

# Japan Pharmaceutical Manufacturers Association Guide

2021

Bringing New Drugs to Everyone Who Wishes Good Health



# Building a Healthcare Ecosystem for creating innovation one after another

**We contribute to improving the healthcare level around the world through creating innovative pharmaceutical products.**

The Japan Pharmaceutical Manufacturers Association (JPMA) is an organization that, as of May 2021, consists of the 74 research and development-oriented pharmaceutical companies. We aim to contribute to improving the health and medical care of people in Japan and around the world through creating innovative pharmaceutical products.

The world is now facing the threat of COVID-19. Under the pandemic of COVID-19, JPMA and its member companies are reaffirming our mission, as R&D oriented pharmaceutical companies, to develop drugs and vaccines and provide the stable supply of high quality medicines. On the other hand, it's essential for Japanese pharmaceutical companies to further strengthen our capability of developing innovative new drugs for unknown infectious diseases in order to fulfil unmet medical needs, which lead to protect the lives and health of patients. In order to strengthen drug discovery capabilities, it is necessary to build a healthcare ecosystem in Japan by establishing life science clusters in Japan consisting of human resources who conduct cutting-edge research to discover innovative seeds, and building a big data infrastructure for accelerating digital transformation (DX) and a drug price system that appropriately evaluates innovation of pharmaceutical companies.

It is also necessary to prepare the environment that innovations created not only by pharmaceutical companies but also by entrepreneurial academia or ventures are properly evaluated at risks and more importantly intellectual properties are protected by the patent system, where younger generation can start their own business one after another following success stories. In the processes, the pharmaceutical industry will play a central role in delivering innovative new drugs to patients by leveraging cutting-edge drug discovery technology, large-scale clinical trials capability and manufacturing know-how.

Currently, digital technologies such as AI, IoT and 5G are rapidly developing. DX brought about by data and digital technology is not only useful for the pharmaceutical industry such as seed discovery and development of new drugs, clinical trials and post-marketing surveillance, and stable supply of drugs, but also for disease prediction / prevention, personalized medicine, and extending healthy life expectancy of people. It has the power to bring great benefits to society as a whole. We aim to be a DX hub in the healthcare field, by combining digital technologies and big data infrastructures of different industries to create unprecedented new value, and contribute to fulfilling the unmet medical needs and improving the health of people around the world.

Furthermore, in order to build an attractive healthcare ecosystem in Japan, it is essential that the results of innovation are properly evaluated. It is now under discussion of reviewing drug prices and other systems in order to achieve both "promotion of innovation" and "sustainability of universal health insurance". JPMA will promote dialogue with all stakeholders toward the realization of a system in which the value of new drugs as a result of innovation is properly evaluated.

In the "JPMA Industry Vision 2025," we advocated "Bringing Innovation in Drug Discovery to the world," and listed "Becoming a trustworthy industry with noble aspiration" as one of our visions. JPMA will continue to pursue a healthier society by promoting our reforms so that we can be strongly trusted in the changing social situation.

