

PMDA Training Seminar

November 29, 2010

Relief Service for Adverse Health Effects in Japan

**Pharmaceuticals and Medical Devices Agency
(PMDA)**



**Deputy Director
Office of Relief Funds
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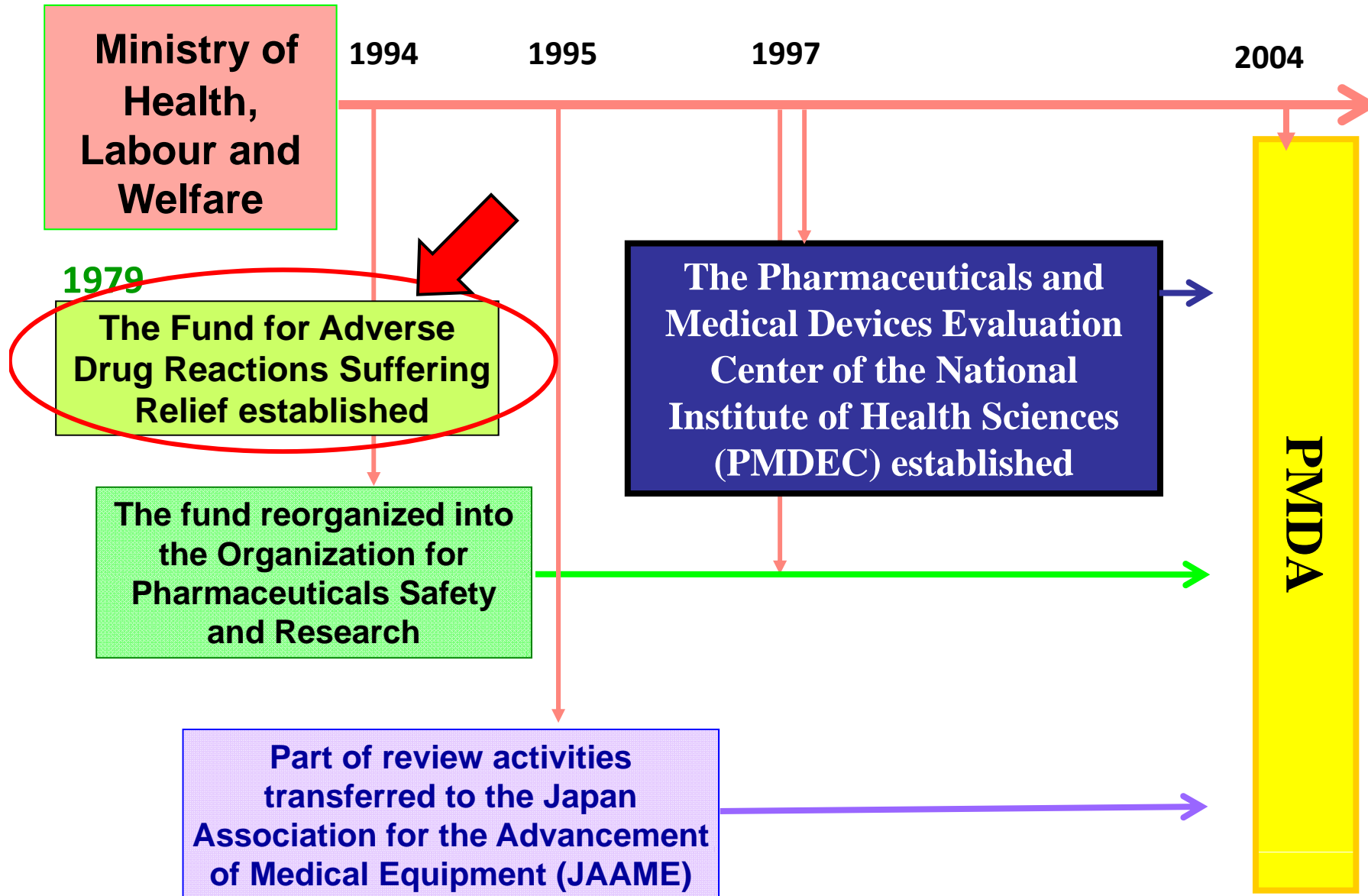
Agenda

