Medical Device
Pre-Market Consultation &
Priority Review Scheme

13 July 2017 (Thursday)

Medical Devices Branch
Health Products Regulation Group
Health Sciences Authority
Scope

Background

Pre-market Consultation (PMC) Scheme
- Medical Device Development Consultation
- Medical Device Pre-submission Consultation
- How to schedule an appointment
- What to prepare for the appointment

Priority Review Scheme
- Qualification Criteria & Priority Review Scheme Routes
- Fees and Turn-Around-Time
- How to apply for the scheme
- What to submit for the scheme
Committee on the Future Economy (CFE) Recommendations

Support Innovation and Device Development Locally
- Engage researchers and developers
- Enable better understanding of regulatory requirements at early stage of device development

Facilitate timely access for Medical Devices that demonstrate the potential to address unmet clinical needs

To differentiate HSA as a trusted regulatory leader to help local enterprises expand overseas
## Background

### HSA’s Initiatives

<table>
<thead>
<tr>
<th>1. Pre-Market Consultation Scheme</th>
<th>2. Priority Review Scheme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support innovation and device development by ensuring devices are in line with regulatory requirements</td>
<td>Facilitate timely access for devices that address unmet clinical needs</td>
</tr>
</tbody>
</table>

To provide support through the device development lifecycle

**DISCOVERY + IDEATION** → **DEVELOP + PRE-CLINICAL** → **CLINICAL** → **REGULATORY SUBMISSION** → **PRODUCT LAUNCH** → **POST – MARKET MONITORING**
Support innovation and device development

MEDICAL DEVICE PRE-MARKET CONSULTATION (PMC) SCHEME
Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

**Medical Device Development Consultation**

Channel for stakeholders to **seek feedback on their device dossier, prior to pre-market submission** in terms of completeness and appropriateness of supporting documents.

**Medical Device Pre-submission Consultation**
1. Medical Device Development Consultation

SCOPE: Clarification on regulatory requirements applicable to the device in development, which may include

- Regulatory strategy
- Regulatory requirements
  - Device claims
  - Safety / Performance studies
  - Sterility
  - Biocompatibility
  - Risk management
  - Clinical trials

Channel for stakeholders to seek regulatory advice during medical device development phase to align with regulatory requirements.
1. Medical Device Development Consultation

**Who**
Medical device developers, researchers

**When**
Any time during device development

**What**
For 1 specific device or a group of devices intended to be used together

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**What it is not**

- Endorsement of any validation plans, test protocols and/or results that were discussed in the consultation
- Does not guarantee approval or marketing clearance
- Not meant to be an iterative process
2. Medical Device Pre-Submission Consultation

**SCOPE:** Seek feedback on the device dossier, in accordance to prescribed Common Submission Dossier Template (CSDT) guidance template, which may include:

- Risk Classification
- Registration Route
- Grouping
- Technical & administrative documents

Channel for stakeholders to seek feedback on their device dossier, prior to pre-market submission in terms of completeness and appropriateness of supporting documents.
2. **Medical Device Pre-Submission Consultation**

**Who**
Stakeholders submitting medical devices for registration locally

**When**
Before submission of pre-market application to HSA

**What**
Devices to be registered in 1 single pre-market application

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**What it is not**

- Not a scientific evaluation of the device
- Does not guarantee regulatory approval or marketing clearance
# Session Duration & Fees

<table>
<thead>
<tr>
<th>Consultation Category</th>
<th>Fees</th>
<th>Duration per session*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Device Development Consultation</td>
<td>$500 per device per consultation</td>
<td>Up to 2 hours</td>
</tr>
<tr>
<td>Medical Device Pre-submission Consultation</td>
<td>$200 per device application per consultation</td>
<td>Up to 1 hour</td>
</tr>
</tbody>
</table>

* Refers to only face-to-face meet-up consultation session.
### Process & Timeline

**5 Months before**

1. **Appointment booking**
   
   Slots are available for booking on the online Appointment Booking System **5 months before** the appointment date.
   
   E.g. on 1 August 2017, applicants will be able to book appointments till 31 December 2017.

**≥ 30 Days before Appointment Date**

2. **Document Submission**
   
   **ALL** required documents **30 days** before appointment date.

   **Failure to submit** required documents by the due date may result in **rescheduling** or **cancellation** of the appointment.

**Request for Information**

Upon submission, HSA will review the documents and may request for further information or clarification via email before the appointment, where necessary.

**Failure to respond** or address deficiencies **by the stipulated period** may result in **rescheduling** or **cancellation** of the appointment.

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**No extension** of due date is permitted.

Only **ONE** rescheduling is allowed per booking reference.