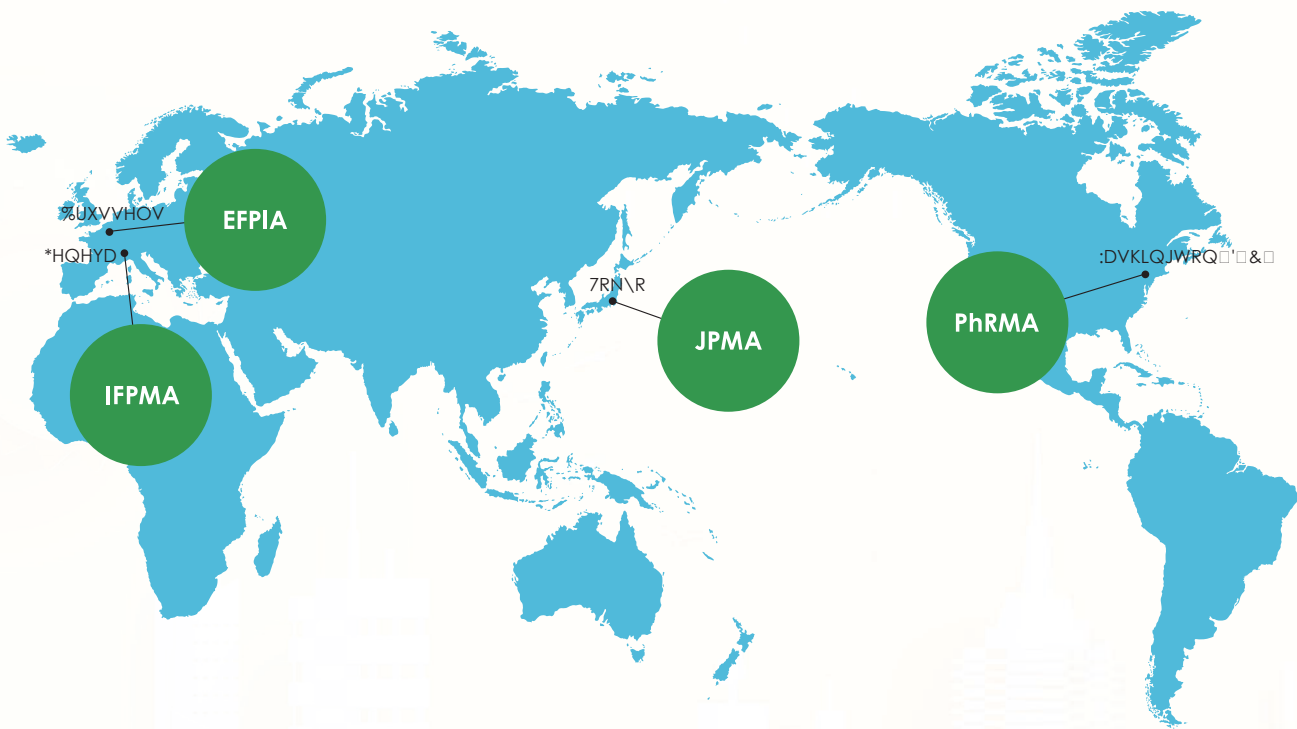


President of Japan Pharmaceutical Manufacturers Association

## Yasushi Okada

Representative Corporate Officer, COO, Eisai Co., Ltd.  
Biography

Mar. 1981	B.A. in Economics, Kwansai Gakuin University
Apr. 1981	Joined Eisai
Jun. 2002	Senior Director, Corporate Management Planning Department
Jun. 2005	Vice President, Senior Director, Administration & Planning, Prescription Drug Division
Jan. 2008	General Manager, Asia, Oceania, and the Middle East Business Headquarters (Singapore)
Jun. 2017	Representative Corporate Officer, Chief Talent Officer Industry Affairs, China Business, General Affairs, Environmental and Safety Affairs
Jun. 2019	Representative Corporate Officer, COO Industry Affairs, China Business, Data Integrity



JPMA is a voluntary association comprising 74 research-oriented pharmaceutical companies (as of April 1, 2021).

JPMA, established in 1968 with the mission of “realizing patient-oriented healthcare,” has been contributing to global healthcare advocacy through the development of innovative ethical drugs.

We are engaged with various initiatives, such as solution of common issues in the pharmaceutical industry, activities to deepen understanding of pharmaceuticals and international collaboration with concerned parties. Especially, we are promoting sound development of the pharmaceutical industry by developing policy, strengthening recommendations, facilitating to internationalization of the industry, and boosting public relations.

In addition, JPMA takes active roles as one of the Founding Industry Members of ICH by working collaboratively with PhRMA and EFPIA, and also leads APAC “to expedite the launch of innovative medicines for the peoples in Asia” as mission.

Furthermore, as a member of IFPMA, JPMA is engaged with various global health issues such as the preparedness and management of the pandemic of infectious diseases including COVID-19, access to medicines and protection of intellectual property, as well as the measures against health-related Sustainable Development Goals (SDGs).

Through close information sharing and collaboration with each sister associations, JPMA continues to act globally for the advancement of medical treatments for patients around the world.

- JPMA : Japan Pharmaceutical Manufacturers Association
- PhRMA : Pharmaceutical Research and Manufacturers of America
- EFPIA : European Federation of Pharmaceutical Industries and Associations
- ICH : International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
- APAC : Asia Partnership Conference of Pharmaceutical Association
- IFPMA : International Federation of Pharmaceutical Manufacturers & Associations



# Bringing innovation in drug discovery to the world

The recent changes in the environment surrounding the pharmaceutical industry are very drastic and severe. The business risks are increasing due to not only factors such as the increasing difficulty of new drug development, spiraling R&D cost, and the intensification of international competition but also the strict control of social security expenditure. In addition, we must continue to create innovative drugs to fulfill our mission of contributing to the improvement in the health and welfare of people around the world as well as to respond to expectation for economic growth.

