



University of Umm Al-Qura  
University  
College of Pharmacy  
Department of Clinical  
Pharmacy  
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# Pharmacy Law and Ethics

Study Guide

Course Number

**1804459-1**

(Second Semester)

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## **Introduction**

Welcome to a new session of study at University of Umm Al-quraa.

An understanding of the Saudi legal system in health care setting gives one the tools to meaningfully participate in our pharmacy practice. In this course, we will discuss the contours of law, specifically focusing on the area of pharmacy law. We will examine the Saudi food drug administration laws alongside with ministry of health laws that impact the practice of pharmacy, while emphasizing the legal and ethical principles applied by pharmacists in their daily decision-making. Students will learn the governmental framework within which pharmacy is practiced, as well as acquire an understanding of the laws, regulations, and the ethical responsibilities applicable to pharmacists so that they will be able to protect the public and ensure patients' wellbeing. Furthermore, students will learn legal procedure, legal terminology, and have an opportunity to reflect upon and evaluate the Saudi legal system, including its impact on the profession of pharmacy, through class readings, videos and discussions.

## **Course Goals**

The focus of this subject is Saudi legal system which impact on the profession of pharmacy. Furthermore understanding of the laws, regulations, and the ethical responsibilities applicable to pharmacists.

## **Course Objectives**

On successful completion of this subject, students will

1. Be able to demonstrate understanding and knowledge the Saudi pharmacy law and legal systems of medication development
2. Be able to describe Saudi regulation of medication dispensing and distribution.
3. Be able to explain the rules relating to controlled substances prescribing, dispensing and Distribution.
4. Be able to discuss the legal and ethical responsibilities of pharmacists.
5. Be able to discuss appropriate risk management strategies for pharmacy practice.

### **Course Coordinator**

Shaimaa Mahmoud Nashat - Paediatric clinical pharmacy specialist

### **Course Coordinator Biography**

Shaimaa Mahmoud is a lecturer in Clinical pharmacy. She obtained her B.Pharm.Sc. at Assuit university, Egypt in 2005. She has completed her MSc [Research mode plus coursework with extensive two year clinical training] at Cairo University, Egypt in 2009. Afterwards, she continued as an international pharmacy graduate with the IPG bridging program at Toronto University, Canada till 2012. She joined the School of Pharmacy at Jazan University as Lecturer in clinical pharmacy in 2012. She was assigned to establish the clinical pharmacy unit in King Fahad governmental hospital in Jazan. She has joined UQU as a lecturer in Clinical Pharmacy in 2013. Her clinical research focuses on the development of novel clinical pharmacy services at the hospital.

### **Assumed Knowledge**

It is assumed that all students have achieved the required competencies for completing all the previous pharmacy courses. Concepts covered in introduction of pharmacy, Pharmaceutics, pharmacology, pharmacokinetics and clinical pharmacology.

### **Competencies covered**

Pharmacy Law and Ethics course is designed to nourish your competencies in:, Professionalism, Collaboration and communication.

### **Course Structure**

<b>Learning Activity</b>	<b>Time allocated</b>
Lecturing	8h
Interactive learning	2h

Activity	2h
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### **Attendance Policy**

- Students are required to attend the first introductory lecture for this subject as it will provide details regarding the course content and assessment tasks.
- Attending lectures is not compulsory but it is highly recommended.
- It is **compulsory** to attend the interactive learning sessions and activity sessions as assessment tasks will be conducted during these sessions.

### **Contact Procedures**

Any questions concerning the teaching of this course can be made by contacting your course coordinator.

Subject Coordinator: **Dr.Shaimaa Mahmoud**

Email: [smabdelhalim@uqu.edu.sa](mailto:smabdelhalim@uqu.edu.sa)

*It is our professional commitment within the College of Pharmacy that when a student directly contacts a teaching staff member for information, advice and/or support, the teaching staff member will respond to the request within 3 working days.*

Ideally, student should provide his/her name, year, course, and enough details regarding the issue to be handled in a titled email. This should facilitate more effective communication and decrease confusion. Please note that emails are legal documents, students must show high level of professionalism and use of appropriate language.

### **Consultation Procedures**

The subject coordinator will be available for student consultation, prior booking via email is necessary.

### **Teaching Staff**

Dr.Shaimaa Mahmoud

[smabdelhalim@uqu.edu.sa](mailto:smabdelhalim@uqu.edu.sa)

Dr.Mohamed Medhat

[mgamaleldin@uqu.edu.sa](mailto:mgamaleldin@uqu.edu.sa)

## Course Content

Saudi Pharmacy practice legal system

- 1- The basis of pharmacy law
- 2- The Saudi food, drug and cosmetics acts: Definitions (drug, device, cosmetic, label, ...etc)

Professional behavior for pharmacist

- 3- Sale and supply of medicines: Evaluation and management of risk and provision of advice
- 4- Basic illegal acts: Adulteration, misbranding
- 5- Prescription exemption
- 6- Guidance for submission of medicines

