efpia

European Federation of Pharmaceutical Industries and Associations

EFPIA Japan

✱ We aim to provide Japanese patients with better access to innovative therapies; achieve appropriate reward for innovation; pursue a better balance between prevention and treatment; make Japan a more dynamic and attractive place to invest in for pharmaceutical companies; and further enhance the credibility of the pharmaceutical industry.

Message from the Chairman of the European Federation of Pharmaceutical Industries and Associations, Japan (EFPIA Japan)

EFPIA Japan was established in 2002, and represents 24 R&D-based European pharmaceutical companies operating in the Japanese market. We are the voice of the European innovative pharmaceutical industry in Japan. Our mission is to contribute to the welfare of the Japanese population through the provision of innovative pharmaceuticals and vaccines without delay.

Combined sales from EFPIA member companies account for around one-quarter of the pharmaceutical market in Japan, and our member companies are all very active in research and development, together generating nearly one-third of all the new drugs introduced in Japan in recent years. In terms of both sales and the development of new treatments, we are therefore an important part of the Japanese health care universe.

The demands on the global as well as the Japanese healthcare environments are undergoing rapid change, and healthcare systems have to evolve in response to the increasing demands. EFPIA Japan engages in constructive dialogue with the government and other stakeholders in order to address current issues and to find solutions that will support a healthcare system able to meet the challenges of e.g. an ageing population or new advanced medical technologies being made available. We actively share best practices from Europe within Japan and make contributions to the policy debate, based on the following four desired outcomes that we believe all stakeholders can support:

- **ensure the sustainability of universal healthcare coverage (UHC)**
- **ensure patient access to innovation**
- **restore the predictability and stability to the Japanese pharma market**
- **reward innovation and improve the quality of healthcare in Japan**

The R&D-based pharmaceutical industry has contributed greatly to the extension of life and the improvement of quality of life for patients around the world. EFPIA Japan is committed to furthering this contribution to the patients and the people of Japan.

Ole Mølskov Bech
EFPIA Japan Chairman

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Chairman:	Ole Mølskov Bech	(Novo Nordisk Pharma Ltd.)
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Board

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Masuhiro Kato
The University of Tokyo

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Access Committee
Committee Chair **Yasuko Aitoku** (Bayer Yakuhin, Ltd.)

Technical Committee
Committee Chair **Naohisa Yokota** (Sanofi K.K.)

Governance and Legal Committee
Committee Chair **Mariko Mimura** (GlaxoSmithKline K.K.)

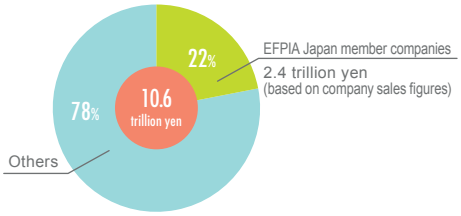
Biologics Committee
Committee Chair **Shinichi Ejima** (Novo Nordisk Pharma Ltd.)

Public Relations Committee
Committee Chair **Noriko Okazaki** (Novo Nordisk Pharma Ltd.)

EFPIA Japan Member Companies (Total 24 Companies)

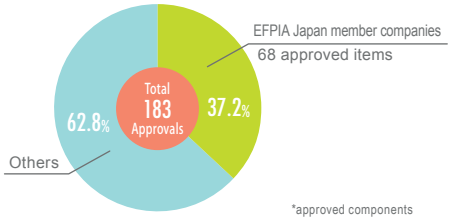
- Actelion Pharmaceuticals Japan Ltd.
- AstraZeneca K.K.
- Bayer Yakuhin, Ltd.
- Bracco-Eisai Co., Ltd.
- CHUGAI PHARMACEUTICAL CO., LTD.
- CSL Behring K.K.
- Ferring Pharmaceuticals Co., Ltd.
- GALDERMA K.K.
- GE Healthcare Japan Corporation
- GlaxoSmithKline K.K.
- Guerbet Japan KK
- Ipsen Pharma Japan Representative Office
- JANSSEN PHARMACEUTICAL K.K.
- LEO Pharma K.K.
- Lundbeck Japan K.K.
- Merck Serono Co., Ltd.
- Mylan EPD G.K.
- NIHON SERVIER COMPANY LIMITED
- Nippon Boehringer Ingelheim Co., Ltd.
- Novartis Pharma K.K.
- Novo Nordisk Pharma Ltd.
- Sanofi K.K.
- Shire Japan K.K.
- UCB Japan Co., Ltd.

