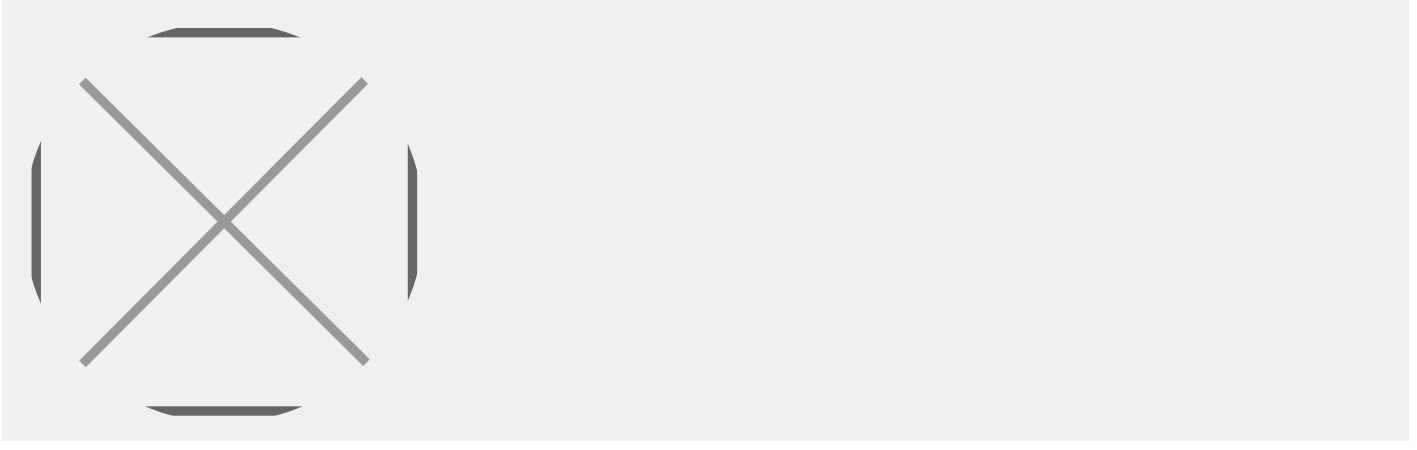


Interview with Turgut Tokgöz, Secretary General, Pharmaceutical Manufacturers Association of Turkey (IEIS)



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IEIS is an association with dual responsibilities. Promotion of generic usage in turkey and ensuring the sustained development of a local manufacturing industry. Before we look into these two aspects, I would like you to give us your perspective on the future role of the association, in an environment where the line between generic and innovator companies is less and less relevant, due to the growing trend of innovators integrating generics products in their portfolio through acquisitions. How is this trend reflected in today's IEIS membership structure, strategy, propositions and is it redefining the role of IEIS?

Since the last time we met, the role of the association has also changed. We were the representative of generic businesses, as well as the local manufacturers. This has changed; we now represent the full spectrum of business models present in the market. We represent both local and multinational manufacturers; we have sole importers, companies with only generic portfolios, others with hybrid portfolios where they not only produce generics but also originator products under licensing and contract manufacturing.

Previously we had around 30 members; now we represent 54 companies.

The 20+ new members came as a result of diversification. The distinction between generic and innovative industries is dissolving. Research-based companies are increasingly realising the value of generics which are growing world-wide. This is a commercial reality now. Given the hardships

with their pipelines and their innovative structure, they are increasingly relying on their generics to get a bigger share in that business line. We cater to everyone as an association. There is a research-based association AFID and there is TISD, primarily concentrating on some local producers. We stand somewhere in the middle.

IEIS has constantly been a force of proposition and an important government partner in Turkey. What have been for you the most striking regulatory improvements implemented in the past few years?

The most important thing is that efforts to contain drug spending in the country have been elevated. Back in 2005 it was the initial phase of restructuring and healthcare reforms. Access to medicines has been increasing ever since, which put enormous pressure on public finances. Although the adverse effects of the problems in the world economic arena have been relatively mild for Turkey, these problems still triggered a more comprehensive effort towards containing healthcare spending and resulted in huge pressure being put on pharmaceutical prices in the country, either through direct price controls or through elevated discounts for the reimbursement category. Those have been the most important items on our agenda for the last few years.

The overall pharma market in Turkey has steadily grown in volume over the past few years, driven by a rising healthcare insurance coverage system (97% of the population now covered). Never the less last year saw a wave of discounts imposed by the government which despite market growth in volume lead to a striking 13% decrease in overall sales. Innovators where strongly hit. What was the impact on generic products? And does IEIS see this type of policy positively?

