

### Detailed Data 1 Results of Prescription Drug Reexamination

(As of the end of FY 2008)

Drugs whose efficacy and safety are recognized		Drugs whose efficacy and safety are recognized with partial revision of approved items		Drugs whose efficacy and safety are not recognized	
Number of ingredients	Number of items	Number of ingredients	Number of ingredients	Number of ingredients	Number of items
989	2,827	50	142	0	0

Source: Pharmaceutical and Food Safety Bureau, MHLW

### Detailed Data 2 Results of Prescription Drug Reevaluation

(As of the end of FY 2008)

	Comprehensive evaluation (number of items)				Total
	Drugs whose efficacy and safety are recognized	Drugs whose efficacy and safety are recognized with partial revision of approved items	Drugs whose efficacy and safety are not recognized	Drugs that the applicants made adjustments on approved items after filing reevaluation application	
1st phase reevaluation	11,098	7,330	1,116	305	19,849 (19,612)
2nd phase reevaluation	105	1,579	42	134	1,860
New reevaluation	4,543	3,315	66	839	8,763

Source: Pharmaceutical and Food Safety Bureau, MHLW

(Notes)

1. Figures in parentheses indicate those that are adjusted for cases in which the same item was officially announced twice or more.
2. 1st phase reevaluation: covers ingredients approved on or prior to September 30, 1967
3. 2nd phase reevaluation: covers ingredients approved between October 1, 1967 and March 31, 1980
4. New reevaluation: covers all ingredient

### Detailed Data 3 Changes in the Number of Reports on Adverse Drug Reaction, etc. in the Past 5 Years

(Unit: case)

FY	Reports from marketing authorization holders				Reports on adverse drug reactions from medical professionals
	Reports on adverse drug reactions	Reports on research results	Reports on measures overseas	Regular reports on infectious diseases	
2004	25,142	1,311	420	1,093	4,594
2005	24,523	971	563	1,077	3,992
2006	26,309	818	485	1,076	3,669
2007	28,500	858	695	1,092	3,891
2008	31,455	855	869	1,074	3,839

Source: Pharmaceutical and Food Safety Bureau, MHLW

### Detailed Data 4 Changes in the Number of Reports on Medical Device Malfunction, etc. in the Past 5 Years

(Unit: case)

FY	Reports from marketing authorization holders				Reports on malfunction from medical professionals
	Reports on malfunction	Reports on research results	Reports on measures overseas	Regular reports on infectious diseases	
2004	15,714	157	287	126	622
2005	11,234	37	436	95	445
2006	12,190	36	482	62	424
2007	16,550	15	525	52	434
2008	6,351	10	748	64	410

Source: Pharmaceutical and Food Safety Bureau, MHLW