU is empowered to develop and conduct monetary policy, organize banking settlements and the foreign exchange system, ensure stability of the monetary, financial and banking systems of Ukraine, and protect the interests of commercial bank depositors.

The principal governing bodies of the NBU are the Council and the Board. The Council, the highest governing body of the NBU, consists of 15 members, seven of whom are appointed by Parliament and seven of whom are appointed by the President. The Chairman of the NBU (nominated by the President and appointed by Parliament for a five-year term) acts *ex officio* as the fifteenth member of the Council. The Council is charged, in particular, with developing the principles of Ukraine's monetary policy and has the right to veto the Board's decisions if they contravene such principles. The Board, which is comprised of the Chairman, his or her deputies and other members of the Board, is responsible for implementing Ukraine's monetary and other policies in the banking sector and generally managing the activity of the NBU.

The NBU is charged with implementing monetary policy. Currently, the NBU implements monetary policy through instruments such as mandatory reserve requirements for banks, interest rates, refinancing of commercial banks, deposit operations, and reverse repo operations. The main channel for the release of funds into circulation is the foreign currency market. With signs of the economy beginning to stabilize after the financial crisis in 1998 and the ensuing economic instability in the region, the NBU reduced the discount rate from 45% at the beginning of 2000 to 12.5% by the end of 2001, and 7% in December 2002. Since then, the NBU has gradually increased the discount rate to 9.5% (effective as of 10 August 2005) and then decreased to 8.5% (effective as of 10 June 2006), and then decreased to 8% (effective as of 1 June 2007). As of 1 January 2008, due to macroeconomic and monetary indicators, the discount rate was raised to 10% and as of 30 April 2008 it was raised again to 12%.

Since 1 March 2004, the NBU has been separately determining interest rates on overnight unsecured loans (10.5% as of 1 November 2006), increased to 25% (effective as of 25 December 2008) and overnight loans secured by state securities (9.5% as of 1 November 2006), increased to 22% (effective as of 25 December 2008) and setting separate interest rates on deposits from banks placed with the NBU for various terms. For example, as of 1 November 2006, the interest rates for 14 day and 30 day deposits were 0.5% and 1% respectively. Since 2007 the NBU ceased to set the latter interest and started determining interest rates on depositary certificates. For example, as of 31 December 2008, the interest rates for 5 day and 14 day certificates were 12% and 25% respectively.

The main goal of the NBU's monetary policy in 2009, as declared by the NBU, was to maintain the stability of hryvnia in order to achieve the main strategic goals, such as sustainment of stable and balanced economic growth, raise of employment, real incomes and life standards in Ukraine.

16.1.3 Commercial Banks

The current Ukrainian legislation distinguishes between “universal” (general) commercial banks and “specialized” commercial banks, with the latter including savings, investment, mortgage, and settlement (clearing) banks.

On 4 October 2006, new amendments to the *Banking Law* came into effect, whereby the minimum statutory capital requirement for all new banks at the moment of registration is established at EUR10 million. This rule will apply to the banks that are established after the law came into effect. In addition, the law provides that banks should be established only in the form of an open joint stock company or cooperative bank (*i.e.*, it will not be permitted to establish banks in the form of a closed joint stock company or limited liability company). The banks established as closed joint stock companies or limited liability companies are obliged to be reorganized into open joint stock companies within three (3) years after the entry into force of the amendments to the *Banking Law*. However, the NBU suggested that all banks, which did not yet comply with this regulatory requirement, should be reorganized into public joint stock companies according to the new law “*On Joint Stock Companies*”, which would become effective after 29 April 2009.

The regulatory capital (*i.e.*, the sum of principal (core) capital and additional capital) cannot be less than the minimum statutory capital requirement and the minimum regulatory capital requirements established by the NBU. From 1 May 2004,

the NBU calculates the minimum regulatory capital requirement in an amount equivalent to the Euro amounts set forth by the Banking Regulation Instruction. As of 1 January 2007, the minimum regulatory capital requirements for newly established banks (those that have been in existence for less than one year) are UAH36.1 million (EUR5 million) for nationwide banks, UAH21.7 million (EUR3 million) for regional banks and UAH7.2 million (EUR1 million) for cooperative banks. The requirements for “existing” banks (*i.e.*, which existed before January 2006) are UAH59.5 million (EUR8 million) for national wide banks, UAH37.2 million (EUR5 million) for regional banks and UAH11.2 million (EUR1.5 million) for cooperative banks. Since 3 October 2008 this regulatory capital requirements schedule is no longer effective. As of 11 October 2008, the minimum regulatory capital requirement for banks is UAH74.1 million (EUR10 million). Banks whose regulatory capital by 10 October 2008 was less than EUR10 million must increase it accordingly: (i) banks with more than EUR8 million regulatory capital must increase it to EUR9 million by 1 July 2009 and then must increase it further to EUR10 million by 1 July 2010; (ii) banks with less than EUR8 million regulatory capital must increase it to EUR7 million by 1 January 2010 and then must increase it further to EUR8,5 million by 1 January 2011 and then finally must increase it to EUR10 million by 1 January 2012.

16.1.4 Banks with Foreign Participation and Branches of Foreign Banks

A foreign bank may establish its presence in Ukraine through a representative office (with no right to conduct banking business) and/or a Ukrainian commercial subsidiary bank. On 16 November 2006, Verkhovna Rada passed the *Law of Ukraine “On Amendments to Law of Ukraine “On Banks and Banking Activity”* (the *Amended Banking Law*) relating to the possibility for foreign banks to open branches in Ukraine. As of 16 May 2008, the *Amended Banking Law* entered into effect.

Foreign participation in a Ukrainian commercial bank is not limited (albeit previously Ukrainian legislation established a threshold of 35% of the charter capital); however the prior permission of the NBU is required for the establishment of a commercial bank with foreign participation, or for the “conversion” of an existing commercial bank into a bank with foreign participation. Notwithstanding that the applicable legislation does not limit the allowed participation in the charter capital of a commercial bank to any maximum threshold (unlike the previously established threshold of 35% of the charter capital), the permission of the NBU is still required for a Ukrainian

or foreign legal entity, or for an individual, to directly or indirectly own, hold, or control various thresholds of a commercial bank's charter capital or voting rights in its governing body, *i.e.*, 10% or more, 25% or more, 50% or more, or 75% or more. At each threshold, a new permission of the NBU must be obtained.

16.1.5 Banking Operations

A commercial bank carries out its banking activities pursuant to a banking license issued by the NBU. A banking license permits a bank to: attract funds (deposits) from legal entities and individuals; open, maintain, and carry out transactions with current accounts of clients and correspondent banks; and place its attracted funds in its own name, on its own terms, and at its own risk. Only a duly licensed commercial bank may carry out all of the foregoing, which are referred to by the applicable legislation as "exclusive banking operations."

In addition, a banking license will, by default, enable a bank to conduct the following transactions, without any need to obtain a separate NBU permit:

- transactions with "currency valuables" (except those transactions for which an individual license of the NBU is required in accordance with applicable Ukrainian currency regulations);
- the issuance of securities;
- the sale-purchase of securities pursuant to a client's authorization;
- transactions with securities (including underwriting) conducted in the bank's own name;
- the issuance of monetary guarantees and third party suretyships;
- factoring;
- leasing;
- the provision of safekeeping services (but not including the custody of securities);
- the issuance, purchase-sale and servicing of checks, promissory notes, and other negotiable payment instruments;
- the issuance of banking payment cards and the conducting of operations with such cards; and

- the rendering of consulting and information services related to banking operations.

A duly licensed commercial bank will also be permitted to carry out the following transactions, but only subject to a separate NBU permit:

- investment in other legal entities or in shares issued by other legal entities;
- the issuance, placement, organization of circulation and redemption of monetary lotteries;
- the transportation of currency valuables and cash collection;
- transacting on a client's or on the bank's own behalf with money market instruments, foreign exchange and interest based instruments, financial futures and options;
- conducting trust operations with funds and securities of legal entities and individuals; and
- conducting securities registration and depository activities.

16.1.6 Loan Provisioning

Banks must meet mandatory requirements to cover net loan risks and review those provisions on a monthly basis. Some loan products, such as so-called “budget loans”, real-estate backed leasing transactions, subordinated loans, uncommitted off-balance sheet credit lines and funds in foreign currency transferred to the NBU under direct repo transactions, do not require any provisions. With effect from 10 April 2007, Ukrainian legislation sets forth separate provisioning requirements for loans in the national or in the foreign currencies as well as for certain consumer loans.

Other loans are classified into five major categories to which, with effect from 28 December 2008, the following provisioning requirements are applied: standard loans (1% provisioning requirement, or 50% for loans in foreign currency to borrowers, who have no foreign currency earnings), loans on watch list (5% or 100% for loans in foreign currency to borrowers, who have no foreign currency earnings) substandard loans (20% or 100% for loans in foreign currency to borrowers, who have no foreign currency earnings), doubtful loans (50% or 100% for loans in foreign currency to borrowers, who have no foreign currency earnings) and bad loans (100%). Provisioning requirements applicable to consumer loans are: 2 per cent for standard loans, 10 per cent for loans on watch, 40 per cent for substandard loans, 80 per cent for doubtful loans and 100 per cent for bad loans.

16.1.7 Competition

As of 1 January 2009, 197 commercial banks were registered in Ukraine, out of which 184 banks were granted licenses by the NBU to perform banking transactions. As of 1 December 2008, the total net assets of all commercial banks in Ukraine amounted to UAH850.6 billion (approximately US\$110.5 billion/EUR83.4 billion), their credit portfolio (including interbank loans) amounted to UAH728.0 billion (approximately US\$94.5 billion/EUR71.4 billion), including UAH428.5 billion of corporate loans and UAH249.6 billion of retail loans; their balance capital amounted to UAH100.3 billion (approximately US\$13 billion/EUR10.2 billion), corporate deposits and current accounts amounted to UAH132.4 billion (approximately US\$17.2 billion/EUR13.5 billion) and retail deposits and current accounts amounted to UAH204.2 billion (approximately US\$26.6 billion/EUR20.8 billion).

According to the NBU, during the thirteen months ended 1 October 2008, the statutory capital of Ukrainian banks having licenses to perform banking operations increased by 71.1%, amounting to UAH60.3 billion as at 1 October 2008, (compared to a 37.4 per cent. increase in statutory capital during previous eight months in 2007). During the nine months ended 1 October 2008, the total assets and total liabilities of Ukrainian banks having licenses to perform banking operations increased by 26% and 25.2%, respectively (compared to increases of 76.2 per cent. and 77.4 per cent., respectively, in 2007). The regulatory capital of Ukrainian banks increased by 50.1% during the eleven months ended 1 December 2008, amounting to UAH107.4 billion (the NBU data does not specify whether this figure refers to all banks or only those licensed to perform banking transactions).

