

Japan Pharmaceutical Manufacturers Association

# -JPMA's Vision for 2035 "Delivering Pharmaceutical Innovations Domestically and Globally"

Realizing this Vision with Patient and Public Involvement and Engagement



# Consistently produce innovations to benefit health spans and the economy

- Pharmaceutical innovations
   Leading-edge scientific technology
- Pharmaceutical manufacturing technology
   Domestic manufacturing infrastructure
   Making Japan a science and technology powerhouse
- Fostering highly skilled talent
   PPI/E\*
   Drug discovery that involves patients and the public
   Co-creation
   Drug discovery ecosystem
- Job creation
   Extending health spans
   Well being
- Pharma as a core industry
   Economic growth



## Bring innovative new drugs to the public more quickly to enhance health security

- A social security system that gives patients swift access to "the latest treatments" and stable access to "global-standard treatments"
- Positive investment cycle
   Building an attractive domestic market
- Drug pricing that properly factors in the worth of innovation
- Health security for Japan



# Commit to ethical conduct and transparency to foster trust in the pharma industry

- Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages)
   Overcome the social challenges raised by Japan's aging population
   Ethical soundness, code of behavior, and transparency
   Boost public literacy in health and medicine
- Social significance of pharmaceuticals and the pharma industry
- Encourage the public and younger people to enter the pharma industry
- Climate change
   Environmental issues

\*PPI/E (Patient and Public Involvement/Engagement)

#### Introduction

Working under a banner that reads "Toward Healthcare with Public Participation," the Japan Pharmaceutical Manufacturers Association (JPMA) is engaged in activities to create innovative new drugs and deliver them to people everywhere as it works to fulfill its mission to "Contribute to Improving the Health and Welfare of People Worldwide."

Society, the economy, medicine, and science have changed markedly since the JPMA released its Vision for 2025 back in 2016. Accelerating globalization has increased the pharmaceutical industry's ability to deliver innovative new drugs to the world but also lowered national barriers to infection, thereby increasing the pace of COVID-19 infections and bringing suffering to humanity. The materialization of geopolitical risks has convinced countries the world over of the need for health and healthcare security. The industry is facing new challenges such as the need to secure supply chains and rethink the locations of research and manufacturing sites as peacetime preparedness for diverse contingencies.

Shifting the focus to Japan, the accelerating decline in the working-age population and sluggish economic growth caused by the country's rapidly aging population will further exacerbate the already difficult situations of rising social security costs and securing funding. Ensuring that the country's social security system remains sustainable is therefore an urgent priority. The decline in Japan's drug discovery capabilities, evidenced by reliance on foreign sources for biopharmaceuticals and other innovative drugs, coupled with eight years of drug price cuts and innovation-stifling policies, have made the Japanese market less attractive. The emerging social challenges of ensuring stable pharmaceutical supply and addressing drug lag and loss are intensifying the increasingly harsh environment surrounding the pharmaceutical industry on an almost daily basis.

Despite these changes, the Japanese economy is finally springing back from two decades of deflation to revert to inflationary growth. Against this backdrop, the Japanese government in 2024 designated the pharmaceutical industry as a core industry capable of driving economic growth, recognizing it to be "a value-added" and "knowledge-intensive" industry that leverages leading-edge basic and applied research and digital technologies across its entire value chain from R&D to manufacturing and distribution. The pharmaceutical industry finds itself at a major turning point marked by expectations for the industry, commitments to its development, and signs of a shift towards policies that value innovation.

Japan must avoid a future in which the public is unable to benefit from innovative new drugs and healthcare as a consequence of "declining international competitiveness in the life science industry and academic research capabilities", "the consequent decrease in the ability to create innovative new drugs", and "stagnation in the domestic development of innovative drugs from outside the country".

The JPMA aims to make the pharmaceutical industry a core industry of Japan committed to 'improving the health and well-being of patients and the public', 'ensuring health security', and 'growing the national economy'. This can be achieved by collaborating with patients, the public, and the government under a patient-centered "Co-creation" approach to develop innovative new drugs and reliably deliver them to the patients who need them.

With the conviction that innovative new drugs will help bring about a society where everyone can live healthy and active lives, we will strive to achieve the JPMA Industry Vision 2035 and work for the future of people young and old.

