Frequently Asked Questions (FAQs)

1. Do all health products have to be declared with HSA Product Codes?

You are only required to declare the relevant HSA Product Codes via the TradeNet import permit applications if the health products to be imported are:

a) Currently subject to HSA's pre-market registration or listing controls (this includes therapeutic products, medical devices, cell, tissue and gene therapy products, Chinese Proprietary Medicines, substances specified as controlled drugs, psychotropic substances and poisons, therapeutic gums and oral dental gums); or
b) Subject to the dealers importing them holding an import licence or other forms of approval issued by HSA

Health products that are not subject presently to any licensing requirement, such as traditional medicines, health supplements, quasi-medicines and cosmetic products need not be declared using HSA Product Codes in the submission of TradeNet import permit applications.

Declaring agents are advised to confirm with the importers whether the products they are importing are subject to any pre-market registration or listing controls or the need to hold any importer licence or approval before importation. If so, **all** the valid product and/or import licence or approval information should be provided to the declaring agents for submission of the TradeNet import permit applications.

2. Which product code should be used when submitting a TradeNet Import Permit application?

The following applies to all declaration types including In-Non-Payment (Storage in FTZ) and Re-Export.

a. For all products that contain any controlled drugs as specified in the Misuse of Drugs Regulations or psychotropic substances as specified in the Health Products (Therapeutic Products) Regulations and Medicines (Export Licence for Psychotropic Substances) Regulations, you should declare using the product code "**HSACDPSY**" regardless of the purpose of the import.
b. For health products that do not contain any controlled drugs or psychotropic substances, the product code you should use will depend on the purpose of the import:

    a) "**HSAHP**" is to be used for registered therapeutic products, registered medical devices, registered cell, tissue and gene therapy products, Class 1 cell, tissue and gene therapy products, listed Chinese Proprietary Medicines and Class A Medical Devices, which are imported for local sale and/or supply.
    b) "**HSAIFRSA**" is to be used for health products that have been approved for import via any of the special authorisation/approval routes (e.g. Import of therapeutic products for Re-export, Import an unregistered therapeutic product on named-patient basis, Import unauthorised medical devices for re-export (GN-28), Import unregistered medical devices on named-patient basis (GN-26), Import of unregistered medical devices for non-clinical purpose (GN-29), etc.).
    c) "**HSAIPU**" is to be used for health products that are imported by individuals for personal use only.
    d) "**HSAPOIS**" is to be used for raw materials/substances specified as poisons in the Poisons Act and non-medicinal products such as laboratory reagents, and reference standards containing poisons.

Important Points to Note for products containing controlled drugs or psychotropic substances:

- Prior approval from HSA is required for the import of **every** consignment of products containing controlled drugs
- Prior approval from HSA is required for the import of **every** consignment of therapeutic products containing psychotropic substances
- Controlled drugs or psychotropic substance import licence/approval/authorisation number granted by HSA must be declared in the TradeNet permit application
- The import licence, approval or authorisation number is valid for a specific consignment and should be used only once, unless otherwise specifically permitted in the import/importer's licence or authorisation
- A valid import/importer's licence, approval or authorisation must be obtained from HSA for every consignment to be imported

3. What information should the importers provide to freight forwarding agents or declaring agents for import declaration?

As importers of health products are subject to licensing or approval requirements before the health products can be imported, you will need to provide the relevant licence and approval information to freight forwarding agents or declaring agents for import declaration.

Examples of information that should be provided include Product registration number, Importer's licence number, Poisons licence number, etc.

For more details, please refer to Tables 3 to 7.

4. Is there any change to the current legal requirement for cosmetic products to be notified to HSA before they are supplied locally?

No, there is no change to the current legal requirement. All cosmetic products should still be notified to the Health Sciences Authority (HSA) at HSA PRISM e-services before they are placed in the market. The regulatory requirements for cosmetic products, including the submission of product notification to HSA before supply, the absence of prohibited substances and the compliance to labelling requirements, still remain in place.

The above legal requirements are separate from the declaration of the importation of cosmetic products via TradeNet. From 3 May 2016, cosmetic products need not be declared using any HSA Product Code for submission of TradeNet import permit application.

5. Where can I check whether the substance being imported is regulated as a poison under the Poisons Act and should be declared using HSAPOIS?

All legislation is available on-line at the portal **Singapore Statutes Online**. You can find the substances regulated as "**poisons**" in the Schedule to the Poisons Act.

6. Can medical devices, therapeutic products, cell, tissue and gene therapy products and Chinese proprietary medicines be declared within the same permit application?

Yes, if you are importing various health products in the same shipment, you are allowed to declare these different health products with different HS codes within the same permit application. This is to facilitate your importation in the same shipment with minimal regulatory burden.