Fees paid are non-refundable.
Step 1: Appointment Booking

Appointment can be made via the online Appointment Booking System at the following url:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html (accessible upon launch date)

Note:

• No CRIS / SingPass / CorpPass login is required.
• Ensure all contact details are keyed in accurately as that will be the only form of verification upon payment and booking confirmation.
Step 1: Appointment Booking

1. APPLICANT INFO - Enter your particulars and contact details and click “Next”
Step 1: Appointment Booking

2. BOOKING INFO

1. Select Consultation Type and Device Type
2. Select preferred appointment date based on availability
3. Select preferred timeslot
4. Add booking

For multiple bookings in a single application, repeat steps (1) to (4)
Step 1: Appointment Booking

Upon addition of all required bookings into the list (i), please click “Next” (ii) for confirmation.
### Step 1: Appointment Booking

**3. CONFIRMATION** - Verify applicant & booking details are accurate before clicking “Submit”.

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**AB1001 Appointment Booking for Medical Devices Pre-Market Consultation**

<table>
<thead>
<tr>
<th>TRANSACTION NO: TMD17503236G</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPLICATION FORM</td>
</tr>
<tr>
<td>1. Applicant Info</td>
</tr>
<tr>
<td>2. Booking Info</td>
</tr>
</tbody>
</table>

*Fields marked with asterisks * are mandatory.

#### 3. APPLICANT INFO

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Name: *</td>
<td>3.2 Email: *</td>
<td>3.3 Contact Number:</td>
<td>3.4 Company Name (Optional):</td>
</tr>
<tr>
<td>3.5 Address Type: *</td>
<td>3.6 Postal Code: *</td>
<td>3.7 Block / House No.: *</td>
<td>3.8 Street Name: *</td>
</tr>
<tr>
<td>3.9 Building Name:</td>
<td>3.10 Level - Unit:</td>
<td>3.11 Country:</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SN</th>
<th>Consultation Type</th>
<th>Device Type</th>
<th>Appointment Date</th>
<th>Appointment Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Device Submission</td>
<td>General Medical Device</td>
<td>31/08/2017</td>
<td>14:00</td>
</tr>
<tr>
<td>2</td>
<td>Device Development</td>
<td>In-Vitro Diagnostic</td>
<td>01/09/2017</td>
<td>11:00</td>
</tr>
<tr>
<td>3</td>
<td>Device Submission</td>
<td>General Medical Device</td>
<td>01/09/2017</td>
<td>14:00</td>
</tr>
</tbody>
</table>

**REMINDER:**
Ensure that you are able to provide with relevant information required for the consultation 30 days before the selected date as fees paid are non-refundable.
Step 1: Appointment Booking

Proceed to complete payment.

Please select one payment method.

<table>
<thead>
<tr>
<th>Description</th>
<th>Unit Price ($)</th>
<th>Qty</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation Fee (Device Submission)</td>
<td>200.00</td>
<td>1</td>
<td>200.00</td>
</tr>
<tr>
<td>Consultation Fee (Device Development)</td>
<td>500.00</td>
<td>1</td>
<td>500.00</td>
</tr>
<tr>
<td>Consultation Fee (Device Submission)</td>
<td>200.00</td>
<td>1</td>
<td>200.00</td>
</tr>
</tbody>
</table>

Total: 900.00

This is a computer-generated payment advice. No signature is required.

The Evaluation Fee displayed above (if any) will be billed to you after the application is accepted for evaluation. Please print a copy of this advice for reference.

1. For GIRO company, the payment will be deducted from your bank account.
2. For on-line payment (e.g., credit card) you will be directed to the Government payment gateway.
3. Please note that cash collection over-the-counter is discontinued on and after 1 April 2008.
4. Please note that cheque payment has been discontinued.
Step 1: Appointment Booking

- Each appointment will be issued with a unique booking reference number.
- A confirmation email will be sent out for each appointment upon successful booking.

- An invoice will be generated. Please ‘Save’ or ‘Print’ the invoice if required as it will not be retrievable subsequently.
Step 1: Appointment Booking

Records of booking can be retrieved from the system through the Appointment Booking Inquiry form with either your contact details or booking reference number.

AB1002 Appointment Inquiry for Medical Devices Pre-Market Consultation

Please fill in at least one field marked with asterisks *.

**APPOINTMENT BOOKING INQUIRY**

Email: *

Contact Number: *

Booking Reference No: *

[Search] [Reset]
Step 2: Document Submission

• Submit the following information at least 30 days before the scheduled consultation:
  (a) Completed consultation form
  (b) Relevant information described in the form

• Information to be provided by replying to the confirmation email, or email to HSA_MD_Tech@hsa.gov.sg and quote the appointment booking reference number.

• The respective consultation form(s) can be downloaded from HSA website. Instructions will be provided in the confirmation email and forms.

