

CHARLES UNIVERSITY

PROFESSIONAL PHARMACY PRACTICE OPERATION

Faculty of Pharmacy in Hradec Kralove

Part I **General Provisions**

Article 1 Purpose

This regulation (hereinafter the “Regulation”) shall aim to improve the quality of education by professional pharmacy practice, which is operated as part of the curriculum of the Faculty of Pharmacy in Hradec Králové, Charles University (“Faculty”), and to provide matters necessary to ensure students' rights/interests and safety.

Article 2 Definition

Unless otherwise defined, the meanings of the terms used in this regulation shall be as follows:

1. The “Professional Pharmacy Practice (“Pharmacy practice”) shall refer to a curriculum in which the application of theory and practical education is provided to pharmacy students through the participation of the faculty of pharmacy (“Faculty”) and the professional pharmacy practice Institution (“Practical Institution”).
2. The “professional pharmacy practice Institution” (“Practical Institution”) shall refer to institutions that have the qualifications as the pharmacy practice Institution proposed by the National and local governments, public institutions, medical institutions, local pharmacies, pharmaceutical companies, Pharmaceutical Associations, or institutions equivalent to the foregoing and can provide the pharmacy practice for students of the faculty of pharmacy which is not limited to EU.
3. The “professional pharmacy practice Committee” (“Committee”) shall refer to the responsible department in relation to pharmacy practice that operates for the supervision and management of the pharmacy practice.
4. “Students enrolled in the pharmacy practice” (“Students”) shall refer to students enrolled in the faculty who engage in the pharmacy practice in accordance with the procedures set by the faculty.

Article 3 Target of regulation

The “Faculty of Professional Pharmacy Practice” subject to the Regulation shall include clinical practice, pharmacology, pharmaceuticals, and pharmaceutical administration practical training conducted as part of the curriculum.

Part II **Operation of the Practical Training**

Article 4 Principle of the Operation of the Practical Training

1. The Pharmacy practice complies with all the minimum practice requirements described in Article 44 of Directive 2005/36/EC, which may take place in pharmacies open to the public or in a hospital under the supervision of a pharmacist, should adequately prepare the student to practice in various sectors, particularly in terms of supplying medicine to the general public, providing information and advice on medicines, and managing a pharmacy.

2. The Pharmacy practice shall be carried out systematically according to the Syllabus of individual subjects focused on professional practice so that the students can cultivate the knowledge, skills, and attitudes necessary to perform related tasks as pharmacists after graduation.
3. The Faculty shall confirm and ensure the Practical Institution by considering the appropriateness of the expertise of the employees in charge of the training at the Practical Institution and the suitability of the Pharmacy practice environment and facilities/equipment through the internal accreditation process.
4. The Pharmacy practice shall meet the requirements as a curriculum according to the following subparagraphs:
 - a) Pharmacy practice & curriculum & Syllabus of the Faculty.
 - b) The Faculty's evaluation method for the Students and grounds and standards for awarding credit.
 - c) The Faculty's supervising department (academic advisor) assignment and teaching plan.
 - d) Other necessary provisions for operating on the duty of Pharmacy practice.
5. The Faculty shall organize a Committee to manage and supervise overall matters related to the Pharmacy practice curriculum, such as the confirmation and verification of the Practical Institution, student assignment, a syllabus of pharmacy practice, progress, and course evaluation.
6. Any case falling under any of the following subparagraphs may not be recognized as Pharmacy practice operated as part of the curriculum. However, in spite of the following cases, exceptions may be made and reviewed by Committee if the requirements for the Pharmacy practice performance standards, operation, management, etc., set forth in the professional pharmacy practice operation regulations are satisfied.
 - a) If there is no formal partnership between the Faculty and Practical Institution based on an agreement or an official document.
 - b) In case an individual student separately contacted a Practical Institution without an internal accreditation process.
 - c) In case an individual student receives a wage or salary for profitable purposes during the pharmacy practice as a curriculum.