Generally speaking, this hurt the marketplace enormously, we do not favour the government's inclination to interfere with our prices as they did; supply-side measures can only work to a certain extent and they also need to work on some demand-side measures, as access to medicines has been increasing. Such an increase brings high costs; however, suppressing prices to contain these costs causes enormous damage to the industry. Turkey has a century-old pharma industry with a very solid culture of production in state-of-the-art facilities. Needless to say, existing policies are not supportive for the industry. The Turkish pharma industry has the potential to become a global player if the government would approach it in a strategic manner. We published a recent report a global player. It was welcomed by the government and a strategic approach is beginning to develop. The incentive package announced by the government last week also gave special attention to the pharmaceutical industry.

Nevertheless, the government's approach in the last four or five years was not supportive in general, but did contain individual elements that were helpful to generics companies. A larger portion of the cost-cutting measures were directed to the originator companies, which was a wise

thing to do, as there was much to gain on that side, rather than simply suppressing generic prices that were already low. Cost containment has emerged in other European markets as well, but the government here was sufficiently astute to address innovative players' prices in order to make savings on that side also. Overall, a bigger percentage came out from the innovative side than the generic side when the comparison is made between them. Now, unlike other European markets, we have a pricing and reimbursement system whereby any off-patent product, whether it is innovative or generic, is being treated in the same way and there is no preferential treatment towards innovative products or against generic products. The current market is now separated in terms of off-patent versus protected when previously it was generic in contrast to innovative. This creates larger savings.

The contribution of generics towards the overall improvement of public health in Turkey is undeniable; generic penetration is at 51%, placing it in the middle of the European rankings. In terms of value, it represents 38%, which is high in comparison to elsewhere; in Romania it is 71% in volume and 31% in value, in Germany those figures are 67% and 32%. Does this reflect relatively high prices of generic products in Turkey? And in that case are they fully playing their role?

On the contrary, this means that the originator prices are low. Comparisons have to be made in absolute, rather than relative terms. In absolute terms, generic prices in Turkey are quite low.

The discrepancy can be explained this way: take another market which has 50% generic penetration in volume, like Turkey, but in terms of value, if the generic figure comes down to 20%, compared with Turkey's 38%, it appears that generic prices are high in Turkey. However, it might simply mean that the originator prices are low, which is the case here.

That does not mean that if originator prices are low, generic prices should be zero, there is a commercial value to them. Unlike other markets, where regulators put pressure on generics instead of originator products, the Turkish officials have addressed the relatively higher prices of originator products which are now off-patent and no longer have IP protection. This means they should not have any commercial exclusivity either. There is a commodity business and a branded business. Turkey is a branded market. Compared to commodity markets, we might see higher prices in terms of generics here.

This is not always the case, however. There are in fact a lot of generic products that are priced lower here than in the UK, which is a pure commodity market. Turkish prices are well below the European average, but originator prices are even lower.

How do you see the evolution of generic penetration in the country, what would constitute a balanced ratio?

The 50% volume of penetration has not been increasing. Five years ago, the value penetration was around 32%, 6% lower than it is now. This is not as a result of a price increase on generics, but rather a decline in originator prices as a result of cost-cutting measures. That is why the government was very careful to make the cost-cutting systematic. They realized that there were a lot of savings to be made in this area, and they have pursued these savings. In most of the European countries regulator's approach to generic medicines is simply a policy tool to suppress originator prices. This does not work. Unless one possesses very specific tools to get generics prescribed or dispensed, no progress will be made, as preexisting brands will simply benefit from their well established status in the market. Regulators do not possess such tools.

Most of the pharma markets run on private or public social security schemes, so people are under coverage. Patients want to make sure that they make use of the premiums they have paid for their coverage to the fullest possible. Brands and brand loyalty are very important, people do not want to use generic medicines simply because they are cheaper, unless they are obliged to spend large amounts of money out-of-pocket.

It is funny to see regulators suppressing generic prices and then trying to devise public campaigns to promote generics and then having them prescribed and dispensed. People do not believe in them. It is a down-grading approach and people question the efficacy and every other aspect of the medicine that is reflected in its price.

You mentioned IEIS's report, which is a very interesting study done in collaboration with the BCG, and seems to argue that Turkey may have missed the opportunity to become a major global pharma player. In a country that seemed to have all the cards in hands with an existing large pharmaceutical manufacturing base, a large population and incredible success stories in the sector, how could the country "miss the train"?

