

# Japan Pharmaceutical Manufacturers Association Guide

2022

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 April 1, 2022, consists of the 73 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.



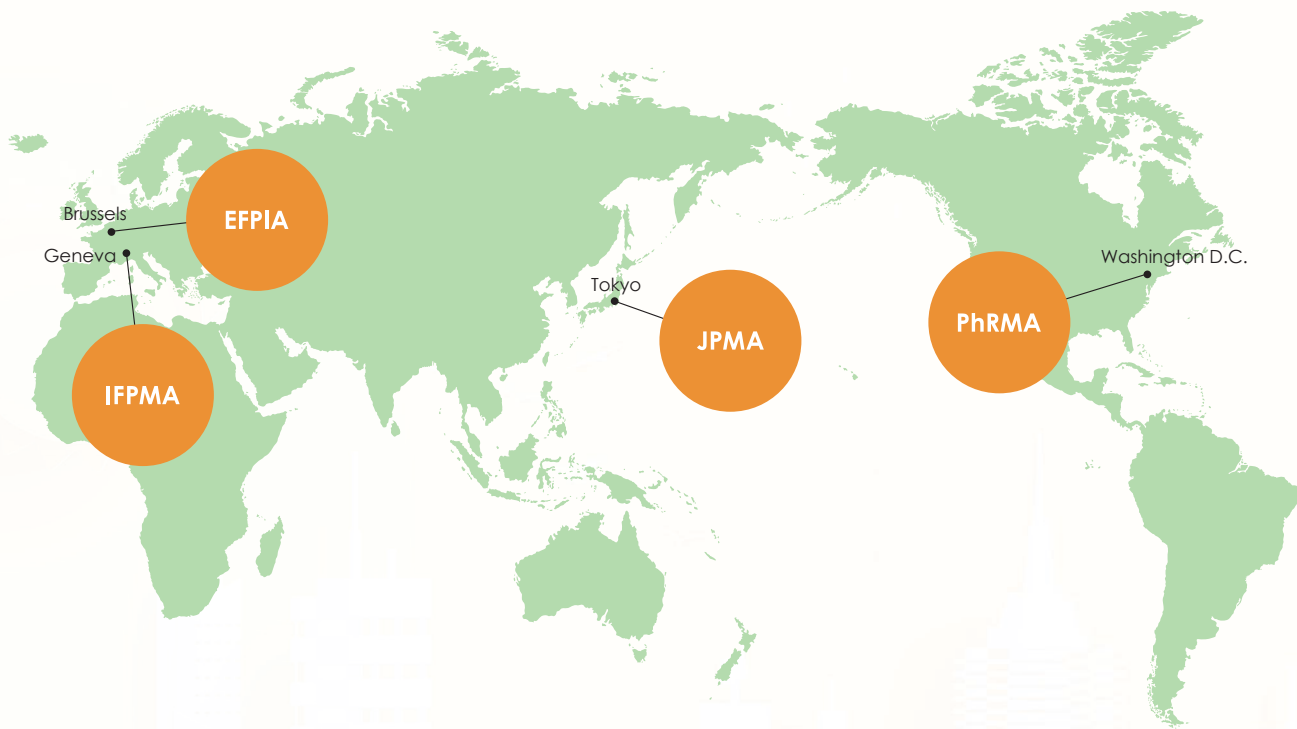
President of Japan Pharmaceutical Manufacturers Association

## 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 (current)
May. 2021	President, Japan Pharmaceutical Manufacturers Association (current)



JPMA is a voluntary association comprising 73 research-oriented pharmaceutical companies (as of April 1, 2022).

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





# The JPMA organization and committees

JPMA and its member companies have established 12 committees comprised of various member companies and 6 specialized organizations, including the Office of Pharmaceutical Industry Research (OPIR) that functions as a think tank, in order to realize the objective of supporting the extension of healthy life expectancy of the Japanese people through the creation of innovative new drugs, as well as to make the industry a key driver of Japanese economic growth. These committees carry out activities based on business policies and plans, while building good relationships with a variety of stakeholders in Japan and abroad.

## List of Committees

- Code Compliance Committee
- Review Board of Ethical Drug Product Information Brochure
- Pharmaceutical Industry Policy Committee
- Distribution Improvement Committee
- Drug Evaluation Committee
- Quality & Technology Committee
- Biopharmaceutical Committee
- Regulatory Affairs Committee
- Intellectual Property Committee
- R&D Committee
- International Affairs Committee
- Public Affairs Committee
- Patient Cooperation Committee
- ICH Project
- APAC Project
- Consumer Consultation Review Committee
- Environmental Issue Committee

## Office of Pharmaceutical Industry Research (OPIR)

In order for pharmaceutical industry to contribute to society and achieve sound development, comprehensive policy research and survey on various issues from a medium-to-long-term perspective are conducted, and findings are disseminated to the pharmaceutical industry and beyond.

As a publication from OPIR, "OPIR Views and Actions," "Research Paper Series," and "Industry Reports." are issued.