In 2009, commercial banks operating in Ukraine are divided by the NBU into four groups according to their regulatory capital and size of assets as at 30 December 2008. In particular, 18 major banks with total assets of more than UAH14.0 billion were classified in the first group. 20 banks with total assets ranging from UAH4 billion to UAH14.0 billion were classified in the second group, 24 banks with total assets ranging from UAH1.5 billion to UAH4 billion were classified in the third group and 120 banks with total assets of less than UAH1.5 billion were classified in the fourth group. As at 1 October 2008, two of the largest banks in Ukraine, namely the Ukrainian Export-Import Bank (Ukreximbank) and the State Savings Bank of Ukraine (Oschadsbank), are state-owned and have approximately 10.6 per cent of the Ukrainian banking sector's total assets. As of 1 December 2008, 50 banks in Ukraine had some foreign capital of which 18 were fully foreign owned. Banks with

foreign capital comprise over 46% of the total statutory capital of banks in Ukraine, as at 1 October 2008. According to NBU information, there are no plans to limit the amount of foreign capital in the Ukrainian banking sector.

No single bank currently has a dominant position in any banking business in Ukraine. The level of concentration in the Ukrainian banking industry (measured using the Herfindahl-Hirschman index) is similar to the levels in the United Kingdom or France.

Ukraine was badly affected by the world financial crisis. The NBU has restricted foreign currency lending in the fourth quarter of 2008 and introduced tighter foreign currency loan provisioning requirements, which would apparently lead to decline in foreign currency lending transactions in 2009. The average annual lending rate of Ukrainian commercial banks as at 29 January 2009 was 28.6 per cent for loans in hryvnia and 11.6 per cent for loans in foreign currency, according to NBU statistics.

16.1.8 Consumer Protection

In 2007 the NBU adopted regulations on mandatory disclosure to individual customers of the essential information relating to consumer loans by Ukrainian commercial banks. According to the NBU Regulation *“Rules Governing Disclosure of Consumer Information by Ukrainian Banks, Related to Consumer Loans Terms and Over all Cost of Credit”*, approved by NBU Resolution No.168 dated 10 May 2007, all banks are required to disclose the effective rate of interest under loans granted to individual consumers in the text of the loan agreement. Also, banks are required to obtain a written confirmation from the consumer stating that he/she has received all the information from the bank relating to the terms and conditions of the loan and, specifically, the costs of the loan to the consumer.

Additionally, on 12 December 2008 Parliament passed the Law of Ukraine No 661/VI *“On Prohibition for Banks to Change the Conditions of Loan and Deposit Agreements Unilaterally”*, whereby the banks now are not allowed to amend and change unilaterally the essential conditions of loan agreements and deposit agreements concluded with their corporate and individual clients. If the agreement contains such clause, then this clause is regarded as void *ab initio*. This measure was introduced by Verkhovna Rada in order to calm down the reaction of the banks to the world financial crises. However, it is unlikely to have a significant impact on the market, because it applies only to those agreements, which will be concluded after new law became effective.

16.2 Insurance

16.2.1 Regulatory Framework

Insurance services in Ukraine are governed, *inter alia*, by:

- (i) the *Law of Ukraine “On Insurance,”* dated 7 March 1996, as restated on 4 October 2001 (the *Insurance Law*);
- (ii) order of the State Commission for the Regulation of the Financial Services Markets of Ukraine No. 4934 “*On the Approval of the Regulation for Entering Data Regarding Legal Entities Seeking Insurer (Reinsurer) Status into the State Registrar of Financial Institutions*” dated 22 November 2005;
- (iii) order of the State Commission for the Regulation of the Financial Services Markets of Ukraine No. 40 “*On the Approval of the Conditions for the Licensing of Insurance Activity*” dated 28 August 2003;
- (iv) regulation of the Cabinet of Ministers of Ukraine No. 1523 “*On the Procedure for the Activity of Insurance Intermediaries*” dated 18 December 1996;
- (v) regulation of the Cabinet of Ministers of Ukraine No. 124 “*On the Approval of the Procedure and Requirements for Reinsurance with a Non-Resident Insurer (Reinsurer)*” dated 4 February 2004; and
- (vi) the *Law of Ukraine On the Prevention of, and the Counteraction to the Legalization of, Money Laundering* dated 28 November 2002, as amended.

16.2.2 Regulation of Activity of an Insurance Company

The State Commission for the Regulation of the Financial Services Markets of Ukraine (the “Regulator”) is the specialized state agency responsible for the regulation and control of the insurance business in Ukraine. The Regulator is authorized to issue licenses to insurance companies as well as to adopt specific insurance regulations. The Regulator is also authorized to carry out on-site inspections and document examinations of insurance companies. Finally, the Regulator may demand an additional annual audit of the financial statements of an insurance company, to be conducted by an auditor appointed by the Regulator at the cost of the insurance company.

Insurance companies are obliged to submit quarterly and annual reports to the Regulator. In addition, insurance companies are obliged to prepare and publish their annual financial statements and consolidated reports. The accuracy of these reports must be confirmed by an independent auditor.

The *Insurance Law* also regulates reinsurance. When the cost of insuring a single object exceeds 10% of the sum of paid charter capital and formed free reserves and insurance reserves, the insurance company is obliged to conclude a reinsurance agreement.

An insurance premium may only be paid in hryvnia. Upon agreement of the parties the financial obligations of the life insurance agreement may be determined in a foreign currency. Insurance benefits are to be paid in the currency stated in the insurance agreement.

16.2.3 Registration of an Insurance Company

A Ukrainian legal entity must undergo the following registration procedures in order to be qualified to carry out insurance activity:

- (a) state registration and various post-registration formalities to allow it to qualify as a local legal entity (subsidiary);
- (b) registration with the State Register of Financial Institutions, which confirms its status of a financial institution; and
- (c) receipt of an insurance license, either for life insurance services or general (non-life) insurance services.

16.2.4 State Registration

Under the *Insurance Law*, foreign insurers are not allowed to conduct direct insurance activity in the Ukrainian market except for:

- (a) insurance of risks related to overseas transporting, commercial aviation, launching of spaceships and freight (including freight of satellites), transit insurance contracts providing coverage against risks relating to cargo in transit and/or transport by which the cargo is transferred, and/or any liability arisen as a result of such cargo transportation;
- (b) reinsurance;

- (c) intermediary services in the form of agency or brokerage operations for reinsurance of risks explicitly mentioned in paragraph (a) above; and
- (d) auxiliary insurance services such as, for example, consulting, actuarial risks assessment and satisfaction of claims.

Only a Ukrainian legal entity in the form of a joint-stock company (open or closed), a general partnership, a limited partnership, or an additional responsibility company may become an insurer in Ukraine.

The *Insurance Law* requires that an insurer must be established by, and must exist with, at least three shareholders (participants). Ukrainian and foreign legal entities and individuals may be shareholders of an insurance company.

Only legal entities with an insurance license may use the words “insurer”, “insurance company” and “insurance organization” in their name.

Insurance companies which provide life insurance are prohibited from providing any other types of insurance, except for:

- (a) re-insurance of life insurance;
- (b) financial activities connected with the accumulation, investment, and management of insurance reserves (asset management);
- (c) crediting the insured individuals; and
- (d) the performance of any operations aimed at satisfying its own business needs.

The charter capital (fund) of an insurer must be paid in cash, with the exception that 25 per cent may be paid by state securities at par value. The statutory minimum for the charter capital of an insurer must be equal to the UAH equivalent of EUR1,000,000.00 for an insurance company not issuing life insurance, and the UAH equivalent of EUR1,500,000.00 for a life insurer. The total amount paid by an insurance company to the charter capital of any other Ukrainian insurer must not exceed 30% of its own charter capital (fund), and 10% of the charter capital per a particular insurer. However, this requirement does not apply to the insurer who provides services different from life insurance and contributes to the charter capital of the insurer who provides life insurance services.

16.2.5 Registration as a Financial Institution

In order to obtain and maintain the status of financial institution a company must file an application for registration with the State Register of Financial Institutions and comply with the following requirements:

- (a) the company's paid-in charter capital must be equal to or exceed the UAH equivalent of EUR1,000,000 (calculated in accordance with the exchange rate of the NBU on the date of its application) for an insurance company, or EUR1,500,000 for a life insurance company;
- (b) the company must have the required number of qualified insurance professionals, office premises, and software, hardware, and communication facilities installed therein.
- (c) the company must present a business plan of its insurance activity for not less than three years.

16.2.6 Insurance License

In order to obtain and maintain an insurance license a financial institution must comply with the following requirements in addition to the requirements discussed above.

A financial institution must adopt and register its insurance conditions (containing a description of all of its insurance products) and any amendments thereto with the Regulator.

The actuary of an insurance company must have (i) a university degree; (ii) at least three years actuarial work experience for a life insurance company; (iii) a special qualification certificate issued by the Regulator; and (iv) a document proving successful completion of the professional exams according to the American or British examinations systems.

The General Manager and Chief Accountant of a company must have advanced professional skills and a good business reputation, in particular:

- (i) the General Manager (or Deputy General Manager) must hold a university (or equivalent) degree in law or economics and have at least five years relevant work experience;

- (ii) the Chief Accountant must hold a university degree in economics and have at least two years relevant work experience;
- (iii) both the General Manager and Chief Accountant must (a) complete the appropriate professional skills enhancement courses organized by the Regulator; (b) not have been the senior manager or chief accountant of a financial institution declared bankrupt or subjected to compulsory liquidation over the previous last five years; and (c) not have any standing conviction for a deliberate crime, including crimes in commercial or administrative spheres.

In order to obtain a license an insurance company must submit to the Regulator the following documents:

- (i) copies of statutory documents and the state registration certificate;
- (ii) a bank or auditor certificate confirming the amount of paid charter capital;
- (iii) a certificate on the financial condition of the insurance company certified by an auditor, where the insurance company is created as a general partnership or limited partnership, an additional liability company or a joint-stock company;
- (iv) insurance conditions;
- (v) a study of the feasibility of the planned insurance or reinsurance activity; and
- (vi) information regarding the participants of the insurance company, the head of the executive body and its deputies; a copy of the diploma in economics of the chief accountant plus information on respective certificates in cases provided by the Regulator.

The Regulator is obliged to decide upon the application of the insurance company within 30 days of obtaining all the necessary documents. In the event that changes are made to the documents submitted to the Regulator, the insurance company must inform the Regulator of such changes within 10 days.

