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ARZINGER – LAW FIRM OF THE YEAR IN MEDICINE AND PHARMA

Life Sciences & Healthcare Newsletter

Kyiv, April – May 2015

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MEDICINAL PRODUCTS

CLINICAL TRIALS

MOH EXPLAINED APPLICATION OF REDUCED VAT RATES FOR IMPORT OF MATERIALS INTENDED FOR CLINICAL TRIALS

— On 16.04.2015 the Ministry of Health of Ukraine (MOH) published its explanation as to documents confirming the right to apply the reduced VAT rate of 7% to materials intended for clinical trials.

More information on the explanation above you may find at this ***link.***

RULES FOR INTERACTION BETWEEN MOH AND THE STATE EXPERT CENTRE ON CLINICAL TRIAL ISSUES HAVE BEEN APPROVED

— On 15.04.2015 MOH issued an order[1] (the Rules) approving the procedure governing the interaction between MOH and the State Enterprise "State Expert Centre at the Ministry of Health of Ukraine" (the Centre) by:

- making a MOH's decision to allow or refuse to allow conduction of a clinical trial or to approve or refuse to approve an essential amendment.
- issuance of MOH's orders on state registration (re-registration) of medicinal products (medical immunbiological products) and introduction of amendments to registration materials, execution and issuance of market authorizations.

The Rules provide details on the procedure and time of each intermediate step/stage of interaction between the authorities in relation to the decisions above, including on the time to transfer materials from MOH to the Centre, conduction of an expert examination of materials and submission of an examination report to MOH etc. In particular, the procedure for interaction between MOH and the Centre by making a decision to allow conduction of a clinical trial/to approve an essential amendment provides that the applicant shall apply to the Centre of administrative services provision at MOH, "one-stop shop", and also shall receive excerpts from the MOH's order issued upon examination of documents there. Within 3 calendar days after receipt of the application MOH shall send it together with a cover letter to the Centre. At the same time, a MOH's assignment letter is generated using the electronic data base, a copy of which is automatically sent to the applicant's e-mail address.

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1 *Order of the Ministry of Health of Ukraine as of 15.04.2015 No. 220 "On Interaction between the Ministry of Health of Ukraine and the State Enterprise "State Expert Centre at the Ministry of Health of Ukraine"*

Upon results of the expert examination and drawing up of the reports, a MOH's order is issued, one copy of which is sent to the Centre, and the second copy is kept by the Administration of the Pharmaceutical Activity and Quality of Pharmaceutical Products (the Administration). A digital copy of the approved order shall be published within one day on the official website of the MOH.

STATE REGISTRATION OF MEDICINAL PRODUCTS

AMENDMENTS TO THE PROCEDURE OF REGISTRATION (RE-REGISTRATION) OF MEDICINAL PRODUCTS

— On 18.03.2015 the Cabinet of Ministers of Ukraine (CMU) approved amendments to the Procedure of the state registration (re-registration) of medicinal products[2] (the Procedure).

These amendments envisage, in particular, the following:

— state registration of original medicinal products registered by EMA is conducted without an expert examination of the registration materials by the State Expert Centre based on an application, registration materials, including an EMA registration file assessment report, a report of the Centre confirming compliance of the application guidelines and the drug quality control measures with the registration materials. The compliance shall be verified according to the procedure as approved by MOH. It shall be noted that provisions above contradict the Law of Ukraine "On Medicinal Products" which does not provide for such simplified registration. Based on the above, abolishment of the respective provisions of the updated Procedure may be expected soon.

— state registration of medicinal products for treatment of tuberculosis, HIV/AIDS, virus hepatitis, cancer and orphan diseases registered by the competent authorities in the USA, Switzerland, Japan, Canada or the EU as a medicinal product is conducted based on an application and a report of the Centre issued based on the examination of the materials attached to the application (the simplified registration). The procedure for such examination shall be specified by MOH.

— abolishment of the mandatory requirement to register separately the active pharmaceutical ingredient (API) being a component of the medicinal product. Instead, the API may be registered in the composition of such medicinal product.