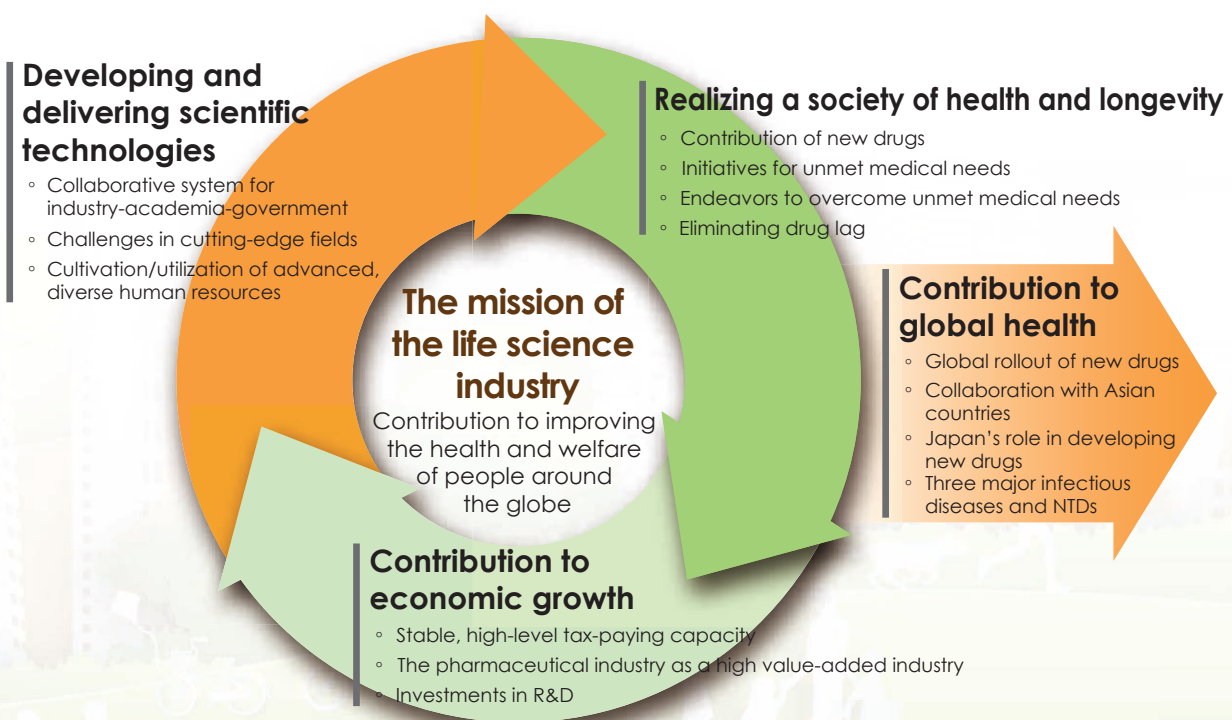


## Contributions and challenges in the pharmaceutical industry

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.

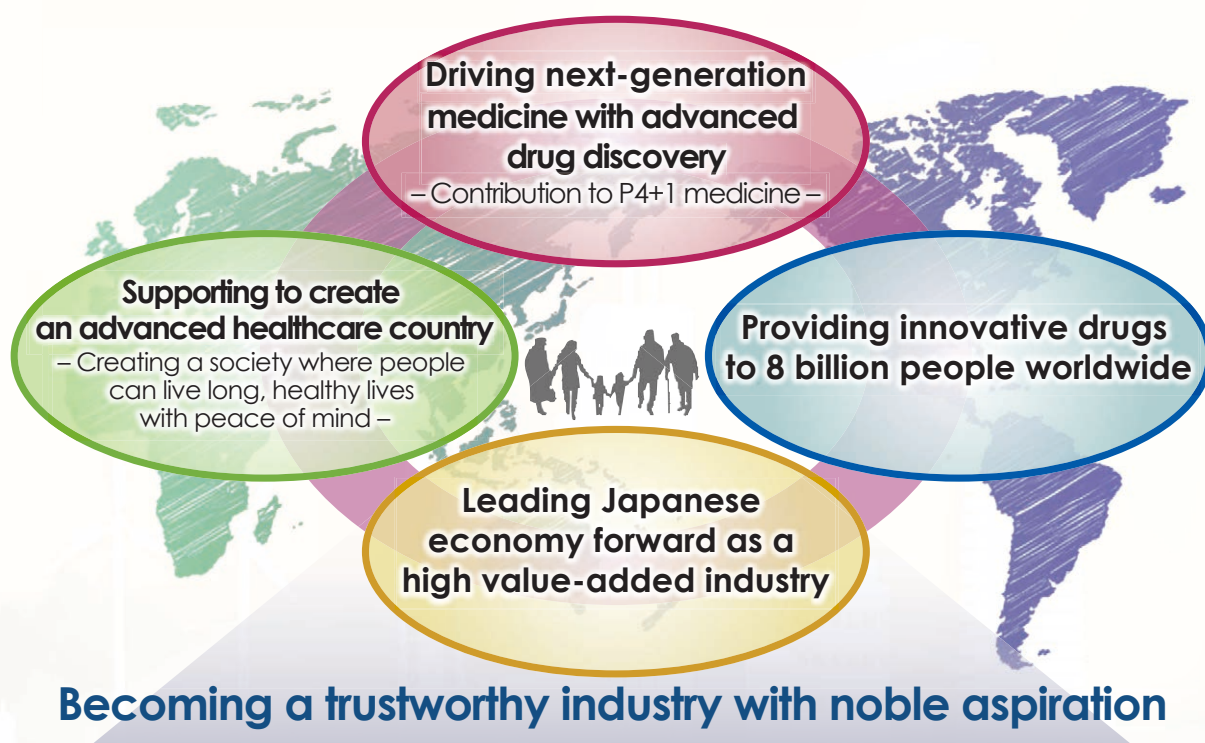
These contributions by the pharmaceutical industry are greatly anticipated to lead the growth and development of Japan as well as the world through contributions to global health that include disseminating first-rate new drugs to the entire world and exhibiting leadership as one of the few countries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



