

**Dear Colleague**

The regulatory aspect of our profession has become increasingly important. The need for us to be updated with regards to the regulatory framework in which we practice is evident. MCPP has felt that it should address this need and invited the Medicines Authority to provide an update on the most relevant areas.

We would like to thank the members of the Medicines Authority for graciously accepting this invitation and for volunteering their time, expertise and experience.

**Maria Cordina**

BPharm(Hons), PhD(QUB), Dip Health Outcomes Research  
President, Malta College of Pharmacy Practice

**SESSION 1****Marketing Authorisation Assessments. How do we carry out this function at the Medicines Authority?****Scope**

In Malta, a system of licensing is in place before the marketing of medicines. Medicines which meet the standards of safety, quality and efficacy are granted a marketing authorisation, which is normally necessary before they can be prescribed or sold. This authorisation covers all the main activities associated with the marketing of a medicinal product.

The Licensing Authority is the designated body established by the Medicines Act to set and operate a system of licensing on medicinal products for human use. The Medicines Authority, in line with its national public health remit with respect to information about medicinal products, throughout the years has embarked and supported different initiatives to strengthen the availability and accessibility of objective information on medicines in Malta.

**Objectives**

- To provide an overview of marketing authorisation documents and the documentation needed to submit an application (the Common Technical Documents).
- To discuss practical examples of assessments in terms of Quality/Safety and efficacy focussing on generics.
- To discuss practical examples by use of Public Assessment Reports.

**Learning objectives**

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

- Understand better the complexities required to assess medicinal products for human use;
- Understand what data is needed by the regulators to be able to arrive at a decision on the benefit/risk of medicinal products for human use.

**Delivered by****John Joseph Borg**

BPharm(Hons), MSc(Agr Vet Pharm), PhD(Bristol)  
Post-Licensing Director, Medicines Authority  
Member of the Committee for Medicinal Products for Human Use (CHMP)

**Date** Thursday, 27 January 2011  
**Time** 19:30 for 20:00  
**Venue** Lecture Centre, Car park 2  
University of Malta  
**Book by** Thursday, 20 January 2011

This workshop provides 4 credits towards the MCPP continuing education requirement.

**SESSION 2****Information on Medicinal Products****Scope**

The provision of high quality information on medicines is fundamental in safeguarding public health; empowerment of health care professionals, patients and consumers in identifying different medicines choices; improving medicines use; and to identify falsified medicines. The main source of information on medicines remains the Summary of Product Characteristics, the Package Leaflet and the Public Assessment Reports which are the regulator's evaluation of the authorised medicine. Yet, while a review of the current legislation on the subject is being discussed at EU level, the Medicines Authority, in line with its national public health remit with respect to information about medicinal products, throughout the years has embarked and supported different initiatives to strengthen the availability and accessibility of objective information on medicines in Malta.

**Objectives**

This session will give an overview of the legislative framework on medicines information; research conducted by the Medicines Authority on the subject; the Medicines Authority communication strategy; and an overview of the available medicines information resources.

**Learning objectives**

By the end of the session the pharmacist will better understand:

- The current and proposed legislation on information about medical products;
- What Maltese consumers know about their medicines;
- The communication strategy of the Medicines Authority;
- What are some of the 'trusted' sources of information on medicines.

**Delivered by****Gavril Flores**

B.A., CYM, M.A., (Leadership and Innovation)  
Operations and Regulatory Affairs Manager, Medicines Authority

**Date** Thursday, 3 February 2011  
**Time** 19:30 for 20:00  
**Venue** Lecture Centre, Car park 2  
University of Malta  
**Book by** Thursday, 27 January 2011

This workshop provides 4 credits towards the MCPP continuing education requirement.

**SESSION 3****Supporting the National Pharmacovigilance System****Scope**

Since not all hazards can be established before a product is authorised to be placed on the market a Pharmacovigilance System is an important aspect of drug safety monitoring and drug regulation. The success or failure of any pharmacovigilance activity depends on the support it attains from the health care professionals within the healthcare system. Voluntary adverse drug reaction (ADR) reporting schemes have operated since the early sixties in many developed countries but it is recognized that only a small proportion of adverse drug reactions are actually being reported. Pharmacists are well positioned and equipped to be key players in the systematic identification and reporting of post-authorisation adverse drug reactions.

**Objectives**

- To highlight the need for drug safety monitoring through pharmacovigilance.
- To give an overview of the national pharmacovigilance system today.
- To identify the role of the healthcare professional in Pharmacovigilance.
- To make clear the process of spontaneous reporting.
- To give an update of the data in the national pharmacovigilance system as of 2010.

**Learning objectives**

By the end of the session the pharmacist will:

- Know the rationale behind Pharmacovigilance;
- Have updated knowledge on the national Pharmacovigilance system;
- Have a better understanding of his/her role in Pharmacovigilance;
- Know the How, When and Where of Adverse Drug Reactions reporting.