— the right of MOH to ban a medicinal product temporary or completely by means of annulment of its market authorization, if:

- the applicant fails to notify MOH in case of circumstances requiring introduction of amendments to the registration materials,
- a medicinal product has not been put into circulation in Ukraine within three years after its state registration (re-registration), unless it is due to the specifics of the drug production and/or application. Previously, such term was two years.

2 *Approved by CMU's Resolution "On Approval of the Procedure for the State Registration (Re-registration) of Medicinal Products and Fees for their Registration (Re-registration)" as of 26.05.2005 No. 376*

— MOH reregisters medicinal products based on an application, registration materials and a report of the Centre containing, in particular, information about correlation between the expected benefits and possible risks of the usage of the medicinal products (except API and "in bulk" products) drawn up according to special MOH procedure.

— the Procedure is extended by a provision that after re-registration the use of a medicinal product in Ukraine is not limited in time, unless MOH decides to annul its market authorization.

— the registration term for an API or "in bulk" products being a component of a medicinal product and information on which is stated in the registration materials for the finished medicinal product is prolonged after re-registration of the finished medicinal product.

RULES FOR INTERACTION BETWEEN MOH AND THE STATE EXPERT CENTRE ON CLINICAL TRIAL ISSUES HAVE BEEN APPROVED

— As mentioned above, on 15.04.2015 MOH issued an order[3] approving the procedure governing the interaction between MOH and the State Enterprise "State Expert Centre at the Ministry of Health of Ukraine" (the Centre), including by issuance of MOH's orders on state registration (re-registration) of medicinal products (medical immunobiological products) and introduction of amendments to registration materials, execution and issuance of market authorizations (the Rules).

The Rules govern procedural issues of interaction between MOH and the Centre, including the timeframes of intermediate stages of such interaction – from transfer of documents to the Centre of administrative services provision at MOH, "one-stop shop" to obtaining a market authorization (insert to the market authorization) and registration materials at the centre above.

DRAFT CHANGES TO THE PROCEDURE OF THE STATE EXPERT EXAMINATION OF REGISTRATION MATERIALS ON MEDICINAL PRODUCTS

— In April MOH published its draft changes (Draft) to MOH's order "On Approval of the Procedure for the Expert Examination of Registration Materials for Medicinal Products Submitted to the State Registration (Re-registration) and the Expert Examination of Materials on Amendments to the Registration Materials within the Validity Term of the Market Authorization"[4] (the Procedure).

Changes envisaged in the Draft include the following:

— the Procedure does not apply to the following categories of the medicinal products:

i. Blood or plasma derived medicines fractionated from human donor blood according to guidelines of the manufacturer in institutions certified pursuant to the sphere of their activity;

ii. Active pharmaceutical ingredients (APIs), intermediate products, starting materials received by

3 *Order of the Ministry of Health of Ukraine as of 15.04.2015 No. 220 "On Interaction between the Ministry of Health of Ukraine and the State Enterprise "State Expert Centre at the Ministry of Health of Ukraine"*

4 *Products submitted to the State Registration (Re-registration) and the Expert Examination of Materials on Amendments to the Registration Materials within the Validity Term of the Market Authorization" as of 26.08. 2005 No. 426*

manufacturers during the manufacture of finished medicinal products and not intended for sale to other manufacturers;

iii. Biotechnological APIs;

iv. Blood and plasma used for industrial manufacture of finished blood medicines;

v. Vaccine antigens.

— applicants submit their applications and accompanying documents to the State Expert Centre at the MOH (the Centre) instead of MOH.

— abolishment of the initial expert examination of registration materials (intended to determine whether the respective medicinal product is one of the medicines prohibited for use in Ukraine and to qualify the type of the application in order to determine the volume of registration materials).

— obligation of the manufacturer to prove the ability to show stable characteristics from series to series by registration of medical immunobiological medicines, blood or plasma derived medicines. For human blood or plasma derived medicinal products the manufacturer is also obliged to prove that there is no specific virus contamination to the extent possible at the current state of the art.

