

WORLD TRADE ORGANIZATION

G/TBT/N/KOR/71
15 April 2004

(04-1691)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>REPUBLIC OF KOREA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Ministry of Health and Welfare (MOHW) Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Pharmaceuticals
5.	Title, number of pages and language(s) of the notified document: Draft Amendment of Ministerial Ordinance of the Pharmaceutical Affairs Act (28 pages, in Korean)
6.	Description of content: <ul style="list-style-type: none">– When applying for approval of biological products, etc., review data to prove its safety and efficacy shall be submitted.– When applying for approval of generic drugs in the form of tablets, capsules and suppositories that are prescription drugs, the protocol to establish their biological equivalence must be submitted.– Subject to the Guidelines on Reporting of Imported Raw Pharmaceutical Materials, all expenses for on-site inspection in the origin countries will be borne by their importers.– Obligations and observances required of quality assurance agencies on pharmaceuticals, etc., have been reinforced.– For pharmaceuticals subject to re-examination to the KFDA, manufacturers (or importers) will be required to submit a protocol on the clinical experience and report on the progress of annual surveillance.– Manufacturers and importers will be obligated to operate a voluntary recall system for defective pharmaceutical products.– The Commissioner of the KFDA (Korean Food and Drug Administration) is authorized to establish provisions for special packing of pharmaceuticals so as to prevent drug-related accidents caused by children.– Manufacturers (or importers) are required to produce (or import) and supply pharmaceuticals in small quantity packagings besides economy-sized ones, as provided for by the Commissioner of the KFDA besides economy-sized ones.

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	<ul style="list-style-type: none"> – Legal grounds will be established for manufacturers to purchase pharmaceuticals produced by other manufacturers for the purpose of developing new products. – For biological substances, the relevant regulations on manufacturing and marketing shall be separately specified. – Pharmaceuticals wholesalers and retailers are obligated to report any unauthorized or illegal products that they become aware of. However, when they are manifestly found to be irrelevant to the obligations, legal punishment will be relieved or exempted by the regulation. – The provision allowing pharmaceutical wholesalers, at the initial stage of separation policy between prescribing and dispensing, to sell pharmaceuticals in open packagings has been deleted. – For pharmaceuticals separately designated by the Commissioner of the KFDA, the name of additives shall be clearly written on the external packets by the manufacturers, and additional regulations will be added hereto as necessary. – Detailed provisions will be established for using electronic money to pay for drug-related service charges.
7.	Objective and rationale, including the nature of urgent problems where applicable: Improving national health
8.	Relevant documents: MOHW notification 2004-68(Available in Korean only)
9.	Proposed date of adoption: Proposed date of entry into force: } July 2004
10.	Final date for comments: 3 June 2004
11.	Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: Documents are available from the Ministry of Health and Welfare website (www.mohw.go.kr). Also available from: <div style="margin-left: 40px;"> Trade Affairs Division Ministry of Health and Welfare 1, Joongang-dong Kwacheon, Kyunggi 427-721, Republic of Korea Tel: +82 2 2110 6458 Fax: +82 2 504 3981 E-mail: ykjeong@mohw.go.kr </div>