Savas Malkoc – Secretary General, IEIS, Turkey

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The secretary general for Turkey's Pharmaceutical Manufacturers Association (IEIS), Savaş Malkoç, highlights their objective of increasing R&D expenditure and Turkey's big opportunity ahead in biosimilars production. In addition, Malkoç discusses the persisting issues within the country's pricing and reimbursement system and why localization policies have been a net gain for both industry and patients.

Can you begin by explaining your prior experience in the public sector and what motivated you to join the private sector with IEIS?

Before joining IEIS, I worked for the Turkish government for 25 years in different levels and institutions. My main focus areas were economy and foreign trade, where I served as undersecretary for foreign trade, focusing on the directorate for exports. I have a very good relationship with the private sector across different industries including the automotive, textile, healthcare, etc. Prior to my appointment as Secretary-General, I was the director general of the Ministry of Trade.

After over two decades, I decided to join the private sector through one of the oldest associations in Turkey; I am proud to be part of their efforts.

Moving to the association, IEIS recently published its annual report about the pharmaceutical industry. Can you tell us what have been the main findings outlined in the report?

The Turkish pharmaceutical and medicinal products market including medicines, diet food for special medical purposes, traditional plant-based medical products, vitamins and food supplements has grown of 19.9 percent in 2020 in hospitals and pharmacies and reached TRY 52.8 billion. On a unit basis, it has declined of 5 percent and dropped to 2.43 billion units.

On the other hand, the Turkish pharmaceutical market has reached TRY 47.9 billion in hospitals and pharmacies in 2020 with a growth of 17.7 percent on a value basis. On the other hand, because of the pandemic, the Turkish pharma market declined of 7 percent on a unit basis and dropped to 2.2 billion units sold.

As it is well known, the Covid-19 pandemic has deeply affected the pharma industry globally. Likewise, the measures taken against the pandemic as of March 2020 in our country and the changes that happened in the flow of everyday life have had an impact on the pharmaceutical industry just like in other sectors. Many factors such as people staying home as a result of the pandemic, the postponing of treatments and needs as long as these are not urgent, access to public health services and doctors being restricted resulted in a recession of the pharmaceutical industry to levels before 2017 with 2.2 billion units.

During the pandemic, the limitation of access to doctors and hospitals and the circulation via many communication channels of news on the importance of strengthening the immune system has had a big impact on the growth of the market. As a result of these factors, in 2020, the health products market constricted by more than 70 percent.

Another interesting finding was an increase of pharmaceutical exports by 400 million, which is expected to grow another 10 percent this year. What has been driving that growth?

I believe that the domestic price pressure has been driving companies to sell products abroad; that is why medicine exports have consistently increased over the past five years. There is a huge gap between the prices you get abroad for medicines from the ones you get in Turkey because the government uses a special exchange rate. Regardless of that situation, we continue to have a trade deficit in pharmaceutical products but there is a clear upward trend in Turkish pharma

industry exports. I foresee this trend, of companies manufacturing in Turkey for foreign markets, will continue in the next years.

Companies operating in Turkey have strong connections with international organizations, making it easier to sell abroad. The industry exports to almost 177 countries, mostly to the European Union (EU), Middle East and North Africa (MENA) and the Commonwealth of Independent States (CIS) countries. The top 10 countries for Turkish exports are South Korea, Iraq, Kazakhstan, Georgia, Azerbaijan, Uzbekistan, Switzerland, Turkish Republic of Northern Cyprus, Slovenia and Iran.

In the last three years, our pharmaceutical export has increased above Turkey's average. As a matter of fact, in 2019, our exports increased 10 percent compared with the previous year and reached more than USD 1.44 billion. As for the end of 2020, it has increased 27.3 percent and reached a record-breaking level of USD 1.84 billion.

Despite such an impressive and comprehensive reach, Turkish pharmaceutical exports are still quite low and far away from their true potential. However, thanks to the increasing awareness on the company level and the strategic efforts of government agencies together with NGOs like ourselves, we have been observing encouraging improvements.

We established the Turkish Pharmaceutical Exporters Platform at the beginning of 2012 with the specific purpose of increasing the export capacity and the competitiveness of the Turkish pharmaceutical industry. Becoming one of the world's leading pharmaceutical producers and exporters is one of the main objectives of our industry. Today, our Platform has a total of 23 national and multinational members.

Has the approach been focused on specific therapeutic areas or trying to build certain capabilities?

One of the most important priorities for our country is biotechnology. As it is known, biotechnological drugs are shaping the present and future of the global pharma industry. In the last 10 years, biotechnological methods in the world pharmaceutical industry have made it possible to treat many diseases. Accordingly, the share of these products in the world's pharmaceutical market has reached up to 30 percent; there is a similar situation in our country. The share of the Turkish biotechnological pharmaceutical market reached 25 percent in 2020.

It is unthinkable for us to lag behind the biotech transformation considering our deep-rooted and powerful pharmaceutical industry, which has a history of more than a century. However, in the

current situation, we see that our country is still largely dependent on foreign sources in this product category. Annual imports in this area are at the level of USD1.6 billion each year. It is necessary to facilitate patients' access to these drugs, to alleviate the burden on the health system, to make our strong national pharmaceutical industry one of the leading players across the globe, and to make a significant contribution to the country's economy by reducing the foreign trade deficit.