— for medicinal products licensed by the European Medicines Agency (EMA) according to the centralized procedure, original medicines for treatment of socially dangerous and orphan diseases registered in countries regulatory authorities in which apply high quality standards[5], and medicinal products re-qualified by WHO may be subject to separate requirements as to the materials of the registration file. At this, no laboratory tests shall be carried out.

Moreover, the Draft envisages a separate procedure for examination of materials attached to the application for the state registration of certain medicinal products, as to their volume (the Examination procedure). It concerns medicinal products intended solely for the treatment of tuberculosis, HIV/AIDS, virus hepatitis, cancer and orphan diseases registered by the competent authorities in the USA, Switzerland, Japan, Canada or the EU.

According to the Draft, there are the following stages of the Examination procedure:

1. Materials are submitted to MOH.

2. Application and materials are transferred to the Centre within 1 business day.

3. Within 4 business days the Centre examines the materials as to their completeness and discrepancies between the application and the materials.

4. The Centre draws up its report upon results of the examination (no specified period of time for this stage is established), sends the report to MOH within 1 business day.

5. MOH decides about the state registration of the medicinal product within 1 business day (by means of approval of MOH's decree).

— etc.

Currently, the Draft is pending public discussion.

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5 *Socially dangerous diseases mean tuberculosis, HIV/AIDS, virus hepatitis, and cancer. Countries whose regulatory authorities apply high quality standards mean the USA, the EU (centralized procedure), Switzerland, Japan, UK, and Australia.*

IMPORT OF MEDICINAL PRODUCTS

CHANGES TO THE CUSTOMS CLEARANCE PROCEDURE

— On 22.04.2015 CMU amended[6] the Procedure for the customs clearance of goods imported to Ukraine and subject to mandatory certification in Ukraine[7] (the Procedure).

These amendments envisage, in particular, the following:

i. Information from the Unified Register of Products Certified in Ukraine shall be published on the website of the Ministry of Economic Development and Trade of Ukraine for public access.

ii. Application of the Procedure to goods under the customs regime of import, if such goods:

- are imported by legal entities and are intended for sale in Ukraine;
- are imported by individuals to Ukraine and are subject to declaration with submission of a customs declaration provided for undertakings;
- fall under vehicles, units, components and parts thereto.

The goal of import of goods to Ukraine which are placed under the customs regime of import, shall be specified in the customs declaration or any other document used instead of a customs declaration pursuant to the legislation.

iii. The Procedure is extended by a provision that controlled goods are released into free circulation in Ukraine, if the Unified Automated Informational System of Ukrainian fiscal authorities contains information that the name, type, kind, brand and manufacturer of the goods (irrespectively of their owner or recipient) have been registered with the Unified Register of Products Certified in Ukraine. At this, certificates of conformity (certificates of conformity recognition) shall be submitted to the customs service only if it is directly provided by the law. It shall be reminded that previously it was necessary to submit such certificates in each case before customs clearance of goods was finished.

Amendments came into effect on 07.05.2015, except items ii, iii above which will come into force on 07.06.2015.

6 *CMU's Resolution "On Amendments to Resolution of the Cabinet of Ministers of Ukraine as of 14 May 2008 No. 446" No. 235 as of 22.04.2015.*

7 *As approved by CMU's Resolution as of 14.05.2008 No. 446 "On Approval of the Procedure for the Customs Clearance of Goods Imported to Ukraine and Subject to Mandatory Certification in Ukraine, and Recognition of Certain Resolutions of the Cabinet of Ministers of Ukraine as Ceased to be in Force"*

MANUFACTURE OF MEDICINAL PRODUCTS

MOH'S RECOMMENDATIONS TO CONDUCT MICROBIOLOGICAL CONTROL DURING MANUFACTURE OF NON-STERILE MEDICINAL PRODUCTS HAVE BEEN ABOLISHED

— On 24.04.2015 MOH declared its order "On Approval of Methodical Recommendations for Compliance with Sanitary and Hygienic Requirements and Conduction of Microbiological Control by Production of Non-Sterile Medicinal Products"[8] as ceased to be in force"[9] (Recommendations).

