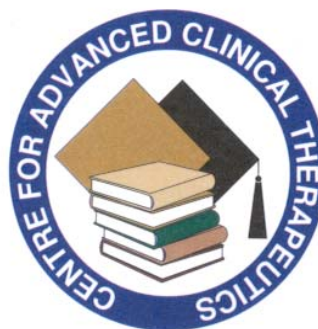
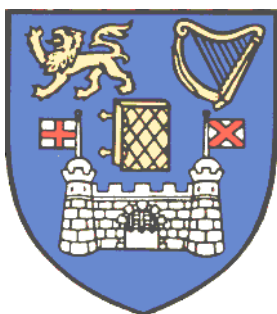


**POSTGRADUATE DIPLOMA/MSc
IN
PHARMACEUTICAL MEDICINE**



2009/2011
University of Dublin, Trinity College
In collaboration with the
Centre for Advanced Clinical Therapeutics
St. James's Hospital,
Dublin

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Introduction

This established course has been designed to improve the knowledge and skills of healthcare professionals in the area of pharmaceutical medicine. It provides comprehensive information to enable students acquire a proper understanding of each topic covered in the course. It looks at each topic from a European and international perspective and therefore is designed to cater for the needs of EU and non-EU students.

The course is aimed at the broad range of professionals working in the pharmaceutical healthcare area. In addition, the module content is in line with the current syllabus of the Faculty of Pharmaceutical Medicine (Royal College of Physicians of the United Kingdom) and the core curriculum of IFAPP (International Federation of Associations of Pharmaceutical Physicians). The course has been accredited by IFAPP.

Aim

The aim of the course is to provide suitably qualified healthcare professionals with specialist knowledge and skills in pharmacology, therapeutics and pharmaceutical medicine to enable them extend their professional role within the pharmaceutical industry and healthcare system.

Intended Participants

Prospective students for the postgraduate diploma and MSc must hold a primary degree in either medicine or another relevant health or science subject. Candidates should have a minimum of 2 years' practical experience in their area of qualification / pharmaceutical industry.

Candidates from within and outside the EU will be eligible for enrolment onto each course, providing their primary degree is from a recognised institution.

Course Structure

Postgraduate Diploma Programme

The course is a taught programme, run over 5 academic terms for a total of 10 modules. Each module lasts for 2-3 days and consists of a combination of formal teaching sessions, workshops and interactive / practical sessions. Pre-module reading lists will be provided and will form part of the module teaching. Two of the modules will be undertaken by way of distance learning (see below). Course materials will be circulated electronically and in paper format for the distance learning modules. In addition all registered students will have access to WebCT, an interactive web-based learning facility. This will allow interaction between students and course leaders.

Assessment will consist of continuous assessment and written and oral examinations at the end of the course.

Continuous assessment assignments must be completed by the students for each module and submitted at designated time points. Students will be expected to submit assignments for all modules.

At the end of the course, all students will be required to undertake written (written paper and multiple choice question paper) and oral examinations.

Completion of each module is obligatory. Students are recommended to attend all of the taught modules as questions from all parts of the syllabus will be included in the final examination. Students will need to have attended at least 6 of the 8 taught modules in order to be eligible to enrol for the final examination.

MSc. Programme

Students will complete the diploma course modules, as per postgraduate diploma course outlined above. Students will then be assigned a research project (including field work), which should be submitted as a dissertation (with the possibility of an oral examination) within six months of completion of the modules, unless an extension is granted by the Faculty.

Course Content and Timetable

Year 1

Module 1

General Introduction to Pharmaceutical Medicine (early Oct 2009)

This module will introduce the aims and objectives of the course. It will discuss the principles of pharmaceutical medicine. It will give an overview of the structure and functions of the medical department and its interaction with other departments within a pharmaceutical company. It will describe the philosophy behind new drug development and how this impacts on the activity of a pharmaceutical company.

Module 2

Biostatistics / Critical Appraisal (mid/late Nov 2009)

The aim of this module is to provide a comprehensive overview of Biostatistics. The student will learn about design of the main types of studies used in clinical research and will explain the type of statistics used in each study. The module will also provide guidance on how to interpret the results of clinical research (critical appraisal).

Module 3

Pharmacoeconomics (Jan 2010)

The aim of this module is to provide a higher understanding of the importance of health economics in contemporary healthcare management. It will give a comprehensive overview of the principles of health economics, economic modelling, QALY's and sensitivity analysis. It will provide practical examples of how economic principles are used to measure the cost-effectiveness of medicines and how this impacts on the pharmaceutical industry in terms of pricing and reimbursement.

Module 4

Drug Development I – Pharmaceutical and Preclinical Development (Feb/March 2010)

The objective of this module is to provide comprehensive information on the pharmaceutical and preclinical stages of drug development (i.e. discovery). It will discuss the principles of initial screening and how the choice of formulation is made with reference to the proposed indication for use. It will provide background information on how potential candidates are tested for bioequivalence, stability, impurity and incompatibility in order to produce the final product specification. It will describe in detail the different stages of pre-clinical testing and how the pre-clinical plan is designed according to the proposed indication for use. It will explain how the pharmacotoxicology findings of the new substance (and metabolites) in animals are evaluated for their potential relevance in man. The aim is to develop a higher understanding of the types of pharmaceutical and pre-clinical testing carried out on new drug substances and how these fit into the overall development plan.

