Malta College
of Pharmacy Practice

c/o Department of Pharmacy
University of Malta
Msida MSD 06 • Malta
Tel: (356) 2340 2899
www.mcppnet.org

MALTA COLLEGE OF PHARMACY PRACTICE

PROFESSIONAL DEVELOPMENT PROGRAMME WINTER 2006

in collaboration with
Department of Pharmacy
Department of Clinical Pharmacology & Therapeutics
University of Malta

REGULATION OF MEDICINES AND PHARMACEUTICAL ACTIVITIES

MALTA COLLEGE OF PHARMACY PRACTICE PROFESSIONAL DEVELOPMENT PROGRAMME

Dear Colleague

Due to changes occurring in the regulation of medicines and pharmaceutical activities, the Malta College of Pharmacy Practice has felt the need to devote the winter professional development programme to address these issues.

We have thus invited the Medicines Authority to provide us with an intensive update in this area. The information provided will be essential for pharmacists practicing in all areas. The sessions will also provide a forum for discussion. We thus urge all pharmacists to become Members of the College and attend these sessions.

We need to emphasize that only **registered pharmacists** are eligible to become members and attend educational events organised by the College.

At the time of going to print the venue for all the meetings was not confirmed. Unfortunately this is beyond our control. We thus urge members to visit the website: www.mcppnet.org for confirmation of venue.

We would like to thank The Medicines Authority for kindly accepting the invitation to address our members. We would also like to thank our sponsors for their support. We would like to make it clear that our speakers are not in any way associated with the sponsoring bodies. We thank our members for their support in our endeavors and we look forward to seeing them during our meetings.

Maria Cordina
BPharm (Hons), PhD (QUB), Dip Health Out Res
President
Malta College of Pharmacy Practice

SESSION 1

REGULATIONS PERTAINING TO PHARMACIES

Scope

This session will focus on the current legislation in respect of standards for pharmacies and the obligations of managing pharmacists at community level. The latest legislation that has been enacted will be reviewed.

Objectives

- to update pharmacists on their legal obligations
- to inform pharmacists of the standards to be achieved
- to discuss the way forward in achieving compliance

Learning objectives

By the end of the session pharmacists will be able to:

- fully understand and appreciate the legal implications and obligations
- fully appreciate the need for high level standards and quality of service
- appreciate more the role of the Inspectorate and Medicines Authority
- assimilate knowledge gained and put theory to practice
- identify key problematic areas in the day to day duties
- propose changes with the aim to improve the status of the profession and the safeguarding of public health

Delivered by

Tonio Cassar BPharm (Hons)
Inspectorate and Enforcement Director,
Medicines Authority

Date Tuesday, 31 January 2006
Time 19:30 for 20:00
Venue Lecture Centre, Car Park 2
University of Malta
Book by Tuesday, 24 January 2006

This workshop provides 1.5 hours towards the MCPP continuing education requirement.

SESSION 2

PHARMACEUTICAL LEGISLATION

Scope

The EU concerns itself a great deal with medicinal products due to the fact that a large internal market for these products is of economic importance, but also because the health of its citizens must be protected against the negative effects of the internal market, such as poor quality medicinal products. This session will give a brief overview of the European and local legislation regulating medicines for human use.

Objectives

- understanding the different types of legislation (directives, regulations, guidelines, ECJ) and guidelines governing the placing on the market of human medicines
- to understand how legislation is tranposed into Maltese legislation
- to understand how the main legislation regulates a medicinal product from the clinical trial phase, through to manufacture, authorisation and placing on the market, wholesale distribution, advertising, pharmacovigilance
- to provide a recent review of legislation - transparency, new registration procedures to improve availability (decentralised procedure, qualified licences), paediatric regulation to increase safe use in children, conditional marketing authorisations to expedite use of drugs under trial in life-threatening and debilitating conditions

Learning objectives

By the end of the session pharmacists will be able to:

- be familiar with different types of legislation
- identify relevance to Maltese scenario
- better ensure patient safety

Delivered by

Helen Vella BPharm (Hons)
Licensing Director, Medicines Authority

Date Tuesday, 7 February 2006
Time 19:30 for 20:00
Venue Lecture Centre, Car Park 2
University of Malta
Venue to be confirmed. Visit www.mcppnet.org
Book by Tuesday, 31 January 2006

This workshop provides 1.5 hours towards the MCPP continuing education requirement.

