KOSTA LEGAL

NEW LEGISLATION IN PHARMACEUTICS: DECEMBER 2019

Dear Clients and Partners,

This legal alert highlights the most important legal developments of December 2019 that affect the Uzbek pharmaceutical industry as a whole and activities of foreign pharmaceutical producers and their representative offices in Uzbekistan in particular.

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1. CUSTOMS BENEFITS IN RESPECT OF PARTICULAR MEDICAL PRODUCTS

- A list of imported medical equipment/goods that are exempted from custom duties until January 1, 2022, has been adopted, as it had been envisaged by the Presidential Decree No. UP-5707 of April 10, 2019. The items included in the list are medical equipment and medical goods that are not produced in Uzbekistan and are used for (i) the maintenance of laboratory animals, (ii) the preclinical research, (iii) the production of medicines (including the intra-pharmacy production), medical products and packaging materials, (iv) the equipping of laboratories and pharmaceutical premises. For the full list of items including 1982 categories, please follow the following link.
- It is the following entities who may rely on the exemption: (i) pharmaceutical manufacturers, (ii) specialized research institutes and higher educational institutions importing the above items for their own

pharmacy production.
- It is provided that state authorities will maintain strict control over effective utilization of the above items for the permitted purposes. Importers who violate the regime will be requested to pay unpaid customs duties and will be fined.

Resolution of the Cabinet of Ministers No. 1008 of December 17, 2019

2. OVER-THE-COUNTER MEDICINES

- Given that the List of over-the-counter drugs shall be renewed at least once a year, last year's list has been replaced by the renewed one. As a result, all the medicines that have not been inscribed on the renewed list are now regarded as prescription medicines. As for the monotherapies, all of them remain on the list with 4 new items being added. However, the number of complex medicines has been decreased by more than 45 items.

Order of the Minister of Healthcare No. 3200 of December 6, 2019

3. FURTHER REFORMS IN THE PHARMACEUTICAL INDUSTRY

A Presidential Decree that envisages the implementation of a number of reforms in the pharmaceutical sector has been signed. According to the Decree, the following developments will, among other things, take place in the near future:

- Starting from July 2020, a system of **reference pricing** in respect of foreign and domestic medicines will be introduced in order to eliminate the overpricing. This implies (i) the setting of price limits for importers and local manufacturers based on relevant prices in chosen reference countries, (ii) constant control and monitoring of prices in the sector by the Agency for the Development of the Pharmaceutical Industry under the Ministry for Healthcare;
- as of July 2020, an institution of a **"secret customer"** will be created to detect violators of the pricing and prescription medicines sale regimes within the pharmaceuticals market;
- the ***Concept for Development of the Pharmaceutical Industry in 2020 – 2024*** has been approved that envisages that (i) projects for the localization of the production of medicines and medical products will be

will be improved, (iii) staged implementation of the requirements for good practices in the industry (GxP) will take place with regard to, in particular, the manufacturing of medicines (GMP), the pharmacovigilance (GVP), the distribution (GDP), and the nonclinical and clinical testing (GLP and GCP);
- It is provided by the Decree that by July 2020, the Cabinet of Ministers will have to develop and submit to the Oliy Majlis draft Laws (i) providing for the setting of an administrative and criminal liability for medical professionals and other individuals infringing the rules for prescribing prescription medicines and (ii) amending and supplementing the Law on the Protection of Citizens' Health for setting a prohibition for medical professionals on receiving financial remuneration or other non-financial benefits from pharmaceutical companies or pharmacies for the prescription of particular medicines.

Presidential Decree No. PP – 4554 of December 30, 2019

4. A REVISED VERSION OF THE TAX CODE

A revised version of the Tax Code has been adopted. A number of notable novelties have been introduced. Some of the most significant changes include:

- cancellation of previously granted benefits – as a number of special benefits and privileges have been abolished, (i) all the tax benefits of the old version of the Tax Code that have not been transferred to the revised version will remain effective till April 2020; (ii) all the tax benefits set in subordinate legal acts (e.g. Presidential Decrees or Resolutions of the Cabinet of Ministers) will remain in force till the date stipulated in the corresponding acts;
- the VAT and the excise tax – turnover of legal entities resulting from the sale of goods (services) purchased for the funds borrowed from foreign/international state financial institutions will not be subject to the VAT and the exercise tax;
- corporate governance – starting from January 2023, individuals or entities holding more than 25% of foreign company's shares (currently, more than 50%) will be regarded as persons in control of a foreign company;
- return of overcharged tax amounts – a mechanism that ensures timely return of excessively charged tax amounts has been introduced, including the obligation of the tax authorities to pay the interest on unreasonably retained amounts;

- new risk analysis tools – all business entities will be divided into 3 categories based on their past tax payment records: entities with a low-risk of non-compliance (no tax inspections will be conducted), with a medium-risk of non-compliance (a desk audit will be conducted, but no financial or administrative fines will be applied, while such entities will be allowed to correct their tax returns), and entities with a high-risk of non-compliance (an on-site audit will be conducted and constant monitoring of compliance will be maintained by the tax authorities);
- some new rules in respect of the status of a permanent establishment;
- tax free shopping – a VAT refund will be offered to foreign individuals who have acquired goods in Uzbekistan.

Tax Code of the Republic of Uzbekistan of December 30, 2019
Law No. ZRU-599 of December 30, 2019

5. ELECTRONIC SYSTEMS IN EMPLOYMENT RELATIONS

- As was previously mentioned in our newsletter, in January 2020, the Government will launch the electronic system "Single National Labor System" (SNLS) for administering employment relationships. The corresponding *Regulation* on the procedure for the registration of employment documentation in the SNLS has been adopted. In accordance with the Regulation, the registration is to be carried out by employers through their personal accounts on a specialized website with the use of their electronic digital signatures. Employers – expect for sole entrepreneurs – must assign a responsible person(s) (by taking the relevant decision in writing) who will have access to the SNLS and will register relevant documents and information.

The following information is supposed to be contained in the SNLS:

- the structure of an entity and relevant distribution of workplaces – all employers must upload information pertaining to their offices and relevant job positions to their personal accounts. The information on vacant job positions (i.e. positions with no matching employment contracts being registered) may be made public by the Ministry of Employment and Labor Relations after a waiting period of 5 days;
- electronic employment contracts, including amendments and additions to them as well as the information about terminations and vacation periods;

in so called “labour books” of employees. Now, labour books will seize to exist in their hard copy and will be maintained electronically. Employers will no longer be required to keep records of experience for employees, as such information will be stored automatically, based on the data entered into SNLS.

Resolution of the Cabinet of Ministers No. 971 of December 5, 2019

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