# 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

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

- Examining the susceptibility to illness
- New diagnostic therapeutic methods

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

- Utilizing apps as new treatment methods
- Telemedicine at home

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

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

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

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

### 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:**

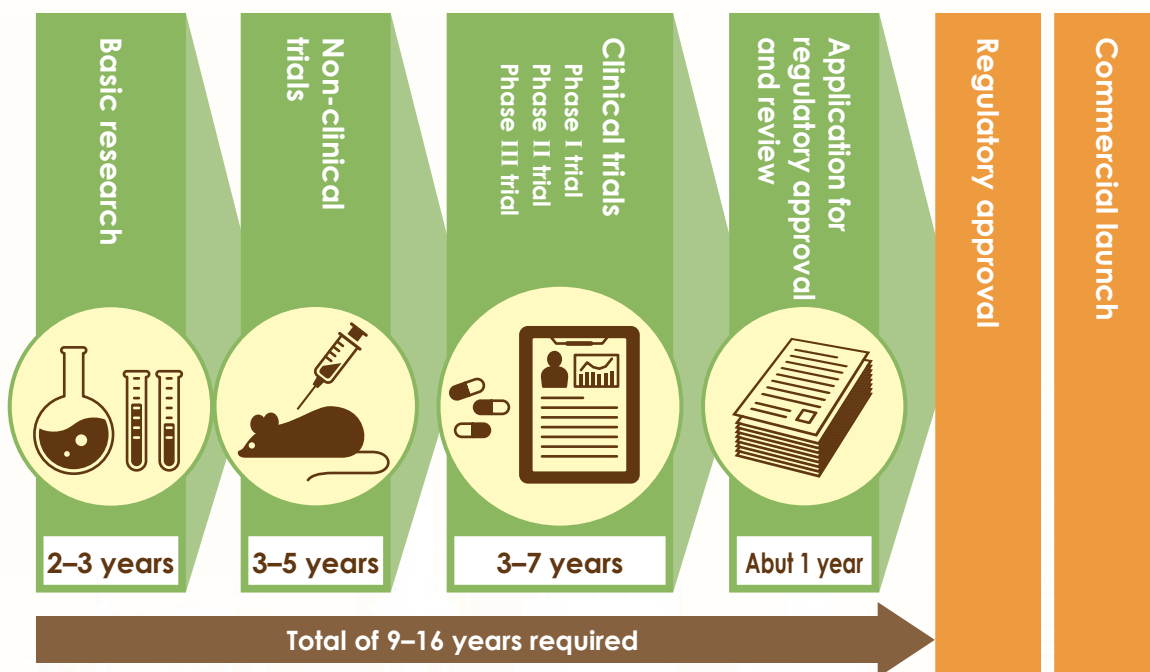
Changes in product characteristics and rising development costs

**Issues in R&D pharmaceutical companies:**

Taking the initiative to pursue and determine optimal solutions for business size and form

## The path to new drug creation

A myriad of compounds are created during the basic research stage, and their mode of actions and effectiveness for disease are explored. Later, their safety and effectiveness are verified through non-clinical researches conducted on animals and cells, and clinical trials on humans. After being reviewed and approved by the Health Authority, they can finally be released on the market. This process requires between 9 and 16 years. Furthermore, only around 1 in 22,000 of all such chemical compounds are launched as new drugs (according to a survey by JPMA). The majority of chemical compounds are never released in the market. Pharmaceutical companies invest considerable time and effort to create pharmaceutical products that protect human life.



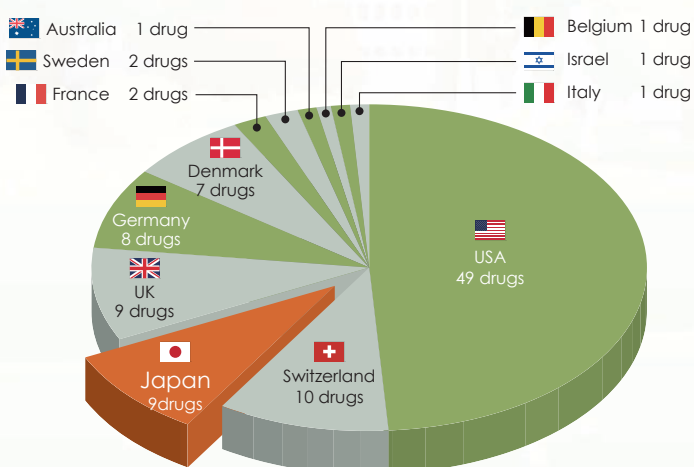
## Outstanding drug development ability of Japan

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.

