

Interview â?? Sevi Firat, Founding Partner, Firat Izgi, Turkey



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Sevi Firat, Founding Partner of Firat Izgi discusses the legal challenges facing pharmaceutical companies looking to penetrate the healthcare market in Turkey, the evolution of the legal landscape and her expectations for the industryâ??s future.

With pricing and regulations as the major challenges facing players within the Turkish pharma and Medtech industries today, what type of services are you offering your clients to help them better compete in the marketplace?

In the past the regulatory environment was far less settled, speaking of ten years ago compared to today. Today we have more of a common language with the regulatory bodies. This is because in the past our legislation was quite vague in many aspects, and now part of adapting these regulations to EU standards has meant that our laws are clearer which has led our interactions with the government to improve significantly. Compared to the past, I can create a clearer picture of a market-entry procedure, and that is because I have a clearer law in front of me explaining what documentation, requirements etc. companies will confront if they choose to enter. This has improved our experience very much over the last 5-10 years.

The work we do depends heavily on the specific needs of the client. When itâ??s a company which has been operating in the Turkish market for decades, this client has very different needs from

someone trying to enter the Turkish market for the first time. If the client has a project with a promotional aspect we evaluate the project and see risk areas to mitigate the potential challenges they will have. Contractual issues are the most common topic we work with. Procedural issues also play a role, reimbursement procedures, governmental contracts, public tenders, relation-management mostly between HCPs, private government and private companies, are among the services we offer. Generally we try to provide preventive legal services, however if our client is in a conflict we will try to solve the issue amicably at first, and if that is not possible we defend them during the litigation.

With the future growth and sustainability of Turkey's healthcare industry in mind, would you say there's more of an emphasis on attracting and localizing MNC operations? Or building up the capabilities of local companies to export Turkish brands abroad?

I think these are going in parallel to each other. As with all governments around the world, the Turkish government has a tendency to want to protect its own industry and promote local production and encourage investment in the country. The Turkish life sciences industry is not so different from other developing countries' markets. The Turkish government has made R&D in pharmaceuticals a priority and we see this as a way to break from the past difficulties the pharmaceutical market faced here. The shift to a differentiated pricing system by going from a cost-based system to a reference pricing system back in 2005 had a very heavy impact on the industry. Around 2008-2009 we received heavy discounts through the reimbursement system by the government, which is the biggest purchaser in the country. In Turkey there is a very strong imbalance between the government and the pharma industry. Perhaps in the future, if the local investment and R&D programs continue and are successful, the pharma industry may gain ground on the government in this regard, and I believe they are now more aware of this. From the government's perspective this is also a good thing. This is an area which generates jobs and income, while showing that Turkey is strong in terms of R&D globally and will become a rising star in its region. This is why R&D is now the area of common interest for everyone within the life sciences sector.

Continuing from that, do you see Turkey continuing to gain importance within the global pharmaceutical sector?

This is not only about the local legal environment, it is more about how Turkish companies need to position themselves globally, as it is a global market. The awareness of this point within the industry is now very much there, which was not the case 10-20 years ago. Today it is truly a global market, awareness is high, Turkey has opened its market to international investors and it is a very good market for many companies. Additionally we are seeing local companies invest abroad as well. We have an aging population of 80 million people, we sit at a crossroads geographically, and all these factors mean that Turkey will be of great importance to many pharmaceutical companies in the future.

How would you go about advising foreign pharma companies looking to penetrate the Turkish market? What type of factors might they need to consider for sustainable and successful operations here, as opposed to other developing countries?

If you are a new market entrant, I believe it is very important to understand the potential conflicts which you might come across in your business. There are different strategies for entering markets. For example you could first go through a distributor to observe how the market and your products are operating before setting up your own business in the country. If that is your plan you will have several challenges such as getting your licences back, portfolio compensation claims and the misconduct of the distributor potentially harming your business. Because of this you need a proper

contractual framework, and a clear timeline within which to operate.

If you plan on directly setting yourself up in the country then your challenges are different. You will need to set up a company, find proper people to go apply for marketing authorization and more. The government is working hard to shorten the time lines for marketing authorization procedures and to conduct the GMP audits promptly. However there are still significant challenges ahead.

Of course how this goes also depends on your product portfolio, if you have several innovative, patented products which you wish to keep proprietary then it is probably a better idea to get into the market yourself. If you have more generic products and will be facing strong generic competition then it is probably better to find the best distributor locally so that you can penetrate the market via a distribution model. So we provide advice and help for our clients to find out what the best way to enter the market is for them specifically, based on our experience.

After two years of being in the business on your own, can you give us an overview of where the firm stands now and what your strategic priorities are moving forward?

Our firm is a very specialized niche firm. We have only three industries that we operate in, these are Life Sciences, Direct Selling and Multilevel Marketing, and Energy industries. We now have 8 lawyers and 4 supportive staff in the office. We have a team for each industry, and each of our lawyers is training to become proficient in at least two industries each as well. All of these are regulated industries in Turkey, and when we established the firm we decided not to become a general practice law firm. We have our strong areas, and regulatory work is one of them.

It's important for us to aim to be strategic partners with our clients in their government relations, as well as helping them to define and manage risk without becoming legal obstacles as lawyers. Our aim is to be a partner to the client and to contribute to their commercial success by providing proper business advice and legal support.

Sevi, you've had quite an extensive background in the Life Sciences sector providing legal services. What were your initial aspirations when you started your own practice back in 2013?

Throughout my career I have worked in the pharmaceutical industry, and I observed a change in the legal needs of companies. Where before it was easier to provide blanket legal services, companies now had far more sophisticated needs, which had made it a more niche-prone area. At the time I was working for one of the leading law firms in the country where I was a partner in charge of the life sciences, white collar crime and anti-corruption departments.

However, being a manager in a big company sometimes means you cannot conduct your business to the standard you would like. As a result, I decided I would continue my career on a different path. This way I could personally involve myself in the work and be the contact point for my clients myself.

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