



50 YEARS

EU PHARMACEUTICAL REGULATION MILESTONES

LEGISLATIVE

THERAPEUTIC

The Declaration of Helsinki establishes **ETHICAL PRINCIPLES FOR CLINICAL RESEARCH**

1964

EU decides that **MEDICINAL PRODUCTS NEED TO BE AUTHORISED** before being placed on the market and develops structured medicinal regulations.

1965

The Thalidomide disaster exemplifies the need for **EVIDENCE-BASED AUTHORISATION**.

1967

A new medicine added to the **TREATMENT OF TUBERCULOSIS** (rifampicin).

1968

A **RELIEF MEDICINE FOR BRONCHOSPASM** in asthma (salbutamol).

1971

A combination **TREATMENT FOR PARKINSON'S DISEASE** (carbidopa/levodopa).

1972

A novel **BROAD-SPECTRUM ANTIBIOTIC FOR BACTERIAL INFECTIONS** (amoxicillin, clavulanate).

First steps towards a **JOINT EU POSITION ON MARKET AUTHORISATIONS** through a multistate procedure and a common committee.

1974

A **PIONEERING MEDICINE** in breast cancer (tamoxifene).

1975

1976

INHIBITORS OF STOMACH ACID production for treatment of peptic ulcers (cimetidine).

1980

A novel **TREATMENT FOR HYPERTENSION** (captopril).

Member States agree on **UNIFORM** way to summarise **KEY CHARACTERISTICS** of an authorised product.

1982

The first **SYNTHETIC INSULIN** is produced.

1983

1986

The **FIRST EVER RECOMBINANT VACCINE** (for Hepatitis B).

The **CONCERTATION PROCEDURE** is introduced: before authorising innovative products national authorities ask **THE OPINION OF AN EU LEVEL COMMITTEE**.

Rules for **COPIES OF BRANDED MEDICINES** ('generics') **ARE BETTER DEFINED**.

1987

The first **ANTIRETROVIRAL TREATMENT FOR HIV/AIDS** (zidovudine).

Additional **EU RULES** are adopted for the authorisation of **VACCINES AND MEDICINES DERIVED FROM BLOOD**.

FIRST GUIDELINES ON GOOD MANUFACTURING PRACTICES are published to improve the quality of medicines throughout the EU.

1989

The conjugated **HAEMOPHILUS INFLUENZA VACCINE** to lower incidence of meningitis and pneumonia in children.

90s

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (**ICH**) provides a platform for international cooperation.

New rules harmonise the **LABELLING** of medicinal products, **ADVERTISING, PRESCRIPTIONS AND DISTRIBUTION**. Additional rules on **HOMEOPATHIC PRODUCTS** are introduced.

Agreement on a **CENTRALISED, EU WIDE PROCEDURE** for the authorisation of human and veterinary medicinal products. A new **EUROPEAN AGENCY (EMA)** will be responsible for scientific evaluations. **MUTUAL RECOGNITION OF NATIONAL AUTHORISATIONS** is facilitated.

As part of the Council of Europe's work, a **EUROPEAN NETWORK OF MEDICINES** control laboratories is created.

1990

1992

1993

1994

EMA - the **EUROPEAN MEDICINES AGENCY** starts business.

FIRST CENTRALISED MARKETING AUTHORISATION is granted by the European Commission.

1995

A **NOVEL TREATMENT FOR MULTIPLE SCLEROSIS** (interferon B).

1996

A **RAPIDLY ACTING INSULIN** analogue.

1998

The first **MOLECULARLY TARGETED CANCER MEDICINE** (rituximab).

1999

A tumor necrosis factor inhibitor for **TREATMENT OF RHEUMATOID ARTHRITIS** (infliximab).

To increase the number of products for rare diseases, **NEW LEGISLATION IS ADOPTED (ORPHAN REGULATION)**.

For the first time, **A PATIENT REPRESENTATIVE IS A FULL MEMBER OF A SCIENTIFIC COMMITTEE** of the European Medicines Agency.

2000

The first **PERSONALISED MEDICINE FOR TREATMENT OF BREAST CANCER** (trastuzumab).

00s

The **CLINICAL TRIAL DIRECTIVE** provides requirements for the conduct of clinical trials in the EU.

2001

The first two **ORPHAN MEDICINAL PRODUCTS** for treatment of a rare metabolic disorder, the Fabry disease (agalsidase alfa, agalsidase beta). An **INNOVATIVE MEDICINE FOR TREATMENT OF CHRONIC MYELOID LEUKAEMIA** (imatinib).

EU agrees on rules regarding **TRADITIONAL HERBAL MEDICINAL PRODUCTS**.

COOPERATION OF NATIONAL AUTHORITIES for the authorisation of products is further formalised.

Introduction of **EU RULES** for copies of **BIOLOGICAL PRODUCTS** ('biosimilars').

2004

EU adopts legislation on **MEDICINAL PRODUCTS FOR CHILDREN**.

2006

The Human Papilloma Virus **VACCINE TO PREVENT CERVICAL CANCER**.

REGULATION ON ADVANCED THERAPY MEDICINAL PRODUCTS is introduced.

2007

2008

In the context of multiple myeloma **THALIDOMIDE IS AUTHORIZED AS A TREATMENT**.

NEW EU PHARMACOVIGILANCE RULES strengthen the system for safety of medicines: better prevention, detection and assessment of adverse reactions to medicines, direct patient reporting of adverse events.

2010

LEGISLATION AGAINST FALSIFIED MEDICINES is adopted.

2011

A **NOVEL TREATMENT FOR MELANOMA** (vemurafenib).

NEW CLINICAL TRIAL REGULATION simplifies procedures across EU and enables cross-border cooperation in international clinical trials.

2012

The first **GENE THERAPY** for the treatment of a severe fat metabolism disorder.

2014

A new generation of antiviral medicines for **TREATMENT OF CHRONIC HEPATITIS C** (sofosbuvir).

2015

COMMON EU LOGO FOR ON-LINE PHARMACIES becomes compulsory.

<http://ec.europa.eu/health/EUpharma50>

10s