#### Delivering Pharmaceutical Innovations Domestically and Globally

## 1: Consistently produce innovations to benefit health spans and the economy

- Rapidly adopt and apply leading-edge scientific technologies so that innovative new drugs can be consistently developed
- ◆ Build a domestic infrastructure to manufacture pharmaceuticals to advance Japan's ability to create
- ◆ Help foster highly skilled talent domestically so that Japan can be a science and technology powerhouse
- ◆ Proceed with a "Co-creation" approach to lead to drug discovery that involves patients and the public
- ◆ Build and develop a drug-discovery ecosystem to broaden the footprint of life science-related industries overall
- ◆ Contribute as a core industry to Japan's economic growth by advancing the global roll-out of innovative new drugs, contributing to the health of people worldwide, boosting exports, and expanding tax revenue

## 2: Bring innovative new drugs to the public more quickly to enhance health security

- ◆ Pursue value in innovation and propose the building of an attractive Japanese market that appreciates this value so that innovative new drugs can be consistently created and delivered
- ◆ Propose a social security system that gives patients swift access to "the latest treatments" and stable access to "global-standard treatments" into the future
- ◆ Engage in discussions with the government, insurers, and healthcare professionals to play a role in Japan's health security

## 3 : Commit to ethical conduct and transparency to foster trust in the pharma industry

◆ Help overcome the social problems that population aging causes by working toward Sustainable Development Goal 3 (Ensure healthy lives and promote wellbeing for all at all ages) and further adding value

- ◆ Endeavor to operate with ethical soundness, a code of behavior, and transparency to earn the trust of society
- ◆ Work with stakeholders to help boost public literacy in health, medicine, and science so that the public is able to use drugs appropriately
- ◆ Continue communicating with the public so that society appreciates the social significance of pharmaceuticals and the pharmaceutical industry and children and younger people who will lead the next generation are motivated to work in the pharmaceutical industry, academia, and clinical settings
- ◆ Engage in efforts to counter climate change and other environmental issues that threaten health to help bring about a sustainable society

## 1: Consistently produce innovations to benefit health spans and the economy

Pharmaceutical innovation refers to creating innovative new drugs that provide solutions for diseases without any or sufficient treatments, thereby benefiting people's health, safety, and well-being. Creating innovative new drugs requires a well-developed foundation and world-class standards to support all drug discovery processes—from basic research to applied research, manufacturing, clinical trials, and post-market clinical application. To achieve this, pharmaceutical companies must quickly adopt cutting-edge science and technology—such as new modalities, digital transformation, health and medical big data, AI, omics analysis of human biological samples, and quantum computing—to better their chances of discovering new drugs and their rate of discovery. Companies must also develop their drug discovery environments and build innovative platform technologies.

Many innovative new drugs require complex manufacturing processes to reach patients as safe and effective products. Japan is increasingly relying on foreign pharmaceutical manufacturing due to changes in modalities and cost considerations. As pharmaceutical manufacturing is a key component of security, a system that allows pharmaceuticals to be manufactured from start to finish in Japan is urgently needed. Manufacturing is a sector where Japan has traditionally excelled. The JPMA is actively involved in the revitalization and advancement of Japan's pharmaceutical manufacturing system through innovation in pharmaceutical manufacturing technology and the building of a domestic manufacturing base.

We will also guide pharma, as a knowledge-intensive industry, toward advancing science and fostering the skilled talent to support it to put Japan on the path to becoming a science and technology powerhouse.

The JPMA is convinced of the need to shift the focus of drug-discovery R&D even further from the perspective of producers to that of patients and the public to better meet individual patient needs. Patients must be willing to proactively provide data and participate in clinical trials if innovative new drugs are to be created in this manner. That's why the JPMA aims to bring about 'patient and public participatory drug discovery' under the concepts of PPI/E (patient and public involvement/engagement) and co-creation.

With the goal of bringing about pharmaceutical innovations, the JPMA will enhance 'the drug-discovery ecosystem' by fostering organic and multifaceted partnerships with the government, academia, related industries, investment institutions, patients, and the public and by promoting international cooperation and the harmonization of regulations governing R&D. To this end, we will advance the development of domestic

R&D systems and open innovation activities. These efforts will expand the footprint of life science-related industries, contributing to job creation and domestic industrial promotion.

These activities will allow JPMA member companies to create and offer innovative new drugs in Japan and globally, which will "extend health spans" and "improve well-being" for people everywhere. This will also boost Japan's economic growth through increased tax revenue and the acquisition of revenue from other countries through exports and intellectual property income. Finally, the JPMA seeks to make the pharmaceutical industry a presence recognized by society as a core industry that supports the country.

