Life Sciences 2017

Last Updated November 07, 2016

Turkey

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Gün + Partners (http://www.chambersandpartners.com/Europe/firm/357323/nsn-law-firm) was founded in 1986 and is now one of the largest law firms in Turkey, with over 65 lawyers. The firm is based in Istanbul and provides transactional, advisory and dispute resolution services to local and international companies throughout Turkey and assists clients worldwide through its established network of correspondents and contacts. The firm's core areas of expertise are corporate and commercial, dispute resolution and IP. It represents clients in numerous industry sectors with a particular focus on life sciences, insurance and reinsurance, energy and natural resources, real estate and infrastructure, technology, media and telecom. The firm's clientele is a blend of foreign and local, medium-sized and large corporations, as well as government organisations and NGOs worldwide, with the majority from the UK, US, Europe and Asia-Pacific regions.

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Turkey

With Turkey having a population of 80 million covered by an extensive social healthcare system, the size and volume of the Turkish life science industry is significant. Additionally, as the 15th largest economy that – with the inauguration of the Health Transformation Project enacted in January 2003 – aims to position itself as a regional hub for healthcare tourism, Turkey's life science industry also presents many opportunities for investment and growth.

However, despite the many opportunities that accompany this potential for growth, it should also be noted that both the Turkish pharmaceutical and medical device industries remain heavily regulated. One result has been a decrease in profits for pharmaceutical companies in the past ten years, mainly due to measures enacted to ensure greater public savings on the health budget. However, as highlighted in an article published in the special tenth-year edition of Forbes in Turkey in December 2015, this has not had a negative effect on investment, and companies continue to view the Turkish life science industry as a worthwhile investment prospect.

Pharmaceutical industry

The pharmaceutical industry in Turkey is heavily regulated, with all aspects ranging from market access to pricing and reimbursement being covered by industry-specific regulation. Furthermore, said measures are strictly enforced by the relevant body of the Ministry of Health ("MoH"): the Turkish Pharmaceutical and Medical Device Institution ("TITCK").

New pricing decree and communiqué

In Turkey the prices of pharmaceutical products are determined in accordance with strictly defined steps that involve reference prices taken from a set of predetermined reference countries. Furthermore, the foreign exchange rate used to convert the lowest of said reference prices to the equivalent Turkish ex-factory price is also fixed and does not accurately reflect the current exchange rate. In fact, said exchange rate had been fixed at the 2009 rate and was only revised in 2015 following a court ruling upon challenge by the pharmaceutical industry.

Consequently, pricing has always been a hot topic in Turkey, as the prices of pharmaceuticals are consistently the cheapest among all European countries. In 2015, some of the areas of complaint – particularly the lack of regular update for the euro exchange rate – were addressed in a new Council of Ministers Decision and subsequent Communiqué on the Pricing of Pharmaceutical Products. Pursuant to the new Council of Ministers Decision, the euro exchange rate to be applied to the pharmaceutical pricing process will be updated annually, with the annual euro exchange rate being set at 70% of the previous year's Turkish Central Bank average euro value.

Thus, while the problem persists with the set exchange rate not accurately reflecting the most current rate, this recent development has addressed the previously unbalanced system in which years passed before the euro exchange rate was updated. Furthermore, even though the reference price system remains, the pricing decision and communiqué have identified different categories of pharmaceutical products that will be subject to different pricing regimes. In this sense, the new pricing decision and communiqué have simplified the previously complicated pricing regime and have allowed for slightly more favourable pricing determinations to be applied for pharmaceutical products that are of particular importance to public health.

In connection with these special categories of products that have been recognised in the new communiqué, there have been positive developments towards the official definition and recognition of orphan drugs, a category of pharmaceutical products that had previously been referenced in legislative measures but had not been granted official designation. Currently, with TITCK authorisation, the industry is working on a draft legislative measure that will define the scope of the orphan drugs designation in Turkey and will determine the incentives that will be given to pharmaceuticals that are granted such designation.

