

**King Saud University  
College of Pharmacy  
Pharmacy Law and Ethics  
Course Syllabus**

### I. GENERAL INFORMATION

<b>Course Number:</b>	PHCL 437
<b>Course Title</b>	Pharmacy Law and Ethics
<b>Lecture Hours Per Week</b>	2
<b>Credit Hours Per Semester</b>	2 (2+0)
<b>Admission Particulars</b>	<b>Pre-requisites:</b> None <b>Co-requisites:</b> None
<b>Course Director:</b>	<b>Male Campus:</b> <b>Dr. Abdullatif Al-Ghaihab, PhD.</b> Professor, Clinical Pharmacy Department <b>Office Location:</b> <b>Phone:</b> 0114677488 <b>Email:</b> <a href="mailto:alatif@ksu.edu.sa">alatif@ksu.edu.sa</a> <b>Office hours:</b> by appointment  <b>Dr. Omar Almohammed, BPharm, PharmD, PhD.</b> Assistant Professor, Clinical Pharmacy Department <b>Office Location:</b> 1A 36 in the college of dentistry <b>Phone:</b> 0114696998 <b>Email:</b> <a href="mailto:oalmohammed@ksu.edu.sa">oalmohammed@ksu.edu.sa</a> <b>Office hours:</b> by appointment  <b>Female Campus:</b> <b>Dr. Noha A. Al Aloola, MSc, PhD.</b> Assistant Professor, Clinical Pharmacy Department <b>Office Location:</b> Building 8, 1 <sup>st</sup> Floor, room 23(2) <b>Phone:</b> <b>Email :</b> <a href="mailto:nalaloola@ksu.edu.sa">nalaloola@ksu.edu.sa</a> <b>Office hours:</b> Office hours posted on door  <b>Dr. Lubna Al Jaffali, MSc, PhD.</b> Assistant Professor, Clinical Pharmacy Department <b>Office Location:</b> Building 8, 3 <sup>rd</sup> Floor, room <b>Phone:</b> <b>Email :</b> <a href="mailto:laljaffali@ksu.edu.sa">laljaffali@ksu.edu.sa</a> <b>Office hours:</b> Office hours posted on door
<b>Clock hours &amp; Locations:</b>	<b>Days and time:</b> Monday and Wednesday, 9:00 - 10:00 AM <b>Male campus:</b> 2 B 102 <b>Female campus:</b> TBA

### III. COURSE DESCRIPTION

This course introduces the students to the rules and regulations for the organization of the profession of pharmacy and the ethics of the profession.

### IV. COURSE OBJECTIVES

**At the completion of the course series, the student should be able to:**

1. Comply with governmental statutes and regulations that affect pharmacy practice.
2. Apply principles of law to the practice of pharmacy.
3. Identify ethical and moral decisions faced by pharmacists during the medication distribution process.
4. Describe local, state, federal and international regulations affecting public health policy development.
5. Evaluate and resolve ethical dilemmas that arise in the development of public health.
6. Policy or find a solution that is acceptable to all parties involved.
7. Describe legal and ethical implications of intervention in life threatening situations such as poisoning or drug overdose.
8. Demonstrate the ability to place health care and professional issues within appropriate historical, cultural, social, economic, scientific, political, and philosophical frameworks.
9. Display a respect and sensitivity for patient and family attitudes, behaviors and lifestyles, paying particular attention to cultural, ethnic and socioeconomic influences and incorporate cultural preferences, spiritual and health beliefs and behaviors into the patient care plan.
10. Use ethical principles and theories to consider alternative sides of a pharmaceutical care and/or health care dilemma.

### V. COURSE ABILITY OUTCOMES

**Following the successful completion of this course, a student will be able to:**

Carry out duties in accordance with legal, ethical, social, economic, and professional guidelines.

