International Federation
of Pharmaceutical
Manufacturers & Associations

Improving Global Health through Collaborations and Dialogue

Representing the Research-Based Pharmaceutical Industry

IFPMA

"Our objective is to improve health around the world by contributing expertise, building trust, and establishing solutions for global health."

Welcome

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) facilitates collaborations, dialogue and mutual understanding between the research-based pharmaceutical industry and other global health stakeholders. Our objective is to improve health around the world by contributing expertise, building trust, and establishing solutions for global health.

I am therefore proud to introduce this brochure which informs fellow healthcare stakeholders about what we at the IFPMA do, how we work, and what our mission and objectives are. We seek to increase transparency about our organization's role and the unique role of the industry we represent and, in doing so, contribute to open and productive global health discussions.

While the world faces many health challenges, advances in medicines, biological products, vaccines and other health technologies mean that many people are living longer and with improved quality of life. There is, however, much work to be done to bring benefits of these advances to all people.

The research-based pharmaceutical industry's unique role in researching and developing new medicines, biological products, and vaccines provides crucial support to global health efforts. The IFPMA and our members are committed to working in partnership with governments, intergovernmental bodies, nongovernmental organizations, civil society organizations and others to implement progressive health policies. We view broad-based partnership approaches as key to addressing the wide array of complex global health challenges.

Valuing transparency and trust, we will continue to explain how our industry develops new medicines, to highlight the regulatory environment in which it operates, and to complement the contributions of many other stakeholders involved in the journey from the research laboratory to the patient's medicine cabinet.

I hope you find this brochure informative and that it provides a better understanding of the role and contributions of the research-based pharmaceutical industry and the IFPMA. We look forward to continuing the dialogue with our partners.

Eduardo Pisani
Director General

Representing the research-based pharmaceutical industry in Geneva

Founded in 1968, the IFPMA is a global, non-profit, nongovernmental organization. With members across the globe and a secretariat based in Geneva, Switzerland, the IFPMA represents the research-based pharmaceutical industry, including the biotechnology and vaccine sectors.

Our members comprise leading international companies as well as national and regional industry pharmaceutical associations in both developing and developed countries. Our primary role is to improve global health by representing our members in dialogue with intergovernmental bodies, nongovernmental organizations, Geneva-based missions of national governments, civil society organizations and others.

The IFPMA has several expert committees and working groups which leverage industry expertise to develop effective approaches to health issues. Its governing bodies are the IFPMA Council, a group of elected representatives from member companies and associations, and the IFPMA Assembly, which comprises the entire membership. The President of the IFPMA is elected by the Council for a two-year term and is chosen from among the Chief Executive Officers of member companies. The IFPMA has two Vice Presidents, also elected for a period of two years.

Our Mission

The IFPMA advocates policies that encourage discovery of and access to life-saving and life-enhancing medicines to improve the health of people everywhere.

Our Objectives

To fulfil its mission, the IFPMA follows these guiding principles:

- Encourage a global policy environment that is conducive to medicines innovation, both therapeutic and preventive, for the benefit of people around the world.
- Promote and support principles of ethical conduct and practices voluntarily agreed upon, as exemplified by the IFPMA Code of Practice.
- Promote and support the adoption of high standards of manufacturing practices and quality assurance for pharmaceutical products.
- Contribute industry expertise and foster collaborative relationships and partnerships with international organizations dedicated to the improvement of public health, especially in developing and emerging countries.
- Ensure regular contact and experience-sharing and coordinate efforts of members towards achieving these objectives.

Official Relationship with the United Nations

The IFPMA's representative role is reflected in its formal consultative status with the United Nations and its specialist bodies, including the World Health Organization (WHO), World Intellectual Property Organization (WIPO), United Nations Children's Fund (UNICEF), United Nations Conference on Trade and Development (UNCTAD), United Nations Economic and Social Council (UN ECOSOC) and United Nations Industrial Development Organization (UNIDO).

The IFPMA also has formal relationships with the World Bank and the World Trade Organization (WTO).

Addressing key issues for global health and the pharmaceutical industry

The IFPMA works to address a range of global health issues including medicines innovation, quality & regulations, global health, and trust & ethics.

