

Detailed Data 1 Results of Prescription Drug Re-examination

(As of the end of FY2009)

Drugs that are approved for effectiveness		Drugs that can be approved for effectiveness with partial revision of matters to be approved		Drugs that are not approved for effectiveness	
Number of ingredients	Number of items	Number of ingredients	Number of items	Number of ingredients	Number of items
1,062	2,991	50	142	0	0

Source: Pharmaceutical and Food Safety Bureau, MHLW

Detailed Data 2 Results of Prescription Drug Re-evaluation

(As of the end of FY2009)

	Comprehensive evaluation (number of items)				Total
	Drugs that are approved for effectiveness	Drugs that can be approved for effectiveness with partial revision of matters to be approved	Drugs that are not approved for effectiveness	Drugs that the applicants made adjustments on matters to be approved after filing re-evaluation application	
Phase 1 re-evaluation	11,098	7,330	1,116	305	19,849 (19,612)
Phase 2 re-evaluation	105	1,579	42	134	1,860
New re-evaluation	4,555	3,315	66	841	8,777

Source: Pharmaceutical and Food Safety Bureau, MHLW

(Note) 1. The figures in parentheses indicate those adjusted for cases where the same item was officially announced more than once.

2. Phase 1 re-evaluation: covers ingredients approved on or prior to September 30, 1967

3. Phase 2 re-evaluation: covers ingredients approved between October 1, 1967 and March 31, 1980

4. New re-evaluation: 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 overseas measures	Regular reports on infectious diseases	
2005	24,523	971	563	1,077	3,992
2006	26,309	818	485	1,076	3,669
2007	28,231	858	695	1,092	3,891
2008	31,455	855	869	1,074	3,839
2009	30,814	933	930	1,108	3,721

Source: Pharmaceutical and Food Safety Bureau, MHLW

Detailed Data 4 Changes in 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 overseas measures	Regular reports on infectious diseases	
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
2009	6,446	6	831	59	363

Source: Pharmaceutical and Food Safety Bureau, MHLW