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Lexology GTDT Pharmaceutical Trademarks 2023 Questionnaire – Turkey Chapter

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Legislation

1. What is the primary law governing trademarks in your jurisdiction?

The Industrial Property Law (‘IP Law') is the primary source in which the trademark law is regulated. The IP Law was published in the Official Gazette on 10 January 2017, with the majority of provisions entering into effect on the same date. The relevant international agreements to which Turkey is a signatory, namely the Paris Convention and the Madrid Protocol, are also applicable in Turkish trademark law.

Agencies

2. Which agency is responsible for the grant and registration of pharmaceutical trademarks?

The Turkish Patent and Trademark Office ('TPTO') is the authority overseeing all types of trademark registrations including pharmaceutical trademarks.

Also, during the marketing authorization proceedings, Turkish Medicines and Medical Device Agency approves the trademark that the pharmaceutical is to be put in the market.

Regulators

3. What are the relevant national and international regulatory bodies and requirements that need to be considered when clearing a pharmaceutical trademark?

Trademark registrations are handled through TPTO. Within the scope of marketing authorization proceedings, the Turkish Medicines and Medical Device Agency also approves the name of the product. These two proceedings are entirely different and do not affect each other. That is to say that obtaining a trademark registration does not mean that the Agency will approve the product's name and obtaining a marketing authorization does not mean that the trademark is going to be registered directly.

Within the scope of the absolute ground examination held by the TPTO, the following are considered:

- Being almost similar to an earlier registered trademark
- Not being distinctive, being delusive, and being descriptive e.g. being dominantly composed of an INN and commonly used in the relevant part of the health sector - customary medicines.

Within the scope of relative grounds examination, TPTO considers the risk of confusion with third-party trademarks. As the average consumer groups are considered to be pharmacists and healthcare professionals, a high level of similarity is sought for recognizing the risk of confusion especially for pharmaceutical goods covered by Class 05. It should be mentioned that the TPTO's approach is not the same for each subclass covered by Class 05: it relaxes its strict approach for the subclasses not covering pharmaceuticals depending on the level of similarity. The decisions of the courts in cases filed against the decisions of the TPTO show that the Court has a stricter approach towards

pharmaceutical trademarks, especially on evaluating the attention level of healthcare professionals.

Regarding the specification on the pharmaceutical goods covered by Class 05, the applicant should also pay attention does not use the trademark names of the commonly used active ingredients. There are too many active ingredients which are known dominantly with their trade names. These are mostly at the limit of losing their source indicating character and become a generic word and indeed there might be jurisdictions which the trademark was cancelled due to becoming a generic word. Accordingly, while managing a multi-country filings at the same time, it is important to flag this issue, as the TPTO asks amendments for these filings which causes delays in the registration proceedings.

The TPTO keeps a record of INNs and they are not available to be registered as a trademark, for anyone's exclusive use. The examiners strictly consider these INNs during the absolute grounds examination.

When granting a product marketing licence, the Agency reviews and approves the names of the pharmaceutical products. According to the Regulation on Packaging Information, Inserts and Tracking of Medicinal Products , the name of the pharmaceutical product cannot be similar to an INN or an extensively used name of a product. The Regulation on Licensing of Pharmaceutical Products does not provide any rule for approval of pharmaceutical names by the Agency, though the Pharmaceutical and Medical Preparations Law states that a ‘suitable name' is one of the conditions for the approval of the licence. However, it is very clear that the Agency does not consider the IP Law perspective. The Agency's primary concerns when approving names are avoiding medication errors and ensuring comprehension by doctors and pharmacists. There is no doubt that the similarity examination is not carried out with the same methods as by the TPTO.

The Regulation on Licensing of Pharmaceutical Products regulates that a pharmaceutical product for human use cannot be licensed with the same name as a traditional herbal medicinal product or a homeopathic medicinal product.