16.2.7 Insurance Agents and Brokers

There are two types of insurance intermediary in Ukraine: (i) agents; and (ii) insurance and reinsurance brokers.

A broker is a representative of an insured entity and may not engage in any activity other than brokerage. Brokerage activities are very narrowly defined in Ukraine and do not include the provision of any services on behalf of and/or in favor of an insurance company.

According to Ukrainian law a broker must have a brokerage agreement with an insured rather than with an insurance company. Moreover, a conservative interpretation of existing Ukrainian law suggests that a broker may not enter into an agreement with an insurance company.

Ukrainian law also states that a broker must receive its fee from an insured rather than from an insurance company.

This conclusion has been confirmed by the Regulator. On at least one occasion a Ukrainian broker has been penalized by the Ministry of Finance of Ukraine for receiving fees and bonus payments from an insurance company.

More importantly, according to Ukrainian law the sale of the insurance products of one company must not constitute more than 35% of a broker's activity. In other words a broker must sell the insurance products of at least three insurance companies. In practice, this restriction will inevitably limit the ability of an insurance broker to sell a significant amount of an insurance company's products in Ukraine.

Insurance agents are individuals or legal entities acting on behalf of, and under the authorization of, an insurance company. They carry out a portion of the insurance company's activities including, in particular, concluding insurance contracts, obtaining insurance premiums and performing functions in connection with insurance payments and reimbursements. Insurance agents are representatives of an insurance company and act in its interests for fees based on the relevant agency agreement with an insurance company.

In Ukraine non-resident insurance and reinsurance brokers may provide their services related to concluding insurance agreements with non-resident insurance companies either independently or through their permanent representative offices in Ukraine.

A non-resident insurance or reinsurance broker which provides its services without permanent representative office in Ukraine must notify in writing the Regulator about its intention to conduct business in Ukraine, and the Regulator, will then publish such information on its official web-site and printed mass media.

16.3 Communications

16.3.1 Regulatory Framework

Significant changes have been introduced into the regulatory framework of the Ukrainian telecommunications sector following independence in 1991. These changes have greatly facilitated the process of adjusting domestic legislation to fundamental principles adopted by the European Union. As a result, the Ukrainian regulatory framework now provides for the separation of the regulatory and operational activities of the Ukrainian telecommunications administration.

As a first step toward its transformation into a traditional regulatory body, the former Ministry of Communications of Ukraine (now the Ministry of Transportation and Communications of Ukraine (the MTC)) created several umbrella organizations to take over its previous operational functions. Consequently, all organizations involved in the planning, building and operating of public telecommunications networks in Ukraine were merged into Open Joint Stock Company “Ukrtelecom” (Ukrtelecom). In 2000, the Verkhovna Rada initiated the privatization of Ukrtelecom, which enjoys a monopolist position on the Ukrainian telecommunications market for local fixed-line telephone communications and services for use of non-switched circuits.

The *Law of Ukraine “On Communications”* (the *Communications Law*) dated 16 May 1995 was adopted by the Verkhovna Rada to provide the legal, economic and organizational frameworks for enterprises, associations and governmental authorities, which were part of the telecommunications and/or postal communications networks in Ukraine.

The *Law of Ukraine “On Telecommunications”* (the *Telecommunications Law*) dated 18 November 2003 repealed the Communications Law.

The *Telecommunications Law* establishes the competence of the Ukrainian state authorities in regulating telecommunications activities, and determines the legal status of telecommunications operators, providers, and consumers of telecommunications services. The *Telecommunications Law* also regulates various issues, including: access to the telecommunications market; the interconnection of the telecommunications networks; right of way; privacy of subscribers and telecommunications; authorizations; pricing policy; and methods of settlement. The scope of application of the *Telecommunications Law* extends to fixed-line and mobile telephone communications; the maintenance and exploitation of on-air and cable broadcasting and television

networks; and the leasing of electronic communications channels and communications services based on the Internet protocol (IP-telephony). The regulatory regime of the Telecommunications Law does not apply to those telecommunications networks which do not interact with the Public Switched Telecommunications Networks (PSTN), except for the use of such networks in a state of emergency or war.

Notably, the *Telecommunications Law* does not require abolishing charges for incoming calls for all kinds of telephone communications as it was previously prescribed by the *Communications Law*. However, after its adoption Ukrainian telecommunications operators have continued to abstain from levying charges for incoming calls on subscribers.

16.3.2 National Regulatory Authority

Until the adoption of the *Telecommunications Law*, the MTC was the governmental authority in charge of the Ukrainian telecommunications sector. However, the *Telecommunications Law* provided for the establishment (from 1 January 2005) of another state regulatory body, the National Commission for Communications Regulation (the NCCR), which has now assumed responsibility for: registration and licensing issues; the allocation of radio frequencies and numbering resources; tariff regulation; the regulation of interconnection agreements; and the resolution of disputes in relation with the interconnection agreements.

16.3.3 Radio Frequency Resource

On 1 June 2000, the Verkhovna Rada adopted the *Law of Ukraine "On the Radio Frequency Resource of Ukraine"* (the *Radio Frequencies Law*). The *Radio Frequencies Law* provides comprehensive rules for the allocation, assignment, interrelation and use of radio frequencies in Ukraine, as well as the licensing of users of radio frequencies and other related issues. In addition, Decision of the NCCR No. 911 "On Approval of the Procedure for Auctions and Tenders for Obtaining the Licenses for the Use of Radio Frequency Resource of Ukraine" dated 6 September 2007 sets forth a detailed procedure of auctions and tenders for the issuance of radio frequencies licenses for specific bandwidths.

The *Telecommunications Law* and *Radio Frequencies Law* prescribe obtaining a license for the use of radio frequencies in order to conduct telecommunication activities, which require use of radio frequencies. For this purpose the prospective licensee must file an application with the NCCR, submit a set of documents, and following the decision of the NCCR to grant the license it must pay the fee for issuance of the license. In addition, starting from the date of issuance the license and regardless whether the radio frequencies are actually used or not by the licensee, the monthly fee in the amount established by the Cabinet of Ministers of Ukraine is to be paid for the use of radio frequencies. Failure to pay the monthly fee for six months leads to revocation of the respective license without any compensation.

16.3.4 Numbering Resource

Until 1 January 2005, the allocation of numbering resources was provided free of charge to telecommunications operators. Currently, according to Resolution No. 1147 of the Cabinet of Ministers of Ukraine “*On the Approval of the Amount of Payment for the Allocation of Numbering Resources and the Payment Procedure*” dated 27 December 2008, Ukrainian telecommunications operators have to pay state fees for the allocation of telephone numbering resources, depending on the types of services to be provided and the coverage area.

Telecommunications operators are required to pay the established fee for the allocation of the numbering resources within 30 days after receiving a decision on such allocation. Failure to pay the fee may result in the revocation of the relevant decision to allocate a share of the numbering resources.

The allocation of short telephone numbers for emergency services and for not-for-profit social services will remain free of charge.

16.3.5 Licensing System

The *Telecommunications Law* provides for the licensing of the following types of telecommunications activities:

- provision of local/inter-city/international fixed-line telephone communications services, with the right of maintenance and exploitation of telecommunications networks and leasing of electronic communications channels;

- provision of local/inter-city/international fixed-line telephone communications services using wireless access to the telecommunications network, with the right of maintenance and leasing of electronic communications channels;
- provision of mobile telephone communications services, with the right of maintenance and exploitation of telecommunications networks and leasing of electronic communications channels;
- provision of services on maintenance and exploitation of telecommunication networks, on-air and cable broadcasting and television networks; and
- leasing of local/inter-city/international electronic communications channels.

In order to obtain the telecommunications license the statutory documents of the prospective licensee must foresee possibility to engage in the respective telecommunications activities.

In the event that it was decided to limit the number of telecommunication licenses, licenses are to be granted on a competitive basis. The number, terms, and conditions for obtaining such licenses are to be established and published in the mass media. Thereafter, licenses will be registered and lists of licenses granted will be published.

16.3.6 Networks Interconnection and Settlements Between the Telecommunications Operators

According to the *Telecommunications Law* interconnection of the telecommunications networks is conducted under the interconnection agreements concluded between the operators, and the binding conditions for such agreements are set out by the NCCR.

The procedure for telecommunication networks interconnection (with respect to PSTN only) as well as the binding conditions for interconnection agreements were determined by Decision of the NCCR No. 155 “*On the Adoption of the Rules of Public Telecommunication Networks Interconnection*” dated 8 December 2005.

Settlement rates for the access to the networks of the operators, which enjoy monopolistic position on the telecommunications market, are subject to determining by the NCCR. Thus, such kinds of the rates were adopted by Decision of the NCCR No. 351 *“On the Adoption of the Procedure for the Settlements Between the Telecommunications Operators for Services of the Access to the Telecommunications Networks While Providing Telephone Communication Services”* dated 6 September 2006. This Decision sets out the rates for the access to the networks of the operators, which enjoy monopolistic position, depending on the kind of telephone communication service (local/inter-city communication) and kind of access service (transit and termination of the traffic).

Settlement rates for the access to the networks of other operators (non-monopolists) are not subject to the state regulation and are provided for in the respective interconnection agreements between such operators.

16.3.7 ISP Services

At present, Internet service provider (ISP) services are not subject to a licensing regime in Ukraine.

However, following the adoption of Resolution No. 132 of the State Committee for Communications and Informatization of Ukraine *“On the Adoption of the Licensing Conditions for the Conducting Business Activity in Telecommunications Area for Provision of Local/Inter-City/International Fixed-Line Telephone Communications with the Right of Maintenance and Exploitation of Telecommunications Networks and Leasing of Electronic Communications Channels”* on 17 June 2004, the licensing regime established by the *Telecommunications Law* was extended to the provision of telecommunication services via the Internet (IP Telephony). Thus, an interested party wishing to provide IP Telephony services is now required to obtain an intercity or international telecommunications license pursuant to the same procedures established for acquiring the ordinary telecommunications licenses. In case the prospective licensee intends to use only IP Telephony technologies for rendering the telecommunication services, the payment for issuance of the license will amount to 6% of the fee established for the issuance of the ordinary telecommunications license.

16.4 Electronic Commerce and Information Technologies

16.4.1 Electronic Commerce

On 22 May 2003, the Verkhovna Rada adopted two laws aimed at facilitating the development of electronic commerce: the *Law of Ukraine “On Electronic Digital Signature”* (the *Digital Signature Law*) and the *Law of Ukraine “On Electronic Documents and the Circulation of Electronic Documents”* (the *Electronic Documents Law*).

