UNIVERSITY OF LONDON INTERNATIONAL PROGRAMMES

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Programme Regulations 2016–17

Postgraduate Professional Development course in Pharmacoepidemiology and Pharmacovigilance

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

Contents

Important information regarding the Programme Regulations

About this document

Last revised: 26 July 2016

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

The Programme Regulations are designed and developed by the London School of Hygiene & Tropical Medicine (LSHTM) which is responsible for the programme and they take account of the associated arrangements within the School. Programme Regulations, together with the London School of Hygiene & Tropical Medicine (LSHTM) Student Handbook, will provide the detailed rules and guidance for your programme of study. Further information about how to use the Programme Regulations can be found in the Student Guide.

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 International Academy 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.

A glossary provides an explanation of the terms used in this document.

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 https://my.londoninternational.ac.uk.

To note:

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

This course is being offered for the first time in 2016-17

1 Structure of the programme

1.1

The **Postgraduate Professional Development course in Pharmacoepidemiology and Pharmacovigilance** consists of:

- One module, PCM100, comprising taught sessions and an Integrating Project.

See the module content at Appendix B.

2 Registration

See glossary for the definition of 'effective date of registration'.

Effective date of registration

2.1

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

Period of registration

2.2

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

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

3 Recognition of prior learning and credit transfer

To be read in conjunction with the General Regulations.

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.

See glossary for the definition of 'examination' and 'written examination'.

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 are expected to complete both the unseen written examination and submit the project in the same academic year. However, if you attempt only one element of the assessment, you will be allowed 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

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 as 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 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. Assignments and the project must be submitted electronically (unless otherwise specified in the assignment guidelines).

4.8

Extensions to assignments or the project deadlines will only be given in mitigating (extenuating) circumstances and will only be considered if you have written to the Programme Director before the deadline. An assignment or project received after the deadline, without an agreed extension, will either be downgraded 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 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 examination or the project) you must ensure that you have registered for the module again and must enter to be examined 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 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 guidance given in programme materials or is not submitted by the stated deadlines. You should check the guidance 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:

1.   the combined unseen examination, and
2.   the project.

The combined marks from the unseen examination (short answer paper and MCQ paper) 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:

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

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 -¼ (-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:

$$MCQ = \frac{100 \times \sum total\ marks}{(number\ of\ questions)}.$$

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:

$UE = (SQ$ x 0.75) + (MCQ x 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:

$$P = \sum project\,marks$$

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 International Programmes 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 or Distinction classification (i.e. obtaining a minimum grade point of 2).

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.

Pharmavigilance

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.