Article 5

Hours of Operation of the professional pharmacy practice

1. The Student shall fulfill the condition and duration of Pharmacy practice, and practice is counted based on working hours. Pharmacy practice shall be based on 8 hours per day, excluding holidays and short illness during the pharmacy practice period that must be worked overtime. If a Student exceeds 8 hours, it is counted for the next working day.
2. The Student may have short temporary discontinuation of the Pharmacy practice with the consent of the practical institution only when it is necessary during the course of Pharmacy practice (e.g., for completing diploma theses research) but must be worked overtime.
3. The Student may perform Pharmacy practice during weekends and national holidays with the consent and consultation of the practical institution during the course of pharmacy practice.
4. The Practical Institution may extend and change the hours of operation with the consent and discuss the details with the Faculty and Students.
5. The Student shall not perform Pharmacy Practice during the academic year, when the compulsory education is being held. However, if it is unavoidable for the purpose of the pharmacy practice, during the academic year may be offered in consultation with the Faculty and Student.

Article 6

Evaluation of the Practical Training

1. The Faculty shall provide the information on the professional pharmacy practice evaluation criteria to the Practical Institution and finalize the evaluation criteria in consultation with the Practical Institution. Also, the Practical Institution shall conduct an evaluation of the Student according to the applicable standards and submit the relevant evaluation documents to the Faculty.
2. The Faculty shall provide the evaluation tools to Practical Institution to examine the student's progress during the Pharmacy practice as a curriculum according to the following subparagraphs:

- a) Verification call (via MS Teams, Zoom): Student must slowly and clearly show the entire place of the Pharmacy, including dispensing area, storage area, laboratory (if possible), and other operating areas in the Pharmacy, by using the webcam (360° view).
- b) The logbook is required to evaluate students' attitudes and activity during practice experience.
3. The Faculty shall provide the evaluation tools and criteria to the Student to examine the student's progress during the pharmacy practice as a curriculum according to the following subparagraphs:
 - a) Students must submit Consent of professional practice before the practice.
 - b) After completing professional practice, the student's supervisor or head of the workplace provides and confirms the practice by signing the Information of pharmacy professional practice, Confirmation of completion of professional practice, and logbook, including the schedule of professional practice, which must be submitted by the students to the faculty.
 - c) Interview (face-to-face): Explaining the basic concept of the pharmacy professional practice. Including Objective Structured Clinical Examinations (OSCEs), which are stations or scenarios where students are assessed on their ability to perform specific tasks or solve problems related to real clinical settings such as patient counseling, medication review, or various clinical scenarios.
 - d) Students must complete the relevant student's task according to the specifications of individual practice subject.
 - e) Students who fulfilled all the obligations will receive the credits based on the Study Plan of the Faculty.
4. The Practical Institution shall provide the evaluation tools provided by the Faculty to examine the student's progress during the pharmacy practice as a curriculum which must be submitted to the Faculty at the end of the practice to the persons who will be responsible for coordinating the students' Pharmacy practice with the Practical Institution according to the following subparagraphs.
 - a) The logbook is required to evaluate and observe students' attitudes, abilities, and activities during practice experience.
 - b) A schedule is required to evaluate students' fulfilled practical training for pharmacists to complete and perform practical skills or procedures.
 - c) To complete the education criteria for professional practice, pharmacists can provide relevant tasks to evaluate and improve practical training skills based on the Syllabus.

Article 7 Confidentiality

The Faculty and the Practical Institution shall keep confidential data and information obtained in the course of the discussion and implementation of the Pharmacy Practice and shall not disclose or divulge such information to any third party without mutual consent.