### 2: Bring innovative new drugs to the public more quickly to enhance health security

Health is a universal desire of humans, and pharmaceuticals are essential for treating disease. Every ill patient needs access to the drugs they require and to be able to use them appropriately.

Recent therapeutic advances, driven by new modalities, are accelerating approaches to previously untreatable or insufficiently treated diseases. A framework for a more effective social security system will be key to ensuring that patients have swift access to these "latest" treatments and stable access to "global-standard" treatments built on clinical evidence. Working toward this framework, we will invite patients, the public, and the government to participate with us in outside-the-box discussions on how medical insurance should be financed and how insurance benefits and payments should be structured to align them with scientific and technological advancements and the industrial growth those advancements bring.

To consistently generate innovative new drugs and bring them to the public, Japan needs "an attractive market" that fosters a positive investment cycle in drug discovery and attracts overseas investment. For this, we propose a regulatory system that gives patients quick access to innovations and a drug pricing system that fairly values innovation.

Other issues we face include political and social challenges such as supply chain problems and supply disruption sparked by geopolitical risks and global pandemics. We are committed to resolving these issues by earnestly discussing, proposing, and advancing solutions with stakeholders including the government, insurers, and healthcare professionals. These solutions will help bring innovative new drugs to the public in both peacetime and times of crisis, contributing to Japan's health security.

## 3 : Commit to ethical conduct and transparency to foster trust in the pharma industry

To fulfill their responsibilities, the JPMA and its member companies will provide appropriate information on pharmaceuticals and engage in sound, transparent business activities based on their social commitments, which include creating innovative new drugs, ensuring environmental health and safety, contributing to the economy and social security.

The public needs proper knowledge and understanding of medicine and pharmaceuticals to use drugs properly. The JPMA will work with stakeholders to promote activities that lead to this knowledge and understanding, such as initiatives to improve public literacy in health, medicine, and science.

Japan is partnering with other countries and international organizations to advance efforts to improve global health, achieve universal health coverage, and counter infectious diseases and antimicrobial resistance. As an association of Japan-based R&D companies, the JPMA will work with the government and international organizations to advance these efforts and help achieve Sustainable Development Goal 3: "Ensure healthy lives and promote well-being for all at all ages." Japan needs stable and ongoing growth in the face of rapid population aging and decline, and the pharmaceutical industry can help overcome social issues by providing innovative new drugs to alleviate labor shortages, reduce the burden of medical and long-term care caused by disease and aging, and enhance productivity and added value.

The pharmaceutical industry will gain public trust only if more people understand not only pharmaceuticals and how to use them properly but also the activities of the pharmaceutical industry and companies, such as drug discovery. The JPMA will provide opportunities for fruitful communication with diverse stakeholders, including patients and the public, in compliance with laws and regulations. In providing these opportunities, we will ensure that the public, and particularly children and younger people who will lead the next generation, appreciate the potential of drug discovery and are motivated to participate as stakeholders.

All industries have a responsibility to address climate change, the serious impact it has on human health, and emerging environmental challenges even as they maintain their routine economic activities. JPMA member companies are promoting tailored initiatives to address environmental issues, such as those for safely managing chemicals and recycling plastics and other resources. They will come together as an

industry to help make society sustainable.

These efforts will make Japanese pharma an industry trusted and valued by all stakeholders and whose practices and initiatives are respected outside the country.

#### Conclusions

The JPMA and its member companies will remain committed to JPMA's Vision for 2035 in their committee activities, policy proposals and other external communication, and corporate activities. Our work will help realize the vision of "Delivering Pharmaceutical Innovations Domestically and Globally" and better the health and welfare of people worldwide.

#### JPMA 70 Member Companies

AbbVie GK

Alfresa Pharma Corporation

Amgen K.K

ASAHI KASEI PHARMA CORPORATION

ASKA Pharmaceutical Co.,Ltd.

Astellas Pharma Inc.

AstraZeneca K.K.

BAYER YAKUHIN, LTD.

Biogen Japan Ltd.

Bristol-Myers Squibb K.K.

CHUGAI PHARMACEUTICAL CO., LTD.

DAIICHI SANKYO CO., LTD.

EA Pharma Co., Ltd.

Eisai Co., Ltd.

