Updates to Special Access Routes (SAR) for GN-26 and GN-27

Medical Devices Cluster

24 March 2022

Overview of SAR

- The import and supply of unregistered medical devices may be facilitated via the following routes:

GN-26

- For licensed **qualified practitioners** to seek approval for the import and supply of **unregistered** medical devices for use on his patient.

GN-27

- For **healthcare facilities licensed under the Private Hospitals and Medical Clinics Act (PHMCA) / Healthcare Services Act (HCSA)** to seek approval for the import and supply of **unregistered** medical devices for use on their patients.

GN-28

- For the import of unregistered medical devices for the purposes of export or re-export

GN-29

- For the import of unregistered medical devices for non-clinical purposes

GN-30

- For the import of registered medical devices on a consignment basis, by dealers not authorised by the Registrant

NOTE

- Supply of unregistered medical devices is prohibited under the Health Products Act (Act) unless prior approval from HSA have been obtained.

SAR (GN-26 and GN-27) for clinical use

- For qualified practitioner or licensed healthcare facilities to seek approval for the import and supply of unregistered medical devices for clinical use on patient.
  - Clinical justification for the request must reflect “Special Clinical Needs”
  - The safety, quality and performance of the device is not assessed by HSA during application review.
  - The responsibility for prescribing an unregistered medical device rests with the qualified practitioner.
  - The qualified practitioner should also ensure the patient has given appropriate informed consent prior to treatment.

Updates to GN-26 and GN-27

Additional safeguard measures for requests by PHI

- With effect from **1 April 2022**, additional safeguard measures will be implemented for GN-26 and GN-27 applications that are:
  - **Requested by Public Healthcare Institution (PHI)**
  - **Applications containing class C and/or D medical devices**

NOTE

- Additional safeguard measures will not apply to requests from private healthcare facilities (as of 1 April 2022).
- HSA and MOH will track and review requests for these higher risk medical devices from the private healthcare facilities and additional safeguard measures will be introduced at a later date.

Updates to GN-26 and GN-27

Additional safeguard measures for requests by PHI

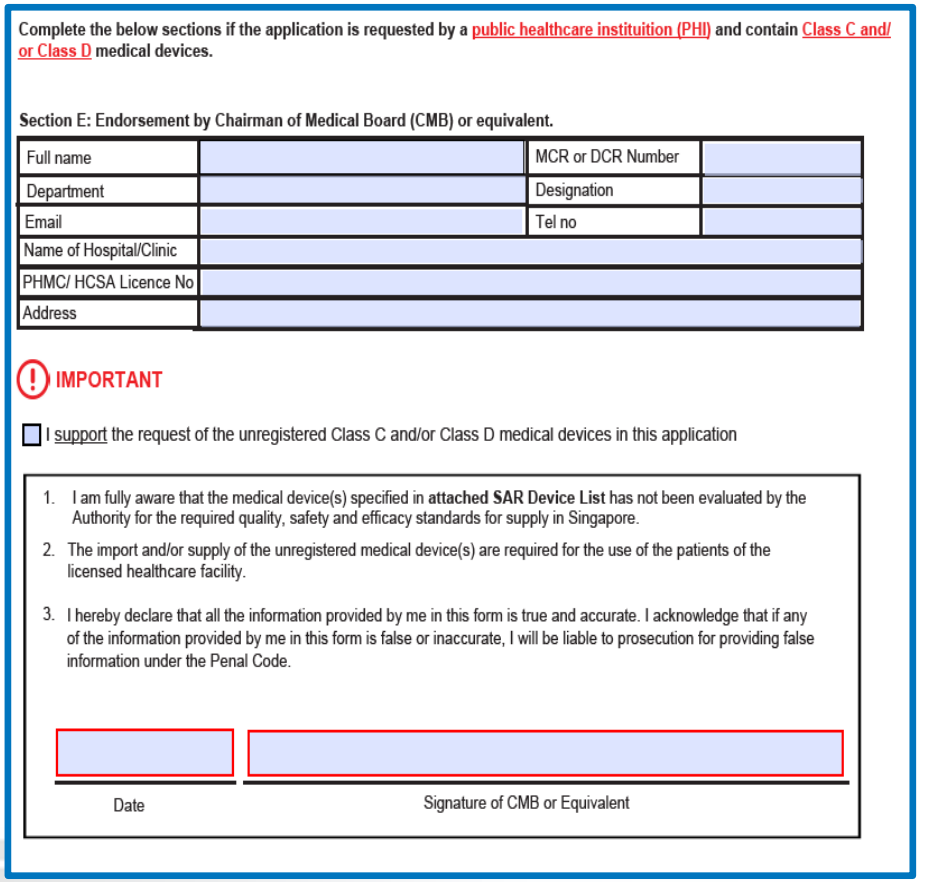
1. Endorsement of SAR application by Chairman of Medical Board (CMB) of the Public Healthcare Institution (PHI) or equivalent

