HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

September 2018

MEDICAL DEVICE GUIDANCE

GN-26: Guidance on the Requirements for Import and Supply of Unregistered Medical Device on Request by Qualified Practitioner for Use on his Patient

Revision 2.2

HSA
Health Sciences Authority

PREFACE

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. ◄

REVISION HISTORY

Guidance Version (Publish Date) *[3 latest revisions]*	Revision
GN-26: Revision 1 (June 2010)	R1
R1.1 ► GN-26: Revision 1.1 (April 2014)	R1.1
R2 ► GN-26: Revision 2.0 (21 June 2016)	R2
R2.1 ► GN-26: Revision 2.1 (3 March 2017)	R2.1
R2.2 ► GN-26: Revision 2.2 (01 September 2018)	R2.2

**Where applicable, changes and updates made in each document revision are annotated with or within the arrow symbol "►". Deletions may not be shown*

1. INTRODUCTION

1.1. Purpose

R2 ►This document provides guidance on the special authorisation route available to licensed qualified practitioners to seek approval for the import and supply of unregistered medical devices for use on his patient(s).◄

1.2. Background

Supply of unregistered medical devices is prohibited under the Health Products Act (*Act*). In order to supply an unregistered medical device, prior approval from HSA shall be required.

There exists a possibility where an unregistered medical device is required for a specific treatment modality for a specific patient/patient population only. In an emergency or in a case where all conventional therapies have failed, the special authorisation route provides an option to qualified practitioners to meet special clinical needs arising in the course of his practice.

1.3. Scope

This document provides guidance on the application requirements for import and supply of unregistered medical device on request by qualified practitioner for use on his patient

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. This includes *IN VITRO* DIAGNOSTIC (IVD) PRODUCT (as set out in the *Regulations*).

PRODUCT OWNER *(as set out in the Regulations)*:

in relation to a health product, means a person who —

(a) supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and

(b) is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

QUALIFIED PRACTITIONER *(as set out in the Regulations)*: 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.

R2 ► SPECIAL CLINICAL NEEDS include:

- Medical devices on compassionate use basis
    - Absence of alternative treatment option; *or*
    - Available alternative treatments failed or deemed ineffective or unsuitable for the patient according to the doctor's or the dentist's clinical judgement; ***and***
    - Patient's health will be clinically compromised without the requested treatment
- Alleviation of stock-out situation
    - The unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device
- Novel or established medical device or upgraded version of established medical devices (new models/ new features)
    - Absence of registered alternatives or lack of a specific feature in registered medical device; *or*

- Available registered medical devices or models are deemed ineffective or unsuitable for the patient according to the doctor's or the dentist's clinical judgement; *or*
- User's (doctor or dentist) familiarity or expertise in terms of device technology, design and/or operation that is likely to support or enhance the safety outcomes of the procedure or treatment for the patient; *and*
- Patient's health will be clinically compromised without the requested medical device

- Established medical devices with history of use
  - The unregistered medical device has been used
    i. before 1 January 2012
    ii. in a licensed private hospital as approved by the relevant authority of that healthcare institution; **or**
    iii. in a licensed medical clinic as required by the doctor or dentist, ***and***
  - There are no known safety issues related to the use of the device◄

2. 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.

