MEDICAL DEVICE GUIDANCE

GN-27: Guidance on the Requirements for Exemption from Product Registration for the Import of Unregistered Medical Devices for Supply to a Clinical Laboratory, Medical Clinic or Private Hospital licensed under the PHMC Act

Revision 1.1
R1.1 This document is intended to provide general guidance. Although we have tried to ensure that the information contained here is accurate, we do not, however, warrant its accuracy or completeness. The Health Sciences Authority (HSA) accepts no liability for any errors or omissions in this document, or for any action/decision taken or not taken as a result of using this document. The information contained in this document should not be a substitute for professional advice from your own professional and healthcare advisors. R1.1
1. **INTRODUCTION**

1.1. **Purpose**

This document provides guidance on the special access route available to laboratories and medical facilities licensed under the Private Hospital and Medical Clinics (PHMC) Act (Cap. 248) to seek approval for the supply of unregistered medical devices.

1.2. **Background**

Supply of unregistered medical devices is prohibited under the *Health Products Act*. In order to supply an unregistered medical device, prior approval from HSA shall have to be sought. In an emergency or in a case where all conventional therapies have failed, the special access route provides an option to licensed laboratories and hospitals to import and supply unregistered medical devices for use by qualified practitioners.

1.3. **Scope**

This document is applicable to laboratories and hospitals licensed under the Private Hospital and Medical Clinics (PHMC) Act (Cap. 248) who import and supply medical devices in Singapore.

1.4. **Definitions**

**IMPORT:** with its grammatical variations and cognate expressions, means to bring or cause to be brought into Singapore by land, sea or air.

**MEDICAL DEVICE:** means a medical device as described in the First Schedule of the Act.

**PRODUCT OWNER:** for the purposes of this guidance document, means a person who sells a medical device under his own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the
person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

**QUALIFIED PRACTITIONER:** means:-

- a person registered under the Medical Registration Act (Cap. 174), when acting in the course of providing medical treatment to a patient under his care; or

- a person registered under the Dentists Act (Cap. 76) whose name appears in the first division of the dentists register kept under that Act, when acting in the course of providing dental treatment to a patient under his care.
2. APPLICATION REQUIREMENTS

2.1. Data requirements

An application shall be accepted for review by HSA if the following documents shall be submitted together with the application form (Ref number: MDSA-HL1):

- List of medical devices, including the following details,
  - Product Owner of the medical device
  - Proprietary name or description of the medical device
  - Quantity
- Intended purpose, as stated in Instructions for Use, Product Insert, or Operations Manual by the product owner,
- A copy of the primary medical device label, and
- A copy of the Clinical Laboratory’s, Medical Clinic’s or Private Hospital’s licence under the Private Hospital and Medical Clinics (PHMC) Act (Cap. 248), with the PHMC Licence Number clearly legible.

Information on the diagnostic or therapeutic purpose for which the medical device is required and the reasons why this could not be accomplished with a registered medical device or conventional therapy shall be provided.

For consumable medical devices, additional justification on the quantity for use is required.

NOTE Qualified practitioners are persons registered under the Medical Registration Act (Cap. 174) or Dentists Act (Cap. 76). Only qualified practitioners are eligible to apply for approval to import and supply an unregistered medical device through this route. The applicant has to indicate his/her Medical Council Registration (MCR) Number or Dental Council Registration (DCR) Number in the application. The PHMC Licence number for the laboratory or hospital has to also be provided as part of the application.

NOTE Any unauthorised modifications to the submitted application form shall render the application invalid and it shall be rejected. Thereafter, the applicant shall not be eligible to obtain approval to import medical devices through any of the authorisation routes.
NOTE  The authorisation routes do not serve to confirm the risk class of the medical devices. It is the duty of the applicant to verify the risk class of the medical devices they submit in the application.

NOTE  It is the duty of the applicant to verify that the medical device requires authorisation prior to supply. There shall be no refund of any application fees for the import of medical devices once the application has been accepted.