Medicines Innovation

Research and Development

Peoples' unmet medical needs drive medicines innovation. IFPMA member companies strive to develop therapies for diseases where no current treatments exist or to develop improved therapies.

Intellectual Property Rights

Intellectual property rights are vital for sustained investment in innovative medicine development. The patent system balances different interests, providing the innovator with a limited period of market exclusivity in which to recoup development costs, while giving society the information needed for follow-on innovation and for manufacturing generic copies when patents expire.

Data exclusivity provides an important complementary incentive by defining a limited time period in which other companies may not use the originators' clinical trials data.

Medicines Quality & Regulation

Regulatory and Scientific Affairs

To improve peoples' access to high-quality medicines around the world, the IFPMA advocates harmonized regulatory standards. Harmonization facilitates the timely introduction of high quality, safe, and effective medicines, including biological products and vaccines.

Biological Products and Vaccines

Biological products and vaccines have more complex molecular structures and properties than many other medicines produced using chemical processes. Because these are generated using more complicated manufacturing techniques, they require different regulatory approaches to ensure their quality, safety, and efficacy.

Fake Medicines

The fake medicine trade is widespread and affects both developing and developed countries. All medicines – branded, generic, oral and injectable – are potentially at risk.

The industry supports responsible trade of medicines and efforts to safeguard patients against the dangers of fake medicines. These include advocating appropriate policies and regulations to secure the legitimate supply chain and medicines' quality and traceability.

"Peoples' unmet medical needs drive medicines innovation."

	Prevention	Treatment	Cure
HIV / AIDS			
Tuberculosis			
Malaria			
Childhood Diseases			
Respiratory Infections			
Cancers			
Neuropsychiatric Disorders			
Cardiovascular Diseases			
Diabetes			
Respiratory Diseases			

Medicines exist
R&D to improve their utility for patients and to overcome the emerging challenges, e.g, drug resistance

No medicines
R&D to bridge the gap

Global Health

Promoting Sustainable Solutions for Access to Medicines and Quality Healthcare

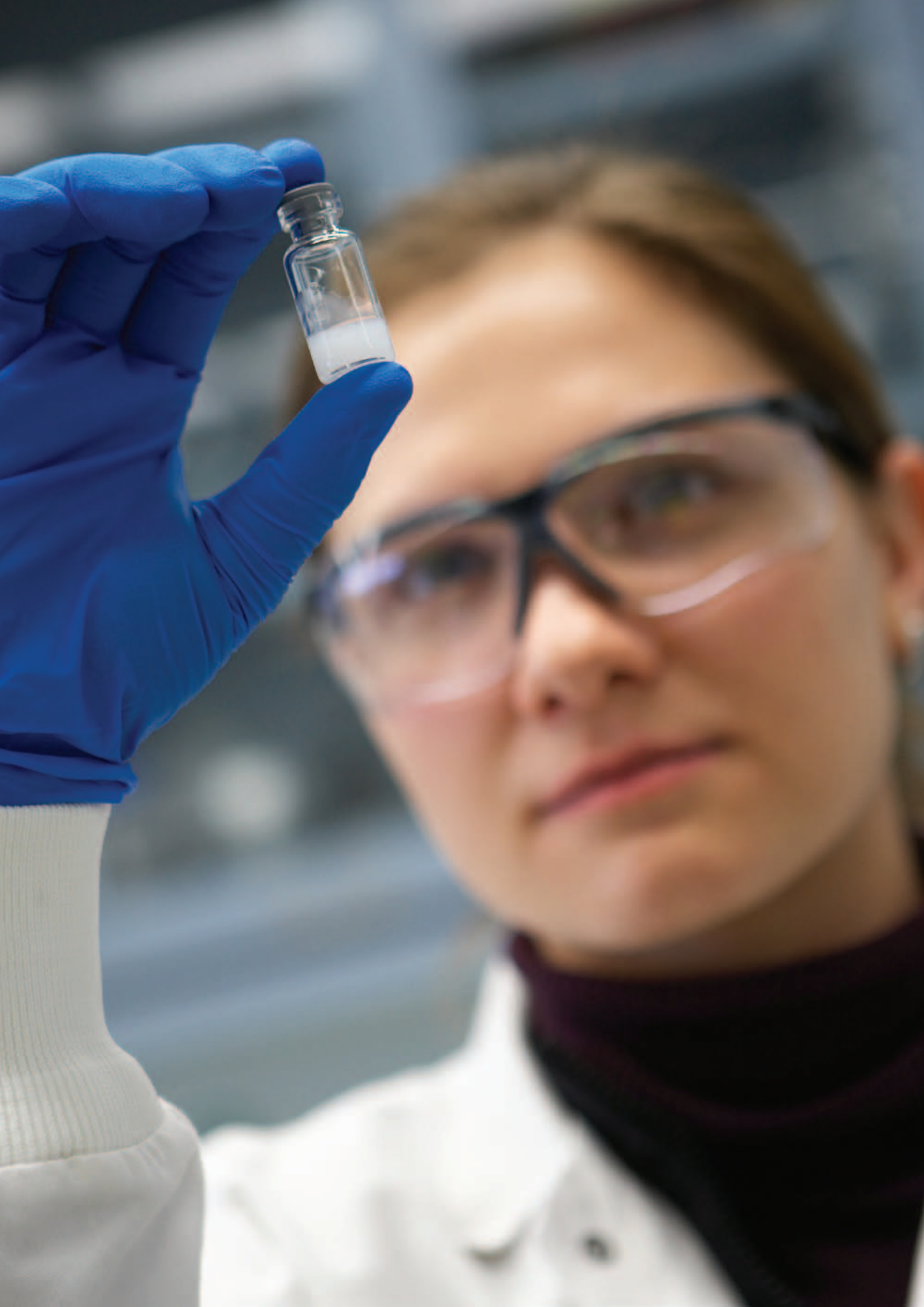
With decades of experience developing novel medicines, biological products and vaccines, the research-based pharmaceutical industry understands the complexity of factors influencing patients' ability to access products around the world. Increased access has been achieved through the industry's long-standing commitment to working with governmental, nongovernmental, and civil society partners to improve access, especially in developing countries.

