EU Pharma Legislation: 59 years

INFARMED: 31 years

EMA: 29 years

From 6 to 30 countries

(including 3 EEA, minus UK)

Fernand Sauer, former executive director
of the European Medicines Agency

LISBON 15 January 2024

EU & international harmonisation 1985- 2001

- *1985*: **DELORS Single EU Market;** 13 pharma topics
- *1986: EU12: + Spain and* ***PORTUGAL***
- *1990:* **Start of ICH** (EU/US/Japan)
- *1993:* **Start of INFARMED**
  Formal adoption of EMEA regulation + seat
- *1994:* EU accession to European Pharmacopoeia
- *1995*: **Start of EMEA** in London
- *1999:* EMEA covers **EEA** and prepares accessions (PERF)
- *2000:* **Orphan drugs** and EMEA/COMP
- *2001:* **Codification** of EU pharmaceutical legislation

International dimension

1990 Tokyo
2nd ICH Steering Committee

1994 Strasbourg, Council of Europe
EU Pharmacopoeia ratification

Building blocks of EU Pharmaceutical Legislation

- *1980s*: Dissemination of first guidelines
- *1986:* "Biotech/High Tech Package" Directives
- *1988:* Transparency of pricing and reimbursement
- *1989:* Extension to plasma, vaccines and radiopharma
- *1991:* EU testing consolidated in Commission Directive

  Publication of the "Rules governing medicinal products in the EC" (50 guidelines, common MA format, GMPs)
- *1992*: Patent term extension up to 5 years; advertising control; legal status, leaflets; wholesale; homeopathics.
- *2000*: EMEA incorporates ICH CTD, e-CTD, Meddra

EMERGENCE OF MEDICINES AGENCIES

(1906: US FDA for interstate commerce)

- 1990: DE, UK, GR, IRL, NL
- 1993: DE, UK, GR, IRL, NL, **PORT,** FR
- 1995: DE, UK, GR, IRL, NL, PORT, FR, **EMEA**, SW
- 2000: DE, UK, GR, IRL, NL, PORT, FR, EMEA, SW, DK, FIN, SP

Heads of Medicines Agencies (HMA) network
https://www.hma.eu/

(Challenges for the African Medicines Agency_AMA)

European Conference, Lisbon 1987

Léon Robert (Luxembourg), first chair of CPMP (Commission BXL), chair of European Pharmacopoeia (Strasbourg)

PORTUGAL SAVING THE EM(E)A PROPOSAL

During the 1992 Portuguese Presidency, Dr Aranda Da Siva organised an informal meeting in Lisbon that saved the EMEA proposal, with a follow-up meeting in Sevilla in 1993

1993: START OF INFARMED

1992 COMMISSION PHARMA

1993 LISBON CONFERENCE

EM(E)A INAUGURATION
LONDON 1995

PARTICIPATION IN EM(E)A STRUCTURES

1996

- **Management Board :**
  José Aranda Da Silva,
  Graça Teixeira Queiros,
  Maria Miranda
- **CPMP :** José Morais,
  Henrique Rodriguez
- **CVMP :** Margarida Pratas,
  José Belo

2000

- **Management Board :**
  Miguel Andrade,
  Rogerio Gaspar
- **CPMP :** José Morais,
  Cristina Sampaio
- **CVMP :** Margarida Pratas,
  Maria Meisel
- **COMP** : José Toscano Rico
  (Bruno Sepodes chaired COMP from 2013 to 2022)

EU REGULATORY SYSTEM

- Reliable regulators, integrity and friendship
- Excellent national expertise network
- Early R&D dialogue (scientific advice/guidelines)
- Science based auditable evaluation process
- Transparency: EPARs, hearings, EMA website
- Strong involvement of patients & professionals
- Doctor and patient info in all EU languages
- Significant international input and output

