

# THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



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## European Regulations for Medicines: Place and role of the EDQM and the European Pharmacopoeia

European Pharmacopoeia Training Webinar  
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EDQM Director

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# STRUCTURE

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- **Council of Europe, European Union and EDQM**
- The EU regulatory framework in pharmaceuticals and its key players
- EDQM and the European Pharmacopoeia
- Pharmacopoeial Harmonisation

## The Council of Europe

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- Founded in 1949
- Headquarters in Strasbourg, France
- 47 member states  
⇒ >820 millions citizens
- The oldest pan-European organisation dedicated to fostering co-operation in Europe
  - Promotes democracy
  - Protects human rights
  - Protects the rule of law



## Member states



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## The Council of Europe

### is not the European Union!



- **European Union (EU):** a unique economic and political partnership between currently 27 European countries  
⇒ more than 440 million citizens
- **European Council:** the EU's main decision-making body. It defines the general political direction and priorities of the European Union

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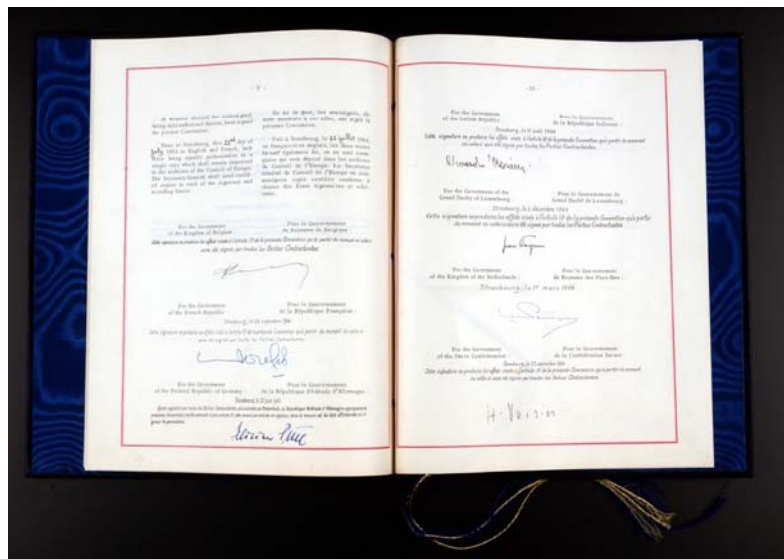
# European Directorate for the Quality of Medicines & HealthCare

- A Council of Europe Directorate, based on the Convention on the Elaboration of a European Pharmacopoeia (PA, 1964)



- Mission: to contribute to a basic human right: access to good quality medicines and healthcare

# European Pharmacopoeia Convention



# European Pharmacopoeia Convention

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## Article 1:

### The Contracting Parties undertake

- a) Progressively to elaborate a Pharmacopoeia which shall be common to the countries concerned and which shall be entitled "European Pharmacopoeia";
- b) To take the necessary measures to ensure that the monographs which will be adopted... and which will constitute the European Pharmacopoeia shall become the official standards applicable within their respective countries.