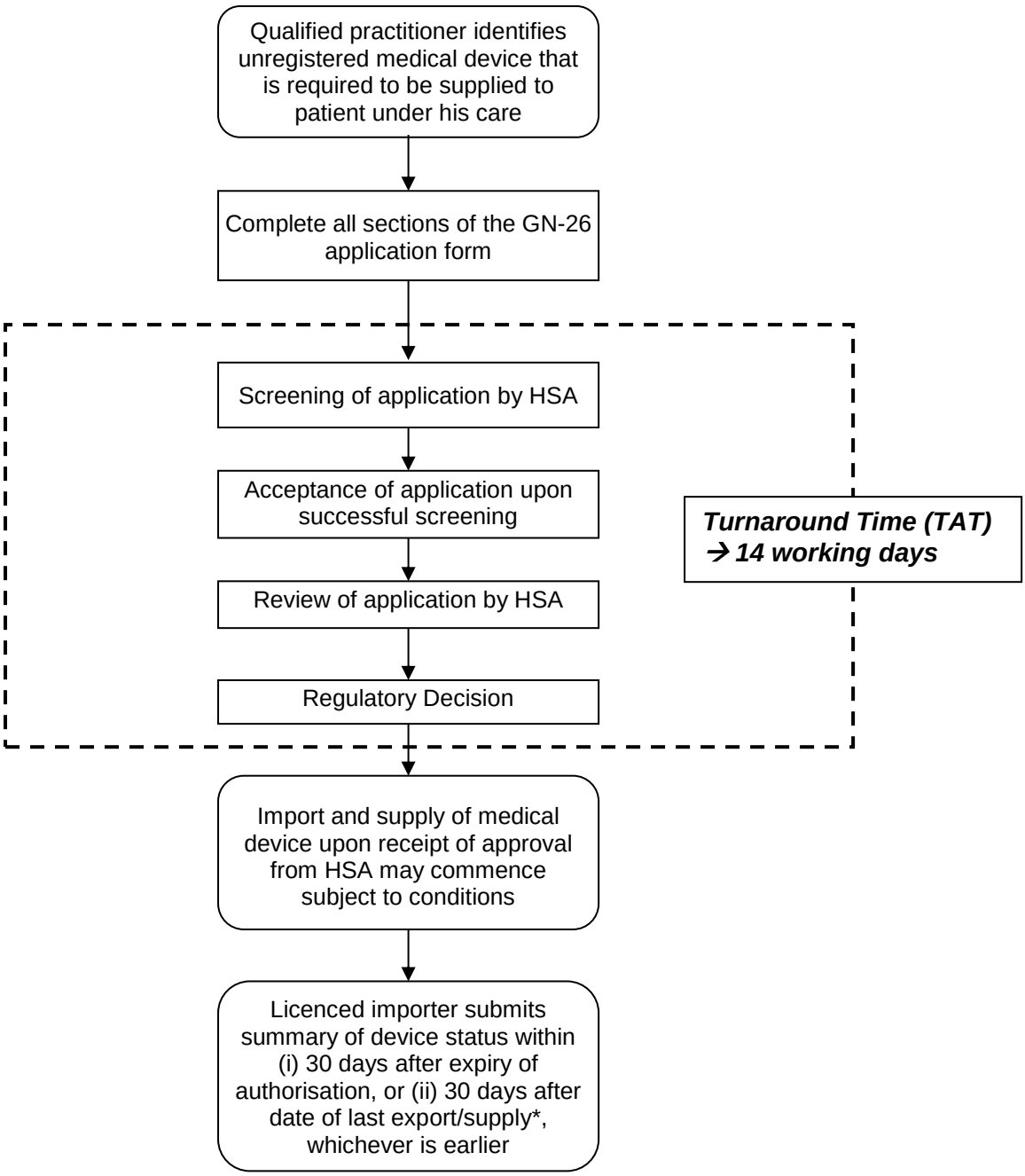
To achieve this balance, each request to supply an unregistered medical device is determined on a case by case basis. Companies should register these medical devices if they intend to supply these medical devices on a long-term basis.

R2 ►HSA requires that applications for the supply of unregistered medical devices be substantiated with the clinical justification including the special

clinical need for the unregistered devices by the qualified practitioner in place of registered products.

Please note that it is the responsibility of the licence holder and qualified practitioner/user to ensure the medical device(s) complies with any other applicable regulatory requirements of other regulatory bodies in Singapore prior to its supply or for its use (e.g. for medical devices also subject to control under the Radiation Protection Act, a licence from the Radiation Protection and Nuclear Science Department (RPNSD) of the National Environment Agency (NEA) may be required). ◄

3. APPLICATION PROCESS



**Export/supply – refers to delivery of medical device to qualified practitioner*

R2 ► A certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS)) is a pre-requisite for application under this authorisation route. ◄

The medical device shall only be imported after the application is approved. A letter of approval would be sent to the applicant via email.

The authorisation shall be valid for a period of **12 months** from the date of approval.

