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Turgut Tokgöz, secretary general of the Pharmaceutical Manufacturers Association of Turkey (IEIS), provides his take on the state of the Turkish pharmaceutical sector, highlighting the challenges that the industry faces with domestic pricing policy, the currency crisis of the Turkish Lira, and the barriers hindering Turkish firms from entering the global export market.

Given the depreciation of the Turkish Lira, the pharmaceutical industry is particularly concerned with the country's drug pricing mechanism. The IEIS liaises closely with the Ministry of Health on this matter - what recommendations has the IEIS given to the government to make the pricing mechanism more favourable to industry?

We have had contact with the Ministry of Health for some time now, and we have proposed alternative mechanisms than those in use today. But this is not an easy topic to address, as when you discuss pharmaceutical prices, everybody involved gets a bit edgy. So, we have come up with a "middle ground" between trying to solve our problem, as the industrial actors, while not adding additional inflationary pressures for the government and public finance.

Nonetheless, the discrepancy between the Euro exchange value and the fixed exchange rate for drugs is an ongoing dilemma. This has been a problem in Turkey for a long time already. Naturally, the government will not be able to correct prices at once, but there is room for reductions in the discounts given to the social security institution SGK, for instance [*with mandatory discounts currently standing at 41 percent - Ed*]. I think that some gradual reductions in discounts could definitely be worked out, and it would not add any inflationary pressures. This is the type of

“middle ground” solution that we are advocating for.

Some industry experts we met have stated that the pricing issue is merely a symptom of a larger problem in the Turkish model of healthcare, claiming that some of its structural features may be outdated and must be updated. Would you agree?

Yes, I do agree with that. There needs to be a new model on every front. The healthcare services need a holistic review – it has been over ten years since we started the Healthcare Transformation Program (HTP). While it worked well initially, we did not end up meeting all our targets. Sure, it enabled one of the widest coverages on earth in terms of social healthcare, but it also created numerous imbalances. We need to have a strong domestic healthcare infrastructure in place, including state-of-the-art companies and manufacturers. In Turkey, we have a long history in pharmaceuticals, and we have the potential and drive to become a global player in the industry.

The government did show an interest in helping the pharmaceutical sector grow. In 2011, we argued that the pharma sector needed to be recognized as a strategic sector by the government. In 2012, the government agreed, and implemented a regime of incentives for the private sector to strengthen its exports, investment activity and R&D. These initiatives have had success – our exports have grown significantly in the past five years and have surpassed USD 1 billion in September 2018 (on a moving annual total (MAT) basis). We have the strength to become a serious global player, but the current regulatory framework is hindering the industry from taking that next step. The regulators have been approaching the matter from solely a public finance viewpoint, and it hasn't led to the best industrial environment.

For example, the fixed exchange rate and very low prices of pharmaceuticals in Turkey even act as barriers for our companies to access export markets. To export, a company has to generate enough resources domestically to cover marketing and distribution expenses overseas and eventually capture a share in new markets. Furthermore, one should bear in mind that foreign pricing and reimbursement authorities only accept local prices, which are among the lowest in the world. In fact, the falling domestic prices have already caused a reduction in the export prices of Turkish firms, although sales volume has been constantly growing.

Last but not least, the pricing mechanism in Turkey prevents the capital accumulation necessary to invest in R&D and innovation. Overall, we have to find a balance between the needs of the state and the needs of the industry in order to find an affordable, yet progressive, “middle ground”.

On the topic of R&D and innovation, many emerging economies have established successful models for developing their biotech sectors, such as South Korea, Taiwan, and India. What model do you envision for Turkey if it is to strengthen its biological sector?

There are different business models for developing a biotechnology presence, but what matters most, for any country in this endeavour, is time to market. If your products are introduced to the market with a lag, while your peer group is gathering profits and clinical data in less regulated markets, you will be left behind. Your peer group will enhance its R&D and gain access to more heavily regulated markets like the EU and the US.

So, no matter what business models Turkish investors and industry executives choose to apply, the crucial aspect is the efficiency of the regulator. Unfortunately, many emerging market regulators “copy and paste” the policies of European or US regulators, which ultimately will keep their countries behind in the field. Unless the emerging markets are more proactive in regulatory approval, they will always be consumers of foreign biotech products and will never become serious producers.

Some emerging markets that have become serious players in the biotech industry, like India and various Asian and Latin American countries, have found ways to be proactive and create their own rules without jeopardizing public health. Regulation has to be fair, and – more importantly – wise.

The enactment of the localization policy in Turkey has bolstered a surge of contract manufacturing services between domestic and international companies. However, when we met with TiTCK’s Hakkı Gürsöz, he told us that “*conceptually speaking, the government does not want the domestic industry to turn itself into a contract manufacturing basis for foreign companies.*” With that in mind, how does the IEIS perceive Turkish localization policies?

In fact, we helped the Turkish policymakers draft the localization policy for the latest development plan [2014-18]. It has since become an action plan for the Turkish government, and there is no turning back from it.

I accept the argument that the Turkish pharmaceutical sector should not transform into a mere sub-contracting hotbed. But that is not really what is happening. There is a great production culture

in Turkey – the pharmaceutical industry was the first manufacturing industry in this country, in fact, having manifested far before the automotive, brown goods, or white goods industries. Turkish pharmacies were producing by the end of the First World War, and laboratories started production at around the time that the Republic was founded. Turkey has its own industrialists, so I don't believe that it will be pigeon-holed into a contract manufacturing role.

Keep in mind, though, that it is not necessarily a bad thing to emphasize contract manufacturing. If you have a competitive advantage and low prices, you can mass produce and achieve a profitable scale – and in pharma, scale is everything. If you can find success as a contracting hub, money will flow, investments will be made, and technology will be transferred. Sometimes, contract manufacturing sectors can become so successful that they turn into formidable exporters. Contract manufacturing is not inherently something to undermine, particularly when a country has excess capacity.

Nonetheless, you will not see Turkey become an area that is defined by contract manufacturing, as some countries become in the automotive industry, for example. Turkey has its own pharmaceutical products, and many more are on the way.

Are you satisfied with the way that the localization policy has been implemented so far?

It hasn't moved at the pace that we would have liked. TiTCK has been working hard, but we can envision a faster pace, for sure – nevertheless, it is working.

I think that many of the MNCs that protested against the scheme, yet engaged with it once it passed, can see how it has worked well and are happy with the results. We even had some of our members oppose the measure, as they are pure importers that had to negotiate with their counterparts in foreign markets to bring production to Turkey. But, overall, we moved forward because it was good for the country and good for this industry. None of our members complain about it, now.

You have been one of the driving forces of this industry for almost 15 years. Given your expertise, what is your vision for the future of Turkish pharmaceutical manufacturing?

I think that it is important that we, as a sector, set medium-to-long term goals and resist getting caught up in the small bumps in the road. When I look back to what happened in 2010 when the

pricing scheme started becoming a problem, we started thinking that, in order to resolve the issue, we needed to show the government and society just how valuable this industry is to the economy. We provide exports, R&D, local employment, etc. Policymakers, at the time, were only concerned with public finances and did not consider a more holistic view of economic welfare.

Overall, while we are going through a crisis right now, it will soon pass and the hard times will end. In the meantime, we are focused on exporting, investing in R&D and strengthening our sector while we navigate the economic hardships we are experiencing now.

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