- For GN-26 or GN-27 application requested by PHI that contains unregistered **Class C and/ or Class D** medical devices

- CMB or equivalent is required to complete the new **Section E** of "***Request Form for unregistered medical device for use on patients by QP and licensed healthcare facility***"

NOTE

- Importer to highlight the **Class C and/or Class D** medical devices in the SAR excel list and re-upload as a separate supporting document under "List of supporting documents" in MEDICS to facilitate processing of application



Complete the below sections if the application is requested by a public healthcare instituition (PHI) and contain Class C and/ or Class D medical devices.

Section E: Endorsement by Chairman of Medical Board (CMB) or equivalent.

Full name		MCR or DCR Number	
Department		Designation	
Email		Tel no	
Name of Hospital/Clinic			
PHMC/ HCSA Licence No			
Address			

IMPORTANT

☐ I support the request of the unregistered Class C and/or Class D medical devices in this application

1. I am fully aware that the medical device(s) specified in **attached SAR Device List** has not been evaluated by the Authority for the required quality, safety and efficacy standards for supply in Singapore.
2. The import and/or supply of the unregistered medical device(s) are required for the use of the patients of the licensed healthcare facility.
3. I hereby declare that all the information provided by me in this form is true and accurate. I acknowledge that if any of the information provided by me in this form is false or inaccurate, I will be liable to prosecution for providing false information under the Penal Code.

Date

Signature of CMB or Equivalent

Updates to GN-26 and GN-27

Additional safeguard measures for requests by PHI

2. Review of clinical justification by Ministry Of Health (MOH) for Class D medical devices

- For GN-26 or GN-27 application requested by PHI that contains unregistered **Class D** medical devices that fall into the following specific categories:

a) ***New technologies and state-of-the-art medical devices for clinical use on patients,*** including novel indications for existing medical devices or technologies.They can expose healthcare professionals and patients to significant risks as these unregistered medical devices have not been reviewed by HSA for their safety and effectiveness.

b) ***Unregistered implants*** (e.g., pacemakers, breast implants) as implants can fail post surgery, and give rise to long term complications, e.g., repeat or revision surgeries, or other clinical interventions that are likely to expose patients to further risks/complications

NOTE

- Further clarification via Input request may be required from the Importer if HSA deems that the devices may fall into the above categories.
- TAT may be extended for applications that include class D medical devices that fall under the specific categories of Class D devices that require review by MOH

Updates to GN-26 and GN-27

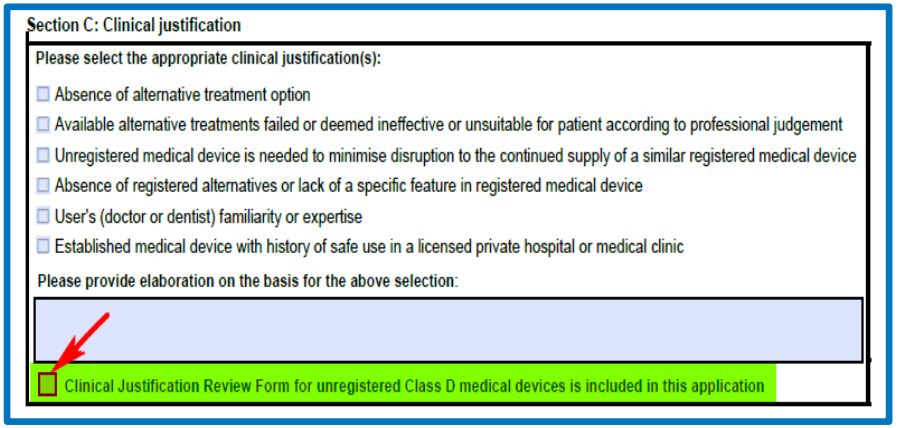
Additional safeguard measures for requests by PHI

Additional document to be submitted by Importer via MEDICS:

- Select the **checkbox in Section C** of ***"Request Form for unregistered medical device for use on patients by QP and licensed healthcare facility if MOH form is included in the SAR application***

- Scanned copy of the original **MOH's Clinical Justification Review Form for unregistered Class D medical devices** shall be submitted to HSA via MEDICS.

