Pharmaceuticals and Medical Devices Agency

Overview of medical device regulation in Japan

Tetsuya Kusakabe, PhD, MPH

Director, Office of Manufacturing Quality
and Vigilance for Medical Devices
/ International Coordination Officer
Pharmaceuticals and Medical Devices Agency

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Outline

1. Key Points for your Development Strategy in Japan
2. Strategy Consultation
3. High Predictability of Review Process
4. Internationally Harmonized Regulations
5. Take-Home Messages

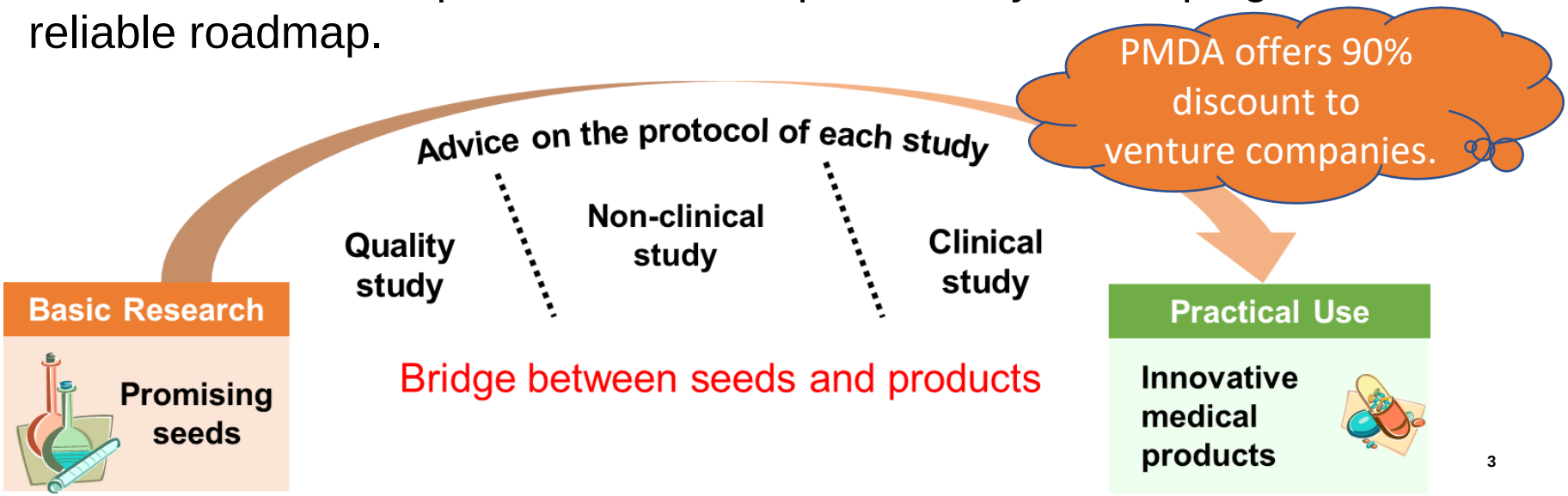
Japan's Advantage

- **2nd largest market** of Medical Devices.
- **ALL citizens (125 Mil.) are covered by NHI.**
- **All medical devices are covered by the NHI in principle** and **no HTA** before the inclusion.
- Regulations are harmonized internationally.
- Hospitable support for venture companies.

A Key for World-Wide Development of Medical Products!

Regulatory Science Consultation on R&D Strategy

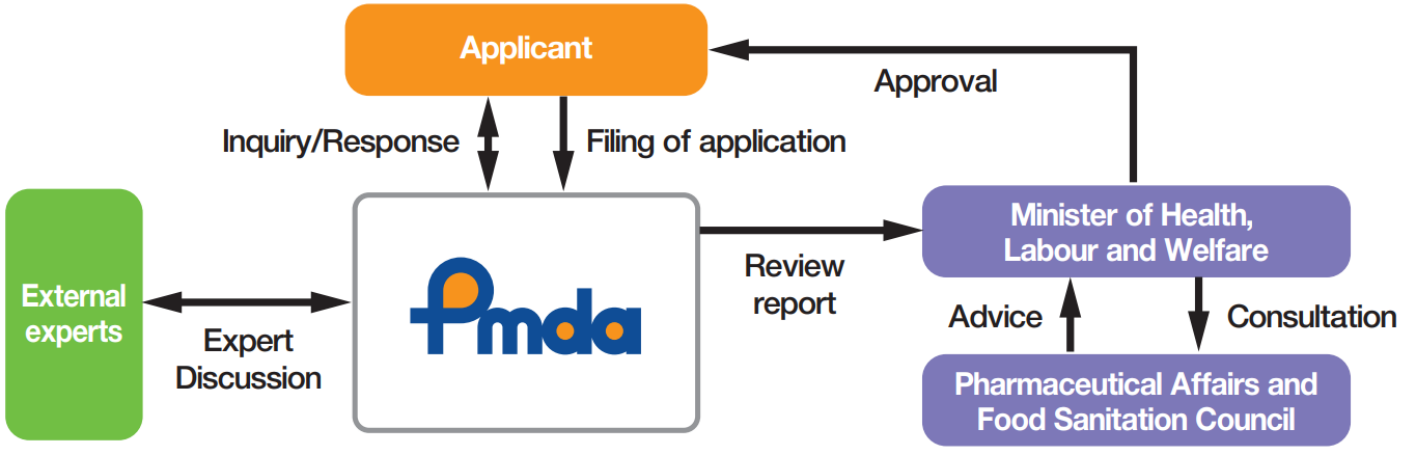
- PMDA supports the establishment of an exit strategy via Regulatory Science (RS) Consultation on R&D Strategy.
- Facilitate the development of medical products by developing a more reliable roadmap.



