

| 2023/2024. ACADEMIC YEAR  |                         |                          |                         |  |   |   |                |
|---|-------------------------|--------------------------|-------------------------|--|---|---|----------------|
| PROGRAM OF STUDY (FOR STUDENTS OF 5TH YEAR)   |                         |                          |                         |  |   |   |                |
| Full (Hun) name of the subject: Gyógyszeripari és gyógyszerfelügyeleti, hatósági ismeretek-Gyógyszerengedélyezés (elmélet+gyakorlat)  |                         |                          |                         |  |   |   |                |
| Program: Undivided program (pharmaceutical)   |                         |                          |                         |  |   |   |                |
| Schedule: full-time   |                         |                          |                         |  |   |   |                |
| Short name of the subject:  |                         |                          |                         |  |   |   |                |
| English name of the subject: Knowledge of the Pharmaceuticoindustrial and Pharmacovigilance Authorities - Drug Licensing (theory+practice)  |                         |                          |                         |  |   |   |                |
| German name of the subject: Behördenkenntnisse der pharmazeutischen Industrie und Arzneimittelüberwachung - Arzneimittelzulassung und Registrierung (Vorlesung+Praktikum)   |                         |                          |                         |  |   |   |                |
| Type of registration: obligatory  |                         |                          |                         |  |   |   |                |
| Neptun code of the subject: GYKGYI102G1A  |                         |                          |                         |  |   |   |                |
| Responsible Department: Semmelweis University, Department of Pharmaceutics  |                         |                          |                         |  |   |   |                |
| Responsible tutor<br><br>Dr. István Antal<br>Contact information:<br>- phone: 06-1-217-0914<br>- email: antal.istvan@semmelweis.hu  |                         |                          |                         | Title, academic degree:<br><br>University Professor, PhD, Dr. habil  |   |   |                |
| Name of the persons responsible for the teaching of the subject:<br><br>Dr. Miléna Lengyel<br>Phone: +36-1-459-1500 Extension: 53069<br>E-mail: lengyel.milena@semmelweis.hu<br><br>Dr. Romána Zelkó<br>Dr. Nikolett Kállai-Szabó<br>Dr. Bálint Basa<br>Dr. Herta Pálfiné Goóts<br>Dr. Zsófia Kohod   |                         |                          |                         | Title, academic degree:<br><br>Assistant professor, PhD<br><br>University Professor, Dr. habil<br>Associate Professor, PhD<br>PhD Student, PharmD<br>invited lecturer, PhD<br>PharmD |   |   |                |
| Class per week: 12/sem lectures<br>12/sem practices   |                         |                          |                         | Credit point(s): 1 credit  |   |   |                |
| Professional content, intent of acquirement and it's function in order to implement the goals of the program:<br>The purpose of the subject is to review the authorization process of medicines and preparations that cannot be considered medicines, but are sold in pharmacies, as well as the aspects of the development and evaluation of the information and documentation that underpins this.  |                         |                          |                         |  |   |   |                |
| Short description of the subject:<br>Students will learn the basics of marketing authorization, the regulatory environment and system of requirements that determine the content and form requirements of technical documentation, including drug quality, as well as the tasks related to the application for marketing authorizations, official evaluation and the maintenance of authorizations. The subject provides an overview of industrial and official processes prior to placing on the market. It presents, in general, the activities and knowledge materials required for maintaining and amending the license after obtaining it. |                         |                          |                         |  |   |   |                |
| Course data   |                         |                          |                         |  |   |   |                |
| Recommend ed term   | Contact hours (lecture) | Contact hours (practice) | Contact hours (seminar) | Individu al lectures   | Total number of contact hours/sem ester | Normal course offer   | Consult ations |
| 9 <sup>th</sup> semester  | 12                      | 12                       | -                       | -  | 24                                      | Autumn semester*<br>Spring semester<br>Both semesters<br>(* Please underline) | On demand      |