**Global sales of prescription drugs:  
A comparison of the top 100 by country of origin (2020)**



Source: Copyright © 2022 IQVIA. Created by OPIR based on IQVIA World Review Analyst, Data Period 2020, IQVIA Pipeline & New Product Intelligence, Pharmaprojects, EvaluatePharma, Clarivate Cortellis Competitive Intelligence (Reprinted with permission).

Reference: OPIR Views and Actions No. 64 (November 2021), JPMA

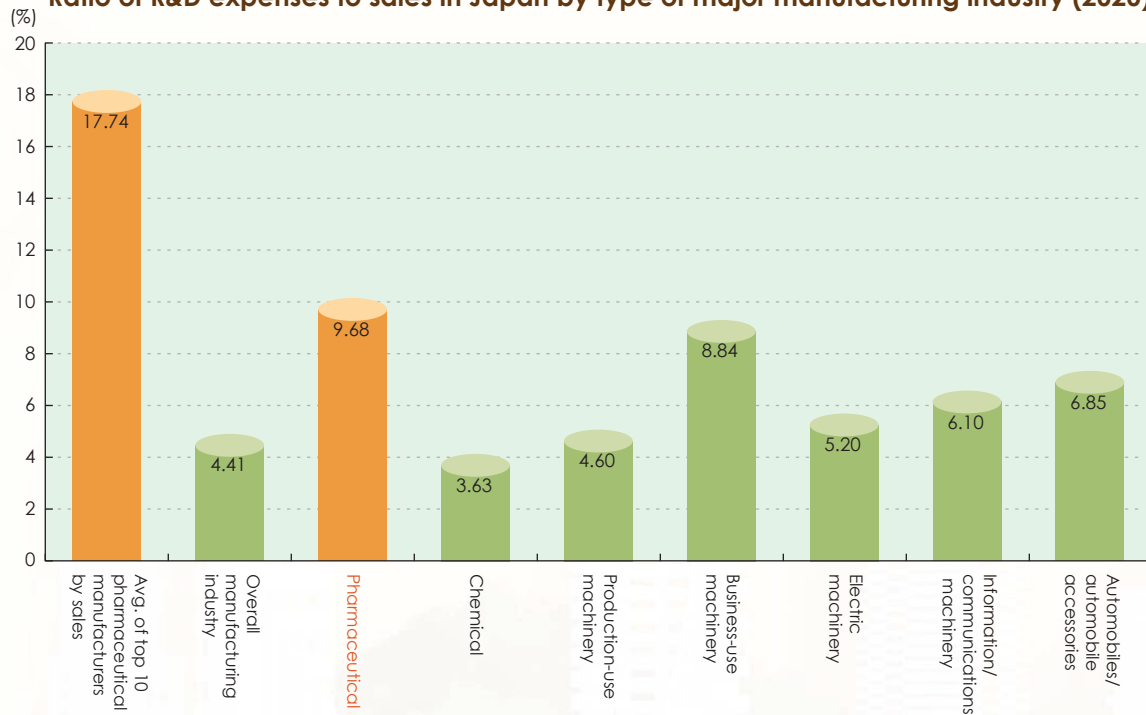
Note: The breakdown is made according to nationality of the company to which the patent(s) belong.



## An R&D-focused industry

Bringing a single new drug to patients involves numerous steps that start with the discovery of a new substance that is the basis for the drug and include basic research, non-clinical trials, clinical trials, and review. The process is said to ordinarily take more than 10 years. In addition, hefty expenses are required to support those long years of R&D. Our passion involved in creating new drugs in Japan is also indicated in the ratio of R&D expenses. While the ratio of R&D expenses to sales in Japan's manufacturing industry was 4.41%, it was 9.68% in the pharmaceutical industry and averages as much as 17.74% for 10 of the major pharmaceutical companies.

Ratio of R&D expenses to sales in Japan by type of major manufacturing industry (2020)



Source: "Report on the Survey of Research and Development," Ministry of Internal Affairs and Communications  
 Reference: Created based on "DATA BOOK 2022" by JPMA

Note 1: The R&D expenses presented here are the research expenses for in-house use defined in the Ministry of Internal Affairs and Communications "Report on the Survey of Research and Development;" that is, research expenses used within the company sourced from company funds and capital received from outside the company. Research expenses paid outside the company for outsourced research, joint research, etc. are not included.  
 Note 2: The average of the 10 companies is the ratio of R&D expenses to consolidated net sales shown in the Annual Securities Reports.

Find more information on "The Process of New Drug Development" here!

"Textbook"

[https://www.jpma.or.jp/news\\_room/issue/textbook/](https://www.jpma.or.jp/news_room/issue/textbook/)



"Capsule-kun" cheers pharmaceutical industry to develop and bring new drugs.

