

PHARMACEUTICAL LEGISLATION

Teaching Weeks	Topics
1	The reasons of pharmacy laws Basic concepts on Turkish legislation process Basic terms: Right, Obligation-Liability, Responsibility, Accountability, Legal Responsibility Distinguishing Criminal, Civil, and Administrative Law
2	Regulations on Medications: Manufacturing and Marketing What is Pharmaceuticals and Medical Preparations? Manufacture and Licensing of Medicinal Products Clinical Researches Labeling requirements Prescription Drug Labeling Information for the Patient
3	Regulations on Medications: Manufacturing and Marketing Advertisement and Promotion of Medicines The Pricing System of Medicines
4	Regulations on Medications: Dispensing The classification of medicines Dispensing written and electronic prescriptions (MEDULA and Ministry of Health's Health Implementation Directive) Reimbursement System Dispensing Controlled Substances Wholesale distributors
5	Regulations on Pharmacy Practices Reasons to regulate professions The requirements to practicing as a pharmacist Licensing of Pharmacies Retail pharmacy: Who can own a retail pharmacy? Retail pharmacy: What are the criteria to own a retail pharmacy? Actions against a license Actions against a pharmacy license
6	Regulations on Pharmacy Practices Practice of Pharmacy Defined Ancillary pharmacy personnel, interns, and pharmacy technicians Absence of a pharmacist
7	Regulations on Pharmacy Practices: Hospital Pharmacist and Clinical Pharmacist Who is a hospital pharmacist? (Regulation on management of hospitals and other health facilities) Who is a clinical pharmacist?
8	MIDTERM

9	Ethics: Three concerns of ethics Principles in Pharmacy Ethics Management and organizational ethics Evaluation of Ethical Pharmacy Situation Contribution of ethics to management and leadership in pharmacy practice
10	What is management? Essential Management Competencies Leadership Essentials for Pharmacists
11	Planning Organizing Motivating Supervising
12	Human Resources Hiring Process Performance Management
13	Third Party Payment: Reimbursement Finance Management Purchasing and Inventory Management
14	Personal Development Developing Professionalism

Objectives

- ✓ **Determine what is pharmacy law.**
- ✓ **Identify the law enacting process in Turkey.**
- ✓ **Describe the basic concepts on Turkish legislation process.**
- ✓ **Describe the basic terms: Right, Obligation, Liability, and Legal Liability.**
- ✓ **Distinguish criminal, civil, and administrative law.**

Pharmacy Laws

- **Pharmacy laws describe for pharmacists the basic requirements of day-to-day practice. Pharmacy laws also define the relationship pharmacists have with the public they serve.**
- **As health professionals, pharmacists are highly regulated because the slightest misstep in drug manufacture, marketing, and drug distribution, pharmaceutical care or development of a medicine could care a life.**
- **The products pharmacists have control on are held to the most exacting standards of any consumer product.**

What is legal for pharmacists?

- The question of ‘What is legal?’ can be addressed by answering ‘What is best for the patient?’
- Pharmacists may not always know the law, but they usually will know what is best for the patient, and this knowledge is ordinarily sufficient. However sometimes things are more complicated than this simplistic approach would suggest.
- Pharmacy laws have been drafted to describe the *best general approach* to specific pharmacy practice situations. They provide *guidance for pharmacists* by establishing rules that reflect societal value choices. It is essential for pharmacists to know these rules and how to use them.

