# Relief Systems for Adverse Drug Reactions and Infections Acquired through Biological Products

#### Overview

#### [Relief System for Adverse Drug Reactions]

The purpose of this system is to provide various relief benefits and prompt relief to patients and their families, apart from civil liability, in relation to injury caused by adverse reactions despite the proper use of drugs.

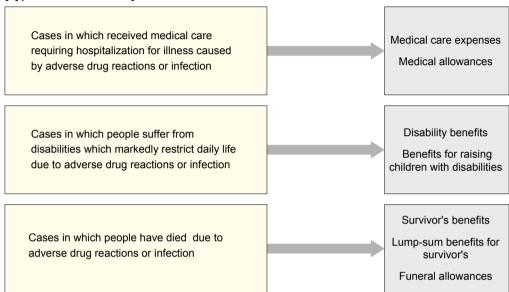
#### [Relief System for Infections Acquired through Biological Products]

The purpose of this system is to provide various relief benefits and prompt relief to patients and their families, apart from civil liability, in relation to injury caused by infections despite the proper use of biological products.

#### [Responsible organization]

Pharmaceuticals and Medical Devices Agency

#### [Types of Relief Benefits]



#### [Activities on the Relief for Caused Damages]

The Agency has been commissioned by pharmaceutical enterprises and the government to pay health management allowances, etc. to SMON (subacute myelo-optico-neuropathy) patients who have settled the lawsuit out of court.

### [Relief Program for AIDS patients, etc. caused by Blood Products]

A survey and research project has been conducted since FY 1993 for helping HIV carriers infected through the use of contaminated blood products to prevent them from developing symptoms. For the prevention of the onset o AIDS and for health management in daily life, the government provides health management expenses and in turn requests the carriers report their health status.

Since FY 1996, assistance on health management expenses has been provided for the health management of those who developed AIDS and accepted the court settlement.

## Detailed Data Changes in Status of Adverse Drug Reaction Relief Payments (as of the end of each FY)

|                           | FY1980<br>-1995 | FY1996  | FY1997  | FY1998  | FY1999  | FY2000  | FY2001    | FY2002    | FY2003    | FY2004    | FY2005    | FY2006    | FY2007    | FY2008    | FY2009    | FY2010    |
|---------------------------|-----------------|---------|---------|---------|---------|---------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Amount (¥1,000)           | 5,365,605       | 692,611 | 797,556 | 928,986 | 920,419 | 935,148 | 1,022,185 | 1,055,984 | 1,204,243 | 1,262,647 | 1,587,567 | 1,582,956 | 1,696,525 | 1,798,706 | 1,783,783 | 1,867,190 |
| Number of claims (case)   | 2,368           | 297     | 399     | 361     | 389     | 480     | 483       | 629       | 793       | 769       | 760       | 788       | 908       | 926       | 1,052     | 1,018     |
| Number of payments (case) | 1,886           | 190     | 294     | 306     | 289     | 343     | 352       | 352       | 465       | 513       | 836       | 676       | 718       | 782       | 861       | 897       |

Source: Pharmaceutical and Medical Devices Agency