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:

- **Sustainability of Universal Healthcare Coverage (UHC).**
- **Patient access to innovation.**
- **Predictability and stability.**
- **Reward for innovation.**

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

Board Members

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Board of Director:	Heike Prinz	(Bayer Yakuhin, Ltd.)
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Organization

Board

Senior Advisor
Masuhiro Kato
The University of Tokyo

EFPIA Japan Office
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Pricing & Economics Committee
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Sanofi K.K.

Access Committee
Committee Chair **Stuart Feldman**
AstraZeneca K.K.

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 **Naoko Miyoshi**
Bayer Yakuhin, 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.

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

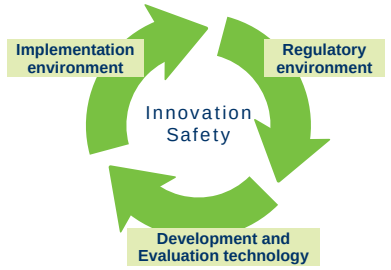
The Access Committee examines broad trends related to Market Access and the Health Technology Assessments (HTA) in Japan. Its primary goal is to ensure that HTA guidelines are formulated and implemented in a manner that values innovation and promotes greater patient access. The Access Committee wishes to ensure that global best practices related to HTA are understood by policymakers and adopted in Japan. These best practices include 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. The Committee develops materials for external stakeholders and meets with policymakers to explain the EFPIA positions on HTA and other market access issues, including the 14 Day Rule.

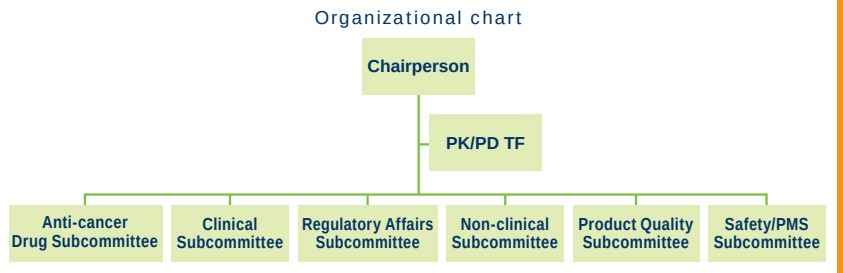
The Technical Committee works to improve the regulations as well as development and evaluation techniques that affect the innovative pharmaceutical industry and the implementation of those regulations. The aim is to ensure the rapid access by Japanese patients to safe and effective treatments.

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.





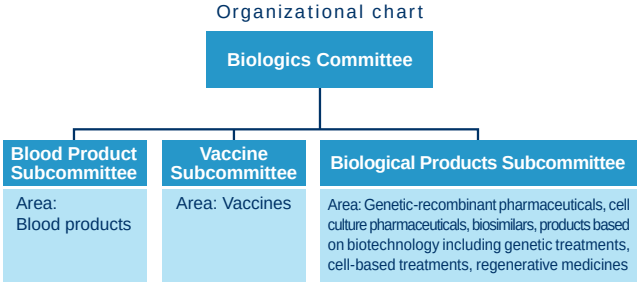
The Biologics Committee engages in a wide range of activities, covering treatments that have already been commercialized such as protein-preparations and antibody-based medicines created using genetic recombinants and other techniques, treatments based on next-generation medical technology that can hopefully 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.

Organizational chart



Governance and Legal Committee, newly established by the merger of Corporate Ethics Committee and Intellectual Property 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.

Innovative Medicines Initiative (IMI)

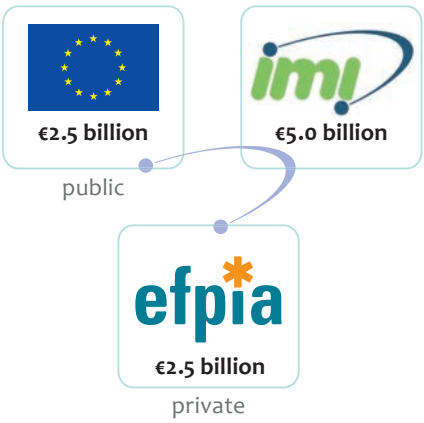
The Innovative Medicines Initiative (IMI), established in 2008 by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the European Commission, is one of the world's largest public-private partnerships. IMI has established its position as the pioneer for open collaboration which dramatically changes the way pharmaceutical research and development is carried out.

