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Amgen, the American biotech giant, established a direct presence in Turkey in 2010 by acquiring a local generics manufacturer for US 700 million. Its general manager in the country, Gülîdem Berkman, explains why their Turkish operations and business model differs from all other affiliates with the exception of Brazil, provides a reflection on the 20-year transformation of the Turkish pharma industry as a way to understand its current struggles, and highlights Amgenâ??s early-phase clinical studies in the country.

Can you begin by explaining the companyâ??s footprint in Turkey and how your current large presence came about?

Amgen opted to establish a direct presence in Turkey in 2010, before that, the company worked through distributors. In 2012, we acquired Gensenta, with its renewed identity, a 90-year-old Turkish company that specialized in generics, with an investment of USD 700 million. The investment is among the top 10 foreign direct investments across all sectors in the country. After the acquisition, Amgen positioned itself to compete across two pillars: biotechnology and generics. Amgen Turkey is the only affiliate, apart from Brazil, to have such a model. As of today, we have 820 people working in Gensenta and two manufacturing facilities, one for biosimilars fill-and-finish and another for active substance production â?? mainly penicillin and over a dozen small molecules.

Our Gensenta affiliate focuses on four different business segments: the domestic generics business, the export business for Europe and North African countries, contract manufacturing where we produce for South Korea's Celltrion, and API production where our main customer is Pfizer.

The Amgen side is clearer since the company's business is well-known; we have oncology and hematology as one pillar, and general medicine as the other. In total, we have 185 people working in the Amgen business and have launched almost all therapies from the company's global portfolio.

Globally, the company's revenue grew in 2020 both in the US and internationally. How did Turkey perform?

Despite COVID-19, Amgen performed at a great level, growing by double digits. Also, the Gensenta business outperformed our internal budget targets with double digit growth. 2020 was a successful year for our Turkey organization.

Our products create real value for patients, saving lives or radically improving their quality of life, but they need to be available for them. Fortunately, the Turkish public healthcare system covers around 95 percent of the population, which is a high number by any international standard. The products can be prescribed multiple times, as long as patients need them.

There are three keys for a healthcare management system: quality, access, and quantity. The only area where Turkey is lagging is the time it takes for innovative products to be available. There is a 4-year gap between access times in European and Turkish.

How important is your biosimilar business in Turkey, considering the significant investment by Amgen and local companies in recent years?

Many companies have interpreted biosimilars as a production opportunity. Around 19 companies have invested in biosimilar production in Turkey, but the total volume is limited; companies must export to global markets. We are proud to have one of the most well-established facilities for such activity, producing for almost 80 countries.

Volume is key in biosimilar production, but you also need the know-how because it is more complex than traditional manufacturing. We are lucky to have Amgen's quality, portfolio and engineering capabilities. The plan is to introduce all our biosimilars in this market.

Many of your counterparts at other companies in Turkey have discussed the lack of a comprehensive regulatory framework for biosimilars. Do you share that view?

First, biosimilars are much more sophisticated products than traditional generics. Since they are biologic products, they require significant follow up to ensure the right quality, clinical efficacy and safety. For that reason, we are in favor of the European biosimilar evaluation as a model for Turkey, which currently has no specific regulation.

For Turkish authorities to follow the European model, companies must be involved in the process through collaboration. Amgen recently announced a collaboration with TUBITAK

(Scientific and Technological Research Council of Turkey) to develop a biologic product. Can you tell us more about that project?

The program started because, while we have significant R&D capabilities in our production facilities, currently working on small molecules, we decided to go further and work on biotechnology products as well. Amgen is working with two institutions, Ä°zmir Institute of Technology and TUBITAK, to develop biotechnology products together, one will be a biosimilar and the other a new product. Our objective is to develop our local R&D capabilities, lifting Turkey's along the way. Both projects are related to oncology.

That must be a challenge for Amgen if we consider the company's pipeline which has 11 assets in phase III clinical trials. How are you preparing for those launches?

We have around 15 new products coming in the oncology and hematology space. To be prepared, the company has invested in several clinical studies in Turkey, including phase I and II. Turkey is an important clinical studies hub for the organization due to the great capabilities of the centers and efficacy results.

