Clinical Trial Regulations

India and International



Module 5 Topic 1_3

What is PMDA?

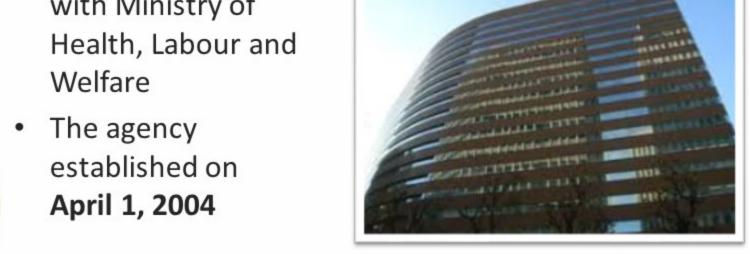
PMDA

 (Pharmaceuticals and Medical Devices
 Agency) is Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare



stands for

Pharmaceuticals and Medical Devices Agency





Objectives of PMDA

- To pursue the development of medical science while performing duty with greater transparency based on mission to protect public health and the lives of Japanese citizens
- Be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices



Objectives of PMDA (contd)

- Make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.
- Play an active role within the international community by promoting international harmonization.
- Conduct services in a way that is trusted by the public based on our experiences from the past.



History of PMDA

Following the Reorganization and Rationalization
Plan for Special Public Corporations, which was
approved at a Cabinet meeting in 2001, the
Pharmaceuticals and Medical Devices Agency
(PMDA) was established and came into service on
April 1, 2004, under the Act on the Pharmaceuticals
and Medical Devices Agency

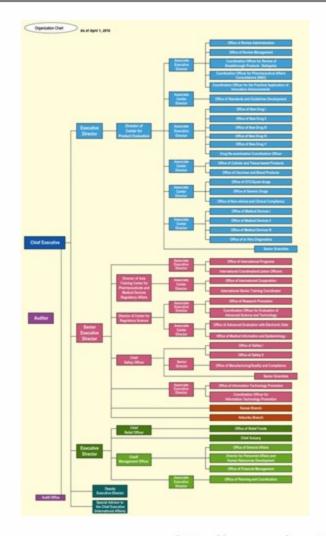


History of PMDA

- The aim of establishment of PMDA was to consolidate the services of
 - Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences (PMDEC),
 - Organization for Pharmaceutical Safety and Research (OPSR),
 - Japan Association for the Advancement of Medical Equipment (JAAME).



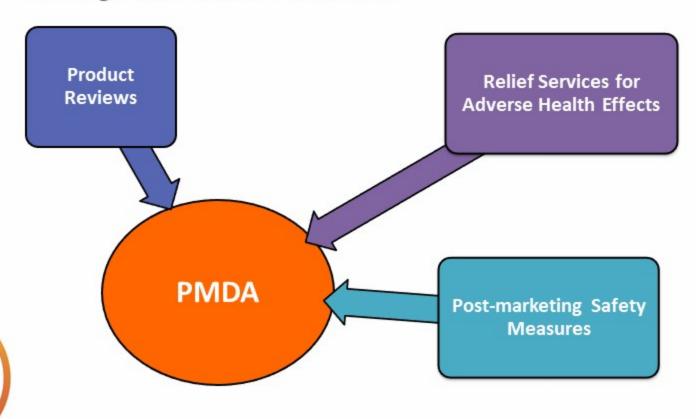
Structure of PMDA





Academ

Safety Triangle: Comprehensive Risk Management through the Three Functions



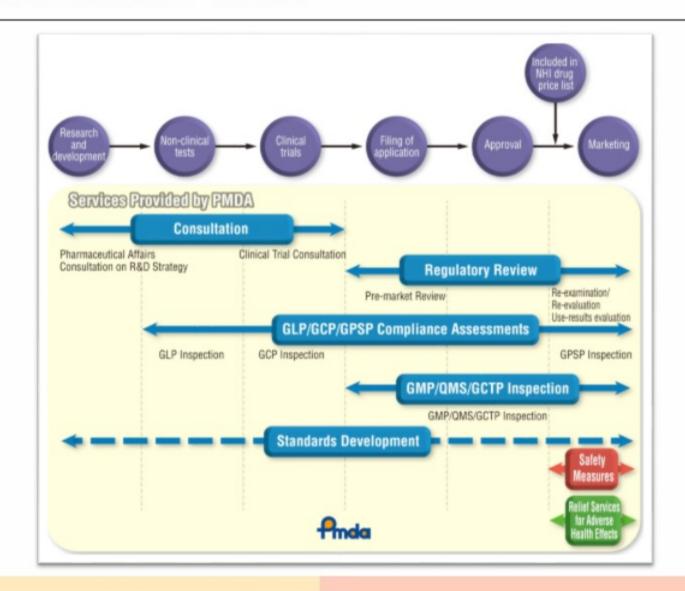
PMDA's mission is to help improve public health in Japan by providing swift relief to people who have suffered health damage caused by adverse drug reactions or infections from biological products (Relief Services for Adverse Health Effects), offering guidance and conducting reviews on the quality, efficacy and safety of drugs and medical devices through a system that integrates the entire process from pre-clinical research to approval (Product Reviews), and by collecting, analyzing and providing post-market safety information (Post-marketing Safety Measures)



