IMDRF International Medical Device Regulators Forum

Japan Update

IMDRF Open Stakeholder Forum

March 2018

厚生労働省
Ministry of Health, Labour and Welfare

pmda

- Regulatory Authorities in Japan -

MHLW

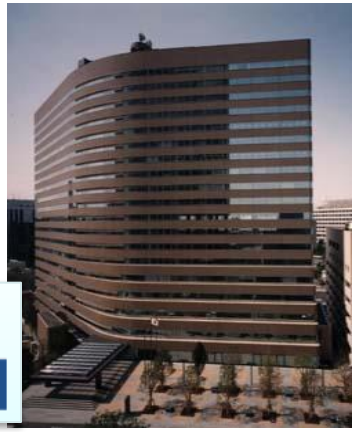
Ministry of Health, Labor and Welfare

- **Final Authorization of applications**
- **Publishing Guidelines**
- **Advisory committee**
- **Supervising PMDA Activities**

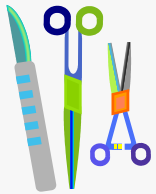
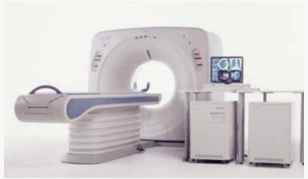
PMDA

Pharmaceuticals and Medical Devices Agency

- **Scientific Review for Drugs & MD**
- **GCP, GMP Inspection**
- **Consultation on Clinical Trials etc.**



Medical Device Regulations in Japan

Classification	Class I	Class II	Class III	Class IV
Category	General MDs	Controlled MDs	Specially controlled MDs	
Premarket regulation	Self-declaration	Third party certification	MHLW approval (PMDA review)	
Example		 	 	  
Post market safety (vigilance/surveillance)	PMDA and MHLW			

JAPAN UPDATE

1. Regulatory Science Center
2. AI
3. Sakigake Designation
4. Summit/ICMRA

Establishment of PMDA Regulatory Science Center

Regulatory Science:Science to predict, evaluate and determine quality, efficacy and safety of medicinal products **based on scientific knowledge properly and expeditiously**

Promotions So far...Science Board , Joint Graduate School, Comprehensive Partnership Agreement
Cross-sectional Standards Development PT, etc.

Regulatory Science Center will be established in April 2018;
will actively collect and utilize scientific knowledge of quality, efficacy and safety especially derived from the "Real World Data" (such us MID-NET®)

- will improve the quality of review and safety measures
- will actively disseminate scientific evidence
- will actively publish guidelines

PMDA will be able to provide consistent assistance throughout the regulatory process from consultation to review and approval

Medical devices incorporating AI technology

Products incorporating Artificial Intelligence (AI)

→ *Medical Devices or not:* based on their use or mode of distribution

→ *If YES:* regulated by Pharmaceuticals and Medical Devices Act

Medical Device Regulations

R&D, Clinical trials → **Product review** → **Manufacturing quality assurance** → **Distribution, Post-marketing safety measures**

Safety/Efficacy Evaluation

Efforts to date → **PMDA proactively engages**

- **Improved its consultation/review framework**
  - to better recognize technological innovations (e.g. Robotics, ICT) (Oct. 2015)
- **Issued a guidance document**
  - to summarize key points on medical device programs review (e.g. diagnostic support (Mar. 2016)
- **Opinion exchanges**
  - with diagnostic imaging devices developers (held since Dec. 2016)

Challenges
medical devices incorporating AI technology

1. Evaluation methodology

- **Evaluation considering characteristics specific to AI utilization**
  (e.g., continuous changes in product performance)

[MHLW] Expert Consultative Meeting on:
Diagnostic imaging products (as first focus).
- **Evaluation standards**
- Outcome: by the end of Mar. 2018
- Opinion exchanges with industry in parallel.