Working to Meet UN's Health-Related Millennium Development Goals (MDGs)

To highlight the industry's commitment to helping achieve MDGs, the IFPMA documents members' long-term public-private partnerships in the IFPMA Developing World Health Partnerships Directory. This directory details partnerships that focus on access, capacity-building, and research and development.

Building on our industry's long-standing commitment to fight diseases in developing countries, the IFPMA announced in 2012 pledges of 14 billion treatments to help end nine neglected tropical diseases as well as continued support with research and development and capacity-building programs. Through the years, similar ongoing efforts have benefitted many people in developing countries by providing medicines, training for healthcare professionals, improving healthcare facilities and equipment, as well as providing health education for patients and populations at risk.

In the IFPMA Status Report on Pharmaceutical Industry R&D for Diseases of the Developing World, the IFPMA also documents industry's R&D efforts for diseases of the developing world.



" Advancing medical knowledge and improving global public health depend on information-sharing from researcher to attending physician and nurse to patient – and integrity is essential to these exchanges."

Trust & Ethics

Advancing medical knowledge and improving global public health depend on information-sharing, from researcher to attending physician and nurse to patient, and integrity is essential to these exchanges. Fundamentally, there must always be confidence that prescription decisions are made on an ethical and patient-focused basis.

The IFPMA Code of Practice embodies the industry's commitment to ensuring the highest ethical and professional standards of practice. IFPMA membership requires adoptions and implementation of this code wherever members operate in the world. It is based on the following guiding principles:

- The healthcare and well-being of patients are the first priority for pharmaceutical companies.
- Pharmaceutical companies will conform to high standards of quality, safety and efficacy as determined by regulatory authorities.
- Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
- Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
- Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
- Pharmaceutical companies will respect the privacy and personal information of patients.
- All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.
- Pharmaceutical companies should adhere in both the spirit and the letter to applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Innovating to improve health

To improve health around the world, the research-based pharmaceutical industry leads innovation of high-quality, safe, and effective medicines.

Developing new medicines is long and expensive but offers important benefits for peoples' health. The industry's 1.3 million employees strive to make a difference in peoples' lives by delivering innovative medicines, biological products, and vaccines.

