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Importing Pharmaceuticals to the Turkish Market

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Given the potential risks posed to public health, the pharmaceutical sector is one of the most strictly regulated sectors in many countries, including Turkey. In recent years, the importation of foreign pharmaceutical product has grown immensely in Turkey. Manufacture and handling of pharmaceuticals in the distribution chain must strictly conform with detailed regulations and is controlled by national, as well as international, authorities. It is important to retain control over product quality standards and prevent illicit trade.

Turkish regulations outline three ways to import a pharmaceutical into Turkey:

- Market consumption of licensed products.
- Patient Sales/Named Patient Program.
- Compassionate Use.

The most common approach to importing pharmaceuticals to the Turkish commercial market is through the first method. The other two avenues are not intended for bringing pharmaceuticals to the commercial market.

Market Consumption of Licensed Products

Importing pharmaceutical products through the licensing method is the quickest and most reliable option. The Turkish Pharmaceutical and Medical Device Institution ("**Institution**"), within the Ministry of Health ("Ministry"), is responsible for granting licenses to pharmaceutical products. These licenses are granted under the Licensing Regulation on Human Medicinal Products ("**Licensing Regulation**"), which outlines the documents and information required. Licenses from the Ministry include permission to import the pharmaceutical product into Turkey.

Pharmaceutical products cannot be launched on the market in Turkey before obtaining a license from the Ministry (Article 5 of the Licensing Regulation; Article 3 of the Pharmaceuticals and Medical Preparations Act). Since the legislative regime prohibits importation of unapproved new drugs into Turkey, importing drugs which lack this Ministry approval violate the law, whether they are for personal use or otherwise.

Importers of pharmaceutical products and active substances must also obtain a certificate of control from the Ministry, as per the Communiqué on Import of Certain Products that are Audited by the Ministry of Health (Communiqué No: 2012/20).

Named Patient Sales

Some pharmaceuticals, especially those critical for treatment of rare or serious diseases such as cancer, may be quite difficult to access due to problems related to obtaining licenses, pricing, and reimbursement of Social Security Institution ("**Institution**"). The named patient sales approach allows patients in Turkey to access

these medicines, under the responsibility of their physician.

This supply method has grown enormously in recent years, developing into a market worth approximately TRY 1.2 billion (USD 450 million) annually. The patient must pay for the pharmaceutical themselves if is not deemed to be one which the Institution will reimburse for. In this case, affordability issues can arise for patients with serious diseases who need expensive treatments.

The Ministry published a Guideline ("**Guideline**"), outlining import principles for pharmaceutical products.1 Accordingly, to import a pharmaceutical product in the way, it must be either:

- Unlicensed in Turkey, or
- If the Ministry has granted a license:
    - The product is not produced in Turkey
    - The product could not be found in the Turkish market.

The pharmaceutical product must be necessary for the patient's treatment and be approved by the Ministry. To obtain Ministry approval, the physician must provide a prescription for the patient.

Debate exists about the Turkish Pharmacists Association's exclusive authority to import pharmaceutical products under the patient sales approach. The Guideline states that the Association is the only organization authorized to import products which are registered in the "Imported Pharmaceuticals Provision System". Authorization was later granted to certain pharmaceutical warehouses under a by-law. However, the by-law is currently subject to a cancellation action and the Council of State has granted a preliminary injunction which prevents it being applied during the cancellation action. These proceedings are ongoing and pending a final decision from the Council of State.

Compassionate Use Program

The Ministry's Guideline outlines requirements for the Compassionate Use Program. However, this alternative is quite strict. To date, only around 20 pharmaceuticals have been permitted to enter the Turkish market via this approach.

The Guideline2 states that this alternative aims to provide free of charge pharmaceuticals, which are not registered in Turkey, to patients which meet all of the following criteria:

- For whom treatment has failed with existing accessible licensed products.
- Who suffer from a serious or urgent life-threatening disease.
- Have not been included in the scope of clinical trials.

The program only includes pharmaceuticals which have completed at least Phase II studies and have initiated Phase III studies across the world. However, an exception exists for scientifically justifiable and very rare exceptional cases. Studies are not required to be conducted in Turkey.

The patient's treating physician must make a written commitment taking full responsibility for including the patient in this program and submit this commitment to the Ministry.

The program is not a clinical trial and the physician conducting the program is not allowed to receive any payment, under any name. The program does not aim to collect information about drug efficacy. Even if such information is collected, it cannot be used in the Ministry's license registration procedures.

The pharmaceutical may be imported to Turkey either by the pharmaceutical company's subsidiary or a clinical research organization ("**CRO**") with permission from the Ministry. Once the product is brought to Turkey, the Ministry grants another permit to the importer (the CRO or subsidiary) for products to clear customs. For this permit, the Ministry wishes to see an invoice for the product issued in the name of the CRO or subsidiary, issued by the pharmaceutical company.

The critical point for pharmaceutical manufacturers is that they cannot cease to supply the product ex parte. The patient's doctor should file quarterly reports and if these indicate that the patient benefits from the drug, the pharmaceutical manufacturer must continue to send the products, until it obtains a license in Turkey

Since the compassionate use program allows access to drugs which are not yet approved, it naturally involves inherent risks. For instance;

- The efficacy or side effects of unapproved drugs may not be known yet.
- Pharmaceutical companies are not obliged to supply unapproved products and there is no tool to require companies to do so.
- Patients may need to pay for the product personally. Therefore, the pharmaceutical may not be in the Institution's reimbursement list.
- The procedure is complicated and onerous, so patients may experience long delays in receiving an answer from the Ministry.

1. http://www.titck.gov.tr/Haberler/HaberGetir?id=294
2. http://www.titck.gov.tr/Mevzuat/MevzuatGetir?id=2126

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