- 1. What is the PMDA**
- 2. Relief Service for Adverse Health Effects in Japan**
- 3. Relief System for Adverse Drug Reactions**
- 4. Relief System for Infections Acquired through Biological Products**
- 5. Others**

1. WHAT 'S



History of PMDA

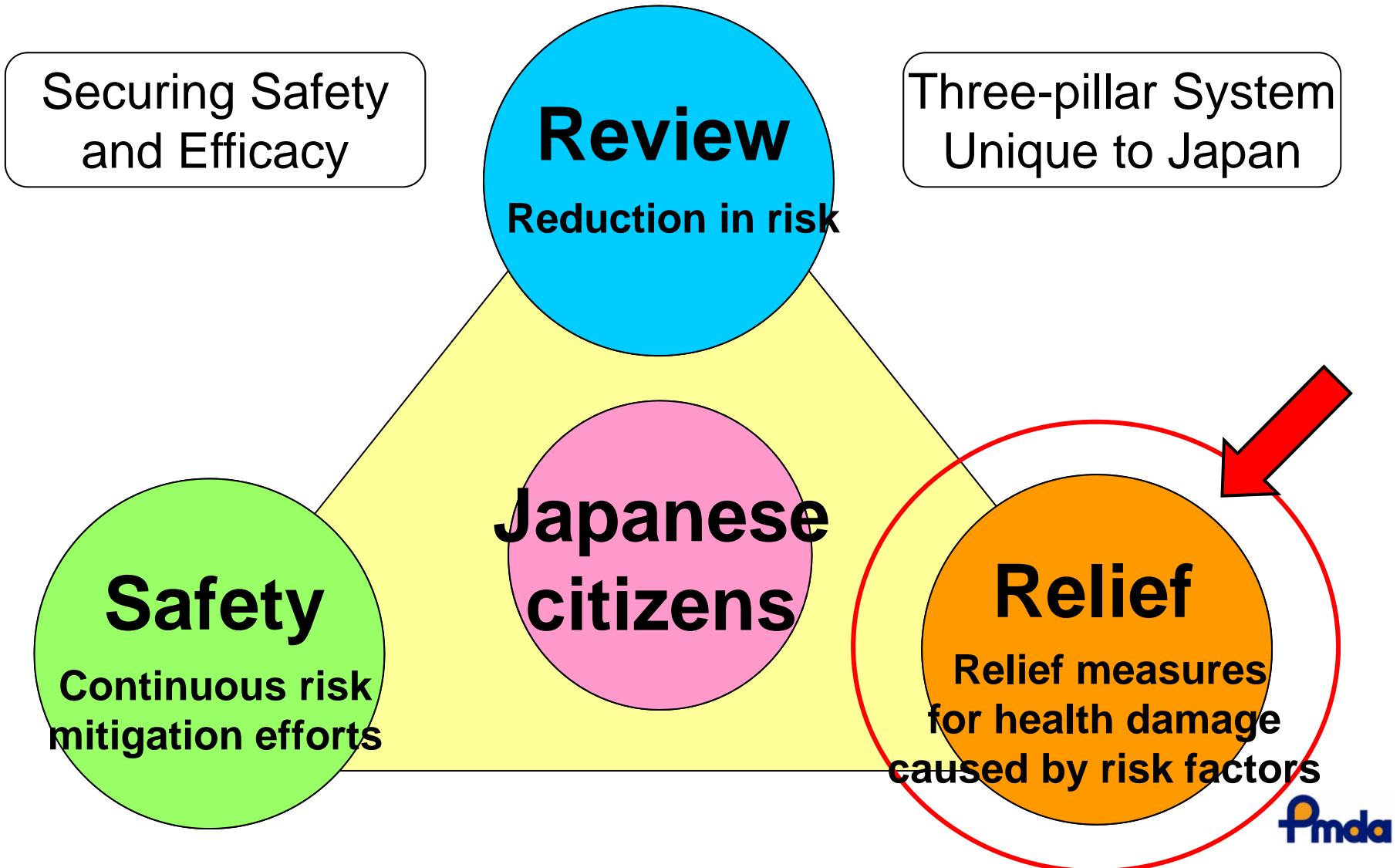


Our philosophy

PMDA continues to improve the public health and safety of our nation by reviewing applications for marketing approval of pharmaceuticals and medical devices, conducting safety measures, and providing relief to people who have suffered from adverse drug reactions.

