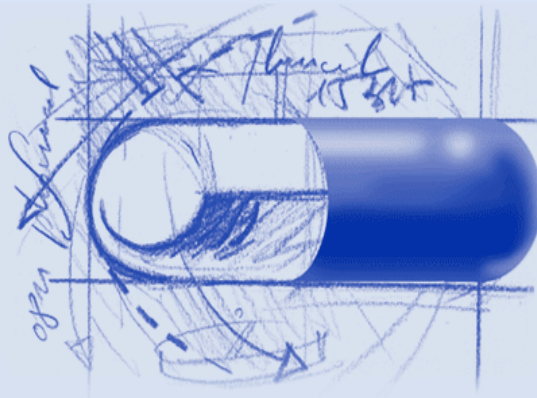


Welcome to PHARMED



ENTER

POST-GRADUATE PROGRAMME IN PHARMACOLOGY AND PHARMACEUTICAL MEDICINE



SEMINAR 7

Regulatory Affairs and Medical Information

17-21 May 2010

TIMETABLE

Monday, May 17

- 13.00 – 15.00 **S. Callewaert**
Drug registration: the European and international environments
- 15.30 – 18.00 **A-M. Georges**
Centralised procedure, role of CHMP working parties and new provisions
The Paediatric Regulation

Tuesday, May 18

- 09.00 – 12.00 **A. Vandenberghe**
Databases & prescribing modules
- 13.00 – 15.00 **A. Hepburn**
Preparation of a new drug application (I)
- 15.30 – 17.00 **D. Vander Mijnsbrugge**
Organisation of the medical department

Wednesday, May 19

Drug registration: Special issues

- 9.00 – 12.00 **A. Lhoir**
- Orphan medicinal products
- Mutual recognition and decentralized procedure
- Generics
- 13.00 – 15.00 **A. Hepburn**
Preparation of a new drug application (II)
- 15.30 – 17.00 **M. Czarka**
Ethics in the pharmaceutical industry

Thursday, May 20

- 09.00 – 12.00 **M. Sangeleer**
Communication with health care practitioners (I)
- 12.00 – 13.30 PHARMED LUNCH**
- 13.30 – 15.00 **M. Sangeleer**
Communication with health care practitioners (II)
- 15.30 – 17.30 **R. Vander Stichele**
Summary of product characteristics and user package leaflets
- 17.30 – 19.00 **D. Dubois**
Correction of Homework 4
“Health Economics”

Friday, May 21

- 09.00 – 12.00 **Zaide Frias**
Drug registration: EU procedures, organisation of the EMA and centralised procedure

**Coffee breaks : 10.30-11.00
15.00-15.30**

Stéphane CALLEWAERT

M.Sc, Molecular Biology, ULB, Manager Worldwide Vaccine Registration, GSK Biologicals

Marc CZARKA

M.D., MBCPM, Adjunct professor at INSEAD, Member of the board of BeAPP, CPD Director of BCPM, Director Healthcare Practice, Green Dragon sprl

Dominique DUBOIS

M.D., KUL, FFPM, FBCPM. Lecturer in Health Economics ULB and Principal Consultant, Patient Value Solutions (PVS) Consultancy, Belgium

Zaïde FRIAS

Head of Regulatory Affairs, EMA, London, UK

Anne-Marie GEORGES

Ph.D., Independent Consultant, Chairperson of the Regulatory Affairs Working Group of European Vaccine Manufacturers Association

Anne HEPBURN

PhD in Medical Biology, Director Scientific Writing and Regulatory Affairs, 4Clinics Belgium.

André LHOIR

M.D., Medical Assessor, Belgian Medicines Commission, Federal Public Service Health, Food Chain Safety and Environment, Member of the Committee for Orphan Medicinal Products

Michèle SANGELEER

M.D., ULB, Medical information & Pharmacovigilance Manager, Eli Lilly Benelux

André VANDENBERGHE

M.D., ULB, Medical Information Department, University Hospital Charleroi

Dirk VANDER MIJNSBRUGGE

M.D., KUL, MBA, Medical Director European Mid Sized Markets, Pfizer Specialty Care Business Unit

Robert VANDER STICHELE

M.D., R.U.G. and V.U.B., Senior Researcher, Health Technology Assessment, Heymans Institute of Pharmacology and Belgian Health Care Council

DRUG REGISTRATION: EUROPEAN PROCEDURES AND INTERNATIONAL ENVIRONMENT

Zaïde FRIAS, Stéphane CALLEWAERT, Anne-Marie GEORGES

S. Callewaert will present an overview of the regulatory environment. European requirements and procedures will be compared to those of the FDA and Japanese authorities. A-M Georges will present in detail the European Centralized Procedure, including new provisions (exceptional circumstances, fast track assessment ...) and the role of working parties. She will also present the new pediatric regulations.

