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Life Sciences & Healthcare Newsletter

Kyiv, June 2015

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MEDICINAL PRODUCTS

STATE REGULATION OF PRICING

SIMPLIFIED REQUIREMENTS AND PROCEDURES IN THE STATE REGULATION OF PRICES FOR MEDICINAL PRODUCTS

— On July 3, 2015 a text of the Resolution of the Cabinet of Ministers of Ukraine (hereinafter – CMU) No. 449 dated April 22, 2015 "On Amending Certain Resolutions of the Cabinet of Ministers of Ukraine" (hereinafter – Resolution) was published at the CMU's official web-site. The Resolution amends certain legal acts regulating pricing of medicinal products and medical devices.

The amendments, first of all, are directed at overcoming drawbacks of the system of declaration of changes of wholesale prices by canceling reference pricing procedure, and are an attempt to solve the problem of exchange rate fluctuations of the national currency in terms of calculating prices by public procurement participants. In addition, some changes to the procedure for calculating the retail mark-ups were introduced, and medicinal products procured through international procurement agencies were exempted from pricing regulations.

The Resolution came into effect on 07.07.2015.

A detailed analysis of the Resolution is provided in *our special newsletter*.

DRAFT ORDER TO CANCEL THE MANDATORY MINIMUM RANGE OF MEDICINAL PRODUCTS AND MEDICAL DEVICES FOR PHARMACIES

— On 01.07.2015 the Ministry of Health of Ukraine (hereinafter – the MOH) published a draft order proposing to repeal the MOH Oder "On Approval of the Mandatory Minimum Range of Medicinal Products and Medical Devices for Pharmacies" dated 29.12.2011 No.1000 (hereinafter – Order No.1000) on its website. It should be recalled that the medicinal products included in the Mandatory Minimum Range of (Socially Oriented) Medicinal Products and Medical Devices for Pharmacies as approved by Order No.1000 shall be subject to state regulation of pricing in form of maximum supply-sale and trade (retail) markups.

The draft order is currently at the stage of public consultation.

PILOT PROJECTS

PILOT PROJECT "INSULIN" TO BE LAUNCHED ON 1 DECEMBER 2015

— 26.06.2015 the Cabinet of Ministers of Ukraine amended[1] the Resolution2 regulating the implementation issues of the pilot project to carry out state regulation of prices for insulin preparations (hereinafter – the Pilot Project).

The Resolution provides for:

— Implementation of the Pilot Project starting from 1 December 2015.

— Introduction of reimbursement for insulin preparations at the cost of local budgets as of 1 January 2016. Such reimbursement will be carried out at reference prices (reimbursement prices) after such prices for preparations are entered into the register of reference prices (reimbursement prices) in the established manner. It should be noted that the list of reference countries is not set in the Resolution.

— The amount of maximum supply and trade (retail) markups for insulin preparations is still regulated by the CMU Resolution "Om Measures to Stabilize Prices for Medicinal Products and Medical Devices" dated 17.10.2008 No. 955.

— the MOH shall be obliged:

- by 1 August 2015 – to approve the Provision on the Register of Patients in need of insulin therapy as well as to enact it by 1 September 2015;
- by 1 December 2015 – to approve the Provision on the Register of Reference Prices (reimbursement prices) for insulin preparations and the procedure to amend it.

— The Register of Reference Prices (reimbursement prices) for insulin preparations shall be made and published by the MOH by 1 January 2016, while the draft act to introduce value reimbursement for insulin preparations from 1 January 2016 should be submitted for consideration to the CMU by 1 December 2015.

The Resolution came into effect on 07.07.2015.

1 *CMU Resolution "On amendments to the Resolution of the Cabinet of Ministers of Ukraine dated 5 March 2014 No.73" dated 26.06.2015 No. 443*

2 *CMU Resolution "Implementation issues of the pilot project to introduce state regulation of prices for insulin preparations" dated 05.03.2014 No. 73*

PUBLIC PROCUREMENT

CLARIFICATION OF THE MINISTRY OF ECONOMY REGARDING SOME BIDDERS' CONFIRMATION OF PUBLIC PROCUREMENT LAW REQUIREMENTS

— On 25.05.2015 the Ministry of Economic Development and Trade (hereinafter – the MEDT) published its letter[3] with clarifications regarding the form for participants of tenders, participants of preliminary qualifications (hereinafter – the bidders) to confirm the requirements of the Law of Ukraine "On Public Procurement"[4] (hereinafter – the Law). The requirements refer to the rules for rejection of bids of bidders recorded in the Unified State Register of Persons That Have Committed Corruption or Corruption-Related Offences (hereinafter – the Register) as well as to legal entities lacking an anticorruption program and an anticorruption program officer (hereinafter – the officer).

