### Frequently Asked Questions (FAQs)

#### 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:

- 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 importer holding an import licence or other forms of approval issued by HSA

Health products that are currently not subject to any licensing requirement, such as traditional medicines, health supplements, quasi-medicines, topical antiseptics 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, <u>all</u> 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 In-Non-Payment (Re-Export).

- a. For all products that contain any controlled drugs as specified in the <u>Misuse of Drugs Regulations</u> or psychotropic substances as specified in the <u>Health Products (Therapeutic Products)</u> Regulations, <u>Medicines (Export Licence for Psychotropic Substances)</u> Regulations and <u>Health Products (Active Ingredients)</u> Regulations 2023, you should declare using the product code "**HSACDPSY**" regardless of the purpose of the import.
- b. For 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:
  - "HSAHP" is to be used for <u>registered therapeutic products</u>, <u>registered medical devices</u>, registered cell, tissue and gene therapy products, Class 1 cell, tissue and gene therapy products, <u>listed Chinese Proprietary Medicines</u> and Class A Medical Devices, which are imported for local sale and/or supply.
  - "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.).
  - "HSAIPU" is to be used for health products that are imported by individuals for personal use only.
  - "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. This product code is also to be used for Active Ingredients regulated under the Health Products (Active Ingredients) Regulations 2023.

### 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 are subject to licensing or approval requirements before the 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 HSA to be notified before cosmetic products are supplied locally?

No, there is no change to the current legal requirement. The Health Sciences Authority (HSA) should still be notified at <u>HSA PRISM e-services</u> before the cosmetic products 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 remains in place.

The above legal requirements are separate from the declaration of the importation of cosmetic products via TradeNet. HSA Product Codes need not be declared in the TradeNet import permit applications submitted for cosmetic products.

## 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 <u>Poisons Act</u> and "Active Ingredients" in the Schedule to the <u>Health Products (Active Ingredients) Regulations 2023</u>.

## 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 different health products classified under the same HS Code be declared together as one item in a permit application?

No, you are required to declare each health product as a separate line item (with the corresponding quantity and information required at the line item) even if they share the same HS Code.

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 Code1 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 the relevant HS codes together 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 <u>raw materials</u> containing ephedrine and pseudoephedrine, they are subjected to CNB's control only and should be declared under the relevant HS codes without using HSA Product Code. The permit applications will be routed directly to CNB for processing.

For more details on the import, export and transshipment of medicaments containing ephedrine or pseudoephedrine, please click here.

11. How do I declare the imports of traditional medicines, homeopathic medicines, health supplements, medicated oil and balm, medicated plasters, medicated beverages, topical antiseptics and raw herbs?

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 importer 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 Code 1, 2 and 3, where applicable, alongside the health products imported include:

	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 (Limited Scope)		
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
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	
Active pharmaceutical ingredients (containing controlled drugs or psychotropic substances)	Active Ingredient importer's licence	Controlled drug import licence number or psychotropic substance import authorisation number	
Active pharmaceutical ingredients (not containing controlled drugs or psychotropic substances)	Active Ingredient importer's licence		

For more details on the information to be declared in the CA/SC Code fields, please refer to <u>Tables</u> 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.

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 reexport, 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 code 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 (Limited Scope )		
CRM imported for disposal	Importer's licence number (Limited Scope)		

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. What information is required to be declared for Active Ingredients used for manufacturing therapeutic products/cell, tissue and gene therapy products (CTGTP), medical devices for clinical research/clinical trial?

An Active Ingredients notification is required if the Active Ingredients(s) are to be imported for manufacturing Clinical Research Materials (CRM). Such Active Ingredients are to be declared using the product code "HSAPOIS".

The information below is to be provided under CA/SC Code 1. 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		
Active Ingredients imported:  • for the purpose of manufacturing therapeutic products, CTGTP or medical devices in Singapore, and  • the therapeutic products, CTGTP or medical devices is intended only for clinical research/clinical trial use (whether in Singapore or overseas)	Active number	Ingredients	Notification