独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Regulatory updates in Japan

日本藥品･醫療器械等監管更新

Daisuke TANAKA, Ph.D.
Office Director, Office of International Program
Pharmaceuticals and Medical Devices Agency, Japan

獨立行政法人
醫藥品醫療機器綜合機構

國際部長
田中 大祐

7 October 2024
12th Joint Conference of Taiwan and Japan on Medical Products Regulation

2024年10月7日
第十二屆台日醫藥交流會議

Today's contents

1. PMDA celebrates 20 years

2. Activities to introduce innovative product quickly in Japan
   (1) Global trend of pharma development
   (2) Japan's regulatory activities
   (3) Strengthening information dissemination

3. PMDA's Overseas Offices and others

Today's contents

1. PMDA celebrates 20 years

2. Activities to introduce innovative product quickly in Japan
   (1) Global trend of pharma development
   (2) Japan's regulatory activities
   (3) Strengthening information dissemination

3. PMDA's Overseas Offices and others

PMDA Enters a New Stage on its 20th Anniversary

April, 2004

- Started with 3 main services, Relief Services for Adverse Health Effects, Product Reviews and Post-marketing Safety Measures
- Organization with about 250 people

2014

- Initiative to eliminate drug lag or device lag
- Strengthening safety measures
- Prompt relief services for adverse health effects

April, 2024

While connecting with all around the world, realizing a world where everyone lives vividly and healthily

New start of PMDA

- Organization with more than 1000 people
- Every staff faces PMDA's Purpose in their work

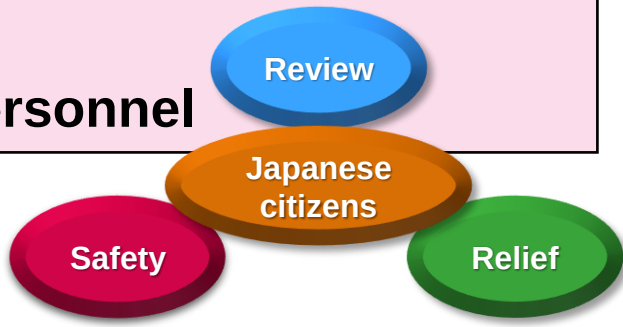
PMDA's Purpose

Making everyone's lives brighter together

We, PMDA, continue to create "Tomorrow's Normal" together,
as a "life platform" that supports everyday life,
where everyone can feel peaceful and can lead vibrant and healthy lives
by PMDA's "Safety Triangle" of review, safety and relief,
with "intelligence" weaved through science and information, and
with "human resourcefulness" accompanying
and bringing the world and the future into harmony.

Direction for 5th Mid-term plan FY2024-2028

- **Enhancement of further "Quality" of PMDA works through Regulatory Science**
  - **Enhancement of consultation/review** for pharmaceuticals etc. *to cope with the innovative products in the world*
  - **Proper follow-up of safety measures**
  - **Establishment of emergent response system** such as pandemics
- **Promotion of strategic international activities**
  - **Strengthen regulatory support / Disseminate regulatory information** to overseas companies *to develop innovative products and to seek the development in Japan*
- **Strengthening governance and professional personnel**



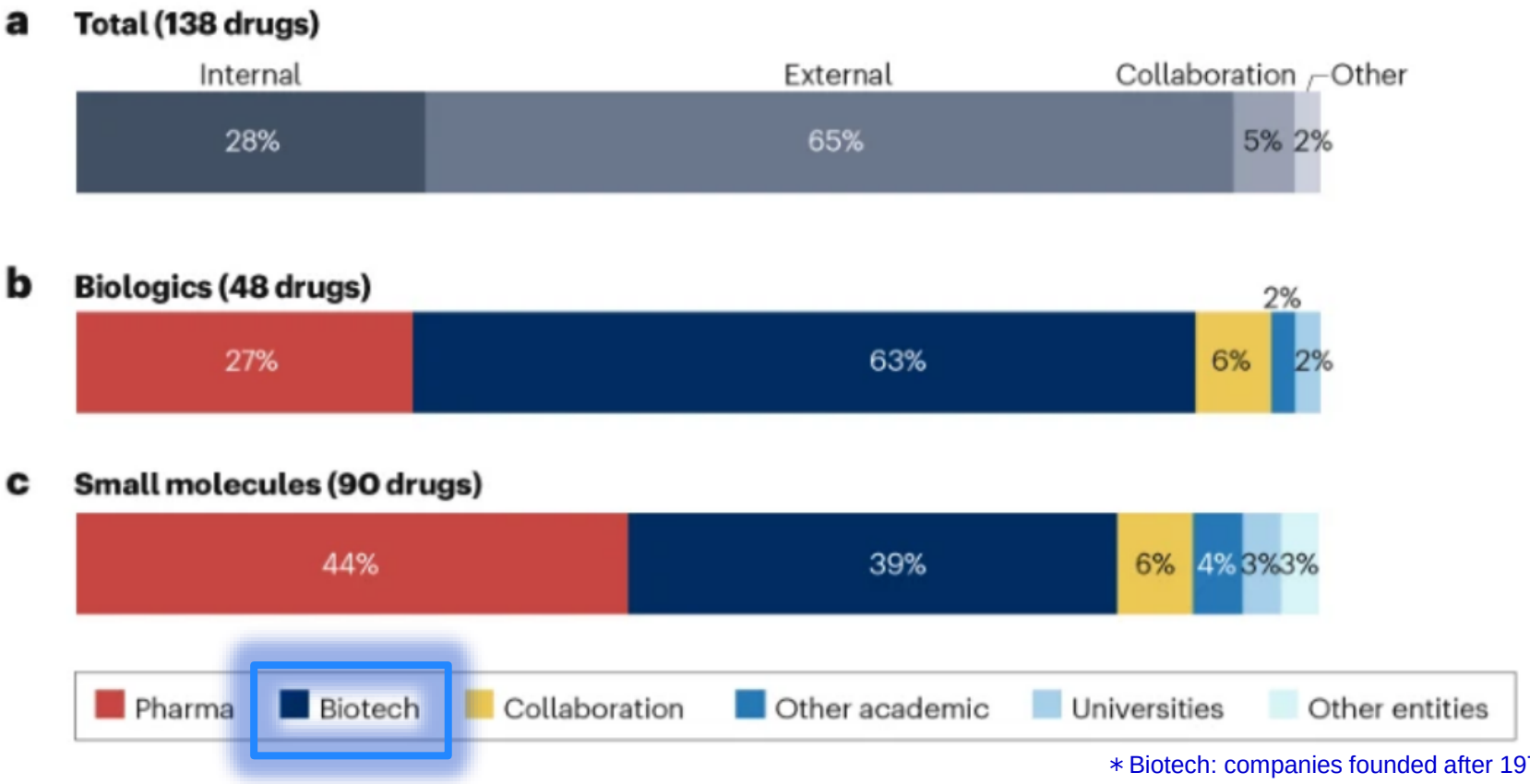
Today's contents

1. PMDA celebrates 20 years

2. Activities to introduce innovative product quickly in Japan
   (1) Global trend of pharma development
   (2) Japan's regulatory activities
   (3) Strengthening information dissemination

