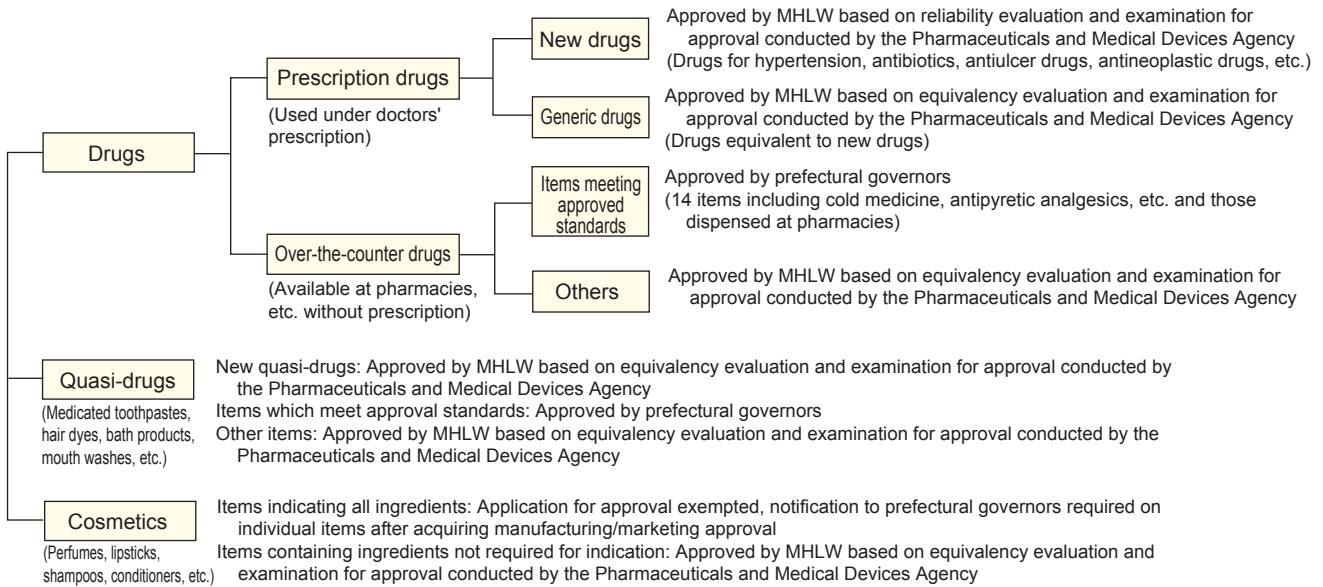
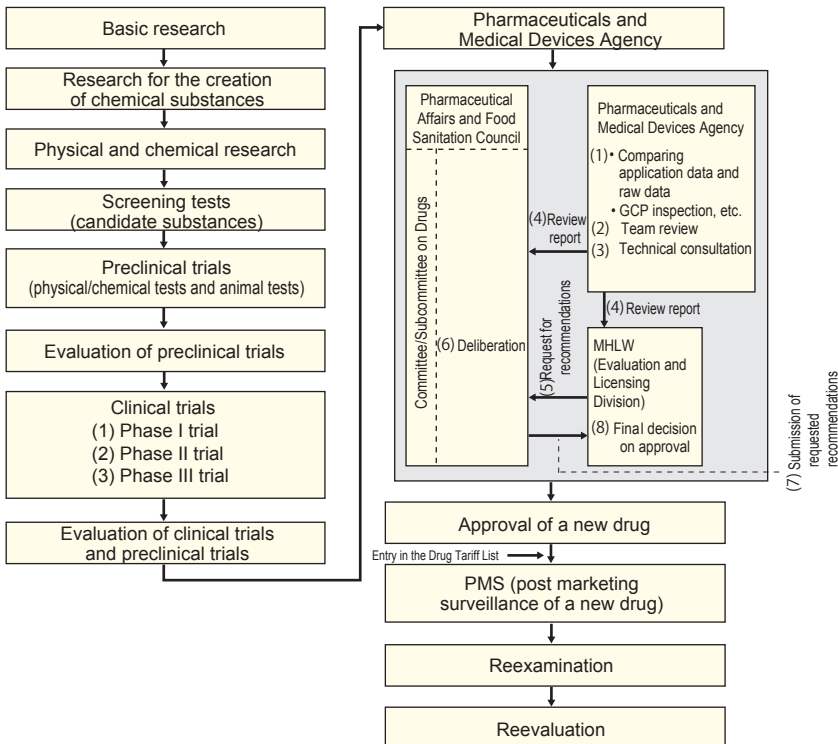


Overview

Classification of Examinations for the Approval of Drugs, etc.



Flow of Examination for the Approval of New Drugs



[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 complies 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.

(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.