From Laboratory to Patient

To develop one approved medicine, researchers may analyze 5,000 to 10,000 compounds of interest. The resources needed to research, develop, and deliver one innovative medicine are considerable but necessary. On average 13.9 years and more than USD 1.3 billion are required for a novel medicine to reach patients. During this period, a new medicine passes through several crucial stages on the long road from the research laboratory to the patient:

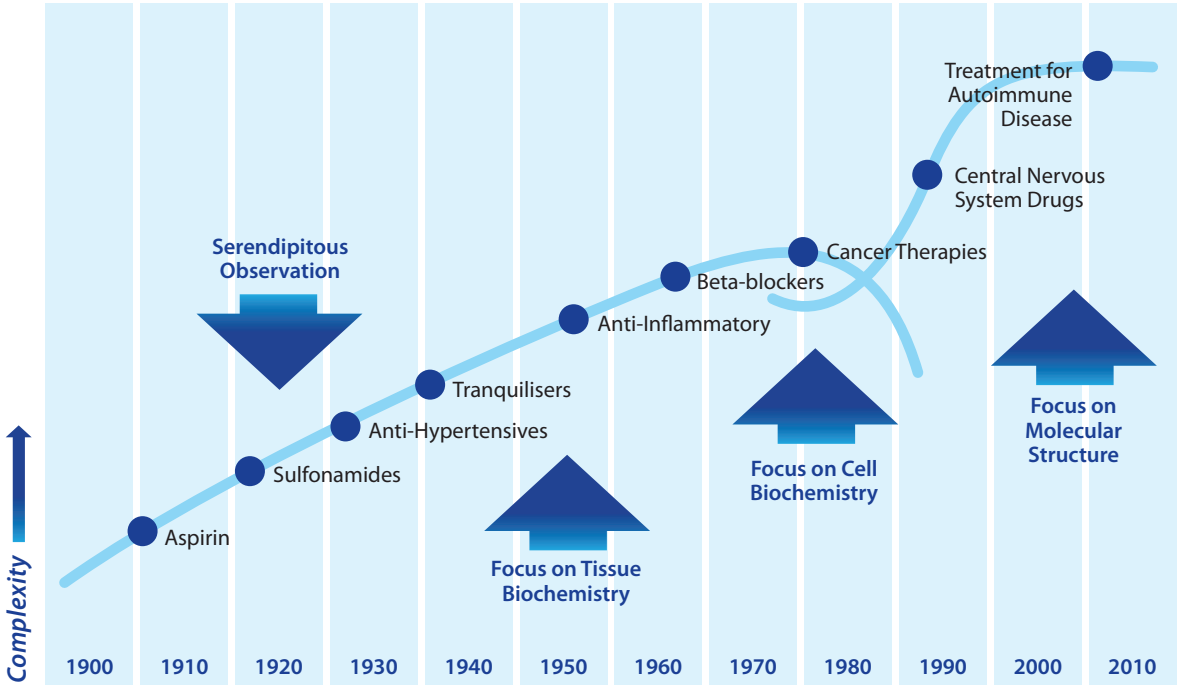
Drug discovery: identification of candidate molecules to prevent or treat a disease.

Pre-clinical testing: before a molecule reaches testing in humans, it undergoes several years of laboratory testing to understand its likely therapeutic and safety profiles.

Clinical trials: to determine if a potential new therapy can safely and effectively treat or prevent a disease, it is studied in human volunteers. Various phases of clinical testing evaluate safety, different doses, and efficacy.