ELI LILLY JAPAN K.K.

Fuji Pharma Co., Ltd.

FUJIFILM Toyama Chemical Co., Ltd.

FUJIMOTO PHARMACEUTICAL CORP.

FUSO PHARMACEUTICAL INDUSTRIES, LTD.

 ${\sf GlaxoSmithKline~K.K.}$ 

Hisamitsu Pharmaceutical Co.,Inc

JANSSEN PHARMACEUTICAL K.K.

JCR Pharmaceuticals Co., Ltd.

KAKEN PHARMACEUTICAL CO., LTD.

KISSEI PHARMACEUTICAL CO., LTD.

KM Biologics Co.,Ltd.

Kowa Company, Ltd.

Kracie,Ltd.

KYORIN Pharmaceutical Co.,Ltd.

KYOTO PHARMACEUTICAL INDUSTRIES, LTD.

Kyowa Kirin Co., Ltd.

MARUHO CO., LTD.

MARUISHI PHARMACEUTICAL CO., LTD.

Meiji Seika Pharma Co., Ltd.

Merck Biopharma Co., Ltd.

MITSUBISHI TANABE PHARMA CORPORATION

MOCHIDA PHARMACEUTICAL CO., LTD.

MSD K.K.

NIPPON BOEHRINGER INGELHEIM CO., LTD.

NIPPON CHEMIPHAR CO., LTD.

NIPPON KAYAKU CO., LTD.

NIPPON SHINYAKU Co., Ltd.

NIPPON ZOKI PHARMACEUTICAL CO., LTD.

NOVARTIS PHARMA K.K.

NOVO NORDISK PHARMA LTD.

ONO PHARMACEUTICAL CO., LTD.

OTSUKA PHARMACEUTICAL Co., Ltd.

PFIZER JAPAN INC.

THE RESEARCH FOUNDATION FOR MICRO-BIAL DISEASES OF OSAKA UNIVERSITY

Sanofi K.K

SANTEN PHARMACEUTICAL CO., LTD.

SANWA KAGAKU KENKYUSHO CO., LTD.

SEIKAGAKU CORPORATION

SENJU PHARMACEUTICAL CO., LTD.

SHIONOGI & CO., LTD.

Sumitomo Pharma CO., LTD.

Sun Pharma Japan Ltd.

TAIHO PHARMACEUTICAL CO., LTD.

TAISHO PHARMACEUTICAL CO., LTD.

TAKEDA PHARMACEUTICAL COMPANY LIMITED

TEIJIN PHARMA Limited

TEIKOKU SEIYAKU CO., LTD.

TOA EIYO LTD.

Toray Industries, Inc.

TORII PHARMACEUTICAL CO., LTD.

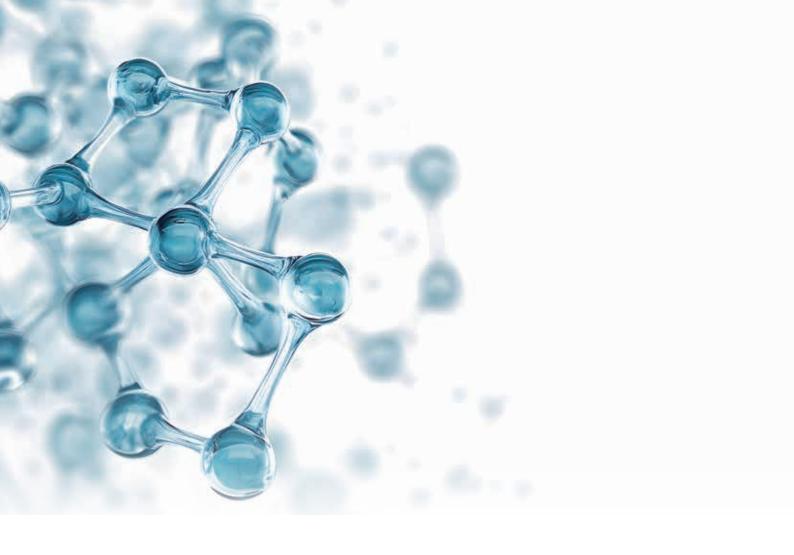
TSUMURA & Co.

UCB JAPAN CO., LTD.

Viatris Pharmaceuticals Japan G.K.

WAKAMOTO PHARMACEUTICAL CO., LTD.

ZERIA PHARMACEUTICAL CO., LTD.





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