The company's investment is giving healthcare professionals the opportunity to observe the products before they are approved.

After the pandemic, the organization has taken a new approach towards marketing and sales; it is not only more digital, but also a closed loop around one customer. The objective is to understand the customer to provide tailor-made messages instead of mass campaigns, helping us better measure the outcomes. We are changing our utilization of CRM systems to fit these 360 degrees customer activities and the results so far have been positive.

Compared to other countries, companies in Turkey rely heavily on their salesforce. Do you believe that a model less dependent on sales reps can succeed in this market?

Currently, and because of cultural aspects, reps remain very important in Turkey. We need to keep the reps at the center but empower them so that they can interact with customers in different ways other than face-to-face. When the pandemic hit in March 2020, our reps were not allowed to make visits at all. Our salesforce shifted to other methods, and we discovered that it could be a sustainable model; face-to-face visits should not be more than 50 percent of total interactions.

Is there specific data that your salesforce can use related to the effectiveness of your products on oncology patients, for example? Are survival rates better in Turkey?

We do have specific and reliable data about the effectiveness of our products. For example, one of our lung cancer products has proven that it can increase life expectancy by at least one year. All our oncology products are adapted to specific gene mutations and biomarkers, becoming tailor-made for specific patients. I am proud to say that Amgen is a precision medicine trailblazer.

Contrary to some of your colleagues in other Big Pharma companies, you seem optimistic about the future of the Turkish market. Are there any particular metrics that support that view

at a moment when questions have been raised about its sustainability?

After working in this market for 20 years, I can say that it is quite sophisticated. To really appreciate what is going on, we must look back at the evolution of the healthcare system. Before 2009, Turkey focused on coverage increase and prices were not under so much pressure; the objective was to incorporate as many people into the healthcare system as possible. From 2009 to 2012, the government explained that the volume of patients could not be increased if they did not implement price cuts. After those three years of significant price reductions, the volume of people covered by the system was good enough.

Today, the main issue for the industry is the devaluation of the currency. All producers, including local manufacturers, depend on the Euro and US Dollar because 85 percent of the manufacturing cost is related to imported APIs. The challenge we face is the exchange rate adjustment. On top of the fixed rate established by the authorities, the lowest European prices are taken with an additional 41 percent discount. We should work hard to have a different approach to price adjustment. The situation has directly impacted our portfolio and we are having internal discussions about it. Hopefully, the situation will improve in 2022.

What is the position of Amgen's regional management on the pricing situation?

They understand the price fluctuation and the devaluation element. We must wait until February of next year to have a discussion about our long-term plans because we are expecting a proper price adjustment.

With your previous experience in Big Pharma companies in mind, how do you evaluate Amgen's corporate culture?

Diversity and inclusion are something close to my heart. I am proud to be one of the leaders of Amgen's Women Empowerment Program, WE2. We have a regional team that works to improve work-life balance, networking, and opportunities for female leaders. I feel very much supported and appreciated by the company.

This progress has not been made at Amgen alone; I have seen real change across the Turkish pharma industry. Today you can see many female executives leading life sciences organizations; we are very competent and competitive.

Moreover, the attitude from professionals in the country has changed. Five years ago, people were keen to stay in Turkey and develop their careers intrastate but today they are much more open to international opportunities. That is why we are exporting plenty of talent. Before the pandemic, we had 20 people that moved from Turkey to our headquarters in California and other geographies.

You mentioned February 2022 as a moment when the company will evaluate its strategy in Turkey. What are your current expectations for the future?

We have an exciting pipeline of upcoming therapies, and I am looking forward to introducing them to Turkey through early-access programs. The mission of our industry is improving people's lives and I want to make a personal contribution.

As a manager in charge of almost 1,000 people in Turkey, my objective is to foster a positive culture and achieve ambitious objectives. People must be engaged and feel proud of working at Amgen and Gensenta.

Broadly speaking, my background as a chemical engineer helps me understand the importance of biotechnology for the future of our species. I am optimistic about the future because we are only at the beginning of biotechnology.

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