Law

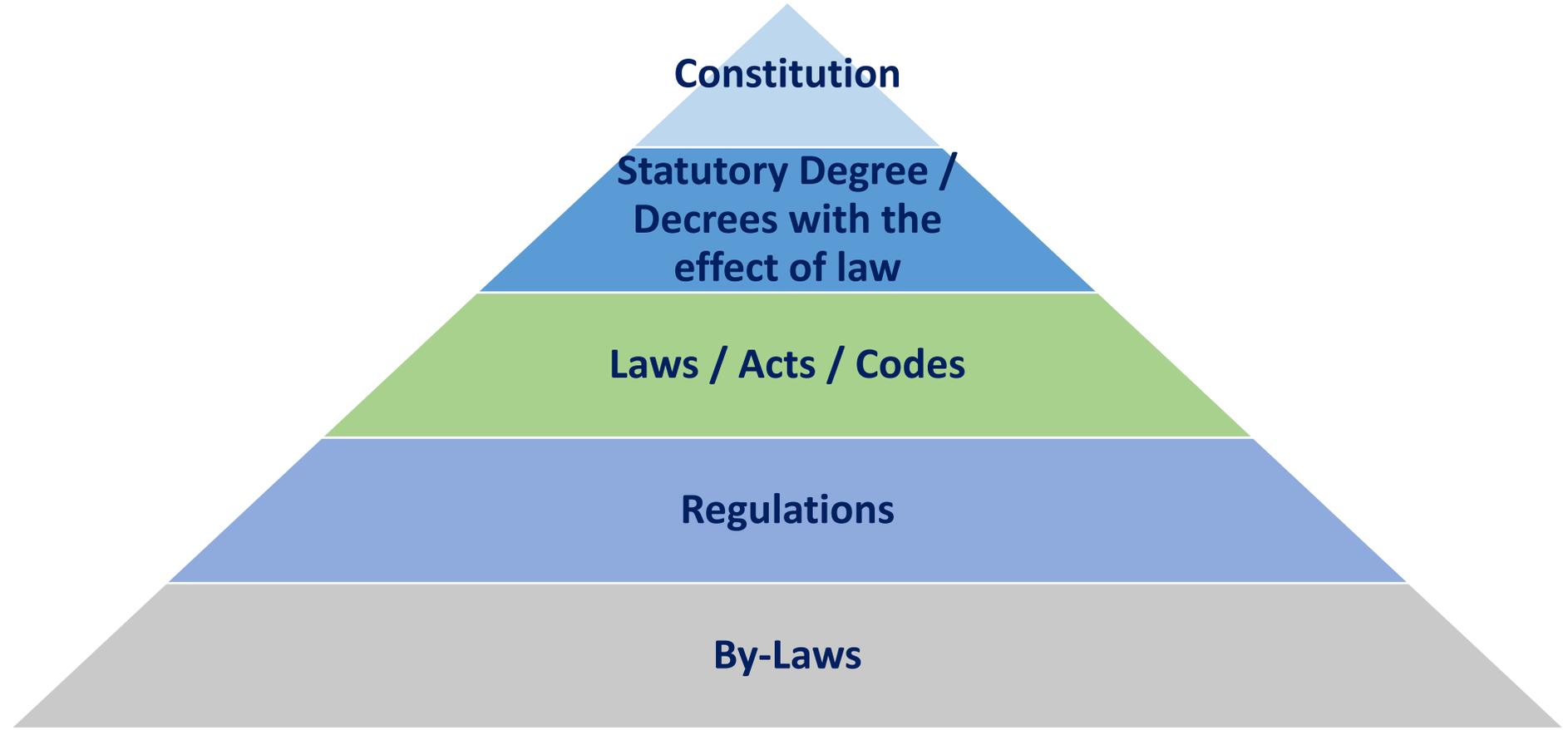
- Laws are generally for the *protection of people* and to *maintain public order*. Laws are there to *guide and protect* people. Laws are more general in nature, and they are not complicated. We get to see what we should do and should not do directly.
 - For example, walking on the railway line is prohibited. Here, we see that walking on the railway line is prohibited. We do not have to spend time trying to understand it as it is simple and direct.
- The term '*law*' in general refers to the set of regulations or rules to be followed. Law can be in the form of an act, regulation, by-laws, circular, international agreements, etc.
- A law is always followed by a penalty.

The Hierarchy of Laws

Coverage
increases



Details
increase



Constitution

Statutory Degree /
Decrees with the
effect of law

Laws / Acts / Codes

Regulations

By-Laws

Constitution

- **The Constitution is the of top ranks in the hierarchy of norms in Turkish Law.**
- **Establishes the innate characteristics of the country and its sovereignty; outlines the rights and responsibilities of its citizens – as such it is the supreme law.**
- **Establishes the country's governance structure.**
- **All other laws must adhere to the constitution.**
- **The constitution should reflect and adhere to a country's international obligations.**

