

Evolution of the Pharmaceutical Industry



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02 Introduction & Problem Statement

- Economic sector dedicated to research, development, manufacturing, and marketing of medicines
 - Intersection between life sciences, chemistry, biotechnology, and healthcare economics
- Four industrial revolutions have transformed pharmaceutical production since 1760:
Transition from craftsmanship to Industry, automation, AI, personalized medicine
 - The COVID-19 pandemic has accelerated the structural transformations of the sector

03 Origins — From Antiquity to the 19th Century

▶ The first pharmacopoeia

- Publication in Nuremberg of the first collection of medicines and chemical products
- Standardization of concentrations and constituents of preparations

▶ Chemistry in the service of medicine

- Swiss physician-chemist of the 16th century, pioneer of medical chemistry
- Critique of speculative alchemy: chemistry must serve to prepare medicines
- Foundation of modern chemical pharmacy and rational therapeutics

▶ Birth of the pharmaceutical profession

- Foundation of the Society of Apothecaries in London
- Separation of apothecaries and grocers
- creation of the Pharmaceutical Society of Great Britain
- First supervised scientific training for pharmacists

04 The First Industrial Revolution (1760-1830)

▶ Historical context

- Origin in Great Britain: new textile technologies, steel industry, steam engines
- Transformation of agricultural societies into industrial societies with large urban centers

▶ Indirect impact on pharmacy

- The industrial revolution had no immediate impact on the pharmaceutical industry
- But it laid the mechanical and economic foundations for mass production
- The scientific revolution of the 17th century opened the way for rational experimentation

▶ First transitions

- Apothecaries began using steam engines for grinding and mixing
- Transition of some pharmacies to the factory
- Drug manufacturers remained small structures: 20 to 30 employees maximum

▶ Foundation of the first major enterprise

- Merck (Germany): founded as a pharmacy in 1668 in Darmstadt
- In 1827, Heinrich Emanuel Merck initiated the transition to an industrial and scientific enterprise
- First large-scale production of alkaloids (morphine, quinine, strychnine)
- Birth of the modern pharmaceutical industrial model

05 The Second Industrial Revolution (1880-1920)

► Foundation of pharmaceutical giants

- Pfizer : founded by two German immigrants as a fine chemicals enterprise
- Bayer : initially founded as a dye manufacturer in Barmen
- Hoechst : another German giant of dye chemistry
- Beecham: world's first factory dedicated exclusively to medicines

► From dye to medicine

- 1856: William Perkin accidentally discovers mauveine, first coal tar dye
- Coal tar derivatives revealed unexpected therapeutic properties
- Crystal violet: topical antiseptic and Gram staining dye
- Aspirin (acetylsalicylic acid) developed by Felix Hoffmann at Bayer in 1899

► American pioneers

- Colonel Eli Lilly (1876): pioneer of research and development (R&D), and industrial pharmaceutical manufacturing
- Johnson & Johnson: introduction of antiseptic surgery techniques and wound treatment
- Switzerland developed its pharmaceutical industry from local dye manufacturers

06 The World Wars - Catalysts for the Industry

▶ World War I

- American chemists had to reproduce German processes
- Aspirin, salvarsan (antimicrobial), barbital (hypnotic): mandatory national production
- Expropriation of German patents by the American Alien Property Custodian

▶ Interwar period: scientific foundations

- 1920s-1930s: major advances in scientific research and pharmaceutical technology: Synthetic vitamins, sulfonamides, antibiotics, hormones, psychotropics, antihistamines
- 1921: isolation of insulin; 1928: discovery of penicillin by Alexander Fleming
- 1935: discovered of the antibacterial properties of Prontosil (sulfonamide)

▶ World War II: mass production

- American government project: production and distribution of penicillin to soldiers
- Collaboration between officials, pharmaceutical firms, and university researchers
- Deep-tank fermentation: key innovation for industrial antibiotic production and enormous production of penicillin

07 The Antibiotic Era - The Golden Age (1945-1960)

▶ The wave of antibiotic discoveries

- Streptomycin (MSD): first effective antibiotic against tuberculosis
- Chlortetracycline (Lederle), chloramphenicol (Parke-Davis), erythromycin (Abbott, Eli Lilly)
- Tetracycline (Pfizer): first semi-synthetic antibiotic
- Nystatin, novobiocin, kanamycin: broadening of the antibacterial spectrum

▶ Other major post-war advances

- Polio vaccine by Jonas Salk, predominantly publicly funded
- Isoniazid (1950): first effective treatment for tuberculosis
- Cortisone: revolutionary anti-inflammatory treatment
- Vitamins A, D, K: large-scale commercialization and mass consumption

