

2023

Japan Pharmaceutical Manufacturers Association Guide



Bringing New Drugs to Everyone Who Wishes Good Health

The Japan Pharmaceutical Manufacturers Association (JPMA) is an organization that consists of 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.

Aiming to become a country where innovation thrives

The three-year-long COVID-19 pandemic had a major impact on our social life, with the global spread of the disease severely limiting the flow of traffic and severely affecting the manufacture and transportation of goods, but thanks to the efforts of many medical professionals and the COVID-19 vaccine and medicines, life before the COVID-19 pandemic has finally returned. During this period, the use of various digital tools has enabled us to have new work styles and lifestyles, such as remote work, that were previously unthinkable. In this respect, the COVID-19 pandemic seems to have changed the social norm.

On the other hand, what we have learned from the COVID-19 pandemic is that medicines and vaccines are essential in the fight against pandemics, and from the perspective of national security, measures must be taken to address this issue from normal times. In addition to pandemic countermeasures, there are many diseases for which there is still no cure, and pharmaceutical companies must work to create new medicines for these diseases. The JPMA will also provide maximum cooperation in the framework of the "Drug Discovery Venture Ecosystem Enhancement Project," which was launched last year to strengthen and accelerate drug discovery innovation, which is becoming increasingly important. The JPMA would like to play a role not only in supporting academia and start-ups, but also in successfully nurturing the seeds generated from these activities to lead to the creation of new drugs originating in Japan. We believe that if each player establishes industry-academia-government collaboration from a new perspective with a strong will under the strong support of the government, drug discovery in Japan will accelerate and innovation will flourish.

In order for innovation to be continuously generated, it is also important to have a system in which innovation is properly evaluated. This is important not only to encourage innovation creation in our own country, but also to attract innovation from other countries. However, the problem of so-called "drug lag/drug loss," in which new drugs approved in other industrialized countries don't easily reach Japanese patients, is becoming more and more apparent. To address these issues, it is necessary to increase the attractiveness of the Japanese pharmaceutical market and attract investment and technology. The JPMA will exchange opinions with stakeholders and make recommendations on policies that should be implemented in order to create a system where the value of pharmaceutical products is fairly evaluated.

We aim to become a "country where innovation thrives" where motivated companies take on the challenge of unmet needs, innovation is continuously generated, and the value of pharmaceutical products is fairly evaluated.



President of Japan Pharmaceutical Manufacturers Association

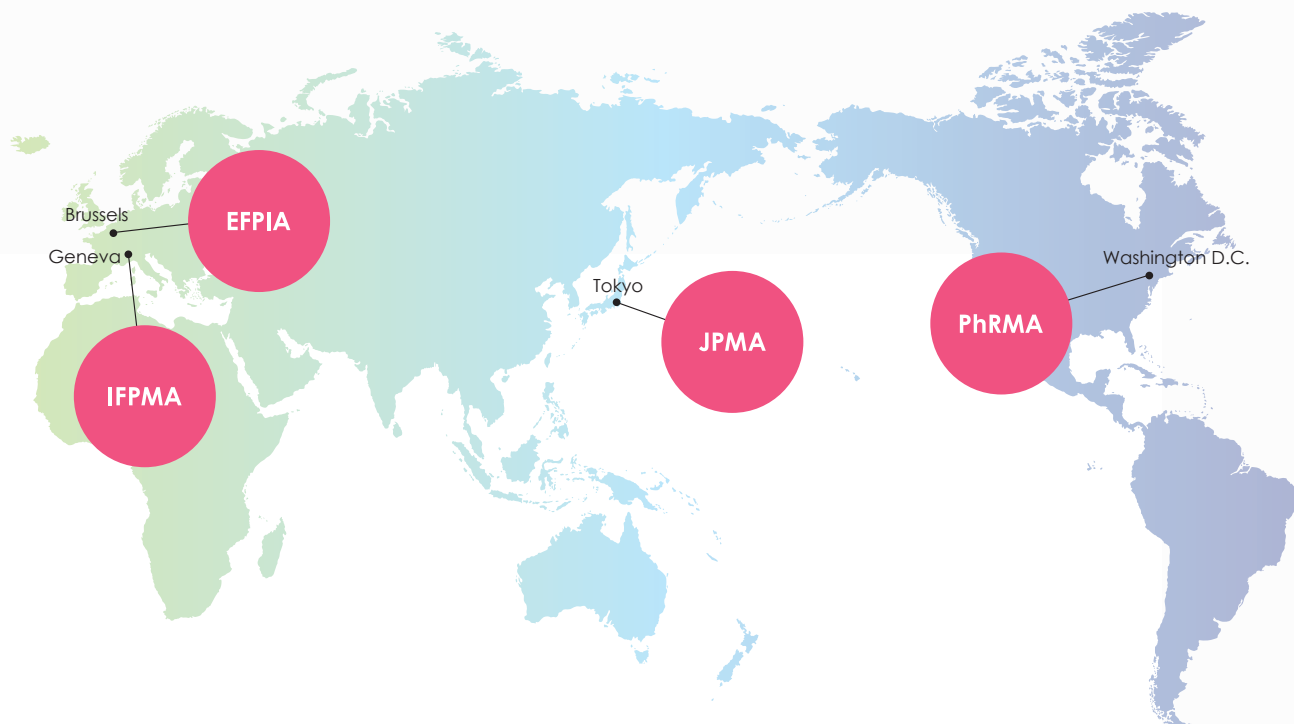
A handwritten signature in black ink, appearing to read "Hiroaki Ueno".