These Recommendations approved, in particular, methodological recommendations as to preparation of production facilities, technological equipment and other issues governed by the Licensing Terms[10] and Good Manufacturing Practice[11].

MEDICINAL PRODUCT RETAIL

MANDATORY ACCREDITATION FOR PHARMACIES HAS BEEN ABOLISHED

— On 09.04.2015 Ukrainian Parliament passed the Law "On Amendments to Article 16 of the Fundamental Principles of the Legislation of Ukraine on Healthcare (as to Accreditation of Pharmacies)" (the Law).

The Law abolishes the mandatory accreditation for pharmacies. From now on, accreditation of pharmacies is voluntary.

The Law came into force on 14.05.2015 and shall be enacted as of 13.06.2015.

8 *MOH's Order "On Approval of Methodical Recommendations for Compliance with Sanitary and Hygienic Requirements and Conduction of Microbiological Control by Production of Non-Sterile Medicinal Products" as of 14.12.2011 No. 502*

9 *MOH's order "On Recognition of the Order of the Ministry of Health of Ukraine as of 14 December 2001 No.502 as Ceased to be in Force" as of 24.04.2015 No. 243*

10 *Licensing terms for manufacture of medicinal products, wholesale and retail with medicinal products as approved by MOH's order as of 31.10.2011 No. 723*

11 *Good Manufacturing Practice, ST-N MOH 42-4.0: 2014, as approved by MOH's order as of 16.02.2005 No. 95*

STATE PRICE CONTROLS

A BILL ON LIMITING MAXIMUM SALES MARK-UP FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

— On 13.03.2015 Ukrainian parliament registered under number 2368 a bill "On Establishment of Maximum Mark-Ups for Certain Product Categories" (the Bill).

The Law sets the maximum sales mark-up for goods irrespectively the number of re-sale operations at 15% of the wholesale price offered by a domestic manufacturer/of the customs value (for goods imported to Ukraine).

These mark-ups are applicable to business entities that sell goods having fundamental influence on the general level and the dynamics of prices and being of essential social importance. The Bill includes to such goods, in particular, medicinal products and medical devices.

MOH'S DRAFTS OF AMENDMENTS TO THE STATE PRICE CONTROLS RULES REGARDING MEDICINAL PRODUCTS AND MEDICAL DEVICES

— On 10.04.2015 MOH published a CMU's draft resolution "On Amendments to Certain Resolutions of the Cabinet of Ministers of Ukraine" (the Draft).

The Draft envisages:

— to establish a single maximum retail mark-up for medicinal products and medical devices included to the National list of Basic Medicinal Products and Medical Devices (except narcotics, psychotropic substances, precursors and medical gases) and a Mandatory Minimum Assortment of (Socially Oriented) Medicinal Products and Medical Devices for Pharmacies at the level of 25% of their wholesale price, inclusive of taxes.

— to provide that prices for medicinal products and medical devices that are subject to the state price controls are established based on the average UAH exchange rate set on the interbank currency market of Ukraine on the date preceding the date of product's sale to the foreign currency of product's purchase. It shall be reminded that for the time being the respective exchange rate on the date of product's sale is applied for these purposes.

— to provide that CMU's Resolution "On Reference Pricing for Medicinal Products and Medical Devices Procured for Public Funds from the State and Local Budgets"[12] (Resolution No. 240) shall not be applied to medicinal products or medical devices procured by specialized procuring organizations (WHO, UN Children's Fund etc.)[13].

— to make the procedure of declaring wholesale prices for medicinal products and medical devices simpler. In particular, it is envisaged not to require submission of an explanatory note with substantiation

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12 *CMU's Resolution "On Reference Pricing for Medicinal Products and Medical Devices Procured for Public Funds from the State and Local Budgets " as of 02.07.2014 No. 240*

13 *Pursuant to paragraph seventeen part three Article 2 of the Law of Ukraine "On Public Procurement" as of 20.04.2014 No. 2289-VI*

of the wholesale prices for medicinal products, or a note about the level of wholesale prices for the same medicinal products in reference countries and in Ukraine. Moreover, the draft envisages abolishing the requirement to obtain a report from the State Inspection of Price Controls as to substantiation of the wholesale price calculations.