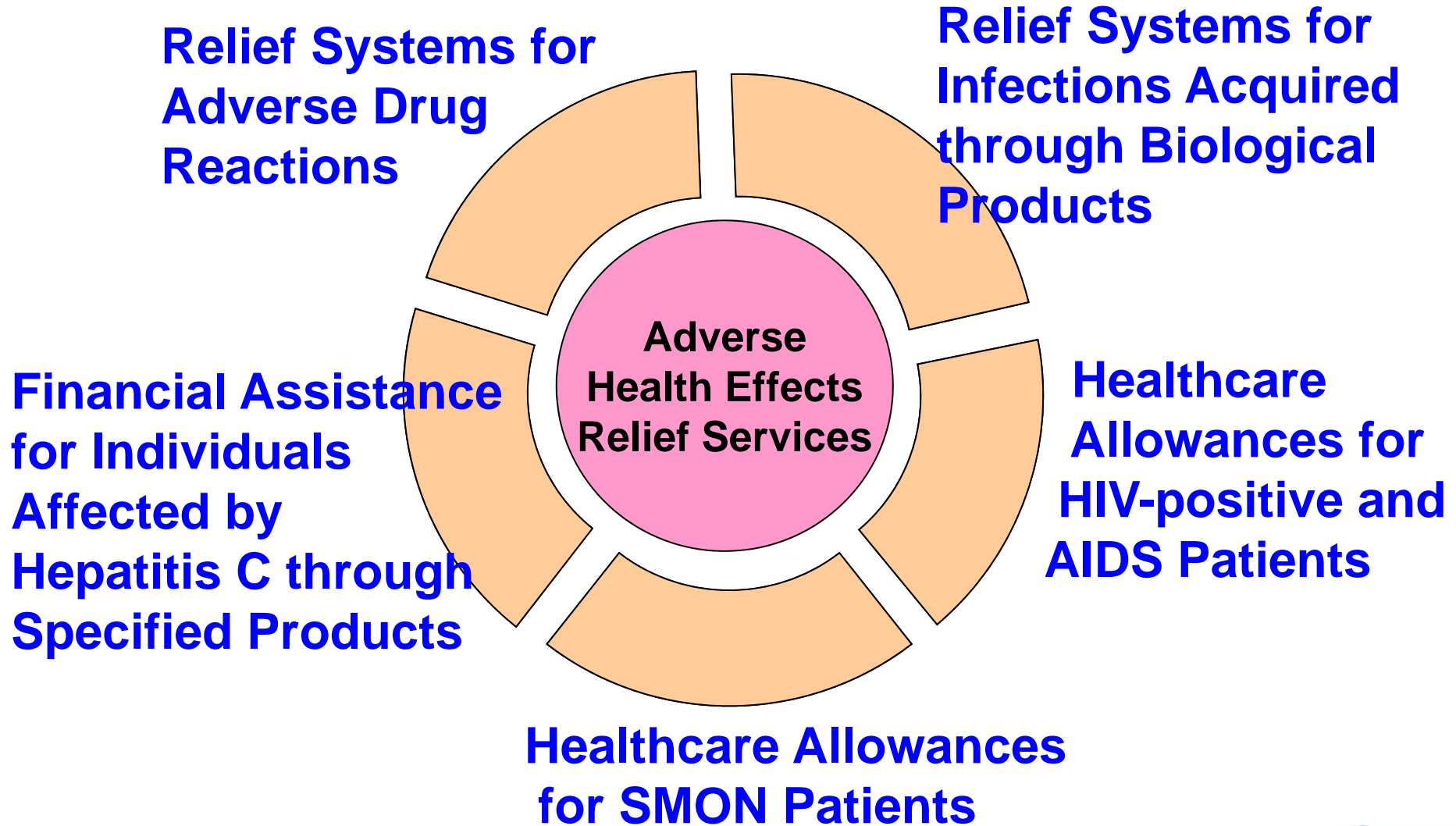
Safety Triangle

- Comprehensive Risk Management through
Our Three Functions –



2. Relief Services for Adverse Health Effects