Hiroaki Ueno Ph.D.

Representative Director, Mitsubishi Tanabe Pharma Corporation

Biography

March 1983	Completed master's course at the Graduate School of Bioscience and Biotechnology, Tokyo Institute of Technology
April 1983	Entered Mitsubishi Chemical Industries Ltd.
April 2018	Managing Executive Officer, Division Manager of Sohyaku. Innovative Research Division of Mitsubishi Tanabe Pharma Corporation
April 2020	President and Representative Director of the Company
April 2022	Representative Director of the Company Executive Vice President Head of Pharma of Mitsubishi Chemical Group Corporation
April 2023	Representative Director of Mitsubishi Tanabe Pharma Corporation (Current)
May 2023	President, Japan Pharmaceutical Manufacturers Association (Current)



JPMA is a voluntary association comprising 72 research-oriented pharmaceutical companies (as of May 1, 2023).

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 committees and specialized organizations

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 and specialized organizations 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
- 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

List of Specialized Organizations

- Office of Pharmaceutical Industry Research (OPIR)
- Review Board of Ethical Drug Product Information Brochure
- 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.



JPMA's Logo Mark



JPMA's 5 Messages

1. Contributing to global healthcare through the development of new drugs
2. Driving Japanese economy as a leading industry
3. Creating innovative, highly effective new drugs
4. Becoming a business association with excellent R&D capabilities
5. Contributing to patient-centered healthcare

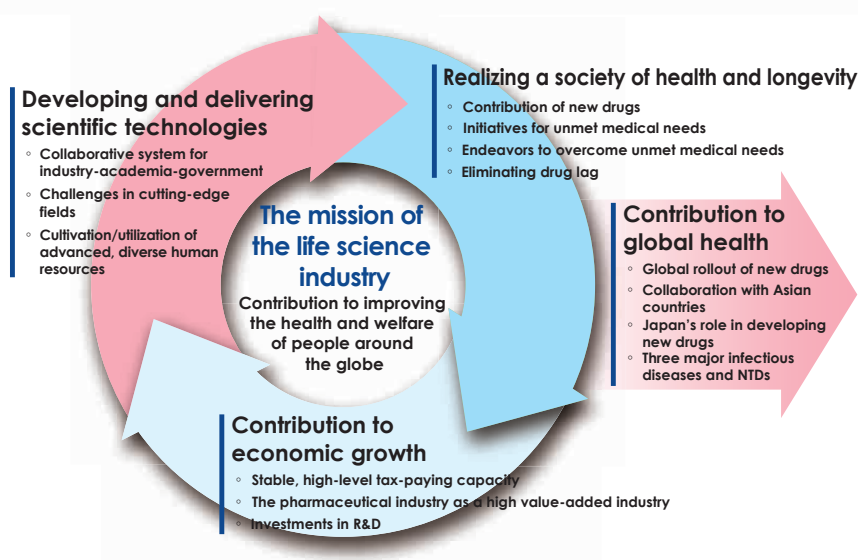
Thoughts behind the logo

Symbolizing the five messages, it expresses the way we continue to move forward with the world. The five arcs are continuous around the sphere, and their ascending shape evokes the image of "leap" or "growth." The color blue is used as a base color to evoke a sense of "progress," "internationality," "high technological capabilities," and "freshness."

Contributions and challenges in the pharmaceutical industry

The pharmaceutical industry is expected to strive for the realization of a society of health and longevity by creating innovative drugs based on patient needs, and 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.



Initiatives on compliance

The mission of pharmaceutical companies is to contribute to the improvement of the welfare and healthcare of people around the world through the continuous development and stable supply of superior pharmaceutical products, thereby contributing to the realization of a healthy and high quality life. To this end, we are required to conduct corporate activities based on a sincere and relentless pursuit of life sciences, which are undergoing remarkable development, and on a high level of ethics and transparency.

In 1997, the JPMA established the "JPMA Charter of Corporate Behavior" as a code of conduct to help member companies fulfill their mission as pharmaceutical companies. In 2001, we also presented the "JPMA Compliance Program Guideline" to further ensure compliance with laws and regulations. Furthermore, in order to ensure appropriate accountability by disclosing information on financial payments from pharmaceutical companies to medical institutions, etc., and by drawing up "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions" in 2011, we are striving to build relationships of mutual trust among member companies and various stakeholders while keeping up with the changing times and conducting optimal corporate activities from the patients' perspective with high ethical standards.