EFPIA Member Companies in Japan Sales (2016)



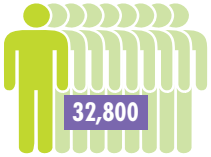
Source ■ IMS Japan Pharmaceutical Market
Data period: 2016 Dec. MAT ©2016 IMS Health
■ EFPIA-J sales: EFPIA Japan figures

The Number of approved New Drugs* (2014 – 2016)



Source: EFPIA Japan figures are based on data provided by the "The Central Social Insurance Medical Council."

Employment by EFPIA Japan member companies (2016)



Source: EFPIA Japan figures

Committees

The mission of **the Pricing & Economics Committee**, or PEC, is to participate in discussions on a wide range of economic issues relating to the pharmaceutical business especially in regards to establishing a better pricing and a better healthcare system. To achieve this goal, the PEC actively engages in talks on healthcare system reform with the Japanese government, other industrial associations, and related stakeholders on behalf of European pharmaceutical companies in Japan.

Mission

Contribute to reform of the NHI drug price system through evidence-based proposals

Help ensure that the drug pricing system appropriately rewards innovation and provides incentives for investment

The Mission of **the Access Committee** is to ensure that Health Technology Assessment (HTA) in Japan appropriately evaluates the value of innovation and contributes to improved access to medicine for patients. The Committee's primary goal is to ensure that HTA guidelines are formulated and implemented in a manner that includes a transparent HTA review process, a robust dialogue between industry and government, and a health care system that continues to encourage the rapid introduction of safe and effective medicines for patients. It also addresses other market access issues, including the 14 Day Rule.

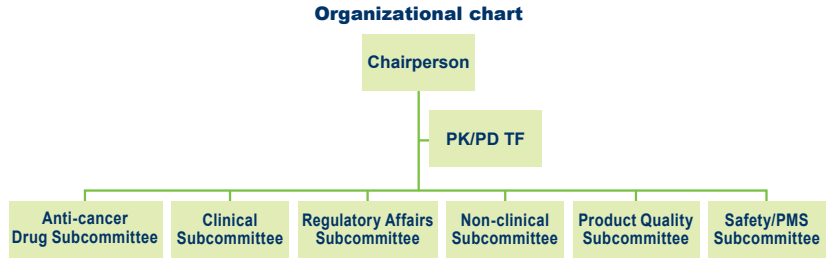
EFPIA Japan recently established **"PASE" (Patient Advocacy Support by EFPIA Japan)**. PASE is dedicated to providing a platform for patient opinions in the healthcare system in order to improve health outcomes. As part of the PASE initiative, EFPIA Japan is contributing grants totaling 1 million yen that are awarded to promising patient advocacy groups. EFPIA Japan hopes that PASE will play an important role in helping patient groups shape a more patient-centric healthcare environment in Japan.

The Technical Committee works to improve the regulations as well as development and evaluation techniques that affect the innovative pharmaceutical industry and the implementation of those regulations. The aim is to ensure the rapid access by Japanese patients to safe and effective treatments.

Contributions to the development (clinical trials) environment: The Clinical Subcommittee regularly conducts investigations of the clinical trials environment in order to confirm changes in the environment and make recommendations based upon those changes. The Anti-cancer Drug Subcommittee makes proposals focused on the environment for implementing clinical trials of anti-cancer drugs, while also working in coordination with governmental and academic parties to participate in and make contributions through the "forum for the development of medicines to combat malignant tumors" which discusses various issues in the development of anti-cancer drugs.

