

PHARMACY LAW

Regulations on Pharmacy Practices

Objectives

- Determine the reasons to regulate professions.
- Identify the conditions to practicing as a pharmacist in Turkey.
- Specify the requirements to open a community pharmacy.
- Describe the actions against a license.
- Describe the actions against a pharmacy license.
- Clarify the conditions to manage a community pharmacy with a responsible manager
- Determine the physical requirements of a community pharmacy place.
- Identify the inspection process of a community pharmacy.
- Describe the working hours and working format of a community pharmacy.

Why do we need to regulate professions?

People without specific training cannot distinguish between qualified and unqualified providers, and people who need healthcare must be protected from unqualified providers.

With regard to pharmacists, the reason to regulate pharmacy profession:

- To increase the qualified pharmacists,
- To inhibit the crime caused by pharmacy practices,
- To increase the quality of healthcare,
- To reduce the cost of health.

The regulations on Pharmacists in Turkey

- ***Law on Pharmacists and Pharmacies- Law no. 6197***
- ***By-Law on Pharmacists and Pharmacies- April 12, 2014, Official Gazette No: 28970***
- ***Law on Making Changes in the Law about Pharmacists and Pharmacies- Law no. 6308- May 17, 2012.***

What are the requirements to practicing as a pharmacist in Turkey?

- To be a Turkish citizen,
- To be graduated from a Faculty of Pharmacy in Turkey,
- In the case of having a diploma from other countries' faculty of pharmacy, passing the exam in Turkey to prove the adequacy
- To have a diploma authorized by Ministry of Health,
- Not to have an obstacle condition to be a pharmacist that stated in the 4th article of the Law no 6197.

What are these obstacles?

- To have not blindness in his/her eyes,
- To have never committed an infamous crime,
- To have never sentenced to heavy imprisonment,
- To have never fined over one year due to occupational crime or have never disqualified from occupational crime more than two times in five years.

What are the requirements of Turkish citizens studied abroad to practice as a pharmacist in Turkey?

- The Ministry of Health registers the diplomas of these people only after the proof of their professional identity.
- **The Professional Identity:** Proving their scientific condition in front of a scientific board whether there is a lack of program and training time.

The process of opening a pharmacy

Pharmacists who wish to open, transfer or transport a community pharmacy: apply to the ***health directorate of the province (il sağlık müdürlüğü)***.

If the necessary documents are complete, a license is issued.

The process of opening a pharmacy: What are the criteria?

The number of pharmacies: According to the population within the boundaries of the district, one community pharmacy per at least three thousand and five hundred people.

The process of opening a pharmacy: What are the criteria?

The Settlement:

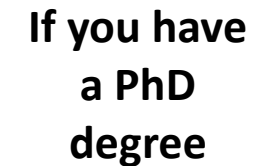
- If the settlement does not have any community pharmacy, the population criterion is not considered.
- However, the population criterion is operated in order to transport these pharmacies to other places.
- If you want to transport your pharmacy in the same district you are not subjected to population criteria.

The process of opening a pharmacy: What are the criteria?

Coefficients

Service Score = County coefficient x The years worked in the district
x **1,25**

Settlement Score = **Service Score** + The years worked as a
pharmacist



If you have
a PhD
degree

The process of opening a pharmacy: What are the criteria?

Coefficients

- The districts where a community pharmacy will be opened according to population criteria are announced by the Ministry of Health at least twice a year.
- If you have a service score higher than others you have more chance to open a community pharmacy in that district that you applied as a candidate. If the settlement score is equal, it is drawn.
- When a pharmacist who has transferred his pharmacy wants to open a new pharmacy, his settlement score is reduced by half.

The process of opening a pharmacy: What are the criteria?

Experience

A pharmacist who wants to open a community pharmacy or work as a responsible manager in community pharmacies has to work as **an auxiliary pharmacist** in community pharmacies for at least one year depending on the service contract. (CHANGED-CANCELLED)

The pharmacists who has worked as a hospital pharmacist or as a second pharmacist, for at least one year are deemed to have fulfilled the requirement of working as an assistant pharmacist.

If it is determined that **auxiliary pharmacists** are not present without an excuse at community pharmacy for three times during inspections, the period worked is not taken into consideration.

New graduated pharmacists shall be paid a fee determined by the parties, not less than one and a half times of the minimum wage.

The process of opening a pharmacy: What are the criteria?

Paperwork

- Pharmacists who would like to open a pharmacy shall make their applications **electronically** by adding the documents specified in the Article 9 of ***By-Law on Pharmacists and Pharmacies- April 12, 2014, Official Gazzette No: 28970*** within thirty days (30 days) from the date of announcement for the districts declared by the TMMDA.
- Pharmacists who can open a pharmacy according to the settlement results, at the latest within sixty days (60 days) from the date of announcement, send the original documents that was entered electronically and additional documents in the first application to the provincial or district health directorate.
- **After the application the pharmacists' chamber checks whether there is a conspiracy or not.**

6308 vs. 6197

These regulations was made by Law no 6308. Before this law has entered into force, **all the pharmacists can open a community pharmacy whenever and wherever they want.**

Law no 6308 entered into force in 2012.