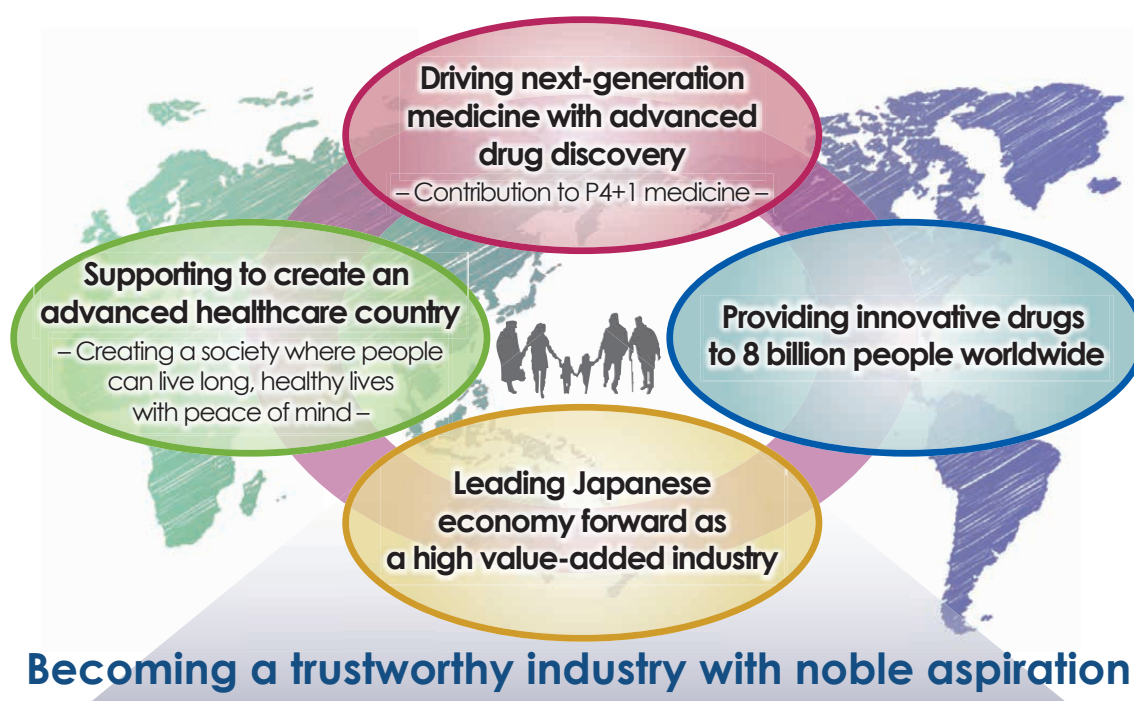


Aiming for Development of Pharmaceutical Industry

JPMA Industry Vision 2025

JPMA envisioned a future image, “Bringing Innovation in Drug Discovery to the World” in which patient-centered medicine is realized by R&D-based pharmaceutical companies, and formulated the “JPMA Industry Vision 2025” as a direction to realize that.

Bringing innovation in drug discovery to the world



Vision 1 Driving next-generation medicine with advanced drug discovery
— Contributing to P4+1 medicine —

Vision 2 Providing innovative drugs to 8 billion people worldwide

Vision 3 Leading the Japanese economy forward as a high value-added industry

Vision 4 Supporting to create an advanced healthcare country
— Creating a society where people can live long, healthy lives with peace of mind —

Vision 5 Becoming a trustworthy industry with noble inspiration

JPMA Policy Proposals 2023

In response to the social environment and recent policy trends of living with COVID-19, and in order to gain a better understanding from the public regarding the creation and assessment of new drugs, the JPMA drew up the "JPMA Policy Proposals 2023." The pharmaceutical industry will strive tirelessly to bring innovative healthcare solutions from prevention and diagnosis to treatment and prognosis to the people as soon as possible, in order to realize a healthy and long-lived society in the age of 100 years of life.

Policy Proposals 2023

1. Changes and issues in the environment surrounding the pharmaceutical industry
2. Creating an environment conducive to innovation creation
3. Ideal sustainable healthcare and social security

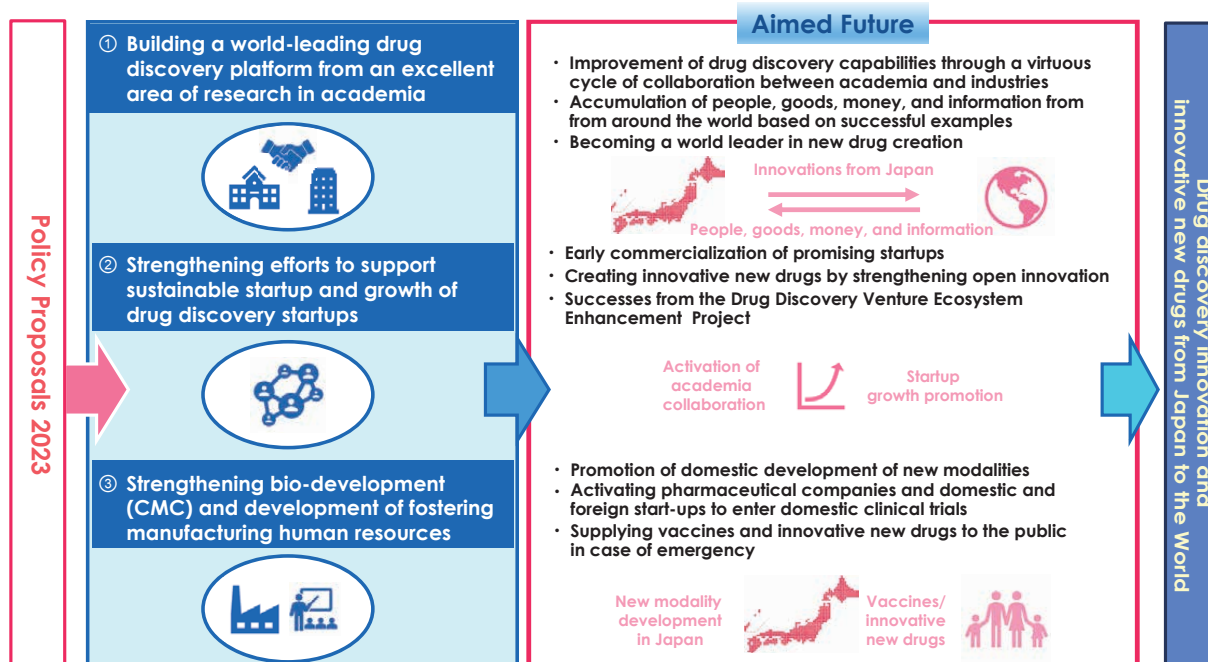
[Addendum] Preparing for future pandemics