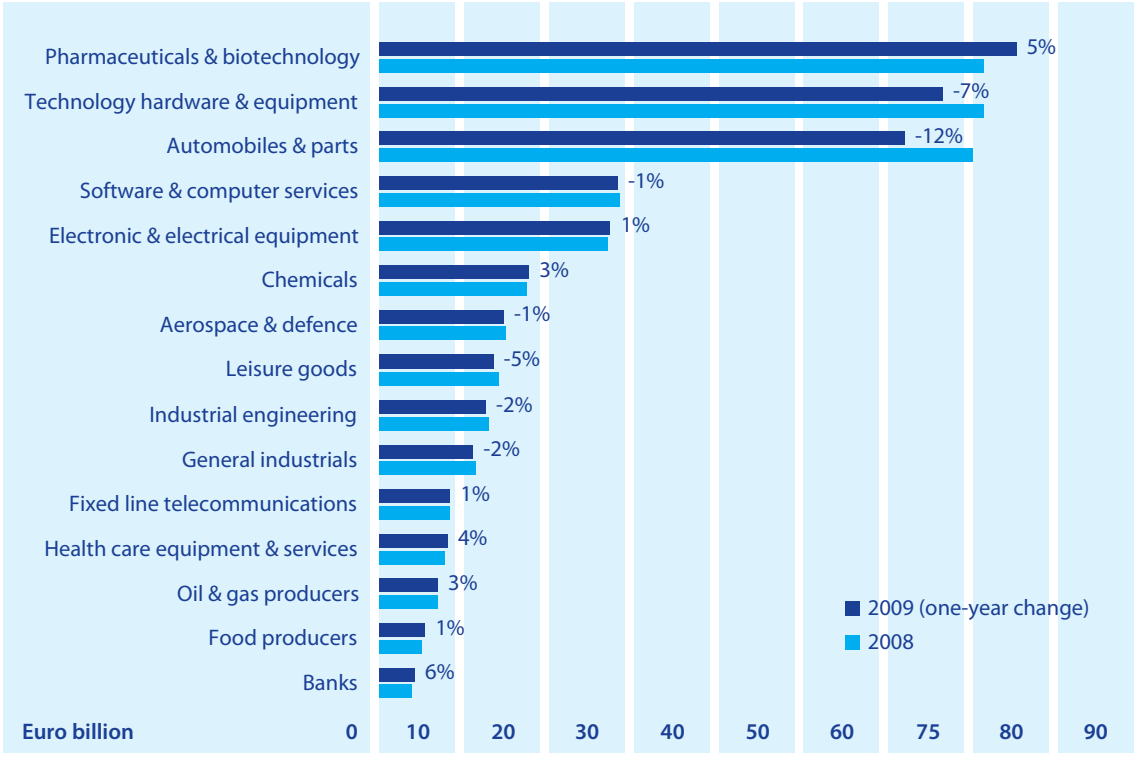
Regulatory review: with clinical data to show that a potential medicine is safe and effective, health authorities review the data and decide whether to approve for patient use.

Drug developments since 1900



Source: Boston Consulting Group.

