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12 April 2016

To: Importers, Traders and Declaring Agents

Dear Sir/Madam

CHANGES TO IMPORT DECLARATION REQUIREMENTS FOR HEALTH PRODUCTS FROM 3 MAY 2016

The Health Sciences Authority (HSA) has undertaken a review of the import declaration requirements for health products, with the goal to streamline trade documentation of health products imported into Singapore and to facilitate the submission of import permit applications via TradeNet[®].

2 We wish to inform you that the key changes, as summarized below, will be implemented from **3 May 2016**:

- (i) Merger of the 4 Competent Authorities (CAs) of HSA for health products into a single unit
- (ii) Removal of the need to declare HSA Product Codes for health products that are currently not subject to licensing/approval requirements
- (iii) Simplification of HSA Product Codes

These key changes are further explained below.

(I) One Single Competent Authority (CA) For All Health Products Controlled by HSA

3 The current 4 CAs of HSA in TradeNet[®], i.e. Cosmetic Control Unit (CCU), Medical Device Branch (MDB), Complementary Health Products (CHP), and Health Products Regulation Group (HPR), will be **merged into a single CA (i.e. HPR)**. With this initiative, different categories of health products may be declared within the same TradeNet[®] permit application.



(II) Health Products Which Need Not Be Declared Using HSA Product Codes

4 The following health products are currently not subject to HSA's licensing/approval requirements before importation. Hence, they are no longer required to be declared using HSA's Product Codes in the permit applications submitted via TradeNet[®]. These health products include:

- (i) Cosmetic products
- (ii) Health supplements
- (iii) Quasi-medicines
(E.g. anti-dandruff preparations, medicated soaps, medicated plasters, medicated beverages, vitamin or nutritional preparations from any plant, animal or mineral, medicated toothpaste, medicated cosmetic products for treatment of pimples or acne which are exempted from product registration requirement)
- (iv) Traditional medicines such as Jamu and Ayurvedic medicines
(Excluding Chinese proprietary medicines)
- (v) Medicated oils and balms
- (vi) Herbal materials
- (vii) Homoeopathic medicines

(III) New and Simplified HSA Product Codes

5 For the following health products that are subject to HSA's licensing/approval requirements before importation, you are required to declare the relevant HSA Product Codes in your import permit applications and to furnish the relevant licence/approval information:

- (i) Medicinal products including medicinal gums
- (ii) Medical devices
- (iii) Chinese proprietary medicines
- (iv) Clinical trial test materials *[as defined in Medicines (Clinical Trials) Regulations]*
- (v) Controlled drugs and psychotropic substances *[as defined in the Misuse of Drugs Act and the Medicines (Export Licence for Psychotropic Substances) Regulations respectively]*
- (vi) Oral dental gums *[as defined in Medicines (Oral Dental Gums) (Specification) Order]*
- (vii) Substances specified in the Poisons Act

6 For the import of the above categories of health products, HSA has also reviewed and simplified the HSA Product Codes into 5 Product Codes as tabulated in Table 1 below. The 5 HSA Product Codes are to be used from **3 May 2016**.



Table 1: HSA Product Codes that will be implemented from 3 May 2016

Product Codes	Applicable for Import of:
HSAHP	Medicinal products, medical devices and Chinese proprietary medicines that have been listed, registered or approved by HSA, or legally exempted from product registration, which include: <ol style="list-style-type: none"> Registered medicinal products Registered medical devices Class A medical devices (non-sterile) Listed Chinese proprietary medicines Registered oral dental gums
HSAIFRSA	Medicinal products, medical devices and Chinese proprietary medicines imported with special authorisation or approval from HSA (including non-clinical use of such products in Singapore) on a consignment basis. <i>E.g. Import of medicinal products for clinical trials, import of medicinal products for use by named patients, import for re-export, import for supply to ships and aircraft, import for non-clinical purposes (such as laboratory/ stability testing, machine test runs, investigations, destruction/disposal, static displays in exhibitions, etc.)</i>
HSAPois	Substances specified in the Poisons Act including diagnostic kits, and reference standards containing these substances.
HSACDPSY	Substances regulated as controlled drugs under the Misuse of Drugs Act and substances regulated as psychotropic substances under the Medicines (Export Licence for Psychotropic Substances) Regulations and all products containing such substances.
HSAIPU	Import of medicinal products, medical devices, Chinese proprietary medicines (not containing controlled drugs or psychotropic substances) for personal use only.

Licence/Approval Information To Be Declared Using HSA Product Codes

7 In addition to the HSA Product Codes in Table 1 above, you are also required to declare all relevant HSA licence/approval information in the CA/SC Code 1, 2 and 3 fields, where applicable. Details of the information to be furnished for medicinal products, medical devices, Chinese proprietary medicines and other types of imports are provided in HSA's website at:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Manufacturing_Importation_Distribution/Overview/import-declarationatradenet.html

Frequently Asked Questions and Enquiries

8 A list of "Frequently Asked Questions" can be found on HSA website. The list will further address some of the questions that you may have.

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9 If you need further clarifications, we will appreciate it if you could send your enquiries via email to: **HSA_TradeNet@hsa.gov.sg**. You may also call our enquiry lines at 6866-3449 and 6866-3432 which will operate from 8.30 am to 12.00 pm and 1.30 pm to 5 pm on Monday to Friday (Saturdays, Sundays and Public Holidays: Closed).

10 Thank you.

Yours faithfully

LAI WENG FAI (DR)
DIRECTOR
LICENSING AND CERTIFICATION BRANCH
AUDIT & LICENSING DIVISION
for GROUP DIRECTOR
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

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