- The original signed hardcopy form **shall be maintained and kept on file** by the applicant. This information shall be submitted to the Authority upon request

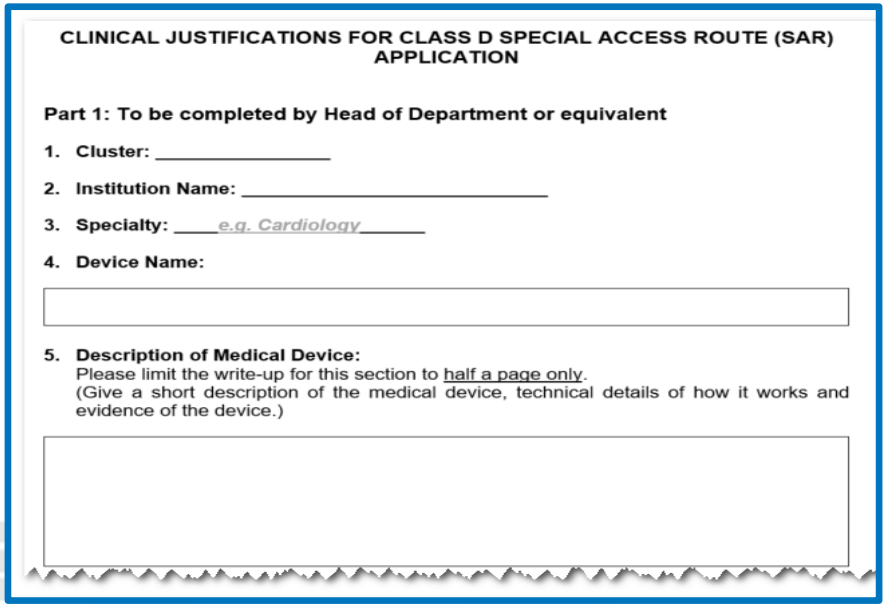

Section C: Clinical justification

Please select the appropriate clinical justification(s):

- ☐ Absence of alternative treatment option
- ☐ Available alternative treatments failed or deemed ineffective or unsuitable for patient according to professional judgement
- ☐ Unregistered medical device is needed to minimise disruption to the continued supply of a similar registered medical device
- ☐ Absence of registered alternatives or lack of a specific feature in registered medical device
- ☐ User's (doctor or dentist) familiarity or expertise
- ☐ Established medical device with history of safe use in a licensed private hospital or medical clinic

Please provide elaboration on the basis for the above selection:

☐ Clinical Justification Review Form for unregistered Class D medical devices is included in this application