Article 8 Qualification of Professional Practice Educator

1. Professional practice Educator shall be verified by the government or chamber of pharmacists (Technician assistants cannot be performed and guide for students).
2. Professional practice Educator shall be those who have the qualifications of pharmacists appointed by the Faculty after verification through the internal accreditation process by the Committee. The appointment period shall be no more than two years to educate and undertake a range of activities for the safe supply of medicines to patients and the public. The reaccreditation process is required to ask every two years.
3. EEA Professional practice Educator shall be recognized who have qualification in the EEA country listed in Annex V, section 5.6.2 of Directive 2005/36/EC, amended by Directive 2013/55/EU with complied all the minimum pharmacy practice requirements described in Article 44 of Directive 2005/36/EC.
4. Outside of EEA, Professional practice Educator shall be requested to apply for internal accreditation process to be recognized as practical educators by submitting according to the following subparagraphs:
 - a) Personal documents: Pharmacist qualifications & Passport copy

- b) Application form: including personal information, location of the pharmacy, facilities details (dispensary room, counseling space), equipment, and computer programs.
 - c) Business permit (pharmacy operating license): including No. of pharmacy registration, date of registration, and VAT ID
5. Professional practice Educator shall be those who are qualified. The total duration of education and Professional pharmacy practice for pharmacists must be at least five years. This usually includes a minimum of four years of academic study, six months of practical training, and work on diploma thesis..
 6. Professional practice Educator shall provide adequate knowledge of subjects crucial to understanding the science of medicines and their use, including medicinal chemistry, pharmaceutical technology, pharmacology, and pharmacotherapy.

Article 9 Duties of Practical Institution

The Practical Institution shall perform each of the following duties:

1. Provision of a licensed Professional practice Educator, implementing pharmacy practice utilizing expertise in each area, who will supervise and educate the students during their pharmacy practice.
2. Evaluation of all matters, including achievement of the Students of the Pharmacy Practice.
3. Provision of a conducive environment for Pharmacy practice, ensuring educators with practical experience are capable of providing professional Pharmacy Practice and education on essential job responsibilities of pharmacists as follows.
4. Provision of opportunities for the students to gain practical experience in the field of Pharmacy:
 - a) Mandatory Scope of practice (work and activities) shall be allowed during students' practice experience. The Scope of practice for students placed at the Practical Institution shall include, but is not limited to, the following activities:
 - b) Dispensing of Medicines: Under the supervision of a licensed Educator, the students will assist in dispensing prescribed medications to patients. This shall involve verifying the accuracy of prescriptions, selecting and packaging medications, and providing instructions to patients on how to use the medications.
 - c) Patient Counselling: Students may assist the pharmacist in counseling patients on the use of their medications, how to manage drug-related problems, and how to manage and prevent patients' diseases or health conditions.
 - d) Compounding of Medicines: If the Practical Institution engages in compounding (customizing) medications, students may assist in preparing these medications under the supervision of the pharmacist.
 - e) Administrative Management: Students shall gain experience in administrative tasks, such as control and supply processes, processing insurance claims, managing the inventory of medications, and maintaining patient records.
 - f) Health and Wellness Services: Depending on the services offered by the Practical Institution, students may assist in providing additional health and wellness services, such as immunizations, health screenings, and educational programs.

Article 10 The Students

1. The Students shall comply with all matters related to the Pharmacy practice, including the items in each of the following subparagraphs:
 - a) Procedures and standards according to the Professional Pharmacy practice operating regulations.
 - b) Work and safety management regulations and standards of the Practical Institution
 - c) Prohibition of disclosure of confidential information of Practical Institution obtained during the Pharmacy practice.
2. The Students shall be guaranteed the following rights:
 - a) The right to receive instruction during the Pharmacy practice.
 - b) The right not to be penalized in relation to the Pharmacy practice, except for intentional or gross negligence on the part of the person during the Pharmacy practice.
 - c) The right to be entitled to certain measures if anything contrary to the Pharmacy practice operating standards or Pharmacy practice operating plan occurs.

Article 11
Safety Accidents during the Professional Pharmacy Practice

1. If an emergency occurs, including accidents or injuries to the Students during the Pharmacy practice, the Practical Institution shall immediately take appropriate measures and report it to the Faculty.