Given this backdrop and forecasts, we as research-oriented pharmaceutical companies envisaged guiding principles and strategic imperatives to achieve our mission towards 2025, and released "JPMA Industry Vision 2025" in January 2016 with the value of the discovery of innovative medicines as its core messaging to strengthen trust from society.



## Vision 2025 expanded edition (May 2021)

— Accelerating the achievement of Vision 2025 by maximizing utilization of digital technologies —

### 1. Creating new drugs by utilizing digital technologies

- Exploring new active ingredient using Artificial Intelligence (AI)
- Online clinical trials

### 4. Providing clear, concise and easy-to-understand drug information

- JPMA website as a platform
- New drug information, tips for a healthy life

### 2. Realizing better life by utilizing big data

- Examining the susceptibility to illness
- New diagnostic therapeutic methods

### 5. Ensuring stable drug supply by utilizing digital technologies

- Providing high quality drugs
- New technologies for storage and transportation

### 3. Enabling the realization of a healthy life by utilizing mobile devices

- Utilizing apps as new treatment methods
- Telemedicine at home

### 6. Contributing to healthcare all over the world

- New drugs for refractory diseases around the world
- Optimal healthcare even in remote areas

## Vision 1

### Driving next-generation medicine with advanced drug discovery

#### — Contributing to P4+1 medicine —

- Contributing to the realization of next-generation medicine (P4+1 medicine) refers to combining the active utilization and application of advanced technologies with the improvement of existing technologies to evolve drug discovery and offer optimal drugs to each patient with their understanding at the proper time, which includes preemptive medicine.

## Vision 2

### Providing innovative drugs to 8 billion people worldwide

- As the vision states, the aim is to provide the innovative drugs we create to people worldwide to meet the expectations of patients throughout the world who long for therapeutic medications.

## Vision 3

### Leading the Japanese economy forward as a high value-added industry

- We will contribute to improving the health of many people in the world by producing innovative drugs especially by optimizing R&D and streamlining management.
- As a result, we will contribute to Japan's economic growth and become a high value-added industry that plays a role in the next generation in Japan.

## Vision 4

### Supporting to create an advanced healthcare country

#### — Creating a society where people can live long, healthy lives with peace of mind —

- We will contribute to the advancement of patient-oriented medical care so that people can live an even higher quality of life and to help boost the sustainability of the social security system.

## Vision 5

### Becoming a trustworthy industry with noble inspiration

- With high aspirations, we will fulfill our mission and become an industry that is highly appraised and trusted by all stakeholders, and whose initiatives and code of practice are respected by both domestically and internationally.
- We will deepen people's understanding of the importance of drug discovery innovation and aim to increase the number of people placing their hopes on, aspiring to a career in, or otherwise wishing to participate in drug discovery.

#### Addendum

#### Our mission and contribution to global health

- R&D:** Partnerships that energize new drug development
- Access to drugs:** Creating a framework to deliver drugs to the world
- Human resources cultivation:** Transferring skills/knowhow

#### Approach to corporate size/reorganization

- Threats to the pharmaceutical industry:** Changes in product characteristics and rising development costs
- Issues in R&D pharmaceutical companies:** Taking the initiative to pursue and determine optimal solutions for business size and form

# Contributions and challenges in the pharmaceutical industry

Our aim is to contribute to improving the health and welfare of people around the world through continuous R&D and a steady supply of exceptional drugs. To accomplish this, in addition to tackling the resolution of a wide range of issues, we are carrying out the mission of the life science industry through endeavors such as earnestly and tirelessly pursuing life sciences, which achieve remarkable developments, and corporate actions based on a high level of ethics. Moreover, not only is the pharmaceutical industry expected to strive for the realization of a society of health and longevity by creating innovative drugs based on patient needs, but it is also expected to contribute to economic growth in terms of stable tax-paying capacity and expansion of investment through assured earnings for the purpose of continuing and energizing R&D activities for new drugs. The pharmaceutical industry is also expected to contribute to the development and spread of scientific technologies through actions including taking up challenges in cutting-edge fields and promoting industry-academia-government collaboration in the process of vigorous R&D activities.