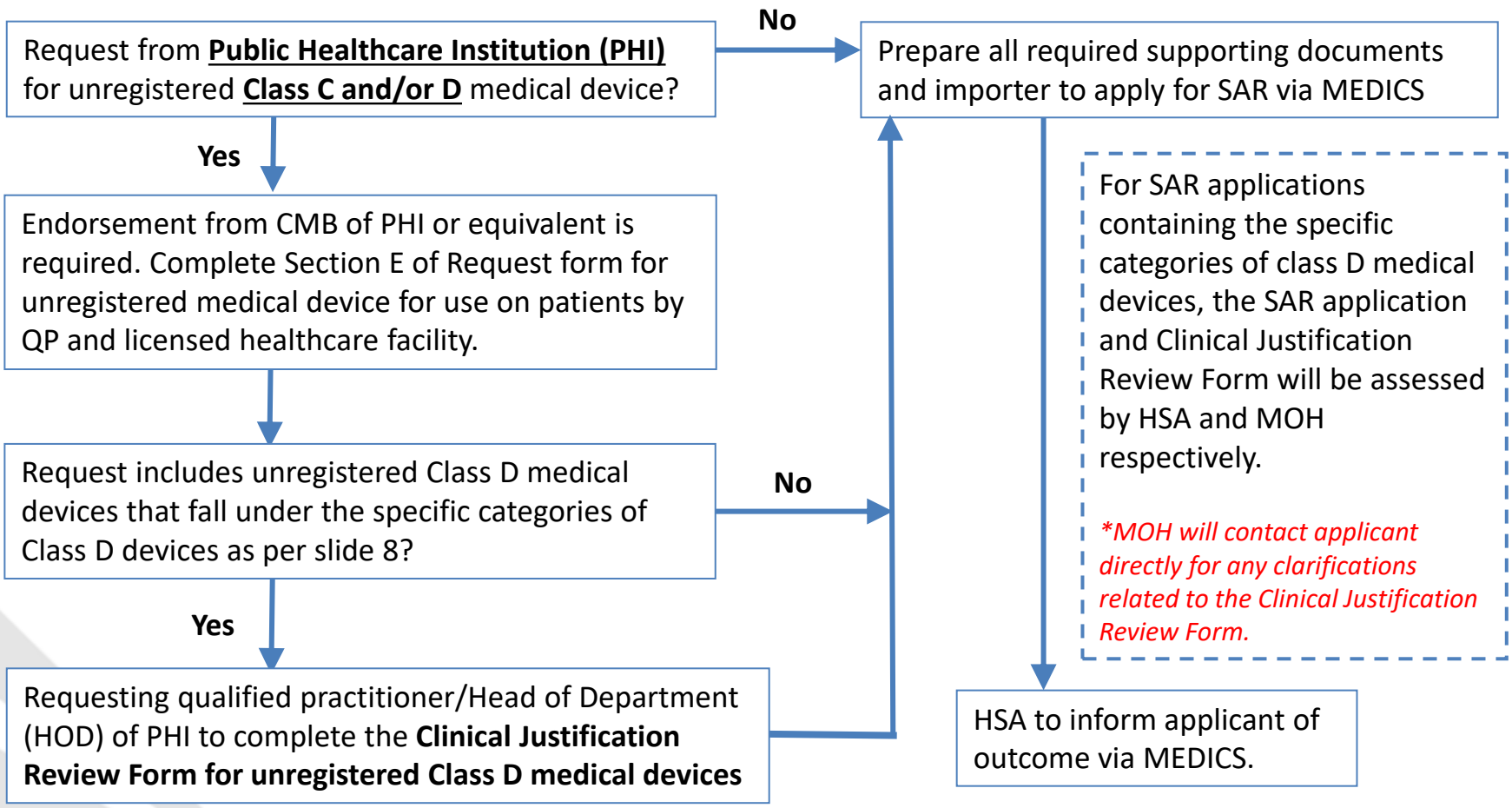

CLINICAL JUSTIFICATIONS FOR CLASS D SPECIAL ACCESS ROUTE (SAR) APPLICATION

Part 1: To be completed by Head of Department or equivalent

1. **Cluster:** _____
2. **Institution Name:** _____
3. **Specialty:** ____e.g. Cardiology_____
4. **Device Name:**

5. **Description of Medical Device:**
   Please limit the write-up for this section to half a page only.
   (Give a short description of the medical device, technical details of how it works and evidence of the device.)

Updates to GN-26 and GN-27
Application Flowchart



Updates to GN-26 and GN-27

Pre-requisite requirements

Pre-requisite requirements for GN-26 and GN-27 application	
Importer in the application	• Has a certified quality management system (e.g. to the requirement of Good Distribution Practice for Medical Devices (GDPMDS))
Unregistered medical device	• Has obtained **<u>at least one</u>** reference regulatory agency approval. ✓ Australia Therapeutic Goods Administration (TGA) ✓ Health Canada (HC) ✓ Japan Ministry of Health, Labour and Welfare (MHLW) ✓ US Food and Drug Administration (US FDA) ✓ European Union Notified Bodies (EU NB)

Reminders

- With effect from 1 April 2022 onwards, to avoid undue delay for GN-26 and GN-27 application, importers are reminded to:
  - ✓ Submit application with the revised "Request Form for unregistered medical device for use on patients by QP and licensed healthcare facility"
  - ✓ Ensure all supporting documents are uploaded via MEDICS

- Companies intending to supply unregistered medical devices on a long term basis should register these devices.

- Supply of unregistered single use medical devices and implants**, including administration or use on patients by licensed healthcare facility or QP** shall not be permitted after the authorisation expires.

FAQ

Question	Answer
Are the SAR updates applicable to applications submitted before 1 April 2022?	The updates to the Special Access Routes (SAR) for unregistered medical devices are only applicable to SAR applications submitted from 1 April 2022.
For SAR applications that include Class D medical devices that require MOH review as well as other devices that do not require MOH review, will the TAT for the entire application be longer or will those that do not require MOH review be approved first?	Yes, the TAT may be extended for the submitted application as long as it includes Class D medical devices that fall under the specific categories of Class D devices that require review by MOH. As such, please plan accordingly prior to submission.
Who is responsible for submitting the Clinical Justification Review Form to MOH for their review and approval?	All SAR supporting documents, including the Clinical Justification Review Form shall be submitted to HSA via MEDICS. HSA will liaise with MOH directly and MOH will contact applicant directly for any clarifications related to the form. HSA will inform the applicant via MEDICS on the outcome of the SAR application.
After expiry of the GN27 application, is a new GN27 application required if the healthcare facility wishes to continue using the device?	For single-use medical devices and implants, these devices shall not be used by the healthcare facility after expiry of the SAR licence. A new GN27 will be required for continued usage by the HCP. As such, companies are recommended to manage their inventories accordingly and only supply the quantity of device that is required by the healthcare facility. For equipment and reusable devices, users can continue to use these devices after expiry of the SAR licence. A new SAR application will not be required.

THANK YOU