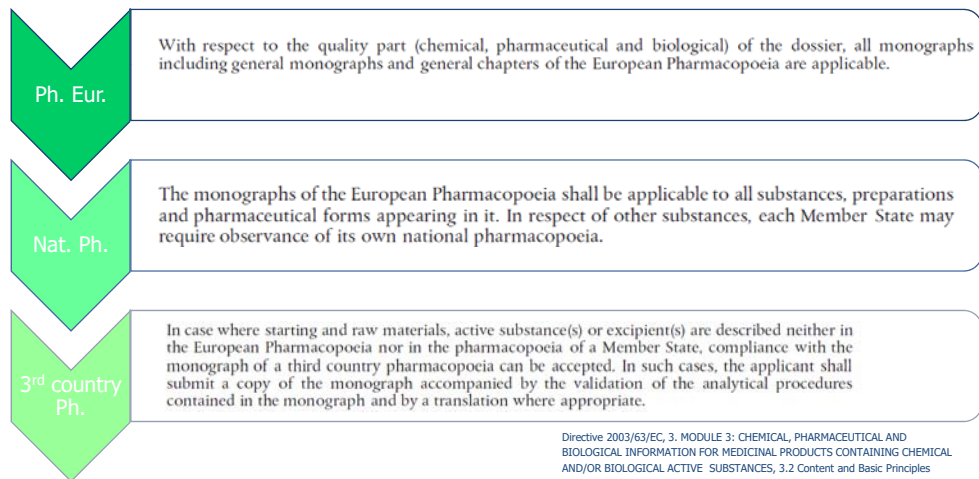
Strasbourg, 22. July 1964

## Why still national Pharmacopoeias?

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- For texts of interest to one Member State only; for texts out of the scope of the Ph. Eur. (e.g. national formularies)
- Three main approaches (country specific):
  - Discontinuation of the national pharmacopoeia (e.g. Sweden, Finland, the Netherlands), Ph. Eur. as the only pharmacopoeia, potentially translated into national language
  - Maintenance of a national pharmacopoeia to complement the Ph. Eur.:
    - Inclusion of the Ph. Eur. in the national pharmacopoeia (e.g. BP, Royal Spanish Pharmacopoeia).
    - Publication of a National pharmacopoeia in addition to the Ph. Eur. (e.g. France, Germany, Switzerland, Austria)

## Ph. Eur. / National Pharmacopoeia / 3<sup>rd</sup> country Pharmacopoeia in the EU



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## The EU Commission – the “Policy and Law Makers” -

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- Development of the regulatory framework
- Marketing authorisation procedures, GMP, GCP, Clinical Trials...
- New/special topics in pharmaceutical politics (e.g. Falsified Medicines Directive)
- International relations and co-operation (ICH, WHO)
- Publication of the relevant legislation and guidance documents in the EU concerning pharmaceuticals (EudraLex ...)

## The European Union Legal System

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### Aim and Definitions

**Core objective:** European unification based on a harmonised legal system

**Community law:** independent legal system

### Precedence over national legal provision

### Three different independent types of legislation

- primary law – the treaties, starting point for EU law
- secondary law – the body of law: regulations, directives, decisions...
- case law

# The EU Pharmaceutical Legislation

	to whom?	
<b>Regulation</b>	all "persons" in the EU	directly binding, super-sedes national law
<b>Directive</b>	EU-Member States	to be transposed into national law
<b>Decision</b>	single "person(s)" (MAH, EU-MS, .. )	directly binding, case by case, super-sedes national law
<b>Guidelines</b>	interested "parties" (MAH, ...)	to give guidance ("soft-law")

## Quality « Players » in the EU

- EMA and national competent authorities (NCA)
- CHMP/CVMP/HMPC Working parties:
  - Quality Working Party (+ CVMP + HMPC)
  - Biologicals Working Party
  - GMP/GDP Inspectors Working Group ....
- EDQM:
  - European Pharmacopoeia
  - OMCL network
  - Certification of Suitability
  - .....



# European Medicines Agency (EMA)

- A European Union body responsible for the evaluation, supervision and pharmacovigilance of medicinal products.
- Set up in 1995 (EC Regulation No. 2309/93), now located in Amsterdam, NL.
- EMA is not the FDA for Europe!
- Coordinates the existing scientific resources of Member States.
- Works through a network of about 4500 European experts. It draws on the resources of the currently 45 National Competent Authorities (NCAs) in 30 EU and EEA countries.
- A single evaluation is carried out through the Committee for Medicinal Products for Human Use (CHMP) or Committee for Medicinal Products for Veterinary Use (CVMP) for the centralised procedure.
- Works closely with the EDQM (Ph. Eur., Certification, OMCL-Network...).