[PMDA] **Science Board** - **AI Subcommittee**
"AI as a New Factor in Medical Device Reviews"
- how to best adapt PMDA's review/consultation services

Challenges
medical devices incorporating AI technology

2. Evaluation framework

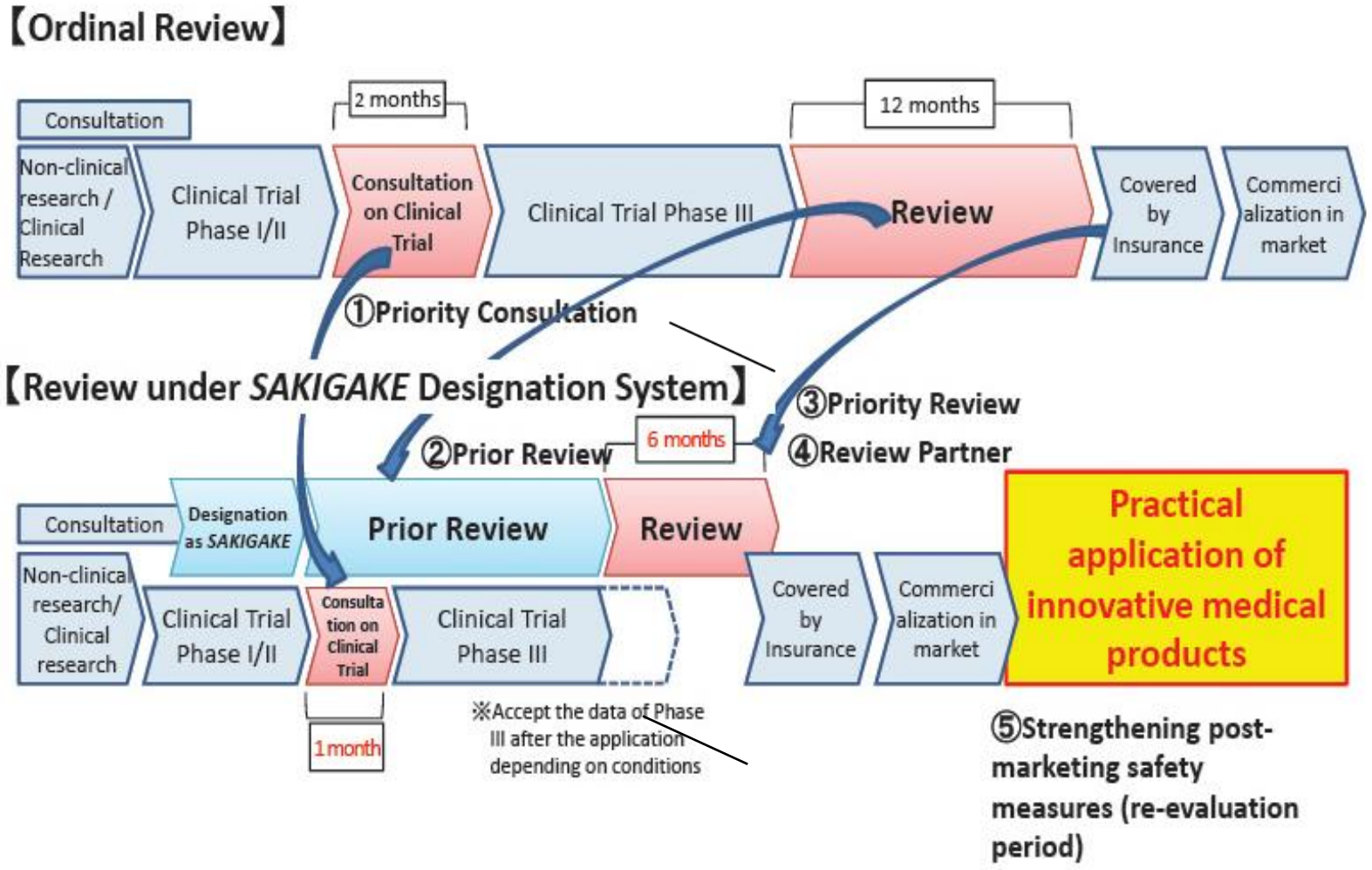
- Post-marketing evaluations/follow-up
  requires sophisticated understanding
  - Characteristics/potential of AI (e.g., dynamism of processing capabilities)
  - Continuous evaluations/information provision: to Health Care Professionals

<possible next steps>

→ **Prepare suitable organizational structures** to be engaged in pre-/post-marketing evaluations