Localisation and prioritisation

A recent trend, particularly with regard to the pharmaceutical industry, has been increased efforts on behalf of Turkish public institutions to increase localisation of pharmaceuticals. While such efforts have included measures incentivising manufacturers, a greater number have been measures that discriminate against imported pharmaceutical products. Although official figures and statements have not been released on the reasons behind this push for increased localisation, it is widely believed that these measures are being implemented to counter the effects that the cost of imported pharmaceuticals is having on an increasingly depleted national health budget.

A primary example of an increasing trend towards localisation can be seen in the MoH's policy towards Good Manufacturing Practice ("GMP") certificates that have been issued by non-Turkish authorities such as the FDA or EMEA. As per this policy, certificates issued by such bodies are not accepted as valid, with MoH personnel being tasked with conducting inspections at the foreign manufacturing sites of the market authorisation ("MA") holder. The only exception to this on-site inspection is for GMP certificates issued by a country that recognises the GMP certificates issued by the MoH.

In practice this requirement for on-site inspection has led to a degree of discrimination between domestic and imported pharmaceutical products, with the advantage being with domestic products with localised manufacturing. In addition to the obvious delays caused by the logistic requirements of having MoH personnel inspect foreign manufacturing sites, the fact that GMP inspections for imported products are conducted on a "product" basis while domestic manufacturing sites undergo GMP inspection on a "site" basis, and the fact that a maximum inspection time period has only been foreseen for domestic inspections, add to the discrepancy between imported and domestic pharmaceutical products.

Another example of this trend towards promoting localisation can be seen in the practices of the Social Security Institute ("SSI"), the state institution in charge of the administration of the reimbursement system. As the majority of pharmaceutical products sold in Turkey are sold through the reimbursement system, it is of vital importance for such products to be included on the list in a timely and transparent manner. However, currently there is no transparency with respect to the evaluation for entry onto the reimbursement list, with a discretion granted to the SSI to prioritise the application of domestic products. Furthermore, in the Structural Transformation Programme

Action Plan for Healthcare Industries announced on 7 November 2014, an action point was included that detailed plans to exclude imported pharmaceuticals, which have generic equivalents in Turkey, from the reimbursement list.

The introduction of a prioritisation application for the evaluation of MA applications also reflects this trend towards increased localisation. With the recent publication of the Turkish Pharmaceutical and Medical Device Institution Guidelines on the Working Principles of the Pharmaceutical Product Prioritisation Commission ("Prioritisation Guidelines"), a new system has been introduced that will allow prioritisation to be granted to MA applications. The Prioritisation Guidelines explicitly state that prioritisation evaluations will also focus on the impact the granted MA will have on public savings and for products that will contribute to the national economy by reducing imports and by increasing local production. Due to the delays that MA applications not granted priority are expected to encounter, in effect it will become mandatory for all MA applications to file an application for prioritisation, thereby subjecting their product to an analysis of impact on public savings and the health budget.

Furthermore, another potential development that may pose a risk to foreign stakeholders in the pharmaceutical industry is the provisions relating to compulsory licensing that have been included in the draft Industrial Property Rights Law that is currently being debated before the relevant commissions before being introduced to the Turkish Parliament. Under said provisions, compulsory patents may be granted on the grounds of public interest or, as per one of the new grounds introduced in the draft, on the grounds of public health in the situation that the patent has not been "worked" to a sufficient degree. This requirement for working entails that the use of the patented invention must reach a level to satisfy the needs of the national market.

Procurement of pharmaceuticals from abroad and alternative reimbursement

In the situation that a pharmaceutical product that has not applied for MA in Turkey (or is currently unavailable on the Turkish market) is deemed necessary by a physician within the scope of a named patient programme, said pharmaceutical is procured from abroad, most commonly at a higher price and reimbursement level than had the product been granted MA in Turkey. However, with the occasionally unfavourable pricing conditions in Turkey leading to a number of pharmaceutical companies delaying or reconsidering their entrance to the Turkish market, the number of pharmaceuticals being procured from abroad has increased, thus taking up an increased percentage of the public health budget.