Z.Frias will present the history of pharmaceutical legislation in EU, the different EU procedures, followed by the organization of EMA (management board, committees, international partners, ...).

DRUG REGISTRATION: SPECIAL ISSUES

André LHOIR,

Dr Lhoir will present the European Regulation 141/2000 concerning orphan medicinal products, that is intended to stimulate sponsors to develop medicinal products for the treatment of rare diseases. He will also describe the activity of the Committee for Orphan Medicinal Products (COMP) which is in place since April 2000. He will present an update on the mutual recognition procedure and the regulation of generics.

PREPARATION OF A NEW DRUG APPLICATION - COMMON TECHNICAL DOCUMENT - SUMMARIES AND OVERVIEWS

Anne HEPBURN

The various parts of an application for a new chemical entity will be reviewed: summary of product characteristics, expert reports, analytical part, toxico-pharmacological part and clinical part. From July 1, 2003, all new licensing applications in Europe must be made using the Common Technical Document (CTD) format. This seminar will first give a rapid overview of this registration dossier. A more lengthy review of Module 2, as defined in the EU Notice to Applicants, will be made. This module contains the Summaries and Overviews, which are roughly the equivalent of the EU Expert Reports as previously defined. These documents have an important role with respect to the assessment and interpretation of the information contained in the rest of the dossier which will be discussed. The legal aspects pertaining specifically to the documents in Module 2 need also to be taken into account and will be summarised. Finally the course will try to provide clues for understanding defects in the applications and improving the chances of approval.

ETHICS IN THE PHARMACEUTICAL INDUSTRY

Marc CZARKA

Ethics is the discipline dealing with what is good and bad and with moral duty and obligation. Professional ethics is a theory or system of moral values, the principles of conduct governing an individual or a group practicing this profession. Setting-up an ethics code and following it is part of compliance.

We will discuss compliance, regulations and focus on ethics and ethics code for the pharmaceutical industry and pharmaceutical physicians, at an international level (IFPMA and IFAPP) and then, review, as an example, the Belgian way to implement it (pharma.be and MDeon) within specific legal Belgian requirements.

MEDICAL INFORMATION

Michèle SANGELEER, Robert VANDER STICHELE

The information to health professionals and to patients is ruled by European directives. Physicians and pharmacists should be provided with enough information and should not be burdened with irrelevant details. The course will encompass the following topics:

- The summary of product characteristics which is at this moment the basis for this information in the different countries of the European Union.
- The EEC directive 92/27 which makes the "patient package insert" or "user package leaflet" compulsory in the European Union. What information this leaflet should contain and how this information should be given will be discussed.
- The ethical and legal rules governing written advertising on medicinal products. Reference will be made to the international, the European and the Belgian regulations namely the requirements for a person responsible for the medical information.
- "Customised information". Customised communication implies the education of the sales force and the build-up of an internal medical information service. It involves the use of communication techniques, the knowledge of ethical and legal regulations, the screening of international literature and the collection of drug safety and interactions data. Finally the customised information should be viewed by the pharmaceutical company as an image building tool.

MEDICAL DATA BASES AND PRESCRIBING MODULES

André VANDENBERGHE

Databases of pharmaceutical product information can provide easy access to drug information to health care practitioners. This can support the prescription of medications by physicians, as well as dispensing by pharmacists. This presentation will describe database structure with reference to the Good European Health Record (GEHR) architecture. It will evaluate database content in relation to functional specifications for the prescription of pharmaceutical products. Utility of database information will be demonstrated using the HEALTH one prescribing module. An introduction will be given to XML and its benefits for medical data storage and transmission.

ORGANISATION OF THE MEDICAL DEPARTMENT

Dirk VANDER MIJNSBRUGGE

This course is devoted to the organisation of the medical department of pharmaceutical companies, its staffing and various functions. Its role in clinical research and medical information have been analysed in detail in other sections of the programme. In this course, special attention will be given to its contribution to product support and promotion, as well as to public relations and the impact of health care policies.



LANGUAGE

All courses are taught in English.

REGISTRATION FEE

900 Euros for the seminar (including access to the electronic documentation), 250 Euros for one day or 2 halves-days.

*Procedure: register by mail by returning a completed registration form.
Payment should be arranged upon receipt of our bill.*

LOCATION

FREE UNIVERSITY OF BRUSSELS
School of Medicine – Building F – Room F2-407
Campus Erasme – Route de Lennik, 808
B – 1070 Brussels
Belgium

TRANSPORTATION

See our web site (venue) : <http://www.ulb.ac.be/medecine/pharmed>

REGISTRATION & INFORMATION

For more information please contact.

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