WORLD TRADE ORGANIZATION

G/TBT/N/JPN/458

12 June 2014

(14-3406)

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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: JAPAN If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: Ministry of Health, Labour and Welfare 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:
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, medical devices, etc.
5.	Title, number of pages and language(s) of the notified document: Partial amendments to the Order for Enforcement of the Pharmaceutical Affairs Act and other related orders, ordinances and public notices, as well as establishment of new ordinances and public notices (2 pages, in English)
6.	Description of content: According to the Partial amendment to the Pharmaceutical Affairs Act and other related acts, the Order for Enforcement of the Pharmaceutical Affairs Act and other related orders, ordinances and public notices are to be partially amended, and new ordinances and public notices are to be newly established.
7.	Objective and rationale, including the nature of urgent problems where applicable: To describe more detailed provisions to enforce the partial amendment to the Pharmaceutical Affairs Act and other related acts.
8.	Relevant documents: Pharmaceutical Affairs Act. The amendments will be published in "KAMPO" (Official Gazette) when adopted.
9.	Proposed date of adoption: End of June 2014 (scheduled) Proposed date of entry into force: End of November 2014 (scheduled)
10.	Final date for comments: 60 days from date of circulation.

11. Text available from: National enquiry point [X], or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

Japan Enquiry Point
International Trade Division,
Economic Affairs Bureau,
Ministry of Foreign Affairs
Fax: (+81 3) 5501 8343
E-mail: enquiry@mofa.go.jp

http://members.wto.org/crnattachments/2014/tbt/jpn/14_2663_00_e.pdf

Partial amendments to the Order for Enforcement of the Pharmaceutical Affairs Act and other related orders, ordinances and public notices, as well as establishment of new ordinances and public notices related amendment od Pharmaceutical Affairs Act

The amendments and establishments of orders, ordinances and public notices related to enforcement of amendment for the Pharmaceutical Affairs Act will include following;

I. Amendments of the Order for Enforcement of the Pharmaceutical Affairs Act
II. Amendments of the Ministerial Ordinance for Enforcement of the Pharmaceutical Affairs Act
III. Amendments of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics
IV. Establishments of orders, ordinances and public notices related to Regenerative and Cellular Therapy Products and Gene Therapy Products

Major Points on the amendments and establishments are as follows;

I. Amendments of the Order for Enforcement of the Pharmaceutical Affairs Act

1. New clauses on medical devices will be established separate from pharmaceuticals.
2. New category on Software as a Medical Device will be added;
   - Diagnostic Software
   - Therapeutic Software
   - Preventive Software
3. Software as a Medical Device with low risk (defined as General Medical Device) will be exempted from the application of the amended Pharmaceutical Affairs Act.
4. New category for Regenerative and Cellular Therapy Products and Gene Therapy Products will be added;
   - Human Cell -Processed Products
   - Animal Cell -Processed Products
   - Gene Therapy Products

II. Amendments of the Ministerial Ordinance for Enforcement of the Pharmaceutical Affairs Law

1. New clauses on medical devices will be established separate from pharmaceuticals.
2. Procedures on the registration of medical device manufacturer will be defined.

3. Procedures on QMS inspection to a marketing authorization holder of medical devices will be defined.
4. Procedures on license to a marketing authorization holder, a manufacturer for Regenerative and Cellular Therapy Products and Gene Therapy Products will be defined.
5. The Conditions where a marketing authorization holder could omit a package insert of medical device will be defined following.
   ① A package insert indicates obtaining way on its information through the internet.
   ② A marketing authorization holder provides a paper package insert promptly when medical professionals request it.
   ③ A marketing authorization holder provides information to the users promptly when package are changed.
   ④ Information of a package insert can be obtained from the webpage of PMDA.

III. Amendments of the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Medical Devices and In-Vitro Diagnostics

1. To harmonize 2nd chapter completely with ISO13485: 2003.
2. To add ISO13485: 2003 such as confirmation by a marketing authorization holder for a manufacturing site to comply the standards, storage period of documents and records, and to establish of reporting system for malfunction or adverse event in 3rd chapter.

IV. Establishments of ordinances and public notices related to Regenerative and Cellular Therapy Products and Gene Therapy Products

1. Since Regenerative and Cellular Therapy Products and Gene Therapy Products has been newly defined in the partial amendment of Pharmaceutical Affairs Act, new ordinances and public notices are established like as those for medical devices as well as pharmaceuticals. These will include the following;
   - Ordinance on Good Clinical Practice for Regenerative and Cellular Therapy Products and Gene Therapy Products
   - Ordinance on Good Laboratory Practice for Regenerative and Cellular Therapy Products and Gene Therapy Products
   - Ordinance on Good Postmarketing Surveillance Practice for Regenerative and Cellular Therapy Products and Gene Therapy Products and
   - Public Notice on designated Regenerative and Cellular Therapy Products and Gene Therapy Products.