Amendments in Kazakhstan's medicinal products registration system: new hope for rights holders

DENTONS

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In January and June 2015 Kazakhstan's legislation was amended in order to protect the interests of developers of new pharmaceuticals and equipment used in healthcare.

Previously, the registration system for medicinal products, medical accessories and medical devices did not provide for the review of the products filed for registration for the presence of protected intellectual property rights. This meant that access to the market for products that violate the rights of patent holders was not adequately prevented. In patent disputes, arguments for permitting the introduction of a medicinal product into circulation in Kazakhstan often prevailed over the protection of the rights to the invention contained in a product.

This issue has been actively discussed for the last 12 months by pharmaceutical companies-developers of new substances and equipment.

As a result of discussions between medical companies and state authorities, the Ministry of Healthcare and Social Development of the Republic of Kazakhstan (hereinafter the "**RK MH**") has attempted to solve the problem of access to market of products containing protected inventions of third parties.

Rules on State Registration, Reregistration and Amending the Registration Dossier of Medicinal Products, Medical Accessories and Medical Devices 2009 (hereinafter the "**Registration Rules**") were amended by adding an option to issue a registration certificate for medical products without the right to sell. Medicinal products containing substances protected in the RK may be registered (by a person other than the patent holder) during a patent's validity period, however the sale of those products is possible only after the patent has expired. Currently this option is provided merely for pharmaceuticals.

At the moment there is the principal opportunity to introduce a ban on sale of a product until the expiration of the patent. However, further work to improve the Registration Rules is necessary. The procedure that precedes issuance of registration certificates without the right to sell the product was not thought out and not included in the Registration Rules. The range of products for which a registration certificate may be issued without the right to sell is unreasonably limited – at present these do not include medical accessories and medical devices.

Dentons prepared a draft law introducing amendments in to the Registration Rules as well as to number related by laws. The aim of the amendments is to establish a clear and simple procedure which effectively prevents access to the market for products containing protected inventions in the RK. The draft amendments were submitted to the RK MH and to the RK Ministry of Justice. Detailed discussion of the project with these state authorities is planned for October-November 2015. Active participation of pharmaceutical companies in these discussions will increase the chance of further improvement in the processes of issue of registration certificates for medicinal products without right to sell.

In order to review the draft amendments into the Registration Rules, please contact our associate Nataliya Shapovalova, telephone: +7 727 2582380.

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