European Directorate for the Quality of Medicines & HealthCare:
Structure, Aims and Role in Providing Safety and Quality of Medicines in Europe

IPA Conference

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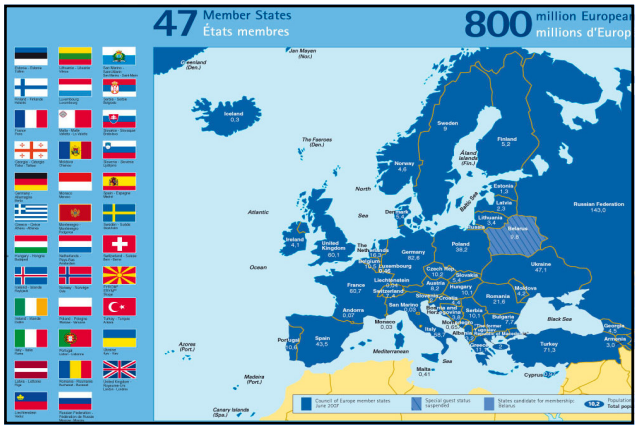
The Council of Europe

- Founded in 1949
- Development of European common and democratic principles
- 47 member countries
- Strasbourg

Core values :
Protection of human rights, pluralist democracy & the rule of law



EDQM – Milestones (1)

- A Council of Europe Directorate
- 1964: Activities based on an International Convention of the Council of Europe to promote free movement of medicines in Europe (Partial Agreement)
- Mandatory status reinforced in 1975 in the EU pharmaceutical legislation
- 1994: EU signed the EP Convention
- 1994: creation of the European Network for Official Medicines Control Laboratories (OMCL)

EDQM – Milestones (2)

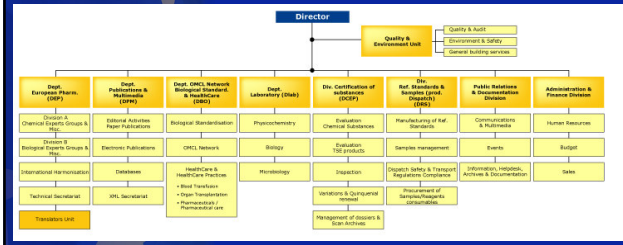
- 1994: creation of the procedure of certification of suitability to the monographs of the European Pharmacopoeia
- 2007: transfer of activities on blood transfusion and organ transplantation
- 2008: transfer of activities on counterfeits, pharmaceuticals and pharmaceutical care
- 2009: transfer of activities on cosmetics and primary packaging for foodstuff

European Directorate for the Quality of Medicines & HealthCare (EDQM)

Mission: to contribute to the human right of access to good quality medicines and healthcare

Health is a social human right indispensable for the exercise of all other human rights, for prosperity and democratic stability of people in Europe

European Directorate for the Quality of Medicines & HealthCare



EDQM Activities (1)

Elaboration of the European Pharmacopoeia

The European Pharmacopoeia

Objectives:

- Provide authoritative quality standards for medicinal substances that are IMPORTANT for PUBLIC HEALTH in Europe
- RESPOND RAPIDLY to new risks to public health (e.g. TSE, heparin….)
- Facilitate the FREE MOVEMENT and trade of medicines among countries
- Facilitate ACCESS to high-quality medicines, by allowing free movement

ENSURING THE SAME QUALITY OF MEDICINES FOR ALL EUROPEAN CITIZENS

The European Pharmacopoeia Convention (1)

Progressively elaborate a Pharmacopoeia which shall become common to the countries concerned…

– *1964:*

19 different national pharmacopoeias in Europe with no links

– *2008:*

one common pharmacopoeia for 36 countries + 22 observers with one common date of implementation (decision of Ph. Eur. Commission)

The European Pharmacopoeia Convention (2)

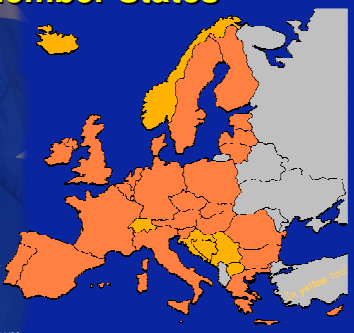
"…take the necessary measures to ensure that the Ph. Eur. monographs… shall become at national level the official standards applicable within their respective countries…"

– Direct implementation in the national legislation
– Indirect implementation through national translation (British, German, Spanish, Portuguese….)
– Priority of pharmacopoeias according to EU legislation Ph.Eur. > national pharmacopoeia > third country pharmacopoeia, e.g. USP, JP