Five Relief Services for Adverse Health Effects



3. Relief Systems for Adverse Drug Reaction

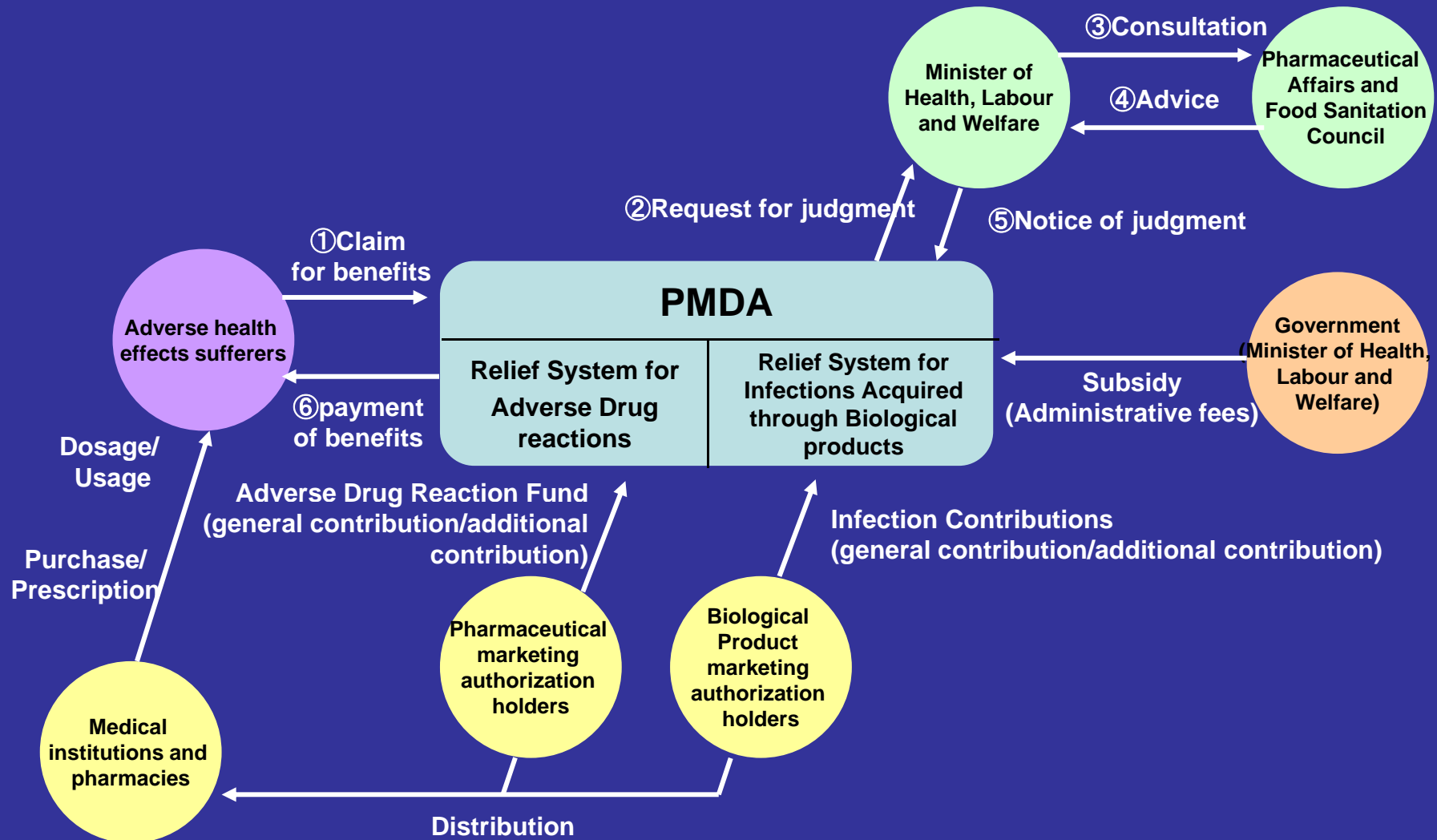
Relief Systems for Adverse Drug Reaction