Non-traditional trademarks

4. What non-traditional trademarks are available in your jurisdiction and how are they registered?

The approach towards non-traditional trademarks is rather strict according to the Turkish Law and practice. There is no direct provision in the IP Law regarding the registration of non-traditional trademarks, so the principles/ conditions applied to the registration of other signs are also applied to non-traditional trademarks.

The commonly filed pharmaceutical-related non-traditional trademarks are shapes of pills, pill containers, plasters and medical devices. Getting a registration for a non-traditional trademark is not a straightforward proceeding. In most cases, the registration proceedings escalate to the IP Courts, and the Court decides on the registration.

Nevertheless, the Office would like to clearly determine the scope of the protection of the non-traditional trademarks in this regard. For example, for 3D trademarks it requires the visuals of the products from up to six different angles (back/front sides, up/down sides, and left/right sides). The aim is to provide the 3D depth of the application, without affecting the integrity of the trademark.

There is no doubt that the Office requires a certain level of distinctive character which serves the purpose of the source indication function of trademarks. In other words, the Office would like to see that the non-traditional trademark is readily distinguished by consumers.

The Office is strict regarding applications that consist of the nature or shape of the products and when there are only aesthetical re-touches.

Cannabis-derived products

5. Does your jurisdiction allow the registration of cannabis-derived products?

Unlike some EU countries, Turkey has a rather strict drug policy including for cannabis/marijuana. All forms of cannabis, including its use for medical purposes, were strictly prohibited under the Turkish law until 2016. Even now, the sale or growing of cannabis or even possessing cannabis for personal use are illegal and accepted as a crime under Turkish Criminal Law numbered number 5237. In 2016, the Turkish government legalized the production of cannabis in 19 Turkish provinces only for medical and scientific purposes by adopting The Regulation on Growing and Control of Cannabis. The growing of cannabis is tightly controlled by the Ministry of Agriculture and Forestry. Those who wish to grow these plants should have a growing licence which is limited to only three years.

In the meantime, the Turkish Medicines and Medical Devices Agency has published the list of pharmaceuticals which could be imported from abroad. The pharmaceutical, with the active ingredient "Tetrahydrocannabinol and cannabidiol", is included in the list dated 12 February 2016. The reference code of pharmaceutical products belongs to the medication SATIREX.

A Turkish patient can obtain these cannabis-based medications only by getting a red prescription from a doctor. However, it must be determined that the patient will receive a treatment from the cannabis-derived medication which cannot be achieved by another conventional medication. Moreover, these cannabis-derived products are imported from abroad for the specific use of the relevant patient. In summary, the importation of cannabis-derived medications depends on strict and specific conditions.

Parallel imports

Regulation

6. What are the rules governing parallel imports of pharmaceutical goods?

The IP Law adopted the international exhaustion principle which means that where goods have been legally sold by the trademark owner or its authorized representatives in any international market, such sale leads to an exhaustion of the right of the trademark owner to prevent the further sale of such goods anywhere internationally.

As long as genuine goods are being imported, trademark infringement will not arise unless the goods that are subject to parallel import are changed or damaged.

However, the importation of pharmaceuticals is a strictly regulated area which has specific provisions. Pharmaceuticals can only be imported and commercialized by the company which holds the marketing authorization from the Ministry of Health. A marketing authorization is granted only to the Turkish subsidiary of the pharmaceutical manufacturer. Therefore, since it is only granted to one company, in practice other companies are not allowed to import the pharmaceutical.

These restrictions mean that in practice parallel import of pharmaceuticals is not allowed in Turkey. In cases where genuine pharmaceutical products are introduced into Turkey, issues on selling unlicensed pharmaceuticals and smuggling will arise.

Strategies against parallel imports

7. What strategies are available to police and enforce against parallel imports?

For pharmaceutical products that require marketing authorisation to be marketed in Turkey, parallel import is not possible. Pharmaceuticals can only be imported and commercialized by the company that holds the marketing authorization from the Ministry of Health. Marketing authorization is granted only to the Turkish subsidiary of the pharmaceutical manufacturer. Therefore, as a part of a dealing strategy, the Customs can be informed about the details of the marketing authorization holder and its Turkish subsidiary.

