

Contact Information

[MHLW]

A1

Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management, Health Policy Bureau, Ministry of Health, Labour and Welfare, Japan

Email: yakka-soudan@mhlw.go.jp

URL:

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/iryuu/shinkou/index.html (Japanese Only)

A2

Research and Development Policy Division, Health Policy Bureau, Ministry of Health, Labour and Welfare, Japan

Email: souyaku-soudan@mhlw.go.jp

URL: <https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/chiken.html> (Japanese Only)

[PMDA]

B1

Pharmaceuticals and Medical Devices Agency (Office of Review Management, Office of International Strategy and Planning)

Email: rs-contact@pmda.go.jp

URL: <https://www.pmda.go.jp/english/int-activities/industry/0001.html>

B2

Pharmaceuticals and Medical Devices Agency (Washington D.C. Office)

Email: Consultation@dc-office.pmda.go.jp

URL: <https://www.pmda.go.jp/english/int-activities/overseas-office/dc/0001.html>

[AMED]

C

Division of Medical Ecosystem Development, Department of Medical Innovation Ecosystem, Japan Agency for Medical Research and Development

Email: v-eco@amed.go.jp

URL: <https://www.amed.go.jp/en/program/list/19/02/005.html>

[JETRO]

D

Investment and Alliance Div., Innovation Dept., Japan External Trade Organization

Email: IVE@jetro.go.jp

URL: <https://www.jetro.go.jp/en/invest/>
<https://www.jetro.go.jp/en/j-bridge.html>

[MEDISO]

E

Medical Innovation Support Office (Initiative of MHLW)

Email: mediso@ml.mri.co.jp

URL: <https://mediso.mhlw.go.jp/en>



対日投資(日)



協業連携(日)



Start in Japan, Transform Global Healthcare

Key Messages

[MHLW]

- We are implementing appropriate drug pricing assessment that balances reducing the public burden with encouraging pharmaceutical innovation.
- Japan is one of the world's leading pharmaceutical markets; however, regulatory frameworks, the drug pricing system, and clinical trial in Japan - pose significant barriers for emerging biopharma (EBP) companies and biotech startups seeking to enter the market. By consulting with ENSEMBLEJ, companies can receive comprehensive support for expanding their business into Japan.

[PMDA]

- PMDA, Japan's pharmaceutical regulatory authority, provides regulatory support to overseas startups and venture companies seeking to conduct pharmaceutical development in Japan.
- Through consultations at Washington, D.C. Office and Tokyo headquarters, PMDA provides clear and practical guidance of Japan's regulatory requirements and development processes.

[AMED]

- Most new drugs in recent years have been developed by pharmaceutical startups, and it is difficult to secure the necessary development funds smoothly in Japan's pharmaceutical startup ecosystem compared to Europe and the United States.
- In response to this situation, under the "Strategy for Strengthening Vaccine Development and Production Systems" approved by the Cabinet in June 2021, this Program was established to support pharmaceutical startup companies engaged in the commercialization and development of technologies related to vaccines and therapeutics for infectious diseases. Furthermore, in October 2022, the "Priority Issues in a Comprehensive Economic Package regarding the Implementation of the "Grand Design and Action Plan for a New Form of Capitalism" included the following statement regarding this Program: "Going forward, it will enhance support for drug discovery startups by expanding support eligibility to drug discovery fields other than infectious diseases and which face difficult in raising funds".

[JETRO]

- Leveraging a network of approximately 130 offices worldwide, JETRO supports overseas companies to expand their business in Japan and foster innovation through collaboration and partnership with Japanese companies.
- Positioning the life sciences sector, including regenerative medicine, as one of our strategic priority area, we are in focus of strengthening support initiatives.

[MEDISO]

- MEDISO is an initiative by Japan's MHLW aimed at supporting medical startups. Experts from various fields provide free consultations to researchers and startups seeking to commercialize pharmaceuticals, medical devices, and regenerative medicine products and expand into the Japanese market.
- Consultations are available in English and free of charge. Through one or two online meetings, experts from diverse fields address questions and concerns related to entering Japan, including regulatory affairs, reimbursement, and clinical development.



ひと、暮らし、みらいのために
厚生労働省
Ministry of Health, Labour and Welfare



JETRO
Japan External Trade Organization



国立研究開発法人 日本医療研究開発機構
Japan Agency for Medical Research and Development



MEDISO
Medical Innovation Support Office

Japan's Government Systems and Support Measures

Basic and Applied Research

Non-clinical Studies

Clinical Trials

Regulatory Review and Approval

Reimbursement Coverage

Manufacturing and Marketing

[JETRO Invest Japan / J-Bridge] **Permanent**
Support from around 130 offices worldwide
Market/Regulatory information, Expert consultation(incorporation, tax, social security), connection with local governments and ecosystems, business arrangements with Japanese companies(J-Bridge) etc.