3. PMDA's Overseas Offices and others

Origins of Pharmaceutical Innovation



＊Biotech: companies founded after 1976

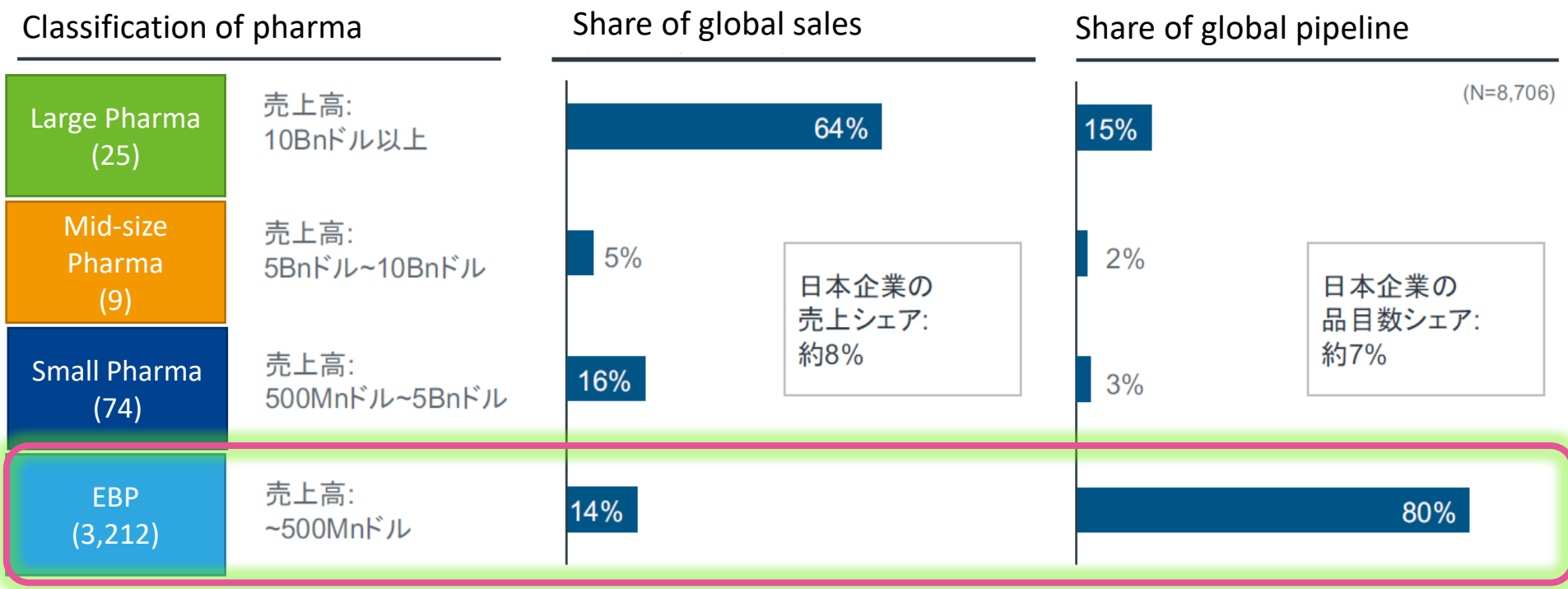
Fig. 1 | Origins of FDA-approved new drugs filed by the top 20 biopharma companies between 2015–2021.

Nat Rev Drug Discov 22:781–782, 2023 (Oct) doi: https://doi.org/10.1038/d41573-023-00102-z

Recent drug development trend

EBP's share of pharmaceutical sales and number of products under development

MHLW
Pharm Industrial Vision 2021
Reference
13 Sep 2021



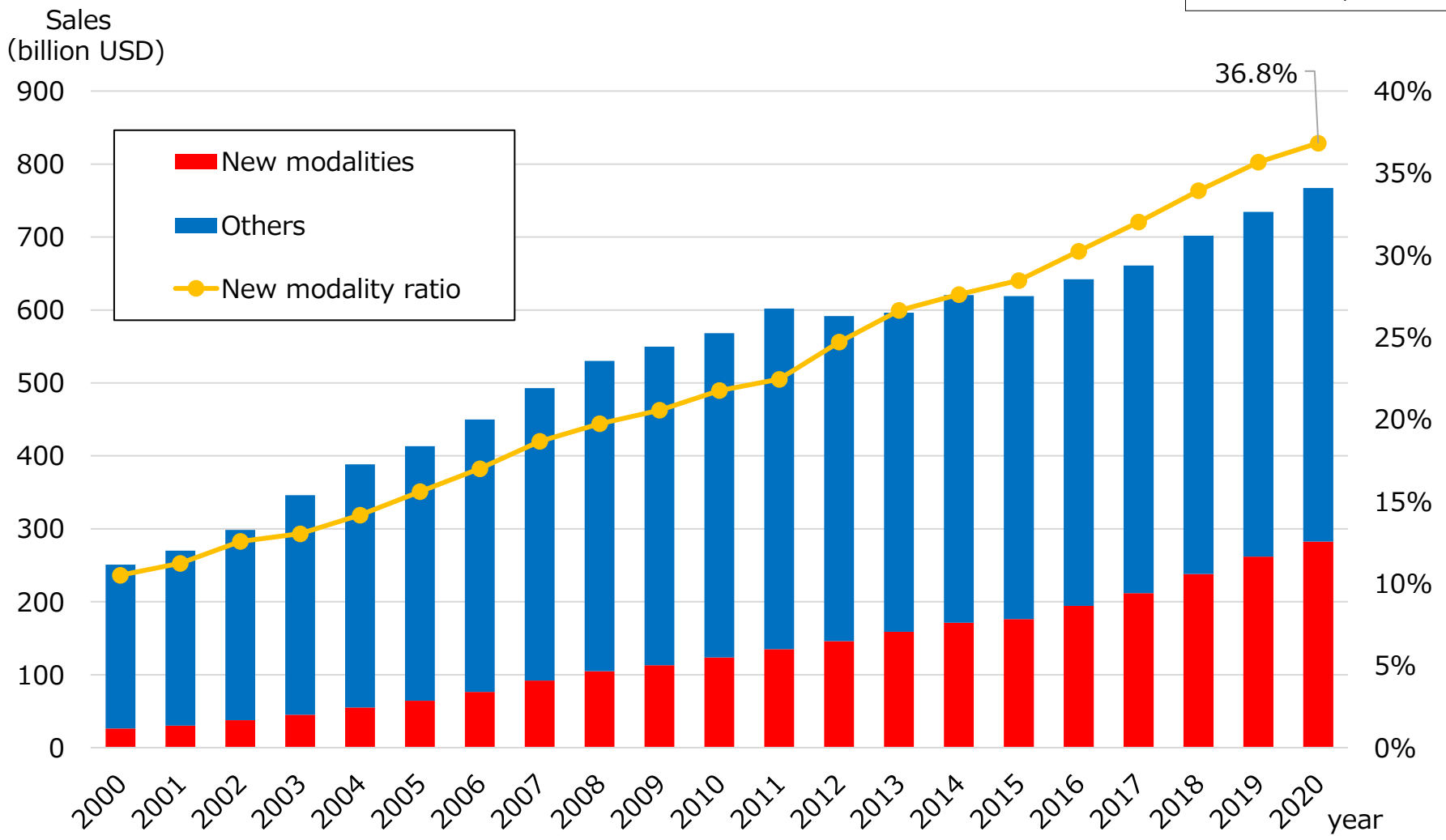
- 日本では新興バイオファーマの存在感が低い (アメリカでは新薬承認数の半分以上を新興バイオファーマの創製品が占める)
- 日本企業は低分子領域の開発品では**10%**近いシェアをもつが、新モダリティ領域の開発品では**3%**程度のシェアにとどまる

