PMDA Training Seminar
November 29, 2010

Relief Service for Adverse Health Effects in Japan
Pharmaceuticals and Medical Devices Agency (PMDA)

Deputy Director
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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

- Ministry of Health, Labour and Welfare
  - 1979: The Fund for Adverse Drug Reactions Suffering Relief established
  - 1994: The fund reorganized into the Organization for Pharmaceuticals Safety and Research
  - 1997: Part of review activities transferred to the Japan Association for the Advancement of Medical Equipment (JAAME)
  - 2004: PMDA

The Pharmaceuticals and Medical Devices Evaluation Center of the National Institute of Health Sciences (PMDEC) established
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 –

Securing Safety and Efficacy

Review
Reduction in risk

Japanese citizens

Three-pillar System Unique to Japan

Relief
Relief measures for health damage caused by risk factors

Safety
Continuous risk mitigation efforts
2. Relief Services for Adverse Health Effects
Five Relief Services for Adverse Health Effects

- Relief Systems for Adverse Drug Reactions
- Financial Assistance for Individuals Affected by Hepatitis C through Specified Products
- Healthcare Allowances for SMON Patients
- Relief Systems for Infections Acquired through Biological Products
- Healthcare Allowances for HIV-positive and AIDS Patients
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

<table>
<thead>
<tr>
<th>Type of Relief</th>
<th>Medical Expenses</th>
<th>Description</th>
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<tbody>
<tr>
<td>In case of disease</td>
<td>Compensation will reflect the actual costs of treatment borne by the patient</td>
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<td>(requiring hospitalization)</td>
<td>Medical Allowances</td>
<td>Financial assistance is provided for costs other than medical costs for disease treatment</td>
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<td>In case of disability</td>
<td>Disability Pension</td>
<td>Financial assistance is provided to compensate living costs of patients over 18 years old, who suffer from a certain degree of disability</td>
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<td>(causing serious Impairment in daily life)</td>
<td>Pension for Raising Handicapped Children</td>
<td>Financial assistance is provided for those who are responsible for raising patients under 18 years old who suffer from a certain degree of disability</td>
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<td>In case of death</td>
<td>Bereaved Family Pension</td>
<td>Financial assistance is provided for bereaved families in rebuilding their life following the death of their main provider</td>
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<td>Lump-sum Benefit for Bereaved Family</td>
<td>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</td>
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<td>Funeral Expenses</td>
<td>Financial assistance is provided for costs in holding a funeral</td>
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Flowchart of Relief Services

1. Claim for benefits
   - Adverse health effects sufferers
   - Dosage/Usage
   - Purchase/Prescription

2. Request for judgment
   - PMDA

3. Consultation
   - Minister of Health, Labour and Welfare

4. Advice
   - Pharmaceutical Affairs and Food Sanitation Council

5. Notice of judgment
   - Government (Minister of Health, Labour and Welfare)

6. Payment of benefits
   - Adverse Drug Reaction Fund (general contribution/additional contribution)

- PMDA
  - Relief System for Adverse Drug reactions
  - Relief System for Infections Acquired through Biological products

- Pharmaceutical marketing authorization holders
- Biological Product marketing authorization holders
- Medical institutions and pharmacies
- Distribution

- Infection Contributions (general contribution/additional contribution)
- Subsidy (Administrative fees)
Contributions to the Relief System

- Payment of benefits
- Adverse health effect sufferers

PMDA

Contributions
- General contributions
- Additional contributions

Marketing authorization holders of drugs and biological products
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

Cases

Unit: Million yen

Fiscal Year

Number of claims accepted
Number of newly paid cases
Amount of payment
Pharmaceuticals and Medical Devices Agency Website


Click here
Thank you for your attention!

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