| <b>Program of semester**</b>  |
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| <b>Topics of theoretical classes (2-week block in the 1-2. weeks of semester)</b> <ol style="list-style-type: none"> <li>1. Introduction. Importance of licensing, legal environment, application</li> <li>2. Drug authorization processes. Modification processes of already authorized pharmaceutical products.</li> <li>3. Border area products and non-pharmaceutical products distributed in the pharmacy</li> <li>4. The planning process for the development of original medicines</li> <li>5. The planning process for the development of generic drugs</li> <li>6. Planning process for the development of generic added value medicines</li> <li>7. Biological medicines and biosimilar preparations</li> <li>8. Planning of WEU and its traditional development</li> <li>9. Official evaluation of medicines</li> <li>10. Quality assurance related to drug licensing</li> <li>11. Audits and inspections in pharmaceutical production</li> <li>12. Pharmacovigilance of medicines</li> <li>13. Instructions for use in everyday life, OTC preparations</li> </ol> |
| <b>Topics of practical classes</b><br>During the exercises, students acquire additional knowledge about the content of the registration documentation in parallel with the theoretical lessons, <ul style="list-style-type: none"> <li>- on the structure of Common Technical Documentation</li> <li>- about the QP declaration,</li> <li>- on the practical implementation of the amendment of marketing authorizations.</li> </ul>  |
| <b>Other subjects (both compulsory and optional) relating to the transversal issues of the subject. Possible overlaps between subjects:-</b>  |
| <b>Schedule of consultations:</b> on demand   |
| <b>Course requirements</b>  |
| <b>Prerequisites:</b><br>Pharmaceutical Technology IV.<br>Pharmacy Administration I.  |
| <b>Conditions of attending the classes, amount of acceptable absents, way of presentation of leave, opportunity for makeup:</b>   |
| <b>The grading method; the conditions for getting the signature; the number, topic(s) and date(s) of the mid-term assessments (reports, term tests), and the process in which they contribute to the final grade; and the possibility of their retake or their upgrading retake (as provided in §§ 25-28 of the STUDY AND EXAMINATION REGULATIONS):</b><br>Attendance of lectures and practicals expected according to study regulations. The written exam (Moodle test on Sept. 29.) or makeup exam (3. educational week) must be passed ("accepted"). The overview lecture slides will be published on Moodle.  |
| <b>Requirements of signature(as provided for in STUDY AND EXAMINATION REGULATIONS § 29):</b><br>Attendance of lectures and practicals expected according to study regulations   |
| <b>Number and type of projects students have to perform independently during the semester and their deadlines:</b>  |
| <b>Type of the semester-end examination:</b> signature*/ <u>practical grade*</u> / comprehensive examination*/final/end-term examination*<br><b>Examination requirements:</b> as published by the education-research department on the MOODLE interface by the start of the academic term.<br>. The written exam or makeup exam must be passed, min 50% ("accepted").   |
| <b>Form of the semester-end examination:</b> <u>written</u> */oral*/combined examination/practical examination/the assessment of completing project work (according to STUDY AND EXAMINATION REGULATIONS 30.§)* (* Please underline)  |

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| <p><b>The possibility and conditions for offering grades:</b></p> <p>-</p>  |
| <p><b>A list of the basic notes, textbooks, resources and literature that can be used to acquire the knowledge necessary to master the curriculum and to complete the assessments, with exact description about which of them is required to acquire which part of the syllabus (e.g. description based on topics)), as well as the main technical and other aids and study aids that can be used:</b></p> <p>Lecture slides will be published on Moodle. All necessary information for the successful exam can be found on the slides, however, the presenters provide deeper understanding of the schematic information slides.</p> |
| <p><b>In the case of a subject lasting more than one semester, the position of the teaching/research department on the possibility of parallel enrolment and the conditions for admission****:</b></p> <p>yes*/no*/<u>on an individual assessment basis*</u> (* Please underline)</p>   |
| <p><b>The course description was prepared by::</b></p> <p><b>Dr. Antal István</b></p>   |