Reminder:
• Incomplete or insufficient information may result in rescheduling or cancellation of the appointment.
• Only ONE rescheduling is allowed per booking reference. Fees paid are not refundable.
Step 2: Document Submission

(a) Medical Device Development Consultation Form

- Proposed agenda
- Brief device information
- Overview of device development status

(b) Supporting documents* in relation to the areas to be discussed. Information can be provided in preferred format, e.g. PowerPoint slides, summary copies etc.

* Please ensure that the supporting information is appropriate and relevant to the questions on hand. Please avoid submission of extraneous information.
Step 2: Document Submission

(a) Medical Device Development Consultation Form

- Proposed agenda
- Brief device information
- Overview of device development status

(b) Supporting documents* in relation to the areas to be discussed. Information can be provided in preferred format, e.g. PowerPoint slides, summary copies etc.

* Please ensure that the supporting information is appropriate and relevant to the questions on hand. Please avoid submission of extraneous information.
Step 2: Document Submission

(a) Medical Device Pre-Submission Consultation Form
- Device information
- Application information

(b) Complete device dossier per CSDT guidance template* based on selected risk class and evaluation route

* Reference guidance documents:
- GN-15: Guidance on Medical Device Product Registration
- GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
- GN-18: Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT
# Step 2: Document Submission

## Summary of Submission Requirements (Class B)

<table>
<thead>
<tr>
<th>Documentary Requirements</th>
<th>Full</th>
<th>Abridged</th>
<th>EBR-1 and EBR-2</th>
<th>IBR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Authorisation</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Annex 2 List of Configurations</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Proof of reference agency’s approval(s)</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Proof of marketing history in the reference agencies’ jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history</td>
<td>✔</td>
<td>✔</td>
<td>Only required for EBR-1</td>
<td>✔</td>
</tr>
<tr>
<td>Declaration of no safety issues globally</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Executive Summary</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Essential Principles Checklist and Declaration of Conformity</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Device Description</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
<td>✔</td>
</tr>
</tbody>
</table>
| Design verification and validation documents including:  
  - Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies  
  - Metrological requirements  
  - Sterilisation validation (if applicable)  
  - Shelf-life studies and projected useful life | Detailed reports<sup>1</sup> | Summary<sup>2</sup> | Summary<sup>2</sup> | Sterilisation validation for Sterile device only<sup>3</sup> |
| Clinical Evidence<sup>4</sup> | | | | If applicable |
| Proposed Device Labelling<sup>4</sup> | ✔ | ✔ | ✔ | ✔ |
| Risk Analysis | ✔ | | | If applicable |
| Manufacturer Information (site’s name and address) | ✔ | ✔ | ✔ | ✔ |
| Proof of QMS – E.g. ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169 | ✔ | ✔ | ✔ | ✔ |
| Manufacturing Process – Flow Chart | ✔ | | | ✔ |

## Summary of Submission Requirements (Class C and D)

<table>
<thead>
<tr>
<th>Document Requirements</th>
<th>Full</th>
<th>Abridged</th>
<th>ECR-1 and ECR-2</th>
<th>EDR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Letter of Authorization</td>
<td>✔</td>
<td></td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Annex 2 List of Configurations</td>
<td>✔</td>
<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Proof of reference agency’s approval(s)</td>
<td></td>
<td></td>
<td>Only required for ECR-1</td>
<td></td>
</tr>
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<td>Proof of marketing history in the reference agencies’ jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history</td>
<td></td>
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</tr>
<tr>
<td>Executive Summary</td>
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<td></td>
<td></td>
<td>✔</td>
</tr>
<tr>
<td>Essential Principles Checklist and Declaration of Conformity</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Device Description</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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  - Preclinical studies e.g. physical test data, biocompatibility studies, animal studies and software verification and validation studies  
  - Metrological requirements  
  - Sterilisation validation (if applicable)  
  - Shelf-life studies and projected useful life | Detailed reports<sup>1</sup> | Summary<sup>2</sup> | Summary<sup>2</sup> | Summary<sup>2</sup> |
| Clinical Evidence<sup>4</sup> | | | | |
| Proposed Device Labelling<sup>4</sup> | | | | |
| Risk Analysis | | | | |
| Manufacturer Information (site’s name and address) | | | | |
| Proof of QMS – E.g. ISO13485 certificate, conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169 | | | | |
| Manufacturing process – Flow chart | | | | |
Pre-Market Consultation (PMC) Scheme

Following are examples of queries which do not require PMC:

- General questions regarding registration procedures or documentary requirements for product registration.
- Clarification on the guidance documents on the website.
- To seek advice on the risk classification or grouping.
- During the review process of a product registration.
- To appeal a decision made during pre-market submission.