7. **Can health products with the same HS Code be declared together as one item?**

No, as one HS code can contain different types of health products to be imported, you are required to declare each individual health product separately (with separate item number), even if they share the same HS Code. This is a requirement by Singapore Customs.

8. **For personal import of therapeutic products, containing controlled drugs or psychotropic substances, which product code should be used, "HSAIPU" or "HSACDPSY"?**

For personal import of therapeutic products containing any controlled drugs or psychotropic substances, you should declare using the product code "**HSACDPSY**".

Please note that HSA's prior approval is required for personal import of products containing controlled drugs or psychotropic substances. Therefore, the personal import reference number issued by HSA upon approval must be specified in the CA/SC Codes 1 during import declaration.

9. **For registered therapeutic products containing psychotropic substances, what is the licence and approval information that needs to be declared in the import permit application?**

Prior approval to import therapeutic products containing psychotropic substances must be obtained for HSA before each consignment is imported. The approval number for the consignment of the product in addition to the importer's licence number and product registration number should be declared in the CA/SC Code fields.

10. **As ephedrine and pseudoephedrine are controlled by Central Narcotics Bureau (CNB) as precursors, how do we declare the imports of therapeutic products containing these two substances?**

Therapeutic products containing ephedrine or pseudoephedrine, are to be declared under HS codes: 30034100, 30034200, 30044100, 30044200 or 30049059 depending on the composition and purpose of import, with the relevant HSA product codes.

In addition, since CNB is the approving authority for the import, export and transhipment of products containing these two substances, please indicate "**CNB**" in the **Customs Procedure Code (CPC) field** in the TradeNet permit application.

For raw materials containing ephedrine and pseudoephedrine, they are subjected to CNB's control only and should be declared using HS Code 29394100 and 29394200 respectively, without using HSA Product Code. The permit applications will be routed directly to CNB.

For more details, please click here.

11. **Imports of traditional medicines, homeopathic medicines, health supplements, medicated oil and balm, medicated plasters, medicated beverages and raw herbs are**

currently being declared via TradeNet for processing by CHP CA. How do I declare the imports of these products from 3 May 2016?

From 3 May 2016, the above mentioned products, which are currently not subject to HSA's pre-market licensing or approval requirements, need not be declared using HSA Product Codes. They may be declared using the product code "MISC", upon confirmation that the goods are not controlled by any Competent Authority (CA).

12. Can complementary health products, which are not subjected to licensing or approval requirements, be declared in the same permit application as therapeutic products which are imported in the same shipment?

Yes, health products imported by an importer within the same shipment may be declared within the same permit application. Those which are not subjected to any HSA's pre-market licensing or approval requirements may be declared using the product code "MISC".

13. What information needs to be declared in the CA/SC Code 1, 2 or 3 fields when submitting TradeNet permit applications for imports of health products which are subject to HSA's licensing/approval requirements?

The CA/SC Code 1, 2 or 3 fields are for you to declare the relevant product, or dealer licence numbers, or relevant approval numbers issued by HSA pertaining to the health products you are importing.

Some examples of the HSA licence or approval information that need to be declared under CA/SC Codes 1, 2 and 3, where applicable, alongside the health products imported include:

Type of Import	Information to be declared under		
	CA/SC Code 1	CA/SC Code 2	CA/SC Code 3
Registered therapeutic products *(not containing controlled drugs or psychotropic substances)* by authorised importers for commercial trading, sales, import or wholesale	Product registration number	Therapeutic product importer's licence number	
Therapeutic products (not containing controlled drugs or psychotropic substances) solely for re-export	Therapeutic product importer's licence number (restricted activity)		
Registered therapeutic products *(containing controlled drugs or psychotropic substances)* by authorised importers for commercial trading, sales, import or wholesale	Product registration number	Therapeutic product importer's licence number	Controlled drug import licence number or psychotropic substances import approval number

Type of Import	Information to be declared under		
	CA/SC Code 1	CA/SC Code 2	CA/SC Code 3
Medical devices *(containing controlled drugs)* listed on Singapore Medical Device Register (SMDR) for commercial trading, sales, import or wholesale	Device registration number	Medical device importer's licence number	Controlled drug import licence number
Unregistered medical devices *(not containing controlled drugs or psychotropic substances)* on request by qualified practitioner for use on his patients	Special Authorisation (SA) number (GN-26)	Medical device importer's licence number	
Registered cell, tissue and gene therapy products (CTGTP) by authorised importers for commercial trading, sales, import or wholesale	Product registration number	CTGTP importer's licence number	
Cell, tissue and gene therapy products (CTGTP) solely for re-export	CTGTP importer's licence number or CTGTP known importer number		
Listed Chinese Proprietary Medicines (CPM), including bulk CPM for commercial trading, sales, import or wholesale	CPM listing number	CPM import licence number or CPM manufacturer licence number	
Laboratory reagents and reference standards *(containing controlled drugs or psychotropic substances)*	Poisons licence number	Controlled drug import licence number or psychotropic substance import authorisation number	

For more details, please refer to Tables 3 to 7.