Very impressive investments have been made in the field of biotechnology in the last 5 years; companies are working hard to enter the global biosimilars market with a long-term perspective. In this regard, the amount of investment incentive certificates received by our companies in the last period has reached USD 1.1 billion. In addition, intensive technology transfer, know-how and human resources investments are being made for these products. The biotechnological pharmaceuticals market is constituted of a total of 141 brands and 348 medical forms. The production of the 29 types of biosimilars under 7 different brands is taking place in Turkey.

We continue our investments abroad and establish strategic partnerships with the world's leading biotechnology companies. Given the rooted pharma production culture we believe that Turkey will also be successful in this field.

In order for Turkey to compete effectively with its competitors in this field, a supportive ecosystem needs to be established. Enhanced licensing regulation that will shorten time-to-market is of utmost importance. New incentive schemes geared towards more public funding would be of help. New patients should be encouraged to begin treatment with biosimilars produced in our country.

Having mentioned an increase of production of high-value products, what else is on IEIS' current agenda?

We have set some goals not only as an industry but as a country: increase the production of high-value products not only in pharma but across all industries, create a suitable research and development (R&D) environment through more funding and new public policies, and promote domestic production of biosimilar products. According to recent reports, the main driving force for European markets will be biosimilars and Turkey has to get on front of that; we have the necessary facilities and capabilities because Turkish companies have been investing heavily in biosimilars, but the lack of regulations and incentives are holding them back. We are expecting to have a new regulatory system for biotechnology products soon.

To summarize, our two main goals are creating a suitable R&D environment, strengthening the relationship between industry and academia, and promoting biosimilars. Our strategy will help balance our foreign trade deficit.

What is the perception that Turkish pharma products enjoy around the world and how do you differentiate from other generics-producing countries such as India?

There is a gap between the reality and perception of the Turkish pharma industry abroad. We have EMA-certified facilities that can even produce biotechnology products, including mRNA vaccines. Our facilities are in great condition and adhere to high-quality standards but, unfortunately, we are producing mostly generics which are not generally associated with high technology. As I explained, the pricing policies and the lack of API production continue to be an obstacle.

We are recognized as great producers of generics across the world, but the industry should be investing even more in R&D in order to produce value added products.

Almost every country aims to build up R&D capabilities, but it is a complicated endeavor that requires many resources. What are the pieces that you believe are realistic for Turkey?

We have to work very hard to achieve our goals. We believe that industry will achieve them step by step. In general, Big Pharma companies spend around 15 percent of their revenues in R&D, but in Turkey the number is still around 5 percent despite the recent positive development in this area. All of our members are aware that the number must be increased substantially. At the same time, we believe that government policies should be re-organized drastically to accommodate more R&D spending and change the current pricing and reimbursement system in pharma market. Turkish companies are unable to boost their R&D expenditure if they cannot generate enough revenue.

The current pricing and reimbursement system negatively affect the development of the sector and the formation of the capital needed for investments in new product development, especially in R&D. I believe that a more sustainable pricing model should be adopted in order to the pharmaceutical industry to develop in a healthy way and to compete with its competitors in the world under fair conditions

We believe that Turkey should change its attitude towards pricing and reimbursement, looking at the industry as a partner rather than a financial burden. Investing in healthcare is a human capital investment, it improves the productivity and effectiveness of the whole Turkish economy; it is similar to investing in the education system.

Fortunately, we are not starting from zero as we have great healthcare infrastructure and large investments from innovative companies.

You have stated that there is enough manufacturing capacity to increase biosimilars production, but are there enough researchers and people with the necessary knowhow?

We have around 34 R&D centers with more than 2,000 researchers but it is not enough compared to other leading countries. The quality of our R&D activities should be increased because Turkey has sufficient human resources coming out of academia, but they do not find the industry sufficiently attractive yet. We should establish new policies to promote the relations between industry and universities and increase the innovation output.

To what extent do you believe that localization policies were validated during the pandemic, seeing that Turkey was one of the countries that did not experience a shortage of medicines?

Turkey’s localization efforts under the leadership of the Ministry of Health in the last five years has produced many positive outcomes. During this process, the industry invested in new technologies, increased capacity utilization and employment while imports diminished. Long-term manufacturing contracts are also focusing on pharmaceutical exports.

IEIS deems the continuation of localization policies of great importance for our industry and therefore we support them. In this context, many of our national and multinational pharmaceutical companies have made all kinds of investments and preparations to contribute to the process. In 2015, the share of locally produced medicines was around 43 percent by sales and increased to 52 percent by 2019.

However, due to the EU’s complaint to the World Trade Organization, the localization practice was stopped shortly after it started. We are of the opinion that the practice does not contradict international resolutions and conventions. From our perspective, the government should continue

with the localization efforts to increase capacity, attract more foreign investment and technology.

How big of an impact does Turkey’s lack of energy production have in the healthcare budget?

We have enough potential resources in renewable energy to reduce the reliance on imports of natural gas and petroleum. Energy is a sensible issue for most of our members because it directly impacts the costs of production and their environmental concerns. Companies always consider the cost of energy when deciding on investments in manufacturing plants and facilities. Not all of Turkey’s industries are ready but the pharma industry is. I have been working on this issue since 2000 and the attitude has changed dramatically.

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