— to provide for automatic adjustment by MOH of wholesale prices for foreign medicinal products put on the register of wholesale prices if the average monthly exchange rate of UAH to USD as set by the National Bank of Ukraine changes by more than 5%.

— to abolish the ban for wholesale price change for more than once a month. Such changes are permitted due to the change of terms of production or sale of medicinal products or medical devices that do not depend on applicant's economic activity.

Moreover, MOH has published a CMU's draft resolution "Some Issues of the State Price Controls for Medicinal Products" (the Draft resolution).

The Draft resolution envisages approval of the National List of Medicinal Products (the National List) and provides that medicinal products put on the National List and/or industry-specific standards in the healthcare sphere may be partially or completely purchased for public funds from the state or local budgets. It shall be noted that experts have criticised the draft of the National List claiming that the draft contains medicinal products whose inclusion in the list is questionable and does not contain medicinal products whose application is advised by international recommendations.

PUBLIC PROCUREMENT

EXPLANATIONS OF THE MINISTRY OF ECONOMIC DEVELOPMENT AS TO THE ANTICORRUPTION PROGRAM

— On 30.04.2015 the Ministry of Economic Development and Trade of Ukraine published an explanation[14] clarifying some amendments[15] to the Law of Ukraine "On Public Procurement" (the Law) which came into force on 26.04.2015.

It concerns amendments to Article 17 of the Law providing that the customer decides whether to deny a participant, a participant of a preliminary qualification (the participant) in the procurement or preliminary qualification and is obliged to reject a bid (qualification, price offer) of the participant, if, in particular:

i. Information about a legal entity acting as the participant is put on the Unified State Register of Persons Who Committed Corruption Offence or Such Connected to Corruption, or

ii. Such legal entity has no anticorruption policy or a legal entity responsible for the anticorruption policy, if they are mandatory pursuant to the law.

It is stated in the explanation, in particular, that as Article 17 does not specify the form of a documentary

14 *Explanation of the Ministry of Economic Development and Trade of Ukraine "On Enactment of Amendments to the Law of Ukraine "On Public Procurement" No. 3302-05/14183-07 as of 30.04.2015.*

15 *Introduced by the Law of Ukraine "On Prevention of Corruption" as of 14.10.2014 No. 1700-VII (taking into account amendments introduced by the Law of Ukraine "On Amendments to Certain Legislative Acts of Ukraine regarding Provision for the Activity of the National Anti-Corruption Bureau of Ukraine and the National Corruption Prevention Agency" 12.02.2015 No. 198-VIII)*

confirmation of participants' compliance with the requirements above, it may be determined by the customer. At the same time, if customer specifies in its tender documentation that as confirmation of participant's compliance with the requirements stated in item i. above the participant shall include in its bid documents issued by the National Corruption Prevention Agency and its bid does not contain such documents as there is no Unified State Register of Persons Who Committed Corruption Offence or Such Connected to Corruption functioning pursuant to the Law of Ukraine "On Prevention of Corruption" but contains, however, instead a confirmation in free form indicating the respective information, customer shall decide to admit the bid of such participant if there are no other reasons specified by the Law to reject it.

ADVERTISING

AMENDMENTS TO THE ADVERTISING LAW

— On 12.05.2015 Ukrainian Parliament passed the Law of Ukraine "On Amendments to the Law of Ukraine "On Advertising" (regarding a Percent of Advertising Distributed on TV and the Radio)" (the Law).

The Law provides, in particular, that advertising or telemarketing time on **TV** shall not exceed **15%** of each astronomical hour of actual broadcasting, and on the **radio – 20%**. It shall be reminded that previously, advertising or telemarketing time **both on TV and the radio** should not have exceeded **15%**, and during elections – **20%** of the actual broadcasting volume during **astronomical day**. During an **astronomical hour** such share should not have exceeded **20%**, and during elections – **25%** of the actual broadcasting.

The Law will come into force on the next day after its official publication.