SESSION 3

LICENSING OF MEDICINES

Scope

The session will give a general overview of the procedures used for registration of medicinal products. The old CPP system will be described in short but focus will be on the different procedures (central, national, mutual recognition, decentralised, parallel importation, qualified licences) that are in the legislation for licensing medicines for human use. The problems encountered by stakeholders and regulators on the local scenario when implementation of the legislation had to be followed up for the licensing of medicinal product for the Maltese market, will be discussed.

Objectives

- to be able to compare the old “registration” system to the new one
- to have an overview of the different procedures that can be used to place a product on the market, including “unlicensed” products
- to understand that the registration systems are there to ensure quality, efficacy and safety of medicines for the patients - dossier requirements explained in short

Learning objectives

By the end of the session pharmacists will be able to:

- be familiar with different procedures for placing medicinal products on the market
- identify licensed and unlicensed products
- better ensure patient safety

Delivered by

Helen Vella BPharm (Hons)
Licensing Director, Medicines Authority

Date Tuesday, 14 February 2006
Time 19:30 for 20:00
Venue Lecture Centre, Car Park 2
University of Malta
Venue to be confirmed. Visit www.mcppnet.org
Book by Tuesday, 7 February 2006

This workshop provides 1.5 hours towards the MCPP continuing education requirement.

PHARMACEUTICAL CARE

...is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life... ...is provided for the direct benefit of the patient and the pharmacist is responsible directly to the patient for the quality of that care."

C.D. Hepler

SESSION 4

PHARMACEUTICAL ACTIVITIES

Scope

This session will focus on the various pharmaceutical activities eg wholesale dealing, parallel importation, within the remit of the Medicines Authority and the current legislation in force in respect of these activities. The latest legislation that has been enacted will be reviewed together with the EU Directives that are applicable.

Objectives

- to update pharmacists working in various fields on their legal obligations
- to inform pharmacists of the standards to be achieved
- to discuss the way forward in achieving compliance

Leaming objectives

By the end of the session pharmacists will be able to:

- fully understand and appreciate the legal implications and obligations
- better understand the regulatory environment
- fully appreciate the need for high level standards and quality of service
- appreciate more the role of the Inspectorate and Medicines Authority
- assimilate knowledge gained and put theory into practice
- identify key problematic areas in the day to day duties

Delivered by

Tonio Cassar BPharm (Hons)
Inspectorate and Enforcement Director,
Medicines Authority

Date Tuesday, 21 February 2006
Time 19:30 for 20:00
Venue Lecture Centre, Car Park 2
University of Malta
Venue to be confirmed. Visit www.mcppnet.org
Book by Tuesday, 14 February 2006

This workshop provides 1.5 hours towards the MCPP continuing education requirement.

SESSION 5

THE ADVERTISING OF HUMAN MEDICINAL PRODUCTS

Scope

The control of medicines advertising in Malta, from 1 May 2004, is based on the system of self-regulation. This session focuses on the rules and obligations of advertising medicinal products for human use. Since 1 May 2004, the Medicines Authority has setup a system to assess complaints from its stakeholders.