The *Digital Signature Law* contains provisions governing the legal status of electronic signatures, the requirements for cryptographic key certification, the provision of relevant related services, and the recognition of foreign cryptographic key certificates.

Under the *Digital Signature Law*, electronic signatures may be used by individuals and legal entities for the identification of the signatory of the respective document and the confirmation of the integrity of any kind of data stored in digital form. The legal effect of a digital signature depends on the type of the relevant key certificate, which is issued by the provider of the certification services and confirms the identity of the public key owner. In this respect, it is important to distinguish:

- qualified key certificates issued by duly accredited certification centers and enjoying certain evidentiary presumptions; and
- key certificates issued by non-accredited certification centers.

The *Digital Signature Law* recognizes a digital signature as having the same legal effect as a handwritten signature or a seal attached to a paper document, provided that such digital signature (i) is based on an unexpired qualified key certificate, (ii) is made by reliable (certified) digital signatures software and (iii) the private key of the signatory corresponds to the one, indicated in certificate. However, a digital signature may not be deemed invalid solely on the grounds that it has electronic form and is not based on a qualified key certificate.

State authorities, local self-government bodies, state institutions and state enterprises, are allowed to use only qualified key certificates. Other legal entities and natural persons may use unqualified key certificates or even utilize digital signatures carrying

no certificates at all. In the latter case, the parties to the electronic transaction are required contractually to agree on the allocation of the risks arising out of the use of uncertified digital signatures.

The *Electronic Documents Law* sets forth provisions governing the legal status of electronic documents. The electronic form of such documents may not serve as the basis for denying these documents legal effect or rendering them inadmissible as evidence. Electronic documents may be used for a variety of purposes, including the formation of contracts and payments. However, under the *Electronic Documents Law*, electronic documents may not be used as original documents certifying bequests.

The general principles concerning electronic contracting are set forth in the new *Civil Code*. The *Civil Code* indicates that a contract qualifies as being entered into in writing if the parties' will is expressed by means of teletype, electronic or other type of technical device for communication. The *Civil Code* further allows using digital signatures in cases envisaged by the law, civil legislation or pursuant to a written agreement of the parties, containing specimens of the appropriate analog of the personal signature.

16.4.1.1 E-Banking

Unlike in other areas, electronic signatures, as well as electronic documents, had already been in use in Ukrainian banking practice for several years prior to the adoption of the new *Civil Code*, the *Digital Signature Law*, and the *Electronic Documents Law*. The use of electronic signatures and electronic documents for banking purposes was governed by the *Law of Ukraine On Payment Systems and Money Transfer in Ukraine* (the *Payment Systems Law*), dated 5 April 2001, which had a definition of an "electronic digital signature" as a block of data received through the cryptographic transformation of the contents of an electronic document which enabled the confirmation of its integrity and the identification of the person who signed it. However, according to the *Law of Ukraine On the Introduction of Amendments to the Payment Systems Law* dated 6 October 2004, the provisions regulating the use of the "electronic digital signatures" were excluded from the *Payment Systems Law* and now the regulation of the "electronic digital signature" is based on the *Digital Signature Law*, and the *Electronic Documents Law* described above as well as a number of regulations.

The applicable regulations of the National Bank of Ukraine (the NBU), which are based on the *Payment Systems Law*, authorize the transmission of electronic notices between a client and a bank in encrypted form, including electronic payment instructions certified by electronic digital signatures (*i.e.*, the “client-bank” system).

16.4.2 The Internet and Domain Names

Thus far, Ukrainian legislation has seen little intervention by the Ukrainian Government in issues governing the Internet in Ukraine. Internet activities in Ukraine (including various Internet-based industries), have been developing on the basis of Ukraine’s general laws and regulations governing “off-line” or real-world life and business. However, numerous changes have taken place in this area, particularly following the entering into force of the *Law On Telecommunications* (the *Telecommunications Law*) on 23 December 2003 and the *Civil Code* on 1 January 2004.

The *Telecommunications Law* defines “domain” as a part of a hierarchic system of names incorporated in Internet Addresses; a unique identifying name, which is served by a group of server domain names and administered centrally.

16.4.2.1 Protection of Intellectual Property Rights in Domain Names

On 10 April 2008, the Verkhovna Rada adopted the *Law of Ukraine “On the Introduction of Amendments to Certain Laws of Ukraine on Intellectual Property Issues in order to Fulfill Requirements on Accession of Ukraine to the WTO”* (the *Amendments Law*). The *Amendments Law* purports to enhance the applicability of some provisions of existing intellectual property laws to the Internet. Most importantly, the *Amendments Law* amends the *Law of Ukraine On the Protection of Rights in Trademarks and Service Marks* (the *Trademark Law*) in order to address, the issue of protecting the rights of trademark owners in connection with the use of trademarks in domain names.

The *Trademark Law* defines a “domain name” as the name which is used for addressing computers and resources over the Internet. The exclusive rights of a registered trademark owner now include the use of its trademark over the Internet, and under amendments introduced by the *Amendments Law*, the use of a trademark in the domain name without permission of the trademark owner shall constitute violation of the trademark owner rights.

It should also be noted that an administrative procedure of protection for trademark owners is reflected in the “Policy of the .UA Domain”, which is currently used for administering the Ukrainian country code Top Level Domain name or .UA Domain. In order to obtain a second-level domain name (*e.g.*, www.companyname.ua), it is necessary to present a trademark registration certificate for the identical name. However, this requirement does not extend to third-level domain names (such as www.companyname.com.ua or www.companyname.kiev.ua), which remain susceptible to abusive registration.

16.4.2.2 Administration of the Ukrainian ccTLD System

A number of organizational and legislative developments indicate the Ukrainian Government’s increased awareness of the issues related to the Internet in Ukraine. In particular, on 13 November 2002, the State Committee for Communications and Informatization of Ukraine (the Committee) announced the establishment of the Ukrainian Net Information Center (UANIC). The purpose of UANIC is to administer and to service the Ukrainian ccTLD system, as well as to adopt rules for the designation of the domain .UA. While this organization was founded by the Committee and by various associations of Internet service providers, the officials of the State Security Service of Ukraine (Ukraine’s intelligence and counterintelligence agency) also participated in the decision to establish UANIC. On 22 July 2003, the Cabinet of Ministers issued Order No. 447-p, “*On the Administration of the .UA Domain*,” which officially recognized UANIC’s powers to administer Ukrainian ccTLDs.

Administered by a Ukrainian limited liability company, “Hostmaster,” since the Ukrainian ccTLD. “UA” began functioning in January 1993, all matters involving the registration and maintenance of domain names have been largely self-regulated by various public associations and Internet service providers.

16.4.2.3 Domain Name Dispute Resolution

The Internet Association of Ukraine has also established the Court of Arbitration for the resolution of various Internet-related disputes, including those related to domain names.

The Court of Arbitration, which is a typical third-party arbitration court, *i.e.*, not a state court, is presently the only specialized institution in this area in Ukraine. Domain name disputes may be referred to the Court of Arbitration by the mutual consent of the parties. The Court of Arbitration aims to help the parties reach

amicable agreements, and keeps confidential the subject matter of the dispute. Pursuant to the applicable Ukrainian legislation, decisions rendered by the Court of Arbitration are binding on the parties. Regularly, domain name related disputes are also heard by courts of general jurisdiction in Ukraine. In this case, no previous consent of the parties to direct the case to a specific court is required (if compared to the Court of Arbitration), and any interested party, which believes that its rights are violated, can turn to a court of general jurisdiction, provided the jurisdictional issues are complied with. The grounds for such domain name related disputes are usually trademark infringement and noncompliance with the “Policy of the .UA Domain”.

16.4.3 Software Development and Protection

16.4.3.1 Protection of Rights in Software

In Ukraine, software is protected under the *Law of Ukraine “On Copyright and Neighboring Rights”* (the *Copyright Law*), dated 23 December 1993, as a literary work of authorship. Copyright protection extends both to operational systems and applications, expressed in source and/or object codes.

For purposes of the *Copyright Law*, “software” is defined as a selection of instructions, expressed in words, numbers, codes, schemes, symbols, or any other means of expression, comprehensible by a computer.

Copying of a computer program without charge is permitted if one copy is made by the lawful user of the computer program for archival purposes, or for serving as a replacement of a lawfully acquired copy in case of loss or damage.

The free modification of a computer program is permitted for (i) attaining compatibility with the user’s equipment and (ii) for correction of appreciable errors, unless otherwise provided by the agreement between the parties.

The free reverse engineering of a computer program is permitted with the intention of receiving the information necessary for attaining the compatibility of an independently-created computer program with other computer programs, provided that the following conditions are met:

- the act of reverse engineering is carried out by the lawful owner of a copy of the computer program;

- the information necessary for attaining such compatibility is not known to the person specified above from other sources prior to the act of reverse engineering;
- the reverse engineering is limited only to those elements of the computer program which are necessary for attaining compatibility; and
- the information obtained in the process of the reverse engineering (i) is used only for attaining the compatibility of the program with other software and (ii) can not be transferred to a third party, except for the purposes of attaining the compatibility with other programs; (iii) cannot be used for the development of the other software, similar to the decompiled one or (iv) for committing any other infringement.

16.4.3.2 Protection of Rights in Databases

Database rights are also protected under the *Copyright Law*. Pursuant to the *Copyright Law*, “databases” are defined as collections of works, data, or any other independent information, selected and arranged as a result of creative work, integral parts of which can be accessed by means of special search engines.

Any database is afforded copyright protection if it is the result of creative work in the selection and assembling of its contents, subject to the condition that no violation of any copyright in the constituent works has taken place during the creation of the database.

Pursuant to the *Law of Ukraine “On Distribution of Copies of Audio and Visual Works, Phonograms, Videograms, Computer Programs and Databases”* No. 1587-I, dated 23 March 2000, the databases distributed on the territory of Ukraine on CDs and DVDs are subject to labeling (marking with control labels).

Illegal reproduction and/or distribution of the databases and software may lead to civil, administrative and criminal liability under the applicable Ukrainian law.

16.4.3.3 Protection of Rights in Layouts of Integrated Circuits

Rights in layouts of integrated circuits are protected under the *Law of Ukraine “On the Protection of Rights in the Layouts of Integrated Circuits”* (the *Layouts Law*), dated 5 November 1997.

The *Layouts Law* defines a “layout of integrated circuits” (the Layout Design) as a three-dimensional pattern of the aggregate of an integrated circuit’s elements fixed in a tangible medium.

Rights in a Layout Design arise upon the registration of the Layout Design with the State Intellectual Property Department of Ukraine. The originality of the Layout Design is a prerequisite for its registration.