- **Established in May 1980.**
- **Service of Relief Benefit.**
- **Health damage caused by adverse reactions to drugs.**
- **There are some exceptions .**

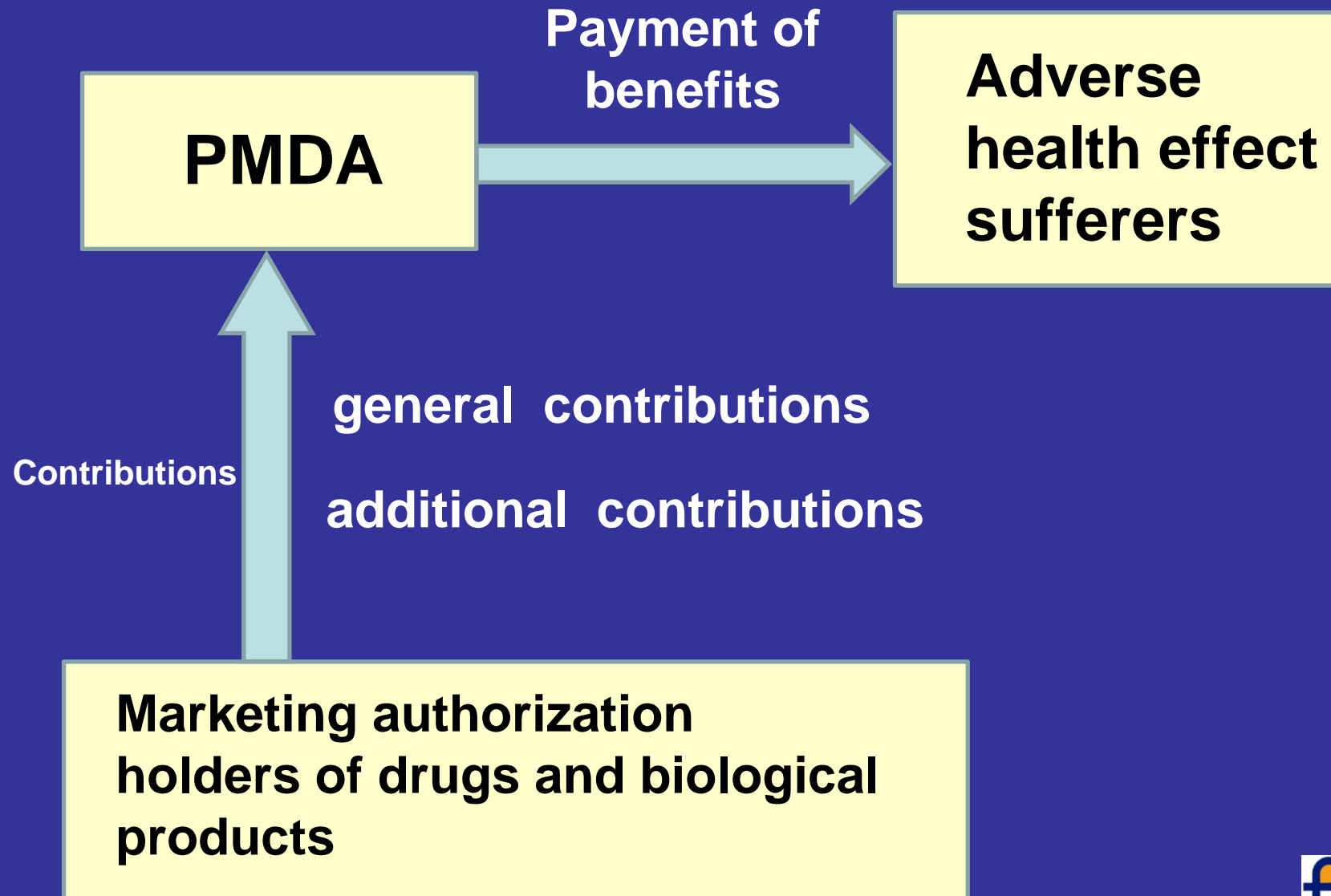
Type of Relief Benefits

In case of disease (requiring hospitalization)	Medical Expenses	Compensation will reflect the actual costs of treatment borne by the patient
	Medical Allowances	Financial assistance is provided for costs other than medical costs for disease treatment
In case of disability (causing serious Impairment in daily life)	Disability Pension	Financial assistance is provided to compensate living costs of patients over 18 years old, who suffer from a certain degree of disability
	Pension for Raising Handicapped Children	Financial assistance is provided for those who are responsible for raising patients under 18 years old who suffer from a certain degree of disability
In case of death	Bereaved Family Pension	Financial assistance is provided for bereaved families in rebuilding their life following the death of their main provider
	Lump-sum Benefit for Bereaved Family	Financial assistance is provided for bereaved families as a gesture of sympathy following the death of their family member who is not the main provider
	Funeral Expenses	Financial assistance is provided for costs in holding a funeral

Flowchart of Relief Services



Contributions to the Relief System



Cases Not Eligible for Relief

- Cases resulting from statutory vaccinations.
- Cases the marketing authorization holder is liable for the adverse health effects.
- Cases where overdosage was necessary for saving life, even if it was acknowledged adverse health effects may occur.
- Not serious cases.
- Cases the drug was not used properly.
- Cases caused by drugs that are not covered by the relief system.