Contributions to the regulatory affairs environment: Each subcommittee and task force is involved in investigating problem points and conducting interviews to gather opinions and requests regarding related regulations, guidelines and Q&As, as well as newly issued proposals in connection to the above, so as to resolve or make recommendations regarding such matters. The Product Quality subcommittee facilitates the appropriate and efficient implementation of submission and review of new drugs developed outside Japan and LCM of approved drugs manufactured outside Japan.

Contributions to technology: The Safety/PMS Subcommittee contributes to improvements in systems for monitoring the safety of Japanese pharmaceuticals through projects involving the participation of regulatory authorities and other pharmaceutical industry groups. The Pharmacokinetics/Pharmacodynamics Task Force (PK/PD TF) contributes to advance global development through activities including cooperation in Ministry of Health, Labour and Welfare-led investigations into differences between different ethnic groups. The Non-clinical Sub-committee contributes to improved evaluations based on the sharing of information, the organization of study meetings, and cooperation in the Pharmaceutical Evaluation Forum.



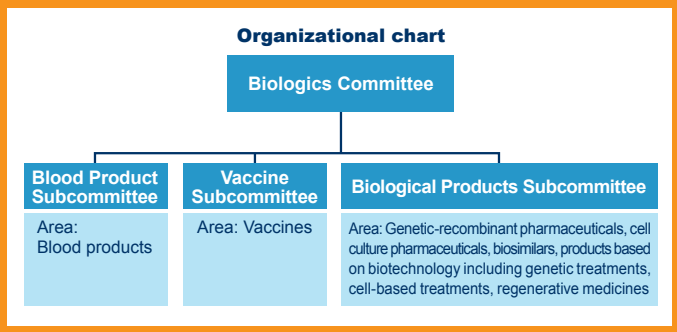
The Biologics Committee

engages in a wide range of activities, covering treatments that have already been commercialized such as protein-preparations and antibody-based medicines created using genetic recombinants and other techniques, treatments based on next-generation medical technology that can hopefully be commercialized in the future such as products for regenerative medicine as well as nucleic acid-based pharmaceuticals, blood products including blood-related genetically-modified products, and vaccines. Three subcommittees, divided according to product group, are engaged in the following activities in order to improve the technical and regulatory environment for development, manufacturing, supply and safety monitoring.

Blood Product Subcommittee (BPSC): BPSC aims to establish a stable supply process for "Plasma Derived Products" manufactured from human blood and for essential products in medical care, and for any plasma related recombinant products that are manufactured with the world's most advanced technology. With an eye to the future, the BPSC is also pursuing recommendations and dialogues with the Japanese Government to solve issues such as a lack of blood donors, and a production and supply process for plasma derived products during both normal times and emergencies.

Vaccine Subcommittee: In recent years, innovative overseas vaccines have been approved and come into use in Japan, and a considerable improvement has been achieved in the vaccine gap versus overseas countries. However, many areas still require work, including certain systemic issues such as the continued inability to use certain pediatric vaccines in Japan as well as low rates of vaccination. The subcommittee makes proposals to resolve these issues and works to provide good vaccines more promptly and more broadly in Japanese clinical settings.

Biological Products Subcommittee: Biological products are diverse but hold out great hope of new and innovative treatments. Among important issues are the future positioning of biosimilars as well as regenerative treatments including genetic treatment. The subcommittee harnesses the experience and track record of EFPIA in Europe in order to evaluate various different issues and produce recommendations.



The Governance and Legal Committee

covers legal, ethics and compliance area of business in which member firms are required to be adaptive to changes in business environment. Governance and Legal Committee keeps its predecessors as two working groups (WG).

Corporate Ethics WG: Makes proposals to enable member firms to conduct business in compliance with a proper level of ethics and compliance standard. Facilitates compliance workshops where member firms can exchange its opinions on ethics and compliance in the pharmaceutical industry. On behalf of EFPIA Japan, closely and proactively working with Japan Pharmaceutical Manufacturers Association and other healthcare industry associations, promotes a level of business compliance in the pharmaceutical industry in Japan.