(出所) IQVIAデータをもとにIQVIA分析

IQVIA

New Modalities Global Pharmaceutical Sales Trends

MHLW
Pharm Industrial Vision 2021
Reference
13 Sep 2021



Source: prepared by the Pharmaceutical Industry Policy Institute based on EvaluatePharma (as of February 2021).

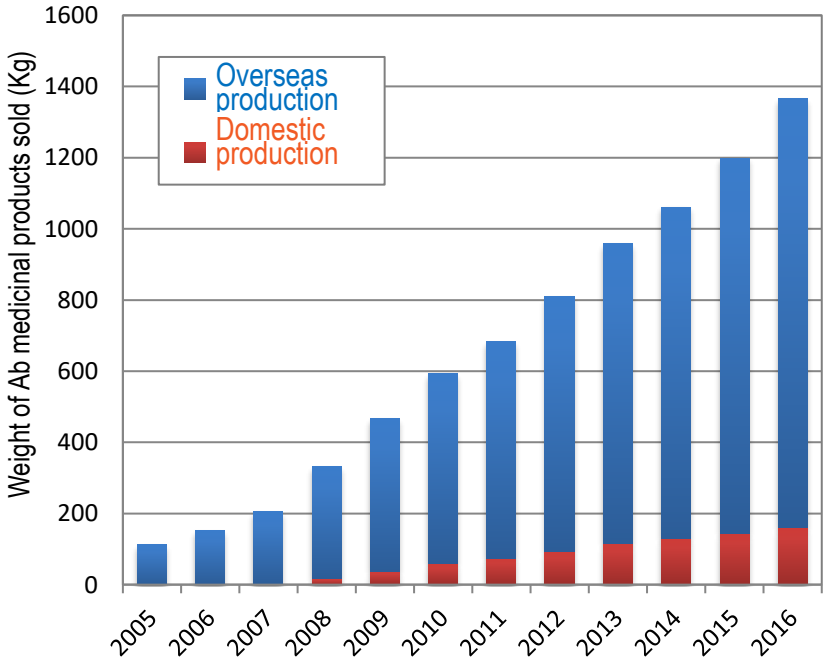
Status of sales and production of biopharmaceuticals in Japan.

MHLW
Pharm Industrial Vision 2021
Reference
13 Sep 2021

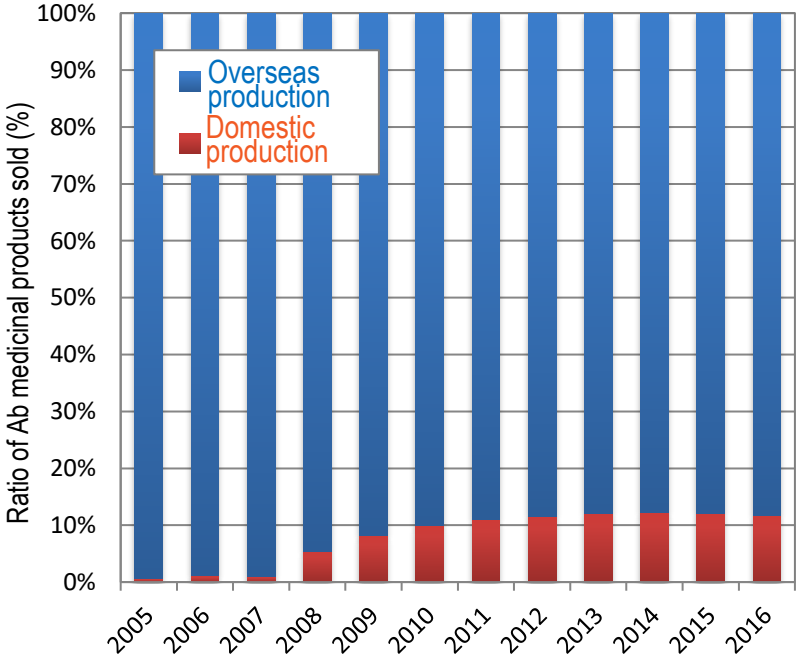
Although **the number of antibody drugs sold in the country is increasing, around 90% of these are produced abroad,** making the country highly dependent on overseas production sites.

Weight of antibody drugs sold by domestic and international production

<Weight>



<Ratio>



Source: copyright©2021 IQVIA. based on individual surveys conducted by IQVIA JPM March 2017 MAT and the Pharmaceutical Industry Policy Institute (all rights reserved).
Source: Institute for Pharmaceutical Industry Policy Research Paper Series No. 71 (March 2018).

Actual situation of drug lag/drug loss

- As of March 2023, there were **86 drugs (60.1% of unapproved drugs)** approved in Europe and the U.S. but not yet developed in Japan. It is said that there is **"Drug loss"** i.e., no companies develop the products in Japan).
- Analysis of 86 products whose development in Japan has yet to start: relatively large proportion of **venture-originated drugs, orphans, and paediatrics.**

Status of drug loss in Japan, Europe, and the United States

	Approved	Unapproved total	Unapproved portion	
			Under development	**Not yet started**
United States	136	7	3	4
Europe	86	57	26	31
Japan	0	**143**	57	**86**

Break-down

Breakdown of items not yet started in Japan

Venture start-up	**Orphan**	**Paediatric**
56 % (48 items)	**47** % (40 items)	**37** % (32 items)

※ Of the 86 loss items, 14 (16%) are not ventures, orphans, nor paediatric.

