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PHARMACEUTICAL INDUSTRY IN UZBEKISTAN: NEW REGULATORY ENVIRONMENT

LEGAL HIGHLIGHT

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02 January 2017

For the last two months, the Government of Uzbekistan has adopted a number of new legislative acts that have significantly amended the regulatory environment of the pharmaceutical business in Uzbekistan. The overall intention of the Uzbek Government is to stimulate local production of pharmaceuticals by providing local producers with a more favorable tax, customs and sales regime as well as to ensure the population of Uzbekistan has access to affordable pharmaceuticals.

LAW "ON STATE YOUTH POLICY" NO. ZRU – 406 DATED SEPTEMBER 14, 2016

The Minister of Public Health of Uzbekistan issued an order No.2118-2 dated September 23, 2016 on amendment of the Regulation on prescription of pharmaceuticals.

According to these changes, when prescribing pharmaceuticals attending medical doctors have to fill in prescriptions by indicating only the international nonproprietary names (INN) of pharmaceuticals without using their branded names. The exception is made for complex pharmaceuticals that have more than one INN as part of their composition.

Additionally, pharmacies are now recommended to offer patients pharmaceuticals of local production prior to offering medicaments of foreign production for the purpose of supporting local producers. Along with the Presidential Decree No. 2647 (below) instructing the Ministry of Public Health to revise and amend diagnosis and treatment standards as well as clinical guidelines so that to provide for the primarily use of pharmaceuticals of local production, this recommendation clearly signals that the Government of Uzbekistan will actively support local producers.

The changes adopted by the Ministerial Order shall enter into force on December 26, 2016. Yet, it will be required to monitor the practical implementation of these changes as well as to see how discrimination claims will be tested in courts.

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Pharmacies are now recommended to offer patients pharmaceuticals of local production prior to offering medicaments of foreign production

Regulation on procedure for prescription of pharmaceuticals and acceptance, storage and usage of pharmaceuticals of patients in medical and preventive treatment facilities as well as sale of pharmaceuticals to the population based prescriptions by pharmacies No.2118 dated June 29, 2010

PRICE FIXING AND MAXIMUM TRADE MARK-UP

Presidential Decree No.ПП-2647 dated October 31, 2016 sets new maximum trade mark-ups applicable for sale of pharmaceuticals. The wholesale mark-up shall not be more than 15% on the purchase price and the retail mark-up shall be not more than 20% on the wholesale price. The mark-ups are applicable without regards to the number of intermediates within the supply chain.

The Decree provides for making the List of Social Significant Pharmaceuticals that will be sold at fixed prices. The prices will be set by the special Republican Commission. Pharmaceuticals of foreign production included in the List will be purchased on tender basis among local wholesale and wholesale and retail trade companies. The tenders shall be conducted by the Ministry of Foreign Economic Relations, Investments and Trade of Uzbekistan.

The new pricing rules will enter into force starting from January 1, 2017.

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Tax and Customs Incentives for Producers of Pharmaceuticals

Presidential Decree No. ПП-2595 dated September 16, 2016 establishes that companies specializing in production of pharmaceuticals – not less than 60% of the overall turn-over – are exempted from the following taxes until January 1, 2021:

- Corporate Income Tax;
- Property Tax;
- Unified Tax Payment;
- Mandatory Payments to the Republican Road Fund.

Moreover, equipment, accessories and spare parts that are not produced in Uzbekistan and are imported for the purpose of implementation of investment projects in the pharmaceutics sphere, the list of which is approved by the Government of Uzbekistan, are exempted from customs payments, excluding the customs clearance payment.

Drug Product Safety Technical Regulations

General Technical Regulations on safety of pharmaceutical products was adopted by the Cabinet of Ministers of Uzbekistan No. 365 dated October 27, 2016. The Technical Regulations bring together all the requirements on safety of the drugs during their development, production, transportation, storage, sale and destruction in one document.

The Regulations also provide detailed description of the packaging and labelling requirements for pharmaceuticals, which have certain deviations from the current requirements.

These Regulations will enter into force on April 30, 2017. Upon entrance into force of the Regulations, all previously adopted policies, standards, and requirements lose their mandatory force and become voluntary.

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