TAXES, FEES AND OTHER MANDATORY PAYMENTS

TAXES FOR EXPIRED MEDICINAL PRODUCTS

— Due to the enactment of the Law of Ukraine "On Amendments to the Law of Ukraine "On Medicinal Products" regarding Circulation of Medicinal Products and State Control of Medicinal Products Imported to Ukraine"[16] (the Law) mandatory re-registration of medicinal products each 5 years after the registration has been abolished. Moreover, the Law envisages that after the first re-registration the use of a medicinal product in Ukraine is not limited in time.

At this, medicinal products released into circulation within the period of time when the medicinal product was permitted for use in Ukraine may be used in Ukraine until expiration of their shelf life specified by the manufacturer and indicated on the package.

However, after introduction of the amendments above, undertakings got some questions concerning the taxation of expired medicinal products. In this connection the following shall be noted.

Pursuant to paragraph 193.1 of the Tax Code of Ukraine[17], tax rates are established according to the taxation basis in the amount of 7% for delivery and import to Ukraine of medicinal products permitted for use in

16 *Law of Ukraine "On Amendments to the Law of Ukraine "On Medicinal Products" regarding Circulation of Medicinal Products and State Control of Medicinal Products Imported to Ukraine" as of 20.10.2014 No. 1707-VII*

17 *Tax Code of Ukraine as of 02.12.2010 No. 2755-VI*

Ukraine and put on the State Register of Medicinal Products, as well as of medical devices according to the list as approved by the Cabinet of Ministers of Ukraine.

Therefore, for purpose of the taxation of delivery and import of medicinal products at 7% VAT two conditions shall be met at once:

— a medicinal product shall be permitted for production and use in Ukraine;

— a medicinal product shall be put on the State Register of Medicinal Products (Register).

Pursuant to paragraph 1 Article 9 of the Law of Ukraine "On Medicinal Products"[18] (the Law), medicinal products are permitted for use in Ukraine after their state registration, except cases provided by the Law. At this, pursuant to paragraph 18 Article 9 of the Law and paragraph 3.4 of the Procedure for Imposing a Ban (Temporary Ban) and Renewal of Circulation of Medicinal Products in Ukraine[19], a medicinal product released into circulation within the period of time when it was permitted for use in Ukraine, may be used in Ukraine until expiration of its shelf life specified by the manufacturer and indicated on the package.

At the same time, pursuant to the Procedure of Keeping the Register of Medicinal Products[20], medicinal products are taken off the informational or reference databases of the Register due to expiration of their state registration term.

Therefore, delivery and import of medicinal products that were taken off the register due to expiration of their state registration term do not comply with the criteria of application of 7% VAT and, hence, are subject to 20% tax – according to the standard procedure. MOH prepares a draft of amendments to the Procedure of Keeping the Register of Medicinal Products in order to solve this problem and to keep information about medicinal products on the Register after expiration of their state registration term. Therefore, it is planned to apply the incentive VAT rate to such medicinal products as well. However, the draft has not been even published for public discussion yet.

BILLS ON IMPORT DUTIES ABOLISHMENT AND EXEMPTION FROM IMPORT DUTY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES

— On 20.04.2015 Ukrainian Parliament registered under number 2674 a bill to recognize the Law of Ukraine "On Measures to Stabilize Ukraine's Foreign Balance pursuant to Article XII of the General Agreement on Tariffs and Trade 1994" as ceased to be in force.

Moreover, on 13.05.2015 Ukrainian Parliament registered under number 2827 a bill "On Amendments to the Law of Ukraine "On Measures to Stabilize Ukraine's Foreign Balance pursuant to Article XII of the General Agreement on Tariffs and Trade 1994" (regarding taxation of medicinal products and medical devices) (the Bill).

The Bill envisages exempting medicinal products permitted for manufacture and use in Ukraine and put on the State Register of Medicinal Products, as well as medical devices according to the list approved by CMU from import duty by means of including such products into the category of vital commodities.

