

# 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).

# 70s

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

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

1976

# 80s

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 **PURPOSE-SPECIFIC RULES** are adopted for the authorisation of **VACCINES AND MEDICINES DERIVED FROM BLOOD**.

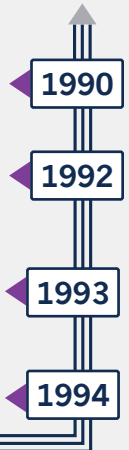
**FIRST GUIDELINES ON GOOD MANUFACTURING PRACTICES** are published to improve the quality of medicines throughout the EU.

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.

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').

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**

# 10s

**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**