### VI. RESOURCES

- (١) نظام المنشآت والمستحضرات الصيدلانية في المملكة العربية السعودية الصادر عن مجلس الوزراء
  - (٢) نظام أخلاقيات البحث على المخلوقات الحية السعودي الصادر عن مجلس الوزراء
  - (٣) اللائحة التنفيذية لنظام المنشآت والمستحضرات الصيدلانية لنظام المؤسسات الصحية الخاصة الصادر عن وزارة الصحة
  - (٤) أسس ومتطلبات وشروط تسجيل المستحضرات الصيدلانية والعشبية وشركاتها الصادر عن الهيئة العامة للغذاء والدواء
  - (٥) اللائحة التنفيذية لنظام المخدرات والمؤثرات العقلية الصادر عن الهيئة العامة للغذاء والدواء
  - (٦) قواعد تسعير الأدوية الصادر عن الهيئة العامة للغذاء والدواء
  - (٧) المدونة السعودية لأخلاقيات ممارسة تسويق المستحضرات الصيدلانية في المملكة العربية السعودية الصادر عن الهيئة العامة للغذاء والدواء
  - (٨) دليل ضوابط حملات التوعية بالأمراض والتثقيف الصحي الصادر عن الهيئة العامة للغذاء والدواء
  - (٩) ضوابط المواد الترويجية التذكارية الغير دعائية الصادر عن الهيئة العامة للغذاء والدواء
  - (١٠) دليل وضوابط وإجراءات الموافقة على الدعاية أو الإعلان لمستحضر صيدلاني أو عشبي الصادر عن الهيئة العامة للغذاء والدواء
- 11) Robert Veatch, and Amy Haddad. Case Studies in Pharmacy Ethics. Oxford University Press; 2nd edition (2008)
- 12) ACCP Position Statement. Pharmacists and industry: guidelines for ethical interactions. Pharmacotherapy 2008; 28(3):410-420.

### **REQUIRED INSTRUCTIONAL MATERIALS:**

All supplemental materials will be available to students electronically through blackboard. (<https://lms.ksu.edu.sa/>) or distributed by faculty members via email or in class. It is the student responsibility to check the blackboard site regularly for any updates.

## VII. COURSE POLICIES

### A. ACADEMIC DISHONESTY/PLAGIARISM

- Students are expected to demonstrate professionalism and honesty during this course. Academic dishonesty includes, but is not limited to, cheating, plagiarizing, fabricating of information or citations, facilitating acts of academic dishonesty by others, having unauthorized possession of examinations, submitting work of another person or work previously used without informing the instructor, or tampering with the academic work of other students. Students found in violation of such policy are subjected to disciplinary actions as per University Policy.
- Please read the manual of study and tests for undergraduate students and operational rule (لائحة الدراسة والاختبارات للمرحلة الجامعية والقواعد التنفيذية المعتمدة) <http://dar.ksu.edu.sa/Regulations>
- Please read the manual of students rights and duties (لائحة تأديب الطلاب بجامعة الملك سعود) <http://dar.ksu.edu.sa/Regulationss>

### B. CLASS PARTICIPATION AND PROFESSIONALISM

It is expected that all students come to class prepared by completing where applicable all assigned readings, online homework, and other assignments before class and ready to actively participate in classroom activities. Faculty will clarify and expand on the reading material. Use of phones is prohibited during class.

### C. GUIDELINES FOR E-MAIL COMMUNICATION

E-mail is often perceived as an informal method of communicating, but some basic rules of style or etiquette are expected. In general, rules of common courtesy for interaction with people should be used for any situation and on the internet, it is especially important where, for example, body language and tone of voice must be inferred.

1. **All emails should be sent from your KSU account ONLY**
2. Mail should have a subject heading which reflects the content of the message.
3. Your message should begin with an appropriate salutation, including the name of the person being addressed, and end with the full name of sender.
4. Use mixed case and proper punctuation.
5. Current e-mail addresses for all students must be maintained in the Blackboard system. Each student must edit this in the "Personal Information" section of "Tools". Faculty will not be able to contact you if your email address is not updated and you could miss important information about courses.
6. **Check your e-mail daily.** Most information and communication from instructors will come via e-mail or will be posted on Blackboard under announcements.
7. **Failure to check email/Blackboard may result in you missing important assignments and subsequently affect your grade.**
8. Direct your request to the appropriate person, as indicated below. Please note that discussion board posts are preferred whenever your questions do not involve personal matters to reduce the number of individual emails.