These contributions by the pharmaceutical industry are greatly anticipated to lead the growth and development of Japan as well as the world through contributions to global health that include disseminating first-rate new drugs to the entire world and exhibiting leadership as one of the few countries developing new drugs.

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- &KDOOHQJHV □ LQ □ FXWWLQJ □ HGJH □ JHOGV
- &XOWLYDWLRQ □ XWLQJ □ DWLRQ □ RI □ DGYDQFHG □ GLYHUVH □ KXPDQ □ UHVRXUFHV

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- &RQWULEXWLRQ □ RI □ QHZ □ GUXJV
- ,QLWLDWLYHV □ IRU □ XQPHW □ PHGFDQ □ QHHG
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- (OLPLQDWLQJ □ GUXJ □ ODJ

## 7KH □ PLVVLRQ □ RI □ WKH □ OLIH □ VFLHQFH □ LQG X VWU \

&RQWULEXWLRQ □ WR □ LPSURYLQJ □ WKH □ KHDOWK □ DQG □ ZHOIDUH □ RI □ SHRSOH □ DURXQG □ WKH □ JOREH

## &RQWULEXWLRQ □ WR □ JOREDO □ KHDOWK

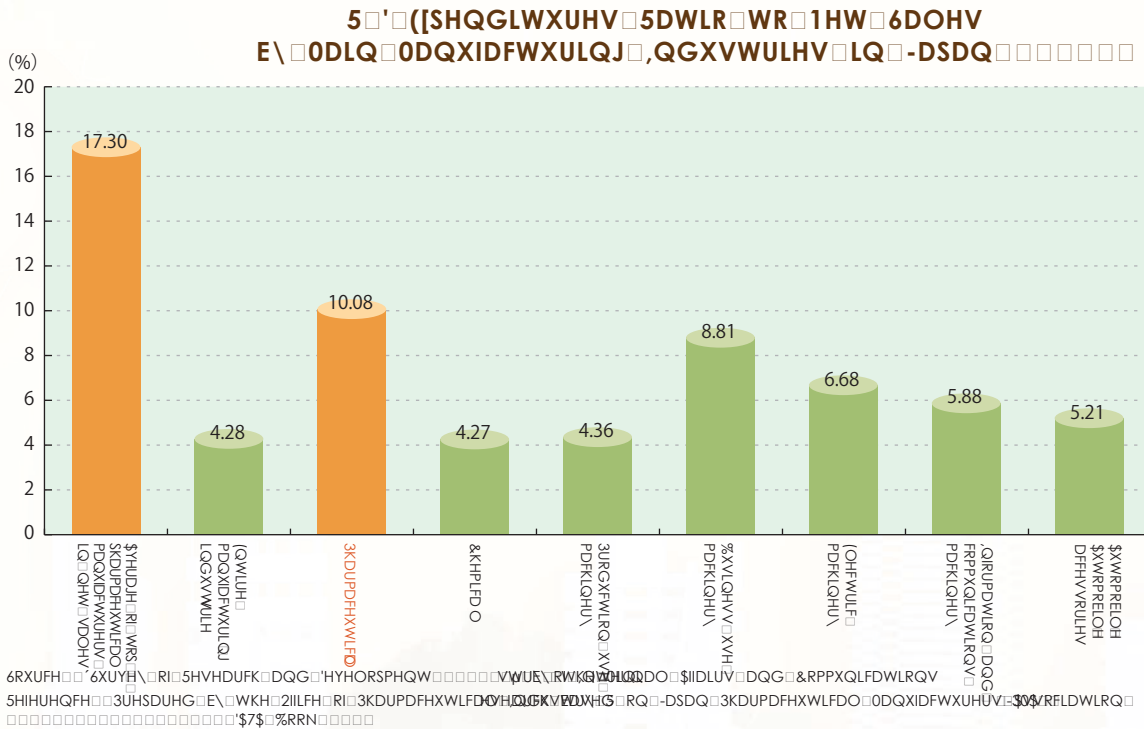
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- -DSDQ □ V □ UROH □ LQ □ GHYHORSLQHZ □ GUXJV
- 7KH □ PDMRU □ LQ □ HFWLRXV □ GLVHDVHV □ DQG □ 17'