https://www.jpma.or.jp/vision/industry_vision2023.html

The future we aim for by realizing Policy Proposals 2023

— Strengthening Japan's drug discovery capabilities through Industry-Academia-Government collaboration —



Source: Press Conference Material for Chairman of JPMA in February 2023

Various drugs around us

There are two types of drugs (medicines): “OTC drugs” which are sold over-the-counter at pharmacies and drugstores, and “ethical drugs” which require a doctor’s prescription.

OTC drugs

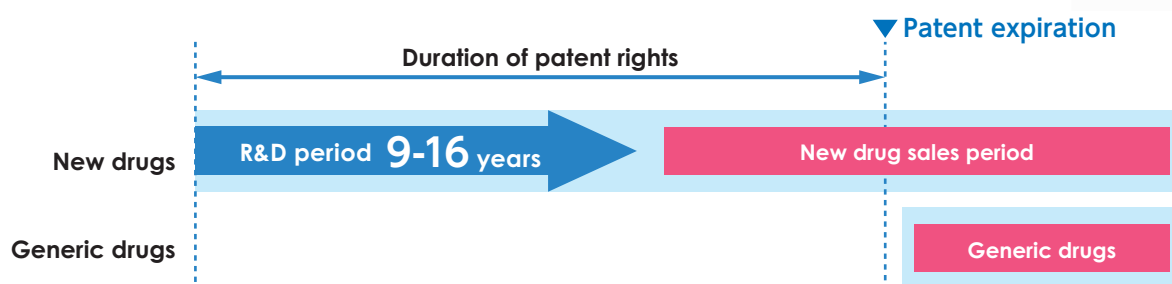
Medicines sold at pharmacies and drugstores, such as cold medicines and gastrointestinal medicines.

Ethical drugs

There are two types of ethical drugs: brand-name drugs (new drugs) and generic drugs.

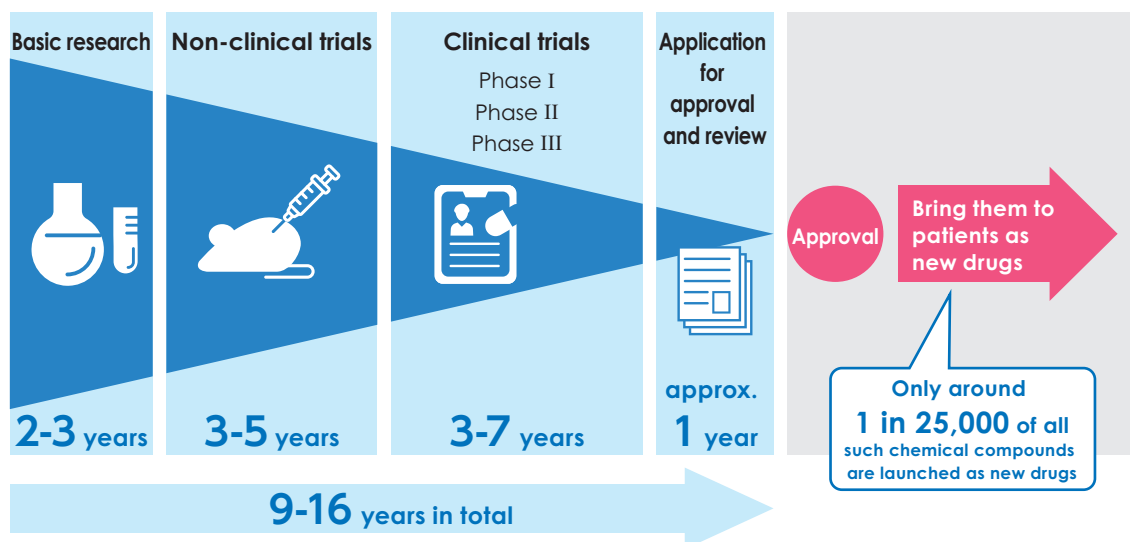
New drugs are ethical drugs that are put on the market after a long period of research and development, after the efficacy and safety of the new ingredients have been confirmed, and after receiving government approval. The member companies of the JPMA are working daily to bring these new drugs to patients.