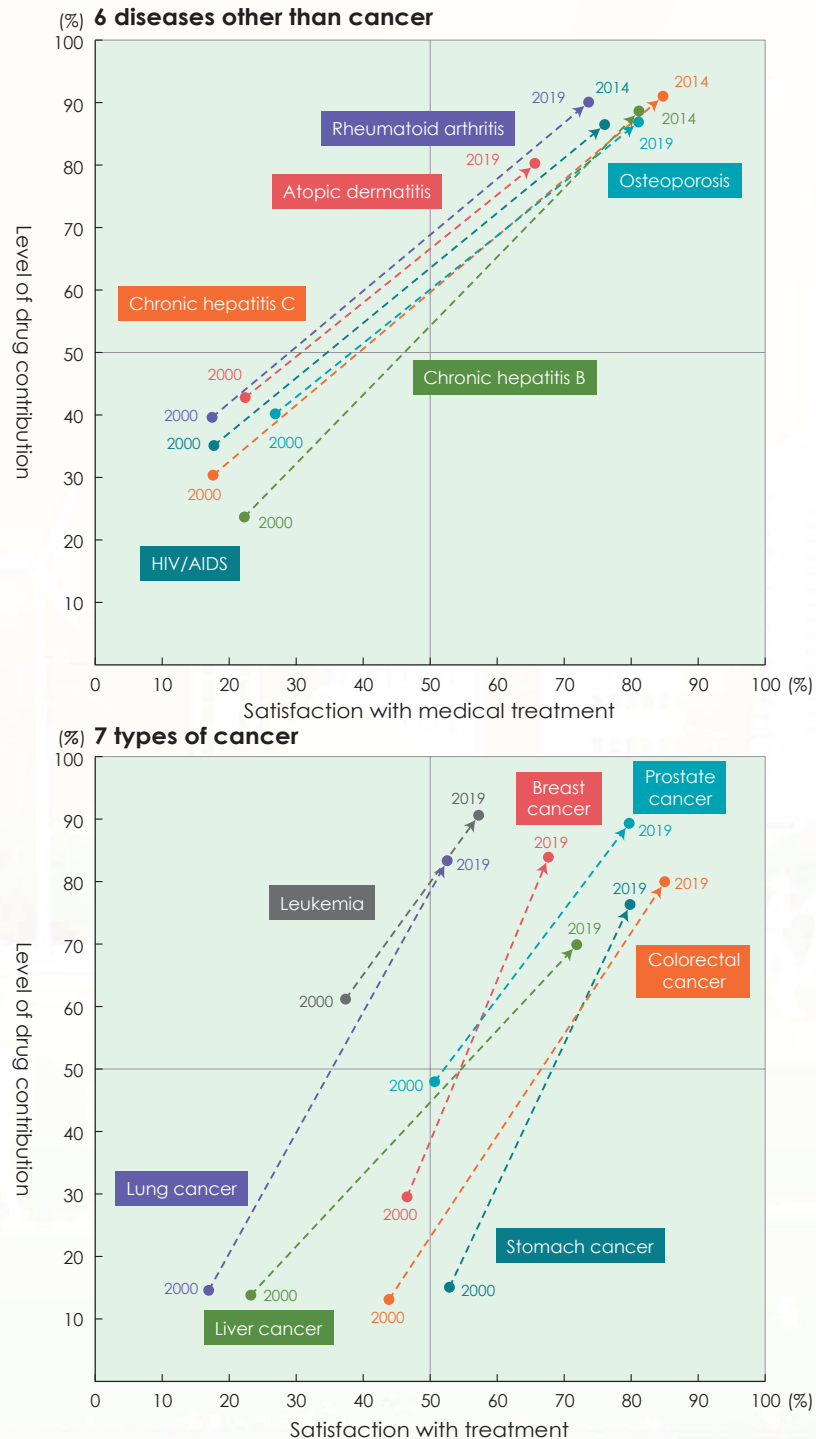


The JPMA cheer ambassador, "Capsule-kun"

# The challenges of unmet medical needs

“Unmet medical needs” mean the strong demand for pharmaceutical products and medical treatment for illnesses for which there are still no established effective treatment methods. In 2000, there were many disease, for which new pharmaceuticals were expected to be effective, with few decisive treatments. The pharmaceutical industry has contributed to improving the level of satisfaction with medical treatments through the development of innovative new drugs that meet such unmet medical needs. Currently, there is a significant improvement in satisfaction with medical treatments for infectious diseases such as chronic hepatitis C and HIV/AIDS, as well as rheumatoid arthritis and cancer that are regarded as having considerable productivity loss.

## Changes in satisfaction with medical treatments and level of drug contribution (2000→2019)

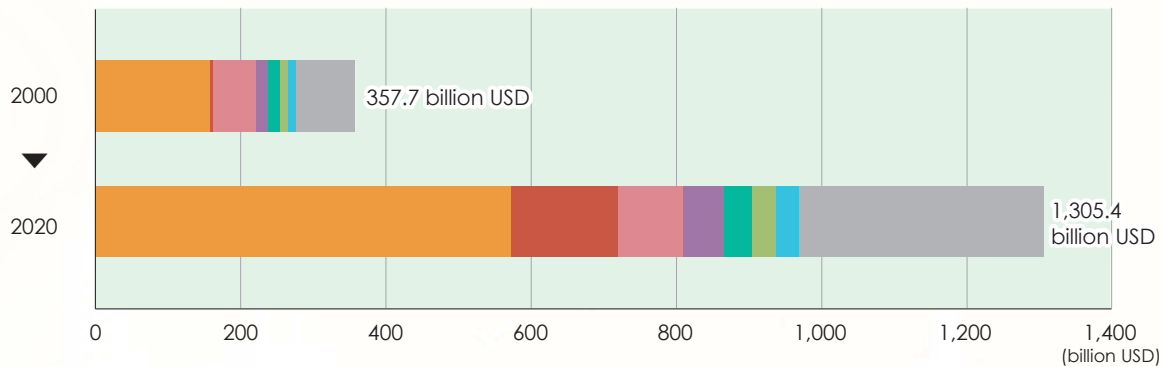


Note: Data from 2014 is used for HIV/AIDS, chronic hepatitis C, and chronic hepatitis B since they were excluded from the diseases subject to research in 2019.  
 Source: Created by the OPIR based on the FY2000/2005/2010/2014 and FY2019 Research Report on Fundamental Technologies in Japan by the Japan Human Science Foundation