## &RQWULEXWLRQ □ WR □ HFRQRPLF □ JURZWK

- 6WDEOH □ KLJK □ OHYHO □ WD □ SD \ LQJ □ FDSDFLW \
- 7KH □ SKDUPDFHXWLFDO □ LQG X VWU \ □ DV □ D □ KLJK □ YDOXH □ DGGHG □
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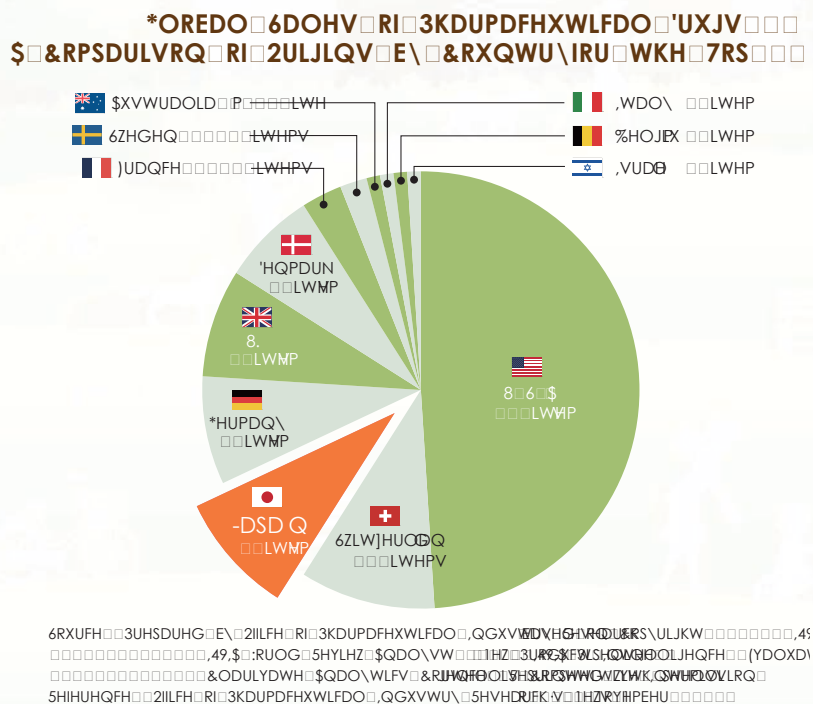
## The R&D industry

Bringing a new drug to patients involves numerous steps that start with the discovery of a new substance that becomes the basis for the drug and include basic research, non-clinical researches, clinical trials and regulatory review. On average, the process is said to take more than 10 years. In addition, significant R&D expenditures are required to support that kind of years-long research and development. The consideration that goes into developing new drugs in Japan is indicated by the ratio of those R&D expenditures. While the ratio of R&D expenditures to sales in the manufacturing industry in Japan is 4.28%, it is 10.08% for the pharmaceutical industry with an average of 17.30% for 10 major pharmaceutical manufacturers.