Following a ruling by the Council of State that ruled against importers other than the Turkish Pharmacists' Association ("TEB") procuring pharmaceutical products from abroad within the context of named patient programmes, the TITCK updated their Guidelines on the Procurement from Abroad and Use of Pharmaceuticals ("Procurement Guidelines"). As per the new Procurement Guidelines, while the underlying system and process of procurement from abroad have remained the same, a provision has been added stating that procurement from abroad only be utilised "once all treatment options in Turkey have been used or there is an obstacle to these options being used on a patient." Thus, the scope of use of procurement from abroad on a named patient programme basis – a method of treatment that is costly for the MoH and SSI – has been narrowed down.

In relation to procurement from abroad and in keeping with the trend of measures aimed at reducing public health spending, the SSI has started to increasingly engage companies manufacturing such pharmaceuticals on the basis of alternative reimbursement models pursuant to the Alternative Reimbursement Regulation that came into effect in February 2016. The most commonly encountered form of the engagement by the SSI is an alternative reimbursement agreement that fixes the price of the product that is being procured from abroad and, more importantly, obtains an undertaking from the company to apply for an MA for their product within one year of the signing of the agreement.

Consequently, by placing pressure on foreign pharmaceutical manufacturers to enter into this agreement, the SSI is imposing a lower price on pharmaceuticals procured from abroad, while ensuring that in the long run said products are introduced onto the Turkish market and thus subject to detailed measures relating to price determination and reimbursement.

Value transfer disclosure

An important recent development in the Turkish pharmaceutical industry has been the introduction of the obligation of disclosure of value transfers provided to healthcare professionals, healthcare institutions and organisations, universities, unions and foundations active in the field of healthcare and NGOs established for the purpose of the protection and the advancement of health.

This new obligation was introduced with the new Pharmaceutical Promotion Regulation and will require MA holders to disclose to the TITCK any value transfer with a monetary value exceeding 10% of the applicable gross minimum wage (currently the gross minimum wage is set at GBP395). The period of disclosure of such value transfers will begin with the disclosure of transfers made during 2016.

The introduction of this requirement is definitely in line with recent developments in the Turkish life sciences industries that favour increased transparency, particularly in areas relating to regulating relationships between companies and healthcare professionals. While this obligation was heavily influenced by the industry association-

based obligation of many foreign pharmaceutical companies to publicly disclose such value transfers, the obligation in its current form only foresees a disclosure to TITCK rather than a more general disclosure to the public.

Medical device industry

While not as heavily regulated as the pharmaceutical industry, the Turkish medical device industry is also subject to regulations that determine market access, sales, promotion and advertisement. Furthermore, as is the situation with pharmaceuticals, the medical device industry also falls within the scope of Turkey's reimbursement model.

However, unlike the pharmaceutical industry in which recent trends and developments have mostly indicated a preference for increased localisation and preference of domestic companies, trends and developments in the Turkish medical device industry have given rise to a number of opportunities for increased market access of foreign companies and new venues of advertisement for various categories of medical device.

Harmonisation with applicable EU Directives

The manufacturing of medical devices in Turkey is governed by three main regulatory measures, the Medical Device Regulation, the Regulation on Active Implantable Medical Devices and the Regulation on In Vitro Diagnostic Medical Devices. These three primary measures were designed to be in accordance with the relevant applicable EU Directives and have integrated the amendments to such directives up to the changes introduced with Directive 2007/47/EEC. Additionally, the MoH has stated that a draft Medical Device Law is being worked on. While it is currently unknown whether this draft will incorporate EU developments with regard to the proposed Medical Device Regulation, as Turkish medical device regulation has generally developed in parallel to EU regulations, it is expected that any draft procedure will reflect the important EU developments.

The main advantage of having Turkish medical device regulations that are in line with the relevant EU Directives is that this harmonisation allows for devices with CE markings to be freely introduced to the Turkish market without any further obstacles being introduced. Furthermore, the applicable regulations allow medical devices that have been manufactured in accordance with harmonised standards published by the EU to be placed on the Turkish market without having to undergo further compliance tests to determine whether they satisfy the basic requirements for such devices as listed in the annexes of said regulations. By placing such important equivalence on EU standards and CE certification, a definite advantage has been afforded to European medical device companies that are planning to enter the Turkish market.