2.2. Grouping of devices

Multiple devices may be submitted under each application.

This authorisation route permits multiple import consignments within the validity period of the authorisation.

NOTE  Medical devices (e.g. Infusion pumps, X-Ray CT scanners, Vital Signs Monitors, etc) which will be used in high frequency on a number of patients, may not be authorised for supply through this authorisation route. Such medical devices shall require registration with HSA prior to their supply for use on patients in Singapore.

2.3. Mode of submission

The applicant (i.e. licensed importer) shall submit the application form by either fax (+65 6478 9028) or email (hsa_md_sa@hsa.gov.sg).

The application form shall be signed, carry the company stamp and be submitted to HSA by the applicant.

2.4. Fees

Please refer to the fee schedule and HSA website for the fees applicable.

ONLY fee payment by GIRO shall be accepted. The application is subject to a fee payment by the licensed importer.

A GIRO account and a Client Registration and Identification System (CRIS)
account with HSA shall have to be set-up prior to payment via GIRO.

To set-up your CRIS account with HSA, please submit an online application at the following webpage:

The application form to set-up a GIRO account with HSA may be downloaded from the following webpage:
3. APPLICATION PROCESS

- Licensed importer submits application to import unregistered medical devices to supply to named PHMC Act licensed facility

- Screening of application by HSA

- Acceptance of application upon successful screening

- Review of application by HSA

- Regulatory Decision

- Import and supply of medical device upon receipt of approval from HSA may commence subject to conditions

- Importer submits summary of device status within (i) 30 days after expiry of authorization, or (ii) 30 days after date of last export/supply*, whichever is earlier

*Export/supply – refers to delivery of medical device to facility licensed under the PHMC Act (Cap.248)

A valid importer’s licence is a pre-requisite for application under this authorisation route.

The medical device shall only be imported after the application is approved. A written approval would be sent to the email address indicated in the application form.
Unauthorised supply of an unregistered medical device is an offence under the *Health Products Act* and penalties of a fine of up to $50,000 or imprisonment for a term not exceeding 2 years, or both will apply.

**Upon receipt of approval, the unregistered medical device shall only be imported by a licensed importer.**

The safety and performance of the device is not assessed by HSA during application review.

The authorisation shall be valid for a period of 6 months from the date of approval.

4. **CONDITIONS OF APPROVAL**

The authorisation would be subject to regulatory conditions of approval. Failure to comply with these conditions will render this authorisation invalid. The list (i.e. not exhaustive) of conditions may include the following:-

- The unregistered medical devices shall only be permitted for import by the licensed importer.
- The licensed importer shall be responsible for ensuring that the quality, safety and performance of the medical devices are not adversely affected during import, storage and distribution of the medical devices.
- Any unauthorised supply would be a contravention of section 15 of the *Health Products Act*.
- The licensed importer shall perform and observe all the Duties and Obligations under Part VIII of the *Health Products Act*.
- The licensed importer or product owner shall inform the Health Sciences Authority of any product-related problems and/or adverse events arising from the use of the medical devices that become known to the licensed importer or product owner in accordance with the provisions specified in the *Health Products Act* and *Health Products (Medical Devices) Regulations*. 
• Any promotional materials or presentation of the medical device that contains any statement to the effect, whether directly or indirectly, that the use of the medical device is being promoted or endorsed by the Health Sciences Authority, shall not be issued.

• The product presentation and/or advertisement, inclusive of brochures, pamphlet and others shall not contain any claims related to the following scheduled diseases and conditions: blindness, cancer, cataract, drug addiction, deafness, diabetes, epilepsy or fits, hypertension, insanity, kidney disease, leprosy, menstrual disorders, paralysis, tuberculosis, sexual function, infertility, impotency, frigidity and conception and pregnancy.

• Professional-use only medical devices shall not be advertised to the general public.