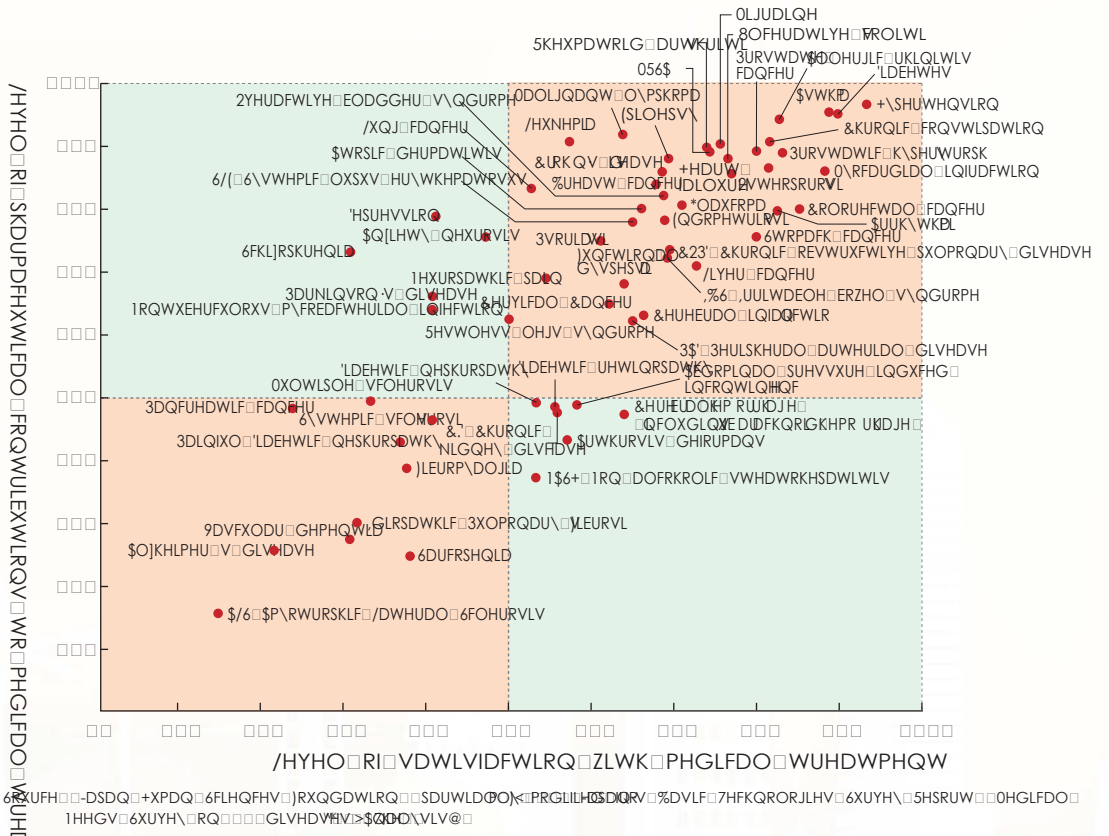
## Outstanding drug development capabilities in Japan

Only a few countries in the world develop new drugs since the technology to do so is extremely advanced and sophisticated. Among these countries, Japan is honored to be ranked third in the world for the number of new drugs developed. Currently, there is fierce global competition in new drug development. Continuous and aggressive R&D is required to maintain Japan's world-class drug development capabilities. JPMA member companies will continue to aggressively challenge on R&D to carry out the mission of the life science industry.

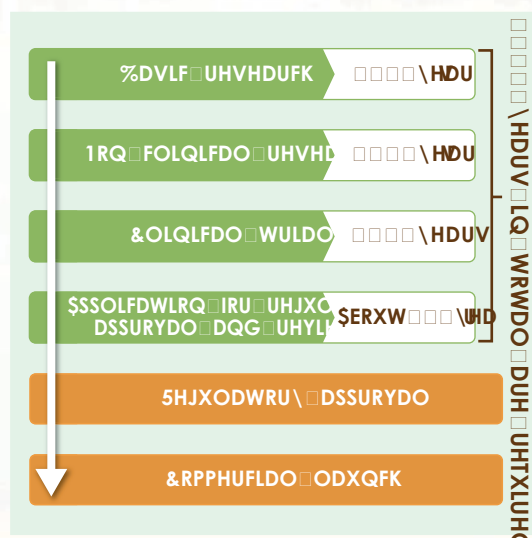


# Taking up the Challenge of Unmet Medical Needs

“Unmet medical needs” refers to the strong demand for pharmaceutical products and medical care targeting diseases for which effective therapeutics approach has yet to be established. The contribution of new drugs has been improving the level of satisfaction with medical treatments for diseases shown in the upper right of the figure. On the other hand, there are few breakthrough therapies for the diseases in the lower left of the figure, and new drugs are expected to contribute. In response to strong societal demand, JPMA member companies are actively tackling R&D for development of medications to satisfy unmet medical needs, such as Alzheimer’s and psychiatric/neurological diseases.



