

## Restructurization of Pharmaceutical Industry

27 December 2017

*The previous month brought significant changes into Uzbek pharmaceutical regulations, having re-established some fundamental patterns of the respective market's operation. Aiming to spur development of the local market and to ensure satisfaction of the increasing demand for cheap medicines, the Government tries to optimize the main regulatory rules set for the industry. The key changes are given below with possible implications outlined at the end.*

### **CANCELLATION MANDATORY TENDERS FOR SOCIALLY SIGNIFICANT MEDICINES:**

The Presidential Decree of October 30, 2017, canceled the mandatory tenders for centralised government purchases of socially significant medicines and medical products ("SSM"), the list of which includes more than 300 products.

Previously, in accordance with the Presidential Decree No. 2647 of October 30, 2016, no direct purchases of SSM were permitted. The Ministry of Foreign Economic Relations and Trade held centralised state-run tenders between local and foreign suppliers on one side and local distributors and medical establishment on the other side. The Decree No. 2647 aimed to resolve the problem of high prices for basic medicines designated as "socially significant" and provided that price caps were to be set forth for these tenders based on quarterly analysis of world prices by the specially created Commission for Pricing Controls in the Pharmaceutical Industry (the "Commission"). No clear methodology and procedural rules were, however, put forward and it, for example, remained unclear whether the price caps would apply to medicines' based on international nonproprietary names or trade names.

In July 2017, the Government, being informed of delays in supplies of certain SSM and inefficiencies in the tender procedure, entitled the state owned enterprise "Uzmedexport" to import SSM based on direct agreements with suppliers without participating in tenders.

Nevertheless, from November 1, 2017, all private domestic companies were allowed to conclude direct import contracts for purchase of SSM without the state being directly involved. With that, relevant price caps are still being set and the direct import contracts may not provide for higher prices. It was, however, resolved by the other Presidential Decree, which is described below, that the Commission would be liquidated and the Ministry of Healthcare would become the price-setter. Moreover, state-owned "Uzmedexport" was reorganized into "Uzbekimpex" under the newly established Agency for Development of the Pharmaceutical Industry and is now only responsible for procuring SSM to state medical establishments as well as organization of tender trades for purchasing medical equipment for state needs.

\* Presidential Decree No. УП-5216 dated 30.10.2017

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## CHANGE OF THE REGULATOR:

Under the Presidential Decree of November 7, 2017, the State Concern “UzPharmSanoat” (being a state-owned holding company with monitoring powers, hereinafter the “Concern”) was proposed to be liquidated with the abovementioned Agency for Development of the Pharmaceutical Industry being created as a semi-independent subdivision of the Ministry of Healthcare (the “Agency”). It was revealed that the Concern was highly inefficient and the state-owned companies under its umbrella were barely able to fill the local market with locally produced medicines (19% of all the enterprises do not function at all and 30% are engaged only in packaging, whereas only 1,3% of all the medicines registered within the country are being produced by the Concern's group). Functions of the Concern for monitoring the industry, overseeing state owned enterprises and coordinating major investment projects will be transferred to the Agency. The Agency will also become responsible for registration of medicines and medical products, centralised purchases of medicines for state medical establishments (through “Uzmedimpex”), development of quality standards for medicines and medical products and creation of a chain of pharmacies selling SSM

With the establishment of the Agency, the State Center for Expertise and Standardization of Medicines, Medical Devices and Medical Equipment under the Ministry of Healthcare, being mainly responsible for registration of medical products, along with a number of research centers is re-assigned to the Agency. The State Commission for Supplying Medicines to State Medical Establishments is, in turn, liquidated and oversight functions are transferred to the Ministry of Healthcare. The internal structure of the Ministry of Healthcare is going to be reconsidered.

Moreover, new regulations for registration and certification of medicines and medical products along with regulations on determination of price caps for SSM are going to be prepared owing to the changes in regulatory oversight.

It is to note that the Ministry of Healthcare plans to establish the chain of social pharmacies, where SSM will be uninterruptedly offered

\* Presidential Decree No. УП-5229 dated 07.11.2017

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In summary, the introduced changes seem to be positive. Obscure and ambiguous regulations on SSM, adopted in explicit haste, significantly shaken the Uzbek pharmaceutical market, where foreign producers are the main players. It was unclear how price caps were to be determined and what procedural rules would govern the tender trades. It was clear that producers of original products would not be able to compete with producers of generic products, if low price caps were set at the trades. It is now clear that oversight costs are too high, and separate subsidization of SSM supplies through Uzmedimpex is a much more viable option. However, the issue of price caps remains to be problematical and unresolved and it is the actual practice of price setting that will reveal pros and cons.

The liquidation of “UzPharmSanoat” is also of a positive nature. Neither an independent state-owned enterprise nor a governmental authority, the Concern was hardly an effective governing structure. The unification of functions under the banners of the single Agency is to be welcomed, as the Agency may be considered as a one-stop shop for investors, both local and foreign, interested in entering the market. With that, however, drastic changes in the industry, shaking its foundations, need to be systematized and quickly digested with new transparent rules being quickly presented to market players.