قواعد مزاولة مهنة الصيدلة في المملكة العربية السعودية

- 7- الدليل الإرشادي لتصنيف المستحضرات والمنتجات
- 8- قواعد تسعير الادوية

## Course Schedule

Week Number	Lecture	Interactive Active Learning	Activity
1	Topic 1: The basis of pharmacy law		
2	Topic 2: The Saudi food, drug and cosmetics acts: Definition (drug, device, cosmetic, label, ...etc.)		
3	Topic 3: Sale and supply of medicines: Evaluation and management of risk and provision of	Session 1	

	advice		
4	Topic 4: Basic illegal acts: Adulteration, misbranding		
5	Topic 5: Prescription exemption	Session 2	
6	Topic 6: Guidance for submission of medicines		
7	Topic 7: الدليل الإرشادي لتصنيف المستحضرات والمنتجات		
8	Topic 8: قواعد تسعير الادوية		
9			Session 1 (Booklet)
10		Session 2: Formative Assessment	
11		Session 3: Feedback from Formative Assessment	

### Prescribed textbooks

1. The pharmacy law and ethics in Saudi Arabia Kingdom.

### Recommended Readings/Resources

- 1) Dale And Appelbe's Pharmacy Law And Ethics (Paperback) Gordon E. Appelbe (Author), Joy Wingfield (Author)

### Electronic Resources

<http://www.fda.gov/>

<http://crusher.neomed.edu/search~S0/?searchtype=t&searcharg=pharmacy+librar&SO RT=D&extended=0&SUBMIT=Search&searchlimits=&searchorigarg=tparmacy+>

[www.sfda.gov.sa/en](http://www.sfda.gov.sa/en)

<http://www.tg.org.au/>

<http://www.ncbi.nlm.nih.gov/pubmed>

<http://www.resourcepharm.com/>

<http://www.revisor.leg.state.mn.us/arule/6800/>

## **Assessment Information**

### ***Pass Requirements***

To qualify for a pass grade (or better) students must:

1. Complete all assessment items.
2. Score an aggregate mark that surpasses the pass/fail boundary (approximately 50%).

### ***Plagiarism***

Definition of Plagiarism: *“stealing and passing off (the ideas or words of another) as one’s own: utilizing (another’s production) without crediting the source”* Merriam-Webster dictionary.

In the academia, the work of students and staff should uphold the values of honesty and integrity. Plagiarism is considered as an ethical crime and a serious academic misconduct. Globally, there is an increased trend to consider plagiarism as a serious offense that can result in punishments such as a failing grade on the particular assignment, the entire course, or even being expelled from the institution [1]. In the continuous strive to promote strict honour codes and ethical standards, students are expected to familiarize themselves with plagiarism and ways to avoid it. Student must ensure that all assessments submitted by him/her are his/her own work.

**In Pharmacy Law and Ethics, students who are caught with plagiarism will be asked to re-submit their assessment and lose 10% of the awarded mark.**

Some Resources & References:

- 1- <https://courses.candelalearning.com/zelixite115/chapter/reading-plagiarism/>
- 2- [https://writing.wisc.edu/Handbook/QPA\\_plagiarism.html](https://writing.wisc.edu/Handbook/QPA_plagiarism.html)
- 3- <http://libguides.kaust.edu.sa/plagiarism>



- 4- <http://admission.kau.edu.sa/GetFile.aspx?id=144962>
- 5- <http://uqu.edu.sa/computer-sciences-information-en/en/205915>
- 6- <http://elearningindustry.com/top-10-free-plagiarism-detection-tools-for-teachers>

### ***Extensions and Misadventures***

Students are requested to do all in their power to meet assessment deadlines. Extensions can only be given when the student is facing unforeseen or unavoidable problems. Students **MUST** submit requests for an extension **in writing** prior to the deadline.

### ***Penalties for late submission***

Pro-rata reductions in the awarded mark (5 % per working day) will be made for items received late without a granted extension.

### ***Feedback***

Apart from the final exam, students should receive a detailed report about their performance in the various assessments within 2 weeks of submission date. However, exam papers will not be returned to students. Students can arrange to view their exam paper and discuss their progress with the course coordinator individually. To arrange individual consultations, students should email their teaching staff member.

### ***Assessment Items***

Number	Title	Type	Value	Duration	Due Date
1	Quiz	Exam	10%	30 minutes	Week 7
2	Activity	Assignment	20%	TBA	Week 9
3	Active Learning	Role play	20%		Week 10
4	End of Year Exam	Exam	50%	2 hours	TBA

TBA: To be advised

**Assessment item 1 Quiz**

Structure: 20 MCQ covering topic 1-3

Rationale: All learning objectives will be assessed.

Competencies: Problem Solving

Marking Criteria: All questions to be attempted. half mark is allocated for each correct answer.

**Assessment item 2: Activity**

Structure: 1 assignments

Rationale: Develop skills of independent learner and

Competencies: Education, Professionalism

Marking Criteria: Rubrics will be provided one week before

**Assessment item 3: Activity (Role play)**

Structure: 1 assignments

Rationale: Develop skills of independent learner and

Competencies: , Professionalism, Care giver

Marking Criteria: Rubrics will be provided one week before

**Assessment item 4: End of year exam**

Structure: This is a 2-hour closed book exam, which includes multiple choice (35 points) and short answer questions on topic 1-9 (35 points).

Rationale: All learning objectives will be assessed.

Competencies: Problem Solving

Marking Criteria: All questions to be attempted. One mark is allocated for each correct answer.

**Variations to Study Guide**

Should it be necessary to change the content of the study guide during a teaching session, it will be done in consultation with the Dean and other support services of the University. You then will be notified of the changes in writing by the subject coordinator