➤ **Questions concerning lecture content:**

- Contact the faculty member teaching that lecture during his/her office hours.
- If you couldn't meet him, E-mail the faculty member teaching that lecture.

**D. ATTENDANCE AND EXCUSED ABSENCE**

- In the case of illness or prolonged absence, it is the student's responsibility to notify the faculty member and/or the Course Director within 5 days from the first date of absence. Exceptions to the five-day notification period are rare and can only be approved by the Vice Dean of Academic Affairs. With acceptable documentation from a student, an official memorandum will be issued notifying faculty of an excused absence. In the case of a legitimate excused absence, course instructors will make all reasonable attempts to assist the student to satisfy requirements of the course.
- Students missing 25% or more on attendance are forbidden from setting in the final exam per University Policy.
- If a student missed a midterm exam for an **ELIGIBLE** reason, Student must submit proper documentation within 2 weeks of scheduled exam time to the faculty member and the course coordinator.
- For any missed exams, student should fill a make-up exam form (pick up from department secretary) and obtain the necessary signatures and approvals from faculty member, the course director and head of the department.
- The faculty member has the right to determine the method for make-up exam, which can be any of the following:
  - Increasing the percentage of the remaining exams to cover the missed exam
  - Assigning the final exam a higher percentage to cover the missed exam for that student
  - A make-up exam (the exam will be based on short answer questions)
  - If the final is cumulative, the section relating to the missed examination material can be used as the grade for that missed exam.

**VIII. EXAMINATION AND GRADING CRITERIA**

**A. EXAMS/QUIZZES:**

Two midterms and a final exam will be administered throughout this course. The final course grade will be calculated based on the total number of points earned on each examination in comparison to the total number of points available.

**B. PROJECT PRESENTATION**

There will be a topic discussion presentation on one of the topics assigned by the course coordinators.

**C. GRADE DISTRIBUTION**

<b>Project</b>	(5 marks for the presentation + 5 marks for write up)	<b>10%</b>
<b>Midterm Exam</b>	Two midterm exams (25 grades each)	<b>50%</b>
<b>Final Exam</b>	Non-cumulative exam, about 60-80 questions. It will include True/False and multiple-choice questions	<b>40%</b>
<b>Total</b>		<b>100%</b>

**D. CONFLICT RESOLUTION:**

- Any issues related to this course teaching, examinations and grading should be resolved with the course instructor promptly to ensure healthy learning atmosphere.
- Unresolved matter should be directed to the course coordinator. If matter is not yet resolved, please direct your complaint to the department head/Vice Head.

**E. CHANGE IN THE COURSE SYLLABUS OR GRADE DISTRIBUTION:**

- Students will be notified with any changes to the course syllabus or grade distribution.

**F. GRADING SCALE:**

- Grades will be earned based on KSU grading policy and the following scale:

Letter Grade	Score Achieved	Letter Grade	Score Achieved
A+	> 95%	C+	75 - 79.99 %
A	90 - 94.99 %	C	70 - 74.99 %
B+	85 - 89.99 %	D+	65 - 69.99 %
B	80 - 84.99 %	D	60- 64.99 %
		F	< 60%

**PROJECT DESCRIPTION:**

Each student will be assigned to a project and project lists are below.

The assessment will be in two parts:

- 10 minutes presentation 5 %
- Report (Write Up) 5%

**List of possible topics for the PHCL 437 Project:**

Discussion of the topic and give an example of case of ethical violation of pharmacy related issues occurred locally or international in the following pharmacy or research areas:

1. Ethical issue in community pharmacy
2. Ethical issue in inpatient pharmacy
3. Ethical issue in outpatient pharmacy
4. Ethical issue in private hospital
5. Children in clinical research
6. Minority in clinical research
7. Embryo in clinical research
8. Pregnant women in clinical research
9. Lactating women in clinical research
10. Physically disable participants in clinical research.
11. Mentally disable participants in clinical research.

