



27 April 2018

(18-2643)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>REPUBLIC OF KOREA</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Ministry of Food and Drug Safety <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>  Documents are available from the Ministry Food and Drug safety website <a href="http://www.mfds.go.kr">www.mfds.go.kr</a> . Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Republic of Korea 363-700 Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: <a href="mailto:wtokfda@korea.kr">wtokfda@korea.kr</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Narcotics
<b>5. Title, number of pages and language(s) of the notified document:</b> Proposed amendments to the "Enforcement Regulations of the Narcotics Control Act" (27 page(s), in Korean)
<b>6. Description of content:</b> The proposed amendments seek to: <ul style="list-style-type: none"><li>- Establish a legal basis in order to include information required to be provided on containers/ packaging under the Pharmaceutical Affairs Act in the Enforcement Rules of Narcotics Controls Act such as the indication of all ingredients, usage, dosage, direction for use, warning signs, and prescription drug labels (if applicable).</li><li>- Specify persons responsible for providing required information of narcotics drugs or psychoactive substances on containers and packaging as follows: manufacturers, importers, exporters, and users of raw materials thereof.</li><li>- Establish a legal basis in order to allow the omission of certain information provided on containers/packaging of standard preparations or reagents for medical use containing narcotic drugs or psychoactive substances while indicating item codes, generated through Narcotics Information Management System, on the containers/packaging thereof.</li></ul>
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Consumer information, labelling

<b>8.</b>	<b>Relevant documents:</b> MFDS PUBLIC NOTICE No 2018-088 (9 March 2018)
<b>9.</b>	<b>Proposed date of adoption:</b> To be determined <b>Proposed date of entry into force:</b> 1 year after the date of adoption
<b>10.</b>	<b>Final date for comments:</b> 60 days from notification
<b>11.</b>	<b>Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b>  Technical Barriers to Trade(TBT) Division Korean Agency for Technology and Standards (KATS) 93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, Republic of Korea, 27737 Tel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682 E-mail: <a href="mailto:tbt@korea.kr">tbt@korea.kr</a> Website: <a href="http://www.knowtbt.kr">http://www.knowtbt.kr</a>  <a href="https://members.wto.org/crnattachments/2018/TBT/KOR/18_2259_00_x.pdf">https://members.wto.org/crnattachments/2018/TBT/KOR/18_2259_00_x.pdf</a>