By the end of 2014, IMI had implemented more than 60 projects and consortiums with the aim of increasing the efficiency of pharmaceutical research and development and improving processes in order to deliver safer, more effective pharmaceuticals to patients. Themes addressed cover a wide range of issues that form bottlenecks in drug discovery including searching for biomarkers related to pharmaceutical safety and efficacy, pre-clinical development, research into pharmacokinetics and pharmacodynamics, pharmaceutical formulation development, database construction, and the development of educational programs.

The success of IMI is determined by collaborations. More than 7,000 researchers affiliated with academic institutions, pharmaceutical companies, small and medium-sized enterprises, patient organizations and regulatory authorities from Europe and around the world participate in the IMI projects. IMI's total budget is €5 billion, with half the budget coming from the EU's research program and the other half of the budget coming from EFPIA's member companies.

In recent years, progress is being made in public-private sector collaboration in the creation of systems for research and development in Japan. EFPIA Japan works to share the European experience of partnership.

Partnership



IMI project examples

NEWMEDS: Novel methods leading to new medications in depression and schizophrenia

IMIDIA: Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes

PharmaTrain: Pharmaceutical and medicine training program

EUPATI: European patients' academy on therapeutic innovation

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

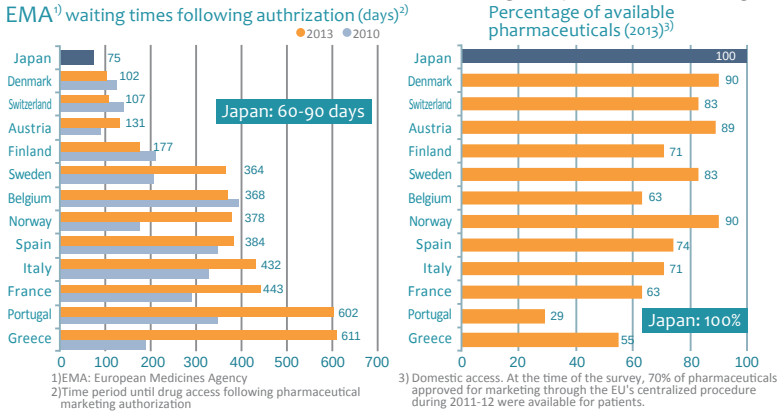
HTA may delay and obstruct access to innovative treatments

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



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

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.

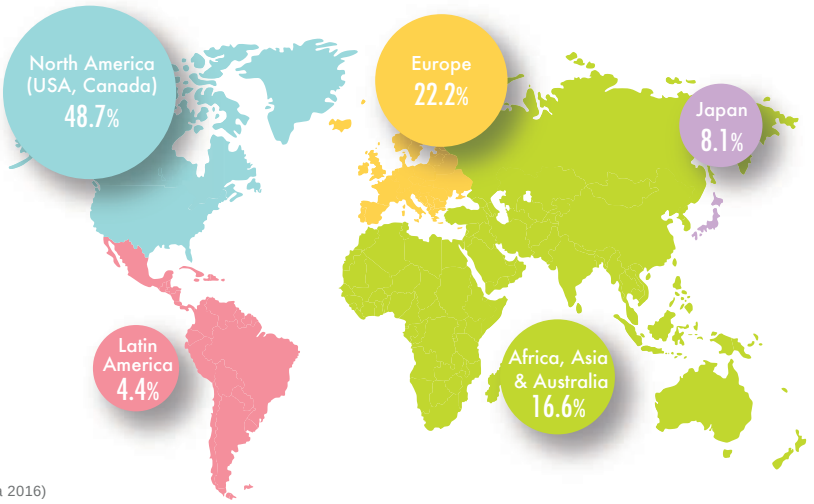
Source: EFPIA annual survey 2010 & 2013.
Note: In the UK and Germany, insurance reimbursement is available from the day of marketing approval, but de facto delays are apparent as a result of HTA (such delays are not covered by this W.A.I.T. analysis).

Pharmaceutical Industry – Global Figures

PHARMACEUTICAL SALES

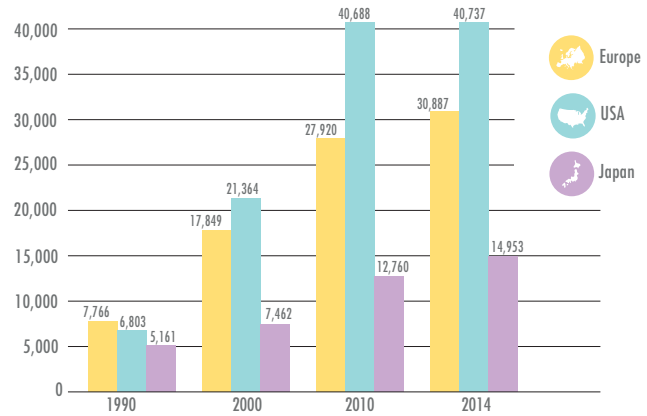
The world pharmaceutical market was worth an estimated € 715,992 million($ 794,393 million) at ex-factory prices in 2015. The North American market (USA & Canada) remained the world's largest market with a 48.7% share. By country, US is the largest followed by China. Japan is the third biggest market in the world.

