New Regulation in Japan and Future Direction of PMDA

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Today's Topics

1. Current situation of PMDA
2. New Regulation in Japan
3. Strategies and Measures for PMDA Innovation

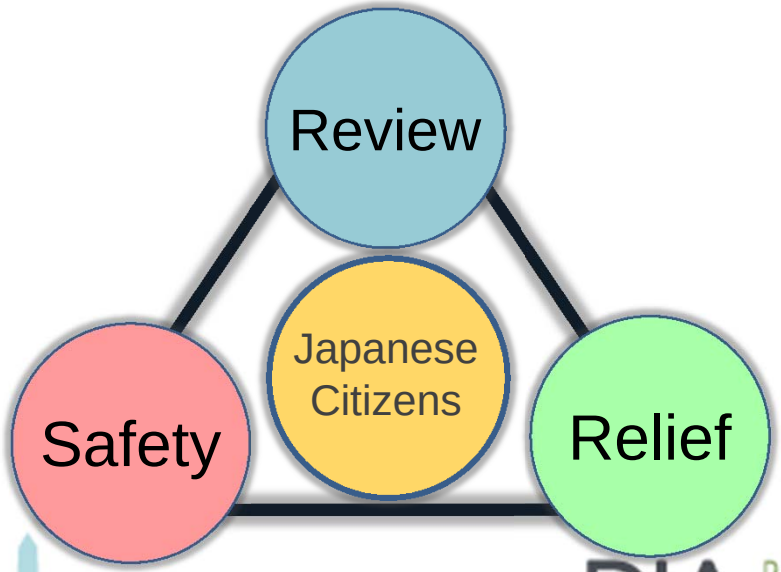
Pharmaceuticals and Medical Devices Agency

Kansai Branch

Major Services

- Scientific Review for Drugs & Medical Devices