3. High Predictability of Review Process

Regulatory Submission and Approval Process

- In the medical device review process, review team reviews the data submitted for a product.
- During the process, the reviewers exchange opinions with external experts to enable more highly specialized reviews.
- Could be approved without Clinical Evidences or with Registry Data.



Medical Device Classification and Regulation

- MDs are classified into 4 categories (Class I to IV) according to risk level.
- Pre-market regulatory process for MDs differs depending on the classification.

Risk Level	Low → High			
International Classification	Class I	Class II	Class III	Class IV
Classification under PMD Act	General Medical Devices	Controlled Medical Devices	Specially Controlled Medical Device	
Regulation	Notification to PMDA	Certification by registered certification bodies	Approval by the Minister of MHLW (based on scientific review by PMDA)	
Specific Description	Devices that may pose an extremely low risk to the human body in case of a malfunction Examples: ● In vitro diagnostic devices ● Steel made small devices (including a scalpel, tweezers) ● X-ray film ● Devices for dental technique	Devices that may pose a relatively low risk to the human body in case of a malfunction Examples: ● MRI system ● Electronic endoscope ● Ultrasonic system ● Dental alloy	Devices that may pose a relatively high risk to the human body in case of a malfunction Examples: ● Dialyzer ● Bone prosthesis ● Automated external defibrillator (AED) ● Mechanical ventilator	Devices that are highly invasive and thus may pose a life-threatening risk in case of a malfunction Example: ● Pacemaker ● Artificial cardiac valve ● Artificial breast ● Stent graft

* Classes I – IV correspond to GHTF categories (Class A – D)

Medical Device Review Times

- PMDA ensures a more predictable review process by achieving review time of 14 months for new MDs, and 10 months for priority review.

Total Review Time for New Medical Devices (Standard Review Applications)

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
percentile	**80th**	**80th**	**80th**	**80th**	**80th**
Total review time	**12.0**	**11.1**	**10.8**	**11.9**	**12.0**
Number of approved applications	**36**	**27**	**29**	**33**	**19**

Note1: Values indicate the data for approved applications that were filed in or after 2004

Total Review Time for New Medical Devices (Priority Review Applications)

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
percentile	80th	80th	80th	80th	80th
Total review time	**8.3**	**7.3**	**8.4**	**8.9**	**8.8**
Number of approved applications	2	3	2	1	2

Note1: Values indicate the data for approved applications that were filed in or after 2004

Accelerated Review Systems in Japan

■ Japan offers various supporting schemes for R&D companies.

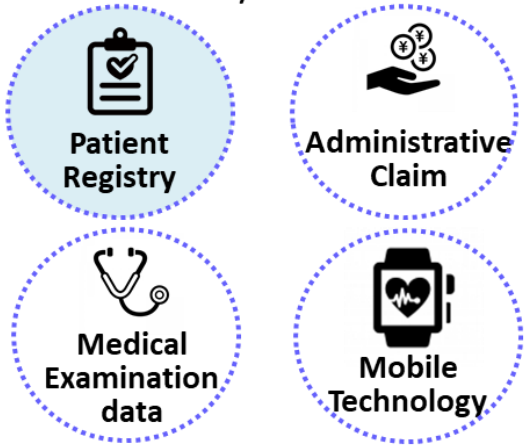
Type	Area	Product features
Expedited review	Any product categories	In a particular situation requiring expedited review
Priority review		Designated as: 1. Orphan 2. Apparent improvement of medical care for severe diseases
SAKIGAKE (Forerunner designation)		• Innovative medical products • For serious diseases • Development & NDA in Japan: The NDA submission being the world's first or simultaneous with other countries • Prominent effectiveness expected based on non-clinical and early phase clinical study data
Conditional Approval	Drugs	Early application through confirmation of a certain degree of efficacy and safety in clinical trials other than confirmatory clinical trials
	Medical Devices	• High clinical needs • Balancing the pre- and post-market requirements
Conditional and Time-limited Approval	Regenerative Medical Products	• Based on the clinical data from the limited number of patients, efficacy is predicted in a shorter time compared with the conventional process. • Early-phase adverse reactions, etc. can be evaluated for safety in a short period of time.

