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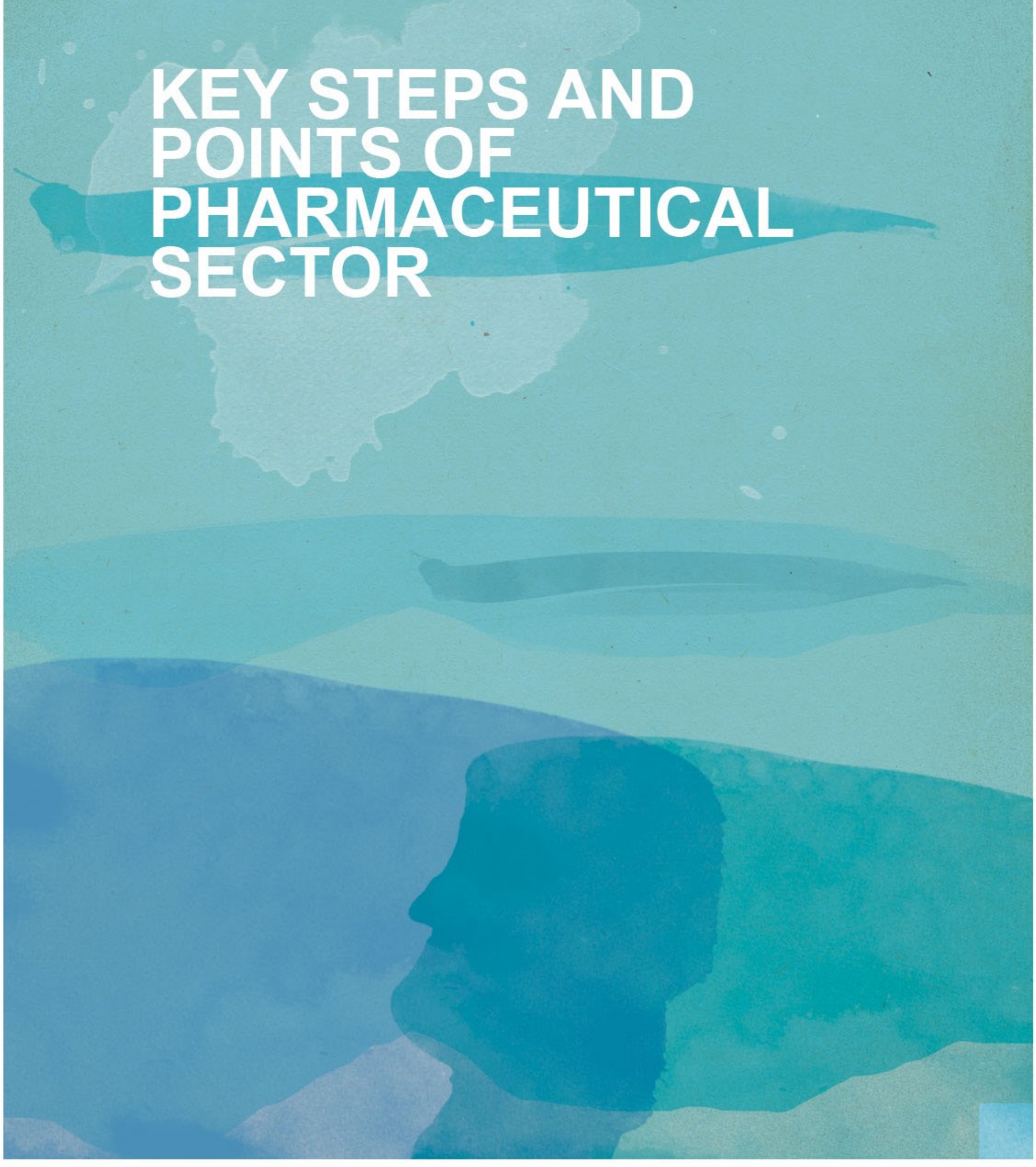
KEY STEPS AND POINTS OF PHARMACEUTICAL SECTOR



Below is a brief overview of the key issues in pharmaceutical sector in the following countries: Georgia, Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan.

This paper is provided as a general information service. Due to the constantly evolving laws and regulations in the jurisdictions mentioned above readers should not rely on the content of this paper without first seeking professional legal advice.

Licensing

Pharmaceutical activity is subject to licensing in all countries stated above but Georgia. In such countries as Kyrgyzstan, Tajikistan and Uzbekistan the license is issued for 5 years. In Kazakhstan the license is general and is valid for unlimited period of time; however, it is subject to periodical confirmation of the qualification requirements. The timeline to review the documents and make a decision on issuance/non-issuance of the license in Kazakhstan and Uzbekistan is around 30 business days, in Kyrgyzstan, and Tajikistan 30 calendar days. A lengthy licensing procedure in Georgia has been changed in August 2009 to a simple notification with the exception for authorized pharmacies.

Registration

Pharmaceuticals

All pharmaceutical products prior to its manufacture and distribution in the countries under the question shall be registered.

In Kyrgyzstan, Kazakhstan, Uzbekistan and Tajikistan pharmaceuticals are registered with the state register.