**Delivered by****Amy Tanti**

B Pharm(Hons)  
Pharmacist, Medicines Authority

**Date** Thursday, 17 February 2011  
**Time** 19:30 for 20:00  
**Venue** Lecture Centre, Car park 2  
University of Malta  
**Book by** Thursday, 10 February 2011

This workshop provides 4 credits towards the MCPP continuing education requirement.

**SESSION 4****Regulation of Medicines Supply Chain and Market Surveillance****Scope**

Regulation of medicinal products is carried out at all levels of the supply chain across the European Community in the interest of public health. A Qualified Person takes responsibility for every batch being released certifying that it has been manufactured in accordance to GMP guidelines and the Marketing Authorisation. Regulation is necessary to ensure that the medicinal product reaching the patient is still as safe and effective as it was intended to be, that its quality has not been compromised and that access to these drugs does not result in misuse.

Market Surveillance is the process a Regulatory Authority ensures from time to time that products placed on the market both at the national and European level are of the desired quality in accordance to the marketing authorisation requirements of the medicinal product.

**Objectives**

- To describe the three levels of distribution present in supply chain of medicinal products and the regulation of each.
- To identify the health risks present in the supply chain of medicinal products and how these risks can be managed.
- Describe procedures of market surveillance, how is it done, legal obligations to the stake holders and procedures if there is a non compliance.

**Learning objectives**

By the end of the session pharmacists will:

- Have updated their knowledge of the regulation of the supply chain of medicinal products;
- Be better able to appreciate why medicines regulation is required;
- Ensure better participation for this exercise to be performed annually.

**Delivered by****Simon Serge**

B Pharm (Hons)  
Medicines Inspector, Medicines Authority

**Christopher Attard**

B Pharm (Hons), MPharmS  
Medicines Inspector, Medicines Authority

**Date** Thursday, 24 February 2011  
**Time** 19:30 for 20:00  
**Venue** Lecture Centre, Car park 2  
University of Malta  
**Book by** Thursday, 10 February 2011

This workshop provides 4 credits 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 5****Counterfeits and buying over the internet and internet pharmacies****Scope**

Counterfeit products have become a phenomenon affecting not only developing countries but also developed countries that in recent years saw the legal supply chains being penetrated with counterfeit products. The advancement in technology and the accessibility of internet to all has also increased the exposure of the general public to a greater risk of counterfeits. To this effect the EU commission has launched a proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

**Objectives**

To discuss what makes a product a counterfeit, how to identify and minimise risks when buying medicinal products over the internet and how the legislation will probably change.

**Learning objectives**

By the end of the session the pharmacist will:

- Learn more on the current threats which patients may encounter and the initiatives being taken to combat this problem.
- As a result pharmacists would be able to better advise their patients on the subject of counterfeits and buying of medicinal products over the internet.
- Learn in what ways the legislation will probably change.

**Delivered by****Mark Cilia**

B.Pharm (Hons), MSc Ind. Pharm Stds.(UK)  
Director Inspectorate and Enforcement, Medicines Authority

**Date** Thursday, 3 March 2011  
**Time** 19:30 for 20:00  
**Venue** Lecture Centre, Car park 2  
University of Malta  
**Book by** Thursday, 24 February 2011

This workshop provides 4 credits towards the MCPP continuing education requirement.

**SESSION 6****Herbal Medicines****Scope**

Herbal medicines, also known as 'green medicines', are well sought by the general public worldwide. The main concern of the European Commission is the consumers' health and safety, but at the same time the EC aims at preserving the European herbal industry competitiveness vis-à-vis the herbal industry worldwide. Herbal medicines are pharmacy-only products, and therefore health care professionals, particularly pharmacists, need to be aware of the current European Union legislation on herbal medicines and the consumers'/patients' needs.

**Objectives**

- To understand the legislative issues governing the marketing or registration of herbal medicinal products.
- To understand the safety-efficacy-quality relationships for herbal medicines.

**Learning Objectives**

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

- Distinguish between herbal medicines and food supplements;
- Have a better understanding of the different categories of herbal medicines;
- Better appreciate the evaluation process required for the marketing/registration of herbal medicines.

**Delivered by****Everaldo Attard**

BPharm(Hons), MSc(Agr Vet Pharm), PhD(Agric)  
Herbal Medicines Consultant, Medicines Authority  
Representative, Committee on Herbal Medicinal Products (HMPC)

**Date** Thursday, 10 March 2011  
**Time** 19:30 for 20:00  
**Venue** Lecture Centre, Car park 2  
University of Malta  
**Book by** Thursday, 3 March 2011

This workshop provides 4 credits towards the MCPP continuing education requirement.