From: TBT APJ-SLG
Date: 27 May 2015 15:52:28 GMT+5:30
To: Director General Pharmexcil
Subject: (G/TBT/N/KOR/574/575/576) TBT notification issued by Korea on Pharmaceutical

Kind Attention Dr. Appaji, Director General, Pharmexcil India

Dear Dr. Appaji,

This has reference to three TBT notification (G/TBT/N/KOR/574/575/576) dated 15th April 2015 is issued by the Ministry of Food and Drug Safety, Republic of Korea. The regulation is deals with pharmaceuticals.

HS Code

The HS Code for the products comes under chapter 30.

Draft Regulation
The main contents of the proposed draft are the following:

- To establish a legal basis to register foreign drug manufacturing plants and perform foreign inspections;
- A penalty shall be imposed on a manufacturer/importer of substandard/spurious/falsely labelled/falsified/counterfeit drugs. The amount of penalty surcharge shall not exceed 5% of the total amount of production/imports in the previous year;
- The head of a clinical trial institution may apply to the Ministry of Food and Drug Safety the assessment of safety and efficacy of off-label uses. The Ministry of Food and Drug Safety shall classify the obtained information by grade and may place a restriction on off-label use if the off-label use is inappropriate;
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The draft also deals with the labeling of quasi-drugs, the name and use-by date of all quasi-drugs. It mandates the labeling for all quasi drugs. If the information on the container or the packaging of the quasi-drug is physically unreadable, the same information should also be indicated on the external containers or packaging.

Economic Analysis

Currently India is exporting medicines to Korea. India's export to Korea is US$ 12.63 million in 2013-14. India's export to world stood at US$ 11139.93 million. The import of India stood at US$ 39.31 million in the year 2013-14. The import of the world by Korea stood at US$ 1553.57 million in 2013-14.

India exports these products to Korea, hence, this approval requirement, if implemented, may significantly impact the registration strategy and timeline for India's exports of pharmaceuticals.

The regulation is only available in Korean language. We have requested the respective authorities to send an English version of the regulation. We will send you the same as soon as it is available with us.

Grateful if you could send your views by 24th April 2015.

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WORLD TRADE ORGANIZATION

G/TBT/N/KOR/574

15 April 2015

(15-2022)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: REPUBLIC OF KOREA If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: Ministry of Food and Drug Safety 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: Documents are available from the Ministry Food and Drug Safety website (http://www.mfds.go.kr) Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro Osong-eup, Heungdeok-gu Cheongju-si Chungcheongbuk-do, 363-700 Republic of Korea Tel: (+82) 43-719-1564 Fax: (+82) 43-719-1550 Email: wtokfda@korea.kr
3.	Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 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: Proposed amendments to the Pharmaceutical Affairs Act (76 pages, in Korean)
6.	Description of content: The main contents are as (but not restricted to) the following: • To establish a legal basis to register foreign drug manufacturing plants and perform foreign inspections; • A penalty shall be imposed on a manufacturer/importer of substandard/spurious/falsely labelled/falsified/counterfeit drugs. The amount of penalty surcharge shall not exceed 5% of the total amount of production/imports in the previous year; • The head of a clinical trial institution may apply to the Ministry of Food and Drug Safety the assessment of safety and efficacy of off-label uses. The Ministry of Food and Drug Safety shall classify the obtained information by grade and may place a restriction on off-label use if the off-label use is inappropriate; • Regarding the labelling of quasi-drugs, the name and use-by date of all quasi-drugs should be specified. If the information on the container or the packaging of the quasi-drug is physically unreadable because it is covered by external containers or packaging, the same information should also be indicated on the external containers or packaging.

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7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8.	Relevant documents: MFDS Notification No. 2015-110 (10 April 2015)
9.	Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10.	Final date for comments: 60 days from notification
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: 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, 369-811 Tel.: (+82) 43 870 55 20 https://members.wto.org/crnattachments/2015/TBT/KOR/15_1610_00_x.pdf

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WORLD TRADE ORGANIZATION

G/TBT/N/KOR/575

15 April 2015

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NOTIFICATION

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2.	Agency responsible: Ministry of Food and Drug Safety 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: Documents are available from the Ministry Food and Drug safety website (http://www.mfds.go.kr) Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup Heungdoek-gu Cheongju-si Chungcheongbuk-do, 363-700 Republic of Korea Tel: (+82) 43-719-1564 Fax: (+82) 43-719-1550 Email: wtokfda@korea.kr
3.	Notified under Article 2.9.2 [ ], 2.10.1 [ ], 5.6.2 [X], 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): Quasi-drugs
5.	Title, number of pages and language(s) of the notified document: Proposed amendments to the "Regulation on Quasi-Drug Approval, Notification and Review" (15 pages, in Korean)
6.	Description of content: • If an additive that has never been used in an "inhalation product" is mixed into it, such additive is designated to be subject to safety and efficacy review; • Allow products for export – only to acquire separate approval (notification) item; • Combine regulation relevant to preservatives (type, content) for quasi-drug (dental) products that are currently part of another regulation into the current regulation; • Determine the scope of submission for materials of safety and efficacy review on products aimed to improve smoking habits through similar inhalation as smoking normal cigarettes.
7.	Objective and rationale, including the nature of urgent problems where applicable: For balanced review of quasi-drug products' approval, notification and examination and strengthened safety management.
8.	Relevant documents: MFDS Notification No. 2015-66 (6 March 2015)

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9.	Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10.	Final date for comments: 60 days from notification
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: 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, 369-811 Tel.: (+82) 43 870 55 20 https://members.wto.org/crnattachments/2015/TBT/KOR/15_1611_00_x.pdf

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NOTIFICATION

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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): Quasi-drugs
5.	Title, number of pages and language(s) of the notified document: Proposed amendments to the "Regulation for the Specification and Test Method of Quasi-Drugs" (48 pages, in Korean)
6.	Description of content: • To delete the article "Mask for hygienic" in this regulation; • To update (improve) testing methods for 'Menstrual Pad', 12 pesticides ingredients including "Deltamethrin", and 4 pesticide items such as "Permethrin granules for fumigation"; • Introduce the specifications of 19 active ingredients for quasi-drug product items that are listed in "Manufacturing Specifications of Quasi-Drugs".
7.	Objective and rationale, including the nature of urgent problems where applicable: To raise effectiveness of quasi-drug products for approval, notification, review and its quality management
8.	Relevant documents: MFDS Notification No. 2015-67 (6 March 2015)

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9.	Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10.	Final date for comments: 60 days from notification
11.	Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: 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, 369-811 Tel.: (+82) 43 870 55 20 https://members.wto.org/crnattachments/2015/TBT/KOR/15_1612_00_x.pdf