

## Online Sale of OTC Pharmaceutical Products in Turkey

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Online sale of over the counter ("**OTC**") pharmaceutical products is banned in Turkey because the legislative framework does not specifically address this market segment. Rather, local legislation deems OTC products to be effectively the same as pharmaceuticals, which can only be sold at pharmacies and pharma-organizations.

In general, OTC products are defined as drugs that have been found to be safe and appropriate for use without supervision from a health care professional such as a physician. Therefore, consumers can purchase OTC products without a prescription<sup>1</sup>. OTC products are used to treat simple diseases which are commonly encountered in daily life. These products are accepted as effective and safe for the disclosed indications<sup>2</sup>. The global OTC product market, where customers can buy drugs or medicines without a prescription, is steadily increasing in value and volume.

Although the OTC product market is generally increasing across around the world, Turkey has not yet developed a detailed legislative framework. According to the Regulation on the Classification of Human Medicinal Products, pharmaceuticals are classified only as prescription and nonprescription pharmaceuticals. A pharmaceutical is classified as prescription pharmaceutical if it meets any of these criteria (Article 6):

- Using the pharmaceutical under medical supervision causes direct or indirect danger to health, even if the pharmaceutical is applied correctly,
- Using the pharmaceutical poses a risk to human health due to frequent and common misuse of the pharmaceutical,
- With respect to preparing the active substance or formulation, the activity and/or adverse effects need further research,
- The pharmaceutical is applied via parenteral methods.

If a product is not classified as prescribed, it is deemed to be a nonprescription pharmaceutical. Turkey does not define OTC products, nor regulate requirements for advertisement or specific sale channels. Therefore, under Turkish regulations, nonprescription pharmaceuticals are effectively equivalent to OTC products. As a result, general Turkish regulations regarding pharmaceuticals apply for nonprescription OTC products, including advertising bans. This is a different approach to countries like the United States which have free market conditions for OTC products.

Sale channels for pharmaceuticals are addressed by the Law on Pharmaceuticals and Medical Preparations, which states that *regardless of whether a pharmaceutical is prescription or nonprescription, it can only be sold at pharmacies and pharma-organizations* (such as pharmaceutical warehouses) (Article 1). Therefore, OTC products are deemed to be nonprescription pharmaceuticals in Turkey, which can only be sold at pharmacies.

Turkish legislation prohibits the sale of pharmaceuticals via the internet or any other electronic medium (Article 24 of the Law on Pharmacists and Pharmacies), even to the extent that pharmacists cannot have websites. Therefore, OTC products cannot be sold online in Turkey.

The restrictions may be considered lucky, considering Turkish society's tendency to use and misunderstand pharmaceuticals. According to research, many Turkish patients do not know the difference between a virus and a bacteria, believing that antibiotics treats diseases caused by either of these infections. The same research showed that 36% of patients believe antibiotics reduce a fever and lower pain, tiredness and lethargy<sup>3</sup>.

The downsides of using nonprescription pharmaceuticals, which may increase through online sale of OTC products, include:

- Patients fail to receive the pharmaceutical's intended result and benefit due to misuse.
- Increased risk of adverse effects and interaction with other pharmaceuticals.
- Increased treatment costs and waste of resources.
- Reduced records of pharmacovigilance.

The number of the crimes committed through the internet increases daily. Counterfeit pharmaceuticals are a growing and profitable business for fraudsters. Generic top level domains can be registered by anybody, including .com, .net, .biz, .org and .info. Therefore, it is not always possible to know who is behind any given domain. Fraudsters can also activate websites cheaply and continue to sell fake pharmaceutical products, even if access is banned to their main website. As a result, although many legislative prohibitions and restrictions exist, fraudsters can easily take advantages of freedom and anonymity available online, using the internet as a tool to commit crimes.

Patients are most likely to buy weight loss medications and aphrodisiacs online. In March 2016, 500 kilograms of fake weight loss medications were seized in an operation organized the by Anti-Smuggling Department of the Istanbul Police. Despite the seizures, it was reported that a large number of the fake weight loss medications had already been sold online before the raid.

From an intellectual property point of view, online sale of OTC pharmaceuticals may pave the way for counterfeit products. Websites are not as easily inspected as physical pharmacies are. The issue is so widespread that the United States' Food and Drug Administration published an announcement warning patients about the dangers of buying pharmaceuticals online (including the risk of counterfeit products), as well as ways consumers can avoid or reduce these risks<sup>4</sup>.

The Turkish pharmaceutical market is criticized for its prohibition on advertising OTC products. Arguably, advertisements could be used to inform society and promote awareness about using OTC products.

Critics argue that online sale of OTC products would enable better access to pharmaceuticals, as well as increase competition, thus lowering pharmaceutical prices. However, since there is no efficient legal way to control online pharmaceutical sales (including OTC products), the Turkish pharma market is not ready for adopting online sale of OTC products yet.

Unlike other countries in the European Union and the United States, Turkey does not specifically regulate OTC products. Therefore, these products are subject to the same prohibitions and obligations as any other pharmaceutical. Since the Turkish OTC product market remains unregulated, the issue of whether local consumers are ready to access pharmaceuticals without pharmacist guidance remain debatable.

1. <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194951.htm>
2. Turkish Pharmacist Association R&D Unit Report - Non-Prescription Pharmaceuticals and Non-Pharmaceutical Products: Definition and Intervention
3. Turkish Pharmacist Association R&D Unit Report - Non-Prescription Pharmaceuticals and Non-Pharmaceutical Products: Definition and Intervention
4. <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048396.htm>

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