## A global view of Japan's drug market size

In the 21 years from 2000 to 2020, the global drug market grew to more than triple in size. However, the Japanese market has seen close to zero growth and was consequently knocked from its previous secondary position behind the North American market to third place in 2013 after being overtaken by the Chinese market. In addition, the 2020 Japanese market share was less than half of what it was in 2000. A global view makes it obvious that the growth of the drug market in Japan has been suppressed due to factors such as repeated drug price reductions.

The composition ratio of the global drug market (2000→2020)



Shifts in global drug market shares

	North America	China	Japan	Germany	France	Italy	UK	Others
2000	44.0%	1.4%	16.2%	4.7%	4.7%	3.1%	3.1%	22.9%
2020	43.8%	11.3%	6.8%	4.4%	2.9%	2.6%	2.5%	25.7%

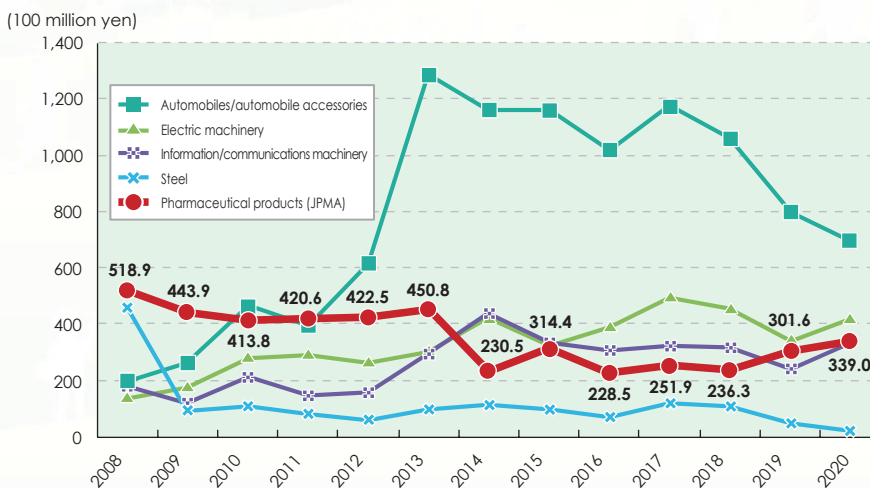
\*Numerical values show shifts in market shares when the total market price is 100% in each year shown in the above graph.

Source: Copyright © 2022 IQVIA. Created by the OPIR based on IQVIA World Review, Data Period – Year 2000–2020 (Reprinted with permission).

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

The pharmaceutical industry not only contributes through pharmaceutical products, but also plays a part in the stability of social infrastructure through reliable tax-paying capacity. In recent years, it has consistently borne a high level of taxes. Furthermore, the pharmaceutical industry is also anticipated to be a significant player in achieving the strategic area of “extending a healthy life expectancy” within the government’s “Future Investment Strategy.”

Shifts in tax payments by major manufactures in Japan



Source: Created by the OPIR based on research on the state of JPMA activities (JPMA) and “Corporate Tax, Residents’ Tax and Business Tax” by the Ministry of Finance Japan Financial Statements Statistics of Corporations (non-JPMA).

Note 1: “Corporate Tax, Residents’ Tax and Business Tax,” excluding adjustments such as corporate tax (tax effects), is used as the basis to approximate the payment amount in each fiscal year.

Note 2: Numerical values for various industries excluding JPMA are estimated values for industries as a whole based on sample surveys.

Note 3: “Financial Statements Statistics of Corporations by Industry” were changed from FY2008 to FY2009.

Note 4: Tabulated data for JPMA is not consistent throughout the entire period for reasons that include changes in member companies due to new membership, withdrawal, and corporate consolidation, etc.; changes in data disclosure due to transition to a holding company, etc.; and differences in disclosure to surveys and responses to surveys in each year.