Product review

- Consultations on clinical trials and other issues
- Regulatory review of drugs, medical devices and regenerative medical products
- Re-examinations/re-evaluations
- GLP/GCP/GPSP compliance assessments for regulatory submission documentation
- GMP/QMS/GCTP inspections of manufacturing processes and facilities
- Inspection of registered certification bodies
- Development of standards e.g. Japanese Pharmacopoeia



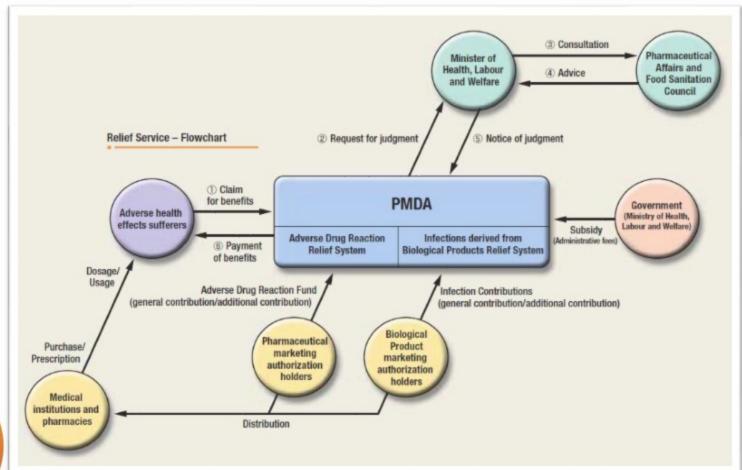




Relief Services for Adverse Health Effects

- Relief service for adverse drug reactions
- Relief service for infections acquired through biological products
- Health allowances etc., for SMON patients
- Health allowances for HIV-positive and AIDS patients
- Financial assistance under the "Act on Special Measures concerning the Payment of Benefits to Assist Individuals Affected by Hepatitis C through Specified Fibrinogen Products and Specified Blood Coagulation Factor IX Products Contaminated by Hepatitis C Virus"





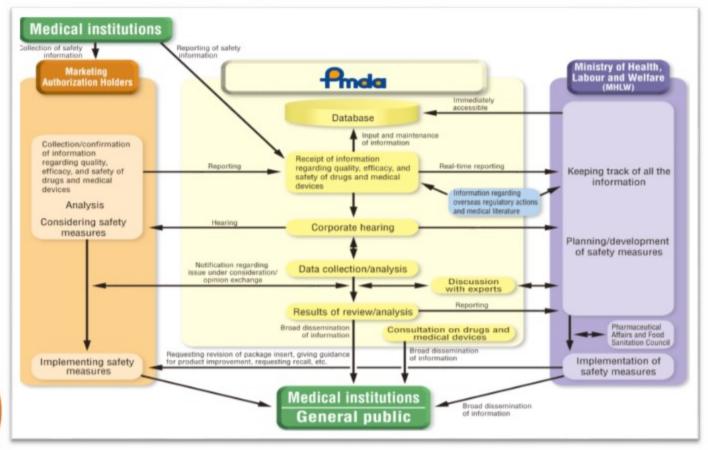


Post-marketing Safety Measures

- Acceptance of submitted labeling information (package inserts)
- Collection and organization of safety information from marketing authorization holders (MAHs) or medical institutions
- Scientific research and analysis of collected information
- Consultation services on safety measures for MAHs
- Consultation services for consumers
- Provision of information on drugs, medical devices, and regenerative medical products



Flowchart of Safety Measures





Regulatory Science

- What Is Regulatory Science?
- Regulatory science plays an important role in adapting the achievements of technology to social and human needs in the most optimal way, by making precise prediction, evaluation and judgment based on evidence.
- When a product obtained as a result of the medical research and development is applied to practical use, regulatory science contributes to making appropriate and prompt prediction, evaluation and judgment of the quality, efficacy and safety of the product in light of scientific findings.



PMDA and International Activities

- PMDA actively promotes international activities in line with the PMDA International Vision established in 2011.
- Specifically, emphases are placed on
 - Strengthening cooperation with the US, the EU, and Asian countries
 - Participation in and contribution to international harmonization activities such as the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and International Medical Device Regulators Forum (IMDRF)
 - Dissemination of information to the international community



References

- https://www.pmda.go.jp/english/about-pmda/index.html
- Profile of Services (2017-2018), Pharmaceutical and Medical Devices Agency, Japan (https://www.pmda.go.jp/files/000221139.pdf)
- Article 13, paragraph 2 of the Act to Promote Healthcare and Medical Strategy
- Basic Program for Science and Technology [approved by the Cabinet on August 19, 2011]

