HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

May 2014

MEDICAL DEVICE GUIDANCE

GN-29: Guidance on the Requirements for Exemption from Product Registration to Supply Imported or Manufactured Unregistered Medical Devices for Non-Clinical Purpose

Revision 1.1

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. ◄ R1.1

1. INTRODUCTION

1.1. Purpose

This document provides guidance on the requirements to obtain approval to import and supply unregistered medical devices for non-clinical purpose.

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. Supply for non-clinical purpose includes any form of use other than use or administration on humans. Examples of such uses include:-

- display of the medical device at an exhibition;
- training equipment (i.e. precludes use on humans);
- use on animals; or
- use of in-vitro diagnostic medical devices for research-use only.

In order to supply a medical device which is not registered for non-clinical purpose, approval has to be first obtained from the Authority.

1.3. Scope

This document is applicable to all persons who manufacture, import and supply by wholesale 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.

NON-CLINICAL PURPOSE: in relation to a medical device, means any purpose other than a purpose described in the second column of the First Schedule to 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-NC1):-

- List of medical devices, including the following details,
  - Product Owner of the medical device
  - Proprietary name or description of the medical device
  - Quantity to be imported
  - Non-clinical purpose
  - Consignee details
- Intended purpose, as stated in Instructions for Use, Product Insert, or Operations Manual by the product owner,
- A copy of the medical device label, including a statement to the effect 'for supply for non-clinical purpose only'.

Failure to submit any of the above documents shall render the application invalid and shall be rejected.

NOTE Any unauthorised modifications to the submitted application form shall render the application rejected. The applicant would be added to a blacklist and shall no longer be eligible to obtain future authorisations to import and supply unregistered medical devices.

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 medical devices

Multiple devices may be submitted under each application.

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

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.

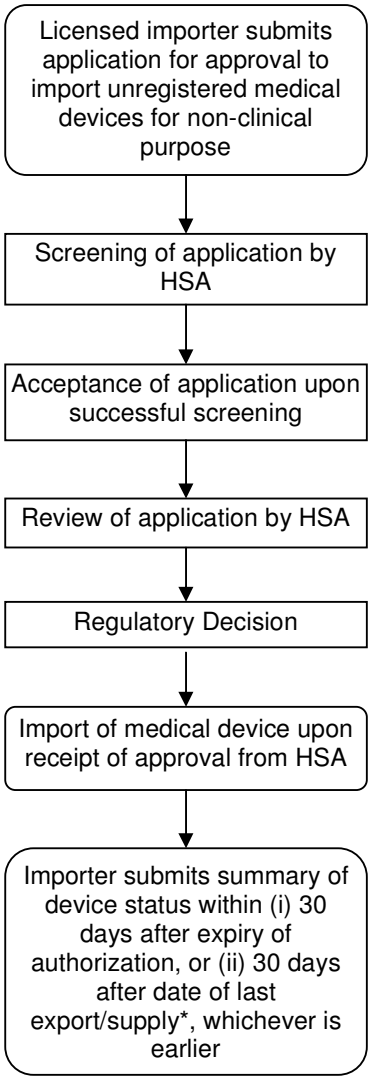
ONLY fee payment by GIRO shall be accepted. The application is subject to a fee payment by the licensed importer.

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:
http://www.hsa.gov.sg/publish/hsaportal/en/services/cris.html

The application form to set-up a GIRO account with HSA may be downloaded from the following webpage:
http://www.hsa.gov.sg/publish/hsaportal/en/services.html

3. APPLICATION PROCESS



**Export/supply – refers to supply of medical device to the consignee who shall be using it for non-clinical purpose.*

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 12 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*. Medical devices imported through this authorisation route shall not be supplied for clinical use, including use on humans in the process of demonstration or during free trials.
- 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 devices approved for import and supply under this authorisation.
- 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.

NOTE Any use of the unregistered medical device by a qualified practitioner on a patient shall require prior authorisation from the Authority.

NOTE The unregistered medical device shall not be used for demonstration on a participant under any circumstances. Such a use is deemed as a use for clinical purpose.

5. DECLARATION ON DISTRIBUTION RECORDS

At the end of authorisation (12 months), the importer shall be required to submit a declaration (Ref number: MDSA-NC2) on the number of devices that have been imported and supplied for non-clinical purpose in Singapore.

The non-clinical purpose of the medical device shall be specifically indicated. For devices on display at exhibitions, the expected export date of the devices shall be specified.

The importer shall have to maintain documentary evidence of supply as part of their mandatory device distribution records. These shall have to be submitted to HSA upon request.

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

Form No.: MDSA-NC2
Date of Revision: June 2010

ANNEX 1

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 – Import for Supply for Non-Clinical Purpose [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.

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]
[Company stamp]

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Contact Information:

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

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