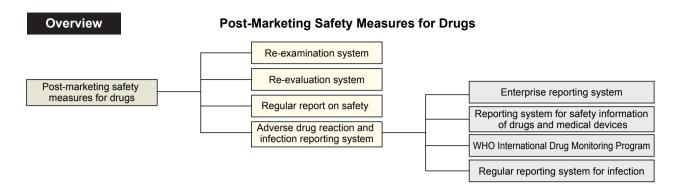
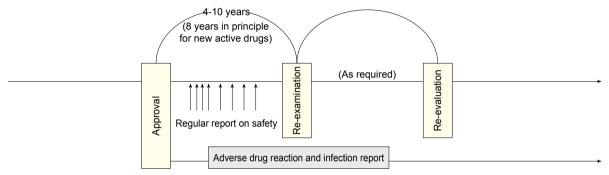
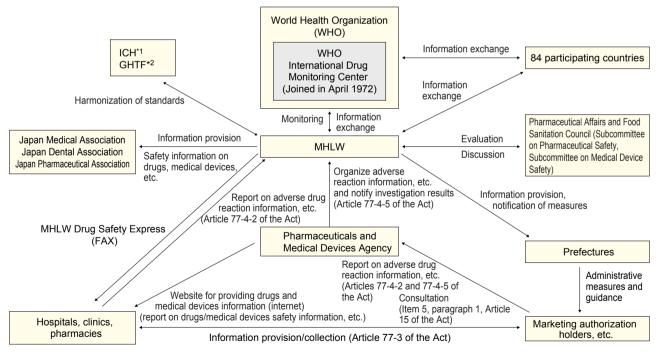
Post-Marketing Measures for Drugs/Medical Devices



Flow of Post-Marketing Surveillance and Re-examination/Re-evaluation 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

(Note) The Act indicates the Act on Pharmaceuticals and Medical Devices Agency

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) | | | | | | |
|-----------------------|--|--|-------|--|----------|--|--|
| | Drugs that are approved for effectiveness | Drugs that can be approved for effectiveness with partial revision of matters to be approved | | Drugs that the applicants made adjustments on matters to be approved after filing re-evaluation application | Total | | |
| 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)

| | | Reports on adverse | | | |
|------|-----------------------------------|-----------------------------|------------------------------|--|---|
| FY | Reports on adverse drug reactions | Reports on research results | Reports on overseas measures | Regular reports on infectious diseases | drug reactions from medical professionals |
| 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)

Reports from marketing authorization holders Reports on Reports on Regular reports on malfunction from FY Reports on Reports on medical professionals research results overseas measures infectious diseases malfunction 11,234 2005 37 436 95 445 12,190 36 482 62 424 2006 2007 16,550 525 52 434 15 2008 6,351 10 748 64 410 2009 6,446 6 831 59 363

Source: Pharmaceutical and Food Safety Bureau, MHLW