

# Relief Systems for Adverse Drug Reaction

- Started in May 1980.
- This is a system that provides relief for diseases and such health effects as disabilities requiring hospitalization that were caused by adverse reactions to pharmaceuticals prescribed at hospitals and clinics as well as those purchased at pharmacies notwithstanding their proper use.
- The system covers adverse health effects caused by reactions to pharmaceuticals that were used properly on and after May 1, 1980. However, there are some exceptions including anticancer and immunosuppressant drugs.

# Cases Not Applicable 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 lifesaving, even if it was acknowledged adverse health effects may occur.**
- **Not serious cases.**
- **Cases the drug was not used for an appropriate purpose and method.**
- **Cases caused by drugs that are not eligible for the relief system.**
- **Cases not approved by the Pharmaceutical Affairs and Food Sanitation Council of MHLW based on medical and pharmaceutical judgment.**

# Type of Relief Benefits

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

# Financial Resources

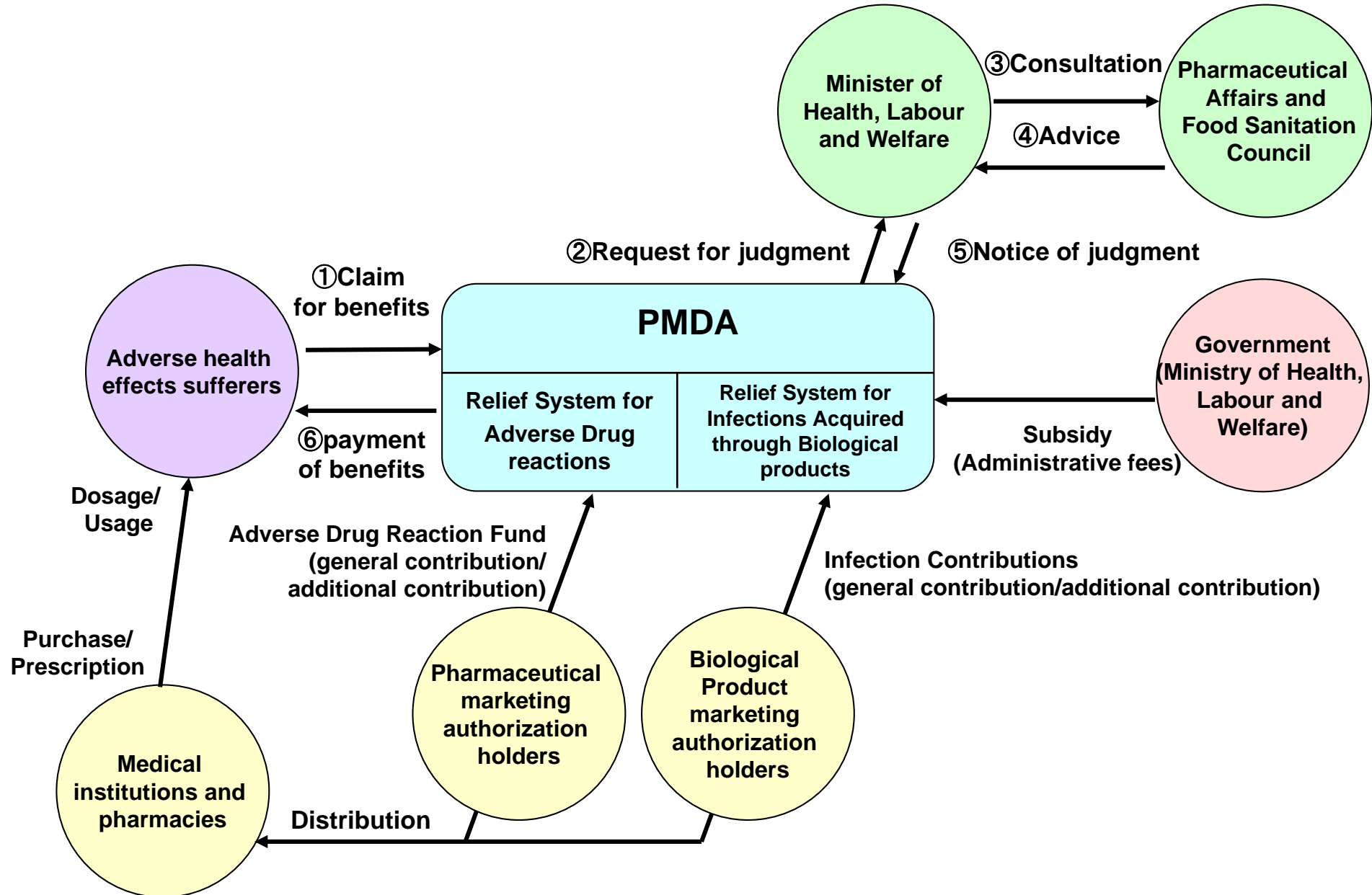
(1) Contributions collected from marketing authorization holders of drugs

\*General Contributions: Certain rate of total sales volume (0.27/1000 at current rate)

