



18 May 2011

Health Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-03 Helios
Singapore 138667
Website: www.hsa.gov.sg
Fax: 6478 9028

Dear Traders,

IMPLEMENTATION OF TRADENET[®] CONTROLS FOR THE IMPORT OF CLASS C AND D MEDICAL DEVICES INTO SINGAPORE ON 01 JUNE 2011

The purpose of this communication is to inform traders on the implementation of TradeNet[®] controls for the import of Class C and D medical devices in Singapore on 01 June 2011. This communication serves to inform traders on the requirements and the procedures to facilitate the process of Import Permit applications of medical devices.

2 The import of medical devices is regulated under the Health Products Act Cap 122D by the Medical Device Branch (MDB) of the Health Sciences Authority (HSA).

3 The definition of 'medical devices' includes health products intended for diagnosis, prevention, monitoring, treatment or alleviation of any disease or compensation for injury and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

4 Traders who import the following Class C and D medical devices will be affected by the implementation of MDB TradeNet[®] controls:

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

LICENCING FUNCTIONS OF MDB

5 The licensing function of MDB includes the following:

- a. Licensing dealers of medical devices
- b. Licensing of medical devices via product registration process
- c. Licensing import and supply of unregistered medical devices via authorisation routes

TYPES OF LICENCES

- 6 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 licences 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 or exempted under the Health Products (Medical Devices) Regulations 2010

TRADENET® REQUIREMENTS

- 7 From 01 June 2011 onwards, for the import of **Class C and D** medical devices, traders need to provide the following information when declaring a TradeNet® declaration:
- a. A valid Importer's licence number is to be declared in 'Licence No.' field for all imports **except** medical devices imported for clinical trial and personal use. For medical devices imported for clinical trial and personal use, 'Licence No.' is to be left blank.
 - b. A valid HS Code controlled by MDB in 'HS Code' field according to the listed device names (e.g. HS code line 1 is 40141000 for item "natural brand water based condoms". HS code line 2 is 40141000 for item "Rabbit condoms").
 - c. A valid Product Code corresponding to the HS Code to be declared in 'CA/SC Product Code' field
 - d. **EITHER**
 - i. A valid medical device registration number (SMDR Listing No.) or a Transition List No. to be declared in 'CA/SC Code 1' field with 'CA/SC Code 2' field left blank
- OR**
- ii. A valid approval number (for Authorisation Routes, Clinical Trials, Custom-Made, Refurbished or Personal Use Only) is to be declared in 'CA/SC Code 2' field with a 'NA' declared in 'CA/SC Code 1' field
- e. Quantity to be imported in 'HS Quantity' field
 - f. HS Quantity Unit of Measurement declared must match that of the Product Code Quantity Unit of Measurement

8 For the import of medical devices that are subject to TradeNet® controls by another Controlling Agency (CA), traders are to declare in accordance to the requirements of these prevailing CA. 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 via TradeNet®.

- 9 Additionally, for the import of condoms (HS Code 40141000) intended for supply in Singapore, the following information is to be submitted to MDB upon TradeNet® declaration approval, via fax at 6478 9028:
- a. TradeNet® Declaration Form or Cargo Clearance Permit (containing the Importer's name)
 - b. Invoice
 - c. Packing List containing Brand Names, quantity of each consignment and batch numbers

10 Additionally, for the import of contact lens solutions (HS Code 33079020) intended for supply in Singapore, the following information is to be submitted to MDB upon TradeNet® declaration approval, via fax at 6478 9028:

- a. TradeNet Declaration Form or Cargo Clearance Permit (containing the Importer's name)
- b. Invoice
- c. Packing List containing Brand Names, quantity of each consignment and batch numbers
- d. Product owner's Certificate of Analysis (COA) containing information on particulate matter content and product sterility for each Brand name and batch number.

11 For the import of Class A and B medical devices:- From 01 Jun 2011 to 31 Dec 2011

- a. For HS codes that are controlled by MDB, traders are to declare 'MISC' in 'CA/SC Product Code' field with both "CA/SC Code 1" and 'CA/SC Code 2' fields left blank
- b. For HS codes that are NOT controlled by MDB, traders are to declare in accordance to other applicable Controlling Agency's requirements.

12 From 01 Jan 2012, Class A and B medical devices will be declared under their relevant HS Codes and Product Codes.

LIST OF HS CODES

13 [Click here](#) for the list of HS code controlled by MDB.

APPROVAL MESSAGES

14 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

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

16 Please keep this communication letter for your future reference.

Regards,



JOANNA KOH (MRS.)
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HEALTH PRODUCTS REGULATION GROUP
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