Article 12
Measures in Case of Violation of the Professional Pharmacy Practice Regulations

1. The Students shall comply with the Professional Pharmacy practice regulations during the Pharmacy practice period.
2. The Practical Institution shall immediately report to the Faculty any serious reason that may hinder the Students from continuing Pharmacy practice.
3. The Faculty shall determine what decisions shall be made for the student by mutual consultation with the Practical Institution within a certain period of time after receiving a report on the problem under the preceding paragraph from the Practical Institution and notify the Practical Institution via email.

Professional Pharmacy Practice General Qualification Criteria and Required Documents for Recommendation

The Faculty of Pharmacy only approve an institute that fulfills the criteria for providing an environment suitable for Professional Pharmacy practice with a conducive environment for Pharmacy practice, ensuring and certifying educators with practical experience and capable of providing professional practice and education on essential job responsibilities of pharmacists as follows.

Criteria	Requirements	
Environmental Criteria	<p>A. It has a dispensary room and a space for medication counseling for students to practice.</p> <p>B. It is equipped with dispensing equipment, which is the main equipment for practice, and computer programs such as prescription review and DUR.</p>	
Content Criteria	<p>It can teach all of the following:</p> <p>A. Prescription dispensing a. Receiving, reviewing, and inputting prescriptions b. Prescription dispensing and review c. Conversation and work mediation</p> <p>B. Medication guidance and administration a. Design and prepare medication guidance b. Medication guidance practice and follow-up management</p> <p>C. Over-the-counter medication administration a. Learning about over-the-counter medicines b. Over-the-counter drug selection counseling c. Over-the-counter medication guidance</p> <p>D. Pharmaceutical information work a. Medical information collection, evaluation, and management b. Provision of drug information and drug identification information c. Understanding and implementation of drug use evaluation d. Adverse drug reaction monitoring</p> <p>E. Pharmacy management a. Drug management b. Facility and equipment, documentation, and operation management c. Pharmacy hygiene management</p>	
Educator Criteria	Qualification	Required document
	<p>A. For those who are qualified, the total duration of education and Professional pharmacy practice for pharmacists must be at least five years. This usually includes a minimum of four years of academic study, six months of practical training, and work on diploma thesis.</p> <p>B. Those who are verified pharmacists from the state or national</p>	<p style="text-align: center;">EEA</p> <p>-Curriculum vitae (CV) or Resume:</p> <p>Personal Information:</p> <ul style="list-style-type: none"> ⑩ Name and surname ⑩ Email address ⑩ Name of graduated pharmacy school ⑩ Pharmacist qualification number or Registration No. of graduation certificate ⑩ Working experience <p>Institution information:</p>

	government or chamber of pharmacists.		⑩ No. of pharmacy operating registration or VAT ID ⑩ Date of registration -Personal ID or Passport copy
	C. Those with a pharmacist license have opened a pharmacy and have been in business for more than one year. D. Those who have completed the Professional Pharmacy Practice more than: a. Three years of work experience as a pharmacist in a hospital pharmacy or/and Community pharmacy or b. Three years of working experience in the pharmaceutical industry	Non-EEA	-Accreditation Application form: With supporting information and pictures regarding dispensing place, space for medication counseling, equipment for dispensary, and computer program for prescription review -Pharmacist qualification certificate -Passport copy -Business permit (pharmacy operating license): including No. of pharmacy registration, date of registration, and VAT ID -Faculty of pharmacy practice agreement

[Remark]

1. Those who meet the general qualification and at least one qualification to D.
2. Based on Annex V, section 5.6.2 of Directive 2005/36/EC, amended by Directive 2013/55/EU, listed EEA countries are automatically recognized by Faculty without submitting an Accreditation application form and Faculty of pharmacy practice agreement. The internal accreditation process is confirmed based on the personal information which is provided by the EEA Educator.