Objectives

- to elucidate the legislative obligations with respect to advertising of medicinal products
- to provide information to stakeholders on how to lodge a complaint with the Medicines Authority
- to provide information on correct advertising which will enable identification of adverts that are not in line with the EU legislation

Learning objectives

By the end of the session pharmacists will be able to:

- understand legislative obligations with respect to advertising of medicinal products
- understand the requirements involved when lodging complaints to the Medicines Authority

Delivered by

Andrea Mallia Milanes BPharm (Hons)
Assessor, Medicines Authority

Date Tuesday, 28 February 2006
Time 19:30 for 20:00
Venue Lecture Centre, Car Park 2
University of Malta
Venue to be confirmed. Visit www.mcppnet.org
Book by Tuesday, 21 February 2006

This workshop provides 1.5 hours towards the MCPP continuing education requirement.

SESSION 6

ADVERSE DRUG REACTIONS AND PHARMACOVIGILANCE

Scope

As from 1 May 2004, health care professionals have to report suspected serious or unexpected ADRs to the Medicines Authority (LN 22 of 2004). This session will focus primarily on Adverse Drug Reactions and the use of the Summary of Product Characteristics to determine unexpected and or suspected adverse events.

Objectives

- to elucidate the legislative obligations of healthcare professionals with respect to pharmacovigilance
- to familiarise pharmacists with the use of the Medicines Authority's Adverse Drug Reporting Card and the Summary of Product Characteristics
- to provide awareness of serious unexpected drug events and expected adverse events

Learning objectives

By the end of the session pharmacists will be able to:

- use the Summary of Product characteristics to identify if an adverse event is either expected, unexpected, serious or non-serious
- use appropriately the Medicines Authority's Adverse Drug Reporting Card

Delivered by

Michael Bonett BPharm (Hons), MA IMC
Sarah Spiteri BPharm (Hons)
Assessors, Medicines Authority

Date Tuesday, 7 March 2006
Time 19:30 for 20:00
Venue Lecture Centre, Car Park 2
University of Malta
Venue to be confirmed. Visit www.mcppnet.org
Book by Tuesday, 28 February 2006

This workshop provides 1.5 hours towards the MCPP continuing education requirement.

THE MALTA COLLEGE OF PHARMACY PRACTICE

PROFESSIONAL DEVELOPMENT PROGRAMME - WINTER 2006

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Mr John Martin Borg BPharm(Hons)

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The Medicines Authority is not in any way associated with the sponsoring bodies and will not benefit, either directly or indirectly, from any of the sponsorship offered. As always, speakers are voluntary and receive no remuneration for services rendered.

RENEWAL OF MEMBERSHIP

October 2005 - October 2006

Lm9 Full Member (≥30 credits)
Lm10 Associate Member (< 30 credits)
Lm10 New Member

Cheques made payable to
Malta College of Pharmacy Practice

	Date	Book by
Regulations pertaining of pharmacies	31 January	24 January
Overview of pharmaceutical legislation	7 February	31 January
Licensing of medicines	14 February	7 February
Pharmaceutical activities	21 February	14 February
The advertising of human medicinal products	28 February	21 February
Adverse drug reactions and pharmacovigilance	7 March	28 February

EXCLUSIVE ATTENDANCE

All registered pharmacists are invited to become members of the Malta College of Pharmacy Practice and attend.

Only registered pharmacists are eligible to become members of the College and thus particiate in the events organised.

BOOKING may be placed **preferably** by email	**info@mcppnet.org**
or by phone	**7947 0720 or 2340 2899** (office hours)
correspondence	**Malta College of Pharmacy Practice** **c/o Department of Pharmacy** **University of Malta, Msida MSD 06**

DO YOU WANT TO RECEIVE MEDICINES INFORMATION UPDATES?

REGISTER ONLINE NOW

Receive regular medicine information updates by email from the Medicines and Poisons Information Service at St Luke's Hospital and The Medicines Authority through the Malta College of Pharmacy Practice by registering online at:

www.mcppnet.org

or send an email to: info@mcppnet.org

1st Announcement

6th Malta Medical School Conference

30th November, 1st, 2nd December 2006

Call for abstracts open

Deadline for submission of abstracts

31st July 2006

www.mmsconf.org