14. Where can we obtain information on the HS Codes and Product Codes for medical devices?

Medical device importers, freight forwarding agents and declaring agents should seek advice from Singapore Customs on the HS Codes to be used for specific medical devices that they are importing.

For more information, please click here.

Alternatively, you may call us at 63552000.

For HSA Product Codes, one of the following Product Codes should be used if the medical devices do not contain any controlled drugs or psychotropic substances:

a) "**HSAHP**"- for registered medical devices and Class A Medical Devices, which are imported for local sale and/or supply.

b) "**HSAIFRSA**"- for medical devices that have been approved for import via one of the special authorisation routes (*e.g. import of medical products for use by named patients, import for re-export, import for supply to ships and aircraft, import for non-clinical purposes such as training, research use orstatic displays in exhibitions*).

c) "**HSAIPU**"- for medical devices that are imported by individuals for personal use only.

Medical devices that contain any controlled drugs or psychotropic substances are to be declared using **"HSACDPSY".**

Please refer to Table 4 for the product codes and information to be declared for the various imports of medical devices.

15. For medical devices that are also controlled by Radiation Protection & Nuclear Science Department (RPNSD), National Environment Agency (NEA), which product code should be used?

There is no change to the current declaration procedure for medical devices which are also regulated by RPNSD. They should continue to be declared using the product code specified by RPNSD.

16. For Class A medical device which are exempted from registration, what should be indicated in the CA/SC codes 1, 2 or 3 fields?

Although Class A medical devices are exempted from HSA's product registration requirement, importers are still required to be licensed by HSA and the Medical Device Importer's licence number should be indicated in the CA/SC Code 1 field.

17. Which product code and licence information should be declared in CA/SC Code 1, 2 and 3 for the import of veterinary products?

Only veterinary products that contain substances specified in the Poisons Act, the Misuse of Drugs Act and the Medicines (Export Licence for Psychotropic Substances) Regulations need to be declared using HSA Product Codes. "**HSACDPSY**" is to be used for veterinary products containing any controlled drugs and psychotropic substances. Poison licence number should be declared in CA/SC Code 1 and controlled drug import licence number or Psychotropic substance import authorisation number should be declared in CA/SC Code 2. "**HSAPOIS**" is to be used for veterinary products containing any poisons and only the poison licence number needs to be declared in CA/SC Code 1.

18. What product code should be used for personal import of veterinary products by pet owners?

Personal imports of veterinary products not containing controlled drugs, psychotropic substances or poisons need not be declared using HSA Product Codes.

You should use the product code "**HSAPOIS**" or "**HSACDPSY**" if the products contain any poisons or controlled drugs/psychotropic substances respectively. The licence number or personal import reference number issued by HSA must be indicated under the CA/SC Code 1 field.

19. What information is required to be declared for Clinical Research Materials (CRM)?

Clinical Research Materials (CRM), not containing any controlled drugs or psychotropic substances, are to be declared using the product code **"HSAIFRSA"**. However, the product code **"HSACDPSY"** should be used instead if they contain any controlled drugs or psychotropic substances.

The information below is to be provided under CA/SC Code 1 for CRM imported for the specified purpose. Declaring agents are advised to confirm the purpose of the imports with the importers.

Type of Import	**Information to be declared under CA/SC Code 1**
CRM imported for clinical research conducted in Singapore	CRM import notification number
CRM imported for re-export for clinical research conducted outside of Singapore	Importer's licence number (restricted activity)
CRM imported for disposal	Importer's licence number (restricted activity)

In addition, the following information is to be provided under CA/SC Code 2 for CRM containing any controlled drugs or psychotropic substances:

Type of Import	**Information to be declared in CA/SC Code 2**
CRM containing controlled drugs	Controlled drug import licence number
CRM containing psychotropic substances	Approval number to import therapeutic products containing psychotropic substances

20. Will there be any change to the approval message to be printed on the cargo clearance permit?

Permit applications that have been declared with the correct information for the imports of health products will be issued with the following message:

"GRANTED BY SINGAPORE CUSTOMS SUBJECT TO THE CONDITION THAT VALID PERMITS, LICENCES, APPROVALS OR SANCTIONS, WHERE REQUIRED, HAVE BEEN OBTAINED FROM THE HEALTH SCIENCES AUTHORITY FOR THE IMPORT UNDER THE APPLICABLE LAWS."