08 The Golden Age of the 1960s -Innovation and Expansion

▶ Revolutionary medicines

- Contraceptive pill : societal impact comparable to that of penicillin
- Valium (diazepam, Roche, 1963): anxiolytic that became the most prescribed medicine
- Monoamine oxidase inhibitors (MAOIs): new class of antidepressants
- Haloperidol: antipsychotic revolutionizing the treatment of mental disorders

▶ New therapeutic domains

- Psychiatric treatments: complement to psychoanalytic approaches
- Antihypertensive medicines
- Anticancer chemotherapies: American government's "war on cancer"
- Paracetamol (1956) and ibuprofen (1969): everyday analgesics and antipyretics

▶ Consolidation and internationalization

- Wave of mergers and acquisitions in the pharmaceutical industry
- 1951: Pfizer opened subsidiaries in nine new countries
- Beginning of the globalization of the production and distribution chain

09 The Thalidomide Scandal — Birth of Regulation

▶ The thalidomide tragedy (1957-1961)

- Thalidomide: anti-nausea medicine prescribed to pregnant women
- Phocomelia: severe congenital limb malformation in thousands of newborns
- Global scandal revealing the dangers of insufficiently tested medicines
- Market withdrawal and historic lawsuits against laboratories

▶ Frances O. Kelsey: a heroine of pharmacovigilance

- Medical reviewer at the American FDA, refused to approve thalidomide in 1960
- Her scientific skepticism and demand for complete data saved thousands of children

▶ Kefauver-Harris Amendments (1962)

- New American legislation requiring proof of medicine efficacy
- Obligation to precisely disclose side effects
- Strengthening of clinical trials before market authorization
- Radical transformation of the global regulatory framework

▶ Helsinki Declaration (1964)

- International ethical charter governing medical research on human beings
- Foundation of modern bioethics and responsible clinical research

10 Consolidation - Birth of "Big Pharma" (1970-2000)

▶ Wave of mergers and acquisitions

- Creation of pharmaceutical giants by absorption of smaller firms
- GlaxoSmithKline: merger of Glaxo Wellcome and SmithKline Beecham
- AstraZeneca: merger of Astra AB and Zeneca Group
- Sanofi-Synthélabo: merger then acquisition of Aventis

▶ Growth strategies

- Therapeutic diversification: covering the maximum number of medical domains
- Patent defense: extension through minor improvements (evergreening)

▶ The blockbuster economic model

- Blockbuster: medicine generating more than one billion dollars in annual revenue
- Lipitor (atorvastatin, Pfizer): over \$125 billion in total sales
- Objective: develop medicines for high-prevalence pathologies
- Increasing economic dependence on a few flagship products

11 Biotechnology and Genetic Engineering - A New Revolution

▶ Scientific foundations

- 1953: discovery of DNA structure by Watson and Crick
- 1973: development of DNA recombination technology (Cohen and Boyer)
- 1982: first approval of recombinant human insulin (Humulin, Eli Lilly)
- Birth of the pharmaceutical biotechnology industry

▶ Rise of biotechnology companies

- Genentech (1976): first biotechnology company dedicated to medicines
- Amgen, Biogen, Cetus: founding of biotech pioneers in the 1980s
- Specialization in recombinant proteins, monoclonal antibodies, gene therapies

▶ Revolutionary biological medicines

- Monoclonal antibodies: precise targeting of cancer cells or inflammatory molecules, Erythropoietin (EPO), Interferon, Recombinant Factor VIII,

▶ Impact on the industry

- Diversification of innovation sources: Big Pharma + biotechs + universities
- New production challenges: cell cultures, fermentation, complex purification
- High prices of biologicals: high production costs, niche markets
- Emergence of biosimilars: generics of biological medicines

12 Globalization and Supply Chain

▶ Production offshoring

- 1990s-2000s: massive offshoring to China and India
- Small chemical molecules: production of active pharmaceutical ingredients in emerging countries
- Biotechnologies: production kept in the United States and Europe
- Cost rationalization and tax optimization

▶ The complex production chain

- 1990s: highly specialized manufacturing with multi-country production chains
- Research and development in rich countries, production in low-cost countries
- Global distribution with regional logistics centers
- Increasing dependence on Asian suppliers for active ingredients

▶ Emergence of new players

- India: "pharmacy of the world", world's largest producer of generics
- China: domination of active pharmaceutical ingredient (API) production
- Chinese biotechs: increasing innovation, record out-licensing deals in 2025
- Brazil, South Korea, Singapore: new emerging pharmaceutical hubs