A Layout Design is presumed to be original if: it is not created by means of the direct reproduction of another Layout Design; it was not known in the field of microelectronics prior to the date of the application for its registration or prior to the date of its first use; and it is characterized by new qualities, differentiating it from other Layout Designs. Any Layout Design submitted for registration is presumed to be original unless sufficient evidence to the contrary is provided.

The rights in a Layout Design include:

- the right to use the Layout Design;
- the right to preclude other parties from using the Layout Design;
- the right to assign rights in the Layout Design to another person; and
- the right to license the use of the Layout Design to another person.

An assignment of rights in, and a license of the use of, a Layout Design are valid if they are concluded in writing and signed by the parties. Rights in a Layout Design are evidenced by a certificate of registration of the Layout Design issued by the patent and trademark authority of Ukraine. This certificate is valid for ten years starting from the date of the application for the registration of the Layout Design, or from the date of its first use.

As a general rule, the author of a Layout Design is entitled to register it. However, in the event that a Layout Design is created by the author in connection with the performance of the author’s employment duties and/or under a specific assignment from the author’s employer, then the right to register the Layout Design rests with the employer, unless the employment agreement provides otherwise. Irrespective of the above, the author retains the right of authorship, which right remains inalienable.

16.4.3.4 Protection of Information in Information and Telecommunication Systems

The protection of information in automated databases is subject to the *Law of Ukraine "On the Protection of Information in Information and Telecommunication Systems"* (the *IT Systems Law*), 5 July 1994. The IT System Law establishes the principles for the regulation of relations between the parties involved in the processing of information in information and telecommunication systems (the IT systems) and the use of such information by third parties. It also provides for the protection of the rights of the owners of the information processed in information and telecommunication systems.

The *IT Systems Law* defines "information and telecommunication systems" as "the set of technical" and program means, functioning as a single whole, designed for the processing and exchanging of data. Information in IT systems and data processing software is subject to protection regardless of the means of expression of the information.

The *IT Systems Law* requires that access to the information in the information and telecommunications systems be subject to rules established by the owner of the processed information.

16.4.3.5 Outsourcing of Software Development

Although the outsourcing of software development has seen rapid development over the past decade, Ukrainian legislation does not currently provide specific legal rules on the outsourcing of software development.

Having regard for certain legal constraints related to the claiming of copyright in developed software products under the applicable Ukrainian legislation (see above), outsourcing of software development projects must be properly structured from a legal standpoint before being implemented in practice.

At the present time, the most widespread business model used by foreign companies for the outsourcing to Ukraine of software development is the establishment of a local Ukrainian subsidiary or a special-purpose company to retain local programmers (as either employees or independent contractors) and coordinate their work. Such local company is required to ensure that all intellectual property rights in the software products developed by such programmers are properly transferred to it from the individual programmers. Thereafter, the corresponding

scope of the intellectual property rights must be further transferred from the local company to its foreign parent pursuant to a written assignment agreement between them.

Alternatively, foreign companies may enter into corresponding outsourcing agreements with independent Ukrainian companies or directly with individual programmers. These types of arrangements, however, must be crafted with precision in order to ensure full and effective transfer of intellectual property rights.

16.4.3.6 Software Register

Over the past few years Ukraine has been subject to considerable international scrutiny on the issues of copyright protection. These have related principally to the protection of copyright and neighboring rights in compact disc (CD) manufacturing which, in turn, has related to the protection of rights in audio and video works and in software products. Ukraine has taken various legislative and practical measures to restore order in the protection of copyright in the above sensitive areas, with particular attention to the protection of copyright in software.

In particular, a special program on the protection of rights in software and on counteracting piracy has been set out under the Resolution No. 247-r of the Cabinet of Ministers of Ukraine, the *“Concept of the Legalization of Software and Fighting Its Illegal Use,”* dated 15 May 2002. On the basis of the above resolution, on 8 January 2003 the Ministry of Education and Science of Ukraine (the Government agency responsible for protecting intellectual property rights in the country) adopted the Regulations *“On the Register of Manufacturers and Distributors of Software”* as approved by Order No. 8 (the Regulations).

In accordance with the Regulations, effective from 1 March 2003, a state authority (the Authority) designated by the State Intellectual Property Department of Ukraine (the structural unit of the Ministry of Education and Science of Ukraine controlling intellectual property issues and the equivalent of a national Patent and Trademark Office) will be charged with maintaining the Register of Manufacturers and Distributors of Software (the Register).

The Register will serve a dual purpose: protecting the intellectual property rights of legitimate software providers, and publicizing information on such providers to potential customers. In particular, such customers will include state authorities interested in purchasing software under government contracts. The information

stored in the Register will be made available through its publication and the maintenance of permanent web pages. The Register may be accessed by central and local state authorities, legal entities, and individuals.

Any business entity, whether domestic or foreign, which manufactures and/or distributes software (the Entity) may, on a voluntary basis, submit a set of required data or documents for their inclusion into the Register. Those Entities which distribute software on CDs will be obliged to present a copy of the software license for manufacturing or importing CDs granted by the holder of the copyright in the relevant software. If the Entity does not manufacture or import such CDs, it will be obliged to submit a copy of such a license and a document evidencing the legal transfer of the ownership of the CDs from the manufacturer or the importer.

The Authority will have one calendar month to consider an application for entry into the Register and may request that the applicant supplement all missing or incomplete materials. The Regulations do not provide for the Authority's charging a fee for its services, nor do they mention the possibility of the denial of an application for entry. After a decision to enter the information is made, the Entity may obtain an official certificate evidencing its listing in the Register.

16.4.3.7 Encryption Technology

Currently, the *Law of Ukraine "On the Licensing of Certain Types of Entrepreneurial Activity"* as amended (the *Licensing Law*), provides that the development, production, importation, exploitation, and use of encryption technologies be subject to the licensing regime. Licenses are issued by the State Service for Special Communication and Information Protection of Ukraine (the State Service) for a term of five years. Licenses may be renewed upon their expiration.

Licenses are granted to "business entities," which are defined in the *Licensing Law* as duly registered legal entities engaged in business activities irrespective of their organizational forms or forms of ownership.

Qualification requirements to the business entities for provision of the business activity in the area of encryption, as well as the kinds of activities which may be provided in the area of encryption that is subject to licensing and peculiarities of the licensing in the area of encryption are determined by the respective regulations

of the State Service. Under the applicable Ukrainian legislation, encryption technologies may qualify as dual-purpose goods/technologies and certain restrictions may apply to their importation into or exportation from Ukraine.

In addition to above, Section 8 of the Regulation “*On the Procedure for the Encryption Protection of Information in Ukraine*” approved by the Decree No. 505/98 of the President of Ukraine of 22 May 1998, provides that all encryption systems which are to be used for purposes of transmitting confidential information must be certified. This relates both to domestically produced and imported encryption systems. Obtaining the respective certification clearance is a pre-requisite for the importation of any such encryption system/technology onto the territory of Ukraine.

16.4.4 Licensing Requirements in the Area of Information Technologies

Pursuant to the *Licensing Law*, the following activities in the field of information technologies are subject to mandatory licensing:

- the development, production, and sale of technologies for the interception of information;
- the development, production, use, examination, importation, and exportation of encryption technologies, the provision of services in the area of encryption, and the sale of encryption technologies; and
- the development, production and servicing of technical means for the protection of information, and the provision of services in the area of the technical protection of information.

A business entity engaging in any of the above-specified activities is required, upon the receipt of the appropriate license, to adhere to certain technical, organizational, and other relevant requirements set forth in regulations adopted by the State Security Service of Ukraine and the State Service for Special Communication and Information Protection of Ukraine. The failure to comply with such requirements may lead to the cancellation of the license for the specific activity.

16.5 Power

16.5.1 Introduction

Until the reform of the Ukrainian power sector, initiated with the adoption of the Decree No. 244/94 of the President of Ukraine “*On Measures Regarding the Market Transformation of the Power Sector of Ukraine*” dated 21 May 1994, the Ukrainian power sector was in exclusive state ownership. It operated through integrated utility companies responsible for generation, transmission and distribution, and was administered accordingly. Another significant reform of this sector was implemented by Decree No. 282/95 of the President of Ukraine “*On the Structural Reconstruction of the Power Sector of Ukraine*” dated 4 April 1995.

In accordance with the Decree No.1573/99 of the President of Ukraine “*On Changes in the Structure of the Central Executive Authorities,*” dated 15 December 1999, the Ministry of Energy of Ukraine, the State Department on Issues of Electrical Energy of Ukraine, the State Department of the Oil, Gas, and Oil-Processing Industry of Ukraine, and the State Department On Issues of Nuclear Energy of Ukraine were liquidated, and the Ministry of Fuel and Energy of Ukraine assumed their respective functions. As a result, the Ministry of Fuel and Energy of Ukraine is currently the principal managing body of the Ukrainian power sector which until 2 November 2006 acted on the basis of Decree No. 598/2000 of the President of Ukraine “*On the Ministry of Fuel and Energy of Ukraine*” and was also responsible for implementing state policy in the coal sector. However, on 2 November 2006, the Cabinet of Ministers Resolution No. 1540 “*On the Ministry of Fuel and Energy of Ukraine*” approved a new Regulation on the Ministry of Fuel and Energy of Ukraine. The Ministry of the Coal Industry of Ukraine was established on the same date. It succeeds the Ministry of Fuel and Energy of Ukraine in the coal sector and is responsible for implementing state policy in this sector. The Ministry of the Coal Industry acts on the basis of the Cabinet of Ministers Resolution No. 1527 “*On Approval of the Regulation on the Ministry of the Coal Industry of Ukraine*” dated 2 November 2006.

The National Electricity Regulatory Commission of Ukraine (the “NERC”) is the principal body that regulates the activity of utility companies in the electricity and gas sectors in Ukraine. Currently, the activity of the NERC is based on Decree No. 335/98 of the President of Ukraine “*On Issues of the National Electricity Regulatory Commission of Ukraine*” adopted on 21 April 1998. However the draft law proposal relating to the status and activity of the NERC currently awaits hearings in Verkhovna Rada of Ukraine.

All electricity generation stations and plants in Ukraine, as well as their respective transmission and distribution networks, constitute the Unified Energy System of Ukraine (UES). These facilities, which ensure the integrity of UES and provide for its operational and technological management as well as the management of the trunk and interstate transmission lines, are excluded from potential privatization.

The national transmission grid remains under the control of the state-owned company “Ukrenergo,” which is responsible for centralized dispatch management (operational and technological) in the power sector.

