Diploma e Master Universitario in Alti Studi Europei
Collegio Europeo di Parma

Seminar on: "EU Pharmaceutical Policy"

Friday 24 April 2015

Location: Collegio Europeo di Parma, Borgo Rodolfo Tanzi 38, Parma

09:00 – 10:30 **50 years of EU Pharmaceutical Legislation**
Prof. Patrick Deboyser

10:30 - 11:00 *Coffee break*

11:00 - 12:15 **Pharmaceutical Market and Economy**
Ms. Marie-Claire Pickaert, Deputy Director General, EFPIA

12:15 - 12:30 **Presentation of the EFPIA Parma Award**
Prof. Patrick Deboyser and Ms Marie Claire Pickaert

13:15 - 13:25 *Departure by bus from Collegio*

Location: Chiesi Farmaceutici S.p.A., Via Palermo 26/A, Parma

14:00 - 15:00 **Outlines of pharmaceutical discovery and development**
Dr. Andrea Chiesi, R&D Project & Portfolio Manager, Chiesi Group

15:00 - 15:30 *Coffee break*

15:30 – 16:30 **Visit of Chiesi Farmaceutici Research Centre**

16:45 – 17:00 *Return by bus to Collegio Europeo*

Annex 1

"Pharmaceutical Policy and Legislation"

A) Historic perspective
1) From the early years to thalidomide
2) From 1965 to 1985
3) A single market for pharmaceuticals

B) Notions
1) Definition of: medicinal product
2) Prescription only v. OTC
3) Herbal medicines, homeopathic medicines and food supplements

C) Application for marketing authorization
1) Notice to applicants
2) Testing and clinical trials
2) Abridged applications

D) Marketing authorisation
1) Criteria for authorization
2) Procedures
3) Maintenance, suspension, revision

E) Control on manufacture and quality
1) Manufacturing authorization
2) Good manufacturing practices
3) Inspections and MRAs

F) Pharmacovigilance
1) Principles
2) Recent EU legislation
3) "Mediator"

G) The European Medicines Agency (EMA)
1) Establishment
2) A network agency
3) Comparison with EMA

H) The protection of pharmaceutical innovation
1) Pharmaceutical patents
2) Complementary protection certificate
3) Protection of the first applicant

K) Orphan medicinal products
1) Rare diseases
2) Regulation (EC) No 141/2000
3) Orphan drugs strategy

I) Generic competition

1) Market access for generic products
2) Generic substitution
3) Biosimilars

J) Cross-border sales

1) Parallel imports
2) Personal imports
3) Internet sales

Annex 2

EU Pharmaceutical Legislation

Directives

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (Consolided version : 05/10/2009).
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf

Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (Official Journal L 348, 31/12/2010, p. 74).
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2010_84/dir_2010_84_en.pdf

Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products (Official Journal L 174, 01/07/2011, p. 74).
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

Directive 2001/20/EC OF the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (Official Journal L 121, 1/5/2001 p. 34 - 44).
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_20/dir_2001_20_en.pdf

Council Directive 89/105/EEC, of 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems (Official Journal L 40, 11/2/1989 p. 8)
http://ec.europa.eu/health/files/eudralex/vol-1/dir_1989_105/dir_1989_105_en.pdf

Regulations

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Consolided version : 20/04/2009)
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2004_726_cons/reg_2004_726_cons_en.pdf

Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (Official Journal L 18, 22/1/2000 p. 1).
http://ec.europa.eu/health/files/eudralex/vol-1/reg_2000_141/reg_2000_141_en.pdf

Annex 3

EFPIA Parma Award

Background

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has a long experience of cooperation with academic circles. In connection with the establishment of a Seminar on "EU Pharmaceutical Policy" at the European College of Parma, EFPIA has decided to create an "EFPIA Parma Award" in support of a DASE thesis covering an area of particular interest to the pharmaceutical industry.

Procedure

The competition will be open to DAES graduates who are seeking to achieve the title of University Master's Degree in Advanced European Studies, by writing under the supervision of one of the professors of the College a thesis covering an area of particular interest to the pharmaceutical industry.

The subject of the thesis will be chosen by the student, and the thesis will be written, under the supervision of one of the professors of the College, and evaluated under the general rules applicable at the College.

In order to be considered for the EFPIA Parma Award, a thesis will have:
- to cover an area of particular interest to the pharmaceutical industry,
- to be written in French or English,
- to have obtained a mark of 15/20 or higher for the purpose of obtaining the title of University Master's Degree in Advanced European Studies**.**

The Award Jury will be composed of the Chairpersons of EFPIA's policy committees. The theses submitted will be evaluated internally at EFPIA and than discussed with Jury members who are more directly involved in issues related to the topic selected by the student.

The evaluation for the purpose of the EFPIA Award will be based on four criteria:
- comprehensiveness;
- coherence of argumentation;
- introduction of new dimensions; and
- understanding of fundamental issues.

Award

The winner will be offered a 12-month stage at EFPIA, or at one of EFPIA's member associations or companies. In addition, the wining thesis will be distributed by EFPIA to oits affiliates, and published on the EFPIA website.