# The New Drug Development Process (the path to new drug creation)

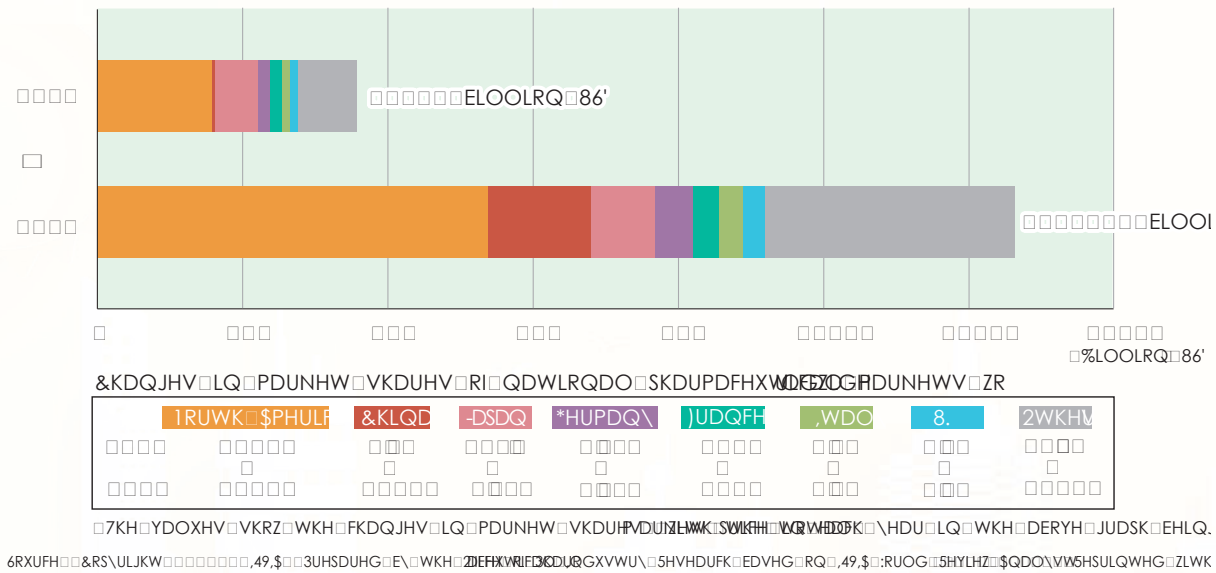


In the basic research stage, researchers produce numerous compounds and explore the kind of actions these compounds possess and whether they have an effect on target diseases. Later, non-clinical researches on animals and cells, and clinical trials on humans are implemented to verify safety and efficacy. After undergoing regulatory review and approval, a new drug can finally be launched for sale. This process requires 9 to 16 years. Furthermore, only about 1 in 22,000 of all such chemical compounds finally became a new drug (according to research by JPMA). Most compounds are never realized as drugs. Pharmaceutical companies exert great efforts over a long period of time to create pharmaceutical products that protect human life.



## The scale of Japan's drug market from a global perspective

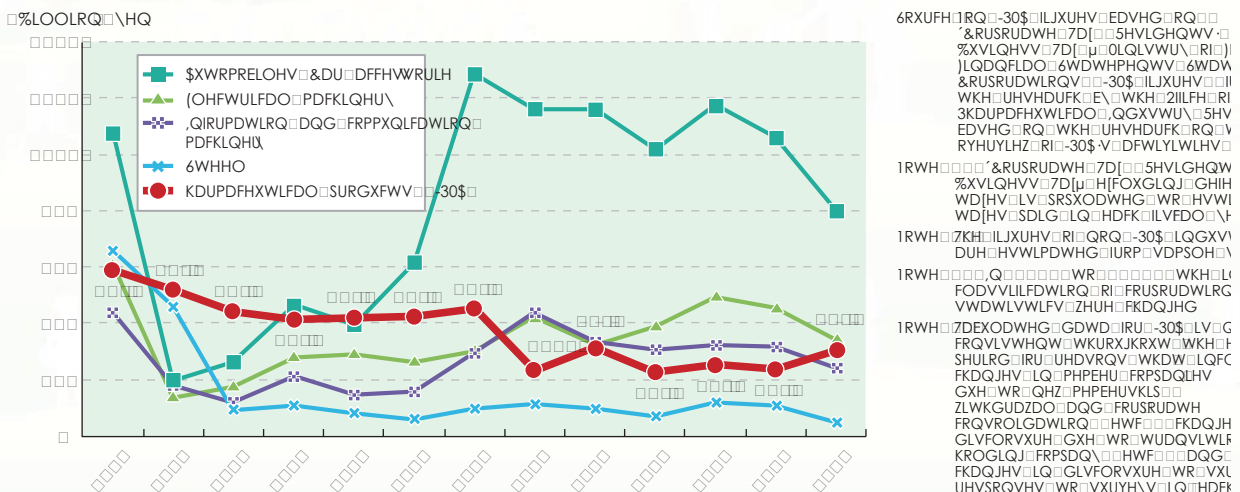
During the 20 years from 2000–2019, the global drug market more than tripled in size. However, growth in the Japanese market became nearly indiscernible. It slipped from having been second only to the North American market in size to third place after being overtaken by the Chinese market from 2013. In addition, Japan's market share in 2019 was approximately half of what it was in 2000. It is evident even from a global perspective that growth of Japan's drug market has been stifled by factors such as repeated reductions in drug pricing.