Since parallel importation of the goods do not constitute trademark Infringement and thus allowed InTurkish practice, imports of pharmaceuticals are strictly followed. Parallel imports bring up the issues of sale of unlicensed pharmaceuticals and smuggling will arise.

As per the reference of Pharmaceutical and Medical Preparations Law article 19 in accordance with the Anti-Smuggling Law, the import of pharmaceutical products without a market authorisation constitutes smuggling and will be punished.

Furthermore, as per the reference of Law on Pharmacists and Pharmacies article 43, the act of selling unlicensed pharmaceuticals should be punished in accordance with provisions of article 193 of the act of producing and trading toxic substances crime that is issued under the Turkish Criminal Law

These issues are prosecuted ex officio by the Public Prosecutors. Therefore, ex officio police raids are possible.

As such goods are not entering Turkey through legal ways, effective tools include working collaboratively and developing a strategy with police and Public Prosecutors. As altering the trademark or damaging products also constitute trademark infringement, these ex officio criminal proceedings are or can be followed or accompanied by trademark infringement claims.

Anti-counterfeiting and enforcement

Types of proceedings

8. What types of legal or administrative proceedings are available to enforce against infringing products?

Trademark infringements can be challenged through:

- Civil actions
- Criminal actions
- Administrative measures

It is possible to start criminal proceedings against the infringing party by filing a criminal complaint, which is followed by seizure of the counterfeit goods. The confiscation and destruction of counterfeit products and a criminal sentence (which is 1 to 3 years imprisonment and a judicial fine of up to 20,000 days-in accordance with the daily limits stated in the law-) is rendered against the infringer at the end of the proceeding. However, it is usually expected that an identical or almost identical trademark is used on the counterfeit products in order to accept the infringement claim in prosecution/criminal proceedings.

Apart from trademark infringement, producing and selling counterfeit pharmaceuticals is specifically accepted as a type of crime in Article 187 titled Production or Sale of Medicine such as to Risk the Life and Health of Others and Article 186 titled the Trade of Decayed or Transformed beverages or pharmaceuticals of Turkish Criminal Law. For these crimes, a penalty of imprisonment for a term of one to five years and a judicial fine is imposed and if the offence is committed by a physician or pharmacist or in the course of a profession or trade which is subject to official permission the penalty shall be increased.

Furthermore, as per the reference of Law on Pharmacists and Pharmacies numbered 6197 article 43, the act should be punished in accordance with provisions of article 193 Producing and Trading Toxic Substances crime that is issued under the Turkish Criminal Law.

Since the injured party in all the above-mentioned crimes (excluding trademark infringement) is the public or the state (if the pharmaceuticals are smuggled), those crimes are defined as the crimes against the public health/state. In such cases, the owner of the trademark or the licensee is not a party to the criminal proceedings. The investigation would be conducted by the public prosecutor ex officio in favour of the public.

A suspect accused of infringing the products can be charged for all of the mentioned offences that arise out of their single act of producing and selling unlicensed/counterfeit pharmaceuticals. If a criminal proceeding has been initiated ex officio in favour of the public against these products, after that (depending on the nature of each case) a trademark infringement complaint can be filed as well.

Also, the Ministry of Health has an online system named Pharmaceutical Track and Trace System to deal with counterfeiting, smuggling, falsification, bar code scamming, illegal diversion and the distribution of pharmaceutical products within Turkey's supply chain. Furthermore, the track and trace system enables easy recall procedures when urgent requirements arise - which was a plus during the Covid-19 pandemic for collecting the pharmaceuticals that were used during treatment protocols.

The Law on Pharmacists and Pharmacies article 18 foresees administrative fines for pharmaceutical products that are not produced in accordance with the marketing authorization files, in case such action does not constitute a crime in terms of the Turkish Criminal Law and Anti-Smuggling Law.

