



**UNIVERSITY
OF LONDON**

Programme Regulations 2019–2020

Pharmacoepidemiology and Pharmacovigilance

Postgraduate individual module

Important document – please read
This document contains important
information that governs your
registration, assessment and
programme of study

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Important information regarding the Programme Regulations

Last revised 19 April 2019

As a student registered with the University of London you are governed by the current General Regulations and Programme Regulations associated with your programme of study.

These Programme Regulations are designed and developed by the London School of Hygiene & Tropical Medicine (LSHTM) which is responsible for the academic direction of the programme. The regulations take account of any associated arrangements at LSHTM. Programme Regulations, together with the [Programme Handbook](#), will provide the detailed rules and guidance for your programme of study.

In addition to Programme Regulations you will have to abide by the [General Regulations](#). These regulations apply to all students registered for a programme of study with the University of London and provide the rules governing registration and assessment on all programmes; they also indicate what you may expect on completion of your programme of study and how you may pursue a complaint, should that be necessary. Programme Regulations should be read in conjunction with the General Regulations.

The relevant General Regulations and the Programme Regulations relating to your registration with us are for the current year and not the year in which you initially registered.

On all matters where the regulations are to be interpreted, or are silent, our decision will be final.

Further information about your programme of study is outlined in the Programme Specification which is available on the relevant Courses page of the website. The Programme Specification gives a broad overview of the structure and content of the programme as well as the learning outcomes students will achieve as they progress.

Terminology

The following language is specific to the **Pharmacoepidemiology and Pharmacovigilance** programme:

Module: Individual units of the programme are called module. Each module is a self-contained, formally structured learning experience with a coherent and explicit set of learning outcomes and assessment criteria.

Throughout the Regulations, 'we' 'us' and 'our' mean the University of London; 'you' and 'your' mean the student, or where applicable, all students.

If you have a query about any of the programme information provided please contact us. You should use the 'ask a question' tab in the [student portal](#)

Changes to Pharmacoepidemiology and Pharmacovigilance Regulations 2019-2020

No significant changes

1 Structure of the programme

[\[Appendix A\]](#) gives the syllabuses and course outlines.

Qualification structure

1.1

The **Postgraduate short course in Pharmacoepidemiology and Pharmacovigilance** consists of one module, PCM100, comprising taught sessions, interactive workshops, formative exercises and an Integrating Project and final exam.

2 Registration

Effective date of registration

2.1

Your effective date for registration will be 1 November for the Postgraduate short course in Pharmacoepidemiology and Pharmacovigilance.

Period of registration

2.2

The maximum and minimum periods of registration, from your effective date of registration, are:

- **Maximum** – Two years
- **Minimum** – One year

3 Recognition of prior learning and credit transfer

To be read in conjunction with the [General Regulations](#).

Recognition of prior learning

3.1 Prior learning and credit transfer will not be considered for this programme.

4 Assessment for the programme

To be read in conjunction with the [General Regulations](#), Section 4.

Assessment methods

4.1

The PCM100 module will be assessed by a timed unseen written examination and a project, weighted on a scale of 60:40.

4.2

The unseen written examination will comprise two parts, a short answer examination and a multiple-choice examination, which comprise 60% of the final mark for the module.

4.3

The project comprises 40% of the final mark for the module.

Marks are awarded and combined as outlined in the [Assessment Scheme](#) (Appendix A).

4.4

You may complete both the unseen written examination in the first year and submit the project in the same year. However, if you attempt only one element of the assessment, you will be permitted to carry forward the grade awarded for the element attempted to a second year. The Board of Examiners will decide if grades can be carried forward for any subsequent years.

4.5

Written assignments, projects and other similar work must be your own work and must be written without the assistance of other people, except in possible instances where you are clearly allowed to work in a group and submit a piece of work jointly. If group work is submitted, all students working in the group must confirm the nature of their contribution to the submitted work.

Date of examinations

4.6

Timed unseen written examinations normally take place in June each year.

See the website for the list of [examination centres](#).

4.7

Any written assignments and the project must be submitted by the deadlines given in the guidelines for the assignments and the LSHTM Student Handbook, both of which are available on the LSHTM Virtual Learning Environment to registered students. Written assignments and the project must be submitted electronically (unless otherwise specified in the assignment guidelines).