Intellectual Property and Legal WG: Investigates and studies the latest legislations, regulations and IP strategies in the healthcare industry in Europe as well as Japan. Exchanges opinions with member firms and industry associations, and makes proposals relating to Intellectual Property and legal matters. Contributes to the advancement of healthcare industry legislations and regulations in Japan.

The Public Relations Committee

works to inform healthcare stakeholders, including patients, the general public, medical professionals and policy-makers, of the positions and activities of the European pharmaceutical industry as well as EFPIA Japan. The committee holds press conferences, issues press releases and organizes media seminars in order to ensure that the appropriate information is shared with the media, and ultimately with the relevant stakeholders.

Health Technology Assessment (HTA)

EFPIA Japan member companies have a wealth of experience on the use of HTA in EU countries and the various issues resulting from such use. Based on this experience, EFPIA Japan proposes the five rules below as guidelines for developing and debating HTA in Japan.

1. Involve all stakeholders in meaningful discussions at all stages of the process (patients, healthcare professionals, industry parties)
2. Set priorities for the initial, trial period of HTA
3. Focus not solely on cost considerations but also on achieving better outcomes
4. Ensure no negative impact on patient access or physicians' freedom to prescribe
5. Reward innovation and minimize the burden for both government and industry

HTA may delay and obstruct access to innovative treatments

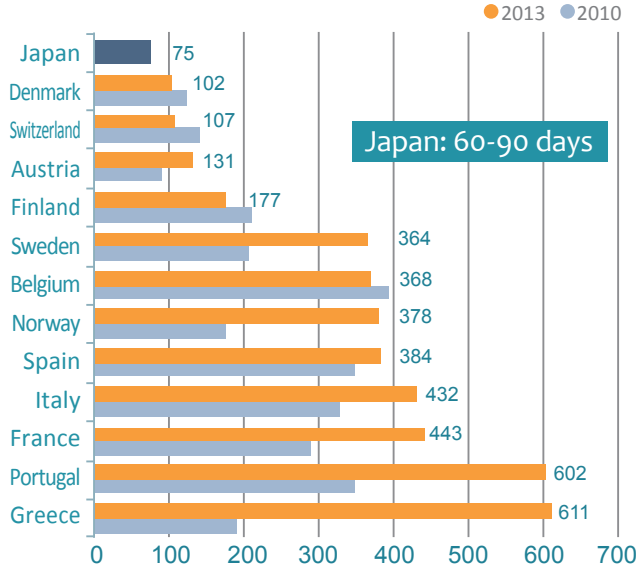
In Japan, there is a comparatively short time period between the regulatory approval of new treatments and the availability of national health insurance reimbursement, with reimbursement available within 60 to 90 days of approval. This provides citizens with access to a wide range of pharmaceuticals. Considering the introduction of cost-benefit evaluations should involve through discussions and investigations on consistency with existing pharmaceutical pricing rules, feasibility with regard to issues such as corporate structures and systems and any potential negative influence on patient access to innovative drugs.

(HTA Viewpoint document on EFPIA Japan website)

Europe: Patients "W.A.I.T." indicator

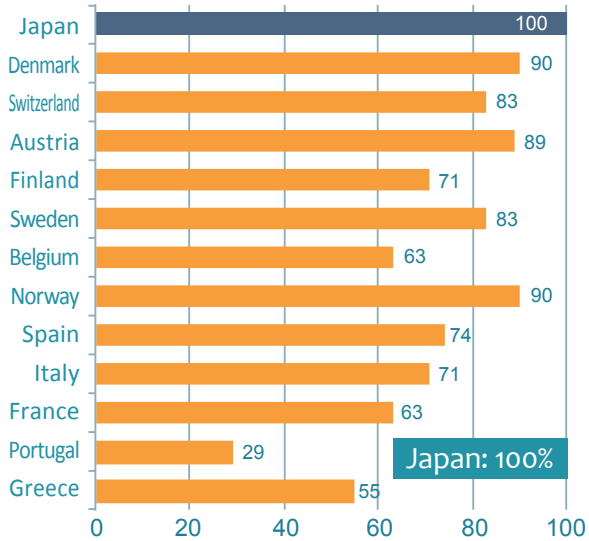
Patient"waiting times" for access to innovative drugs