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

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

Unauthorised supply of an unregistered medical device is an offence under the *Act* and penalties of a fine of up to $50,000 or imprisonment for a term not exceeding 2 years, or both will apply.

4. APPLICATION REQUIREMENTS

4.1. Data requirements

An application shall be accepted for review by HSA if the following documents shall be submitted:

- Application Form (Ref number: MDSA-NP)
- Annex 2 List of Devices (*if applicable*)
- A copy of 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 qualified practitioner's registration under the Medical Registration Act (Cap. 174) or Dentists Act (Cap. 76) with the Medical Council Registration (MCR) Number or Dental Council Registration (DCR) Number clearly legible.
- A copy of quality management system certificate (e.g. Good Distribution Practice for Medical Devices (GDPMDS)) if a valid Importer licence with GDPMDS is unavailable.

R2 ►Where necessary, the Authority may require additional justification on the quantity of the device requested for use for the patient.

Records on the particulars of patient are to be maintained and kept on file by requesting qualified practitioner and to be submitted upon request by the Authority.

There shall be no amendments to the application or no refund of any application fees for incorrect applications once the application has been approved. ◄

Multiple devices that are required for a patient may be submitted under one application.

R2 ►Capital equipment refers to medical devices that are installed as part of the PHMC's fixed infrastructure. Examples are X-ray machines, CT scanners, MRI machines. These medical devices shall not be authorised via Special Authorisation Routes. Product registration 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.

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.

4.2. Submission mode and procedure

A Client Registration and Identification System (CRIS) account with HSA have to be set-up prior to application submission.

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

  R2.1►http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/CRIS.html ◄

- The turn-around time: 4 working days

The applicant (i.e. importer) shall submit the application form by email to hsa_md_sa@hsa.gov.sg.

- The application form shall be signed and be submitted to HSA by the applicant.

4.3. 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 importer.

A GIRO account with HSA shall have to be set-up prior to payment via GIRO.

- The application form to set-up a GIRO account with HSA may be downloaded from the following webpage:
  R2.1►http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services/Accessing_MEDICS/Payment_Options.html **◄**

5. 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.
- **R2** ► All medical devices intended for qualified professional use should not be advertised to 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 supply under this licence is as indicated in the attached application form.
- The qualified practitioner shall accept responsibility for any adverse consequence that results from the use of the medical device on a patient.
- Health Sciences Authority shall not be held 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 Health Sciences Authority 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.
- **R2** ►In the event of occurrence of a FSCA for the device authorised under this licence within the validity period of this licence, the licensed importer shall undertake the following measures:
    - Inform all consignees and users included in this licence regarding the FSCA immediately.
    - Further supply of the medical devices authorised under this licence will be dependent on the advice provided by the Authority in the context of the FSCA review. ◄
- Once the authorisation has expired or has been cancelled, 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.

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 authorisation route lies primarily with the importer who arranged for its supply. It is a condition of approval that the importer reports the details of any FSCA or adverse event to the Authority according to applicable timelines.

7. DECLARATION ON DISTRIBUTION RECORDS

R2 ►The importer shall be required to submit a declaration (Annex 1) on the distribution records using the prescribed format in Annex 1 within 30 days after expiry of authorisation, or within 30 days after date of last import.

The document should be submitted by email to (hsa_md_sa@hsa.gov.sg).

Importer shall be required to maintain documentary evidence of supply (e.g. traceability records) as part of their mandatory device distribution records for the devices imported under this authorisation. This information shall be submitted to the Authority upon request. ◄

ANNEX 1

Form No.: Annex 1
Date of Revision: September 2018

Declaration on Distribution Records Template

[To be printed on Company Letterhead of Licensed Importer]

Medical Devices Branch
Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

[Date]

Dear Sir/Madam,

Subject: Status of Medical Devices Imported under Authorisation Route – [*GN26 / GN27 / GN28 / GN29] [Reference number for CURRENT authorisation] – Expiry date (DD/MM/YYYY)

I, <Name >, on behalf of < Importing company name>, hereby declare that the information listed in the table below is complete and accurate.

Product Name	Identifier	Total Quantity approved	Total Quantity imported	Total Quantity consumed	Balance Quantity

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]

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

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