4.8

Extensions to written assignments or the project deadlines will only be given in mitigating (extenuating) circumstances and will only be considered on application to the LSHTM Extenuating Circumstances Committee before the deadline. An assignment or project received after the deadline, without an agreed extension, will either receive a grading penalty or will not be marked.

Materials and aids allowed in the examination room

4.9

Pre-programmable calculators may be used (see the 'Permitted materials list' that will accompany your 'Notice to candidates'). These must not have a wireless or internet connection.

See [General Regulations](#): Rules for taking written examinations.

5 Number of attempts permitted at an examination

5.1

The maximum number of attempts at the unseen written examination or project is two. If you fail the examination or project at the first attempt, you will be allowed to make a second attempt (resit). Mitigating (extenuating) circumstances may be taken into account which allow for more attempts.

5.2

If you fail both the unseen examination and the project, you will have to resit both elements (a resit fee will be payable).

5.3

If you pass one element but not the other (unseen written examination or project), you will have to resit the failed element (a resit fee will be payable). You cannot resit an element you have already passed.

5.4

If you need to complete or resit one element of assessment (either the unseen written examination or the project) you must ensure that you have registered for the module again and must enter to be assessed in the element that you need to complete or resit, paying the resit fee as appropriate. Assessment guidelines or deadlines are subject to change annually so you must ensure that you follow any updated guidelines or deadlines for the year in which you are registered.

5.5

If you fail the project at the first attempt, the Board of Examiners will decide the deadline by which you must revise and resubmit the failed project.

More details can be found about [mitigating \(extenuating\) circumstances](#) on the webpage and in the [General Regulations](#). Details of the LSHTM resits and mitigating (extenuating) circumstances policies are available to registered students on the LSHTM Virtual Learning Environment.

6 Assessment offences and penalties

6.1

Penalties may be applied to assessed work that does not comply with requirements given in programme materials or is not submitted by the stated deadlines. You should check the requirements given for individual assignments and projects on the LSHTM Virtual Learning Environment. Penalties such as grade reductions (including reduction to a fail grade) may apply for work that is late, over-length or for poor academic quality and plagiarism.

See the [General Regulations](#) for assessment offences and penalty information.

7 Scheme of award

7.1

The Board of Examiners will make a decision on the final course classification once the criteria for the course have been met.

7.2

All unseen written examinations and the project will be marked and grades combined according to the Assessment Scheme ([Appendix A](#)).

7.3

The final outcome of the course and the final classification (pass or distinction) will be determined as set out in the Assessment Scheme ([Appendix A](#)).

See [Appendix A](#) for information on the Assessment Scheme.

Appendix A – Assessment Scheme

There are two components to the formal assessment of this course:

- a) the unseen examination, and
- b) the project.

The unseen examination is made up of a short answer paper and MCQ paper and the combined marks from these two elements contribute 60% of the overall marks, and the project contributes 40%.

1. The combined unseen examination component

The Short Question examination is blind double marked. Marks are reconciled between the two markers. The Multiple Choice Paper is marked by computer scanning. All assessments are numerically marked according to a mark scheme agreed in advance, and converted to a percentage. Marks are confirmed by the Board of Examiners.

1.1. The Short Question Examination contributes 75% towards the unseen examination component (45% towards the final mark for the course). Students are asked to complete 9 questions. Each question is then marked out of 10. The highest total possible mark for this examination is 90.

The percentage score for this examination is then calculated as follows:

$$SQ = \frac{100 \times \sum \text{marks for each question}}{90}$$

1.2. The Multiple Choice Question Examination contributes 25% towards the unseen examination component (15% towards the final mark for the course). There are five possible answers to each question, and students select the most appropriate answer. Correct answers receive 1 mark; incorrect answers receive $-\frac{1}{4}$ (-0.25) mark. An unanswered question receives zero marks. The highest total possible mark for this examination is 40. MCQ papers are marked by computerised scanning.

The percentage score for this examination is then calculated as follows:

$$MCQ = \frac{100 \times \sum \text{totalmarks}}{(\text{number of questions})}$$

1.3. Unseen Examination component (UE)

The Short Question (SQ) and Multiple Choice Question (MCQ) examinations are combined to produce the unseen examination component percentage. Compensation is permitted between the two papers i.e. given that an overall mark of not less than 50% is achieved a student may score less than 50% on one paper.