※Source: Published information from PMDA, FDA, and EMA, prepared by the Pharmaceutical and Industrial Policy Research Institute based on tomorrow's new drugs (Technomic Co., Ltd.), and tabulated by the Ministry of Health, Labour and Welfare.
※1:Of the NMEs approved in Europe and the United States in 2016-2020, those not approved in Japan as of the end of 2022 are counted as unapproved.
※2:As of March 2023, items for which no development information was available are counted as undeveloped products in Japan.
※3:Figures are totaled for development companies with sales of less than US$500 million within 30 years of approval in Europe and the U.S.
※4:Compiled as orphans for items designated as orphan drugs by the time of approval in Europe and the U.S.
※5:2022 Calculated based on pediatric products approved for pediatric use in Europe and the U.S.

Adapted from "Reference Material 4 of the 1st Meeting of the Committee on Regulatory Measures for Strengthening Drug Discovery Capabilities and Securing Stable Supply" implemented by the Pharmaceutical and Environmental Health Bureau, MHLW

Today's contents

1. PMDA celebrates 20 years

2. Activities to introduce innovative product quickly in Japan
   (1) Global trend of pharma development
   (2) Japan's regulatory activities
   (3) Strengthening information dissemination

3. PMDA's Overseas Offices and others

Expert Panel on Comprehensive Measures for the rapid and stable supply of pharmaceuticals (MHLW)

(13 meetings from 22 September, 2022 to 6 June, 2023)

Main topics discussed

Securing Stable supply

Many products, mainly generics, are suspended. It is due to the structural problems of the generic industry, such as many companies are small-scale and have limited-capacity, and low-volume with high-diversity production of generic medicines.

Strengthening Pharma R&D

Japan's pharma development capacity has declined, with the global market share of Japanese origin decreasing. The transition to new modalities has been delayed, and a shift to an R&D-oriented business model needs to be accelerated.

Elimination of Drug Lag / Loss

143 products approved in Europe and the US have not been approved in Japan. Of these, 86 have not yet started development in Japan, raising concerns about drug losses. Venture-origin medicines, orphan drugs and paediatric drugs account for a large proportion of these medicines.

https://www.mhlw.go.jp/stf/shingi/other-iyaku_128701_00006.html

Study Group on Pharmaceutical Regulations to Strengthen Drug Discovery and Ensure Stable Supply (MHLW)

（Jul 10, 2023 – Mar 21, 2024）

Considering the pharmaceutical regulations in order to eliminate drug loss issues, ensure stable supply and accelerate pediatric drugs development

Considerations

Promotion of development	How to designate orphan drugs	*10 Jul, 2023*
	Pharmaceutical reviews that contribute to promote development of pediatric drugs	*7 Aug, 13 Sep,13 Dec, 2023; 8 Feb, 2024*
Clinical trials	Arrangement of necessity of Japanese data for approval review in Japan Introduction of further efficiency in trials (ecosystem)	*12 Mar, 2024*
Post-market safety measures	Post marketing use-results surveys Use of real world data in regulatory affairs system	*12 Jan, 2023; 12 Mar, 2024*
Quality	Regulatory reviews on manufacturing methods of drugs	*13 Oct, 15 Nov, 2023*
Information dissemination	Disseminating the information on Japanese regulatory system around the world	*15 Nov, 2023*

(only in Japanese) https://www.mhlw.go.jp/stf/shingi/other-iyaku_128701_00006.html

What we can do to accelerate R&D in Japan ?

Support for development of drugs for rare diseases, paediatric drugs and others

- ❖ Orphan drugs: new mechanisms for accelerated designation
  - ➢ Accelerated designation (expanded part starts with non-priority review, priority review can also be given depending on evidence)
- ❖ Paediatric medicines: support for promote development
  - ➢ Confirm need for paediatric drug development during adult drug development (MHLW: incentives on drug prices)
- ❖ Establishment of the Consultation Center for Pediatric and Orphan Drugs Development (CCPODD) (as of 1 July 2024).
  - ➢ The project of the Consultation Center for Pediatric and Orphan Drugs Development (CCPODD) is planned to be launched. (Establishment of a consultation framework (implementation guidelines already published)/subsidy for consultation fees).
- ❖ Sakigake designation system: aim for total review period of 6 months.
- ❖ Sakigake general consultation: all applications handled
- ❖ Promoting early introduction of the clinical trial ecosystem
  - ➢ Launch of the project to promote introduction of clinical trial ecosystem (public call for project implementing organisations underway).

What we can do to accelerate R&D in Japan ?

Creation of an environment and dissemination of information for innovative medicines development in Japan.

- Provide information on Japan's pharmaceutical regulations and PMDA operations to overseas venture companies at international conferences, and conduct RS general consultations.

- Provide consultation and support to overseas venture companies through PMDA's US office (to be established by the end of this year).

- Provide accurate advice in clinical trial consultations regarding participation in international multi regional clinical trials
  - Clearly indicate in notifications when Japanese Phase I trials are not required before participation

Towards a revision of the requirements for the orphan designation

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

【Requirements and Issues for Orphan Designation】

Eligibility

The number of patients was **less than 50,000** in Japan

※ Effective April 1, 2015, 50,000 or more cases of designated intractable diseases shall satisfy this requirement.

Medical needs

No appropriate alternative medicines or treatments, or **significant higher** efficacy or safety is expected

If there is an approved drug, it may be judged an alternative is available regardless of its efficacy.

Direct comparison with approved drugs may be required

Possibility of development

With a rationale for the product to use for the disease concerned and with **appropriate developmer**

・Phase II trial completed and Phas agreed with PMDA
・Result from a phase III trial

【Points to consider toward revision】

Clarification of “salami slicing" requirements

Clarification of criteria based on medical and pharmaceutical considerations

For example, based on medical and pharmacological considerations, target diseases limited to those for which development has not progressed may not fall under “salami slicing"

Clarification of “medical needs”

Clarification of Concept on Alternative Therapy

Clarification of Concept on Comparison with Existing Therapy

Speeding-up of designation and clarification of withdrawal conditions

Clarification of requirements for acceleration and withdrawal of designations

of

16 January 2024, Notifications were issued by the MHLW

Establishment of the Consultation Center for Pediatric and Orphan Drugs Development (CCPODD)

Since 1 July 2024

For promoting development and introduction of medicinal products for paediatric and rare diseases, **the Consultation Center for Pediatric and Orphan Drugs Development (CCPODD)** is established to provide the necessary consultation.