Utilization of RWE to Evaluate Clinical Outcomes of Medical Devices

- Utilization of RWE through pre/post marketing phase is often effective for development of MDs required repeating improvements and MDs for orphan disease.

Source of RWD

- National / International
- Academic / Sponsor
- Procedure / Medical Device

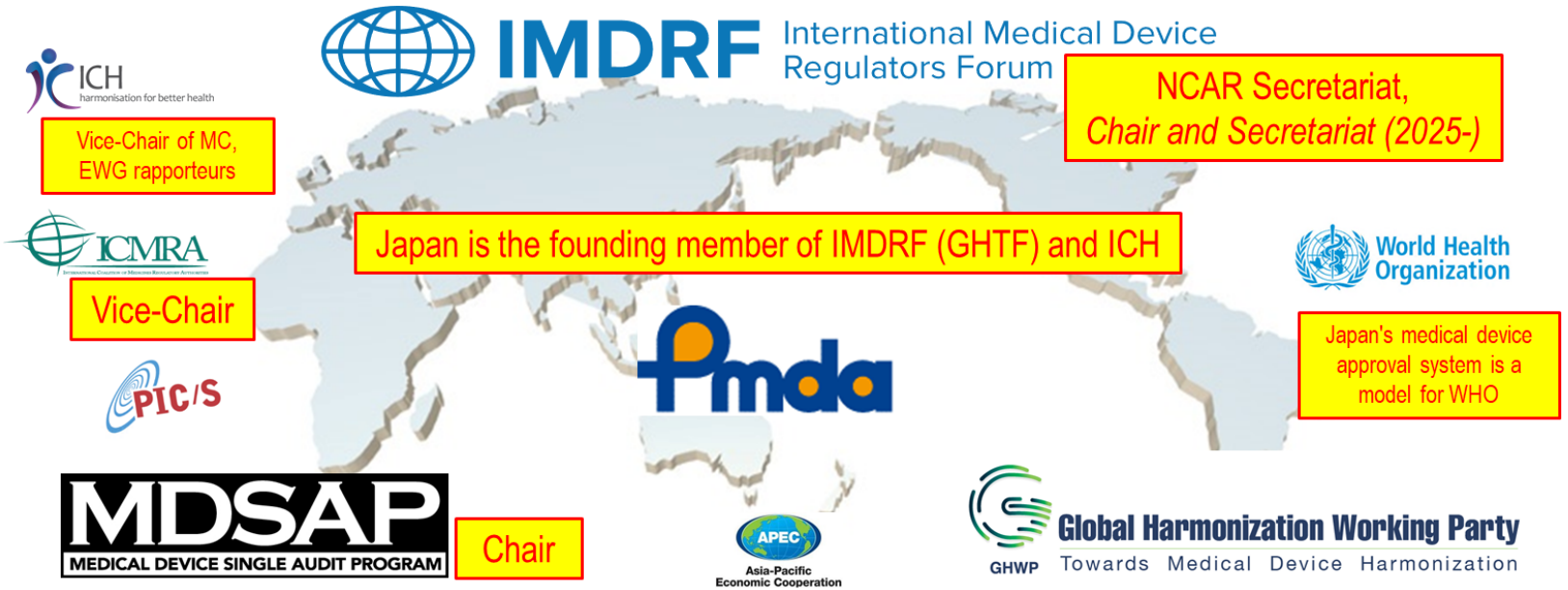


Purpose of Utilization in regulatory use

1. External control of clinical trials
2. Primary data or complement of clinical trials
3. Efficacy and/or safety evaluation of conditionally approved items
4. Post-marketing surveillance for safety measures

