Orhan Mutlu Topal – General Manager, Emre Ecza Ilac, Turkey



The localization of vaccine production will be a groundbreaking achievement for Turkey.

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Dr Orhan Mutlu Topal, general manager at Emre Ecza Ilac, offers an insider take on the Turkish vaccine industry, the challenges on the horizon for the Turkish pharmaceutical sector, and the country's technology transfer from localization policies.

This is the first time that we are meeting you as the founder of Emre Ecza Ilac. Can you introduce this company to our international readers?

The story of Emre Ecza Ilac is deeply embedded in my family history. The Topal family have been in the pharma industry since the 1960s. Specifically, my father entered the vaccines business, and today, we are continuing our work in vaccines. In the 1970s, he established his own business, Keymen**,** which we subsequently sold in 2016. Throughout our family's long history in the vaccines business, we have also established ourselves in other branches of the pharmaceutical industry; we have registered many medicines. However, given the pricing regulations in Turkey, we have unfortunately had to sell the MAs of many of our products. We have maintained only a few products in our line.

We established Emre Ecza Ilac as a drug wholesale company in 2004. But, after we sold Keymen, we converted Emre from a drug wholesaling company into a pharmaceutical company. We currently have a few registrations, but we are trying to develop some specialty medicines and we are hard at work with some vaccine projects. We are in preparation for bidding in a government

tender for the rights over local vaccine production that will last for seven years if we are successful.

In sum, the focus of Emre Ecza Ilac is on vaccines, per the family tradition, and we are working collaboratively with international partners in securing public contracts from the Turkish government. At the moment, we are hard at work with our preparation, ensuring that we will win the government tender. Despite Turkey's current reliance on imports for finished vaccines, in a few years, vaccines will be completely manufactured in Turkey, if all goes to plan.

The localization of vaccine production will be a groundbreaking achievement for Turkey.

Do you think that the localization process in Turkey is effective in encouraging a technology transfer?

On the whole, I think that it is a positive policy for our country. However, you must take into account that despite Turkey's high birth rate, a flourishing vaccine production hub will likely not sustain itself on our current population – it would be best to have our producers export their vaccines to our neighbouring markets. However, Turkey is not the only country targeting tech transfers… Iran, Egypt, Saudi Arabia, Algeria, and Russia are all experimenting with similar policies to achieve similar ends, and each of those countries wants an eventual vaccine industry to export to *their* neighbours.

Accordingly, this process will take some time. International partners do not want to establish production hubs in all of these countries, which are in the same region. It is therefore somewhat of a race – whoever establishes a production presence first will obtain regional dominance in this sector.

In the meantime, we are waiting for the government to advance the problem, and we will see what we can do.

Given that you have experience with one of Turkey's first vaccine businesses, can you comment on the change in the domestic vaccines market since your career started?

There is much more competition now. Many firms have started working in the vaccine industry, but it is not an easy industry to penetrate – the big, global players have an enormous leg up on the competition. Large multinationals could offer vaccines to Turkey for one year, free of charge, and it would not impact their balance sheet. An expenditure of that size does not put a dent in their

billions of turnover. Local companies have no such luxury – we do not have the cash flows to compete in that sense. This is why government tenders are so important for us local producers; the seven-year agreement would give us a guarantee of purchase. While we would have to fend for ourselves come the eighth year, the seven-year security is instrumental in the growth of the domestic vaccine companies.

Domestic companies do hold a competitive advantage over our competitor countries. Turkey is strong due to its location – we are strategically positioned adjacent to Europe, the Middle East, and Africa. We are also known for our high quality as manufacturers. Furthermore, we have an educated labour force. While our competitor nations do possess certain strengths, such as Iran's history of vaccine production, they all struggle with problems in the international trade arena with which Turkey does not. Turkey has strong relations with Europe and Africa, and we are best poised to become a production and export centre for vaccines.

Turkey is known for having a long history in the pharmaceutical sector, but not in vaccines. Do you really believe that Turkey has the human capital necessary to rise to international prominence in this field?

Turkey was a human vaccine manufacturer but unfortunately, the public-owned institute could not be able to maintain and develop itself for current technology. So the local production was totally stopped in 1998.

Turkey certainly lacks some necessary data, but I am confident that this problem could easily be abated through collaborations with international players. The basic knowledge and human capital is here and experienced. But, we lack the data and the technology necessary to start producing vaccines – we cannot create such technology on our own. We must in-license it from other countries and borrow from their advancements.

These technology transfers are coming, too. For example, there are four or five companies investing in biosimilar production in Turkey. However, their success will be completely contingent upon their ability to establish export markets. Companies could not solely rely on the domestic market in Turkey because of the low prices – when biosimilars emerge to steal market shares from the new product, the profits will be too greatly diminished. Originator companies oftentimes lose half of their market shares to the biosimilars (which will have reduced the price of the drug by providing competition), and that will place the innovative company in an unfavourable position. This is especially likely considering that the SGK (Sosyal Güvenlik Kurumu) has indicated that

Turkish firms will get priority for reimbursement; there will be no stopping the domestic biosimilar companies from quickly taking market shares.

You are an expert in attracting foreign partners to Turkey, even though the international pharmaceutical community is not pleased with the Turkish pricing system. How do you still manage to attract partners?

When it comes to pharmaceuticals, it is true that international investors are dissuaded. Nobody wants to come and register in Turkey because Turkey's prices are used as a reference in other countries. Registering here would reduce their returns elsewhere. This is why many companies prefer to sell through the Turkish Pharmacists Association, which lets them sell in Euros. I do the same for my two medicines, and ultimately, the pricing mechanism in Turkey is the reason that I sold off my medicines businesses.

For vaccines, though, the government accepts either US dollars or Euro. Accordingly, I believe that partners for the vaccines industry will not be too hard to find.

Where do you see the company in five years?

If we get the seven-year tenders from the government, we will be building vaccine production centres in five years – otherwise, we will carry on with our pharma company.

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Further, we are currently cooperating with a Russian vaccine institute that sells seasonal influenza vaccine in Latin America. We give them fill & finish service through our contract manufacturer in Turkey. Turkey has a favourable manufacturing and filling capacity and our regulators are partnered with both Europe and the PIC/s (Pharmaceutical Inspection Convention Scheme), so such arrangements are possible in the future. These agreements are also heavily dependent on winning government tenders, though.

What is your outlook for the Turkish pharma industry moving forward?

Regarding the production side of things, our manufacturing facilities are in a world-class position – even better than their counterparts in the US, Europe and elsewhere. Our facilities are recently built and they are frequently updated because asset costs in Turkey are relatively low.

However, commercially speaking, our pricing scheme creates an unsustainable environment. Production costs are increasing while profits are decreasing, and companies are suffering. Many are slashing their marketing budget, which makes their R&D investment less profitable in the long run. The companies need to make money to produce new products. And, given the daunting process of producing pharmaceuticals, it is hard to get investors that leave the sector to return – it is easier to make money in other sectors. If somebody closes a factory, they do not reopen it.

What is your motivation to carry on in the industry?

The production of vaccines has always been a family passion for us. I will carry on in this industry until it is no longer feasible.

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