A new drug is protected by a patent on the invention for a certain period of time (patent duration), but once the term of protection expires, several other pharmaceutical companies can manufacture and sell drugs with the same active ingredients as the new drug as generic drugs.



The path to new drug creation

In basic research, various fundamental types of testing are conducted on the properties of substances that form the basis of new drugs and their relationship to diseases. Later, their safety and effectiveness are verified through non-clinical trials 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 25,000 of all such chemical compounds are launched as new drugs. Pharmaceutical companies invest considerable time and effort to create pharmaceutical products that protect human life.

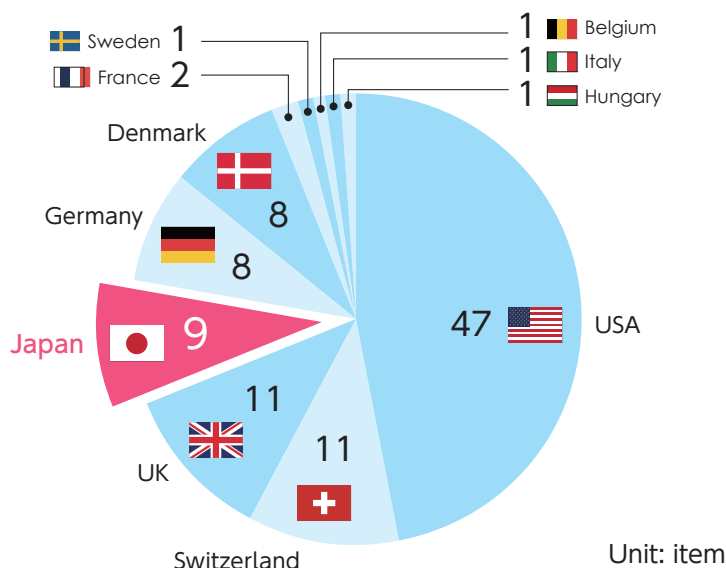


Souce: Prepared based on JPMA DATA BOOK 2023

Japan's superior drug discovery capabilities

The technology used to develop new drugs is so advanced and complex that there are only a few countries in the world that create new drugs. Among them, Japan boasts the world's fourth largest drug discovery capability. There is very stiff competition around the world for the development of new drugs. In order to continue to be one of the world's leading countries in the creation of new drugs, it is necessary for Japan to maintain ongoing research and development capabilities. JPMA's member companies will continue to engage in aggressive research and development.

**Global sales of prescription drugs:
A comparison of the top 100 by country of origin (2021)**

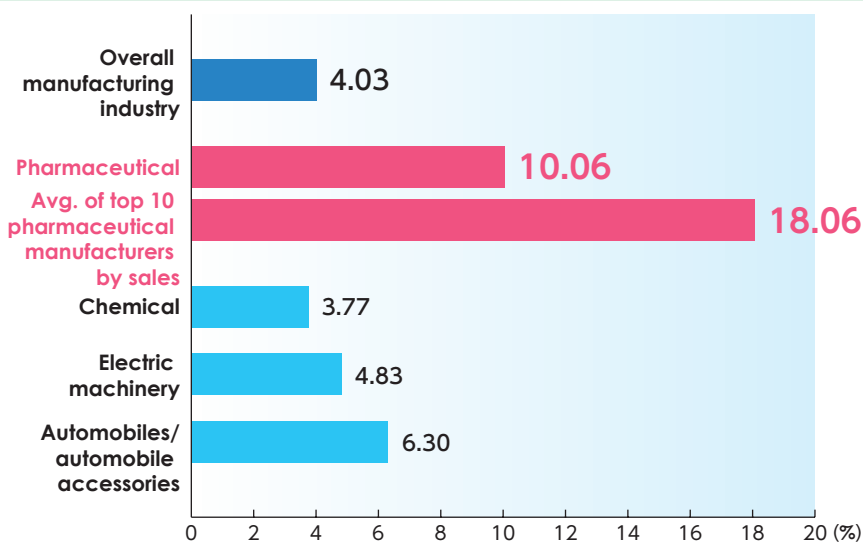


Note: The breakdown is made according to nationality of the company to which the patent(s) belong.
Source: Copyright © 2023 IQVIA. Created by OPIR based on IQVIA World Review Analyst, Data Period 2021, IQVIA Pipeline & New Product Intelligence, Pharmaprojects, EvaluatePharma, Clarivate Cortellis Competitive Intelligence (Reprinted with permission).
Reference: OPIR Views and Actions No. 67 (November 2022), JPMA

World-class R&D expenditure ratio

New drug development is characterized by a long R&D period and a low probability of success due to its difficulty. Furthermore, the pursuit of efficacy and safety for the benefit of patients requires significant research and development expenditures. Looking at the ratio of R&D expenditures to sales in the manufacturing industry, compared to 4.03% for the entire Japanese manufacturing industry, the ratio is 10.06% for pharmaceuticals and 18.06% on average for the 10 largest pharmaceutical companies, which is a very high percentage compared to other manufacturing industries.

Ratio of R&D expenses to sales in Japan by type of major manufacturing industry (2021)



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.