- North America (USA, Canada)
- Europe
- Japan
- Africa, Asia (excluding Japan) & Australia
- South America



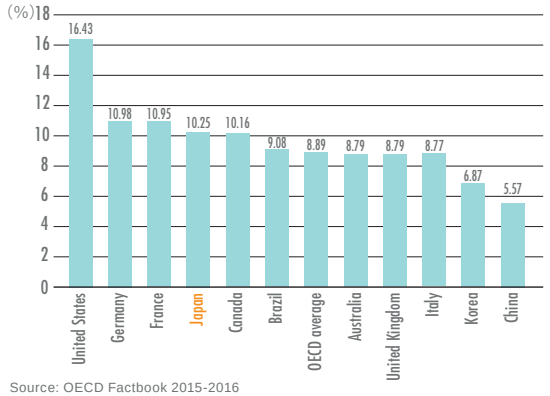
Source: EFPIA (The Pharmaceutical Industry in Figures – Key Data 2016)

PHARMACEUTICAL R&D EXPENDITURE IN EUROPE, USA AND JAPAN (MILLION OF NATIONAL CURRENCY UNITS*), 1990-2014



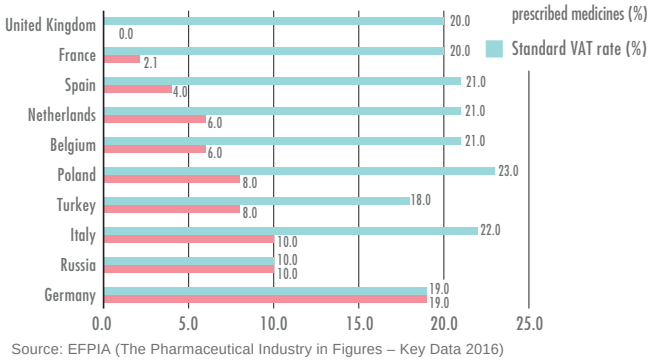
*Note: Europe: € million; USA $ million; Japan ¥ million × 100
Source: EFPIA (The Pharmaceutical Industry in Figures – Key Data 2016)

HEALTHCARE SPENDING AS A PERCENTAGE OF GDP IN OECD MEMBER NATIONS (2013)



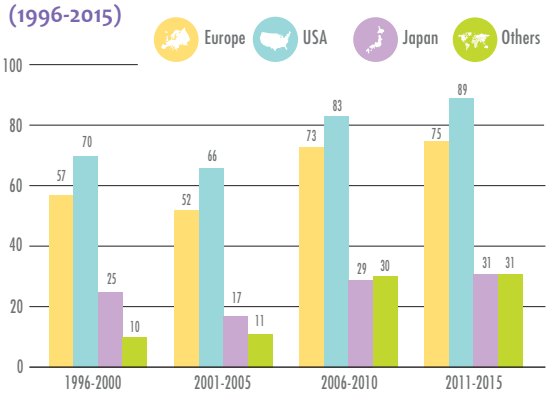
Source: OECD Factbook 2015-2016

VAT RATES APPLICABLE TO MEDICINES



Source: EFPIA (The Pharmaceutical Industry in Figures – Key Data 2016)

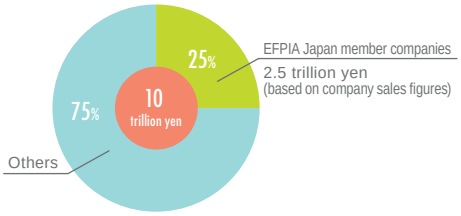
NUMBER OF NEW CHEMICAL OR BIOLOGICAL ENTITIES (1996-2015)



Source: EFPIA (The Pharmaceutical Industry in Figures – Key Data 2016)