It should be noted that according to the latest information from the Ministry of justice the updated Register was already launched and is functioning in the test mode.

In its letter the MEDT recommends the customers, until the National agency on counteracting corruption, authorized to issue certificates on the absence of information about persons in the Register, actually starts performing its functions, **to set the following means to confirm compliance with the above requirements in the bidding documentation/bid requests:**

1) Information in free form about the lack of records on the legal entity in the Register;

2) Information about the availability of an anticorruption program and an anticorruption program officer, where they are mandatory in accordance with the Law, with a copy of the legal entity's anticorruption program and a copy of the order on appointing the officer.

The bidders participating in public procurement should pay attention to the above recommendations of the MEDT. It was expected that the practice would take the line of requiring the bidders to provide only information on whether an anticorruption program and an officer are available, without the need to produce copies of the program proper and of the order on appointing an officer.

POSSIBLE CHANGES IN THE LAW ON PUBLIC PROCUREMENT

— On 30.06.2015 the Parliament of Ukraine adopted the Bill of Ukraine "On Amendments to Some Laws of Ukraine on Public Procurement for Bringing Them into Line with the International Standards and Taking Measures to Combat Corruption" (Reg. No.2087a), hereinafter – the Bill, on first reading.

Among other things, the Bill provides for the following changes:

— increased threshold values for the subject of procurement which, if reached, make procurement subject to the effect of the Law; for goods and services, the threshold is supposed to be increased from UAH 100,000 to UAH 200,000, and for works – from UAH 1,000,000 to UAH 1,200,000;

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3 *MEDT Letter dated 25.05.2015 № 3302-05/16476-07 "On the Entry into Force of Amendments to the Law of Ukraine "On Public Procurement"*

4 *Law of Ukraine " On Public Procurement" dated 10.04.2014 No.1197-VII*

— publication of the annual procurement plan and amendments thereto on the customer's website (if there is none – on the website of the chief budget holder);

— mandatory publication of evaluation reports on competitive bids (price quotations) on the web portal of the MEDT;

— roll-call votes cast by the committee members present at the meeting on each issue shall be reflected in the minutes of the bidding committee;

— the customer's duty to reject a bid, if:

  - the relevant legal entity has no anticorruption program or anticorruption program officer in cases where they are mandatory under the Law or when the value of the procured object constitutes or exceeds UAH 20 million;

  - there is no information about the ultimate beneficiary (controller) of a resident legal entity in the Unified State Register of Legal Entities and Individual Entrepreneurs.

At the same time, according to the Bill, information about the lack of grounds for rejecting a bid should be provided in free form. The method of documentary confirmation of a bidder's compliance with most requirements of the Law should be determined by the customer, for such documents to be provided only by the winning bidder. According to the Bill, the winning bidder will be obliged to submit such documents within 10 days after the bid acceptance decision is passed. If a bidder fails to submit such documents during the specified period, the customer will determine the most economically advantageous bids of those with an unexpired validity period. On its part, the CMU should approve the procedure for issuing a single document confirming a bidder's compliance with the requirements established by the Law.

Apart from that, the Bill also forbids customers to demand information contained in open state registers with free public access from bidders.

— the right of a bidder, whose offer is rejected, to require the customer to provide information about the reasons why its bid is incompliant with the bidding documentation requirements, in particular with technical specifications and/or its incompliance with the qualification criteria. In this case the customer should provide its response no later than 5 days upon receipt of such a request.

TAX

LIST OF MEDICINAL PRODUCTS AND MEDICAL DEVICES EXEMPT FROM VAT FOR THE PERIOD OF ATO

— On 27.05.2015 the CMU approved the Ordinance "On Volumes of Medicinal Products and Medical Devices that Shall Be Exempt from Value Added Tax for the Period of the Anti-Terrorist Operation and/or Martial Law in Transactions for Their Import into the Customs Territory of Ukraine and Delivery to the Customs Territory of Ukraine" No. 544-p (hereinafter – the Ordinance).

The Ordinance contains 5 trade names of medicinal products as well as 8 UKTVED codes of medicinal products exempt from VAT in import and supply transactions in the amount prescribed by the Ordinance. It should be recalled that approval of the volume of medicinal products and medical devices intended for use by healthcare institutions and participants in the antiterrorist operation to provide medical care to

individuals, who have suffered injuries, concussions or other damage to health during the anti-terrorist operation and/or martial law, that shall be exempt from VAT in transactions for their import and supply to the customs territory of Ukraine, was envisaged by the Law of Ukraine "On Amendments to the Customs Code of Ukraine and Some Laws of Ukraine regarding the Import of Personal Protective Equipment and Medicinal Products" dated 01.07.2014 No.1560-VII.

