Interview: Gökhan Gökçe Partner – YükselKarkınKüçük Attorney Partnership (YKK) – Turkey

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A founding partner of

YükselKarkınKüçük, Gökhan Gökçe discusses the firm's involvement with several high profile cases concerning the healthcare and life science sector's reference pricing system, and also elaborates on the strategic trends in different types of operating structures as a result of shifting dynamics faced by the broader Turkish pharmaceuticals and medical device sectors today.

As an introduction, can you please introduce yourself and your firm to our readers?

I am one of the founding partners of the law firm and currently head up a group called Intellectual Property, & Technology (IPT). Since the firm's beginnings, the pharmaceutical and medical device sectors have been under my scope. More broadly speaking, YükselKarkınKüçük is one of the leading institutional law firms in the country, employing around 100 lawyers and 50 administrative staff. We have a very detailed departmental structure where we offer expertise and expansive resources to our clients. For instance, on the corporate side, we've handled several larger M&A deals and high profile dispute resolution cases for the pharmaceutical industry. From the regulatory side, we advise on all lifecycle stages of a pharmaceutical product, from clinical trials to marketing authorization, from pricing to promotion. Other practice areas encompass employment, competition, and tax law, all of which incorporate the longstanding expertise and industry experience that our lawyers bring to the table, which is especially relevant for the complex dynamics of the pharmaceutical industry. That's the business philosophy of our firm. We know the

sectors, we know our clients, and we closely follow their activities to develop robust and effective legal solutions.

Specifically from a legal perspective, what are the common challenges pervasive across your pharmaceutical and healthcare clients today?

The government has pinpointed healthcare as a strategic sector to invest in and develop under vision 2023. Within this context, there's a large emphasis on attracting greater volumes of FDI in hopes of bolstering local production capabilities, technological innovation, and industry best practices. Given the country's favorable characteristics including young demographics, an effective reimbursement system, and relatively understandable legislative frameworks, Turkey serves as an appealing investment opportunity for many multi-national companies and local entrepreneurs. In terms of trends, localization and innovation are the most pertinent topics across the industry today. Not surprisingly, however, economic factors, such as pricing in particular, are placing downward pressures on all players across the value chain in terms of profitability.

Starting from 2004, the reference pricing system has been implemented. Perhaps more specific to Turkey, there are two government authorities controlling the dynamics of this system—the Ministry of Health, which sets the prices, and SGK, which provides reimbursement. Although both parties are supposed to be aligned with each other, they sometimes pursue differing strategies and day-to-day practices, making it difficult for market authorization holders to align their own strategic initiatives with the current economic and regulatory environment.

Under the reference pricing system, by definition, the prices for Turkish pharmaceutical products reference a basket of EU countries, including Greece, Spain, France, Portugal and Italy, and require real conversion rates to convert EUR to TRY. In the past, as a part of detailed legislation, the Price Evaluation Commission updated the fixed rate whenever the Euro band was exceeded. This was performed consistently up until 2009. However, starting from 2009 and in particular at the term following 2011, the Government has refrained from updating the so called "Periodical Euro Value" by relying on the excuse of controlling the public spend despite the explicit regulation that had been published by itself. Consequently, due to this illicit ad hoc implementation, the sector faced approximately 30 – 40 percent depreciation in value in the subsequent years. As a result, on behalf of the Association of Research-based Pharmaceutical Companies (AIFD) and the Pharmaceutical Manufacturer Association of Turkey (IEIS), we filed and won two lawsuits in the past four years against the Ministry and the other members of the Price Evaluation Commission for failure to update the periodical exchange rate. Now, the very recent legislation details that the reference price shall be 70 percent of the previous year's average EUR/TRY exchange rate, which will be the

basis for reference prices until January 2016. At 2.0787, the rate is still understandably low with only a slight numerical impact for pharmaceutical players. As such, the industry will most likely file further lawsuits to contend these decisions.