Registration and certification requirements

While there is an ease of market access for medical devices that have been manufactured in accordance with EU standards, it should be noted that all medical devices that are introduced to the Turkish market are subject to a registration requirement. As per the relevant provisions of the Medical Device Regulation, medical devices that have been placed on the Turkish market and those responsible for placing these devices on the market must be registered with the MoH. Furthermore, in the situation that a foreign manufacturer plans to place a device on the Turkish market using their own brand name, an authorised representative must be designated within Turkey. Said designated representative will be the party that undertakes the registration for the medical devices to be placed on the Turkish market.

The registration requirement has been determined as the registration of devices and companies on the Turkish National Pharmaceutical and Medical Device Database ("TITUBB"). The TITUBB database can be publicly searched and – on an administrative level – the database and the approved/unapproved status of the products are integrated into the verification databases maintained by the MoH, the SSI and the Public Procurement Authority. With the most recent administrative developments regarding TITUBB, including a support call centre and regularly updated user manuals placed on the official website, registration procedures have become a more readily accessible process.

Another development with regard to official requirements of registration and certification for medical device companies was introduced with the Regulation on the Sales, Promotion and Advertising of Medical Devices ("Medical Device Promotion Regulation"). As per the Medical Device Promotion Regulation which came into effect on 15 May 2014, a general certification requirement was introduced for companies engaged in the sale of medical devices in Turkey. While not intended as a complementary measure to the requirement to register to TITUBB, this requirement for certification can also be viewed as a part of the trend of ensuring that the medical device industry can be tracked by the MoH and that the relevant stakeholders can be subjected to increased accountability as a result of their activities.

The certification obligation requires such companies to obtain certification as "sales centres" from the TITCK. While the general conditions and the contents of the application file have been detailed within the relevant provisions of the Medical Device Promotion Regulation, the most important of these conditions relate to mandatory key personnel that must be employed by such sale centres. As per the Medical Device Promotion Regulation, any such sales centre must employ a qualified director who will be responsible for all actions of the sales centre, at least

one certified sales and promotion personnel and, if necessary, a suitable number of clinical support personnel. In this sense, the requirement for mandatory certified personnel follows the previous developments in the pharmaceutical industry, which also introduced such requirements for Turkish MA holders.

Reimbursement

Unlike the pharmaceutical sector, where the reimbursement prices for each product are determined and listed on the Health Budget Notification (which is published and updated by the SSI), the reimbursement determinations for medical devices are made based on general product category. In this sense, as a maximum reimbursement price is determined for each category of medical device within the Health Budget Notification, a maximum sales price is determined, as public institutions are unwilling to accept higher-priced offers which fall outside the scope of reimbursement.

Furthermore, while such reimbursement practices do not have the same effect as the trend towards localisation in the pharmaceutical industry, it can be said to create a slight advantage for domestic producers. This advantage is mainly due to the fact that the reimbursement prices are listed for each product category, rather than for individual product type of brand, with this price being determined by taking into account all such medical devices of the same category on the market. Therefore, certain categories or packages of products may be set at a lower rate than the preferred price for foreign, research-based medical device manufacturers. The determination of reimbursement prices is further complicated by the fact that reimbursement prices are not regularly updated to reflect the changes in foreign exchange rates. In this sense, a medical device company that is granted a reimbursement price when they first enter the market may find that, due to failure to update the foreign exchange rate, the determined price no longer reflects the cost of manufacture or importation.

Therefore, while entrance to the medical device market has been maintained as easier when compared to the pharmaceutical market, the reimbursement practices can be said to present slightly more favourable conditions for local manufacturers. However, it should be noted that previous examples in which the reimbursement rates for product categories as stated in the Health Budget Notifications were updated to a level that was perceived as too low by many foreign manufacturers, were later reversed due to public institutions being unable to procure medical devices that were essential for their medical procedures.

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