The Ordinance came into effect on 27.05.2015.

DRAFT ORDER TO SETTLE THE PROBLEM OF 7% VAT RATE FOR MEDICINES WITH EXPIRED REGISTRATION TERM

— As we reported in our ***previous newsletter issue***, the current problem is that the reduced 7% VAT rate does not extend to import and supply transactions with medicinal products with an expired registration term. The problem is due to the fact that under paragraph 193.1 of the Tax Code of Ukraine[5] the above tax rate is set for supply and import transactions with medicinal products allowed for manufacture and use in Ukraine and entered in the State Register of Medicinal Products (hereinafter – the Register) to the customs territory of Ukraine. Whereas under the Procedure for Keeping the Register of Medicinal Products[6] (hereinafter – the Procedure) medicinal products shall be excluded from the Register upon expiry of their validity term of state registration, medicinal products with an expired registration term do not meet the criterion for application of the 7% VAT rate.

To solve this problem, the MOH drafted amendments[7] to the Procedure, under which information about a medicinal product released into circulation during the period of validity of its marketing authorization, which has expired, shall be kept in the Register within two years upon its expiry in a separate line.

In our view, the Draft should be refined, as it contains a number of contradictions and inconsistencies.

The Draft is currently at the stage of public consultation.

NEW DRAFT LIST OF MEDICAL DEVICES SUBJECT TO VAT AT THE RATE OF 7%

— On 02 July 2015 the MOH published the CMU Draft Resolution "On Approving the List of Medical Devices That Shall Be Subject to Value Added Tax at the Rate of 7 Percent In Transactions for Their Supply and Import to the Customs Territory of Ukraine" (hereinafter – the Draft) on its official Website.

The Draft stipulates that the list of medical devices that shall be subject to VAT at the rate of 7 percent in transactions for their supply and import to the customs territory of Ukraine shall be comprised of all medical devices:

— that are included in the State Register of Medical Equipment and Medical Devices as well as

5 *Tax Code of Ukraine dated 02.12.2010 No.2755-VI*

6 *Approved by Order of the MOH "On Approval of Procedure for keeping the Register of Medicinal Products of Ukraine" dated 08.05.2014 No. 314*

7 *MOH Draft Oder "On amendments to paragraph 6 of the Regulation on the State Register of Medicinal Products"*

— medical devices and aids, for which:

- a declaration is drawn up, or
- a certificate is issued, or
- a statement on special-purpose medical devices, or an application concerning medical devices for in vitro diagnostics intended for assessment of characteristics is drawn up according to the requirements of the relevant technical regulations.

In other words, the draft proposes to extend the 7% VAT rate to all registered medical devices as well as to medical devices, for which the documents required to put such devices into circulation have been prepared/ issued under the existing technical regulations.[8]

It should be recalled that the currently effective list for the purpose of application of the 7% VAT rate consists of medical devices named after the appropriate UKTVED codes under the CMU Resolution "On Approving The List of Medical Devices Subject to Value Added Tax at the Rate Of 7 Percent in Transactions for Their Supply in and Import to the Customs Territory of Ukraine" dated 03.09.2014 No.410.

The Draft is currently at the stage of public consultation.

HEALTHCARE INSTITUTIONS

ACCREDITATION OF HEALTHCARE INSTITUTIONS IN THE ATO ZONE

— On 27 May 2015 the CMU amended[9] the Accreditation Procedure for healthcare institutions.[10]

Under the amendments, the validity period of accreditation certificates issued by healthcare institutions operating in localities where public authorities temporarily do not exercise their powers or that are located on the contact line, according to the lists approved by CMU Resolution[11] shall be extended for the period of the antiterrorist operation. Therefore, healthcare institutions located in the above territories shall be exempt from further accreditation for the period of the antiterrorist operation.

The amendments came into effect on 12.06.2015.

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8 *Technical regulation for medical devices approved by Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 No.753, Technical regulation for medical devices for in vitro diagnostics approved by Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 No. 754, Technical regulation for active implantable medical devices approved by Resolution of the Cabinet of Ministers of Ukraine dated 02.10.2013 No. 755*

9 *CMU Resolution "On Amendments to paragraph 10 of Accreditation Procedure for Healthcare Institutions" dated 27.05.2015 Nr.329*

10 *CMU Resolution "On Approval of Accreditation Procedure for Healthcare Institutions " dated 15.07.1997 No.765*

11 *CMU Ordinance "On Approval of the list of localities, where public authorities temporarily do not exercise their powers or that are located on the contact line" dated 07.11.2014 Nr.1085*

VACCINATION

RECOMMENDATIONS OF THE ROUND TABLE "STATE POLICY REGARDING IMMUNOPROPHYLAXIS IN UKRAINE"

— On 02 June 2015, the round table "State Policy regarding Immunoprophylaxis in Ukraine" held with participation of the MOH, other state authorities and local governments, non-government organizations and experts approved *inter alia* the following recommendations:

  — To draft the State Programme for Immunoprophylaxis and Protection from Infectious Diseases for 2016-2022.