The overall percentage for the unseen examination component is then calculated as follows:

$$UE = (SQ \times 0.75) + (MCQ \times 0.25)$$

2. Project

The project contributes 40% towards the final mark for the course. All projects are blind double marked. Students are given a numerical grade for each section of the project and the highest total possible mark is 100. The project sections vary according to the topic selected for any year and students will be given a section/marks breakdown with their project instructions. The highest total possible mark for this examination is 100.

The marks in each section of the project are totalled to give a total sum of marks and the percentage score is calculated as follows:

$$P = \sum \text{project marks}$$

3. Calculation of the Overall Percentage

The overall percentage is obtained as follows: **Overall % = (UE x 0.6) + (Project x 0.4)**

4. Overall final mark

The final mark and classification is determined by considering the overall percentage and the following rule:

For the student to automatically achieve an overall pass, the percentage for both the unseen exam and project component must be 50 or above, regardless of the overall percentage. Any component with a percentage of <50 is considered a fail.

The final mark may be classified as follows:

Pass with Distinction	A distinction is automatically awarded if the percentages for both the unseen examination and project component are 80 or above
Consider Distinction	A candidate may be considered for distinction if the percentage score for either of the two components is 80 or above and the percentage score for the other component is >70 and <80.
Pass	A pass is automatically awarded if the overall percentage is 50 or above and no individual component percentage is below 50.
Fail	A candidate is failed if they meet none of the criteria above.

5. Re-sits

5.1. Unseen examination

A student who attains a percentage of <50 in the unseen examination component but passes the project will be allowed to re-enter the examination on one further occasion only (further attempts may be allowed by the Extenuating Circumstances Committee). This will normally be to the corresponding examination one year later.

5.2. Project

A student who attains a percentage of <50 in the project component may re-submit the project within a time limit set at the Chairman of the Board's discretion. This will count as a resit attempt. Only one resit attempt is allowed (further attempts may be allowed by the Extenuating Circumstances Committee).

5.3. Both the unseen examination and project components must be passed. If both are failed, the student must resit both.

6. Notification of results

6.1. The final mark and classification must be agreed by the Board of Examiners and signed off by the Chair and the External Examiner(s).

6.2. The University of London and LSHTM will advise candidates of their results.

Results will be presented according to the following points system:

Percentage	Grade point
80-100	5
70-79	4
60-69	3
50-59	2
40-49	1

7. Credits

30 credits are awarded on successful completion of the course, having achieved a Pass (i.e. obtaining a minimum grade point of 2) or Distinction classification (i.e. obtaining a grade point of 5).

Appendix B – Module content

The course includes sessions addressing the following topics:

Pharmacoepidemiology

Students will learn about the fundamentals of pharmacoepidemiology, its conduct, practical uses and limitations in determining the effects of medications in large groups of people. The statistical basis underpinning pharmacoepidemiology will also be introduced, and students will integrate statistics and epidemiology to gain competence in critically appraising pharmacoepidemiology studies.

Pharmacovigilance

Students will be introduced to the key elements of pharmacovigilance and its basis within drug regulation. Within the risk management elements of the course, students will gain insight into how pharmacoepidemiology and pharmacovigilance are combined in the investigation of the effects of medicines. Principles will largely be demonstrated within the European legislative context, whilst recognizing these general principles apply more broadly throughout the world.

Health economics

Students will be introduced to the fundamental concepts involved in assessing the cost effectiveness of health technologies and methodologies used to assess the health related quality of life. Real world examples will be used to illustrate concepts

Integrating Project

An integrating project will enable students to demonstrate their global understanding of pharmacoepidemiology and pharmacovigilance. A currently live drug safety issue will be selected, for which students will be given a selection of study reports (usually 5 or 6). The task is to critically appraise the evidence, to make decisions based on the totality of the evidence, and to make suggestions for future regulatory action and research.

Broadly, the project contains the following sections:

1. Introduction to the subject (subjects will differ from year to year).
2. Outline of the requisites for the report, covering:
 - (i) a summary of the key points of the project and an introduction of the topic
 - (ii) a critical appraisal of each of the individual studies provided, including an assessment of their strengths and weaknesses
 - (iii) an overall assessment of the possible causal association presented in the papers
 - (iv) a recommendation of any regulatory action students think is warranted based on the evidence provided