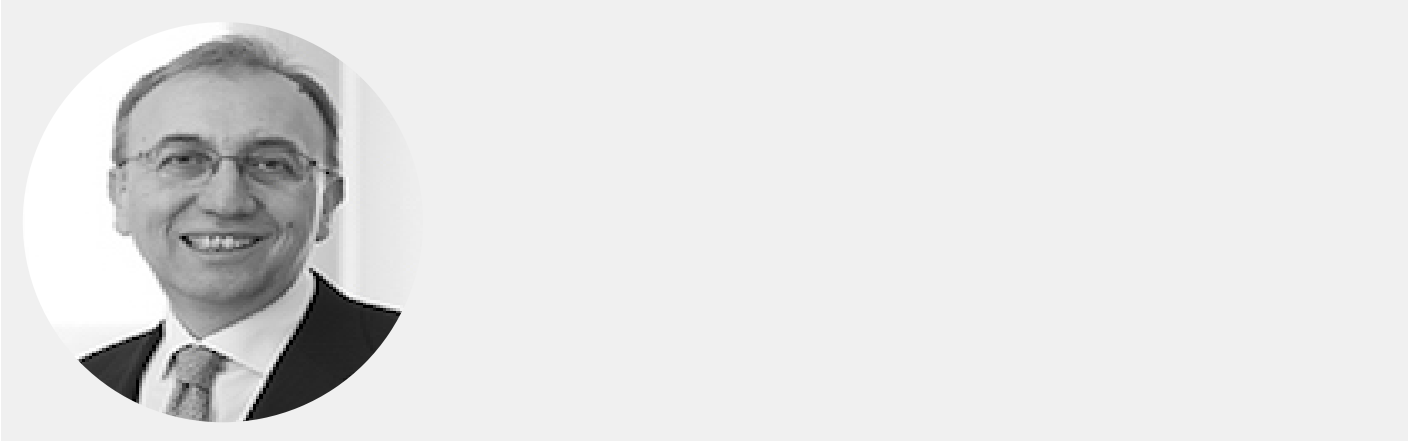
Interview: Murat Çıtıroğlu – Business Development Director & Board Member, Ekin Kimya – Turkey



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The co-founder of Ekin Kimya discusses the need for greater regulation and monitoring of raw materials used in Turkish pharmaceutical manufacturing, his company's key role as an educator and advisor to the industry with regards to international regulatory standards, and unique role as a supplier that provides robust support services, including formulation and product development support.

Things have evolved a lot in Turkey, particularly since 2009. Many suppliers have begun to lessen their commitment to Turkey; how has Ekin Kimya stepped in to fill the void?

As Ekin Kimya, we represent many of the biggest names in the global chemicals industry, including BASF, Dow Chemicals, and Avantor, and are the leading supplier of excipients, active ingredients, and pharmaceutical chemicals in Turkey. A little more than two years ago, we took our first steps to engage with the Indian and Chinese pharmaceutical markets; the price pressures on our customers were significant enough that they felt it is not sustainable using higher priced supplies from Europe and the US, and there was a demand from our customers for products of reliable quality sourced from India.

We began to attempt to do business with Indian companies at this stage, but our efforts were unsuccessful as we struggled to find companies that we found trustworthy, sold products of consistent quality, and that were actually the producers and not middlemen misrepresenting

themselves. To work through these challenges, we opened a sourcing office in Mumbai two and a half years ago, and through this office we are able to audit, inspect and monitor our suppliers to ensure that the products we are importing to Turkey are of quality that we are comfortable bringing to our customers. This way we are able to provide different grade products at different price points, but of tightly monitored consistency, to our clients; we do not deal in lower quality products.

Does Turkey's growing reliance on Indian and Chinese products pose any risk to the industry?

In general, the Indian and Chinese market still have a lot of progress to make, regarding quality, supply stability and security, financial solvency, and even input availability. However, such issues must be expected in such a massive industry; I was told that there are over 1000 API producers in India alone! This figure is incredible, but majority of these companies are not reliable; the top 50 are fantastic, and there are probably a total of 100 to 150 companies that can be considered good partnership material, which is about ten percent of the companies in the industry.

Recognizing the potential for Indian and Chinese sourced products to jeopardize the quality of medicines manufactured in the EU, the European Directorate for the Quality of Medicines (EDQM) recently introduced regulations requiring that Indian and Chinese manufacturers provide a Written Confirmation to be allowed to sell their excipients or APIs in the EU. The Written Confirmation is a document demanded for each active substance. It has to be issued by a competent authority of the exporting country and confirms that the standards of good manufacturing practice and control of the manufacturing plant are equivalent to those in the European Union.