* By the Evaluation Committee on Unapproved and Off-label Drugs with High Medical Need. (Independent of the Center)

Development of consultation system

- ❖ Consultation on Confirmation of the Paediatric Drug Development Program
  - ➢ To confirm the paediatric development plan, which leads to an additional premium on the NHI Drug price list
- ❖ Consultation on Orphan Drugs eligibility for Priority Review
  - ➢ To evaluate whether products designated as orphan drugs are eligible for priority review
- ❖ Drug application data package consultation for unapproved or off-labeled drugs with high medical
  - ➢ Consultation on the st
  - ➢ Consultation on comp the main clinical trial

Established on 1 July 2024, in PMDA

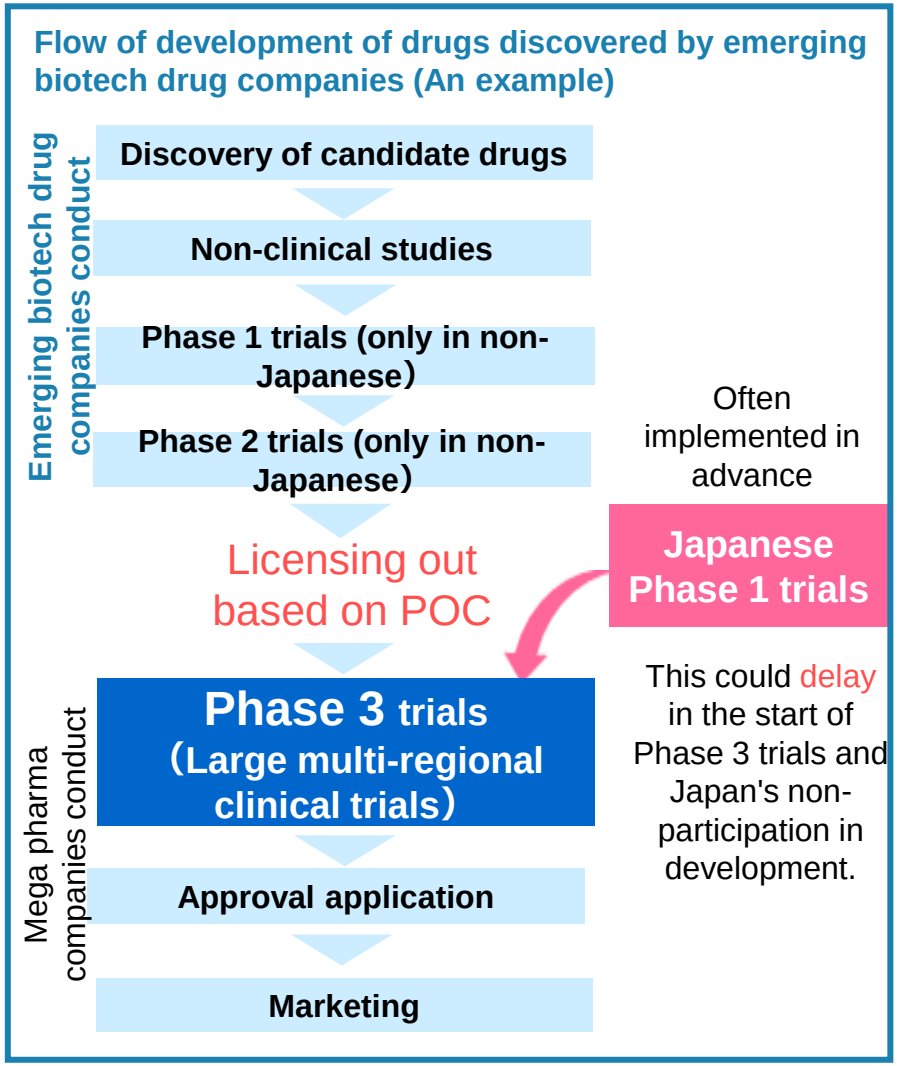
Necessity of Japanese Phase 1 Trial

[PMDA's principle]

- If there are **ethnic differences** between Japanese and non-Japanese, we recognize that **the Japanese data are important in using drugs safely in Japan**

- **We have not uniformly required Phase 1 trials in Japanese before participating in multi-regional clinical trials**, and determines synthetically by considering multiple perspectives.

- It is desirable that **Japan participates in multi-regional clinical trials from early stage in development and Japanese data are collected**.



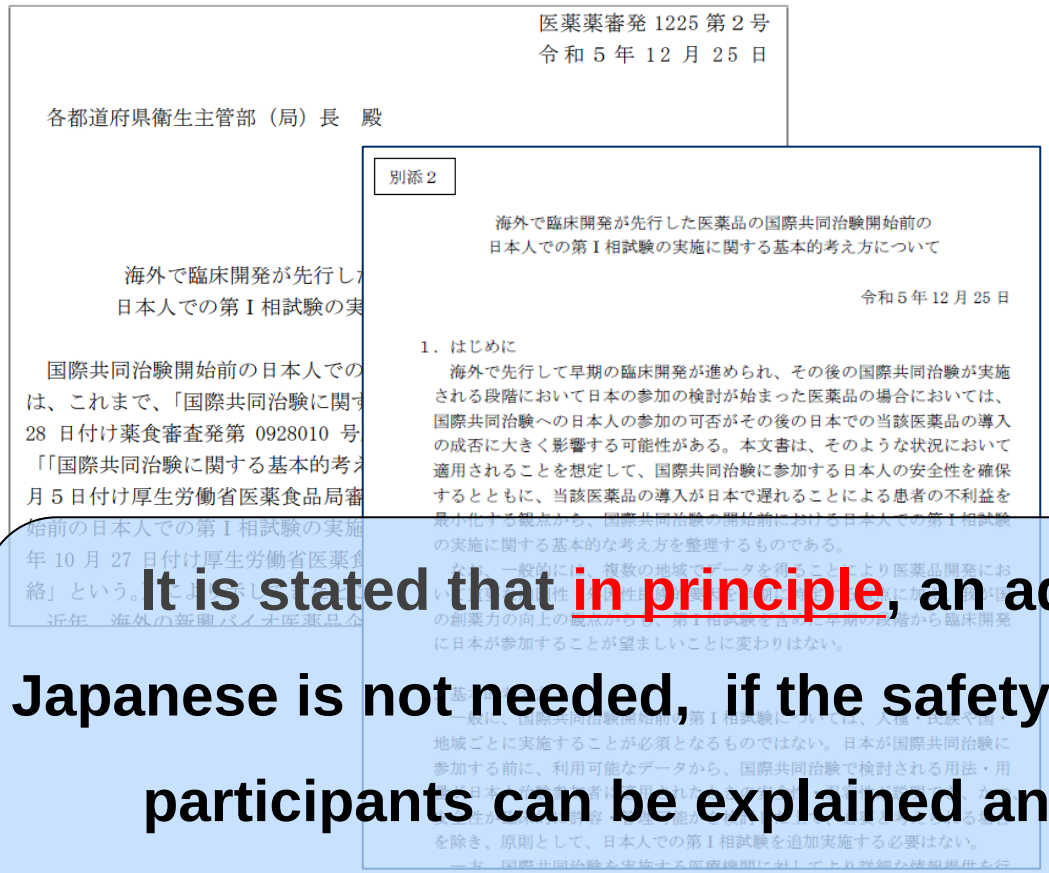
(only in Japanese) https://www.mhlw.go.jp/stf/shingi/other-iyaku_128701_00006.html

