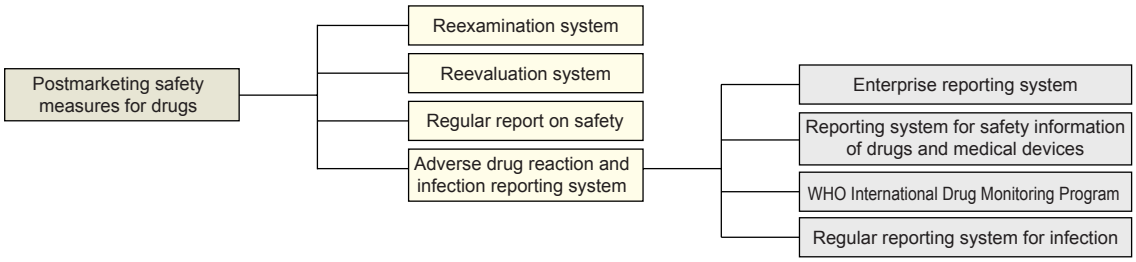
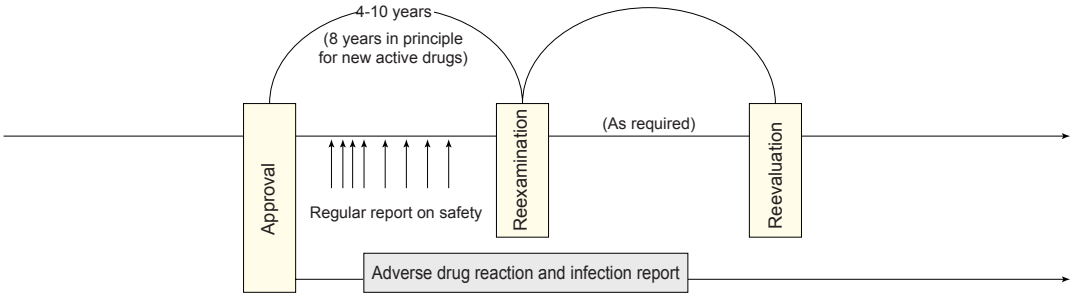
Postmarketing Measures for Drugs and Medical Devices

Overview

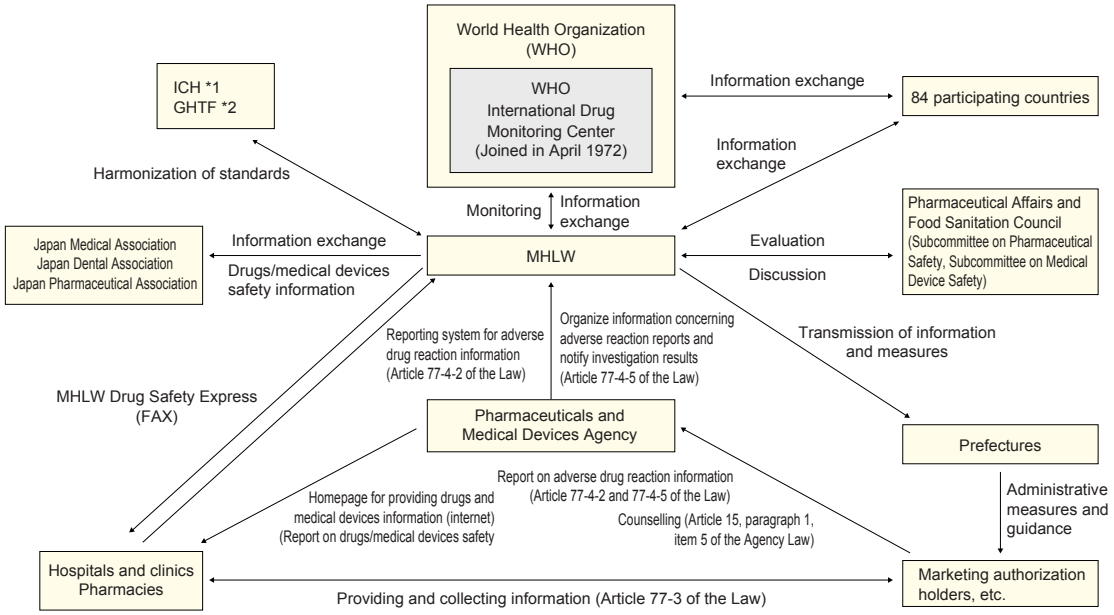
Structure of Postmarketing Safety Measures for Drugs



Flow of Postmarketing Survey and Reexamination/Reevaluation of Drugs



Outline of the Adverse Drug Reaction, etc. Reporting System



*1: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
*2: Global Harmonization Task Force

Detailed Data 1 Results of Prescription Drug Reexamination

(As of the end of FY 2006)

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
838	2,361	49	139	0	0

Source: Pharmaceutical and Food Safety Bureau, MHLW

Detailed Data 2 Results of Prescription Drug Reevaluation

(As of the end of FY 2006)

	Comprehensive evaluation (number of items)				
	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	Total
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	4,020	3,321	66	766	8,173

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	
2002	24,221	1,228	-	-	4,195
2003	28,004	1,276	201	648	5,399
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

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 malfunctions from medical professionals
	Reports on malfunctions	Reports on research results	Reports on measures overseas	Regular reports on infectious diseases	
2002	5,026	54	-	-	226
2003	5,013	38	191	66	370
2004	15,714	157	287	126	622
2005	11,234	37	436	95	445
2006	12,190	36	482	62	424

Source: Pharmaceutical and Food Safety Bureau, MHLW