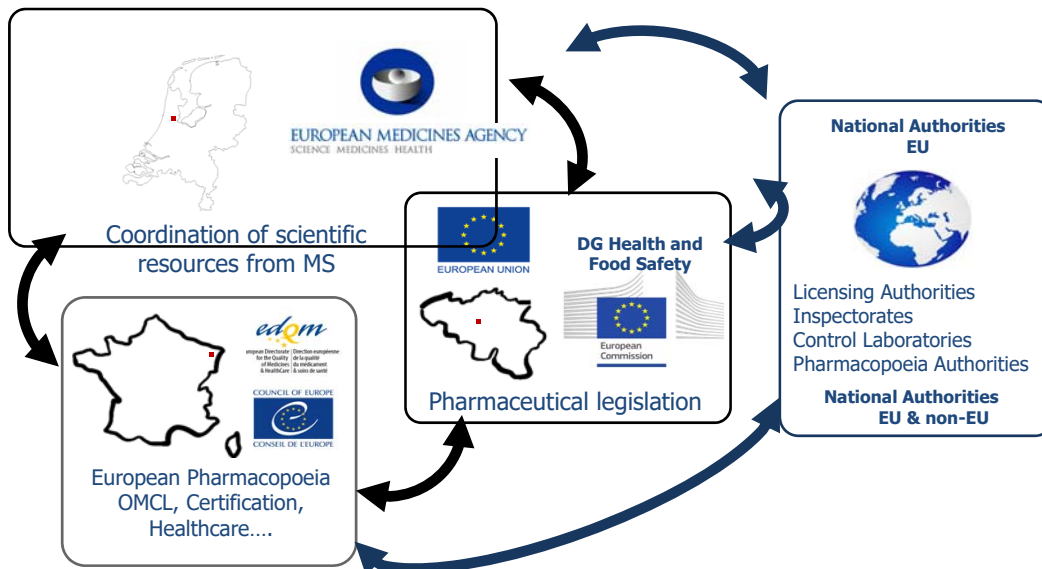


# National Authorities

Act as “full provider” for the applicants – responsible for the different marketing authorisation procedures and different kinds of medicinal products.

- Nominate experts for the evaluation of the application for the centralised marketing authorisation process.
- Act as rapporteur or co-rapporteur in the assessment of centralised applications via their CXMP members.
- Participate in working parties, *ad hoc* groups, promote pharmaceutical politics development.
- Responsible for pharmacovigilance.
- Contribute to the activities of the EDQM.

# Key players for the quality of medicines



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## From the European Pharmacopoeia...

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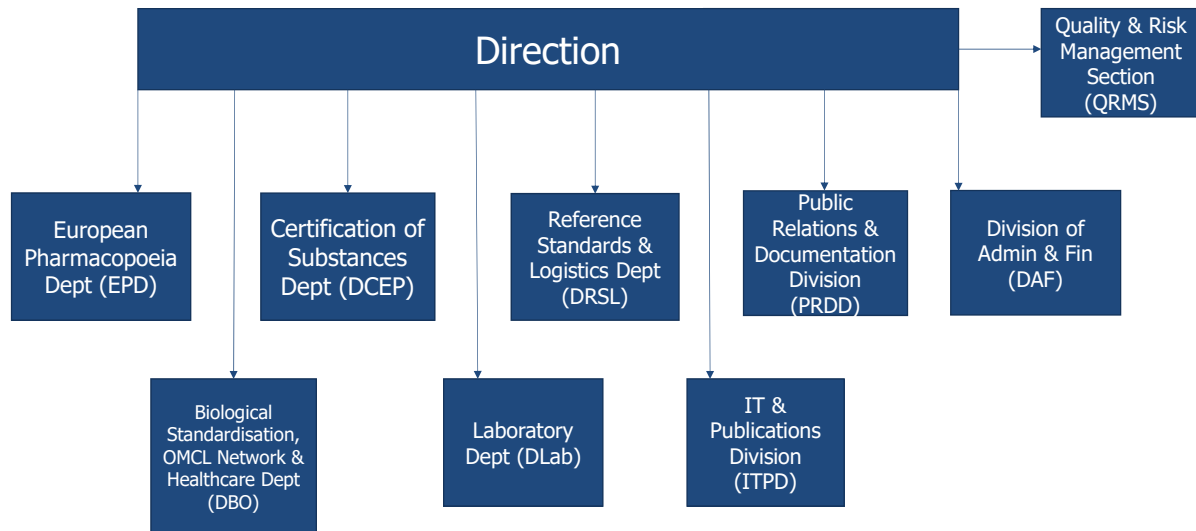
- 1964: Activities based on an International Convention of the Council of Europe to develop harmonised and common standards for medicines
- Mandatory status for all EU/EEA Member States since 1975 via EU pharmaceutical legislation
- 1994: EU signs the Ph. Eur. Convention
- 1994: creation of the European Network of Official Medicines Control Laboratories (OMCL)

## ... to the EDQM

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- 1994: creation of the procedure of certification of suitability to the monographs of the Ph. Eur.
- 2007: transfer of activities on blood transfusion and organ transplantation
- 2008: transfer of activities on combating counterfeits and healthcare activities
- 2009: transfer of activities on cosmetics and food-packaging

