Tuğçe Koç – Board Member, Onko Koçsel, Turkey

By working with experienced American consultants, we created a facility that is fit for European and US markets

26.11.2018

Tags: Turkey, Generics, Onko Koçsel

Tuğçe Koç reveals how Onko Koçsel was able to quickly grow from an in-licenser to a production-oriented pharmaceutical company with an international reach. She also offers her take on how the Turkish healthcare sector could encourage more companies to grow and how existing companies can combat economic fluctuations.

Could you describe to our readership how Onko Koçsel has expanded in the past three years?

At first, our company was primarily focused on original products – at the time, the fields of haematology and oncology were quite new. Universities and research centres did not yet have separate institutes or wings dedicated to these sub-fields. Accordingly, there were only *new* products on the market, and due to the patenting rights of these drugs, Onko Koçsel had to focus on in-licensing these original products from foreign multinationals.

In 2012, the government's strategy changed – when the patents expired, generics became more and more prominent on the Turkish market. After all, the government prefers generic alternatives to oncological and haematological treatments in order to minimize the social security bill. It was when the generics market opened up that Onko Koçsel "saw the light" – we recognized that 96% of oncological drugs were imported to Turkey, straining the government budget. The generics market's opening also happened to coincide with the government's localization policy, so we decided to leverage our expertise in this niche market and open a factory. At first, we considered finding toll manufacturers, until we realized that there were not any facilities capable of producing our oncological portfolio.

Everybody thought we were crazy when we set out on our mission; granted, it was difficult, as we work with cytotoxic products. Nonetheless, we managed, and by working with experienced American consultants, we created a facility that is fit for European and US markets. After the factory opened, we applied for EU GMP status, which we were granted within the year. The auditors did not detect *any* significant flaws in what they found, and we were the only Turkish facility to be awarded certification for its entire production line.

Does Onko Koçsel use its factory only for company-specific production, or does it sub-contract as well?

We are involved in contract-manufacturing as well. When we built the facility, we purposefully included more production capacity than we needed. As I mentioned, we knew first hand that there were not any toll manufacturers available for complex oncological drugs in Turkey, as we had searched for them ourselves. We figured that other companies may have been searching, too, and we were right – now we produce for many multinational companies.

Onko Koçsel is on the verge of acquiring many new, lucrative partnerships. We recognized that the economic situation in Turkey has led to unfavourable outcomes for multinationals; the Lira lost much of its value, the exchange rate causes problems, and companies are losing money. In order to balance the market, we decided that we would turn this economic fluctuation into an opportunity and grow our export business. Now, as you know, one cannot simply export pharmaceutical products at will. Companies have to undergo a lengthy registration process. Nonetheless, Onko Koçsel has made headway – we already export to Malaysia, Bulgaria (from which we file our European dossiers for registration), North Africa, the United Kingdom, Italy, and Spain. We have plans to increase our scope in Europe and, subsequently, the United States. Within the year, we aim to apply for our FDA certification.

At Onko Koçsel, we are proud to contribute positively to the Turkish economy as we continue on our path to internationalization. Companies like Onko Koçsel are helping to reduce the pharmaceutical deficit in Turkey and help the broader economy with our highly valuable products (which add USD 29 in value per kilogram exported while the current export value of the Country is around 1,5 USD/kg). With our continuous in-house and outsourced training both in Turkey and

Germany as all our machinery and systems are from there, we generate highly qualified employment.

How have the Turkish pricing and localization regulations helped/hurt Onko Koçsel in its expansion?

The localization process has helped us immensely. When companies want to introduce two or three new lines to the Turkish market, they do not want to have to build a brand new factory in order to comply with the localization policy – instead, they come to us. As our machines all come from Germany and our facilities are incredibly high-tech and having EU-GMP approved lines, we are the clear partner of choice.

Regarding the pricing strategy, our bottom-line for domestic sales has also been hurt by the low fixed exchange rate and the current Lira devaluation. But, we have turned to our exports to balance our revenues. The Lira’s devaluation has actually helped us in this regard, as we are cost-competitive in the international arena.