Statutory Decree / Decrees with the effect of law

- **The Statutory Decree is the written legal norms on the definite topics regulated by the Council of Ministers, based on the authorization directly from the constitution (anayasa) or the Parliament.**
- **These decrees are binding equally by the law.**

Law / Act / Code

- **Acts are the written rules of law which are issued by the Council of Ministers after the opinion of the Council of the State is received and come into force after being approved by the President of the Republic and published in the Official Gazette, which demonstrate the practice of law and the matters it orders.**
- **Acts are enacted by the legislative branch of government, and govern a wide range of issues that require regulation in a modern, democratic state – including elections. For example; Turkish Labour Act.**
- **Must adhere to the constitution.**

Regulations (Tüzük)

- **Provide the implementation of the acts.**
- **Every valid regulation is dependent upon an act.**
- **Must adhere to the constitution, codes, and can be enforced in the same way as acts.**

By-Laws

- **Ensure the enforcement of acts and regulations related to their particular fields of operation and in conformity with such acts and regulations.**
- **Prime Ministry, ministries and public legal entities may issue by-laws to provide how to apply the acts and regulations.**
- **They are more detailed than acts and regulations.**

What is a Right?

- A right can be defined as an entitlement to have or do something. Rights allow people to be aware of what they are entitled to and what they are not entitled to do.
- In different societies and cultural groups, there are various rights. These may be backed up by social, ethical or legal boundaries. When speaking of rights, a universal set of values applies to all human beings irrespective of nationality, sex, culture, religion, or ethnic group. These are known as *human rights*.

What is a Right?

- Human rights are in the form of laws that apply to all human beings without any discrimination. It is the obligation of all states to implement these and create an ambiance where human rights can be enjoyed by all people. Some of these rights are *right to live, right to equality, freedom of expression, the right to education, right to work, right to enjoy economic, cultural, and social privileges*, etc.
- It is believed that rights lay the foundation for the effective functioning and stabilization of any society. For example, let us take the rights of children, such as to be educated, to be loved and nourished. If the child is given the opportunity to enjoy his rights, he will learn to be a good citizen in the future. It is then that the child will perform his obligations to others as well.

What is an Obligation (Liability)?

- An obligation can be defined as something that ***one must do*** because of a law, necessity or because it is their duty. There are various forms of obligations such as ***legal obligation, moral obligation, social obligation*** etc.
 - For example respecting adults, or else looking after your parents when they are old, is not a legal obligation. There are no laws that force you to do them. However, they are your moral obligation.
- Obligations are individual tasks that need to be completed by those who are privileged by their rights.
- Just as rights, obligations play a vital role in society.

Rights

- Rights are *entitlements* that people have.
- Rights are for *one's self*.
- Rights are what we *gain* from the society.

Obligations

- Obligations are individual *tasks* that need to be completed by those who are privileged by their rights.
- Obligations are mostly *for others*.
- Obligations are what we *do* for the society.

What is Responsibility and Accountability?

- Responsibility is *an obligation* to perform the delegated task.
- The term accountability means a sense of *being answerable* for the final consequences. When a person is accountable for something, he is supposed to explain the outcomes of his actions, decisions, and omissions.
- The origin of responsibility is the *assigned authority*. On the contrary, *accountability* arises from responsibility.
(*authority > responsibility > accountability*)
- The performance of a person is not necessarily measured when he/she is responsible. Unlike, accountability, wherein the person's performance is measured.

Responsibility vs. Accountability

- It is clear that accountability makes the person accountable for the **consequences** of the actions or decisions made by him/her. As against this, consequences are not necessarily attached to the responsibility.
- Accountability **requires** a person to be liable and answerable for the things, he/she does. Conversely, responsibility **expects** a person to be reliable and dependable to complete the tasks assigned to him.