Basic Principles for conducting phase 1 studies in Japanese prior to MRCTs including Japan

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Notification (25 December 2023)

by the Director of the Pharmaceutical Evaluation and Licensing Division, MHLW



医薬薬審発 1225 第２号
令和５年 12 月 25 日

各都道府県衛生主管部（局）長　殿

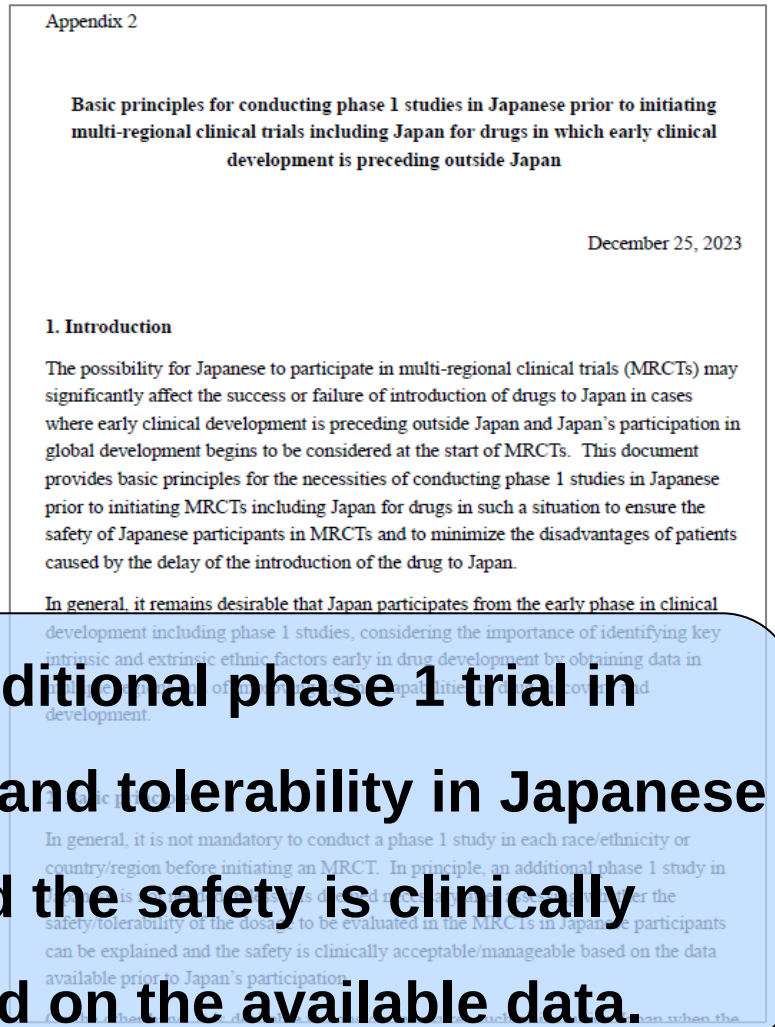
別添２

海外で臨床開発が先行した医薬品の国際共同治験開始前の
日本人での第Ⅰ相試験の実施に関する基本的考え方について

令和５年 12 月 25 日

１．はじめに

海外で先行して早期の臨床開発が進められ、その後の国際共同治験が実施される段階において日本の参加の検討が始まった医薬品の場合においては、国際共同治験への日本人の参加の可否がその後の日本での当該医薬品の導入の成否に大きく影響する可能性がある。本文書は、そのような状況において適用されることを想定して、国際共同治験に参加する日本人の安全性を確保するとともに、当該医薬品の導入が日本で遅れることによる患者の不利益を



Appendix 2

Basic principles for conducting phase 1 studies in Japanese prior to initiating multi-regional clinical trials including Japan for drugs in which early clinical development is preceding outside Japan

December 25, 2023

1. Introduction

The possibility for Japanese to participate in multi-regional clinical trials (MRCTs) may significantly affect the success or failure of introduction of drugs to Japan in cases where early clinical development is preceding outside Japan and Japan's participation in global development begins to be considered at the start of MRCTs. This document provides basic principles for the necessities of conducting phase 1 studies in Japanese prior to initiating MRCTs including Japan for drugs in such a situation to ensure the safety of Japanese participants in MRCTs and to minimize the disadvantages of patients caused by the delay of the introduction of the drug to Japan.

In general, it remains desirable that Japan participates from the early phase in clinical development including phase 1 studies, considering the importance of identifying key intrinsic and extrinsic ethnic factors early in drug development by obtaining data in

development.

In general, it is not mandatory to conduct a phase 1 study in each race/ethnicity or country/region before initiating an MRCT. In principle, an additional phase 1 study in

safety/tolerability of the dose to be evaluated in the MRCTs in Japanese participants can be explained and the safety is clinically acceptable/manageable based on the data available prior to Japan's participation.

It is stated that in principle, an additional phase 1 trial in Japanese is not needed, if the safety and tolerability in Japanese participants can be explained and the safety is clinically acceptable and manageable based on the available data.

https://www.pmda.go.jp/english/rs-sb-std/rs/0011.html

Today's contents

1. PMDA celebrates 20 years

2. Activities to introduce innovative product quickly in Japan
   (1) Global trend of pharma development
   (2) Japan's regulatory activities
   (3) Strengthening information dissemination

3. PMDA's Overseas Offices and others

Strengthening overseas information dissemination on Japan's pharmaceutical regulations

by PMDA Chief Executive, Dr Fujiwara

In 5th Mid-term Plan, Active contribution to the development, Strengthening of the ability to make international proposals, and Improvement of PMDA's operations, are stipulated.

➡ Information on Japan's pharma regulation be directly provided for overseas ventures to develop innovative products also in Japan.