13 Regulation and Quality - An Ever-Stricter Framework

▶ Historical evolution of regulation

- 1906: Pure Food and Drug Act (USA) — first federal regulation
- 1938: Food, Drug, and Cosmetic Act — mandatory safety tests
- 1962: Kefauver-Harris Amendments — proof of efficacy required
- 1990-2000: international harmonization (ICH, FDA, EMA)

▶ Marketing Authorization (MA)

- Rigorous multi-phase process: preclinical, phases I, II, III clinical trials
- Benefit/risk assessment by regulatory agencies
- FDA (United States), EMA (Europe), ANSM (France): reference agencies
- Average development time: 10 to 15 years for a new medicine

▶ Good Manufacturing Practices (GMP)

- Harmonized international standards for pharmaceutical production
- Hygiene, equipment qualification, process validation
- Exhaustive documentation: batch records, standardized procedures
- Regular inspections: possible suspension of marketing authorization

▶ Pharmacovigilance and post-marketing surveillance

- Continuous surveillance of adverse effects after market launch
- Regional pharmacovigilance centers, international databases (VigiBase)
- Medicine withdrawals: phenacetin (1970), rofecoxib/Vioxx (2004)
- Increased transparency: public clinical trial registries, data access

14 Generics and Biosimilars - Democratization of Care

▶ The generics market

- Medicines containing the same active ingredient as the original, at reduced price
- Marketing possible after patent expiration (generally 20 years)
- Demonstrated bioequivalence: same efficacy and safety as the original
- Reduction in healthcare expenditure: generics 20-80% cheaper than originals
- Teva, Mylan, Sandoz: global giants of generics

▶ Biosimilars

- Generic versions of complex biological medicines
- More complex development: demonstrated similarity, not perfect identity
- First biosimilar approved in Europe in 2006, in the United States in 2015
- Strongly growing market
- Resistance from innovative laboratories: patent evergreening strategies
- Interchangeability (switching): possibility of substitution between originals and biosimilars

15 The Global Pharmaceutical Market in 2024-2026

- United States: 46% of global market — undisputed dominant position
- China: 7% — second place, rapid growth
- Germany: 4% — third place, European leader
- France: 3% — fifth place worldwide
- 10 markets concentrate 74% of global revenue

▶ Gene and cell therapies

- CAR-T therapy: genetic modification of T lymphocytes to fight cancer
- Kymriah (Novartis, 2017): first approved CAR-T treatment
- Gene therapies: correction of genetic mutations at the source

▶ Messenger RNA and next-generation vaccines

- mRNA technology: cellular instruction to produce therapeutic proteins
- COVID-19 vaccines (Pfizer-BioNTech, Moderna): record development in 11 months
- Revolution in development speed and production flexibility

▶ Artificial intelligence and drug discovery

- AI for virtual screening of millions of candidate molecules
- Machine learning for predicting pharmacological properties
- Reduction of time and costs for discovering new molecular entities
- DeepMind (AlphaFold): protein structure prediction, accelerating research

▶ Personalized medicine and pharmacogenomics

- Adaptation of treatment to the individual genetic profile of the patient

17 Current Challenges and Future Perspectives

▶ Antimicrobial resistance (AMR)

▶ Access to medicines and health equity

- Stark disparities: 10% of the world's population consumes 90% of medicines
- Prohibitive prices of innovative therapies: inaccessible for low-income countries
- Debates on patents, compulsory licenses, and generics

▶ Environmental sustainability

- Pharmaceutical industry: 4th most polluting sector in the world
- Active ingredient releases into the environment: ecotoxicity, bacterial resistance
- Carbon footprint of global production and distribution
- Emergence of "green pharmacy": eco-design, circular economy

▶ Digital transformation and e-health

- Telemedicine, remote monitoring, online dispensing: new care models
- Big data and artificial intelligence: predictive and preventive medicine

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19 Conclusion

- From the 17th-century artisanal apothecary to 21st-century global Big Pharma
- Four industrial revolutions transformed medicine production and distribution
- Chemistry, molecular biology, and computing successively revolutionized drug discovery
- ▶ **Unprecedented challenges**
 - Antimicrobial resistance, equitable access to care, environmental sustainability
 - Permanent balance between innovation, profitability, and social responsibility
 - Need for strengthened global governance and international collaboration
- ▶ **Future perspectives**
 - Precision medicine, gene therapies, artificial intelligence: a new era
 - Biotechnology and mRNA: redefinition of therapeutic standards
 - The pharmaceutical industry remains at the heart of 21st-century health, economic, and geopolitical issues