Distinguishing Criminal, Civil, and Administrative Law

- **Criminal law deals with crimes and their prosecution.**
- **Civil law is the law governing the relations between private persons or organizations.**
- **Administrative law is the law regarding the rules or regulations made and enforced by governmental agencies.**

Criminal Law in Pharmacy Practices

- **A pharmacist's wrongful act may subject the pharmacist to a criminal, civil, or administrative action, or perhaps all three at the same time.**
 - **In criminal law, the acts forbidden by law are considered criminal.**
 - **For example, a pharmacist who sells a prescription-controlled substance without a prescription may be subject to a criminal action. Because the pharmacist may lead to the death of the person.**

Administrative Law in Pharmacy Practices

- **A health professional is directly responsible to administrative law when serving as a government employee and have to comply with all the rules regulated by administrative law.**
- **Health professionals who work privately (community pharmacists, physicians who have their private clinic) must comply with the rules of administrative law, especially in their relations with the public.**

Civil Law in Pharmacy Practices

- **Civil law is the area of law that regulates the rules of person and family. In particular, the law of persons regulates the issue of harm to persons.**
- **In the case of civil law, the person who inflicts damage will pay compensation to the person he / she hurts. Whether intentional or unintended, the damage suffered by the counterparty may require compensation in monetary terms.**
- **For example, the patient may demand financial compensation in case of harm to his health and body.**

Tort Law

- **Tort: Violation of a duty imposed by law on an individual based upon a relationship to another individual.**
- **What is the difference between a tort and a crime?**
 - **A crime is a wrong against the public at large.**
 - **A tort is a wrong against an individual.**
- **A person who commits a tort is called tortfeasor.**

The Types of Torts

- **Two types of faults:**
 - 1. Intentional Torts:** The crime is committed by anticipating, predicting and intentionally consequences of person action. For example; trespass, assault, nuisance, battery..
 - 2. Negligence:** A failure of expectation of something that should be expected. The reason of a negligence can be imprudence, carelessness, unskillfulness in his art or profession or non-observance of regulations.

Trespass is a wrongful injury or interference with anothers' prosperty.

Assault is a threat that results in fear.

Nuisance is an interference with the enjoyment of life or property.

Four Elements of a Tort Claim

1. Duty
2. Breach of that duty
3. Causation
4. Harm (Injury)

Think about a case:
A pharmacist distribute a wrong medicine that is not in prescription.
As a consequence, the patient had an injury because of this mistake.



Duty

- **Duty is the requirement to behave in a certain manner for the benefit of another.**
- **The defendant (the pharmacist) had a duty of care to the plaintiff (the patient).**
- **Pharmacists do have certain duties to their patients. There is a long line of cases that indicate that a pharmacist has a duty to fill a patient's prescription correctly. Previous to changes in pharmacy practice, this was the pharmacist's only duty to their patients. Today, we have additional duties, such as patient counseling and drug regimen reviews.**

Breach of a Duty

- **The duty was violated or breached by the defendant.**
- **A duty can be breached in one of two ways:**
 1. **The required duty is not performed (nonfeasance) or**
 2. **The activity is performed, but it is incomplete or incorrectly done (malfeasance).**
- **A pharmacist must fill prescriptions correctly. If he does not, that is a breach of duty.**

Harm

- **The plaintiff suffered actual damages.**
- **The patient must prove in order to prevail (gain) is that they were injured or harmed.**

Causation

- **The defendant's conduct caused the plaintiff's harm.**
- **The injury that the patient suffered must have been proximately caused by the breach of duty.**
- **That is, if a prescription is misfilled, the injury suffered must be due to the misfill and not some other cause or underlying condition. For example, a person who experiences high blood pressure after taking an overdose of an antihypertensive drug would cause you to question if the misfill actually caused those symptoms.**

Types of Negligence

Gross Negligence

Gross negligence is a type that's so *reckless* or wanton that it shows a complete lack of concern for the safety of others. It is the most serious form of negligence, and can result in punitive damages.

Negligence becomes gross negligence if the defendant "recklessly" breached her duty of care.

For example; Hospital staff does not change a surgery patient's bandages for several days, resulting in a serious infection.

A woman who fell into a hypoglycemic coma after a pharmacist dispensed tablets which reduce blood sugar levels, typically given to diabetic patients, despite her having never suffered from diabetes.

Types of Negligence

Contributory Negligence

The idea is that an individual has a duty to act as a reasonable person. When a person does not act this way and injury occurs, that person may be held entirely or partially responsible for the resulting injury, even though another party was involved in the accident.

For example; You drive through a green light but are struck by someone running a red light. You sustain serious injuries because you were not wearing a seatbelt.

**Thank you for your attention.
See you next week.**