

Pharmaceutical Trademarks 2021



Turkey

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OVERVIEW

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.

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 authorisation 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 authorisation 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; and
- not being distinctive, being delusive, and being descriptive (eg, 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, the 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 recognising 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.

The TPTO keeps a record of international non-proprietary names (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 and Medicinal 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.

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 or 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 being a source indication 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 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 No. 5237. In 2016, the Turkish government legalised 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 that is limited to only three years.

In the meantime, the Turkish Medicines and Medical Devices Agency has published the list of pharmaceuticals that 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 treatment from the cannabis-derived medication that 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 authorised 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 that has specific provisions. Pharmaceuticals can only be imported and commercialised by the company that holds the marketing authorisation from the Ministry of Health. A marketing authorisation 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 commercialised by the company that holds the

marketing authorisation from the Ministry of Health. Marketing authorisation is granted only to the Turkish subsidiary of the pharmaceutical manufacturer. In this regard, as a part of a dealing strategy the Customs can be informed about the details of the marketing authorisation holder and its Turkish subsidiary.

As parallel imports of pharmaceuticals are possible in Turkish 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 the Pharmaceutical and Medical Preparations Law article 19 in accordance to 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 the 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; and
- 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 one to three 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 to accept the infringement claim in the prosecution or 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 the 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 that 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 abovementioned 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 or 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 offences mentioned that arise out of their single act of producing and selling unlicensed or 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 authorisation 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; and
 - 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 or destruction of infringing products;
- recall of infringing products and removal from the market; and
- 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 with 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 person's 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 or 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. 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.

There has been a notable rise in the sale of pharmaceuticals through online platforms and this raises many concerns about public health since most of them are unauthorised 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?

Supply shortages of medical devices and medicines owing to the covid-19 pandemic caused a significant increase in counterfeit medical devices and medicines especially masks and sanitisers. During the lockdown quarantine from late March until June, the Presidency banned the sales of mask other than those the government itself distributed to the public. Also, there were many police operations for counterfeit pharmaceutical products during the quarantine.

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

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 cessation of the broadcasting 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 the 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 organising 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 the substitution of (branded) generics for original products or other branded generics prescribed by doctors if the substitute is pharmaceutically equivalent,

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providing the same quality, efficacy and safety profiles. However, since generic substitution can also include additional substances different from original pharmaceuticals, the pharmacists should pay attention and have been well-informed beforehand against any patients' possible risk of reactions or allergies 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 the discretion to choose the original pharmaceuticals over the generic products, but have to pay the difference between the price of the products. Moreover, if a patient insists on taking original pharmaceuticals but they are not in the pharmacy's stock, the pharmacist is obliged to put in an 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 the Circular dated 18.06.2009 No. 43081 approved by the Turkish Ministry of Health explicitly accepted as a right of pharmacists to suggest to patients a generic substitution for original products.

Besides, the Communiqué on Social Security Institute Health Practice defines generic substitution practice as 'the products containing the 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 generic substances, and the pricing policy is specified in article 4.4.2 of the 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?

Influencer marketing is a social phenomenon and its impact on advertising regulations cannot be denied. Since it is a non-direct form of

advertising and the impact is hardly proven considering the huge amount of content shared on social media platforms, it has not been controlled in terms of advertising rules until recently. Considering that advertisements for pharmaceuticals and other medical products for human use are prohibited, sellers of products such as dietary products and food supplements may prefer to promote products by using influencers. This causes a serious threat to public health as the therapeutic effects of these products are not even proven by the Ministry of Health. Public health has become the primary concern for both public and government after the worldwide covid-19 epidemic. In this regard, the Advertisement Board imposed a sanction against the advertising of a food supplement on a social media platform for the first time as they promoted the food supplements as if they treat a disease the way pharmaceuticals do. This shows that false health claims are strictly tracked and sanctioned by the Advertisement Board. This decision offers an insight into the Advertisement Board's position for future breaches.

Defining the intended customer group for pharmaceuticals is another controversial hot topic in the protection of pharmaceutical trademarks over the years. The first instance courts' decisions varied from case to case and there had been contradictory outcomes: in some cases, the intended customers for pharmaceuticals were understood as informed customers (doctors or pharmacists) and in other cases end customers. However, recently the Court of Appeal has established the approach and accepted that the intended customers for pharmaceuticals are doctors and pharmacists whose attention level is high.

There is also an increasing trend in anticounterfeiting efforts regarding pharmaceutical products.

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