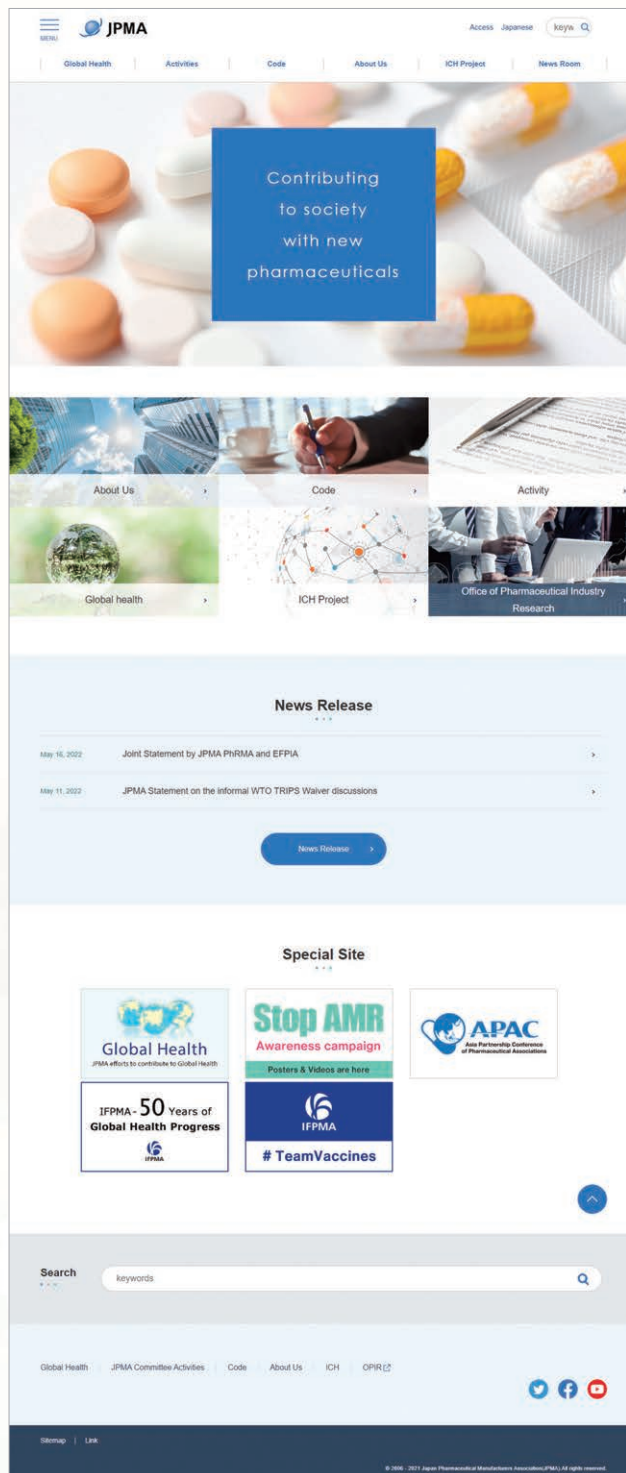


## Website

The JPMA website was revamped in August 2021. It provides timely information on drugs and the pharmaceutical industry, and messages from JPMA.

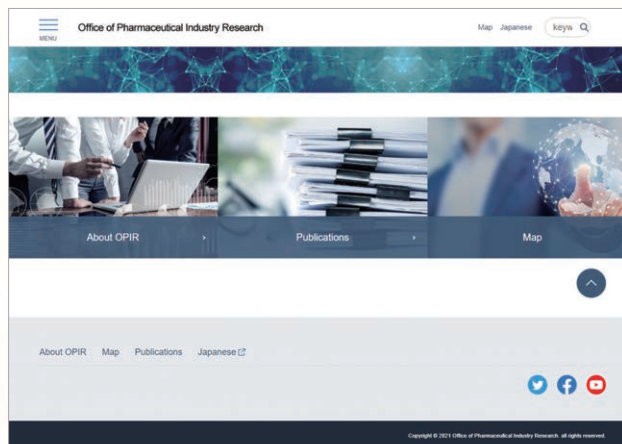
### ■ The Japan Pharmaceutical Manufacturers Association (JPMA)

<https://www.jpma.or.jp/english/>



### ■ Office of Pharmaceutical Industry Research (OPIR)

<https://www.jpma.or.jp/opir/en/>



### ■ Learning about drugs

Helpful information on drugs is provided for the general population and elementary/junior high school students, including the "Kusuri Labo" (The Drug Lab) and "List of Facilities to Visit."

#### Kusuri Labo (The Drug Lab)

Study materials are provided for learning accurate information on drugs in a fun way together with Capsule-kun.



<https://www.jpma.or.jp/junior/kusurilabo/>

#### List of Facilities to Visit

Facilities are introduced such as pharmaceutical factories that can be toured, drug resource centers, and museums.



An example of a facility to visit: Medicine Laboratory, Science Museum  
<https://www.jsf.or.jp/en/exhibits/3f/>

## Official social media accounts

Information is shared on JPMA's endeavors and events. Future PR events are being planned that link the JPMA website and social media accounts.