These enquiries can be sent as general enquiries / using dedicated enquiry form(s) to HSA_MD_Info@hsa.gov.sg, or to contact officer in charge for clarification related to specific application.
Facilitate timely access for Medical Devices that demonstrate the potential to address unmet clinical needs

MEDICAL DEVICE PRIORITY REVIEW SCHEME
Medical devices* to be registered via **FULL** Evaluation Route

**Route 1**

1. Falls under 1 of the 5 healthcare focus area
   - Cancer
   - Diabetes
   - Ophthalmic diseases
   - Cardiovascular diseases
   - Infectious diseases

**Route 2**

2. Designed & validated to meet unmet clinical needs
   - Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis
   - Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

*Class A and devices incorporating registrable medicinal products are not eligible for the Priority Review Scheme.*
# Turn-Around-Time (TAT) & Fees

## Risk Class

<table>
<thead>
<tr>
<th>Risk Class</th>
<th>TAT (in working days)</th>
<th>Evaluation Fee ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Route 1 &amp; 2</td>
<td>Route 1</td>
</tr>
<tr>
<td></td>
<td>25% reduction by mid 2018</td>
<td>35% reduction by end 2019</td>
</tr>
<tr>
<td>Class B (FULL)</td>
<td>120</td>
<td>105</td>
</tr>
<tr>
<td>Class C (FULL)</td>
<td>165</td>
<td>145</td>
</tr>
<tr>
<td>Class D (FULL)</td>
<td>235</td>
<td>205</td>
</tr>
</tbody>
</table>
Selection to opt for the Priority Review Scheme can be performed while submitting your product registration application in MEDICS*, at:


MEDICS e-Services

In general, the estimated time to complete form: 5-10 mins.
Except for Product registration and Change Notification for Registered Devices *: estimated time 45 mins (time may vary based on the number of and the file size of the supporting documents to be uploaded)

apply@medics

- Dealer’s Licence & Registrant’s Account
- Product registration
- Export-Only Unregistered Medical Devices
- Certificates

Procedure to apply for product registration application remain unchanged. Application Guides with step-by-step guidance are available on website.

* MEDICS (Medical Device Information and Communication System) is an online system for companies to submit applications to HSA.
Make the relevant selection under ‘3. Priority Review Scheme’ section, in the Pre-Market Application form.

<table>
<thead>
<tr>
<th>APPLICATION FORM</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Dossier &amp; Supporting Document(s)</td>
</tr>
</tbody>
</table>

3. Priority Review Scheme

Please note that applications under Priority Review Scheme will be reviewed via the Full Evaluation Route with relevant evaluation fees applicable.

1. Would you like to opt in for the Priority Review Scheme? *
   - Yes
   - No

2. Does your application meet the Priority Review qualifying criteria? *
   - Yes
   - No

3. Please select the relevant healthcare focus area: *
   - Cancer
   - Diabetes
   - Ophthalmic Diseases
   - Cardiovascular diseases
   - Infectious Diseases

3. Please select the relevant description to your device: *
   - The device is intended for a medical purpose with no existing alternative treatment or means of diagnosis
   - The device represents a breakthrough technology that provides a clinically meaningful advantage over existing locally marketed technology

(1) Confirm if you would like to opt in for Priority Review Scheme.
(2) Confirm if devices meet qualifying criteria ii) and iii).
   → Select ‘Yes’ for Route 1, ‘No’ for Route 2.
If ‘No’ is selected, subsequent fields will be greyed out. Click ‘Save’ to proceed.
(3) For Route 1, select the relevant fields under ii) and iii).
(4) Click ‘Save’ before proceeding to next section.
1) Submission requirements for **FULL Evaluation Route**.

Refer to following guidance documents for details:
- GN-15: Guidance on Medical Device Product Registration
- GN-17: Guidance on Preparation of a Product Registration Submission for General Medical Devices using the ASEAN CSDT
- GN-18: Guidance on Preparation of a Product Registration Submission for In Vitro Diagnostic (IVD) Medical Devices using the ASEAN CSDT

2) **Justification** to substantiate that the device fulfill criteria 2, for **Priority Review Scheme Route 1**.

ALL documents to be submitted under ‘7. Dossier & Supporting Document(s)’ section in MEDICS.
Upon Submission

Request for Information

HSA reviews if devices fulfil all qualification criteria for the selected Priority Review Scheme Route and may request for further information or clarification via Input Request (IR), where necessary.

Submission of Information

Company will be given 2 weeks to respond to queries regarding qualification for the Priority Review Scheme.

Failure to respond or address deficiencies may result in application being switched to normal route under non-Priority Review Scheme.

No extension of due date is permitted for IRs related to qualification criteria.
Tentative Launch Date:

1 Aug 2017

Information of the Pre-Market Consultation and Priority Review Scheme will be available on HSA website below, upon official launch of the schemes:


For enquiries relating to the new schemes, please contact us at HSA_MD_Tech@hsa.gov.sg (upon official launch of the schemes)
THANK YOU