Despite various setbacks in its legislative regulation, Ukraine’s power sector presents attractive privatization opportunities with respect to thermal power generation stations and regional electricity distribution companies. There are also possibilities for the greenfield development of new power production facilities, or the purchase or sale of existing facilities by strategic investors.

16.5.2 Distribution

The distribution of electricity in Ukraine is carried out by 27 regional distributors (“*oblenergos*”), which purchase electricity on the wholesale electricity market from the state company “Energoynok.” These distributors sell electricity to consumers in their respective regions at a regulated retail tariff. Each regional power distributor controls the regional transmission network for lines of less than 220kV. In addition, a number of companies are licensed to distribute energy at a non-regulated retail tariff.

16.5.3 Wholesale Electricity Market

Currently, the model upon which the wholesale electricity market operates in Ukraine is the so called “Single Buyer Model”. Under this model, a specialized legal entity purchases all bulk electricity generated by the electricity generating companies and simultaneously is the sole wholesale seller of the electricity to power distribution companies. The purchase and sale of electricity in the wholesale electricity market is carried out in accordance with the Market Rules approved by the NERC.

To ensure the organizational functioning of the wholesale electricity market, the wholesale electricity market members (*i.e.*, electricity generating and distribution companies) and the wholesale electricity supplier entered into the Wholesale Electricity Market Members Agreement approved by the NERC.

On 16 November 2002, the Cabinet of Ministers adopted Resolution No. 1789 “*On the Approval of the Concept of the Operation and Development of the Wholesale Electricity Market of Ukraine*” (the “WEM Concept”). The WEM Concept provides for the gradual liberalization of the wholesale electricity market with the intention of creating a full-scale competitive market operating through a system of bilateral contracts between producers, suppliers and end consumers of electricity. The Concept establishes phased in transition from the Single Buyer Model to the model of bilateral contracts and a balancing market. Such an approach is in compliance with the recently adopted EU Directives on Electricity⁴ and Gas⁵ which provide for the full opening of the market to end consumers by July 2007. The Concept aims at greater efficiency in the generation, transportation, distribution and supply of electricity, independent regulation of the power sector, the development of competition and the possibility of integration into the EU power market.

To enhance competition, the construction of new power generating facilities must be based on a tender and/or licensing procedure under European Union legislation; the exportation, importation and transit of electric power must be performed under non-discriminatory procedures in accordance with EU energy legislation; and suppliers of electric power must be provided with fair market conditions.

The Concept calls for the adoption of necessary amendments to current legislation including: the Electricity Law; legislation on natural monopolies; company profit tax; VAT; the budget; customs; and construction. The Concept also calls for the adoption of new legislation, including legislation on state regulation in the power sector. In the future, the operation of the electricity market will be governed by the proposed Rules for Functioning of the Bilateral Contracts and *Codes of the Main and Distribution Networks*, which are intended to integrate relevant organizational, technological, and technical provisions.

On 28 November 2007 the Cabinet of Ministers of Ukraine by its Resolution No. 1056-r approved the Plan of measures (the “Plan”) related to implementation of the WEM Concept. The Plan specifies the measures that need to be taken by the responsible bodies within the years of 2008-2014 to ensure transition from the Single

4 Directive 2003/54/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in electricity and repealing Directive 96/92/EC

5 Directive 2003/55/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in natural gas and repealing Directive 98/30/EC

Buyer Model to the model of the bilateral contracts and balancing market. The listed measures need to be taken in three stages. At the first stage, which comprises the period of the years 2008-2009, the responsible bodies will need to develop certain normative acts, rules and methodologies based on which the bilateral contracts will be gradually introduced. Within the year of 2010, *i.e.*, at the second stage, the NERC, the Ministry of Fuel and Energy of Ukraine and state company “Energorynok” are responsible for implementation of the special mechanism for balancing the volumes of the electricity sales having in place the centralized load schedules. At the third stage, within the years of 2011 - 2014, the market members should make their own load schedules and the responsible bodies should ensure establishment of the electricity stock exchange. Under the Plan, it is foreseen that during the year of 2014, the bilateral contracts and balancing market should start to operate.

16.5.4 Privatization

The privatization of power companies in Ukraine began in earnest in 1995. Privatization covered both power generation companies (*i.e.*, only thermal power generation companies), and power distribution companies.

In an attempt to reduce Ukraine’s considerable external debt, privatization of power companies was initiated at the end of 1999. The Decree of the President of Ukraine No. 944/99, “On Certain Issues Concerning Privatization of Objects of the Electricity Sector” dated 2 August 1999, provided for the sale of controlling stakes in power distribution companies and blocking stakes in power generation companies through tenders. Subsequently, controlling shareholdings in almost half of all Ukrainian power distribution companies were sold to private investors, with one quarter of all power distribution companies now in 100% private ownership.

Further privatization in the electricity sector of Ukraine was promoted by the Presidential Decree No. 1169/2001 “*On Additional Measures for Reforming the Electricity Sector*,” of 3 December 2001. Accordingly, in 2002, controlling shareholding packages (*i.e.*, more than 50%) of 12 power distribution companies, and blocking shareholding packages (*i.e.*, more than 25%) of seven power distribution companies were identified to be sold through open tenders.

The outstanding indebtedness of nine of these power distribution companies was one of the obstacles to be resolved prior to the privatization tenders. On 31 July 2002, the Cabinet of Ministers approved unified conditions for holding tenders on the sale

of blocks of shares of these power distribution companies. These conditions stipulate a number of qualifying criteria (aimed at ensuring the stability of the power industry), to be met by potential bidders. Privatization of the power sector has since stalled however, although a revised state privatization policy is anticipated pending approval in the Verkhovna Rada.

The Cabinet of Ministers of Ukraine adopted Resolution No. 794 “*On Creation of National Joint Stock Company ‘Energy Company of Ukraine’*” dated 22 June 2004 (the Resolution). According to the Resolution, state-owned blocks of shares in 19 regional energy distribution companies were to be transferred to the charter fund of the new National Joint Stock Company “Energy Company of Ukraine.” These blocks of shares varied from 25% plus 1 share to 75% of shares of the 19 regional energy distribution companies.

The transfer of the state-owned blocks of shares in energy distribution companies to the charter fund of the newly created National Joint Stock Company “Energy Company of Ukraine” effectively meant keeping these shares in state ownership under one umbrella.

16.5.5 The Electricity Law

The legal framework for regulation of the generation, transmission, distribution and supply of electricity in Ukraine is governed by the *Law of Ukraine “On Electricity”* (the *Electricity Law*) dated 17 October 1997, which came into force on 20 November 1997.

The objectives of the Electricity Law include the following:

- to provide protection of consumers’ rights and interests;
- to provide for the reliable and stable functioning of UES;
- to ensure the creation of conditions for the secure operation of energy objects; and
- to promote the development of competitive relations in the electricity market in Ukraine.

In addition to the *Electricity Law*, a number of presidential decrees, government resolutions and other normative acts regulate the generation, transportation, distribution and supply of electricity in Ukraine. A number of new legislative initiatives in this sector are currently under consideration by the Verkhovna Rada.

16.6 Natural Resources, Mining, and Oil & Gas Exploration

16.6.1 General

The principal legislative acts governing mining and oil and gas exploration activities in Ukraine are the *Code of Ukraine On the Subsurface* (the *Subsurface Code*), and the *Laws of Ukraine On Oil and Gas, On Production Sharing Agreements, On Mining in Ukraine, On the Exclusive (Maritime) Economic Zone of Ukraine, and On Pipeline Transportation*, among others.

The *Subsurface Code* defines the subsurface as “that part of the earth’s crust underlying the land surface and the reservoirs’ bottom and stretching to the depths accessible for geological survey and development.” The subsurface is the exclusive property of the people of Ukraine and may only be granted for use to Ukrainian and foreign legal entities and individuals.

16.6.2 Licenses and Permits

Business entities and/or individuals seeking to engage in the mining of minerals on the territory of Ukraine must follow the established procedure for obtaining the necessary licenses and permits. This procedure depends on whether a company plans to commence the development of an unexplored mineral deposit or an explored one. In the former case, such company must obtain a license for the exploration of mineral deposits under the *Law of Ukraine “On Licensing of Certain Entrepreneurial Activities”* (the *Licensing Law*), dated 1 June 2000, and must undertake exploration activities bearing all associated expenses. In the latter case, where a deposit has already been explored and registered in the State Fund of Mineral Reserves of Ukraine by the Ministry of Environmental Protection of Ukraine, the company in question will be obliged to reimburse the state for the completed geological survey of the territory by purchasing a so-called “geological information package”. The price of this geological information package is calculated on the basis of numerous coefficients and may vary, depending on the composition of the particular deposit.

Due to the amendments introduced to the Licensing Law in 2006, a separate license is also required for mining of deposits of state importance, which are included into the State Fund of Mineral Reserves of Ukraine.

Separate licenses are required for the extraction and production of precious metals, and precious and semi-precious stones.

As of the end of 2008⁶, subsurface use rights are granted in the form of a special permit (license), which can be issued for the following types of activities:

- geological survey of mineral deposits, including the scientific and industrial development of deposits (for up to five years), geological survey of oil and gas fields, including industrial development in onshore and exclusive economic (maritime) zone (for up to 10 years);
- extraction of minerals (for up to 20 years); extraction of oil and gas in onshore and exclusive economic (maritime) zone (for up to 30 years);
- geological survey of oil and gas deposits, including the scientific and industrial development of hydrocarbons with further extraction of oil and gas (for the validity terms of special permits for geological survey and extraction, but for no more than 20 years for land activity and 30 years for onshore and exclusive economic (maritime) zone activity);
- construction and use of underground facilities unrelated to minerals extraction (for up to 20 years);
- construction and use of underground oil or gas storage facilities (for up to 50 years); and
- other types of subsoil use (for up to 10 years).

The applicable legislation provides that subsurface use rights are, as a rule, to be granted on a competitive basis, i.e., through tenders or auctions. Nonetheless, a bidder who has explored the mineral deposits at its own cost and wishing to undertake the extraction of the explored mineral deposits may obtain the required permit without competitive bidding.

A subsurface user is not authorized to bestow, sell or otherwise transfer the rights granted by a permit. Transfer of such rights to charter capital of legal entities (even created by such subsurface user), or their transfer into joint activity are also prohibited.

⁶ Please note that the Cabinet of Ministers of Ukraine has not yet adopted respective ruling, regulating procedure of granting of special permits in 2009.

The conditions for the use of natural resources must be set forth in an agreement between the winner of the tender or auction and the authorized governmental agency. The winner of the tender or auction must launch exploration operations within two years after the issuance of the special permit (180 days for the exploration of oil and gas deposits.)