CHARLES UNIVERSITY
Faculty of Pharmacy
in Hradec Králové

ACCREDITATION APPLICATION FORM

FOR ACCREDITATION OF PROFESSIONAL PRACTICE PROVIDERS

Instruction: Please accomplish this form and submit it together with the required accreditation documents.

APPLICANT'S INFORMATION			
Surname		First name	
Date of Birth (DD/MM/YYYY)		Phone/Telephone No.	
Passport (Identity card) No.		E-mail address	
Name and country of Graduated school		Year of Graduation	
Qualification/License No.		Position in the pharmacy	
Country of permanent residence		Legal Nationality	
Working experience			
PHARMACY DATA			
Name of Pharmacy			
Pharmacy address			
City		Country	
Business Permit No. (pharmacy operating license)		Date of business register	
ORGANIZATION DATA			
Name of Head Pharmacist			
No. of employed staff	Pharmacists:	Pharmacy technicians:	Others:
Name of Owner			
No. of employed staff	Head of Pharmacist: Pharmacy Assistant	Pharmacy technician: Others:	
FACILITIES DATA			
To support all the data, please submit relevant pictures together with the application form			
Dispensing area	Yes / No	Pharmacy software	Yes / No
Compounding area	Yes / No	Counseling area	Yes / No
Head Pharmacist Office	Yes / No	Storage area	Yes / No
Safe for psychotropic and narcotic drugs	Yes / No	Refrigerator	Yes / No
Dispensing area	Yes / No	Pharmacy software	Yes / No
Others			
EQUIPMENT LABORATORY DATA			
To support all the data, please submit relevant pictures together with the application form			
Machinery / Equipment		Tools	

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MEDICATION DATA

To support all the data, please submit relevant pictures together with the application form

No. of OTC medications (approx. Nr.)		No. of prescription medications (approx. Nr.)	
Sale for Medical devices	Yes / No	Sale for Veterinary medication	Yes / No
Sale for Cosmetics	Yes / No	Sale for Supplements	Yes / No
Sale for herbal drugs	Yes / No		

LIST OF REQUIRED ACCREDITATION DOCUMENTS (FOR NON-EEA)

I. FOR ACCREDITATION PROCESS (2-3 weeks)

- ⑩ Application form with supporting pictures
- ⑩ Passport copy
- ⑩ Pharmacy Qualification/ License
- ⑩ Business permit (pharmacy operating license): including registration number, date of registration, and Tax ID

II. AFTER APPROVAL

i. Before the practice

- ⑩ Faculty of pharmacy practice agreement

LIST OF REQUIRED DOCUMENTS FOR STUDENT'S EVALUATION

After completing professional practice, the student's supervisor or head of the workplace provides and confirms the following documents, which must be submitted by the students to the faculty.

I. BEFORE THE PROFESSIONAL PRACTICE

- ⑩ Consent for professional Pharmacy practice

II. AFTER THE PROFESSIONAL PRACTICE

- ⑩ Confirmation of professional pharmacy practice
- ⑩ Logbook
- ⑩ Schedule of professional practice
- ⑩ Information on pharmacy for Professional Practice

According to permission to Charles University, residing in Ovocny trh 560/5, 116 36 Prague 1, company registration No.:00216208(hereinafter "CU"), acting as a controller of personnel of all faculties and other parts of CU, to process applicant's personal data:

My Application form is collected, stored, and processed for the purpose of evaluating and ensuring the accreditation process (both in printed and electronic form).

I grant the consent for the period of two years, and I am aware of the fact that it is not possible to remove the data from the already printed publications.

Based on the professional pharmacy practice operation Part II, Article 7(confidentiality) shall not disclose or divulge such information to any third party without mutual consent.

In witness whereof, the parties hereto have executed this Agreement as of the period of the agreed term stated in the consent of the professional practice.

Place and date:

Name and surname of applicant:

Position in pharmacy:

Signature and stamp of the
applicant