Membership & Observership

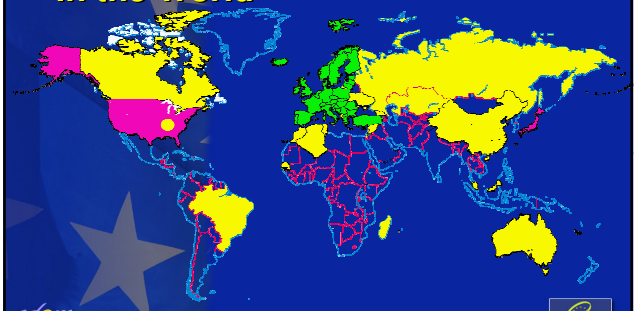
- 36 member countries + the European Union
- Ph. Eur. is the official Pharmacopoeia in Europe for all issues more than one Member State is interested in
- 22 observer countries and international organisations including World Health Organisation (WHO) and USA (FDA)
- In 2008: 2 new observers (Moldova and Argentina)

Ph. Eur. Member States



Ph. Eur. Member States & Observers

In the World



EDQM Activities (2)

- Establishment and provision of reference standards and materials (chemical and biological)
- Pharmaceutical terminology
  - Standard terms for
    - Dosage forms
    - Routes of administration
    - Containers
  - ISO

EDQM Activities (3)

Certification of Suitability

- European pharmaceutical legislation requires the applicant to demonstrate the suitability of the pharmacopoeial monograph to control the quality of active substances used
- EDQM's certification scheme as the « preferred way » for existing substances
- Recognised throughout Europe and in many other countries (e.g. Canada)
- Includes GMP inspections for API (in line with the EMEA « trigger document »)

EDQM Activities (4)

The OMCL Network

General coordination of activities

Fostering of mutual confidence & recognition

- Implementation of quality assurance system
- Audits of OMCLs by peers (EDQM and Network members)
- Proficiency testing studies (PTS)
- Training courses (Procedures, QA and techniques in OMCLs)

EDQM Activities (5)

Blood Transfusion

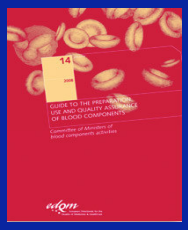
Program based on three general principles:

- Non-commercialisation of substances of human origin
- Volontary and non-remunerated donation
- Protection of health of donors and receivers of blood transfusions

NEW: Blood Transfusion

Quality system for

- Blood establishments
- Blood collection
- Blood components
- Transfusion practices
- …



EDQM Activities (6)

Organ Transplantation

General principles of the work program:

- To garantuee the dignity of the human being,
- To ensure adherence to human rights and fundamental freedom,
- To ensure the non-commercialisation of substances of human origin,
- To protect donors and receivers.

NEW: Organ Transplantation

Guidelines on

- Living donor kidney transplantations
- Living donor liver transplantations
- …

EDQM Activities (7)

Medicinal Products and Counterfeits:

Multisectoral program based on the protection of public health, risk management and risk prevention and improvement of international cooperation:

- Elaboration of model procedures for risk management in the public and private sector,
- Establishment of an internationl network of Single Points of Contact (SPOC)
- Training programs and conferences
- Databases
- « Track-and-trace » pilot
- …

Council of Europe Anti-Counterfeitung Convention

- 2008: preparation of a draft convention *against counterfeiting of medical products and similar crimes involving threats to public health* (mandate by the CoE Committee of Minsters)
- Possible negotiation and finalisation by Council member states, observers, participants (2009)

EDQM Activities (8)

Legal Classification of Medicines

- The work program forsees harmonisation of the legal classification of medicines with regards to their prescription status, which has an important impact on the safety of patients, access to medicines and the responsible management of health expenditures.
- A specific data base for this activity, MELCLASS, is publicly available and is linked to a network of other international data bases on this subject.

New Activities – to come in 2009

Cosmetics

Packaging material for foodstuff

EDQM: Future & Action plans

- To continue to develop and contribute to European collaboration and work sharing
- standards = monographs & reference standards
- control of marketed products
- biological standardisation & replacement of animal testing
- fight against counterfeiting
- healthcare activities

Quality is never an accident.
It is always the result of high intention, sincere effort, intelligent direction and skilful execution; it represents the wisest choice of many options.

John Ruskin

Thank you!