Those who are currently working as a pharmacist and those who are studying at pharmacy faculties when this law entered into force shall not be subjected to the restrictions of opening a pharmacy.

Actions against a license

1. If the documents submitted to obtain community pharmacy license are fake,
2. If there is some obstacles to preventing to give pharmacy services.
3. Not to have an obstacle condition in the 4th article of the Law no 6197.

If there is a conspiracy the pharmacist cannot open a pharmacy for five years.

Actions against a pharmacy license

- If there is a conspiracy,
- If the pharmacist gives up his license,
- If the pharmacist will go bankrupt and this is confirmed by the court,
- Pharmacists with mental illness, and those who lead their family into poverty because of extravagance, sobriety, bad life, and those who convict a year or more with a freedom sanction,
- If the pharmacist refuse to emplyee a second pharmacist although he have to,
- If the pharmacist has died.

What is a 'Second Pharmacist'?

Eighty thousand (80.000) prescription per year

or

More than three billion (3.000 ₺) Turkish Liras

The maximum number of second pharmacists to be employed in line with the prescription number or turnover data is max three.

The pharmacists must declare the turnover information of their community pharmacy via MEDULA.

Second pharmacists shall be paid a fee determined by the parties, not less than three times of the minimum wage.

Some important issues

- Public servants and the pharmacists doing their military service cannot open a community pharmacy and cannot be a responsible manager of a pharmacy.
- A pharmacist cannot own *more than one* community pharmacy or cannot be a responsible manager of more than one community pharmacy.
- During the hours of service of the pharmacy, the responsible pharmacist and the second pharmacist, if any, should be on their duty.
- If a community pharmacist wants to leave the pharmacy more than 24 hours, he should inform provincial health directorate with a letter. If this period is to continue for up to fifteen days, another pharmacist who does not own a pharmacy or a second pharmacist manage the pharmacy. If the period is exceeds fifteen days, a responsible manager should be appointed.

Outside of the pharmacy: Physical Requirements

- Name of the Pharmacy (signboard)
- E- logo
- A door bell
- A list of pharmacies on shift duty
- Lighting system

Advertisements can not be pasted to the windows of pharmacy.

Inside of the pharmacy: Physical Requirements

- Part for patients
- Laboratory
- Stocking area for pharmaceuticals and cosmetic

Inside of the pharmacy: Physical Requirements

The properties of the place

Min. 35 m²

Laboratory should be separated.

Except the pharmacies in airports, ports, bus stations and train stations, all the community pharmacies should be located on the streets.

Can have more than one door.

These doors should not be opened to another shop.

Inside of the pharmacy: Physical Requirements

Should have a refrigerator.

A thermometer and a recording system must be provided to maintain and control the temperature.

Should not be placed in the same building with a health centre except laboratory diagnostic centers, which provide only screening and imaging services,.

Inside of the pharmacy: Physical Requirements for Part for Patients

There should be;

- cabinets for pharmaceuticals and cosmetics,
- banks,
- table for pharmacist,
- computers,
- pharmacists' diploma and license to open pharmacy,
- portrait of Atatürk,
- pharmacopeia,
- fire extinguisher (one per 25 m²)

Inside of the pharmacy: Physical Requirements for Laboratory

There should be;

- a marble counter to prepare magisterials,
- two locker colored red and green (red part for severe poison and green part for poison that should be put separate),
- refrigerator,
- plumbing,
- scales,
- tools and equipment to prepare drugs that stated in the Law

Working hours / Working format

Pharmacies must adhere to the working hours and opening closing hours of the pharmacy in the region in which they are connected.

For example in Ankara pharmacies open at 9 am and closed at 7 pm.

The pharmacies which are on their shift duty can be opened except these working hours and official holidays.

Pharmacies in shopping centers closed at night are exempt from shift duty.

Pharmacies in airports open to international flights may also be opened for 24 hours a day. In this case, it is mandatory to have one pharmacist for every 8 hours.

Working Costume

The Inspection Process of Community Pharmacies

Health inspectors of TMMDA

The pharmacist to be appointed by the health directorate.

What is the type of this inspection?

Community pharmacies should be inspected **at least twice a year**.

In case the deficiency is determined as a result of the inspection, the pharmacist is requested to eliminate deficiencies in a maximum of ten working days. At the end of this period, another inspection is made whether the deficiencies are eliminated. If not pharmacist will be fined.

In case the deficiencies detected in the pharmacy or the contradictions to the legislation are not cleared at the next inspection despite the application of the penalty, the license is suspended until the deficiency is completed.

Shutting Down a Pharmacy

- When the pharmacist wants to shut down the pharmacy on his own wish, he applies to the provincial health directorate with his petition and his license. License will be canceled after the necessary procedures.
- If a counterfeit is determined, the pharmacy is shut down and the parties imprisoned and fined.

Keeping Pharmacy Closed

- In places where there are more than one pharmacy, the pharmacy can be kept closed for **not more than two years** with the request of the pharmacist based on illness and other excuses.
- In places where there is a single pharmacy, the pharmacy is temporarily closed **until** the provincial directorate of health appoints a **responsible manager** to the pharmacy.

Thank you for this week...