- GCP, GMP Inspection
- Consultation on Clinical Trials
- Safety Measures
- Relief Services

Unique Three-pillar System Securing Nation's Safety



PMDA Homepage:
http://www.pmda.go.jp/english/index.html

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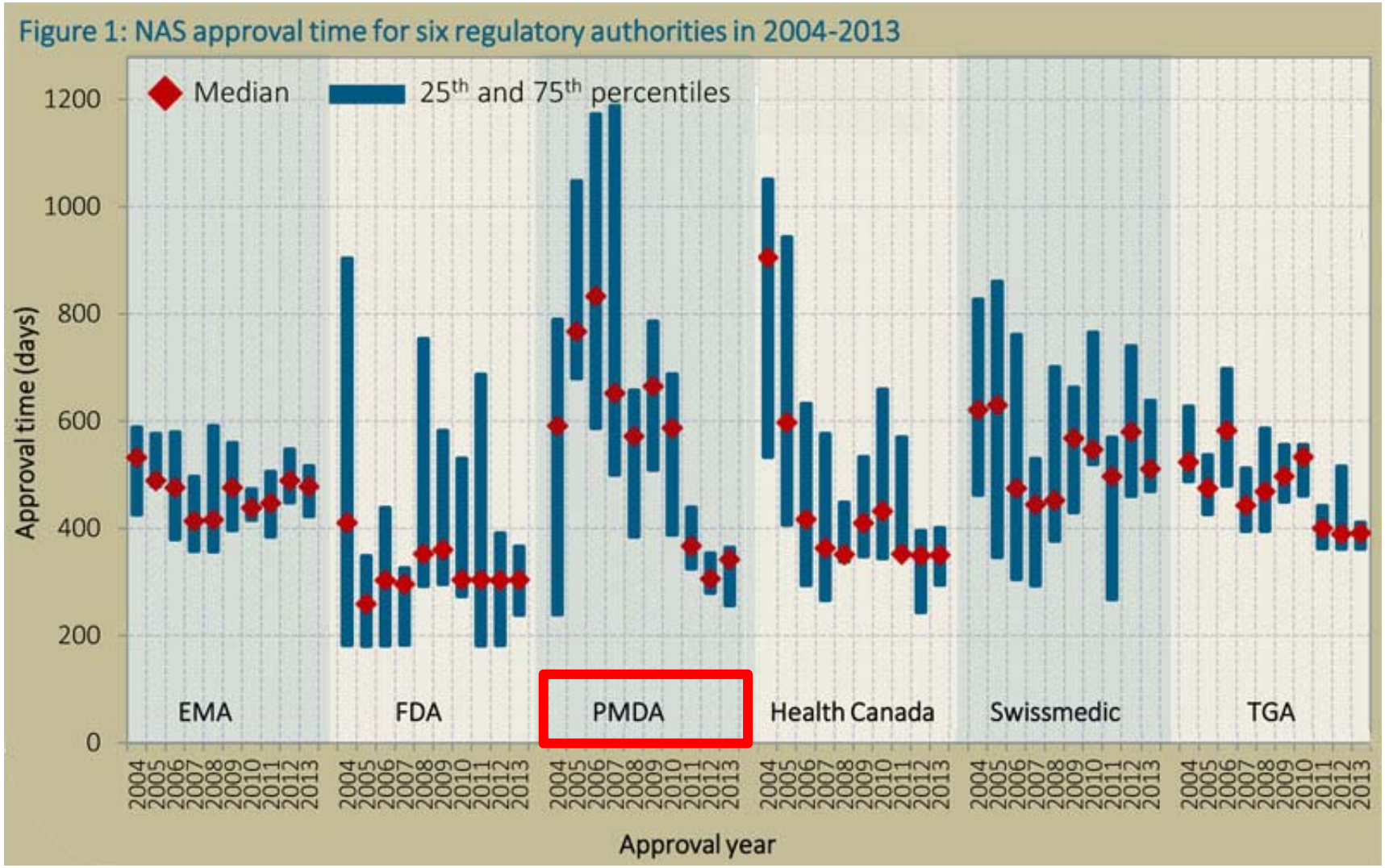
Strategies and Measures for PMDA Innovation