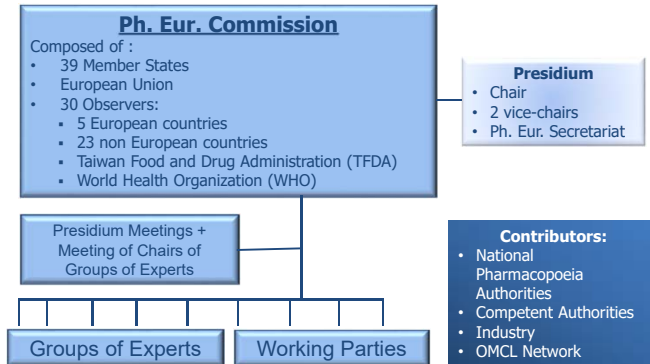
# EDQM Organisational Chart



## European Pharmacopoeia (Ph. Eur.)

- Protecting public health - one common compulsory standard.
- The Ph. Eur. is the official pharmacopoeia in Europe – complemented by national pharmacopoeias for texts of interest to only one Member State.
- Mandatory at the same date in 39 Member States (CoE) and the EU (decision of Ph. Eur. Commission).
- Legally binding quality standards for ALL medicinal products in its member states, i.e. raw material, preparations, dosage forms, containers must comply with the Ph. Eur. requirements when they exist.

# Ph. Eur. Commission



- One delegation per Member State / Observer
- Three sessions a year
- Texts are adopted by **unanimous** vote
- Composition of groups of experts decided by Ph. Eur. Commission
- Since 2016: open to experts throughout the world

# Ph. Eur. Network



- Currently **21 active Groups of experts** and **40 working parties** (+13 "dormant") elaborating and revising texts, meeting up to 3 times a year
- **More than 800 experts** (mainly from the Competent Authorities (NPAs, Assessors, OMCL, Inspectors), Industry, University)
- Mainly from Ph. Eur. member states, but since 2016 also from abroad (US FDA, Australia, China, India, Korea, Madagascar...)

## Members and Observers

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## The Pharmacopoeia in the EU Legislation

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“The monographs of the European Pharmacopoeia shall be applicable to all substances, preparations and pharmaceutical forms appearing in it. In respect of other substances, each Member State may require observance of its own national pharmacopoeia.....”

## The Pharmacopoeia in the EU Legislation

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However, where a material in the European Pharmacopoeia or in the pharmacopoeia of a Member State has been prepared by a method liable to leave impurities not controlled in the pharmacopoeia monograph, these impurities and their maximum tolerance limits must be declared and a suitable test procedure must be described.

## The Pharmacopoeia in the EU Legislation

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In cases where a **specification** contained in a monograph of the European Pharmacopoeia or in the national pharmacopoeia of a Member State might be **insufficient** to ensure the quality of the substance, the competent authorities may **request more appropriate specifications** from the marketing authorisation holder. ...

## The Pharmacopoeia in the EU Legislation

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...The **competent authorities shall inform** the authorities responsible for the pharmacopoeia in question. The **marketing authorisation holder shall provide** the authorities of that pharmacopoeia with the **details** of the alleged insufficiency and the additional specifications applied.

Directive 2001/83/EC, Annex 1, 3. MODULE 3: CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR MEDICINAL PRODUCTS CONTAINING CHEMICAL AND/OR BIOLOGICAL ACTIVE SUBSTANCES, 3.2 Content and Basic Principles

## The Pharmacopoeia in the EU Legislation

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### To summarise:

The Ph. Eur. is legally binding, but the legislation foresees a mechanism to provide the pharmacopoeia authority with information on the quality of products on the market; an excellent tool to ensure that monographs are not cast in stone but routinely updated to reflect the state-of-the-art.



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## Harmonisation – Why ?

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- Global market: Pharmaceutical supply chain is globalised
- Harmonisation helps to increase availability of medicines, makes industry more efficient
  - Better able to serve multiple markets with the same processes and plants
  - Elimination of redundant testing
  - Minimises duplication of testing requirements
- Harmonisation helps to strengthen pharmacopoeias - strong, state-of-the-art standards reflecting the global reality
- Ultimately to the benefit of patients!

# International Collaboration

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- Ph. Eur.: successful model of work-sharing and harmonisation between currently 39 countries, but based on strong political will and legal commitment
- EDQM, USP and the Japanese Pharmacopoeia, with WHO as an observer, are partners in the Pharmacopoeial Discussion Group (PDG)
- Bilateral Agreements / MoUs with pharmacopoeia authorities (e.g. ChP) on collaboration and exchanges; involvement of observers in the elaboration of texts.
- Global harmonisation (Good Pharmacopoeial Practices): EDQM key player in IMWP (International Meeting of World Pharmacopoeias)

# Conclusion

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EDQM's activities contribute to:

- Protecting public health
- Fostering animal welfare
- Ensuring economical use of member states' resources...

... and have a big international impact beyond Europe

# Thank you for your attention

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