### Twitter

<https://twitter.com/Seiyakukyou>

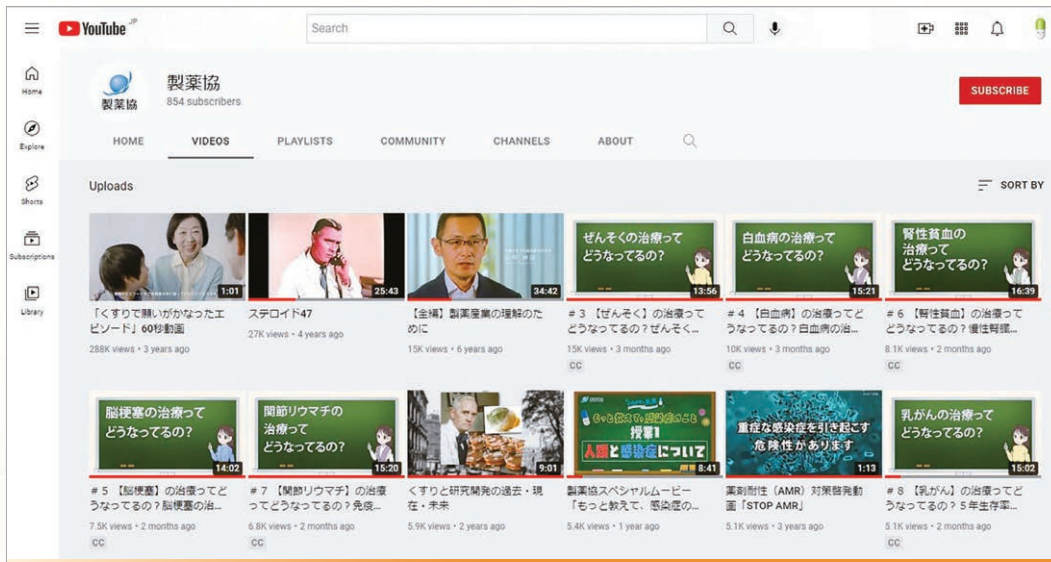
JPMA created an official Twitter account in February 2022 to share JPMA news and activities, as well as information on the pharmaceutical industry.



### YouTube

<https://www.youtube.com>

Videos are available for viewing on the official JPMA YouTube channel to promote understanding of the pharmaceutical industry. They include "The Past, Present, and Future of Drugs and R&D," "Educational Videos on Antimicrobial Resistance (AMR) Countermeasures," and "Learning about New Drug Innovation with the Pharmacy Student, Aoi."



## Major publications

JPMA releases "JPMA News Letters" that simply explain the activities of JPMA as well as publications that help people deepen correct understanding of drugs.



The JPMA Newsletter (digest version)



Drug Information Q&A 55



Tell Me More About New Drugs!



Textbook



## Special websites

### ■ “Discover the Experience” pharmaceutical industry project for university students

<https://www.jpma.or.jp/lp/>

Targeted primarily at university students and other youth, the project is a combination of online seminars and participatory programs such as gatherings and workshops. The goal was to increase understanding of the pharmaceutical industry and promote awareness of industry engagement in the future among youth.

#### First stage:

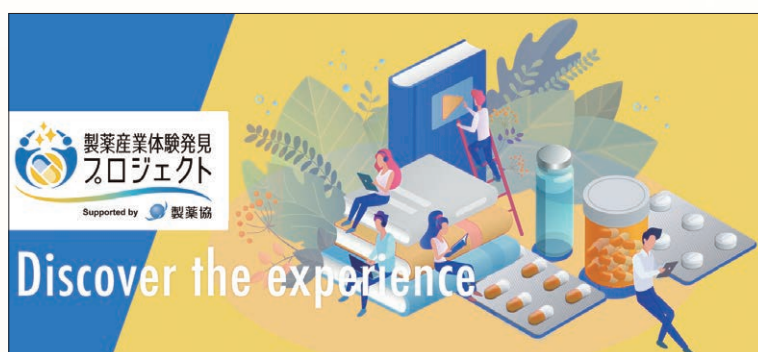
Remote seminars for viewing are made available to learn about jobs in the pharmaceutical industry and pharmaceutical companies.

#### Second stage:

Gatherings are held to understand the hopes and realities of pharmaceutical jobs through interaction with people working in the pharmaceutical industry.

#### Final stage:

Presentations are made summarizing study outcomes and future possibilities through group work.



### ■ YouTube videos communicate the value of new drugs: “Learning about New Drug Innovation with the Pharmacy Student, Aoi”

<https://www.jpma.or.jp/lp/aoi/>

YouTube videos featuring the pharmacy student, Aoi communicate the value of new drugs. Each video addresses topics such as familiar ailments including breast cancer and asthma, and preventing and treating infectious diseases. They bring new awareness of how new drugs contribute to medical treatments and people's health, in addition to the importance of innovation in drug discovery.



### ■ A tie-up with Tokyo Graffiti: Digital mook, “YELL for New Drugs”

[https://www.jpma.or.jp/news\\_room/campaign/campaign2021/](https://www.jpma.or.jp/news_room/campaign/campaign2021/)

JPMA partnered with Tokyo Graffiti, a youth-oriented culture magazine that broaches social themes through novel approaches, to create a digital mook (magazine-type book) that collects the voices of “what to expect for new drugs”. The objective is to help people think about the creation of new drugs by a matter of themselves, and deepen their understanding of the current state of Japan's pharmaceutical industry.





# 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 20<sup>th</sup> JPMA Forum



The 11<sup>th</sup> Asia Partnership Conference of Pharmaceutical Associations

## Asia Partnership Conference of Pharmaceutical Associations (APAC)

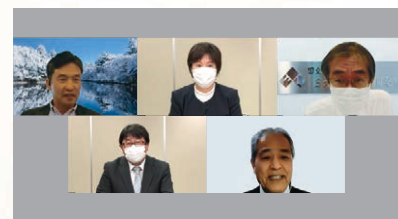
### Accelerate access to innovative medicines for Asia

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.



2022 Life Science Intellectual Property Forum



The 33<sup>rd</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 37<sup>th</sup> JPMA Patient Group Seminar



Contributing Society with New Pharmaceuticals

## Japan Pharmaceutical Manufacturers Association (JPMA)

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