



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

Seminar on: "EU Pharmaceutical Policy" - 2016

Lecture by Prof. Deboyser

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) Mission and organization
- 2) A network agency
- 3) Comparison with EFSA

H) The protection of pharmaceutical innovation

- 1) Pharmaceutical patents
- 2) Complementary protection certificate
- 3) Protection of the first applicant (data exclusivity)

K) Orphan medicinal products

- 1) Rare diseases
- 2) Regulation (EC) No 141/2000
- 3) Market exclusivity / pricing

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