What more can be done to encourage the Turkish pharmaceutical export sector?

The government has so far been very helpful as we have entered export markets. They granted us a special strategic incentive package that gives Onko Koçsel certain tax exemptions for ten years while we establish an international presence – we are the only company in the pharmaceutical industry to receive such strategic investment incentive program. In this way, the government has been instrumental in encouraging our growth.

To return to your question, establishing a world-class facility can be called an important entity to start the export business studies. After determining the territorial strategy, launching a pharmaceutical product in the international market has some significant costs for the companies including the clinical studies to be done specifically for the Territory, facility approval by the health agency of the related country, registration procedures etc.. It is not easy for the companies to undertake these costs. Some noteworthy incentives will surely improve and accelerate the rate of registration outside of Turkey, so the export value of the Country.

What are some of the trends that you have noticed shaping the global oncological pharmaceutical market, more broadly?

Oncology is becoming increasingly important – it is the largest treatment area in the healthcare world and is poised to remain so. As the global population ages, oncological drugs will become more highly demanded and economically important. Furthermore, the pharmaceutical industry is highly political. Politicians focus on the healthcare sector more and more during their campaigns, and pharma companies have a direct impact on state-run healthcare networks. Accordingly, I think that it is crucial for Turkey to continue strengthening its domestic pharmaceutical industry. We are a proud country and it would benefit us to have multinational pharmaceutical companies headquartered in Turkey.

Can you highlight Onko Koçsel's R&D activity to our international audience?

Onko Koçsel has a state-of-the-art R&D centre. Our centre is unique because it is GMP certified – we aspire to produce orphan drugs in this laboratory and commercialize them immediately. Orphan drug production is tremendously expensive, as it is done in small quantities and necessarily entails foregoing other production in the meantime, creating opportunity costs. Thankfully, our GMP-certified laboratory prevents such opportunity costs and allows us to take orphan drugs to market immediately.

Furthermore, in our special cytotoxic laboratory in the R&D centre, we are creating quality generics and new products. At the moment, we are focused on producing new drugs that combine popularly used chemical formulas in order to reduce side effects and increase the quality of life of our patients. We have filed several domestic and international patents for our new products.

Lastly, we engage in technology transfers and we sell dossiers. In our R&D centre, we are very flexible. Having grown up in pharmaceutical laboratories, I can truly say that we have built something incredible. We have top-of-the-line isolators that augment the quality of our products and the safety of our employees.

How has Onko Koçsel's product portfolio developed since 2015?

We currently have 90 molecular products in our portfolio, and we have 25 products in our R&D pipeline. Concerning our growth strategy, we have a very aggressive approach at Onko Koçsel – we are expanding our portfolio much faster than the average pharmaceutical company.

Why is Onko Koçsel the partner of choice in the Turkish market?

Our beginnings as an in-licenser helped us build an excellent rapport with companies from all areas of the world – accordingly, we are comfortable working with partners from any country and we can ensure them the highest quality. We believe in win-win situations, and we are very flexible.

When we start a business collaboration with a company for any kind of work, in somehow, it turns to a partnership like study and we start strengthen our relationship by adding new different business collaborations. So, a cooperation starting with licensing in a product turns to a stronger cooperation by giving cmo service to them or licensing out our products. I think, seeing our collaborator as a partner and offering a mixture of work is very valuable as we always try to add value to our relationship with them.

When we return in 2023, where will we find you and Onko Koçsel?

Hopefully, you will find us in the United States, for starters. Onko Koçsel has a promising ten-year plan; I always say to my employees that we have planted the seeds for success. Soon, we will flourish.

What would be your advice to a young girl that wants to achieve success as a pharmaceutical executive?

I would stress that you must be eager to learn. I am hungry to learn each and every day, and I am not ashamed of learning something from my employees. You need to be open to being taught new things, especially in the pharma industry. Secondly, as my father taught my sister and me when we were young, you must be responsible. And lastly, you must have dreams to follow. Only then can you find success.

See more interviews