Ref: HSA 600:07/04(063)

16 May 2012

Health Products Regulation Group
Health Sciences Authority
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Dear Traders,

UPDATE ON THE IMPLEMENTATION OF TRADENET® CONTROLS FOR THE IMPORT OF MEDICAL DEVICES INTO SINGAPORE, WITH IMMEDIATE EFFECT

This communication is to update traders on the controls of medical devices, in particular Class A medical devices, via TradeNet® with immediate effect.

2 HSA has enhanced the regulatory framework for Medical Devices. This has been announced on 20 April 2012 and detailed in the HSA Letter to MD Industry [HSA Ref: HSA 600:07/04(058)].

3 From 01 May 2012, all Class A medical devices, except sterile Class A medical devices, are exempted from product registration. Nonetheless, a valid medical device importer's licence is still required to conduct such importation. Please refer to *GN-22: Guidance for Dealers on Class A Medical Devices Exempted from Product Registration for the details. Annex 1 to GN-22* has also been updated with examples of devices categories that are exempted. Click here for *Annex 1 to GN 22.*

4 Traders who import non-sterile Class A medical devices, please declare:

a. The exempted Class A medical devices under MDB controlled HS Codes with the product code of **HSAMDX00200**. There is no change to the requirement for a valid medical device importer's licence to conduct such importation.

5 Traders who import sterile Class A medical devices are not impacted by the enhancement. The following requirements remain in force:

a. Device is a registered medical device listed on the Singapore Medical Device Register (SMDR); or
b. Device is listed on the Transition List; or
c. Device is an unregistered medical device that is approved for import via Authorisation Routes; or
d. Device is an unregistered medical device that is approved for import for Clinical Trials; or
e. Device is an unregistered Refurbished medical device; or
f. Device is an unregistered Custom-made medical device.

TYPES OF LICENCES

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

a. Importer 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

7 For the import of **all** medical devices, traders are to adhere to the following procedure when declaring an import permit application:

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

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

9 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)

10 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

11 HSA has implemented the HS Codes as per the ASEAN Harmonized Tariff Nomenclature (AHTN) 2012 for use with the TradeNet® version 4.1 system.

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

APPROVAL MESSAGES

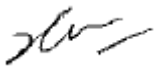
13 Upon the approval of the Import Permit application, the importer is required to comply with all the requirements and conditions stated in the approval message(s).

ENQUIRIES

14 For any other enquiries, you may contact HSA TradeNet Unit at 6304 5857 or email to hsa_mdb_tradenet@hsa.gov.sg.

15 Please keep this communication letter for your future reference.

Yours faithfully,



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