An applicant obtains a registration certificate upon review and approval of the required documents. Package of the documents varies depending on the jurisdiction. Registration certificate in Uzbekistan and Kyrgyzstan is valid for 5 years, in Kazakhstan for 3-5 years with possible subsequent re-registration.

Along with the general registration procedure Kyrgyzstan legislation envisages a simplified registration procedure. An applicant may apply to the simplified procedure if a generic drug, subject to registration, is equivalent to its registered original/branded one.

Georgian legislation provides for two ways of registration through recognition regime, and through national regime. Pharmaceuticals recognized and admitted to respective markets by the authorized agency of other countries or certain interstates fall under the state registration through recognition regime. All other pharmaceuticals go through national regime. The circulation of pharmaceuticals is allowed within 5 years from the registration date.

Medical devices

Medical devices are subject to registration as well as pharmaceuticals in Kyrgyzstan, Kazakhstan, Uzbekistan and Tajikistan. As a rule, among the documents submitted for registration there are GMP and/or ISO certificates, registration certificates issued in the country of the manufacturer, etc. The issuance of the registration certificate is a confirmation of registration. The validity term of the certificate in Tajikistan and Kyrgyzstan is 5 years, in Kazakhstan 3-5 years.

Currently in Georgia medical devices/equipment do not require registration.

Certification

Pharmaceuticals and/or medical devices should undergo a certification procedure prior to their distribution in Uzbekistan and Tajikistan. Such certificate is awarded by the authorized agency to the manufacturer. It demonstrates that a conformity assessment procedure has been adequately applied to the pharmaceutical/device and that such pharmaceutical/device complies with the state requirements.

Kyrgyzstan has replaced a certification procedure by a technical regulation procedure in accordance with the World Trade Organization requirements.

Certification procedure of pharmaceuticals and medical devices in Kazakhstan has been changed to safety and quality evaluation procedure from July 2012.

Import

It should be noted that Kazakhstan is a member of the Customs Union. Currently the members work to harmonize the legislation of the Customs Union. Until such harmonization the import of pharmaceuticals in Kazakhstan is subject to licensing. The term of the license shall not exceed one year from the date of issuance.

To import pharmaceuticals into Tajikistan a permit of the authorized agency shall be obtained. The agency issues two types of permits: general and one-time. General permit is issued for 1 calendar year and one-time permit - for 3 months.

Import into Uzbekistan is allowed only with a conformity assessment certificate. Such certificate is issued for products of one type or a group of similar products, and applies to the entire consignment of goods imported into the territory of Uzbekistan.

To import into Kyrgyzstan a license for pharmaceutical activity or permit of the authorized agency is required. Foreign pharmaceutical manufactures and wholesale distributors are entitled to import pharmaceuticals under the condition that they have representative offices within Kyrgyzstan.

As for Georgia there are no specific licensing procedures other than notification and the drug registration regulation.

After the admission of pharmaceuticals to Georgian market for the first time import of the same pharmaceuticals with different packaging and marking Georgian legislation envisages simple notification process rather than another registration/approval process. In this case with the notification the importer submits with the respective agency the required documentation demonstrating authorization and approval of the provider, the product, and its packaging and marking under the laws of the source country. Within 5 working days, the authorized body is obliged to accept the parallel import notification and add it to the registry, or otherwise notify the importer of a refusal and grounds for refusal.

Taxation

In Kazakhstan import of pharmaceuticals and medical devices is not levied with VAT. Moreover, currently there are no import taxes on pharmaceuticals. However it is expected that such taxes will be gradually increased starting from 2013 in accordance with the regulations of the Custom Union.

According to the Tax Code of Uzbekistan there is no VAT on pharmaceuticals, medical devices and drug raw material. However, imported pharmaceuticals which are also produced in Uzbekistan according to the list approved by the respective authority are levied with VAT.

There are no import tax and VAT on pharmaceuticals and medical devices in Georgia. In addition, there is no VAT charge to a consumer neither when purchasing pharmaceuticals, nor to companies purchasing pharmaceuticals for resale (e.g., pharmaceutical retailers do not have to pay VAT to pharmaceutical distributors). It was adopted as a policy in order to achieve better prices for customers.

Supplies of the prosthetic & orthopedic products, specialized products for the disabled in accordance with the list determined by the Government of the Kyrgyz Republic including their repairs as well as supplies of pharmaceuticals are exempt from VAT.

The supply of drugs, medical equipment and instruments included in the list defined by the Government of Tajikistan is VAT exempt.

Pricing

There is no price regulation policy related to pharmaceuticals in Georgia, Kyrgyzstan, Tajikistan, Kazakhstan and Uzbekistan.

However, it is worth to note that the Kazakh government signed the Memorandum on price regulation which includes 200 pharmaceuticals. This was done to support low-income people and make essential pharmaceuticals available.

The Government of Uzbekistan has also approved the list of 20 pharmaceuticals that are to be sold at maximum retail prices.

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Colibri Law Firm is available for inquiries on any aspect of or in connection with this article. We remain hopeful this article would provide a useful backdrop for any related references. However, we caution that this article is not intended as a specific advice with respect to a particular deal.