Issues in the past	Basic policies to address the issues	Efforts made so far
◆Drug / Device lag ◆Insufficient Safety measures	◆Philosophy (**Mission Statement**) ◆Regulatory science ◆Global partnership **(Win-Win Relationship)**	● **Increase staff members** ● **Enhance training program** ● **Academic cooperation** ● **Industry-Government-Academia collaboration** ● **Pharmaceutical affairs consultation** ● **Cross-sectional project within PMDA** ● **IT-based safety measures** ● **Risk Manager（RM）** ● **Risk Management Plan（RMP）** ● **GLP, GCP, GMP ,QMS inspection programs** ● **Adverse health effect relief system** ● **International strategic plan** ● **Global partnership**

Pharmaceutical affairs are the ultimate medical ethics, and regulatory science is the underlying science.

Japan’s Performance on NDA Review



“Japan's PMDA and Health Canada may have had the most notable improvements over the past decade.”
Regulatory Affairs Professionals Society 14 January 2015

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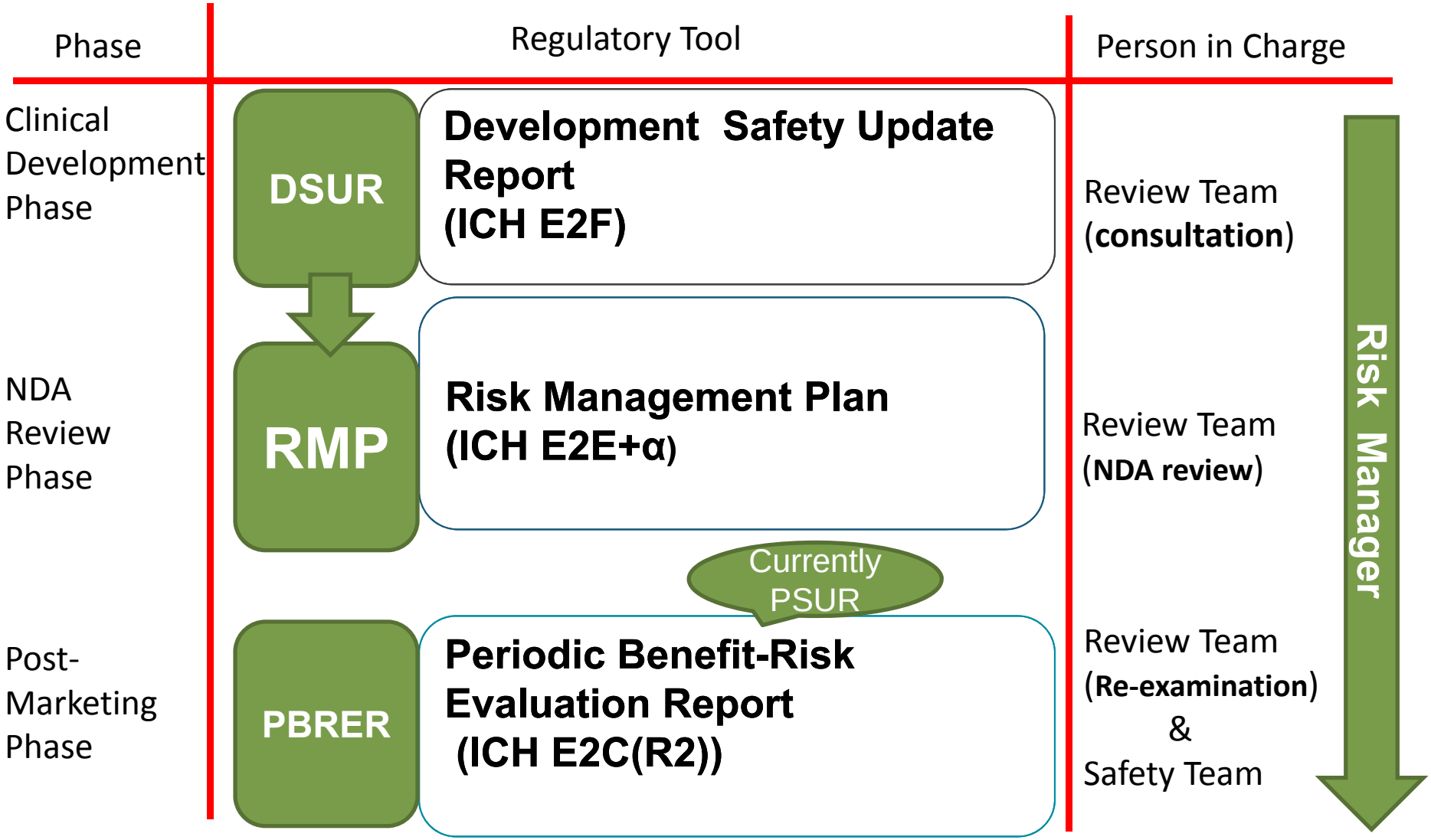
Continues Risk Management through Product Life-cycle



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Revision of Pharmaceutical Affairs Law

1. **Strengthen safety measures regarding drugs and medical devices**
2. **Revise medical device regulations based on its characteristics**
3. **Introduce cellular and tissue therapeutic product regulations based on its characteristics**

PAL has been renamed as

"Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics"

= Pharmaceutical and Medical Device Act, or "PMD Act".

Expedited approval system under PMD Act (Time-limited Conditional Approval)

Conventional Regulatory Approval Process

Regulatory System That Facilitates Early Practical Application of Cellular or Tissue-based Products

Faster access of patients to new products is expected.

Each patient is informed of the risks of the product and consent is obtained from the patient, while post-marketing safety measures are taken.

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Six regulatory innovations in Japan