The country was too inward-looking. The local market was vibrant and as the pharma industry is heavily regulated, it requires a large amount of effort and capital to export products. Unfortunately, the industry has taken the easy route and has been focusing on the local market, which has been growing quite handsomely. Now that they are somewhat squeezed domestically, they are very much interested in export markets. This puts Turkey in a late-comer phase and it is not easy to gain a good market share in export markets. The train has already been moving, but it is still possible to catch it.

As a late-comer, what should be done to mitigate against the disadvantages that such a position bestows? How should Turkey position itself in relation to manufacturing giants such as China, India, even Brazil? Or should it strive to be an innovative hub, such as Singapore or South Korea?

First of all, the fact that we lack vertical integration does not put us in a favorable position when it comes to tapping large markets such as the US. The simple role that generic producers are assigned from a regulatory point of view, is to devise a product that is as good as the existing product, not better.

The expectation is that generic companies will make something as good as the existing product, but cheaper. As a consequence, there is little R&D in the generics side of the business. In other high tech industries late-arrivers develop products that are superior to the existing ones. There is higher innovation and product improvement. This does not happen in the pharmaceutical industry. There is a very open niche area in value-added generics that could be exploited by simply going further and improving existing products rather than spending large amounts of money on a highly innovative structure and trying to seize a role in the innovative industry.

Due to the production culture that we have, Turkey could fill this role.

When we were last here we had the chance to interview an iconic figure of the sector, former president of IEIS, Bülent Eczacıbaşı, who at the time said that increased pressure of imports would drive Turkish companies to focus more on R&D and exports. Apart from a few very large players, this is yet to happen.

It has happened, actually. When Mr. Eczacıbaşı was making these comments, exports were low, they have doubled since then. Seven years ago, R&D centers such as we have now did not exist. They were very small. Now the big companies have large R&D centers, certified by the state. Many foreign R&D personnel have been brought in for a large number of projects. There are already 300 projects supported by Tübitak, which is the state R&D center. There have been enormous changes. The yield of such a change will become apparent in the next fifteen to twenty years.

Looking at the trade balance, it is roughly USD 5 Billion in imports, for USD 600 million in exports; it is still a huge deficit. Do you believe that your members are ready to take the necessary steps in terms of investment in order to address this?

That is why we have built up an alliance of pharmaceutical exporters that currently has 22 member companies. With such a platform, we are going to be present at the upcoming 2012 Bio International Convention in Boston in June. We are most probably going to be participating in the CPhI Events in October in Madrid. These are events which we were not present collectively before.

Companies were being represented on an individual basis, however, a collaborative effort is now taking place. The change exists; we have to reap the yield in the coming years. If changes are not made, the situation deteriorates. We are currently making the U-turn, at the bottom of the U.

Multinationals who have long delayed production investment in this country are now rumored to be considering acquiring local pharmaceutical companies. Apart from the

historic deal between Eczacibaci and Zentiva, there has been very little done in that respect. Are Turkish companies reluctant to allow themselves to be acquired?

There have been one or two other deals, for instance, Recordati bought Yeni Ilac and Dr. Frik lately, and MN was acquired by Amgen. Negotiations are in progress elsewhere as well. For the last three years, there have been significant changes in the pricing and reimbursement structures which hugely effected the valuations.

It is not easy for a buyer to value a company under circumstances where rules are changing that will result in reevaluations. There has been a stagnant, 'wait-and-see' period, during which estimates about the final outcome have been made.

Everyone looks at the "Indian Miracle", to my knowledge India has only USD 3 Billion worth of exports, which is very little considering the size. They are present in almost every market in the world and that is what makes them a global player. Unless the big Turkish players acquire companies in other marketplaces that are for sale, they are going to be bought out somehow.

Turkey is a large branded market. Trying to start a business from scratch in this market is very uncertain; it requires a lot of marketing investment to get prescribed and dispensed. It is not an easy market; there are a number of dominant players in place. Buying them out, trying to gain a respectable market share and expand one's portfolio over an existing portfolio is a better business model than trying to build from scratch. There are players willing to pay the premium for access to that existing market share and of course that premium always attracts the Turkish sellers.

Why should companies still view Turkey as a great prospect for investment, as opposed to a great place to import?

They will not be able to import as comfortably as they did before. The government has a very clearly-defined policy that anything which can be produced here should be produced here and anything that will be produced here will have some sort of preferential treatment.

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