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18 *Law of Ukraine "On Medicinal Products" as of 04.04.1996 No. 123/96-VR*

19 *As approved by MOH's order "On Approval of the Procedure for Imposing a Ban (Temporary Ban) and Renewal of Circulation of Medicinal Products in Ukraine" as of 22.11.2011 No. 809*

20 *As approved by MOH's order "On Approval of the Procedure of Keeping the Register of Medicinal Products of Ukraine" as of 08.05.2014 No. № 314*

It shall be noted that on 28.04.2015 the World Trade Organization (WTO) held a meeting on the issue of import duty introduced by Ukraine and its was stated that the import duty will be annulled by the end of 2015 at the latest. WTO members declared that it is necessary to present economic rationale for measures introduced by Ukraine, their effectiveness, criteria for the selection of rates, and criteria to determine the possibility to annul the duty. It shall be noted that representatives of Ukraine declared that if the foreign balance of Ukraine achieves at least the level of 2013, the duty might be annulled even earlier.

COSMETICS

ELABORATION OF TECHNICAL REGULATIONS ON COSMETICS IS PLANNED FOR IV QUARTER 2015

— On 01.04.2015 the Ministry of Economic Development and Trade approved an order providing for development of Technical Regulations as to safety of cosmetics (the Technical Regulations) in IV quarter of 2015. MOH was appointed as responsible authority for the elaboration of the Technical Regulations. Arzinger's lawyers are engaged in the work on the draft.

21 *Decree of the Ministry of Economic Development and Trade of Ukraine "On Amendments to the Working Program for the Elaboration of Technical Regulations till 2020" as of 01.04.2015 No. 323*

SCREENING OF OFFICIALS

A REGISTER OF OFFICIALS TO BE SCREENED FOR CORRUPTION PRACTICES COMMENCED ITS WORK

— In April the online register of officials to be screened for corruption practices created by the Public Screening Committee commenced its work.

The search is carried out by branches of government or by regions of Ukraine. You may access the register by following this link – *http://lku.org.ua/registry/dashboard*.

Kind regards and best wishes,

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/ Analytical Issue "Yurist & Zakon", 25.07.2014 – 31.07.2014, No. 29

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/ Yurydycheskaya Praktika, April 2014/

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Lana Sinichkina, Partner
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/ Law Business Research Ltd, Getting the Deal Through – Pharmaceutical Antitrust 2014 /

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ARZINGER'S LIFE SCIENCES & HEALTHCARE PRACTICE

Arzinger provides legal services to leading international and local pharmaceutical companies doing business on the territory of Ukraine on various legal issues, from planning business in the Ukrainian market to interacting with government agencies; intellectual property; settlement of disputes with monitoring / supervising / regulatory agencies and contractors etc.).

Arzinger's working languages are Ukrainian, Russian, German, and English.

Arzinger's team is a recognized leader on the legal services market in the sphere of pharmaceutical business of Ukraine.

Our life sciences and healthcare practice employs 12 experienced lawyers who have worked as legal advisors (in-house lawyers) to leading pharmaceutical companies, clinical research organizations and medical institutions. At the same time, we are constantly developing and expanding our team to meet our clients' needs. In addition, if required for a project, we engage lawyers from other Arzinger's practices specialized in certain areas of law (e.g. intellectual property rights, tax and customs law, public procurement, corporate law, advertising, etc.). Thus we can provide clients with integrated and comprehensive advice on all aspects of doing business in Ukraine.

The symbiosis of knowledge of law, a personal-touch approach to each assignment and our practice's significant experience enables us to offer our clients high-quality legal services. In 2012 and 2013 the Ukrainian rating "Ukrainian Legal Firms. Handbook for Foreign Clients" rated Arzinger highly in the areas of medicine, healthcare and pharmaceutics. Timur Bondaryev, Managing Partner, and Lana Sinichkina, Counsel, were ranked individually in the area of healthcare and pharmaceutics.