D

[MEDISO One-spot Consulting(MEDISO)]
MEDISO experts from various fields provide free consultation to researchers and startups aiming to commercialize pharmaceuticals, medical devices, and regenerative medicine products who are seeking to enter the Japanese market.

E

[Japan Entry Acceleration Program]
An acceleration program designed for overseas companies aiming to expand business base in Japan and build collaborations with Japanese corporations, universities, and research institutions.



D

[PMDA Washington D.C. Office]
The office provides startups and venture companies without a base in Japan with information on Japanese regulations, including approval reviews and post-marketing safety measures. It also offers free general consultation services in English for development in Japan. The office supports procedures for formal consultations at PMDA in Tokyo.



B2

[PMDA Scientific Consultation]
PMDA offers a framework for scientific consultation on study design and data interpretation with regulatory experts at every stage of drug development. By engaging in direct scientific dialogue with PMDA reviewers, developers can proactively address potential regulatory concerns. This process helps to enhance the predictability of the development pathway. PMDA also provides a dedicated consultation track specifically tailored for early-stage development (prior to Proof of Concept (POC)), particularly for academia and startups.

B1

[Strengthening Program for Pharmaceutical Startup Ecosystem]
This Program registers venture capitals (VCs) that provide hands-on commercialization support specializing in drug discovery, and supports the development and commercialization carried out by Japanese Pharmaceutical Startups in the development stage of non-clinical, phase 1, phase 2, or exploratory clinical trials, with the requirement of investment by the registered VCs (Hereinafter referred to as "Registered VC".), thereby raising the foundation of Japan's pharmaceutical startup ecosystem. In particular, we will actively support commercialization plans in overseas markets in addition to Japan in order to achieve sufficient sales and growth.

C

[Project for Establishing Infrastructure for First-in-Human Trials for New Modalities]
To develop an internationally competitive FIH trial framework that can support emerging and innovative therapeutic modalities.

A2

[Drug Price System] **A1**
• **Patent-Period Price Maintenance Program for Innovative Drugs**
Drug prices are maintained for up to 15 years.
• **60-90 Day Rule Insurance coverage**
In principle, within 60 days, and at the latest within 90 days, after regulatory approval.
• **Clear Drug Price Calculation Rules**
The standards for calculating drug prices are explicitly specified, resulting in high predictability of price calculation.

["ENSEMBLExJ" - the One-Stop Service Platform for Global Biotech] **A2**
This project is intended for overseas biotech companies without a development presence in Japan.
(1) Proactive support through cross sector collaboration between industry, government, and academia for these companies, (2) Helping these companies enter the Japan market by offering development strategy as well as business expansion opportunity.

[SAKIGAKE Designation] **B1**
Support to put innovative products rapidly into medical practice in Japan
<Incentives>
(1) Concierge service offered by senior review partner, (2) Priority scientific consultation and Priority review, (3) Premium drug pricing, (4) Extension of marketing exclusivity period

[Orphan Drugs Designation] **B1**
Promote the R&D of the products for rare diseases to provide the patients with safe and effective medicines as early as possible
<Incentives>
(1) Grant-in-Aid for R&D, (2) Tax deduction for R&D expenses, (3) Priority scientific consultation and Priority review (incl. fee reduction), (4) Premium drug pricing, (5) Extension of marketing exclusivity period

[Considerations on Japanese Phase 1 Study for MRCT Participation] **B1**
For drugs with prior clinical development overseas, participation in Multi-Regional Clinical Trials (MRCTs) without prior local studies in Japan is possible in principle, provided that the following is appropriately explained:
• Scientific Justification: The safety and tolerability of the drug for Japanese participants under the MRCT dosing regimen are clinically acceptable and manageable based on available data.

[Conditional approval of Drugs] **B1**
Aims to accelerate patient access to highly necessary medicines for serious, life-threatening diseases without effective existing therapies. Under this system, products may be granted approval based on evidence of efficacy and safety from non-confirmatory clinical trials. Approval is contingent upon post-marketing commitments to conduct further surveillance or studies to verify clinical benefit and safety of the drug. This pathway may be available even when clinical data specifically for the Japanese population is unavailable or limited, provided that the overall scientific evidence support the product's value.