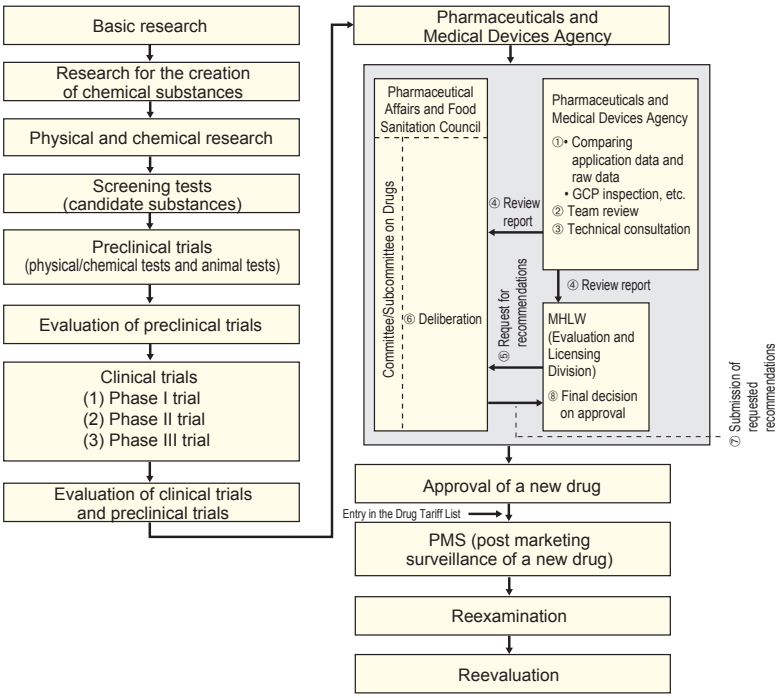
(4) Drugs

Approval and Licensing System for Drugs, Quasi-drugs, and Cosmetics

Overview **Classification of Examinations for the Approval of Drugs, etc.**

- **Drugs**
  - **Prescription drugs** (Used under doctors' prescription)
    - **New drugs** — Approved by MHLW based on reliability evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency (Drugs for hypertension, antibiotics, antiulcer drugs, antineoplastic drugs, etc.)
    - **Generic drugs** — Approved by MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency (Drugs equivalent to new drugs)
  - **Over-the-counter drugs** (Available at pharmacies, etc. without prescription)
    - **Items meeting approved standards** — Approved by prefectural governors (14 items including cold medicine, antipyretic analgesics, etc. and those dispensed at pharmacies)
    - **Others** — Approved by MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency
- **Quasi-drugs** (Medicated toothpastes, hair dyes, bath products, mouth washes, etc.)
  - New quasi-drugs: Approved by MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency
  - Items which meet approval standards: Approved by prefectural governors
  - Other items: Approved by MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency
- **Cosmetics** (Perfumes, lipsticks, shampoos, conditioners, etc.)
  - Items indicating all ingredients: Application for approval exempted, notification to prefectural governors required on individual items after acquiring manufacturing/marketing approval
  - Items containing ingredients not required for indication: Approved by MHLW based on equivalency evaluation and examination for approval conducted by the Pharmaceuticals and Medical Devices Agency

Flow of Examination for the Approval of New Drugs



(Note) The trials which are deemed necessary for the NDA filing can be roughly divided into two categories: preclinical (physical/chemical tests and animal tests) and clinical trials. Clinical trials are conducted on a phased basis from phase I trial (a small number of healthy volunteers), the phase II trial (a small number of patients), and the phase III trial (a large number of patients), as indicated in the chart above.

[Examination for the Approval of New Drugs]
The quality, efficacy, and safety of new drugs require an especially careful review. Therefore, a mechanism is in place in which the Pharmaceutical Affairs and Food Sanitation Council (an advisory organ to the Minister of Health, Labour and Welfare) composed of experts in the fields of medical science, pharmaceutical science, veterinary science, and statistical science deliberates on these subjects based on many data derived from basic and clinical studies. This mechanism also include the decision making process in which the Minister of Health, Labour and Welfare makes decisions on the approvals of new drugs based on the results of the deliberations of the Council.
Good Laboratory Practices (GLP) for the implementation of animal testing (against toxicity) among non-clinical tests and Good Clinical Practices (GCP) for the implementation of clinical tests are set forth by ministerial ordinances. Each test is regulated by GLP and GCP to assure appropriate testing.

[License for Marketing and Manufacturing Drugs, etc.]
The approval and licensing system for drugs, etc. was revised. Since April 2005, the system has been applied separately to a marketing authorization holder that ships products to markets and to a manufacturer of the products.
To obtain a license, a marketing authorization holder will be reviewed whether it complies with the standards on quality control procedures, as well as post-marketing safety control procedures. A manufacturer will be reviewed whether it compiles with the standards on structure and facilities of manufacturing sites and on quality control procedures.
Prefectural governors issue the license for marketing and that for manufacturing, except for manufacturing of some drugs that require sophisticated manufacturing technology.

Detailed Data 1 Number of Approvals for Marketing Drugs, etc.

(As of the end of 2007)

Classification	Drugs			Quasi-drugs	Cosmetics	Total
		Class 1 drugs	Class 2 drugs			
Marketing	1,291	252	1,039	1,266	2,973	5,530

Source: Pharmaceutical and Food Safety Bureau, MHLW
(Note) Licenses are granted by prefecturel governors. (Since April 1, 2005)

Detailed Data 2 Number of Approvals for Manufacturing/Import/Marketing Drugs, etc. (2007)

		Prescription drugs	Over-the-counter drugs	Quasi-drugs	Cosmetics
Manufacturing	Approval	57	92	18	0
	Approval with partial revision	84	15	1	0
	Total	141	107	19	0
Import	Approval	8	2	9	0
	Approval with partial revision	34	8	0	0
	Total	42	10	9	0
Marketing	Approval	1,636	1,050	2,079	0
	Approval with partial revision	783	221	464	0
	Total	2,419	1,271	2,543	0

Source: Pharmaceutical and Food Safety Bureau, MHLW
(Note) Excluding in vitro diagnostic medical products.

Detailed Data 3 Number of Approvals for Manufacturing Drugs, etc.

(As of the end of 2007)

Classification	Drugs	Quasi-drugs	Cosmetics	Total
Manufacturing	2,333	1,481	3,302	7,116

Source: Pharmaceutical and Food Safety Bureau, MHLW
(Note) Licenses are granted by prefecturel governors since April 1, 1995 (Excluding some drugs).