16.6.3 Payments for Subsurface Use

Without prejudice to any other taxes and/or fees payable under the applicable Ukrainian legislation, Article 28 of the *Subsurface Code* provides for the payment of the following dues for subsurface use:

- subsurface use payments;
- fees for exploration work performed at the expense of the state budget;
- fees for the issuance of special permits (licenses); and
- excise duty.

Under the *Subsurface Code*, subsurface use payments (payments) may be levied as single or regular payments, which are determined on the basis of the relevant ecological and economic calculations. In particular, the payment due for the conducting of exploration works will depend on the economic and geographical conditions and the size of the particular subsurface area; the type of minerals; the duration of the works; the degree of completion of the geological survey of the territory; and the degree of risk.

The payment due for the extraction of minerals will be calculated on the basis of the geological features of the deposits and the condition of their development. The payment due for subsurface use within the continental shelf and the exclusive marine economic area will be determined depending on the territory area, the sea depth, and the purpose of the intended subsurface use. The payment due for subsurface use unrelated to mineral extraction, including the construction and use of underground facilities, will depend on the size of the particular subsurface area, its utility characteristics, and the ecological safety of its development.

16.6.4 Production Sharing Agreements

In most cases, if engaged in mining activities through a Ukrainian company with foreign investment, the investor will fall under the general requirements of the applicable Ukrainian legislation. On balance, the applicable Ukrainian legislation envisages certain incentives for foreign investors which undertake mining activities directly pursuant to agreements on the sharing of the output of such activities (the Production Sharing Agreement, the PSA, or PSAs).

The basic legal requirements with respect to PSAs are set forth in the *Law of Ukraine "On Production Sharing Agreements"* (the *PSA Law*), dated 14 September 1999. Under the PSA Law, the Cabinet of Ministers (together with the relevant local authorities, acting on behalf of the state, and the foreign investor(s)) may enter into a PSA whereby the foreign investor agrees to undertake certain mining activities at its own expense, and is entitled to reimbursement of its expenses and to a certain share of the relevant output. If entered into with a number of foreign investors, such a PSA should provide for the joint and several liability of each investor.

Foreign investors are selected by tender, announced by the Cabinet of Ministers, and held by the Special Inter-Agency Commission. If the minerals contained in a deposit are below the established threshold, then the Cabinet of Ministers, together with the relevant local authorities, may decide to enter into the PSA without such a tender.

The PSA may be concluded for a period agreed to by the parties; however, such period may not exceed 50 years.

The list of mineral deposits which may be developed under PSAs is approved by the Cabinet of Ministers. At the same time, the investor may apply to the Cabinet of Ministers or to the Special Inter-Agency Commission to include any newly discovered mineral deposits in such list.

Products explored or extracted under a PSA should be distributed between the state and the investor. Until such distribution, the state retains the ownership of the relevant products as prescribed by the PSA. The investor gains ownership rights to the cost recovery and the profit portion of the products at the moment of the distribution of the production. The outstanding portion of the products remains state owned.

The cost recovered portion of the extracted products may not exceed 70% of the total quarterly production until the investor has recouped its investment.

The investor is free to use and dispose of a portion of the extracted products owned under the PSA and which is not subject to license or quota requirements. The investor may be obliged to sell its share of the extracted product within Ukraine only if it is expressly required by the PSA. Any other limitations on the investor's rights are not permitted, unless expressly specified in the PSA.

The title to the assets created or acquired by the investor for performing its obligations under the PSA is transferred to the state on the date when the value of such assets is completely covered by the cost recovery portion of the products, or whenever the PSA is terminated. However, the investor enjoys a pre-emptive right to further use such assets.

The rights and obligations under the PSA may be assigned by the investor to a third party only with the prior consent of the state, and only if such third party possesses sufficient financial and technical capacity and experience in PSA activities. The state is deemed to have consented to the assignment if it fails to provide the investor with its answer within 90 days after the date of the investor's request.

The investor enjoys the following incentives for the duration of the PSA:

- the investor may pay certain taxes and other mandatory payments in kind, rather than in cash, as provided by the PSA;
- the investor and its subcontractors are exempt from licensing and quota requirements when importing the equipment necessary for their performance under the PSA; the same applies when such equipment is shipped out of Ukraine upon the termination of the PSA; such equipment is also not subject to the value added tax (VAT) or customs duties (with the exception of customs fees);
- any product obtained by the investor is subject to VAT when sold within Ukraine, but it is not subject to any VAT, other tax or customs duties when exported out of Ukraine;
- depreciation rates, other than those provided by the applicable legislation, may be established in the PSA;
- profits received under the PSA are exempt from the profit repatriation tax;

- funds received under the PSA are exempt from any restrictions on conversion into Ukrainian or foreign currency, and may be repatriated abroad under the terms and conditions of the PSA; any requirements for the mandatory sale of foreign currency are not applicable to such funds; and
- forcible withdrawals of funds from bank accounts opened in Ukraine by the investor in order to finance its operations under the PSA are not permitted.

Additionally, investors are provided with certain other tax advantages. The law also indemnifies investors against adverse changes in Ukrainian law.

16.6.5 Pipeline Transportation

The pipeline transportation system of Ukraine consists of a trunk pipeline transportation system and an industrial pipeline transportation system.

The trunk pipeline transportation system is of paramount importance to the national economy and security, and is run by the state. The state-run trunk pipeline transportation companies are not subject to privatization or any other actions leading to private use of such enterprises.

The title to industrial pipeline transportation facilities may be transferred as provided by the applicable Ukrainian legislation.

The following activities are subject to licensing:

- transportation of oil and oil products by a trunk pipeline;
- transportation of natural and oil gas by pipeline, as well as its distribution;
- supply of natural gas; and
- storage of natural gas in amounts that exceed the threshold determined by the licensing condition.

Licenses are issued by the National Energy Regulation Commission of Ukraine.

Finally, activities connected with construction, maintenance and usage of trunk or industrial pipelines are conducted on the basis of a license and are subject to mandatory certification.

16.7 Pharmaceuticals

16.7.1 General

The production and circulation of pharmaceuticals and medicinal products in Ukraine is subject to strict control. The Law of Ukraine “*On Medicinal Products*” (the *Medicinal Products Law*), dated 4 April 1996, is the principal legislative act setting forth the basic requirements for the development, registration, production, quality control and distribution of medicinal products in Ukraine. In addition, the Law of Ukraine “*On the Circulation in Ukraine of Narcotic Substances, Psychotropic Substances, their Analogies, and Precursors*” (the *Narcotic Substances Law*), dated 15 February 1995, sets forth the conditions for the production and circulation of narcotic substances in Ukraine.

The specific regulatory authority for medicinal products is vested with the Ministry of Health of Ukraine (the Ministry of Health) and a number of governmental agencies empowered by it.

16.7.2 Scope of Applicability

As defined in Article 2 of the *Medicinal Products Law*, “medicinal products” are “substances or combinations of substances of natural, synthetic, or biotechnological origin used for preventing pregnancy or for preventing, diagnosing, and treating human diseases, or for modifying the state and functions of the organism. “The above definition includes active substances; ready-prepared medicinal products (pharmaceuticals); homeopathic products; products used for the detection and removal of pathogens or vermin; cosmetic products with medicinal properties; and medical food supplements.

16.7.3 Registration and Marketing of Medicinal Products

Under the *Medicinal Products Law*, medicinal products may be used in Ukraine only after their official state registration (*i.e.*, marketing authorization). The above rule exempts from the mandatory registration regime those medicinal products which are prepared in pharmacies in accordance with medical prescriptions for individual patients or in accordance with orders placed by healthcare institutions, provided that such medicinal products are prepared from active and auxiliary substances allowed for use in Ukraine. Official state registration involves a three-step procedure consisting of pre-clinical research, clinical trials, and the filing of an application for the registration with the Ministry of Health.

16.7.4 Pre-Clinical Research

Ukrainian legislation prescribes the conducting of pre-clinical research (including chemical, physical, biological, microbiological, pharmacological, toxicological and other scientific studies) by specialized research establishments in order to determine the specific activity and safety of a given medicinal product. The detailed requirements for the conduct of such pre-clinical studies are determined by the Ministry of Health under Order No. 441 *“On the Approval of the Procedure for Conducting the Pre-Clinical Research of Medicinal Products, the Procedure of Determination of the Establishments that Can Conduct Pre-Clinical Research of Medicinal Products”* dated 1 November 2001.

16.7.5 Clinical Trials

Under the *Medicinal Products Law*, a medicinal product may be admitted for clinical trials provided that its pre-clinical research brings positive results, and the expected benefits of the medicinal product’s use significantly outweigh the risks of side effects. Clinical trials are conducted by specialized medical institutions determined by the Ministry of Health. The program of trials is subject to the mandatory assessment of its ethical, moral and legal aspects, by Central Commission. Procedures for clinical trials are set forth in the *“Procedure of the Conducting of Clinical Trials of Medicinal Products and the Examination of Materials on Clinical Trials and Model Regulation on the Ethics Commission”* approved by Order No. 66 of the Ministry of Health on 13 February 2006.

The purpose of clinical trials is to determine the safety of a given medicinal product, its therapeutic effectiveness, optimal dosage, short-term, long-term and side-effects, and, after registration and market entry, its therapeutic significance, the strategy for its further use, the incidence of side reactions, and its action when combined with other medicinal products.

The application for clinical trials must be accompanied by the medical product’s general product information, the results of its pre-clinical research, specimen of medicinal products, and outline of the clinical trial program. The applicant is required to obtain insurance policies to cover the lives and health of patients (volunteers) before the commencement of the clinical trials.

The Ministry of Health will order the clinical trials to be halted in cases of danger to the health and life of a patient or volunteer, the ineffectiveness of a medicinal product, or a breach of any ethical norms.

16.7.6 Registration Application

The state registration of a medicinal product requires the filing of an application with the Ministry of Health according to the provisions of the *Medicinal Products Law*, further detailed in Resolution No. 376 of the Cabinet of Ministers “*On the Approval of the Procedure for the State Registration (Re-Registration) of a Medicinal Product and the Amounts of Fees for the State Registration (Re-Registration) of a Medicinal Product*” (the Registration Resolution) dated 26 May 2005.

A registration application must contain information on the applicant and the medicinal product, specifying *inter alia*: its indications and contraindications; dosage; sale conditions; storage and packaging; GMP certificate (if any) and registration in other countries, *etc.* In addition, the application must be accompanied by reports on: the pre-clinical research and the clinical trials of the medicinal product; the pharmacopoeia description or information on quality control methods; a description of the production technology; samples of the medicinal product and its packaging; and a receipt evidencing payment of the registration fee. Materials submitted are examined by the State Pharmacological Center (the Center) and the relevant division of the Ministry of Health.