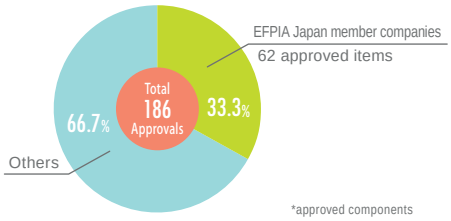
Pharmaceutical Industry – Japan Figures

EFPIA Member Companies in Japan Sales (2015)



Source ■ IMS Japan Pharmaceutical Market
Data period: 2014 Dec. MAT ©2014 IMS Health
■ EFPIA-J sales: EFPIA Japan figures

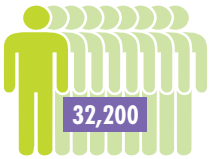
The Number of approved New Drugs* (2013 – 2015)



*approved components

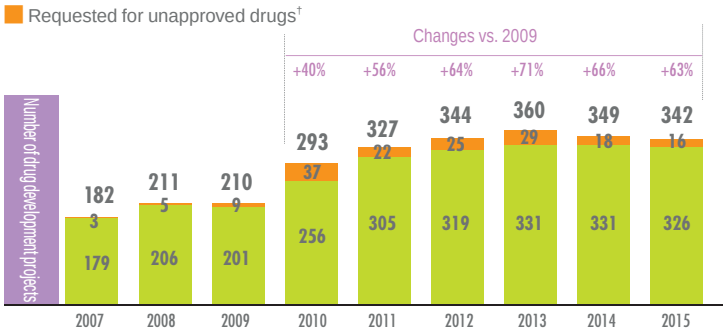
Source: EFPIA Japan figures are based on data provided by the "The Central Social Insurance Medical Council."

Employment by EFPIA Japan member companies (2015)



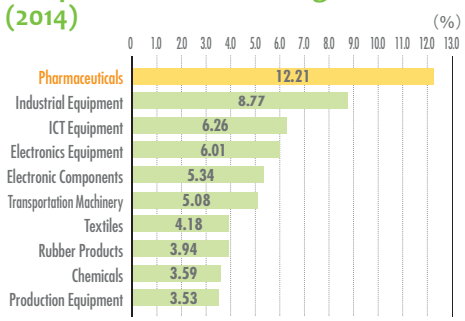
Source: EFPIA Japan figures

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

Ratio of R&D expense to sales revenue in Japanese manufacturing market (2014)

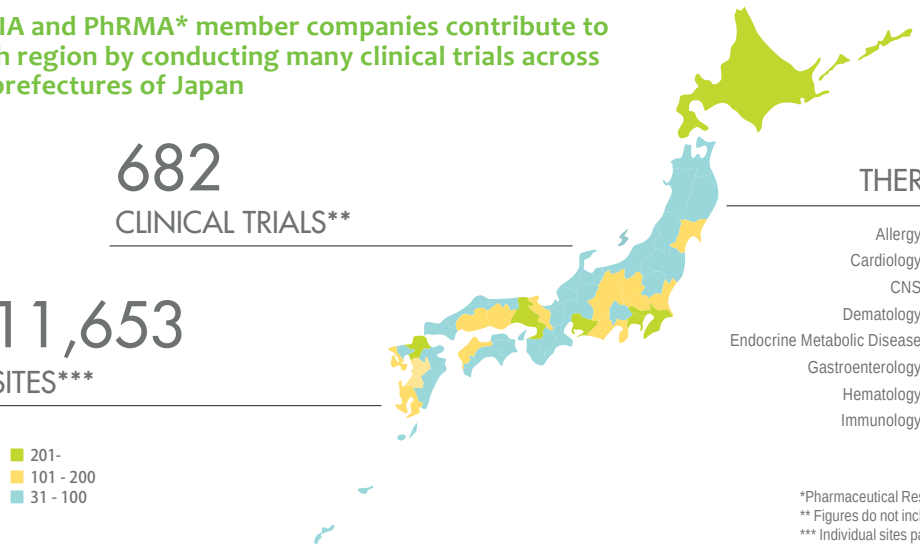


Source: Ministry of Internal Affairs and Communications
(Survey of Research and Development)

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

682
CLINICAL TRIALS**

11,653
SITES***



16+
THERAEUTIC AREAS*

Allergy	Infectious Disease
Cardiology	Musculoskeletal Disease
CNS	Oncology
Dematology	Ophthalmology
Endocrine Metabolic Disease	Respiratory Disease
Gastroenterology	Urology
Hematology	Rare Disease
Immunology	Others

*Pharmaceutical Research and Manufacturers of America
** Figures do not include post marketing surveillance
*** Individual sites participating in multiple trials are counted multiple times

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