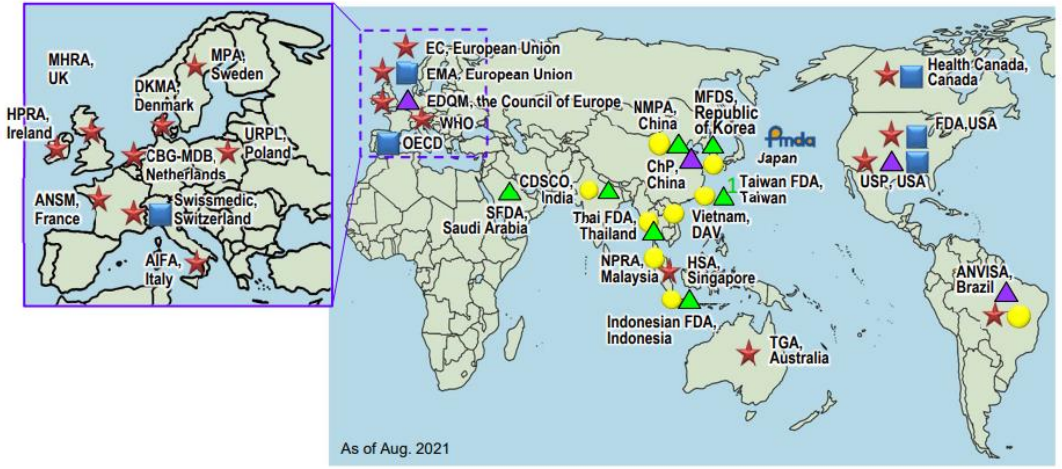
Multilateral Cooperation

- Cooperate with international harmonization frameworks for MD regulations.
- Multilateral cooperation will support the expansion of MDs into international market.



Bilateral Cooperation

- Promote regulatory reliance including review and post-market safety through bilateral cooperation between two countries.



Examples of countries/regions which recognize Japan as reference country [As of September 2022]

Country/ region	System	Population* (million) (2022)	Medical Devices Market scale (billion USD) (2018**, 2020***,****)
Taiwan	• Reduction of documents on quality management systems for medical devices and IVDs (2018)	23.3	4.4***
Singapore	• Accelerated medical device and IVD review (2010)	5.6	2.0****
Malaysia	• Accelerated medical device and IVD review (2014)	32.6	1.4**
Mexico	• Accelerated medical device review (2012)	126.0	54.0**
India	• Acceptance of QMS investigation results in Japan for medical devices and IVDs (2015) • Exemption from conducting clinical trials in India (2017)	1417.2	48.9**
Australia	• Accelerated medical device and IVD review (2018)	25.8	4.6***
Thailand	• Accelerated medical device and IVD review (2019)	66.1	14.7**

<Source>
* https://www.mofa.go.jp/mofaj/index.html ** https://healthcare-international.meti.go.jp *** https://www.trade.gov/ **** https://www.statista.com/

Not only providing review reports PMDA supports these RAs by responding to their queries!

Take-Home Messages

- Japan is the world's 2nd largest MD market.
- All citizens are covered by the National Insurance System.
- PMDA provides generous development consultation and discount fee for SMEs.
- Product review is completed within a standard period with high predictability.
- Expedited/priority review is applied depending on the characteristics of MDs.
- RWD during pre/post market stages can be accepted.
- Regulations are internationally harmonized, and many countries use Japan as a reference country.

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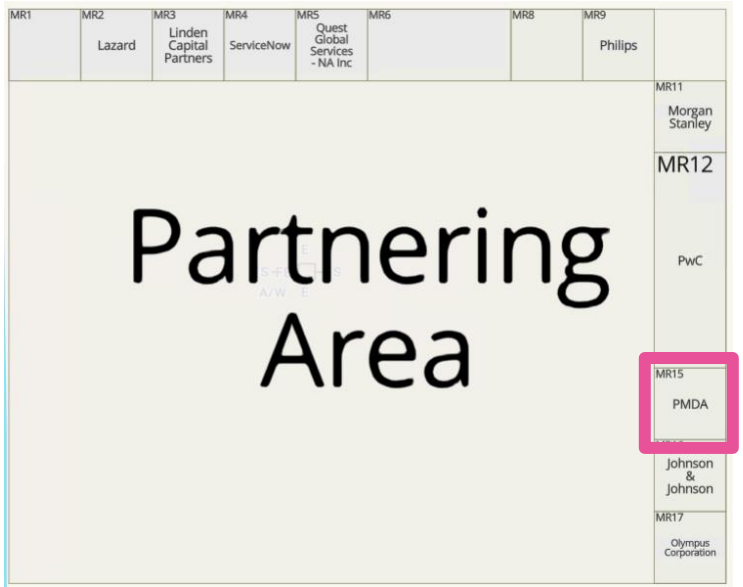
Information about 30-minute free regulatory consultation at meeting room



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PMDA

Please send your meeting request to **pmda-md-intl@pmda.go.jp** or via medtech app with specific questions and a preferred day/time if you are interested in having a private meeting with us.

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Thank you!