  — To establish an electronic register of conducted vaccinations for children and adults since 2016 as a mechanism to monitor the state of epidemic safety with respect to controlled infections.

  — To amend the Law "On Protection of Population from Infectious Diseases" by providing for the possibility to attend organized children's groups without conducted vaccinations. Also, it is proposed to establish that the State Programme for Immunoprophylaxis shall be implemented for free. However, in case of a registered refusal of vaccination according to the calendar of preventive vaccinations further vaccination is possible for a fee in the absence of contraindications.

OPERATIONS WITH DONOR BLOOD

APPROVED AMENDMENTS TO PROCEDURE FOR SELLING COMPONENTS AND DONOR BLOOD PREPARATIONS ABROAD

— On 20 May 2015 the CMU approved[12] the amendments to the Procedure for selling donor blood components and preparations made of donor blood and its components outside Ukraine as well as for exporting donor blood and its components from Ukraine (hereinafter – the Procedure).

In particular, under the amendments special permits for selling donor blood components and preparations made of donor blood and its components outside Ukraine shall be provided to business entities annually.

Apart from that, such permits are now provided by the CMU (previously – by the Vice Prime Minister of Ukraine, which, in accordance with the distribution of functional powers, shall organize the development and implementation of public health policies) on reasonable representation of the Ministry of Health, which shall determine the list and amounts of such sale.

The amendments came into effect on 26.05.2015.

12 *CMU Resolution "On amendments to paragraph 3 of Procedure for selling donor blood components and preparations produced from donor blood and its components outside Ukraine as well as for exporting donor blood and its components from Ukraine" dated 25.05.2015 No.318*

NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND PRECURSORS

LIST OF ILLICITLY TRAFFICKED CONTROLLED SUBSTANCES HAS BEEN EXTENDED

— On 15 May 2015 the MOH amended[13] the tables of small, large and extra large amounts of illicitly trafficked narcotic drugs, psychotropic substances and precursors (hereinafter – the tables)[14].

To view the list of substances put in the tables, please ***use this link***.

13 *MOH Order "On amendments to the Order of the Ministry of Healthcare of Ukraine dated 1 August 2000 No.188" dated 15.05.2015 No. 280*

14 *Approved by MOH Order "On approval of the table of small, large and extra large amounts of illicitly trafficked narcotic drugs, psychotropic substances and precursors" dated 01.08.2000 No.188*

DETERGENTS

MANDATORY CERTIFICATION CANCELLED FOR DETERGENTS

— On 06 May 2015 the MEDT approved the order[15] cancelling the mandatory certification for a number of products, including detergents.

The Order came into effect on 05 June 2015.

15 *MEDT Order "On amendments to the List of products subject to mandatory certification in Ukraine and invalidation of some orders of the State Committee of Ukraine for Standardization, Metrology and Certification" dated 06.05.2015 No.451*

ACTIVITIES OF FOREIGN COMPANIES' REPRESENTATIVE OFFICES

REGISTRATION OF FOREIGN COMPANIES' REPRESENTATIVE OFFICES WILL BE TWICE AS FAST

— On 10.06.2015 the Minister of Economic Development and Trade of Ukraine A. Abromavichus issued a special directive regarding terms for issuance of a registration certificate for a representative office of a foreign business entity in Ukraine.

Pursuant to the directive, a registration certificate for a representative office of a foreign business entity in Ukraine shall be issued within 30 business days after payment of the state duty provided the applicant has submitted all documents in compliance with the Guideline on the procedure for registration of representative offices of foreign business entities in Ukraine[16].

Amendments to the current legislation of Ukraine governing the legal relations in this sphere, including amendments to the Guideline above, are expected in the nearest future as well.

Kind regards and best wishes,

Timur Bondaryev, Managing Partner,
Attorney-at-law,
Head of Life Sciences and Healthcare Practice

Lana Sinichkina, Partner,
Head of Life Sciences and Healthcare Practice

16 *Instruction on registration procedure for representative offices of foreign business entities in Ukraine approved by order of the Ministry of Foreign Relations and Trade of Ukraine dated 18.01.1996 No.30*

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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.