Remedies

9. What are the available remedies for infringement?

According to the Turkish IP law, the following remedies are available (which are subject to a civil action):

- Preliminary injunctions to prevent the infringing act
- Cessation and prevention of infringement
- Compensation for:
    - Actual loss
    - Material damages
    - Immaterial damages
- The disclosure of the court's judgment by means of publication to the public, the costs of which are to be met by the defendant party.
- Handing over documents in the possession or property of the infringer;
- Delivery up / destruction of infringing products;
- Recall of infringing products and removal from the market;
- Reimbursement of the official court expenditures and fees for bringing the action.

Border enforcement

10. What border enforcement measures are available to halt the import and export of infringing goods?

When considering border enforcement measures, it should be kept in mind that where counterfeiting activities on pharmaceutical trademarks are on the table, there are other strict restrictions on export and import of pharmaceutical products. Non-compliance to these restrictions constitutes crimes regulated in the Turkish Criminal Law and Anti-Smuggling Law which are closely followed by Customs officials, police and related bodies of the Presidency. The customs authority is entitled to ex officio act in a smuggling case and the suspected persons belongings, loads and vehicles can be searched by customs officers for customs control purposes. If they detect that the goods are smuggled, they can seize the products immediately. If such a case occurred specifically for pharmaceuticals, it is also subject to an administrative fine pursuant to Article 19 of the Pharmaceutical and Medical Preparations Law.

In matters only related to trademark infringement, the customs authority does not take any ex-officio actions against possible counterfeit goods at the borders. The trademark owners should file a customs watch application before the Customs Authority to monitor the export or import of possible counterfeits. The Customs Authority has an online system where customs watch applications can be filed. When a trademark owner has applied for a customs watch,

the Customs Authority informs the recorded trademark agent of the holder about the suspicious products bearing the same/almost similar trademarks and suspends these products for 10 working days for any possible trademark infringement claim to be filed. The right owner has the right to examine the products first and then file a complaint and start a criminal action against these products. If no proceeding is started, the suspected goods are released by Customs.

The import of pharmaceutical products is strictly regulated, but export proceedings are not the same. This causes the export of parallel-imported goods from Turkey into other countries. Controlled pricing policies provide lower prices for pharmaceutical products in comparison to other markets, and this makes Turkey an attractive point for markets where products are priced higher. If parallel import is not available at the destination country, these kinds of activities will be considered within the scope of anti-smuggling laws. In order to circumvent this option, the pharmaceutical companies tend to include non-import clauses in their agreements with relevant parties in Turkey taking into account competition law requirements as well.

Online pharmacy regulation

11. What rules are in place to govern online pharmacies?

The sale and distribution of pharmaceuticals is strictly regulated by the Turkish Ministry of Health and the online sale of pharmaceutical products is explicitly prohibited by the law. The Law on Pharmacists and Pharmacies regulates that the sale of pharmaceuticals is restricted through the internet or any other online environment and a website cannot be operated on behalf of a pharmacy and pharmacist.

Moreover, this restriction is not only limited to pharmaceuticals but also applied to traditional herbal medical products, homeopathic medicinal products, dietary foods for special medical purposes including enteral nutrition products, and special medical purpose baby food. These products can be sold exclusively in the physical store of pharmacies. Though, the products, supplements that are governed by Ministry of Agriculture and Forestry do not fall into this limitations.

There is a notable rise in the sale of pharmaceuticals through online platforms and this raises many concerns about public health since most of them are unauthorized or counterfeit products. In recent years, the Ministry of Health has strictly controlled online markets where these prohibited products are sold and has cancelled these websites and imposed fines.

Recent cases

12. What are the most notable recent cases regarding the enforcement of pharmaceutical marks?

Post-Covid-19 measures caused delays in supply chains which caused a growing trend in smuggling and counterfeit cases, in this regard there were many police operations for counterfeit pharmaceutical products.

Many of these police operations had made to the headlines. Enormously high amount of counterfeit pharmaceutical products was seized including the ones used in Covid-19 treatment protocol, steroids, slimming and fat-burner products. Raising demands for vitamins during the pandemic has increased counterfeiting activities for that area as well.