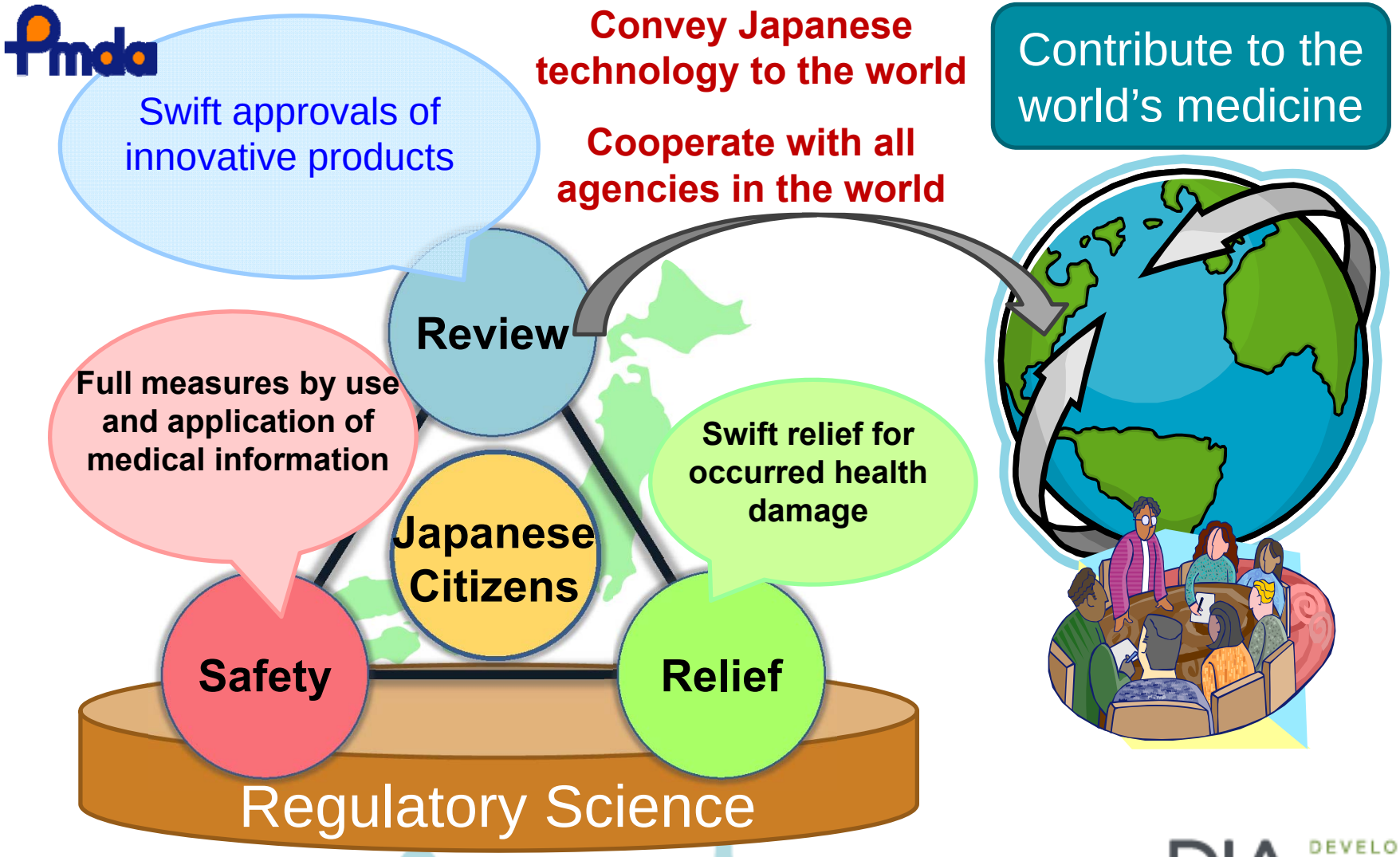
Stage	Agendas for PMDA	
Development	○ Support for promising seeds to forward the development.	→Pharmaceutical Affairs Consultation on R&D Strategy (from July 2011)
Review	○ Approaches to cutting-edge technologies ○ Early practical use of regenerative medical products. ○ Encouraging Japan-first development and approvals. ○ Improve efficiency of development	→Science Board (from June 2012) →Time-limited Conditional Approval (from November 2014) →SAKIGAKE designation system (from FY 2015) →Advanced review system (under development)
Post-marketing	○ Utilize medical information database	→MIHARI project (from FY 2009)

PMDA's next step

- PMDA is currently working on the new international strategic plan to further promote internationalization.
- The plan includes
  - Enhancing dissemination of information
  - Internationalization of pharmaceutical regulations
  - Work sharing.
  - Contribution to the regulatory harmonization

13

PMDA for the World -To create society to receive the essential forefront medicines-



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Thank You

For Win-Win Relationship

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