Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-03 Helios
Singapore 138667
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Fax: 6478 9028

25 November 2011

Dear Traders,

UPDATE ON THE IMPLEMENTATION OF TRADENET® CONTROLS FOR THE IMPORT OF MEDICAL DEVICES INTO SINGAPORE ON 01 JANUARY 2012

This communication is to update traders on the controls of medical devices via TradeNet® from 01 January 2012.

2 Traders who import the following medical devices will be affected by this update:

a. Registered medical devices listed on the Singapore Medical Device Register (SMDR).
b. Medical devices listed on the Transition List
c. Medical devices listed on GN-22
d. Unregistered medical devices that are approved for import via Authorisation Routes.
e. Unregistered medical devices that have been approved for import for Clinical Trials
f. Unregistered Refurbished medical devices
g. Unregistered Custom-made medical devices

TYPES OF LICENCES

3 Medical Device Branch (MDB) issues the following licences for the importation of medical devices:

a. Importers licences to traders who import medical devices.
b. Product licences to medical devices that have been registered successfully.
c. Authorisation Routes approvals for the import and supply of unregistered medical devices.
d. Other authorisation approvals may be issued to facilitate the import of medical devices that are on Transition List (T-List) or exempted under the *Health Products (Medical Devices) Regulations 2010.*

TRADENET® DECLARATION REQUIREMENTS FOR HS CODES CONTROLLED BY MDB

4 For the import of **all** medical devices from 01 January 2012, traders will need to adhere to the following procedure when declaring an import permit declaration:

Field	Input
1. *Licence No.* (i) For Clinical Trials (ii) For all other cases	 *(i) Importer Licence is not required. This field is to be left blank.* (ii) Importer Licence Number
2. *HS Code*	HS Code for the item to be imported
3. *CA/SC Product Code* (i) Products listed on the SMDR **OR** T-List (ii) Authorisation Routes, Clinical Trials, Custom-Made and Refurbished medical devices (iii) Medical devices listed in GN-22	 (i) *CA/SC Code 1:* SMDR Listing No **OR** Transition List No *CA/SC Code 2: This field is to be leave blank* (ii) *CA/SC Code 1:* 'NA' *CA/SC Code 2:* A valid approval number (iii) *CA/SC Code 1: This field is to be leave blank* *CA/SC Code 2: This field is to be leave blank*
4. *HS Quantity*	Quantity of items to be imported

5 HS Quantity Unit of Measurement declared must match that of the Product Code Quantity Unit of Measurement.

6 The current import controls for condoms (*HS Code 40141000*) and contact lens solutions (*HS Code 33079020*) shall continue to apply.

TRADENET® DECLARATION REQUIREMENTS FOR HS CODES CONTROLLED BY PREVAILING CONTROLLING AGENCIES (CAs)

7 Traders are to declare in accordance to the requirements of the prevailing CAs. For example, medical devices that are also controlled by National Environment Agency – Centre for Radiation Protection and Nuclear Science (NEA-CRPNS), traders are to declare according to NEA-CRPNS requirements.

LIST OF HS CODES

8 01 January 2012 onwards, HSA will implement the HS Codes as per the ASEAN Harmonized Tariff Nomenclature (AHTN) 2012 for use with the TradeNet® version 4.1 system.

9 Click here for the list of AHTN 2012 HS codes controlled by MDB.

APPROVAL MESSAGES

10 Upon the approval of the Import Permit application, the importer is required to comply with all the requirements and conditions stated in the approval message(s).

ENQUIRIES

11 For any other enquiries, you may contact MDB at 6866 3560 or email to hsa_mdb_tradenet@hsa.gov.sg.

12 Please keep this communication letter for your future reference.

Regards,

JOANNA KOH (MRS.)
DIRECTOR,
MEDICAL DEVICE BRANCH
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY