June 13th, 2024

PMDA's Vision in New (Fifth) Mid-term Targets - International Vision -

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DISCLAIMER : The contents of this presentation represent the view of this presenter only, and do not represent the views and/or policies of the PMDA

PMDA Enters a New Stage on its 20th Anniversary

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

April, 2024

New start of PMDA

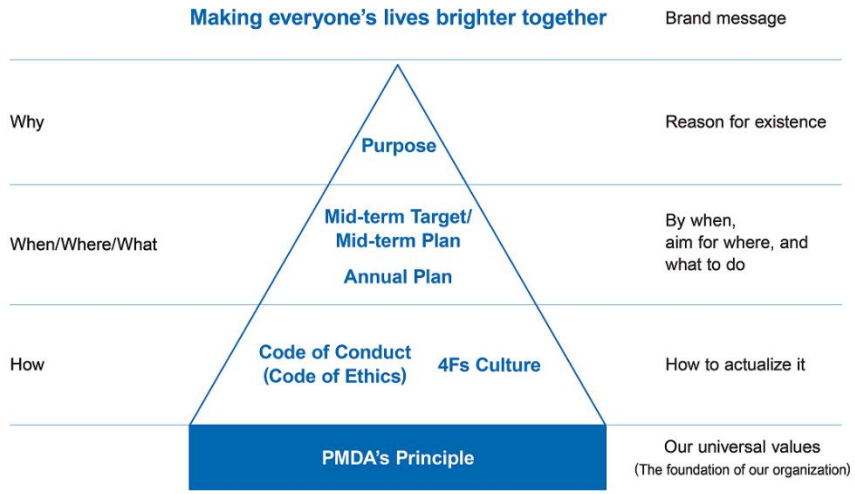
- Organization with more than 1000 people
- Every staff faces PMDA' s Purpose in their work

2014

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

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



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

(Jul 10, 2023 – Mar 21, 2024)

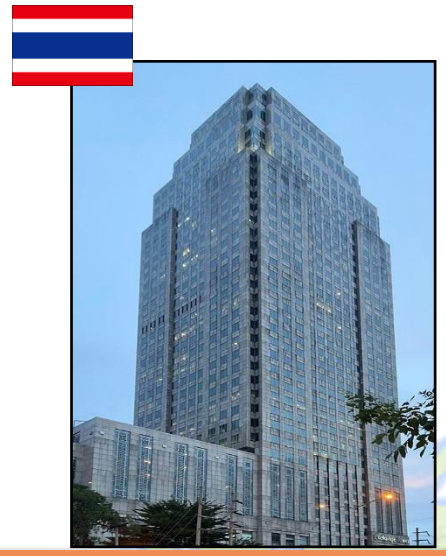
Considering the pharmaceutical affairs regulations in order to eliminate drug loss issues, ensure stable supply and accelerate pediatric drugs development

Considerations

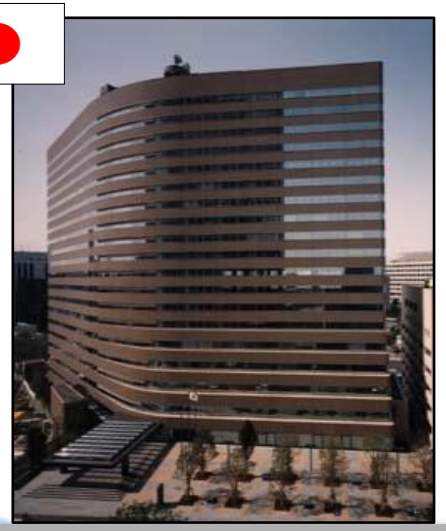
Promotion of development	How to designate orphan drugs	*Jul 10, 2023*
	Pharmaceutical reviews that contribute to promote development of pediatric drugs	*Aug 7, 2023; Sep 13, Dec 13, Feb 8, 2024*
Clinical trials	Arrangement of necessity of Japanese data for approval review in Japan	*Mar 12, 2024*
	Introduction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

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

PMDA's International Hubs



Asia Office, Bangkok



PMDA Central Office, Tokyo

To be established FY2024

Washington D.C Office

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

Thank you very much!!

Please also see below information on the support of development in Japan

Reference materials on development in Japan for overseas ventures

https://www.pmda.go.jp/files/000266927.pdf

Regenerative Medical Products

1. Regulatory Framework

Regenerative medicine, which is expected to overcome intractable and serious diseases, is expected to play an important role in conventional medicine worldwide. The Japanese government must implement comprehensive policies to promote the development of regenerative medicine, inform the public, and increase public acceptance, and ensure that medical professionals and investigators cooperate with the policies. In this background, two regulatory frameworks for regenerative medicine, "The Act on the Safety of Regenerative Medicine " (ASRM) and the "Pharmaceuticals, Medical Devices, and Other Therapeutic Products Act " (PMD Act), came into effect in November 2014. The ASRM sets out legal regulations not only for research, but also for the daily medical practice of cell therapy, which had previously been under the jurisdiction of the Medical Practitioners' Act and the Medical Care Act .

The PMD Act regulates the commercialization of regenerative medical products. Regenerative medical products in the PMD Act are defined as:

a. Processed (more than minimal manipulation) live human/animal cells that are intended to be used for either

- reconstruction, repair, or formation of structures or functions of the human body

https://www.pmda.go.jp/english/review-services/reviews/0003.html