Currently, in Turkey it is solely the responsibility and challenge of the manufacturing company to procure good quality and safe raw material. However, if the procuring company does not have substantial experience and a reliable network in markets like India and China, it is very difficult, almost impossible, to ensure a sustainable product quality as you have hundreds of alternatives to choose from. At Ekin, we only supply from trustworthy suppliers who can comply to international quality standards. The local team in our Mumbai sourcing office develops long term relationships with local manufacturers and monitors our suppliers continuously.

What should the government do in your opinion?

The government is responsible for public health, and must set the rules for the market to ensure that all the products produced and sold in the country are safe, which means introducing policies to ensure that producers are using good quality excipients and APIs. The EDQM and FDA have

introduced these requirements following multiple public health incidents caused by adulteration and/or contaminated supply. We have discussed this issue with the industry leaders in Turkey, and they agree that in Turkey it will be to the benefit of the public and the industry at least to follow the EU's regulations.

Of course, most Turkish producers have their own quality standards and use good quality products, especially those that are exporting products to other countries, but not all companies have reliable and rigid internal controls. Pharmaceutical industry is one of the few industries that is wide open to health hazards and even one incident will harm the reputation of the whole industry. Government regulations on raw material standards will help prevent such cases of crisis and accelerate Turkish pharmaceutical industry's aim to become a more influential player in the international arena.

Looking at these challenges in the market, and your position as a company trying to provide safe products from reliable suppliers, what is the extra value that you bring to your clients?

While Turkish companies would like to use cheaper products, there are many advantages to using higher-grade products; of course, those seeking to export to the EU must use higher quality supplies. Moreover, using cheaper products poses many risks to the producer, the biggest being the risk of a recall or poisoning incident, so many companies think twice about the products that they are using. We represent the leading chemical producers in the world, so for the companies looking for top quality excipients, coatings, solvents, and other laboratory chemicals, Ekin Kimya is the supplier.

More importantly, we know what we are selling. It is critical that pharmaceutical manufacturers are 100 percent sure who their suppliers are, which means that if you are dealing with a trading company or distributor, you must trust them. We have seen distributors selling products with fake certificates of analysis, such that the quality of the products looks perfect on paper, but in actuality is no-where near that quality; when you contact the supposed producer, if you can get in touch with them to verify the analysis, they are shocked to see it an in some cases don't even produce the product that their logo has been put on. Ekin Kimya goes to great lengths, such as opening a sourcing office in India, to ensure we know who produces the products that we sell, where they produce them, and what exactly it is that we are selling.

However, when in terms of added value outside of our role as a vendor, Ekin Kimya is completely unrivaled in the Turkish market. In most cases, the industry doesn't consider us to be a supplier but a service provider and consultant of sorts, and as such we are members of the Turkish

Pharmaceutical Manufacturers Association (IEIS). The services we offer range from formulation support, to process consulting, R&D project outsourcing, and advise on a range of technical and regulatory subjects.

You're referring to you formulation laboratory; what are some of the services to provide to clients from this facility?

We represent the giant companies, they are producers on a massive scale, and innovators, but not service oriented companies. For example, one of our suppliers who is strong in excipients, including high-functionality excipients, as well as color coatings doesn't have a team in Turkey that can listen to the needs of their clients and provide them with the right solution; that's the job of Ekin Kimya in Turkey. We work closely with our clients to understand the challenges that they face, and provide solutions to overcome them, not just raw materials.

In general, our clients need support in formulation because while they may understand how they can improve some of their products, they don't have the time, money, and specialized people to develop the product and take it through a clinical trial. For this reason we decided to open our formulation lab to help support the industry's development; we are not their competitors, but partners, and we focus on contributing to the long term growth of the industry, not our own revenues in the short term. As such, most of the industry classifies us more as a service provider than a supplier.

The lab, which we opened two years ago, is 300 square meters, and started with an initial equipment investment of EUR 500,000. This was a key step to differentiate ourselves from other suppliers and is a key to our success in the coming years; we are very sure that it was the right decision. Now, after we talk to our clients about how they can improve their business, for instance how they should stop using sugar coatings on their tablets because we offer more cost effective solutions, which allow for faster production, we can actually help them develop the new product, take it through the necessary clinical trials, and get it registered. We also run many other projects, such as laboratory chemical optimization studies, where we look at the needs of the lab, what they are actually buying, and how they are currently using what they are buying; we then select the optimal products for them based on their precise needs, and this can create substantial savings.

Does your advising and consulting role extend to proving professional education?

Ekin Kimya is a key educator in the Turkish market; we regularly organize seminars and scientific meetings to discuss regulations, upcoming regulatory changes, how to select products, how they can be sure about the products quality, and many other important subjects. When you look at the

level of technical education in Turkey, it is not as high as in Europe, largely because Turkish culture doesn't embrace or encourage reading very much; people like to talk and listen instead. As such, they are happy that we can prepare and deliver presentations to them on different important subjects such as regulatory changes, and usually we are organizing at least two seminars per month. We also warn clients about upcoming regulatory changes due to changes in regulatory guidelines and the like, and explain how they must update their internal regulations to prepare for the changes; one year later, the changes we warn about usually become reality.

How is this role enhanced as by Ekin Kimya's position as the authorized Turkish distributor for USP?

Being an authorized distributor for USP, which is a foundation and not a company, is something we are very proud of. We are in contact with them every day, and as such have up to date information regarding global standards and regulations. Moreover, as USP's representative in Turkey we have organized six conferences in the past, which brought together the Turkish industry, academia, and government, as well as representatives from the USP, the FDA, and other foreign regulators. We are organizing the seventh edition at present, which will take place in November, and are also working to organize a regional level conference here in Istanbul. Some of the topics that we are planning include biopharmaceutical production and regulation, the need for regulation of raw materials, which we discussed earlier, and of course upcoming regulatory developments at the global and domestic level. It has severed as a great platform in the past, where perspectives from the government, industry, academic, and global authorities like the USP and FDA are all shared. The Turkish MOH has embraced the conferences in particular, as it serves as a chance for them to meet and share information with the FDA and USP; they are always asking when the next USP meeting will be.

As for the regional level conference, we feel that many of the topics that need to be discussed need to be set in a regional context. Looking at the need for regulating pharmaceutical inputs, each country has their own approach; we know how the EU is handling the situation, but we cannot say the same about countries in the Middle-East. As it has been for Turkey, we feel a regional USP conference would also serve as a great platform to discuss these issues, and for companies and governments from different countries to interact with each other. The Turkish industry is interested in such a conference due to the networking opportunities and potential to find export opportunities, while the government participants would benefit from the opportunity to discuss potential policy changes and regulatory strategies before putting them in place.

You mentioned biopharmaceuticals as a key topic; do you feel that Turkey is ready to take this step?

Turkey is moving towards biopharmaceuticals just as the global industry is; at present, 15 percent of pharmaceutical sales globally are biopharmaceuticals, and that number will rise to 25 percent in ten years. Turkey needs to develop some expertise in biopharmaceuticals and biotech due to this trend, and whether we are ready or not is somewhat inconsequential. Several Turkish companies like Nobel, Atabay, Koçak Farma, and Abdi Ibrahim are investing in biopharmaceutical; Abdi Ibrahim recently began construction of their AbdiBio facility, while the others are developing biosimilar products. So the market is moving in the direction of biotech, as it needs to be. However, this is not easy and biotech is a completely different world from generic pharmaceutical manufacturing. In the beginning many of these players didn't understand just how different and were saying its easy, we can do it; now they are starting to realize just how difficult it will be to get into this market, and that developing production for just one biosimilar API can easily take USD 100 million of investment.

Why do your multinational partners choose to work with Ekin Kimya in Turkey?

For the same reason as our clients: our reputation, experience, and trustworthiness. Many of the giants we work with for years, selected Ekin Kimya as their local distributor after interviewing many companies in the market, gathering opinions, and meeting with us and other chemical distributors in Turkey. Following this market research, they selected us, and they prefer us because of our behavior, approach, and our team. If they work with us, then it is a trouble free relationship for them.

What are your ambitions for the industry over the coming five years?

Turkey is becoming a regional pharmaceutical hub, and we hope this trend continues and accelerates. When you look to the state the assets and technology of the sector as a whole, 40 percent of production capacity isn't utilized, that capacity is quite high quality seeing as most plants have EU GMP or FDA approval, and the manufacturing teams are very well. When you think about the potential market for the Turkish pharmaceutical industry, don't think about a country of 75 million people, but a region of 280 million when you look at countries like Syria, Iraq, Iran, and others that Turkey is well positioned to serve. This is to say, that Turkey is in a transition period at present, but the future looks very bright.

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