## G. COURSE SCHEDULE

Week #	Lecture #	Day	Date	Topic of lecture	Presenter M/F
1	1	Mon	7 January	Introduction, objectives and assessments of the course	AA/NA
	2	Wed	9 January	Introduction to ethics in pharmacy practice	AA/NA
2	3	Mon	14 January	Pharmacy law and ethics - 1	AA/NA
	4	Wed	16 January	Pharmacy law and ethics - 2	AA/NA
3	5	Mon	21 January	Pharmacy law and ethics - 3	AA/NA
	6	Wed	23 January	Pharmacist in different clusters with different ethical issues – 1	AA/NA
4	7	Mon	28 January	Pharmacist in different clusters with different ethical issues – 2	AA/NA
	8	Wed	30 January	Ethical issues in pharmaceutical research in Saudi Arabia - 1	AA/NA
5	9	Mon	4 February	Ethical issues in pharmaceutical research in Saudi Arabia - 2	AA/NA
	10	Wed	6 February	Ethical issues in Health Advertisement	AA/NA
6	11	Mon	11 February	Ethical issues in Health education	AA/NA
	12	Wed	13 February	Midterm Exam - 1	AA/NA
7	13	Mon	18 February	Institutions and Pharmaceutical Products Law – 1	OA/LA
	14	Wed	20 February	Institutions and Pharmaceutical Products Law – 2	OA/LA
8	15	Mon	25 February	Drugs Companies and its Products Registration Guideline - 1	OA/LA
	16	Wed	27 February	Drugs Companies and its Products Registration Guideline - 2	OA/LA
9	17	Mon	4 March	Medication pricing - 1	AG/LA
	18	Wed	6 March	Medication pricing - 2	AG/LA
10	19	Mon	11 March	SFDA Regulatory Framework for Drug Approvals - 1	HA/LA
	20	Wed	13 March	SFDA Regulatory Framework for Drug Approvals - 2	HA/LA
11	21	Mon	18 March	Presentation 1 <sup>st</sup> Group	OA/LA
	22	Wed	20 March	Presentation 2 <sup>nd</sup> Group	OA/LA
12	23	Mon	25 March	Presentation 3 <sup>rd</sup> Group	OA/LA
	24	Wed	27 March	Midterm Exam - 2	OA/LA
13	25	Mon	1 April	Presentation 4 <sup>th</sup> Group	OA/LA
	26	Wed	3 April	Presentation 5 <sup>th</sup> Group	OA/LA
14	27	Mon	8 April	Presentation 6 <sup>th</sup> Group	OA/NA
	28	Wed	10 April	Discussion and revision	OA/NA
				Final Exam	OA/NA

AA: Dr. Abdullatif Al-Ghaihab; OA: Dr. Omar Almohammed; AG: Ahmad Alghamdi; HA: Dr. Hamoud Almutairi  
 NA: Dr. Noha Al Aloola; LA: Dr. Lubna Aljaffali

## Appendix Project Presentation Evaluation

Students' Names: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Title: \_\_\_\_\_

- 1 = Unacceptable  
2 = Poor  
3 = Acceptable or good  
4 = Very good  
5 = Excellent or exceptional

Dimension	Score				
1. The group covered aspects of the issue comprehensively	1	2	3	4	5
2. The group appeared engaged during the presentation, used eye contact with class members and spoke in a loud and clear voice	1	2	3	4	5
3. The presentation generally flowed well	1	2	3	4	5
4. The group answered questions from the audience	1	2	3	4	5
5. Level of student involvement	1	2	3	4	5
Total score					
Grade of in class discussion out of 5 (Divide the total score by 5)					

Comments:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Preceptor Name & Signature: \_\_\_\_\_ Date: \_\_\_\_\_

### Reports:

It should be handled 1 week before the presentation for the groups.

### Grading of the project:

	Presentation %	Report %
Clear introduction of the topic	1	1
Clear description of the topic	1	1
Discussion and your reflection on the issue	1	1
References	-	1
Spelling and organization	1	1
Team work	1	-
<b>Total</b>	<b>5</b>	<b>5</b>