SUPPORT FROM PORT. MINISTERS

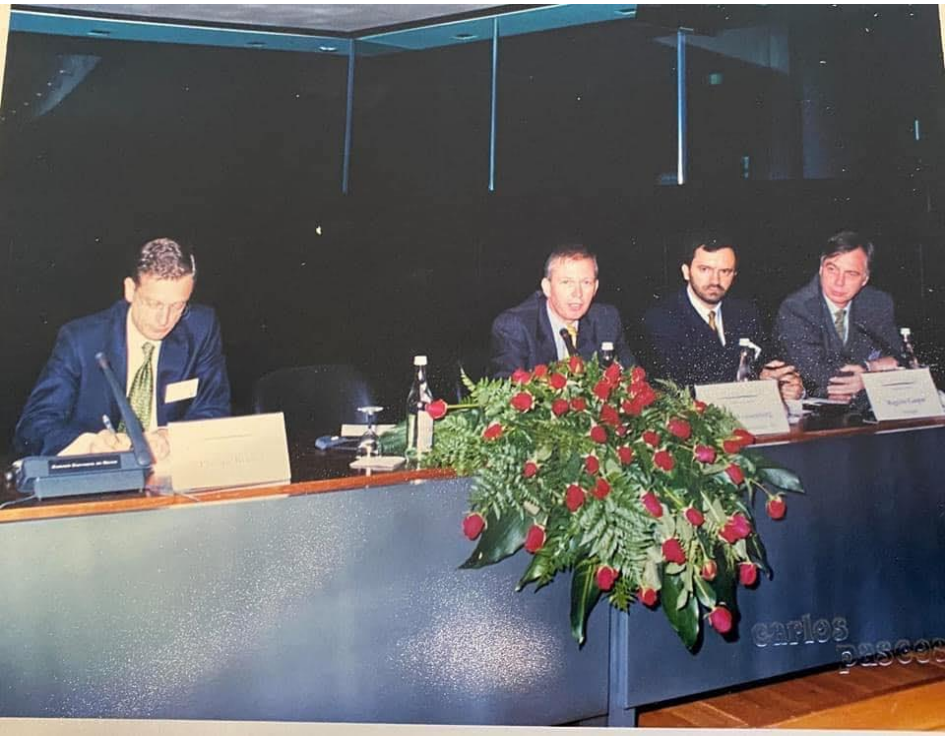
LISBON 1997

LISBON 1999

INFARMED CELEBRATION 1999

EUROPEAN CONFERENCES IN 2000

INFARMED, LISBON



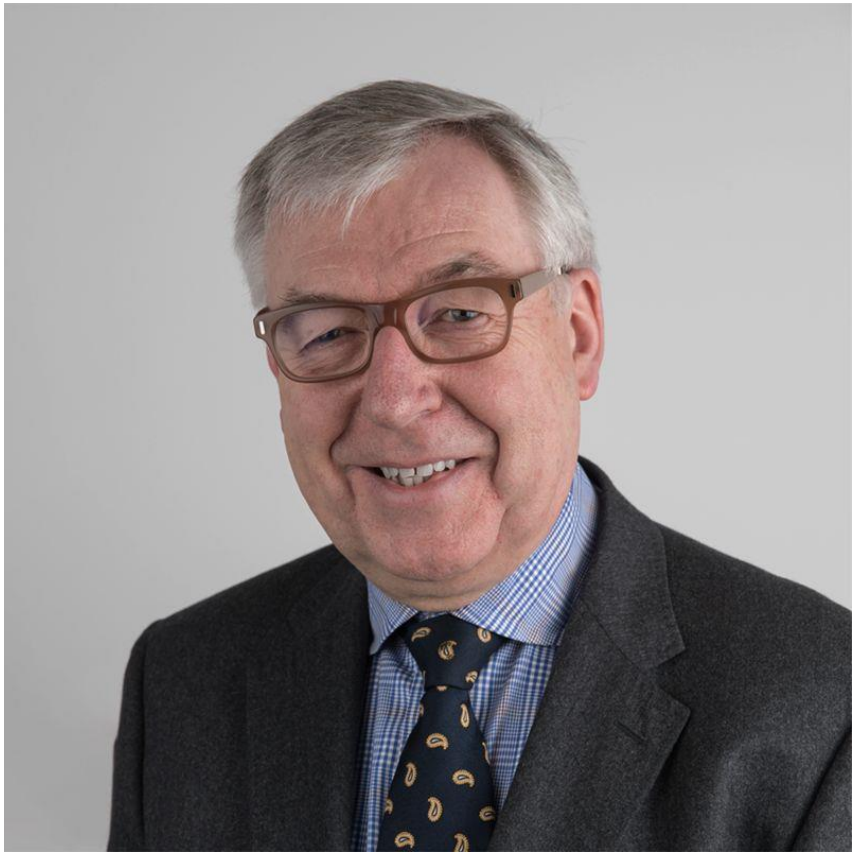
EMEA 5th, PORT. MINISTER

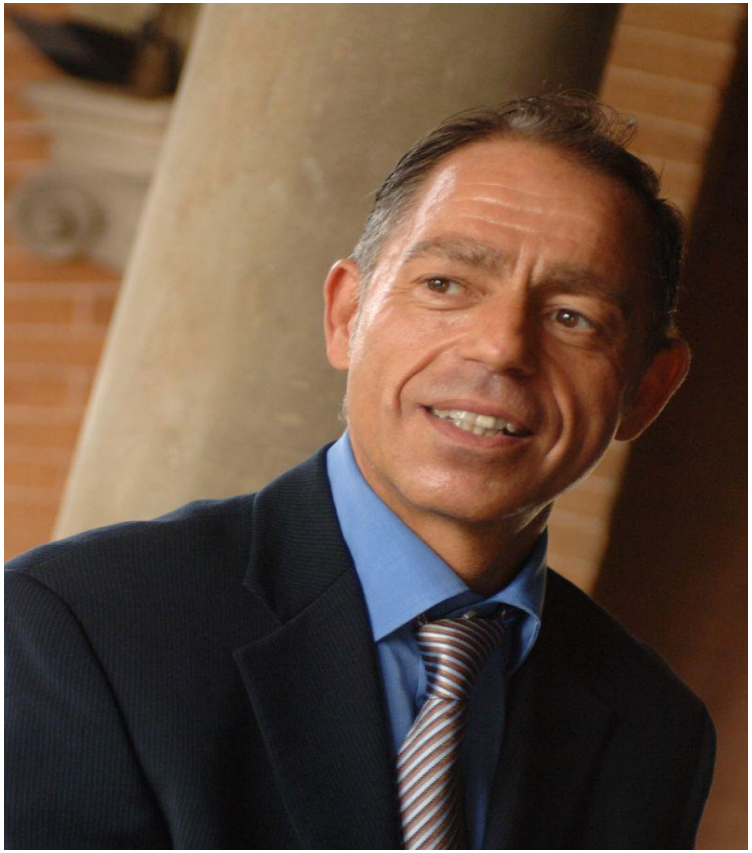
SOME KEY PEOPLE

LONDON 2000, EMEA 5th anniv.

PARIS 2015, EMA 20th anniv.

TRIBUTE TO GOOD FRIENDS:
Noel Wathion & Bep Farnell





EU PHARMA REFORM 2023-(2026?)

- **Many positive aspects**: innovation, regulatory simplification and «sand boxes», shortage reduction, orphan and pediatric medicines, environnement protection, antimicrobial resistance, etc..
- **Controversial**: complex incentives regime
- **Missing**: EMA central authorization scheme (« INDs ») for multi-centric clinical trials

HEADS OF AGENCIES' CRUCIAL ROLE

EMA + Agencies Heads anticipation capacity :

- Intense cooperation in EU regulatory system
- Shared Covid expertise
- Tackling shortages MSSG + HERA support
- Artificial-intelligence-workplan-2023-2028