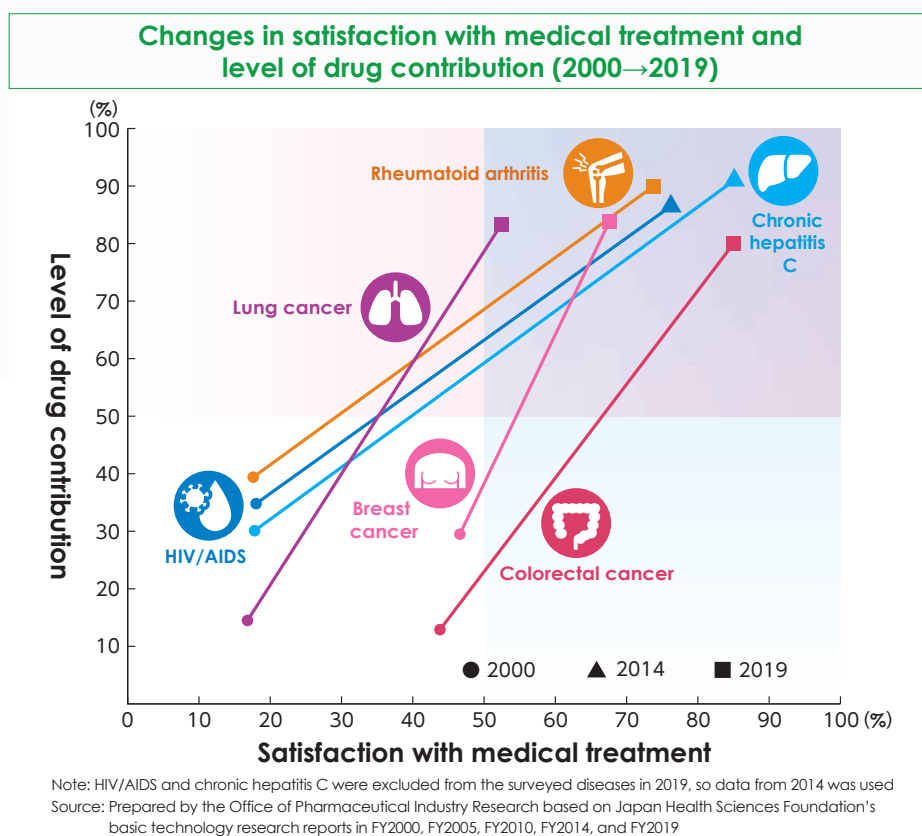
Source: "Report on the Survey of Research and Development," Ministry of Internal Affairs and Communications

Reference: Created based on "DATA BOOK 2023" by JPMA

The challenges of unmet medical needs

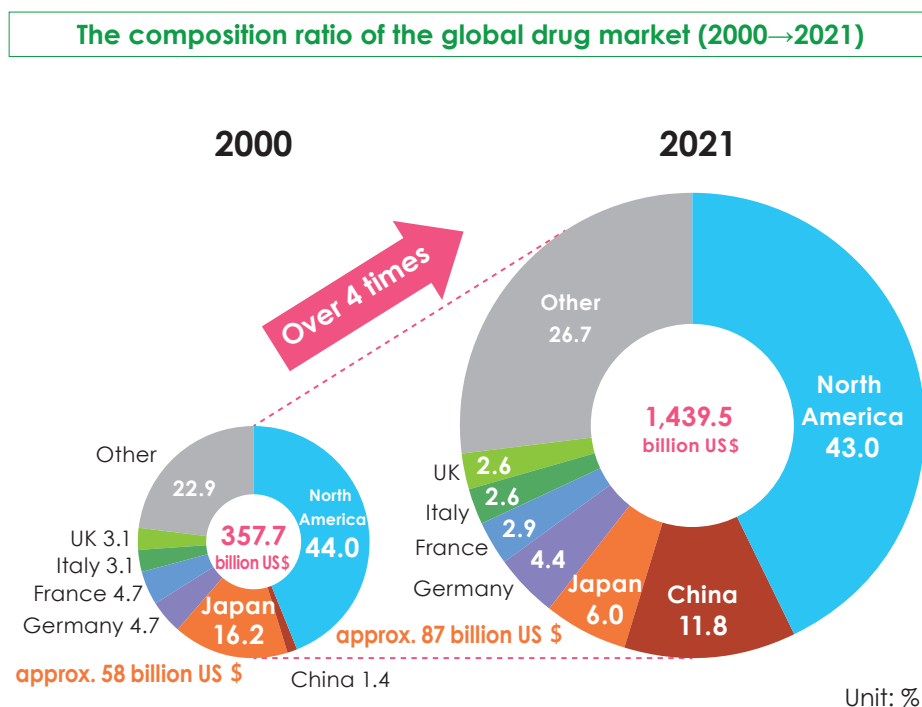
“Unmet medical needs” mean the strong demand for pharmaceutical products and medical treatment for illnesses for which there are still no established effective treatment methods. The pharmaceutical industry has contributed to improving the level of satisfaction with medical treatments through the development of innovative new drugs that meet such unmet medical needs.

In 2000, there were many diseases, for which new pharmaceuticals were expected to be effective, with few decisive treatments. 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.