According to the ranking "Client's Choice. Top-100 Best Lawyers of Ukraine" conducted by Yurydychna Gazeta in 2010-2011 and 2012-2013, Timur Bondaryev, Managing Partner and Head of Arzinger's Life Sciences and Healthcare Practice, has been recognized as one of the best lawyers in Ukraine specializing in health and pharmaceutical law. Lana Sinichkina, Counsel and Head of the Life Sciences and Healthcare Practice, was listed by the 2012-2013 rating among 300 Ukrainian lawyers, whose names have been mentioned most frequently by representatives of business, customers and peers.

ARZINGER PROVIDES LEGAL SERVICES IN RELATION TO:

— ANTITRUST AND COMPETITION LAW

— CLINICAL TRIALS

— ADVERTISING AND OTHER TYPES OF PROMOTION OF MPS AND MEDICAL DEVICES

— REGISTRATION, PROTECTION AND TRANSFER OF INTELLECTUAL PROPERTY RIGHTS

— PUBLIC PROCUREMENT

— TAX AND LEGAL ADVICE ON BUSINESS DEVELOPMENT

— BUSINESS RESTRUCTURING

— PUBLIC-PRIVATE PARTNERSHIP

— LOCALIZATION OF MANUFACTURING, CONTRACT MANUFACTURING

— REGISTRATION (RE-REGISTRATION) OF MPS, FOOD AND DIETARY SUPPLEMENTS AS WELL AS FUNCTIONAL FOODS AND FOODS FOR SPECIAL DIETARY USE, MEDICAL EQUIPMENT AND MEDICAL DEVICES

— MPS MANUFACTURE

— MPS AND MEDICAL DEVICES IMPORT

— MPS AND MEDICAL DEVICES SALES IN THE TERRITORY OF UKRAINE (WHOLESALE AND RETAIL, PRICING, PUBLIC PROCUREMENT ETC.)

— STATE ACCREDITATION OF PHARMACIES AND HEALTHCARE INSTITUTIONS

— LICENSING OF MEDICAL ACTIVITIES

— OBTAINING A SPECIAL LICENSE FOR MEDICAL PRACTICE IN THE SECTOR OF FOLK AND ALTERNATIVE MEDICINE

— CERTIFICATION OF PHARMACISTS, PHYSICIANS AND NURSES

— HEALTHCARE INSTITUTIONS ACTIVITY

— LEGALIZATION AND EMPLOYMENT OF FOREIGN SPECIALISTS

— REPRESENTING PHYSICIANS AND PATIENTS IN CONFLICT SITUATIONS

— SUPPORT DURING REGULATORY AUTHORITIES RAIDS

— ADVISING CLIENTS ON LEGAL ISSUES REGARDING PERSONAL DATA PROTECTION, LEGAL SUPPORT OF REGISTRATION OF PERSONAL DATA BASES

— LITIGATION, INCLUDING DISPUTES WITH TAX AND CUSTOMS AUTHORITIES AND DISPUTES ON DEBT COLLECTION.

THE DAILY CONSULTING OF PHARMACEUTICAL BUSINESS CLIENTS INCLUDES:

— CORPORATE ISSUES

— CONTRACT MAINTENANCE

— REVIEWING CLIENTS' MARKETING AND ADVERTISING MATERIALS FOR COMPLIANCE WITH ADVERTISING AND COMPETITION LAWS

— DRAFTING/AMENDING INTERNAL DOCUMENTS (POLICIES, PROCEDURES, INSTRUCTIONS)

— LEGAL SUPPORT OF HR DEPARTMENTS

— PROTECTING CLIENTS' INTERESTS DURING INSPECTIONS CONDUCTED BY STATE AUTHORITIES (SECURITY SERVICE OF UKRAINE, PUBLIC PROSECUTION BODIES, AMCU, STATE TAX INSPECTION ETC.).

Arzinger's lawyers conduct corporate workshops/trainings for employees of pharmaceutical companies on the most topical issues of Ukrainian legislation.

As part of Arzinger Academy Legal Days we hold monthly business breakfasts for pharmaceutical representatives to let the participants know experts' opinions, to discuss current market issues and to share experience. Moreover, Arzinger is a general partner of Pharmaceutical and Medical Law School created by all-Ukrainian public organization Ukrainian Bar Association.