Key messages

1. World's fastest review and high quality review
2. Efforts to promote MRCT (e.g. clarifying principle that the Japanese P1 study is not required for participation in MRCT)
3. Support for development in Japan (e.g. scientific consultation from early development to post-approval, international regulatory harmonisation)

Recent initiatives (first half of 2024) (by **Chief Executive himself**)	
Panelist, **American Society of Clinical Oncology** (ASCO)	Chicago, US
Speaker and Panelist, **BIO** International Convention (BIO)	San Diego, US
Speaker and Panelist, **Welcome Trust** Regulatory Science of Antimicrobial Agents Workshop	Singapore
Speaker and Panelist, **DIA*** 2024 Global Annual Meeting （also PMDA Town Hall at DIA Global 2024）	San Diego, US

* Free consultation for development of medicinal products is also done at exhibitions such as DIA.

Approaches to overseas start-ups / ventures

<BIO International Convention 2024> June 2024

- Promote attractiveness of obtaining Marketing Authorisation in Japan to venture companies by introducing Japan's efforts to harmonize pharmaceutical regulations and PMDA's efforts to make Japan a reference country in the Asian region.
- Conducted in cooperation with the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Economy, Trade and Industry (METI).

<DIA Euro, DIA Global > March and June 2024

- PMDA Townhall to provide Information on the Japanese Pharmaceutical Regulation and Market Situation
  - Japan's approval system (SAKIGAKE, priority review, conditional approval, etc.)
  - Pre-trial consultation system and contact information
  - Introduction of the NHI drug price system, etc.
- Conduct a brief consultation with companies seeking to develop medical products in Japan.

<Future expected Plan>

- To communicate in PMDA's own language (in English).
- Establish Washington D.C. office at an early stage, and collaborate with JETRO and others, based in the US to encourage venture companies to bring their products to Japan’s market.

Information Dissemination at the PMDA Website

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Jump to body | Font size: Standard | Large | › 日本語 | › English | Site map | Search within PMDA site | Search | Favorite pages | Contact us

About P

Home | Reviews | Post-marketing Safety Measures | Relief Services for Adverse Health Effects | Regulatory Science(RS)・Standard Development(JP,GL) | International Activities

Home > Reviews and Related Services > Regulatory Information

Add this page to "Favorite pages" | Print the text

Reviews and Related Services

Regulatory Information

PMDA's Support to Venture Companies

Pharmaceuticals and Medical Devices Agency

https://www.pmda.go.jp/english/index.html

August, 2024

SAKIGAKE (Forerunner) drugs - Designation System

<Objective>

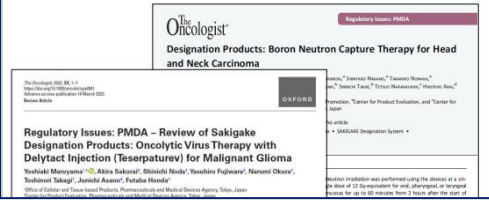
To put innovative products into medical practice in Japan

<Criteria for designation>

1. Innovativeness - new mode of actio
2. Severity of the target disease - life-t
3. Prominent efficacy - no existing ther
   improvement in efficacy or safety co
4. Plan/System - to submit the NDA in

Examples of the world-first approval granted in Japan

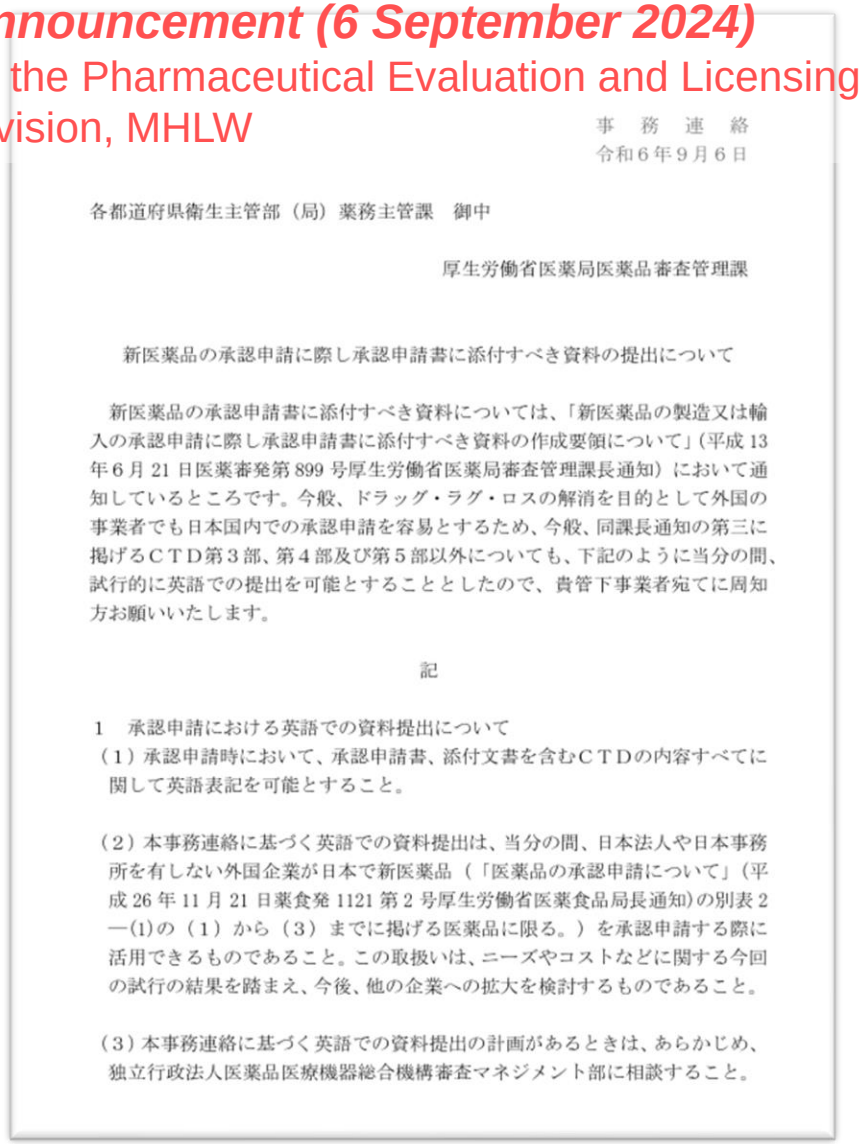
These were designated as SAKIGAKE and/or Orphan Drugs.



First approval in Japan!