## The pharmaceutical industry as a high value-added industry

The pharmaceutical industry not only makes contributions through pharmaceutical products, but it also promotes the stabilization of social infrastructure through reliable tax-paying capacity. In recent years, it has maintained a high level of tax payments. Moreover, in the Future Investment Strategy determined by the government, the pharmaceutical industry is expected to play a major role in achieving the strategic area of extending a healthy life expectancy.

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## Ensuring more accurate understanding of pharmaceutical products and the pharmaceutical industry

Ensuring accurate understanding of pharmaceutical products and industry is critical to realize the value of medicines. JPMA communicates information of pharmaceutical products to a wide range of relevant parties and develops PR activities to deepen understanding of our products and industry.

### JPMA Forum

#### Communicating with leaders in various fields

The JPMA Forum is held to bring together representatives of member companies to exchange opinions with leaders in a variety of fields related to the JPMA, including Diet members, the government, relevant organizations, opinion leaders, patient groups and media.



The 19<sup>th</sup> JPMA Forum



The 10<sup>th</sup> Asia Partnership Conference of Pharmaceutical Associations

### Asia Partnership Conference of Pharmaceutical Associations (APAC)

#### Accelerate access to innovative medicines for Asia

APAC is an industry-driven initiative led by R&D-based pharmaceutical associations affiliated with the International Federation of Pharmaceutical Manufacturers & Associations, regulatory authorities from various countries and academia. The key objective is to accelerate access to innovative medicines for people in Asia by promoting mutual understanding of common issues and discuss solutions.

### Intellectual Property Forum

#### Strengthening Japan's global competitiveness in the pharmaceutical industry

The purpose of Intellectual Property Forum is to exchange opinions with a wide range of experts and related parties on various issues related to intellectual property in order for pharmaceutical industry in Japan to maintain competitiveness and continue to develop in the international economic society, and to actively/effectively announce JPMA's proposals related to intellectual property, and ultimately to promote its realization.



2021 Life Science Intellectual Property Forum



The 32<sup>nd</sup> JPMA Policy Seminar

### Policy Seminar

#### Visions of the pharmaceutical industry

The Policy Seminar shares the future vision of the pharmaceutical industry through panel discussions and lectures by experts of government and academia, with the aim of further enhancing integrated initiatives by industry, academia and government.

### Patient Group Seminars

#### Communicating with patients

Patient Group Seminars are held to promote cooperation with patients to exchange opinions and efforts towards developing new medicines through R&D. In addition, the "Together with patients" page at JPMA website provides a variety of useful information for patient and their family.



The 36<sup>th</sup> JPMA Patient Group Seminar

JPMA widely announces information on medicines and the pharmaceutical industry and our messages on the JPMA website. In addition to publications for proper understanding of medicines, we also publish the JPMA Newsletter to communicate our activities in an easy-to-understand manner.

Website



JPMA website top page

Drug information for elementary and jr. high school students



Useful information on drugs is uploaded for elementary and jr. high school students, including "Kusuri Labo" (The Drug Lab).

Office of Pharmaceutical Industry Research

The Office of Pharmaceutical Industry Research (OPIR) functions as a thinktank for the pharmaceutical industry and publishes the "Research Paper Series," "Industry Reports," and "OPIR Views and Action." These are also publicly disclosed through its website.



(URL <http://www.jpma.or.jp/opir/index.html>)

Major publications



The JPMA Newsletter (digest version)



Drug Information Q&A 55



Tell Me More About New Drugs!



Textbook

The JPMA Newsletter is also distributed as an email magazine. Registration can be made on the website.



Contributing Society with New Pharmaceuticals

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