PHARMED

Module 12

24 - 25 April 2019

Regulatory affairs

- Drug registration : European procedures and international environment
- Drug registration: special issues
- Preparation of a new drug application – Common Technical
- Specific regulatory aspects of biologics
- Medical devices – overview from manufacturer to patient

For more information please contact :

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http://www.ulb.ac.be/medecine/pharmed/

DRUG REGISTRATION : EUROPEAN PROCEDURES AND INTERNATIONAL ENVIRONMENT

Stéphane CALLEWAERT

S. Callewaert will present an overview of the regulatory environment and medicines registration in the EU and compare European requirements and procedures with those of the US FDA and Japanese authorities, as well as with requirements in international & emerging markets.

DRUG REGISTRATION: SPECIAL ISSUES

André LHOIR

A. Lhoir will present the European Regulation of orphan medicinal products, that is intended to stimulate sponsors to develop medicinal products for the treatment of rare diseases, and the Committee for Orphan Medicinal Products (COMP).

PREPARATION OF A NEW DRUG APPLICATION - COMMON TECHNICAL DOCUMENT

Anne HEPBURN

The various parts of an application for a new chemical entity will be reviewed. All new licensing applications in Europe must be made using the Common Technical Document (CTD) format. The course will try to provide clues for understanding defects in the applications and improving the chances of approval.

SPECIFIC REGULATORY ASPECTS OF BIOLOGICS

Koen BRUSSELMANS

This session will be devoted to the specific regulations of biologics in the European Union, including the biosimilars.

***Stéphane* CALLEWAERT**
M.Sc., Molecular Biology, ULB, Senior Manager Regulatory Policy & Intelligence, Global Regulatory Affairs, GSK Vaccines

André LHOIR
M.D., Medical Assessor, Federal Agency for Medicines and Heath Products, Belgium, Member of the Committee for Orphan Medicinal Products (COMP) of EMA

Anne HEPBURN
Ph.D. in Medical Biology, ULB, Director scientific writing and regulatory affairs, 4Clinics Belgium

Koen BRUSSELMANS
Master in Bioscience Engineering, Ph.D. in medical sciences. Quality Assessor, Scientific Institute of Public Health (Belgium)

WEDNESDAY 24 April 2019

Welcoming participants
9.30-10.00

Drug Registration – European and international environments
Stéphane CALLEWAERT
10.00-13.00

Drug Registration – European and international environments
Stéphane CALLEWAERT
14.00-16.00

Coffee break
16.00–16.20

Medical devices : overview from manufacturer to patient
Valérie NYS
16.20-18.20

THURSDAY 25 April 2019

Preparation of a new drug application
Anne HEPBURN
09.00-10.50

Coffee break
10.50–11.10

Orphan medicinal products
André LHOIR
11.10-12.30

Lunch
12.30–14.30

Specific regulatory aspects of biologics
Koen BRUSSELMANS
14.30-16.30

MEDICAL DEVICES – OVERVIEW FROM MANUFACTURER TO PATIENT

Valérie NYS

This lecture aims to give an overview of what is a medical device and what are the major steps to access the market. It is estimated that there are over 30,000 general medical device technology types available on the European market constituting over 500,000 individual medical devices. Over recent years significant growth has occurred in diagnostic technologies, connected health technologies and medical device software (including mobile apps). The new Regulation, published in May 2017, represents a significant development of the existing regulatory system building on the experience gained over the last 25 years.

Valérie NYS
Project Manager MDR/ IVDR
Federal Agency for Medicines and Health Products