

PwC Azerbaijan Times

Issue №10

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Amendments to the Law on Medicinal products

According to the amendments, the Ministry of Health of the Republic of Azerbaijan, in addition to state regulation measures stated under Article 4.2 of the Law, will carry out the following:

1. *Pharmacosurveillance of medicinal products.* Pharmacosurveillance is the measure taken to detect, evaluate and preclude side effects of medical products and other undesirable outcomes arising out of use of such products;

2. *Preparation of list of specially controlled medicinal products.* Specially controlled medicinal products are the products that require special control over the use of medical products in terms of their adverse effects on human health;

3. *Classification of medicinal products.* Classification of medicinal products implies the systematization and cataloging of the medicinal products due to origin, release order, physical-chemical, toxicological, pharmacological, therapeutic and other characteristics;

4. *Expertise of medicinal products.* Expertise of medicinal products is examinations and inspections to determine the quality, effectiveness and safety of the medicines through physical, chemical, biological, clinical researches clinical tests (clinical investigations), identification of bioequivalence, as well as examinations and inspections carried out by examining the documents upon registration, pharmacosurveillance and standardization of the medical products.

One of the concepts added by the Amendments is the recall/ withdrawal of the medicinal products. Recall/withdrawal of medicinal products means partial or complete withdrawal of medicinal products from circulation, which have been considered as unsuitable or dangerous to human health by the manufacturer or the Ministry of Health*. According to the respective Decree* of the President of the Republic of Azerbaijan, the Cabinet of Ministers of the Republic of Azerbaijan will approve the procedure for recall / withdrawal of medicinal products by agreeing with the President in 3 months (including rules for the expertise of medicinal products and pharmacosurveillance of medicinal products).

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With the Amendments, circle of persons authorized to import the medicinal products into the country has been also identified. For state registration purposes, specimens of medicinal products and the medical substance, which is used in the production of medicinal products, might be imported into the country by the Ministry of Health*, enterprises engaged in production or wholesale pharmaceutical activity, representative office (branch or authorized person) of the foreign manufacturer in the Republic of Azerbaijan in the quantity defined by the Cabinet of Ministers.

According to the Amendments, in order to control the effectiveness and safety of the medicinal products, regardless of ownership and organizational legal form all treatment-and-prophylactic enterprises, the holder of the state registration certificate or the person authorized by such, for ensuring safe use of medicines, take pharmacosurveillance measures and determine the person in charge of pharmacosurveillance in accordance with the procedure set by Cabinet of Ministers.*

Responsible persons for pharmacosurveillance of treatment-and-prophylactic enterprises, owner of state registration certificate on medicinal product or the person authorized by it have to submit additional information as to side effects of the medicinal product and other undesired consequences arising from use of the medicines, as well as information on pharmacosurveillance and report documents to the relevant state authority.

* - According to the Decree of the President of the Republic of Azerbaijan on the implementation of the Law on Amendments to the Law of the Republic of Azerbaijan on Medicinal products dated No. 1150-VQD of May 18, 2018.

Amendments to the Tax Code of the Republic of Azerbaijan

According to the Amendments, tax rates of some excisable products - tobacco products have been increased. The tax rate for 1000 units cigars, cutting cigars and cigarillas has been raised from 10 to 20 AZN, and for 1000 units of tobacco cigarettes and its substitutes has been raised from 4 to 12 AZN.

Limits and Procedures of providing information on financial transactions performed by foreign legal and natural persons in the territory of the Republic of Azerbaijan to competent authorities of these Countries

The rules approved by the decision No. 211 of the Cabinet of Ministers of the Republic of Azerbaijan dated June 3, 2015, have been approved in the new edition. With new rules, the following procedures, rules, and lists have been defined:

1. Comprehensive inspection procedures related to the identification of accounts peculiar to legal entities and/or individuals of the United States, as well as detailed inspection procedures of accounts owned by individuals and/or legal entities of foreign countries in accordance with the General Accountability Standard;
 2. Issuance limits on Financial Transactions of Legal Entities and Individuals performed in the territory of the Republic of Azerbaijan to competent authorities of these countries;
 3. Procedure for providing information on financial transactions carried out by individuals and legal entities of foreign countries from financial institutions to the Ministry of Taxes of the Republic of Azerbaijan;
 4. Procedure for providing information on transactions carried out by individuals and legal entities of foreign states in the territory of the Republic of Azerbaijan from the Ministry of Taxes of the Republic of Azerbaijan to competent authorities of those parties;
 5. List of financial institutions of the Republic of Azerbaijan that do not report;
 6. List of accounts that are not reported from.
- Amendments to the Resolution of Cabinet of Ministers of the Republic of Azerbaijan on Terms of business trip expenses***
- According to the Amendments, the 1 day norm of business trip expenses in the territory of the Republic of Azerbaijan has been increased and determined in the following amounts:
- In Baku - 90 AZN;
 - In Ganja, Sumgayit and Nakhchivan - 70 AZN;
 - In other subordinate cities, regional centres, urban-type settlements and villages - 65 AZN.

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PwC Azerbaijan's 2nd Annual CEO Survey was presented at AmCham Members` June Luncheon

On 22 June 2018, Aysel Suleymanova, Marketing and Communications Leader of PwC Azerbaijan presented the key findings of the 2nd Annual CEO Survey in Azerbaijan to AmCham Azerbaijan business community. She shared the insights on mega-trends, including the growth rates of the world economy, increase of profitability, business, economic, political, social threats, along with the lack of trust in business.

The Azerbaijan CEO report is part of PwC's Annual Global CEO Survey introduced at the World Economic Forum, in Davos for the past 21 years. The CEOs of 40 private and public companies from all the key industries in Azerbaijan participated in the survey and shared their insights on the economic trends, business issues and opportunities.