\*Additional Contributions: 25% from holders of main cause

(2) 50% of administrative fees at the government's expense

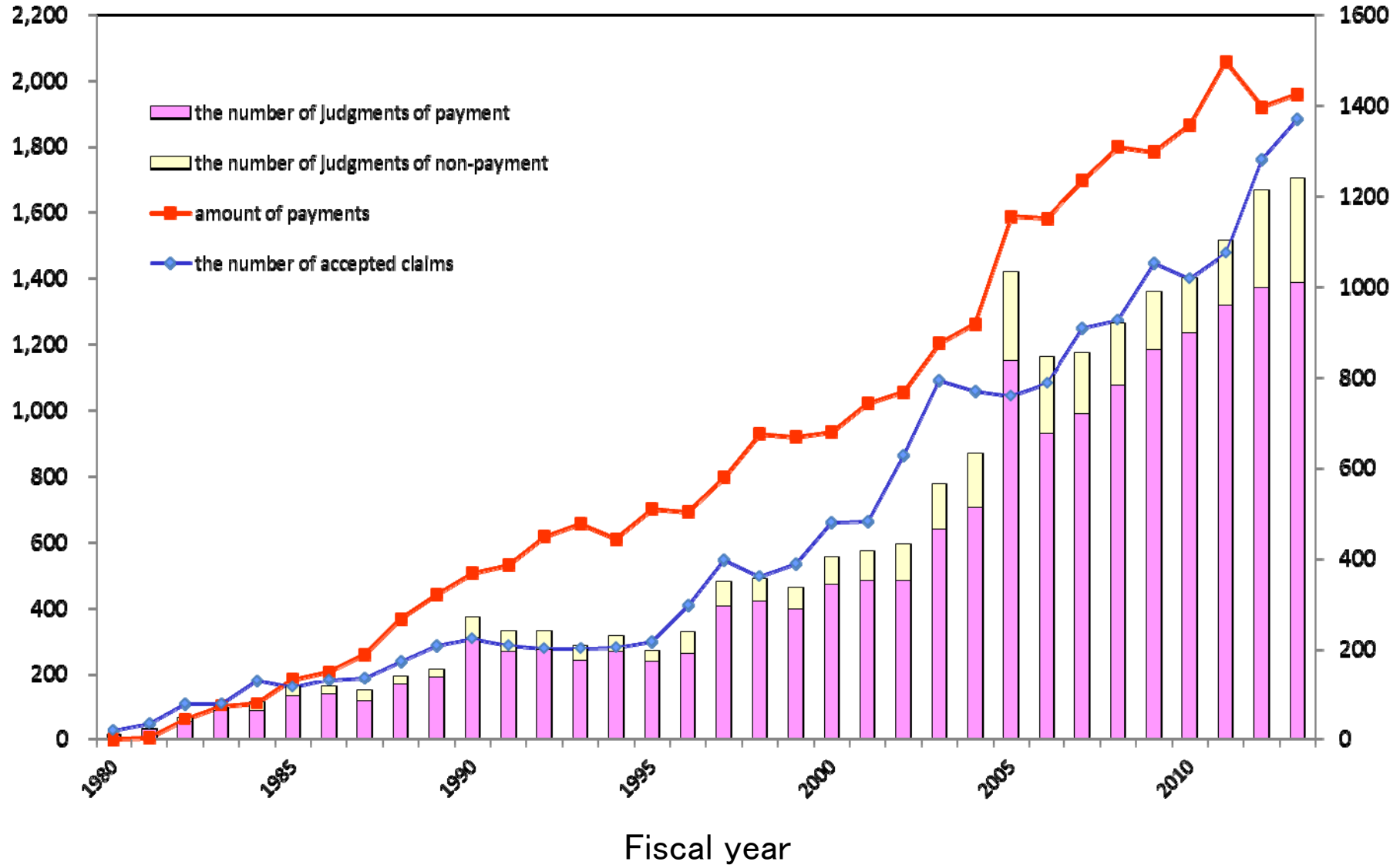
# Flowchart of Relief Services



# Payment of Relief Benefit

Unit : million yen

cases



## Details of SOC and LLT of Health Damages by Adverse Drug Reaction in the Applications for Relief Paid in FY 2009-2013

System Organ Classes	Health Damage from Adverse Drug Reaction (LLT)
Skin and subcutaneous tissue disorders	Hypersensitivity syndrome, Erythema multiforme etc, etc
Hepatobiliary disorders	Hepatic function disorder, Hepatitis fulminant, etc
Nervous system disorders	Hypoxic encephalopathy, Neuroleptic malignant syndrome, etc.
Immune system disorders	Anaphylactoid shock, Anaphylactoid reaction, etc.
Blood and lymphatic system disorders	Agranulocytosis, Thrombocytopenia, etc.
Respiratory, thoracic and mediastinal disorders	Interstitial pneumonia, Asthma, etc.
Infections and infestations	Meningitis, Sepsis, etc.
Musculoskeletal and connective tissue disorders	Aseptic necrosis of bone, Rhabdomyolysis, Osteonecrosis of jaw, etc.
Gastrointestinal disorders	Colitis haemorrhagic, Colonic perforation, Gastric ulcer haemorrhage, etc.
Others	