Other hurdles include lengthy marketing authorization procedures and a challenging reimbursement system, which subjects pharmaceutical products to mandatory institutional discounts. SGK publishes and frequently updates the Healthcare Implementation Communique (SUT) to include provisions on reimbursement details, such as authorized prescribers, medical assembly report requirements, and compensation percentage. Collectively considering all these economic implications, many global companies are instructed by HQ to refrain from expanding their commercial activities in Turkey—invariably causing significant supply shortages in the market. The implications of these inhibiting factors even extend beyond the country's borders, as Turkey is also utilized as a reference country by more than 20 other countries. Needless to say, the long-term commercial sustainability of Turkey is very much within the spotlight of both the public and private sectors at the moment.

Under vision 2023, the governments aims to position Turkey as one of the top 10 economies in the world for health services. In terms of regulation reforms or incentive mechanisms, what kind of support can the government provide pharmaceutical players in achieving this goal?

Trust, transparency, and predictability are all areas that the Government can improve in. Companies are working on a P&L basis, so they want to be able to forecast how much revenue they will generate and estimate how much costs they will incur. The current situation is bad in that sense. As a EU candidate, Turkey's legislative environment, to a significant extent, has been harmonized with that of the European Union's. That being said, however, there's substantial room for improvement. Positioning Turkey as one of the top 10 economies for health services is certainly an ambitious goal. In progressing towards this vision, one particular segment requiring further development is clinical trials. Turkey has strong fundamentals in that regard: growing population, widespread hospital network, talented medical staff, accessible medical services, and in turn, patients. In working towards a more innovative and higher value-adding Turkish pharmaceutical landscape, more efforts can be made to leverage these resources and attract all stages of clinical trials in the country.

How would you evaluate the shifting dynamics of current operating structures for pharmaceutical and medical device companies operating in Turkey?

Within the healthcare sector especially, the government is putting a large emphasis on localization. It seems that only importing products and selling them in Turkey will not be sufficient and sustainable. Considering the many limiting factors associated with importation, multinational companies are increasingly forced to localize production in Turkey in order to maintain a competitive positioning in the market. As such, we've seen multiple cases of asset takeovers or shares acquisitions. Furthermore, aside from the longstanding players who utilize their own manufacturing plants, a large number of companies have traditionally been operating in Turkey through distributors and toll-manufacturing agreements with local companies. Now, in the interest of profitability, efficiency, and long-term sustainability, many of these pharmaceutical and medical device companies are contemplating on going direct to market.

Additionally, the Turkish Pharmacists Association (TEB) has conventionally been the solely dedicated entity for importing both registered and unregistered products from abroad. Recently, SGK commenced an initiative to involve more Turkish affiliates of multinational pharmaceutical companies with importation. Currently, although more so in the past, trading companies have been supplying products to TEB, after which point, TEB would sell to SGK. Now, the subsidiaries of those large manufacturers in Turkey will be the ones interacting with SGK and adopting alternative reimbursement models. This scheme will enable foreign companies to be more involved in Turkey and allow them to expand their current operating structures and commercial capabilities in Turkey.

What makes YükselKarkınKüçük the ideal partner of choice for the pharmaceutical and healthcare industry?

Simply put, experience, expertise and efficiency. At the end of the day, we are performing consultancy services, which are predicated on the human factor. Establishing trust is perhaps the most fundamental component in having any degree of productive dialogue with our clients—a decree that's been communicated top down in YükselKarkınKüçük. In addition to our local client network, we are in close cooperation with leading foreign law firms, which helps us improve our services in line with global standards and share know-how. In conclusion, aside from our international network and alignment with global standards, we pride ourselves on providing our clients with the utmost standards in reliability and expertise. Perhaps as a testament to our success, we've been trusted and involved with several high profile cases in the past, such as the ones with AFID, that have materially impacted industry-wide operating standards for all players across the value chain.

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