

HEALTHCARE & LIFE SCIENCES REVIEW



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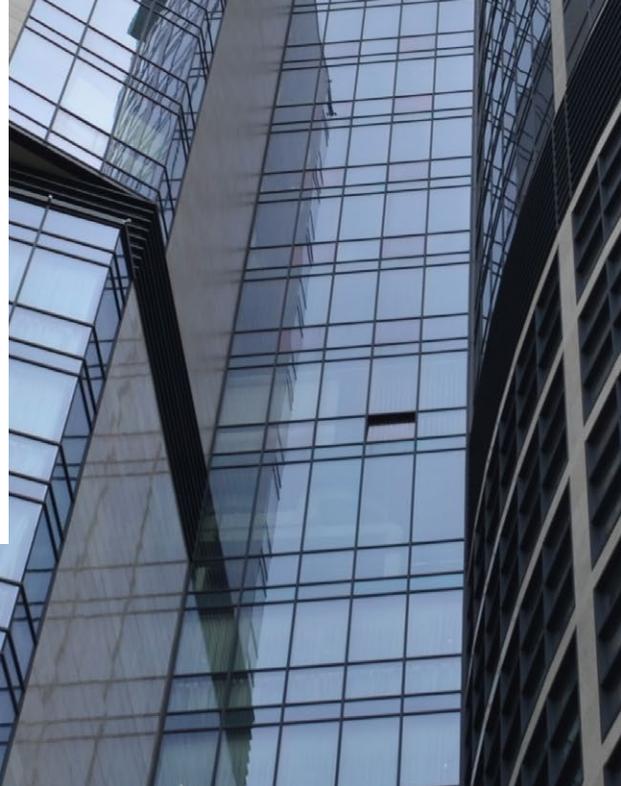
UKRAINE

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A SHIFTING LANDSCAPE

Alexey Starodubov, business partner at leading Ukrainian law firm, Sayenko Kharenko, and founder of UADirect, the go-to partner for international and local companies looking to do business in Ukraine, discusses the potential impact of proposed medical reforms and the growing importance of strategic alliances between foreign and national pharmaceutical manufacturers.



The Ukrainian pharmaceutical market has traditionally been considered one of the most developed in the entire post-Soviet space. This positive assessment is based on a number of factors including the existence of large pharmaceutical production facilities in Ukraine, a good educational background and, as a consequence, qualified personnel involved in the pharmaceutical industry. The size of the Ukrainian pharmaceutical market as of 2013 exceeded USD 3.2 billion. However, the situation on the market is undergoing changes.

Proposed medical reforms, recently announced by the government of Ukraine, have caused a storm of indignation among national pharmaceutical manufacturers. First of all, this concerns the re-registration of pharmaceutical

products previously authorized by the Ukrainian regulator in accordance with European requirements. Such “know-how” is justified by the Ministry of Health of Ukraine (MHU) by the need to harmonize the two systems - Ukrainian and European. This argument has a dual nature. On the one hand, indeed, Ukraine has signed an Association Agreement with the EU and harmonization is a part of the country’s planned European integration. On the other hand, the association agreement does not provide for a rigid period for harmonization, and in the absence of a clear understanding of Ukraine’s future EU membership perspectives, it is quite difficult to see the above-mentioned “know-how” as a priority goal.

The MHU’s argument regarding the need for the re-registration of pharmaceutical products for national manufacturer is also quite

questionable. Following the MHU’s logic, this will allow Ukrainian companies to enter Western markets without impediment and thereby increase the export of their products. This argument does not hold water as it directly concerns the strategic planning of



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pharmaceutical companies. Most Ukrainian companies in this sector do not strive to enter highly competitive Western markets.

Nevertheless, we have what we have. The need to re-register pharmaceutical products significantly weakens the position of national pharmaceutical manufacturers in the pharmaceutical market. At the same time, the introduction of so-called simplified registration procedures for imported pharmaceutical products creates favourable conditions for the expansion of foreign manufacturers of pharmaceutical products in Ukraine. This simplified procedure entitles manufacturers of the pharmaceutical products certified in other countries to import and sell their pharmaceutical products in Ukraine. Within the simplified procedure, registration data is verified with the country of origin of the pharmaceutical product. Prior to the introduction of this simplified procedure, the process of Ukrainian registration took approximately two years.

These changes create permanent confrontation between national pharmaceutical manufacturers on the one hand and the MHU and foreign producers on the other. Inability to find a compromise in this confrontation leads to serious weakening of the pharmaceutical market.

The current situation on the market of pharmaceutical products in Ukraine creates certain economic and social effects. In particular, the increase in imported pharmaceutical products to Ukraine negatively affects the country's economy, and creates grounds for various antitrust investigations regarding fair competition in the pharmaceutical market.

At the same time, it is assumed that the introduction of a simplified procedure for the import and sale of pharmaceutical products on the territory of Ukraine will significantly reduce the prices for imported pharmaceutical products and will allow foreign pharmaceutical products to enter the Ukrainian market. This, in its turn, can positively affect the health of Ukrainian citizens.

Moreover, the current situation in the pharmaceutical market creates fertile ground for the establishment of strategic alliances of foreign and national pharmaceutical manufacturers. In other words, the weakening of national manufacturers may result in mergers of national pharmaceutical manufacturers with their foreign competitors. This, in turn, can reduce the import of pharmaceutical products into the country, and increase the investment component in the structure of Ukraine's GDP. ❄️

* THIS ARTICLE WAS WRITTEN BY ALEXEY STARODUBOV.