



50 YEARS

EU PHARMACEUTICAL REGULATION MILESTONES

LEGISLATIVE

THERAPEUTIC



60s

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). **1968**

70s

A combination **TREATMENT FOR PARKINSON'S DISEASE** (carbidopa/levodopa). **1971**

A novel **BROAD-SPECTRUM ANTIBIOTIC FOR BACTERIAL INFECTIONS** (amoxicillin, clavulanate). **1972**

First steps towards a **JOINT EU POSITION ON MARKET AUTHORISATIONS** through a multistate procedure and a common committee. **1974**

An **AROMATASE INHIBITOR** to **LOWER THE RISK OF REOCCURRENCE** of breast cancer (tamoxifene). **1975**

INHIBITORS OF STOMACH ACID production for treatment of peptic ulcers (cimetidine). **1976**

80s

A novel **TREATMENT FOR HYPERTENSION** (captopril). **1980**

Member States agree on **UNIFORM** way to summarise **KEY CHARACTERISTICS** of an authorised product. **1982**

The first **SYNTHETIC INSULIN** is produced. **1983**

The **FIRST EVER RECOMBINANT VACCINE** (for Hepatitis B). **1986**

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). **1987**

Additional **PURPOSES** 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. **1989**

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.

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).

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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').

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 myeloma multiplex **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**

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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).

COMMON EU LOGO FOR ON-LINE PHARMACIES becomes compulsory. **2015**