EMA[1] waiting times following authrization (days)[2]



1)EMA: European Medicines Agency
2)Time period until drug access following pharmaceutical marketing authorization

Percentage of available pharmaceuticals (2013)[3]

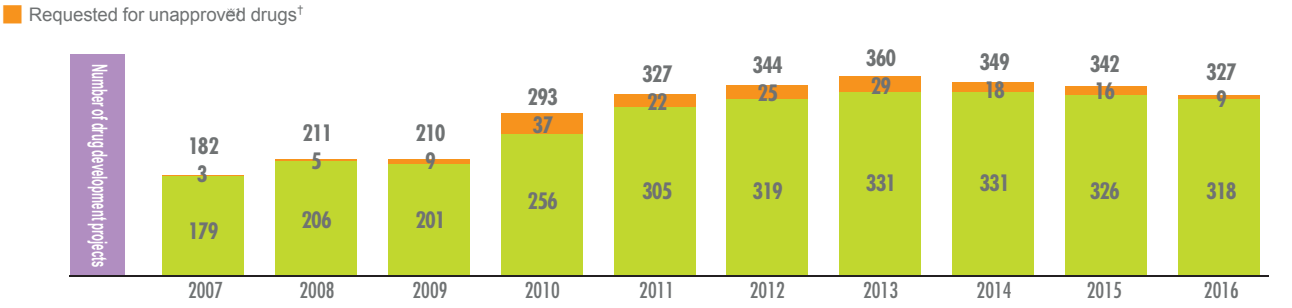


3) Domestic access. At the time of the survey, 70% of pharmaceuticals approved for marketing through the EU's centralized procedure during 2011-12 were available for patients.

Source: EFPIA annual survey 2010 & 2013.
Note: In the UK and Germany, insurance reimbursement is available from the day of marketing approval, but de facto delays are apparent as a result of HTA (such delays are not covered by this W.A.I.T. analysis).

Pharmaceutical Industry – Global Figures

The pace of drug development by EFPIA member companies in Japan has accelerated

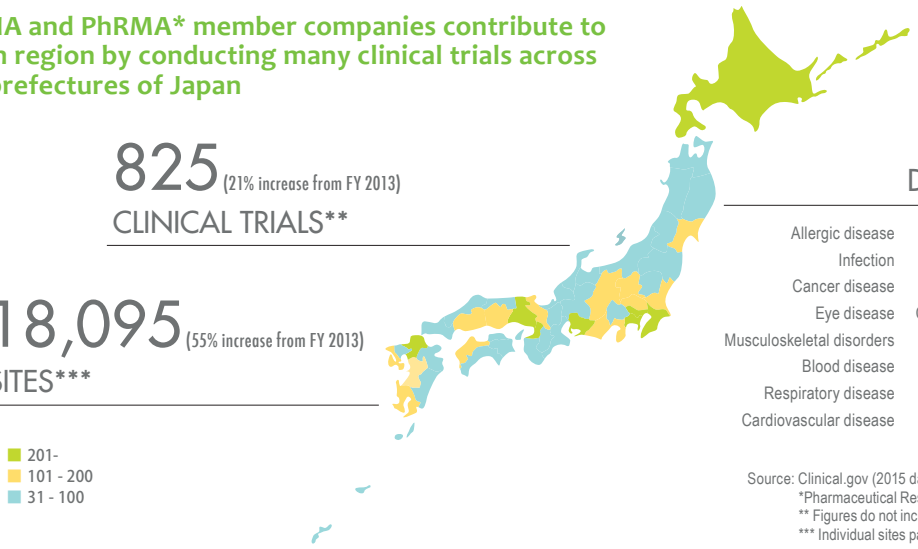


†: Some projects were initiated prior to request for unapproved drugs Source: EFPIA Japan figures

EFPIA and PhRMA* member companies contribute to each region by conducting many clinical trials across all prefectures of Japan

