European Commission

50 YEARS
EU PHARMACEUTICAL REGULATION MILESTONES

LEGISLATIVE | **THERAPEUTIC**

60s

1964 — The Declaration of Helsinki establishes **ETHICAL PRINCIPLES FOR CLINICAL RESEARCH**

1965 — 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).

1974 — An **AROMATASE INHIBITOR** to **LOWER THE RISK OF REOCCURRENCE** of breast cancer (tamoxifene).

1975 — First steps towards a **JOINT EU POSITION ON MARKET AUTHORISATIONS** through a multistate procedure and a common committee.

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

80s

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

1982 — The first **SYNTHETIC INSULIN** is produced.

1983 — Member States agree on **UNIFORM** way to summarise **KEY CHARACTERISTICS** of an authorised product.

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

1987 — 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).

1989 — 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

1990 — The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use **(ICH)** provides a platform for international cooperation.

1992 — New rules harmonise the **LABELLING** of medicinal products, **ADVERTISING, PRESCRIPTIONS AND DISTRIBUTION**. Additional rules on **HOMEOPATHIC PRODUCTS** are introduced.

1993 — 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.

1994 — As part of the Council of Europe's work, a **EUROPEAN NETWORK OF MEDICINES** control laboratories is created.

1995 — EMA - the **EUROPEAN MEDICINES AGENCY** starts business. **FIRST CENTRALISED MARKETING AUTHORISATION** is granted by the European Commission.

1996 — A **NOVEL TREATMENT FOR MULTIPLE SCLEROSIS** (interferon B).

1998 — A **RAPIDLY ACTING INSULIN** analogue.

1999 — The first **MOLECULARLY TARGETED CANCER MEDICINE** (rituximab).

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

00s

2000 — 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.

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

2001 — The **CLINICAL TRIAL DIRECTIVE** provides requirements for the conduct of clinical trials in the EU.

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).

2004 — 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').

2006 — EU adopts legislation on **MEDICINAL PRODUCTS FOR CHILDREN.**

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

2007 — **REGULATION ON ADVANCED THERAPY MEDICINAL PRODUCTS** is introduced.

2008 — In the context of myeloma multiplex **THALIDOMIDE IS AUTHORIZED AS A TREATMENT**.

10s

2010 — **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.

2011 — **LEGISLATION AGAINST FALSIFIED MEDICINES** is adopted.

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

2012 — **NEW CLINICAL TRIAL REGULATION** simplifies procedures across EU and enables cross-border cooperation in international clinical trials.

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.