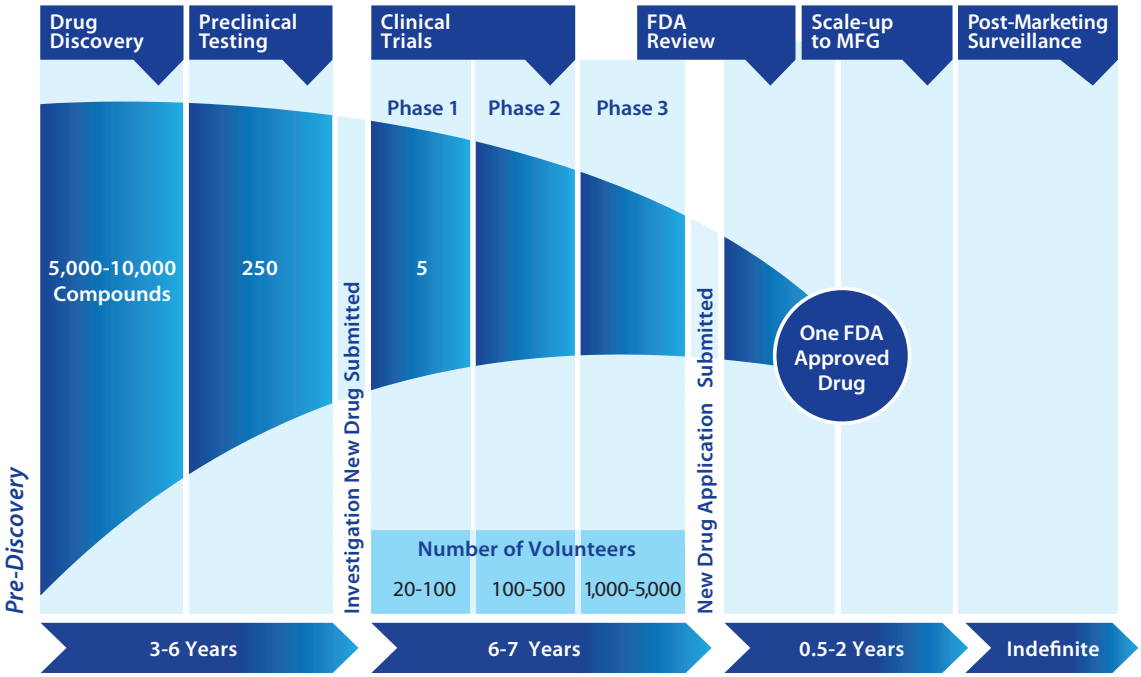
R&D investments by sector



Source: EFPIA. The Pharmaceutical Industry in Figures. Key Data - 2011 update p.10. And, 2010 Edition. p.1.

"...the need for continued innovation remains large. Emergence of new disease threats and the re-emergence of old ones, such as resistance development to existing treatments, underscore this ongoing need."

The research & development process



Source: PhRMA 2011 profile, Pharmaceutical Industry. p.12.
Available at: http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf

The Need for Innovative Medicines

The primary role of the research-based pharmaceutical industry is innovation: to research and develop new medicines, including biological products and vaccines. Recent achievements, such as innovative, first-in-class medicines for cancer, heart disease, respiratory ailments, and HIV/AIDS as well as novel vaccines for conditions such as rotavirus, pneumococcal and human papilloma virus, illustrate the industry's unique role as innovator of life-saving and life-changing medicines.

Despite enormous progress made over the past decades, the need for continued innovation remains large. Emergence of new disease threats and the re-emergence of old ones, such as resistance development to existing treatments, underscore this ongoing need.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Thought leadership, tools and resources

The IFPMA leads a number of activities to provide insights into how the research-based pharmaceutical industry operates and contributes its expertise and resources to addressing global health issues.

Position Papers and Media

As the industry's representative in Geneva, the IFPMA serves as a partner and thought leader on issues related to medicines and global health. It publishes a wide range of position papers, articles, press releases and other information for policymakers and the media.

Events

The IFPMA regularly organizes events on key issues such as capacity-building, innovation, regulatory and quality, and sustainable access to medicines. It also participates actively in meetings organized by other stakeholders such as the World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO).

Online Resources

The IFPMA website (www.ifpma.org) is a comprehensive source of information about global health, innovation, quality, ethics, partnerships, and other topics.

The IFPMA's Ethics online resource provides information on the IFPMA Code of Practice as well as the codes of IFPMA member associations.

The IFPMA Developing World Health Partnerships Directory documents the research-based pharmaceutical industry's long-term partnership programs to improve health in developing countries. The database is searchable based on country, disease type, program type, and partner organization.

The IFPMA Vaccines online resource provides insights to vaccine innovation, the public health value of vaccines, and initiatives to broaden access to vaccines.

The IFPMA Influenza Vaccine online resource provides information on seasonal and pandemic influenza.

The IFPMA Clinical Trials Portal is an easy-to-use tool to help patients and healthcare professionals access information on ongoing clinical trials and summary results of completed trials.

Publications

The IFPMA provides several publications about key health-related topics. Available on the IFPMA website (www.ifpma.org), these publications include:

- A Shared Commitment to Fight Non-Communicable Diseases
- Data Exclusivity: Encouraging Development of New Medicines
- Delivering the Promise of the Decade of Vaccines
- Ending Neglected Tropical Diseases
- Evidence on Access to Essential Medicines for the Treatment of HIV/AIDS
- IFPMA Code of Practice
- Improving Access to Medicines for Non-Communicable Diseases in the Developing World
- Improving Global Health through Pharmaceutical Innovation
- Non-Communicable Diseases Health Improvement Card
- Seasonal Influenza Vaccination Series
- Technology Transfer: a Collaborative Approach to Improve Global Health
- The Pharmaceutical Industry and Global Health: Facts and Figures
- Woman & Child Health Partnerships for the Developing World

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