825 (21% increase from FY 2013)
CLINICAL TRIALS**

18,095 (55% increase from FY 2013)
SITES***



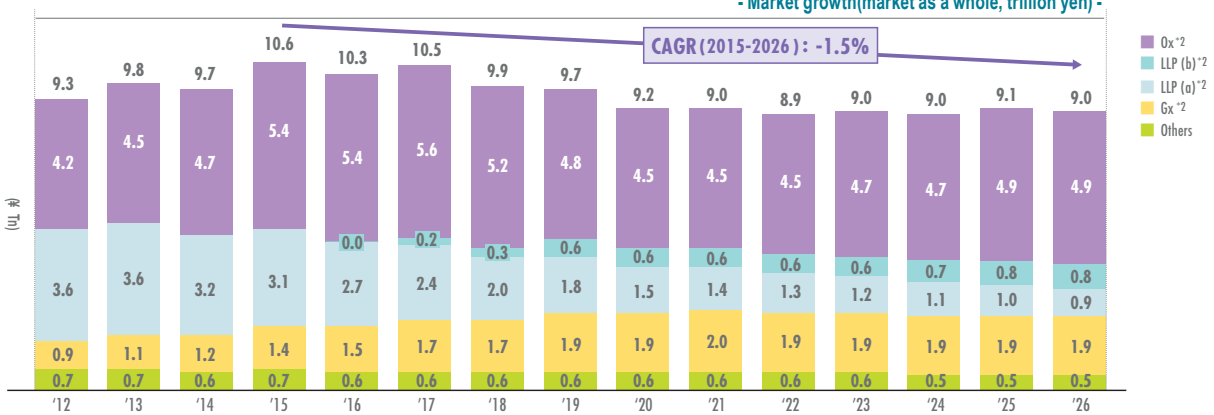
16+
DISEASE AREAS*

Allergic disease	Gastrointestinal disease
Infection	Metabolic disease
Cancer disease	Immune disease
Eye disease	Central nervous system disease
Musculoskeletal disorders	Urological disease
Blood disease	Skin disease
Respiratory disease	Rare disease
Cardiovascular disease	Others

Source: Clinical.gov (2015 data)
*Pharmaceutical Research and Manufacturers of America
** Figures do not include post marketing surveillance
*** Individual sites participating in multiple trials are counted multiple times

Forecast of Japanese Market

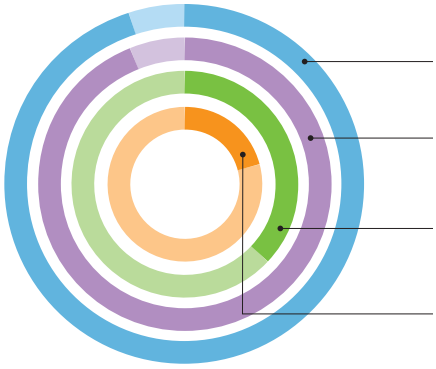
Drug cost is well controlled. If further cost controlling measures have been implemented, market will decrease by CAGR -1.5% *1



*1: Assumption: Continuation of price maintenance premium, achievement of 80% Gx rate, annual price revision for LLP and Gx with large deviation etc. Consumption tax rate was fixed at 8% through the forecast period.
*2: Ox: Original products, LLP (a): generic drugs launched before March 2016, LLP (b): generic drugs launched after April 2016, or planned to be launched, Gx: Generic products
Source : The result from EFPIA-J and QuintilesIMS joint simulation project

The impact of medicines

Medicines are some of the most powerful tools in treating and curing diseases



95% of the 15 million patients in Europe living with HEPATITIS C can be cured through an 8-12 week course of treatment.

94% Since 1991 there has been a 94% reduction in age-standardised death rates for patients living with HIV in France.