4. Relief System for Infections Acquired through Biological Products

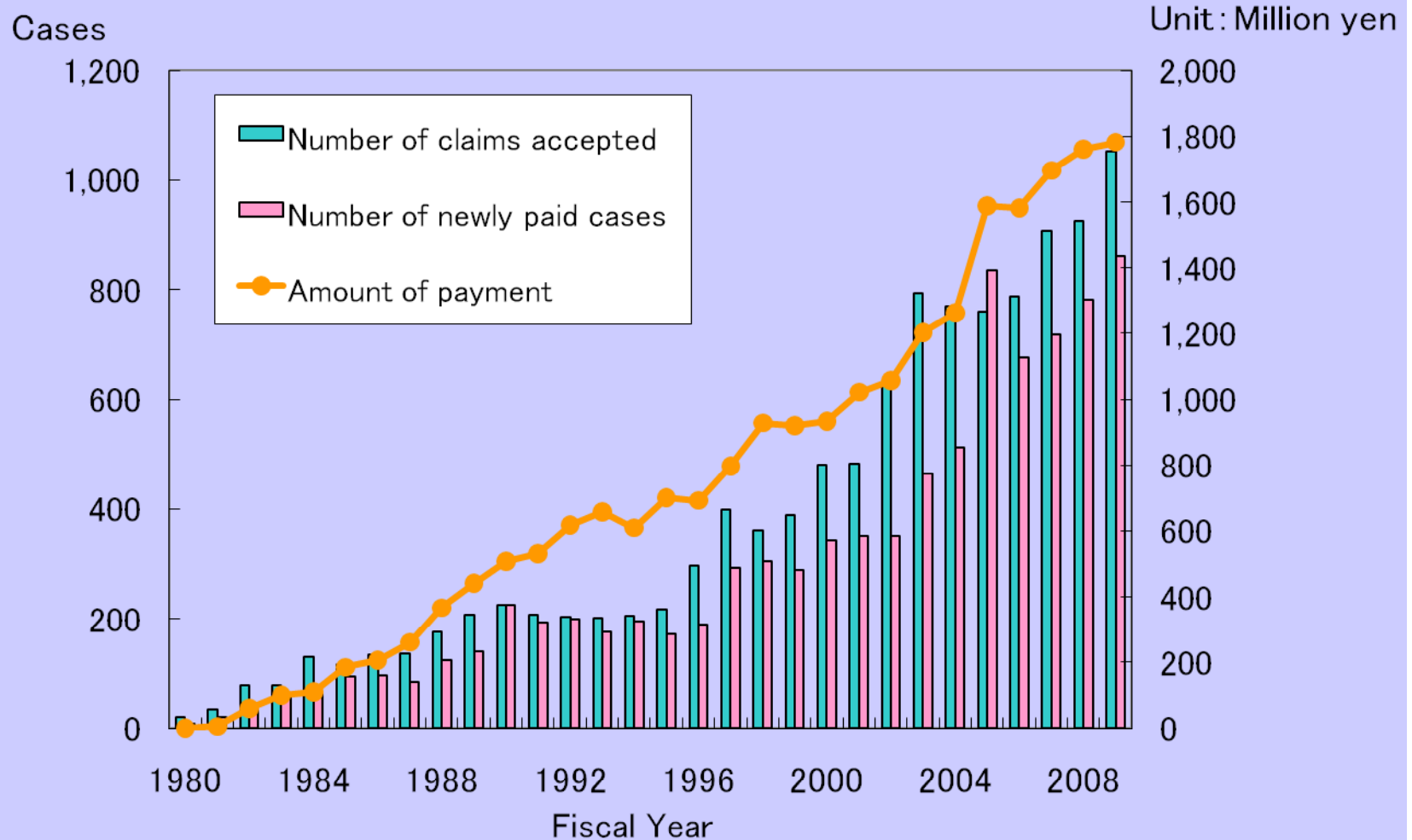
Relief System for Infections Acquired through Biological Product

- **Established in April 2004.**
- **Service of Relief Benefit.**
- **Health Damage caused by infections acquired through Biological Product.**
- **Treatment to prevent the onset of infection and secondary infection case are also eligible.**

5. Others

**Result of judgment for Relief
benefits and Analysis of Cases**

Payment of Relief Benefit



Pharmaceuticals and Medical Devices Agency Website

Pharmaceuticals and Medical Devices Agency, Japan

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

Japanese

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Drug and Medical Device Reviews

Post-marketing Safety

Relief Services for Adverse Health Effects

Safety Information

Approved Products

Regulatory Information

Pharmacopoeia / Standards

Seminar 3, 2010

What's New

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- October 29, 2010 **New**
MHLW Pharmaceuticals and Medical Devices Safety Information posted: Issue of 272, 2010
- October 28, 2010
Ministry of Health, Labour and Welfare (MHLW) and PMDA concluded Confidentiality Arrangement with the Medicines and Healthcare products Regulatory Agency (MHRA)

Click here

mda.go.jp/english/service/outline_r.html

インターネット

Thank you for your attention !



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