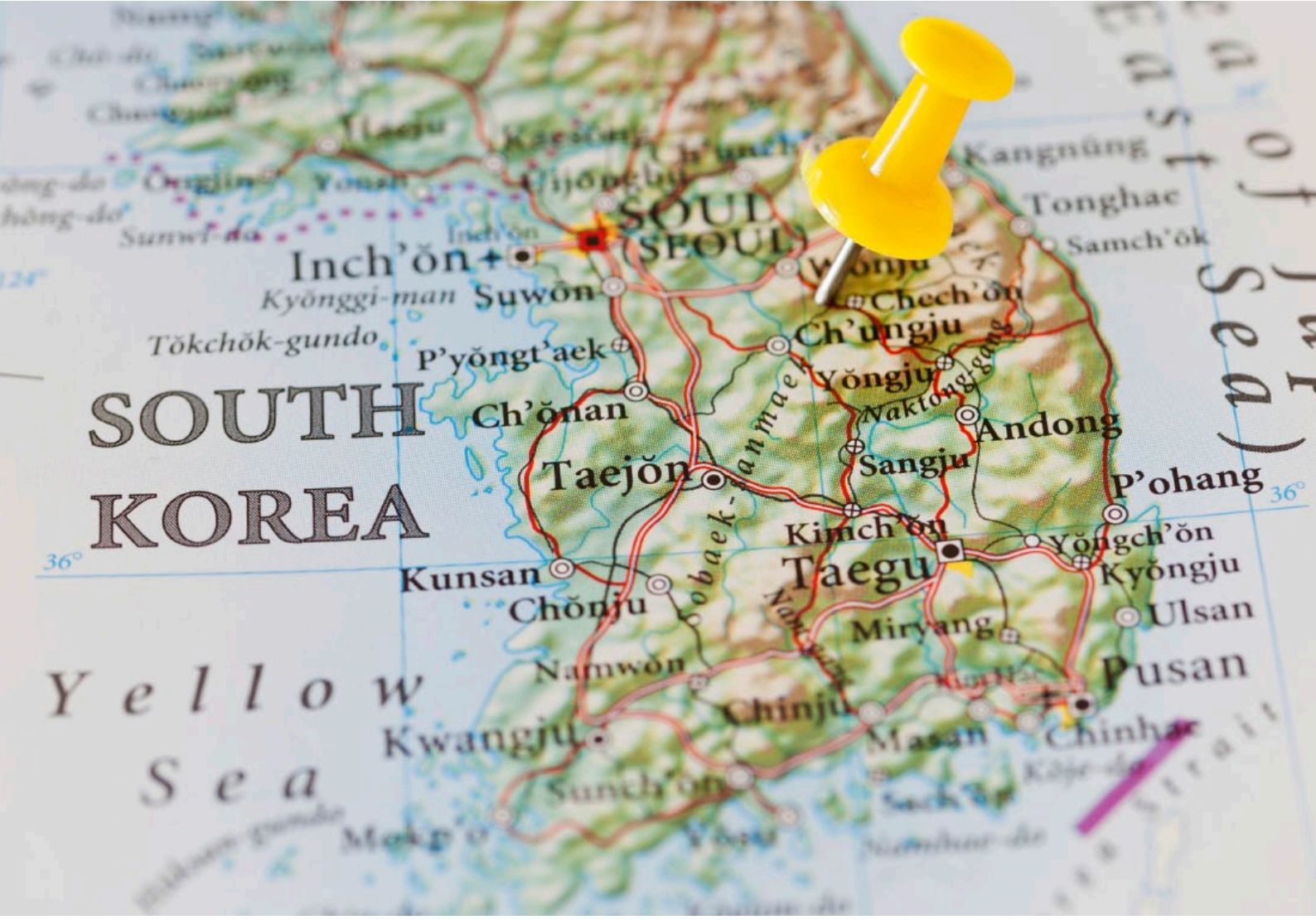

Provisions for Labeling of Quasi Drugs

医药外品标示相关规定

Korea Ministry of Food and Drug Safety

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Provisions for Labeling of Quasi Drugs

Article 1 (Purpose): In order to providing the right information of quasi-drugs, this regulation formulates the labeling method and exceptional items on the container, packaging, or other attachments of quasi-drugs are formulated according to Article 65 (2) of "Pharmaceutical Affairs Law" (hereinafter referred to as "the law") and Article 75 (10) of "Regulations on Drug Safety".

Article 2 (Definition): Point used in this regulation refers to unit of font size specified in South Korean industry specifications.

Article 3 (Applicable Object): According to Article 31 and 42 of the law, quasi-drugs declared or getting category license shall be marked with information required on the container or packaging or attached files according to the method specified in this regulation, but the quasi-drug for export use can be exempted.

Article 4 (Labeling Method):

① According to Article 65 of the law and Article 74 of "Regulations on Drug Safety", the font size for information marked shall comply with the following standards.

1. Container and packaging

1) Condition for content liquid agent, content solid agent, ointment, cataplasma agent, spraypas for external use

1.1 The name, date of manufacture or expiration date of drug, the font size of "quasi-drug" shall be greater than 7piont.

1.2 The font size of other items except the item mentioned above shall be greater than 6piont.

2) Condition for other dosage forms except that described in 1)

2.1 The name, date of manufacture or expiration date of drug, the font size of "quasi-drug" shall be greater than 7piont.

2.2 The font size of company name and manufacturing number of manufacturer, importer shall be greater than 6point.

2.3 The font size of other items recorded except that described in 2.1 and 2.2 shall be less

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