A global view of Japan's drug market size

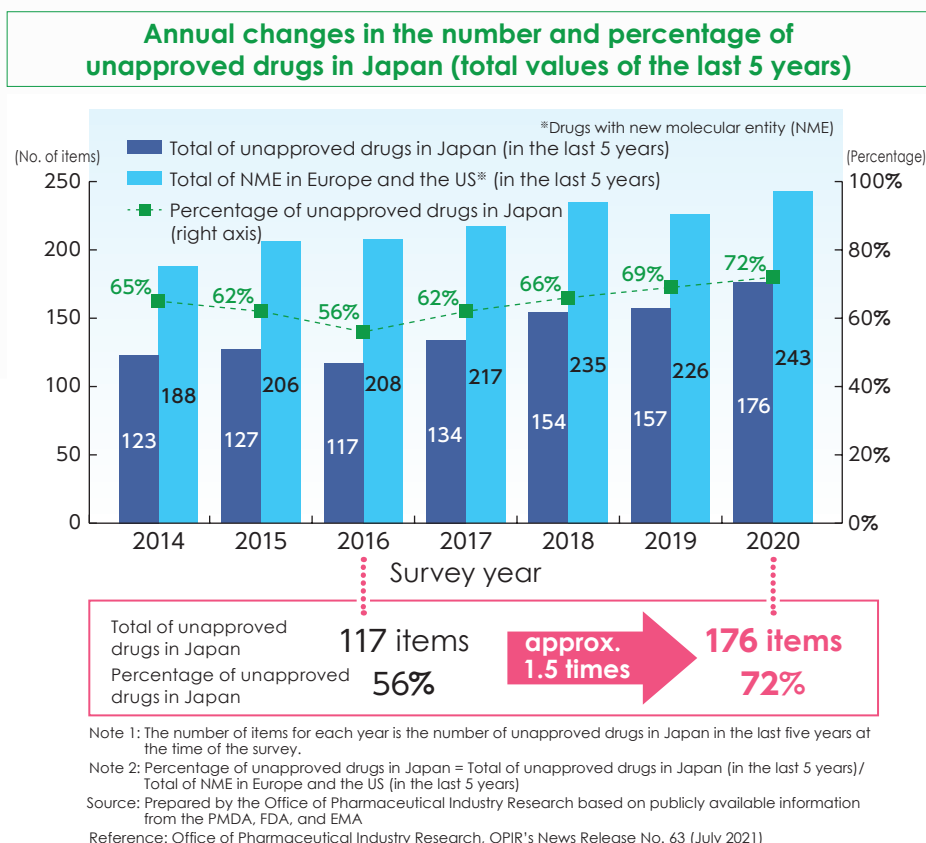
In the 22 years from 2000 to 2021, the global drug market grew to more than four times in size. However, the Japanese market has seen close to zero growth and was consequently knocked from its previous secondary position behind the North American market to third place in 2013 after being overtaken by the Chinese market. 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.



Note: The values represent changes in the shares of total market prices in each year in the above graph as 100% of total market prices
Source: Copyright © 2023 IQVIA. Prepared by the Office of Pharmaceutical Industry Research based on IQVIA World Review, Data Period-Year 2000-2021 (Reprinted with permission)

Increasing number of unapproved drugs in Japan

The number of unapproved drugs in Japan, which are approved in Europe and the US but not in Japan, has been increasing since the late 2010s. Compared to 2016, when the number of unapproved drugs was the lowest in recent years, the most recent number of unapproved drugs in Japan at the end of 2020 was 176, an increase of approximately 1.5 times. Unapproved drugs in Japan include drugs that are considered clinically important in Europe and the U.S. and drugs for rare diseases, and there is concern that this may lead to a drug lag in Japan compared to other countries and drug loss, where development itself is not conducted in Japan.



3 major infectious diseases and Neglected Tropical Diseases

The three major infectious diseases, HIV/AIDS, tuberculosis, and malaria, still claim more than 2.5 million lives each year, mainly in developing countries. Neglected tropical diseases are referred to as such because they are infectious diseases caused by parasites and bacteria that are widespread mainly in tropical and subtropical regions and have not been considered major diseases by developed countries. These infections not only lead to economic deprivation for individuals, but also contribute to poverty in the country or the entire region. In collaboration with international organizations, member companies of the JPMa are working on various initiatives to eradicate these infectious diseases including the development of therapeutic drugs.

3 major infectious diseases and Neglected Tropical Diseases

Endemic in 149 countries and regions/Over 1 billion patients (WHO)
 Billions of dollars in damage to developing countries each year

3 major infectious diseases

**HIV/AIDS
tuberculosis
malaria**

Neglected Tropical Diseases

20 diseases (defined by WHO as of March 2023)

Dengue fever, rabies, trachoma, Buruli ulcer, Treponema infection, leprosy, Chagas disease, sleeping sickness, leishmaniasis, cysticercosis, Guinea worm infection, encrustation, food-borne insect infections, lymphatic filariasis, river blindness, schistosomiasis, soil-borne parasitosis, mycetoma, scabies, snakebite

Goal 3 (Target 3.3) of the SDGs calls for the eradication of these infectious diseases by 2030

Ensuring more accurate understanding of pharmaceutical products and the pharmaceutical industry

Website

The website of the JPMA provides timely information on drugs and the pharmaceutical industry, and messages from JPMA. The website of the Office of Pharmaceutical Industry Research (OPIR) regularly publishes research and survey results through the OPIR news and research papers.