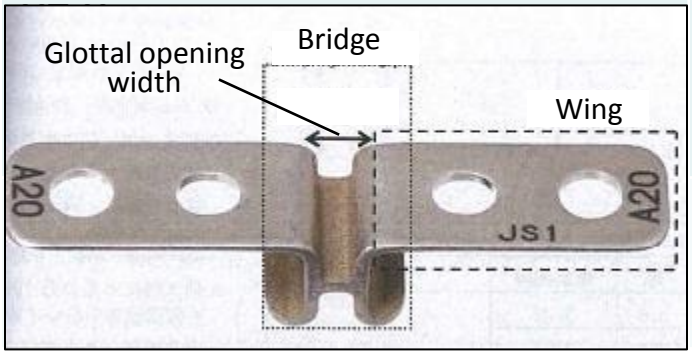
→ **Development/issuance of science-based guidelines prior to product development** with Regulatory Scientific Principles

SAKIGAKE Designation System

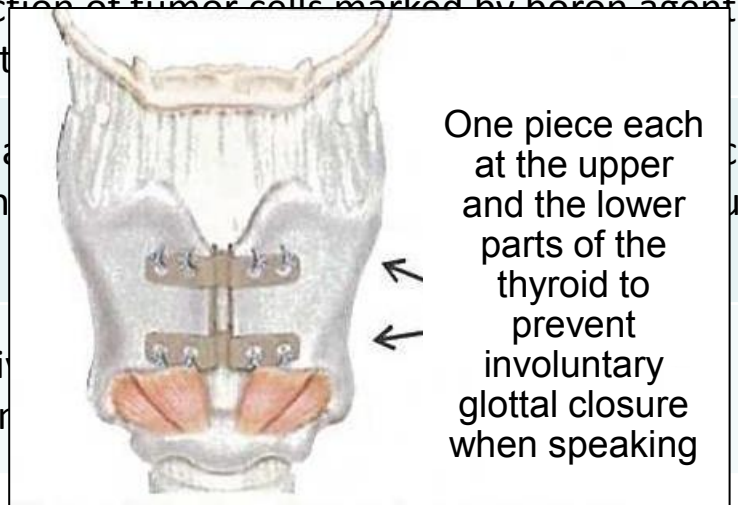


Designation of Sakigake products

Titanium Bridge, the first designated medical device submitted in June 2017, was reviewed in the priority review scheme and approved after only 6 months!

No.	Product name	Expected performance/effectiveness
MD1	**Titanium Bridge** (Hinge-type plate with titanium)	Adduction-type spasmodic dysphonia
MD3	**Artificial tracheal** (made of polypr… sponge)	…reconstruction of tracheal while maintaining …moval.
MD4	**Boron neutr…** **(BNCT) system** (Neutron irradiation system for BNCT)	…Selective destruct… …ts, without…
MD5		Higher … resynch… failure. …cardiac …us heart
IVD1		Collecti… decisior… …aid

First Approval of Sakigake Designation (December, 2017)



One piece each at the upper and the lower parts of the thyroid to prevent involuntary glottal closure when speaking

Summit and ICMRA 2017 in Kyoto

Japan hosted the 12th Summit of Heads of Medicines Regulatory Agencies, ICMRA (International Coalition of Medicines Regulatory Authorities) and "Summit Symposium" in Oct. 23-27 2017 in Kyoto.

Summit of the Heads of Medicines Regulatory Agencies: started in 2006; consists of the heads of 23 regulatory agencies; chaired by a host country; and discusses the future vision of regulation (Regenerative Medical Products, Novel Information Databases, AMR, SSFFC .etc).

ICMRA (International Coalition of Medicines Regulatory Authorities): started in 2012; consists of 22 regulatory agencies; chaired by MHRA (UK) at present; and discusses strategically important areas (Crisis Management, Pharmacovigilance, and Supply Chain Integrity .etc).

Outcome of Kyoto Summit

1. Innovation

- **Regulatory convergence on regenerative medicines**
- **Use of Real Word Data (RWD)**

2. International Cooperation

- **Fight against Antimicrobial Resistance (AMR)**
- **Countermeasures against substandard/falsified medical products**

IMDRF International Medical Device Regulators Forum

Summit and ICMRA 2017 in Kyoto

https://www.pmda.go.jp/english/symposia/0121.html

Thank you!