In addition, if an application for the registration of a generic is submitted, the application should include materials that confirm the generic’s therapeutic equivalence with the referent product defined by the Ministry of Health pursuant to the recommendation of the World Health Organization. In the course of its examination of the application materials, the Center can request an examination of the production facilities, if the Center deems this to be necessary. After its examination of the materials, the Center will rule on the effectiveness, safety, and quality of the medicinal product, on the basis of which the Ministry of Health will either grant or refuse the product registration.

Experts should not be involved in any activity that might give rise to a conflict of interest while those experts are simultaneously involved in the evaluation of a medicinal product.

The registration will be refused if the effectiveness and quality of the given medicinal product are not proven. A refusal to grant registration may be appealed in accordance with Ukrainian law.

If a registration is granted, the Ministry of Health will issue a registration certificate for a term of up to five years. Information on a medicinal product will be entered into the State Register of Medicinal Products. The Ministry of Health may later prohibit, fully or temporarily, the use of the registered medicinal product if the product displays previously unknown dangerous effects.

Throughout the term of the validity of the registration certificate, the certificate holder will be responsible for the quality of the medicinal product and must report any proposed change of the product registration materials to the Ministry of Health, stating the reasons for the change and its effect on the product.

16.7.7 Re-Registration

Following expiry of the registration certificate, the medicinal product may be allowed for further use in Ukraine, provided that it is re-registered under the same procedure as the initial registration. An application for re-registration must be submitted no earlier than a year and no later than 90 calendar days before the expiry date of the previous registration certificate.

16.7.8 Registration Fees and Other Costs

Fees for the official state registration or re-registration of medicinal products are set in Euros, and vary from EUR5 to EUR100 per product. In addition, applicants are required to pay the cost for examination of the medicinal product, which is charged separately.

16.7.9 Licensing Requirements

The *Law of Ukraine “On the Licensing of Certain Types of Economic Activity”* (the *Licensing Law*), dated 1 June 2000, provides for the mandatory licensing of the production and the wholesale and retail sale of medicinal products, as well as the handling of narcotic and psychotropic substances and precursors. In addition, a licensing requirement exists for the processing of, and the production of medications from, donor blood and its components.

Detailed licensing requirements are set forth in the *“Licensing Conditions for Conducting the Economic Activity of the Production, Wholesale and Retail Sale of Medicinal Products”* (the *Licensing Conditions*), approved by Joint Order No. 3/8 of the State Committee of Ukraine on Regulatory Policy and Entrepreneurship and the Ministry of Health dated 12 January 2001.

Obtaining a license requires the filing of an application with the relevant department of the Ministry of Health (the Department). The application must be accompanied by a number of documents listed in the *Licensing Law* and the relevant regulations. The Department will issue the license after a maximum of a ten business days period of examining the application documents, provided that the applicant has complied with all of the licensing conditions. The license holder is required to pay the license fee. Each standalone sub-division of the license holder must have on its premises a copy of the license certified by the Department.

The licensing conditions include both general conditions, established by the legislation on entrepreneurship, consumer protection, trade, healthcare, and medicinal products, and special conditions as to the production, the wholesale and retail sale of medicinal products, as well as to the qualifications of the personnel employed at these activities.

The license holder is required to re-register the license in the case of changes to its name or residence or the licensed activities. An application for re-registration must be filed within a period of ten business days after the relevant changes take place.

The *Licensing Law* provides for at least a three-year term of validity of a license. During this term, the license holder will be subject to control by various state authorities as to its compliance with the licensing conditions. The failure to comply with the licensing conditions may lead to the revocation of the license.

16.7.10 Certification

Under the *Medicinal Products Law* and the Licensing Conditions, a given medicinal product may be admitted for sale in Ukraine only if its quality is certified by its producer. Such a certificate of quality confirms the compliance of each series of the medicinal product with the requirements set during its state registration.

Under Order No. 436 of the Ministry of Health “*Instruction on the Procedure for the Control of the Quality of Medicinal Products During Wholesale and Retail Sale*” dated 30 October 2001, certain types of medicinal products must be additionally certified by laboratories authorized by the State Inspection for the Control of the Quality of Medicinal Products. Such laboratories issue conclusions on the quality of the medicinal product after testing samples of such product. This requirement applies, among others, to narcotic and psychotropic substances and precursors, radiographic contrast media, and medicinal products used for narcosis.

16.7.11 Import and Export of Medicinal Products

Medical substances may be imported into Ukraine only upon their proper registration with the Ukrainian state authorities, and upon receipt of the quality certificates from the producers of such medicinal products. Exceptions to that rule are: the import of medicinal products to Ukraine for the purpose of conducting pre-clinical research and clinical trials: for their state registration; for exhibitions, conferences, and other similar purposes without the right of distribution of such medicinal products; and for use by individual patients. In addition, unregistered medicinal products may be imported into Ukraine in the event of a natural disaster, catastrophe, or an epidemic. Any importation of unregistered medicinal products requires a special permit of the Ministry of Health. The import of unregistered medicinal products is regulated by Order No. 143 of the Ministry of Health “*On the Procedure of Import of Unregistered Medicinal Products on the Territory of Ukraine*,” dated 15 May 1997.

16.7.12 Labeling

The labeling of medicinal products is regulated by Article 12 of the *Medicinal Products Law*, which requires that the following information appear on the label and the outer and inner packaging of the medicinal products: the name of the medicinal product; the name and address of the manufacturer; the registration number; the series number; the consumption method; the dosage of the active ingredient in each product unit; the number of units per package; the consumption term; the storage conditions; and the possible restrictions on the product administration.

In addition, all medicinal products in circulation must be accompanied by an appropriate instruction containing information required by Article 12 of the *Medicinal Products Law*.

As a rule, all labels of medical products distributed in the territory of Ukraine must be in Ukrainian, although, under certain circumstances, the Ministry of Health will accept Russian language labels.

16.7.13 Advertising

Pursuant to the *Law of Ukraine “On Advertising”* (the *Advertising Law*) dated 3 July 1996, any advertising of medicinal products on the territory of Ukraine may be carried out provided that: the medicinal products in question have been registered in Ukraine; and the respective medicinal products are over-the-counter products.

Generally, the use of language in advertising must comply with the applicable Ukrainian language laws. As to trademarks, they must be used in the same form in which they are granted legal protection by the applicable legislation, including Article 6 of the *Paris Convention for the Protection of Industrial Property*, dated 20 March 1883. This provision effectively allows foreign-language trademarks to be used in their original languages.

According to the *Advertising Law*, advertisements of medicinal products may not contain, *inter alia*: comparisons to other medicinal products intended to enhance the advertising effect; references to actual cases of successful application; recommendations or references to the recommendations of medical professionals, scientists or medical establishments; thank-you letters or narratives by individuals; or images and/or names of popular personalities, movie, TV or cartoon characters, or reputed organizations. In addition, advertisements of medicinal products may not feature physicians or people resembling physicians. Any advertising of medicinal products is prohibited if it implies that: there is no need to consult a doctor if the medicinal product in question is consumed; the eventual medical effect of the product is guaranteed; and/or the medicinal product in question is generally accepted as a food or cosmetic product or other consumable product.

Certain other restrictions apply when placing advertisements on television, radio, in the printed media, over the telephone, and other electronic means of communications. Advertising on the Internet must comply with the general legislative provisions governing the types of information allowed for dissemination.

Order No. 177 of the Ministry of Health “*On the Approval of Legislative Acts Governing the Advertising of Medicinal Products*” dated 10 June 1997, establishes additional requirements to advertising medicinal products when targeting minors and/or professional medical specialists/establishments.

The contents of prospective advertisements of medicinal products for minors must be approved by the Ministry of Health on the basis of the expert conclusion of the Pharmacological Committee of the Ministry of Health.

Advertisements of medicinal products targeting medical professionals and/or medical establishments must be founded on scientific data and contain full, accurate, and clear professional information. It is forbidden to overestimate the positive effects of the medicinal products in question.

Advertisements of prescription medicinal products targeting medical professionals and/or medical establishments may only be placed in special printed media for medical and pharmaceutical professionals.

16.7.14 Distribution of Medicinal Products

Under the *Medicinal Products Law*, medicinal products in Ukraine may be sold either pursuant to a doctor's prescription or over-the-counter. The Ministry of Health's approval is necessary before a medicinal product may be sold over the counter.

The retail sale of medicinal products is subject to various legislative provisions on entrepreneurship, consumer protection, trading rules, sanitary and epidemic control, and so on. Under the Licensing Conditions and Resolution No. 1570 of the Cabinet of Ministers "*On Adoption of Rules of Sale of Medicinal Products in Pharmacies*," dated 17 November 2004, medicinal products may be sold only through pharmacies with the appropriate retail license. The owners of such pharmacies must ensure the availability of the minimal mandatory assortment of medicinal products and the proper conditions for their storage, production, and sale.

16.7.15 State Regulation of Prices of Medicinal Products

Certain types of medicinal products, both imported and domestically produced, are subject to price regulation by the Cabinet of Ministers. Local state authorities are also authorized to establish the marginal levels of retail markups on medicinal products.

16.7.16 Taxation

In Ukraine, the sale of medicinal products is (with certain exceptions) currently free of value added tax (VAT).

16.7.17 Registration of Medical Devices

The state registration of a medical devices requires the filing of an application with the State Service of Medical Devices (the Medical Devices Service) according to the provisions of the Resolution No. 1497 of the Cabinet of Ministers "*On the Approval of the Procedure for the State Registration of a Medical Devices*" dated 9 November 2004.

A registration application must contain information on the applicant and the medical device, the manufacturer (if other than the applicant), safety, *etc.* In addition, the instruction on medical device usage, the Certificate of Origin and the Certificate of Conformity must be provided, as well as a sample label or marking for the medical device, and some other documents. A new standard on labeling of medical devices is in effect from 1 February 2008.

The Medical Devices' Service has 90 days to consider the application. Then the Medical Devices' Service issues to the applicant a letter of referral for a further step - the expert examination. Additional documents may be requested from the applicant in course of the expert examination.

Once the document with the conclusions of the expert examination is obtained, the Medical Devices' Service will appoint trials of the medical device. Only after such trials will be conducted, the Medical Devices' Service will decide on registration of a medical device (which may be for a term of up to 5 years).

If registration is granted, the Medical Devices' Service will issue a registration certificate for a term of up to five years.