• The licensed importer shall submit a declaration on distribution records in accordance to the format prescribed by the Authority. This declaration shall be submitted to the Authority within 30 days after the date of expiry of the authorisation or date of last export/supply, whichever is earlier.

• The quantity of the unregistered medical device approved for import and supply under this authorisation.

• Should treatment be discontinued before the end of the treatment period approved, HSA is to be notified of the reasons for discontinuation within 6 weeks of the treatment being discontinued.

• The qualified practitioner and PHMC Act licensed facility shall accept responsibility for any adverse consequence that results from the use of the medical device.

• HSA shall not be responsible for any defects in the medical device whatsoever, including defects related to manufacture, distribution and directions for use.

• The licensed importer shall indemnify and hold HSA harmless against all actions, claims or proceedings in respect of any adverse event, injury to or death of any person whomsoever arising out of or in connection with the use of the unregistered medical device.
• All remaining unused supplies of the medical device shall be returned to the product owner or licensed importer.

• Once the authorisation has expired, no further import and supply of the medical device, at any quantity, shall be permitted.

This authorisation may be cancelled by the Authority by informing the applicant in writing. If the authorisation is cancelled, all unsupplied or balance medical devices imported under this authorisation shall be placed under quarantine by the applicant in their facility. The applicant shall not supply or remove medical devices under quarantine unless authorised by the Authority.

5. ADDITIONAL INFORMATION

In considering requests to supply an unregistered medical device, there is a need to maintain a balance between individuals gaining timely access to important new therapeutic developments and maintaining a broader community interest for medical devices to be evaluated for quality, safety and efficacy.

To achieve this balance, each request to supply an unregistered medical device is determined on a case by case basis. Companies should register these medical devices if they intend to supply these medical devices on a long-term basis.

HSA requires that applications for the supply of unregistered medical devices justify adequately why available medical devices registered with HSA are not suitable for use.

6. POST-MARKET OBLIGATIONS

Unregistered medical devices have not been evaluated for quality, safety or efficacy by HSA. Therefore, the responsibility for prescribing an unregistered medical device rests with the qualified practitioner.
The qualified practitioner is best placed to determine the needs of the patient and to monitor the outcome of therapy. The qualified practitioner should ensure the patient has given appropriate informed consent prior to treatment.

The responsibility for reporting field safety corrective actions (FSCA) and adverse events for medical devices that are supplied through the special access scheme lies primarily with the party who arranged for its supply (i.e. treating doctor, clinical diagnostic laboratory or hospital). It is a condition of approval that the treating doctor reports the details of any FSCA or adverse event to the Authority according to applicable timelines.

7. DECLARATION ON DISTRIBUTION RECORDS

At the end of authorisation (6 months), the importer shall be required to submit a declaration (Ref number: MDSA-HL2) on the number of devices that have been imported and supplied in Singapore.

The prescribed format in Annex 1 should be utilised. The document should be submitted by email (hsa_md_sa@hsa.gov.sg).
Declaration on Distribution Records Template

[To be printed on Company Letterhead of Product Owner]

Medical Device Branch
Therapeutic Products Division
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Status of Medical Devices Imported under Authorisation Route – PHMC Act licensed facility
[Reference number for CURRENT authorisation] – Expiry date (DD/MM/YYYY)

I, <Name & NRIC/Passport Number>, on behalf of <Importer>, hereby declare that the information listed in the table below is complete and accurate.

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<th>Product Name Identifier</th>
<th>Total Quantity approved</th>
<th>Total Quantity imported</th>
<th>Total Quantity consumed</th>
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I further declare that as at <date>, * the stock balance is zero / the continued supply of the balance stock is authorised under <Reference number for NEW authorisation>.
(*Delete accordingly)

[Signature]
[Full Name and Title of Company Representative]
[Company stamp]


Contact Information:

Medical Device Branch
Pre-marketing Division
Health Products Regulation Group
Health Sciences Authority

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