

Hatice Öncel - CEO, Ilko Pharmaceuticals



We are close to having the technological capacity to develop all types of biosimilar products, even some novel ones

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Ilko Pharmaceuticals is a family-owned Turkish generics and biosimilars company. General Manager Hatice Öncel explains the company's investment in biosimilars in collaboration with South Korea's Genexine and how recent success in consumer health has allowed them to overperform the local market with 27 percent growth in 2020. In addition, she discusses the upcoming biosimilars legislation in Turkey, the complications of succeeding in the European market due to low margins, and the opportunities in the CIS and MEA regions.

Can you begin by introducing yourself and Ilko Pharmaceuticals?

I am a chemical engineer by training. [Ilko Pharmaceuticals](#) is a family-owned company and I am a member of the family's second generation, which is currently occupying the company's management board. The Öncel family has been involved with the Turkish pharmaceutical industry for over five decades. We used to operate another company but sold it in 2006 to a venture capital firm and, after a period of non-competition, we reinvested in the sector through Ilko Pharmaceuticals. I am currently a member of the board and serve as the executive management of the company.

How did the re-entry journey to the Turkish pharma market come about and how did the company develop afterwards?

After the mandatory wait of three years, in 2009, we began preparing and invested in a manufacturing plant. In parallel, the priority was to spend in research and development. Our current R&D centre is located in Beytepe Technopark of Hacettepe University in Ankara and the manufacturing plant in Anatolia while the head office is in Istanbul. Finally, in 2015 we invested in a biotech R&D centre near Istanbul.

Ilko Pharmaceuticals began commercial and manufacturing activities in 2012; we applied for an EU GMP certification and began doing export activities at the same time.

Our business strategy since the beginning has been to create a wide portfolio and, after examining the future of the industry, pivoted from a simple-generics-only approach to include differentiated products with advanced technologies such as controlled-release tablets. In 2015, the company opted to make a considerable investment in the biotech field through a joint venture with Genexine, a South Korean company. With them, we are developing biobetter products. To support this investment, Ilko established its own biotech R&D centre through which it will enter clinical development of its pipeline at the end of this year. The rationale behind this investment is that the future of pharma will rely on biological value-added products as the strongest segment.

With the aim of diversifying our portfolio, the company entered the consumer health field with its Wellcare brand. In hindsight, it was the correct decision after the developments we experienced during the pandemic. On top of that, we are gaining market share in the local market and increasing our export activities every year.

We are present in three key diverse areas (value added generics, biotech, and consumer health products) and did it all in less than nine years since starting the company.

During a recent interview, you stated that Ilko Pharmaceuticals grew around 50 percent in 2019 which is significantly higher than the Turkish market average. Did that trend continue in 2020?

There was a steep decline in the market last year; the Turkish market grew by 17 percent last year but, since there was a 20 percent price increase, it decreased slightly in real terms. Fortunately, Ilko managed to grow above the market average again, growing by 27 percent due to our management of the pandemic and the balancing of local losses with exports increase. 2020 was a challenging year, we were forced to revise our targets but succeeded because of our wide portfolio; there was a steep decrease in acute products but chronic and consumer health grew. Talking about

specific therapeutic areas, Ilko is strong in cardiovascular, CNS, rare diseases, HIV-related products, gastroenterology, gynaecology and respiratory.

Ilko appears to be following a trend among Turkish companies that are venturing into biosimilar production and development. What is your strategy to lead that segment going forward considering your big presence in the Turkish market?

We are currently working on the development of biological products and will manufacture them in the future. Unfortunately, the development period of these products is extensive, whether they are new or biosimilars.

For the last five years, we invested in development to gain the know-how that will allow us to compete and win in the segment. Ilko is currently the only company that can develop all the way from the master cell line until the end. While some companies have opted to do manufacturing and provide CMO services with technology transfer, we are the only company that has been focusing on developing the products from the start. I have now confirmed how correct our strategy was because we are close to having the technological capacity to develop all types of biosimilar products, even some novel ones.

How supportive has the Turkish government been in your R&D efforts at a moment when they have emphasized the importance of clinical development to foster a globally competitive industry?

We are currently running one project with the Scientific and Technological Research Council of Turkey (TUBITAK). The council is supporting three projects in the area and ours is one of them; it is a biosimilar program that has been conducive to obtaining R&D know-how.

We have two other products in development; one is a biobetter product being developed with our South Korean partner through and we have sent applications to the Health Institutes of Turkey (TUSEB) for phase III clinical trials. If it succeeds, it will be our first biological product on the market.

For us, the strategy to commercialize the product internationally will be focused on a rapid penetration of regional countries and Europe; the second stage will be an FDA application so we can enter the US market.

The phase III clinical trials are interesting since there is no consensus among the WHO, EMA and US FDA as to whether they are really necessary for all biosimilar products. We expect regulatory changes soon that will help companies develop biosimilar products at a more reasonable cost.

Turkey does not currently have clear guidelines for biosimilar products, but we expect one to be signed soon by the Minister of Health. We expect these guidelines to meet the industry needs because it establishes the different clinical studies needed for different products. It is an opportunity to open the door for the industry, but the guidelines alone are not enough, the industry also requires new governmental policy for the biotech industry including a funding strategy.

With the current challenges around pricing and the currency devaluation in Turkey, what is your strategy to find opportunities in the international markets?

The biotech industry in Turkey is not large enough yet to recover your investment, so we are looking at export markets as well. In fact, 25 percent of our revenue is coming from abroad already, mostly from CIS countries, the Middle East and Africa. We enjoy a competitive advantage since Turkish products are considered high-quality and less expensive than European pharma products. Penetrating the European market for Turkish companies is complex because, while it is stable, the margin is low; you can succeed with certain products such as biosimilars but not as much with generics.

It is true that Turkish companies were slow to invest in biosimilars but, fortunately, we are targeting the products that will lose patent protection after 2026-28 so we can be on a level playing field. To seize the coming opportunities, we are open to collaborations with Big Pharma companies.

Is the necessary know-how available in Turkey in order for the industry to succeed in the future of biologic products?

In the beginning, we had to bring experts from abroad, but we already obtained the knowledge of the core elements and the local talent coming out of the industry and academia should be enough. In general, the country has evolved plenty in the last five years, experiencing rapid progress with the universities, startup companies, manufacturing organizations and the government.

As a member of the family that owns the company, what are your personal ambitions for the company?

The company has short-, mid- and long-term strategies, but my personal mission is to help the company reach at least the mid-term goals so it can be in a good position when the next generation takes charge and eventually becomes a global company.

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