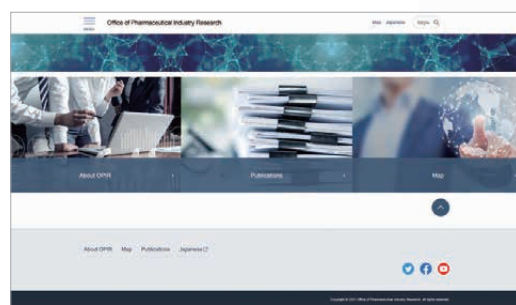
The Japan Pharmaceutical Manufacturers Association (JPMA)

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



Office of Pharmaceutical Industry Research (OPIR)

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



About Drugs Drug Guide for the General Public

Drug Information Q&A

"Drug Information Q&A" is posted to encourage patients and the general public to use drugs correctly. The website shows information on drugs in a 55-question Q&A format, from the history of drugs in Chapter 1 to the social contribution of the pharmaceutical industry in Chapter 7. For example, Q9 "Why are there various types of drugs, such as oral and injectable drugs?" and Q27 "Can food affect drugs?" The website is full of drug information you need to know in your daily life.



JPMA's cheering ambassador
Capsule-kun

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.



List of Facilities to Visit

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



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 began disseminating information via Twitter in February 2022. We provide information on news and initiatives from JPMA, as well as monthly updates on topics related to health and disease.



YouTube

<https://www.youtube.com/@Seiyakukyou>

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."



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



"Discover the Experience" pharmaceutical industry project for university students

<https://www.jpma.or.jp/lp2/>

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.

Connection with Stakeholders

The JPMA is committed to disseminating information on pharmaceuticals and the pharmaceutical industry to a wide range of stakeholders in order to deepen their understanding of the industry.



JPMA-sponsored lectures

Policy Seminar

Information dissemination in cooperation with government and academia

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.

Intellectual Property Forum (IP Forum)

Exchange of opinions on intellectual property with experts

The IP Forum is held to exchange opinions with a wide range of experts and stakeholders on various issues related to intellectual property in order for the pharmaceutical industry to continue to develop in the international community, and to disseminate and implement various proposals of the JPMA regarding intellectual property.

International Conference

Asia Partnership Conference of Pharmaceutical Associations (APAC)

Improving Challenges for the People of Asia

APAC is an international conference led by the JPMA with the aim of improving access to innovative new drugs for the people of Asia. Representatives of Asian pharmaceutical-related organizations under the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), regulatory authorities and academia in Asian countries work together to recognize issues and make proposals in the international conference.



JPMA's Publications

JPMA publishes publications such as "Textbook", an introduction booklet on the pharmaceutical industry to deepen proper understanding of pharmaceuticals, and "Survey on People's Attitudes toward Drugs and the Pharmaceutical Industry," as well as the "JPMA Newsletters," which provide information on the activities of the JPMA in an easy-to-understand way.

"Textbook", an introduction book on the pharmaceutical industry

As an introduction to understanding the pharmaceutical industry, this booklet provides an easy-to-understand overview of what medical products are, the drug discovery process, the healthcare system, the contributions and challenges of the pharmaceutical industry, an overview of the Japanese and global pharmaceutical industry, and the environment surrounding the development and approval of new drugs.



"Survey on People's Attitudes toward Drugs and the Pharmaceutical Industry", a report

This is a report on the opinions of people living in Japan and an awareness survey to ascertain the progress of the activities of the JPMA. The survey began in 1996 and has continued annually since 2014. In addition to items related to people's health and their relationship with drugs and medical care, the survey also shows questionnaires about their level of trust in the pharmaceutical industry, their image of the industry, and their awareness of its activities.

JPMA Newsletter

https://www.jpma.or.jp/news_room/newsletter/

It is the JPMA's bimonthly newsletter. It provides easy-to-understand coverage of topics such as presidential press conferences, JPMA-sponsored lectures, and events.



Environmental Measures in the Pharmaceutical Industry

The pharmaceutical industry is actively engaged in global environmental protection measures to achieve a sustainable society.

(1) Reduction of environmental impacts

The production of pharmaceuticals is increasing every year. We are committed to reducing our environmental impact to minimize the environmental impact of our pharmaceutical industry's business activities. With regard to greenhouse gas emissions, we are actively working to reduce CO₂ emissions by improving the efficiency of our production activities, introducing high-efficiency equipment, and switching to energy sources that emit less carbon dioxide (CO₂). For the various chemicals used in R&D and production of pharmaceuticals, we are continuing our efforts to reduce chemical emissions into the environment by installing exhaust gas purification systems and adopting safer chemicals.

(2) Environmental measures for containers and packaging

As part of our environmental measures, we are focusing on all aspects of drug containers and packaging, including simplification, use of recycled paper, and adoption of structures and labeling that facilitate waste sorting.





Contributing Society with New Pharmaceuticals

Japan Pharmaceutical Manufacturers Association (JPMA)

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