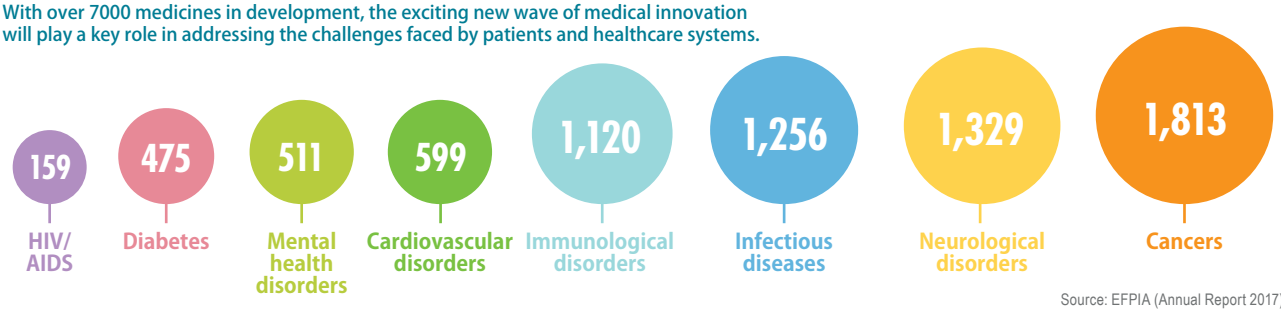
37% Between 2000 and 2012, the death rate from CARDIOVASCULAR DISEASE fell 37% in the EU5.

21% Since 1991, in Europe there has been a 21% reduction in mortality rates from all CANCERS.

Source: EFPIA (Annual Report 2017)

Innovation in Numbers

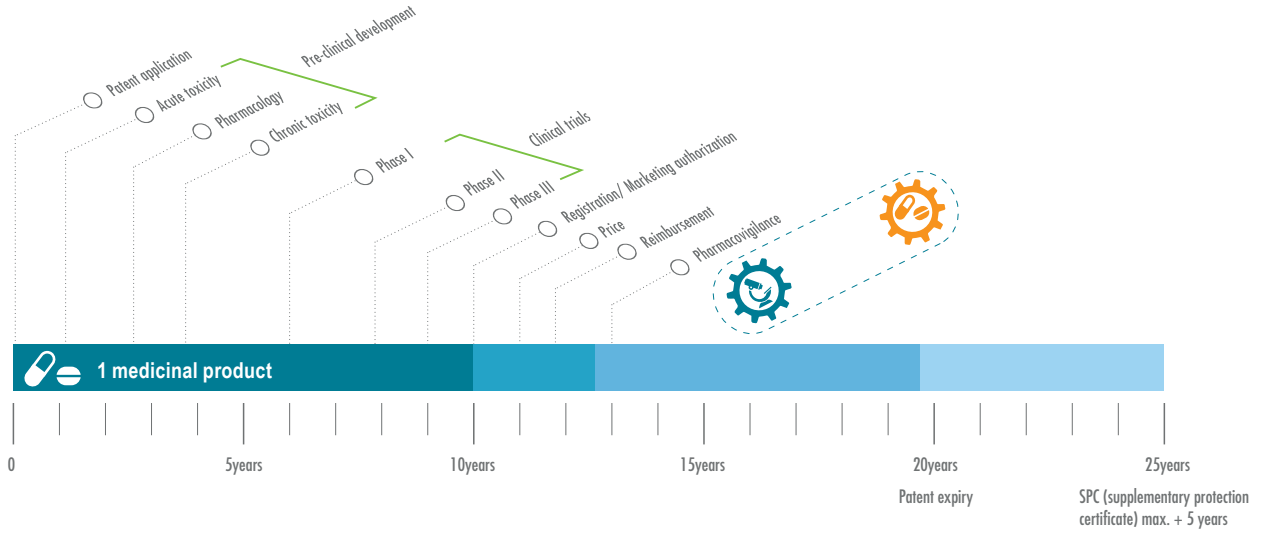
With over 7000 medicines in development, the exciting new wave of medical innovation will play a key role in addressing the challenges faced by patients and healthcare systems.



Source: EFPIA (Annual Report 2017)

Phases of the research and development process

All new medicines introduced into the market are the result of the series of research and development (R&D) conducted by pharmaceutical companies. By the time a medicinal product reaches the market, an average of 12-13 years will have elapsed since the first synthesis of the new active substance.



Source: EFPIA (The Pharmaceutical Industry in Figures – Key Data 2017)

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