In addition, due to its geopolitical position in the Middle East and Europe, Turkey faces serious problems regarding drug diversion and drug trafficking and continues to be a smuggling route for the illegal drug trade. Beyond the trademark infringement perspective, drug trafficking in Turkey is handled by government and police forces as well as by international operations.

Authorities conducted counterfeit drug operations in various cities, most notably in Istanbul. In Istanbul, an operation was carried out against suspects who bought many drugs, including cancer drugs, from pharmacies with fake

prescriptions issued on behalf of others, and sold them at exorbitant prices in war zones. While 10 people were detained in the operation, drugs with a market value of 15 million TRY were seized. There were also actions conducted against suspects determined to produce and sell hormone drugs used for bodybuilding. In an action, a large number of hormone drugs worth 14 million TRY were seized.

Pharmacies and cosmetic stores were inspected regarding the sale of counterfeit drugs and medical products, and sanctions were imposed. Under the coordination of the Interpol General Secretariat, the operation named "Pangea XV" was carried out in order to increase cooperation between international units in the fight against the illegal trade of medical products against manufacturers, distributors and websites of fake and illegal medical products.

Advertising

Regulatory bodies

13. Which bodies are responsible for oversight of pharmaceutical advertising in your jurisdiction (and what are their powers)?

The Turkish Radio and Television Supreme Council and the Advertisement Board are the main administrative bodies overseeing the issues for the use of misleading information and health claims in advertisements for pharmaceuticals and food supplements. Both the Advertisement Board and The Turkish Radio and Television Supreme Council are entitled to order the cessation of the broadcast of the said advertisements in any media and to impose an administrative monetary fine against advertisers and media channels regarding prohibited and misleading advertisements.

Advertising rules

14. What specific rules are in place regarding the advertising of pharmaceutical products?

Advertising of pharmaceutical products is regulated by Pharmaceutical and Medical Preparations Law and the Regulation on Promotional Activities of Medicinal Products for Human Use. Moreover, the general regulations on advertisements, such as the Law on the Protection of Consumers and the Regulation on Commercial Advertisements and Unfair Commercial Practices, also apply to advertisements.

Advertisements for prescribed pharmaceuticals are not allowed. Although the legislation does not specifically address non-prescribed pharmaceuticals, under Turkish law regulations regarding pharmaceuticals are applied for non-prescribed OTC products, including advertising bans.

According to the Regulation on Promotional Activities of Medicinal Products for Human Use, the only exception to the no-advertisement rule is for promotional activities addressed to healthcare professionals. Promotion of pharmaceuticals can be performed for healthcare professionals under certain circumstances such as by using promotional materials specifically addressed to physicians, dentists and pharmacists, or organizing or supporting scientific meetings and product promotion meetings, or visiting physicians, dentists and pharmacists by product promotion representatives.

Medicinal products that are used in cases such as vaccination campaigns and epidemic diseases that are important in terms of public health can also be subject to information campaigns carried out by the Ministry of Health to promote health, or by obtaining permission from the Ministry and within the framework of the procedures and principles approved by the Ministry.

Generic substitution

Legality

15. Is generic substitution permitted in your jurisdiction?

Generic pharmaceuticals are allowed in Turkey and can be marketed only after the expiration of the data exclusivity period and patent protection covering the original pharmaceuticals. They are also subject to a licence procedure by The Medicines and Medical Devices Agency and proof of their bioequivalence is required except for certain products. The generics should have the same therapeutic effect as the original pharmaceuticals.

Pharmacists are only allowed to suggest substitution of branded generics for original products or other branded generics prescribed by doctors if the substitute is pharmaceutically equivalent, providing the same quality, efficacy, and safety profiles. However, since generic substitution can also include additional substance different than original pharmaceuticals, the pharmacists should pay attention and have been well-informed beforehand against any patients' possible risk of reactions or allergies against to these substances.

