

Partial Revision of the Pharmaceutical Affairs Law Enforcement Regulations (draft)

**Drugs**

The labeling of risk classification listed below shall be indicated on the immediate container or package with the name of drug.

- " **第 1 類医薬品** " for first-classified OTC drug.
- " **第 2 類医薬品** " for second-classified OTC drug which needs cautious usage.  
( ※ 1 )
- " **第 2 類医薬品** " for second-classified OTC drug.
- " **第 3 類医薬品** " for third-classified OTC drug.

( ※ 1 ) If second-classified OTC drugs need cautious usage, it shall be indicated using enclosed character "2" with a border, such as **2**.

The labeling shall be indicated using 8 pts or larger letters except when there is not enough space.

The labeling shall be indicated on the same place as the name of drug. If it appears in more than one place, the labeling shall be described in all the places.

The black characters and border should be used for labeling of above-mentioned text, unless white letters and border on a dark background are more readable.

The labeling of “配置不可” ,which means “not for household distribution” , shall be indicated on the immediate container or package of drugs other than those designated for household distribution.

**Quasi-Drugs**

The labeling of classification listed as below shall be indicated on the immediate container or package of quasi-drugs.

- " **防除用医薬部外品** " for quasi-drugs used for extermination or prevention of rats, flies, mosquitoes, fleas, etc. to assure the health of humans or animals.
- " **指定医薬部外品** " for quasi-drugs designated by the Minister of Health, Labour and Welfare to include the name and the quantity of each active ingredient on the labeling ( ※ 2 ) .
- " **医薬部外品** " for quasi-drugs other than the quasi-drugs mentioned above.

( ※ 2 ) Products which shifted from drug to quasi-drug in 1999 or 2004.