Module 5

Drug Development II – Clinical Trials and Strategy (April 2010)

This module will provide comprehensive information on how new drugs are evaluated in man. It will describe the choice of clinical trial design and target populations, according to the proposed indication for use. It will examine in detail the conduct of the studies (including GCP and legal requirements) and will describe their statistical analysis and reporting. It will highlight the importance of evaluation in at-risk populations and explore the concept of benefit / risk assessment in clinical development. It will also describe the strategy behind drug development within the pharmaceutical industry and in particular the basis for assessing continuing viability of development projects. The aim of this module is to ensure comprehensive knowledge in the area of clinical development and how the clinical development programme interacts with the overall activities of the pharmaceutical company.

Module 6

Principles of Drug Regulatory Affairs***

The aim of this module is to provide comprehensive information on the role of drug regulation in the pre- and post-authorisation phases of drug development and marketing. It will detail the current national and international requirements for the authorisation of medicines. It will look at the guidelines which are published to aid new drug development by the various regulatory agencies and will focus on recent developments relating to international co-operation and drug development for use in special groups (children, orphan drugs)

A workshop will be organised during this module. All core documents and exercises presented during the workshop will be posted on the WebCT website.

Year 2

Module 7

Principles of Pharmacology and Therapeutics***

The overall aim of this module is to develop a higher understanding of the principles of pharmacology and to appreciate how these principles are applied in drug development and regulation.

Module 8

Drug Safety, Pharmacovigilance and Pharmacoepidemiology (mid/late Nov 2010)

The aim of this module is to promote a higher understanding of the benefit/risk evaluation of drugs. It will provide comprehensive information on pharmacovigilance and the existing regulatory requirements for the pharmaceutical industry and regulatory authorities at EU and international level. It will explain the principles of pharmacoepidemiology and how these are used to evaluate drug safety in practice. It will discuss drug interactions and how they can be avoided; medication errors and their prevention +/- management and will provide information on search methodology in pharmacovigilance.

Module 9

Communication and Legal Issues in Pharmaceutical Medicine (Jan 2011)

This module will focus on communication between the pharmaceutical industry and healthcare professionals and patients. It will examine the provision of information and educational and promotional activities within a pharmaceutical company. It will cover the legal and ethical issues involved in the provision of product-related information both before and after licensing. The aim is to provide a comprehensive understanding of how to undertake such activities in accordance with existing legislation and codes of practice.

Module 10

Emerging Issues in Pharmaceutical Medicine (Feb/March 2011)

This module will focus on emerging/topical issues in pharmaceutical medicine. It will provide updates on legislative and regulatory changes that have occurred during the course. Particular emphasis will be placed on enabling students to put into practice the principles and techniques learnt during the course, with the aim of ensuring that students have a thorough and workable understanding of the principles and practice of contemporary pharmaceutical medicine.

***These modules will be undertaken by way of distance learning, therefore submission of personal assignments will be according to a predetermined timetable.

Course Venue

The course will be held in the Trinity Centre for Health Sciences Building in St. James's Hospital, Dublin 8. Enrolled students will be notified of the exact venue in advance of each module.

Course Materials

Comprehensive course materials will be supplied for each module. In addition, students will be provided with pre-module reading before each of the taught modules. The students will be expected to review all material provided and to study the reading lists contained in the course materials. Personal assignments for each module must be completed by each student and returned within the designated time frame. Late assignments will be subject to penalties.

Students will be expected to provide their own computer and online access for the modules undertaken by distance learning.

Fees *

		EU	Non-EU
		€	€
Diploma fee	<i>Year 1</i>	5,141	14,023
	<i>Year 2</i>	3,999	12,708
MSc.	<i>Year 1</i>	5,141	14,023
	<i>Year 2</i>	5,141	14,023

*Fees shown represent the 2008/2009 rates

Course Faculty

Head of the Department

John Feely is Professor (Head) of the Department of Pharmacology & Therapeutics, University of Dublin, Trinity College. He is director of the National Centres for Pharmacoeconomics and Medicines Information in Ireland, and was Chairman of Committee on Drug Usage and Adverse Reactions, National Drugs Advisory Board (1990-95). He has undertaken extensive research and has numerous publications in the areas of pharmacovigilance, pharmaco-epidemiology and cardiovascular pharmacology. He is the National Specialty Director for training in Clinical Pharmacology & Therapeutics, Royal College of Physicians in Ireland.

Course Director

Mary Teeling is the director of the Centre for Advanced Clinical Therapeutics, St. James's Hospital, Dublin. She is also medical advisor to the National Medicines Information Centre. She has extensive experience in the area of pharmaceutical medicine. She is former medical director of the Irish Medicines Board and served as the Irish delegate to the CPMP pharmacovigilance working party for 10 years. She was a member of the CPMP for 7 years and was its vice-chairman from 1998-2000. She is a former steering committee member of the International Conference on Harmonisation (ICH) and was actively involved in the CPMP Scientific Advice Group (Chairman 1999-2000) and Committee on Orphan Medicinal Products.

Course Co-ordinator

MaryJo MacAvin is the course co-ordinator, responsible for the day to day running of the courses. She is also medical advisor to the National Medicines Information Centre. She trained in general practice in Scotland. She worked as a general practitioner for five years and worked for five years in child health. More recently she has spent 2 years working as a drug safety physician in a contract research organization (CRO) in Dublin.

In addition to the faculty members from the academic staff of the Dept of Pharmacology and Therapeutics, Trinity College and the Centre for Advanced Clinical Therapeutics, the course will include contributions from experts from the National Centres for Pharmacoeconomics and Medicines Information, the Irish Medicines Board and the pharmaceutical industry. Modules will also include lectures from internationally known experts.

For Further Information

Contact the Course Co-ordinator, Dr Mary-Jo MacAvin at:

macavinm@tcd.ie or cact@stjames.ie

Phone: 00 353 1 4103671

Fax: 00 353 1 4730596

Applications for this course should be made online through www.pac.ie/tcd

(March 2009 update)