An online system alerts the pharmacist if a cheaper equivalent is available, and the pharmacist is expected to inform the patient about such an option. Patients have discretion to choose the original pharmaceuticals over the generic products but has to pay the difference between the price of the products. Moreover, if patient insists on to take original pharmaceuticals but they are not in the stock of pharmacy, the pharmacist is obliged to make order for them.

Regulations

16. Which regulations govern generic substitution by pharmacists of brand-name drugs?

The communiqué and circulars by the Ministry of Health govern this area. In Circular dated 18.06.2009 and numbered 43081 approved by Turkish Ministry of Health explicitly accepted as a right of pharmacists to suggest patients generic substitution for original products.

Besides, Communiqué on Social Security Institute Health Practice defines generic substitution practice as "*the products containing same active ingredient that can be used for the same indication; in the same equivalent groups or on the basis of the same price comparison, but in separate equivalent groups in terms of pharmacy substitution".* Reimbursement schemes of the Social Security Institute (SSI) are also a factor in prescribing of generic substances**,** and the price policy are specified in the Article 4.4.2 of Communiqué on Social Security Institute Health Practice.

Update and trends

Key developments and future prospects

17. What were the key judicial, legislative, regulatory and policy developments of the past year in relation to the protection and enforcement of pharmaceutical trademarks? What are the prospects for future developments?

In 2022, various legislative changes were made with respect to health sector. However, these updates were mainly regulatory changes.

Among these legislative changes, the most notable one is the publishment of Guideline on Counterfeit, Illicit or Out-of-the Legal Supply Chain Medicines. On 5 January 2022, the Turkish Medicines and Medical Devices Agency published the Guideline on Counterfeit, ?llicit or Out-of-the Legal Supply Chain Medicines. The Guideline provides guidance on the actions that can be carried out by the relevant third parties, primarily the Authority and the license holder company, in the fight against counterfeit, illicit or illegal medicines. The Guideline highlights that the sale or promotion of medicines over the Internet is against the law, and it is the Agency's responsibility to determine these activities and to take the decision to block access.

The Agency continues to conduct periodical market surveillance and inspection on cosmetics and biocidal products. All cosmetic and biocidal products are required to fully comply with the applicable Turkish laws and regulations, and

manufacturing companies must ensure they do not sell or distribute unsafe, unlicensed or noncompliant products. In July 2022, the Agency announced the results of its cosmetics sector market surveillance and inspection conducted in January, February and March 2022. The results revealed that even though the number of inspected products and noncompliant products decreased significantly, the total amount of administrative fines has increased compared to the results of the fourth quarter of 2021.

The Agency also published Withdrawal Guideline on 17 December 2021. The aim of the guide is to regulate the rules, authorities and responsibilities regarding the investigation of products that are suspected or found to be illegitimate, or unfavourable, and when necessary, effectively withdraw them from the market in accordance with the periods determined in the legislation.

Influencers' marketing activities are still hot topic in Turkey. Considering that advertisements for pharmaceuticals and other medical products for human use are prohibited, using social media influencers are a commonly used channel for promotional activities primarily dietary products and foods supplements.

Alongside with the influencers, there are too many online companies (dietary products and foods supplements) which are trying to support their business by raising online marketing activities.

The Advertisement Board continued to impose sanctions against the influencers and companies. False health claims are still strictly tracked and sanctioned by the Advertisement Board.

In its decisions the Advertisement Board has recognized the followings as false health claims:

- Implying/stating the product is good for the immune system because of its ingredients,
- Implying/stating the product protects against all kind of viral infections (flu, cold, etc.) including Covid-19,
- Implying/stating the product the product can recover the infected people in a very short time,

Also, the Advertisement Board continued to examine the influencers activities within scope of "Testimonial Advertisement" and concluded that despite the perception that the products were personally experienced by influencers, it does not reflect the truth and the contents are deceptive, misleading and violates the provisions regarding "Testimonial Advertisement".

Law stated date

Correct on

18. Give the date on which the above information is accurate.

As of 04 October 2022.

**This content was originally published in Lexology Getting The Deal Through's Pharmaceutical Trademarks 2023 Questionnaire - Türkiye Chapter.*

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