MHLW / PMDA accept NDA Submission in English for non-Japanese sponsors with no Japan branches/offices

Announcement (6 September 2024)
by the Pharmaceutical Evaluation and Licensing Division, MHLW



事　務　連　絡
令和６年９月６日

各都道府県衛生主管部（局）薬務主管課　御中

厚生労働省医薬局医薬品審査管理課

新医薬品の承認申請に際し承認申請書に添付すべき資料の提出について

新医薬品の承認申請書に添付すべき資料については、「新医薬品の製造又は輸入の承認申請に際し承認申請書に添付すべき資料の作成要領について」（平成13年６月21日医薬審発第899号厚生労働省医薬局審査管理課長通知）において通知しているところです。今般、ドラッグ・ラグ・ロスの解消を目的として外国の事業者でも日本国内での承認申請を容易とするため、今般、同課長通知の第三に掲げるＣＴＤ第３部、第４部及び第５部以外についても、下記のように当分の間、試行的に英語での提出を可能とすることとしたので、貴管下事業者宛てに周知方お願いいたします。

記

１　承認申請における英語での資料提出について
（１）承認申請時において、承認申請書、添付文書を含むＣＴＤの内容すべてに関して英語表記を可能とすること。

（２）本事務連絡に基づく英語での資料提出は、当分の間、日本法人や日本事務所を有しない外国企業が日本で新医薬品（「医薬品の承認申請について」（平成26年11月21日薬食発1121第２号厚生労働省医薬食品局長通知）の別表２―(1)の（１）から（３）までに掲げる医薬品に限る。）を承認申請する際に活用できるものであること。この取扱いは、ニーズやコストなどに関する今回の試行の結果を踏まえ、今後、他の企業への拡大を検討するものであること。

（３）本事務連絡に基づく英語での資料提出の計画があるときは、あらかじめ、独立行政法人医薬品医療機器総合機構審査マネジメント部に相談すること。

- All documents for NDA submission, including the Common Technical Document (CTD) and labelling in English are allowed for the time being.
- Eligible for non-Japanese companies without any branches nor offices in Japan.
- A consultation with the Office of Review Management of PMDA prior to submission is required.

Today's contents

1. PMDA celebrates 20 years

2. Activities to introduce innovative product quickly in Japan
   (1) Global trend of pharma development
   (2) Japan's regulatory activities
   (3) Strengthening information dissemination

3. PMDA's Overseas Offices and others

Initiatives to strengthen cooperation with Asian countries and the United States

- To support innovative medicines & medical devices access in Japan and Asian countries,
  - To strengthen cooperation with ASEAN countries
  - To support the promotion of regulatory harmonisation with Asian countries
  - To develop an environment for smooth clinical development
- Close collaboration between Japan and US regulatory authorities is essential in supporting in flexible manner and without time-zone difference;
  - Development of innovative medicines and medical devices
  - Regulatory review
  - Post-marketing measures.

Cooperation with Asian countries and the US, including the establishment of overseas offices in the Asian region and the US, in order to promote the development of and access to innovative medicines & medical devices.

Establishment of PMDA's Overseas Offices

Objective: work directly with counterpart authorities and others at overseas offices, flexibly without time-zone difference

Asia Office, Bangkok , Thailand (since July 2024)

- Establishment of pharma regulatory infrastructure in Asian countries (collection of local needs, local implementation of PMDA-ATC training, local implementation of bilateral regulatory harmonisation activities).
- Exchanging info and consultation with companies and organisations entering the Asian region and with local companies and organisations.
- Others (collaboration with the National Cancer Centre Thailand Office, etc.).

Washington D.C. Office, USA (expected by the end of 2024)

- Disseminating information and consultation services to start-ups in the US (Local conduction of PMDA outreach activities)
- Strengthening on-site regulatory cooperation and exchange of regulatory-related information with US administrative agencies, including the FDA.

PMDA's International Hubs

Asia Office, Bangkok

PMDA Central Office, Tokyo

To be established in central D.C. area by EOY

Washington D.C Office

Establishment of PMDA's international hubs
to enhance international contribution/capability for regulatory proposal

PMDA established PMDA Asia Office as its first oversea base

PMDA Asia Office

International Symposium for Asia Regulatory Coordination (29 August, 2024, Bangkok)

Website:
https://www.pmda.go.jp/english/int-activities/overseas-office/asia/0001.html

PMDA Washington D.C. Office

Enhance international contribution / capability for PMDA's regulatory proposal

- Strengthening cooperation with US FDA and related administrative agencies such as
  - to further promote access to innovative human medicines/medical devices/regenerative products
  - to engage in further discussion on MA and post-marketing measures
- More opportunities for communication with stakeholders
  - in the same time zone without considering time-zone difference
  - face to face meeting with more in-depth discussions

Missions of PMDA Washington D.C. Office (To be established by the end of 2024)

- Promoting dissemination of information on Japanese regulation at the office/on the site
  - to offer consultation to small business/start-up companies on early development in Japan
  - through sharing Japanese regulatory information and tips
- Strengthening regulatory cooperation/direct information exchanges
  - with U.S. FDA and related administrative agencies
  - on regulatory affairs on human medicines/medical devices/regenerative products

Hosting long-term trainees from Asian regulators

❑ The principle of 5th Mid-term Plan

To play a leading role in the international arena as one of the world's trilateral regulators along with US and EU counterparts, and to establish Japan as a reference country for Asia through the establishment of overseas bases, with promoting strategic international activities.

❖5th Mid-term Plan (2024-2028)
Strengthening the foundation for cooperation with Asian countries by **hosting long-term traininees** from Asian regulators

❖Annual Plan for 2024
To accelerate regulatory harmonisation, strengthen the foundation for cooperation with Asian countries by establishing an Asian base and **hosting long-term trainees** from Asian regulatory authorities.

Specific Activities	
FY 2023	Basic agreement on long-term training programme (July) and agreement on long-term training programme (October) signed with the Indonesian Ministry of Health for hosting of the Regulatory officials from April 2024.
<< 5th Mid-term Plan >>	
FY2024	**The training (trial) for Indonesian trainees to gain hands-on experience of Japanese medical device regulations (review, safety, standards and quality) and the PMDA's actual operations**, based on the requests of Indonesian side. Through this training, regulatory harmonisation with Indonesia and strengthening of trust with PMDA are expected. The training is implemented at PMDA's medical device departments, including the review, preparation & coordination of standards and accompanying QMS inspection. The content of training in and after FY2025 will be reviewed based on the status of training in FY2024, requests from Asian regulatory authorities, and other factors.
FY2025 -	Implement long-term training for Asian regulators in a planned manner **to establish reference country status amongst Asian regulators.**

独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

Thank you for listening !

感謝您的關注！

Daisuke TANAKA, Ph.D.
Office Director, Office of International Program
Pharmaceuticals and Medical Devices Agency, Japan

7 October 2024
12th Joint Conference of Taiwan and Japan on Medical Products Regulation

獨立行政法人
醫藥品醫療機器綜合機構

國際部
田中 大祐

2024年10月7日
第十二屆台日醫藥交流會議