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

Background

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

1. Pre-Market Consultation Scheme

Support innovation and device development by ensuring devices are in line with regulatory requirements

2. Priority Review Scheme

Facilitate timely access for devices that address unmet clinical needs

To provide support through the device development lifecycle

Support innovation and device development

MEDICAL DEVICE PRE-MARKET CONSULTATION (PMC) SCHEME

Pre-Market Consultation (PMC) Scheme

1 Medical Device Development Consultation

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

2 Medical Device Pre-submission 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.

1. Medical Device Development Consultation

Channel for stakeholders to **seek regulatory advice during medical device development phase** to align with regulatory requirements.

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

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

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

2 Medical Device Pre-submission 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.

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

What it is not

- Not a scientific evaluation of the device
- Does not guarantee regulatory approval or marketing clearance

Session Duration & Fees

Consultation Category	Fees	Duration per session*
Medical Device Development Consultation	**$500** per **device** per consultation	Up to 2 hours
Medical Device Pre-submission Consultation	**$200** per **device application** per consultation	Up to 1 hour

**** Refers to only face-to-face meet-up consultation session.***

Process & Timeline

5 Months before	≥ 30 Days before	●●●	Appointment Date

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.

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.

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:

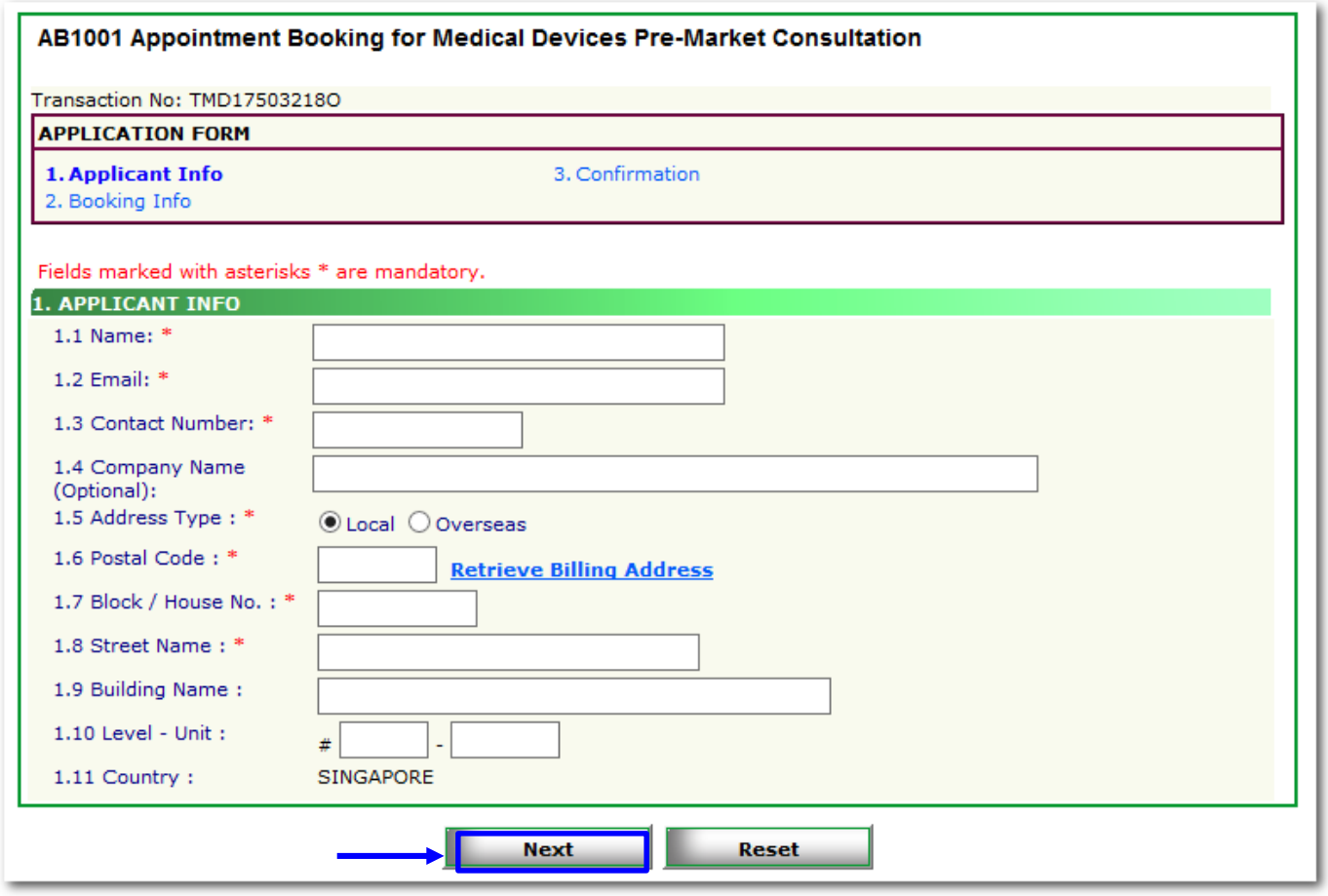
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html (accessible upon launch date)

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.*

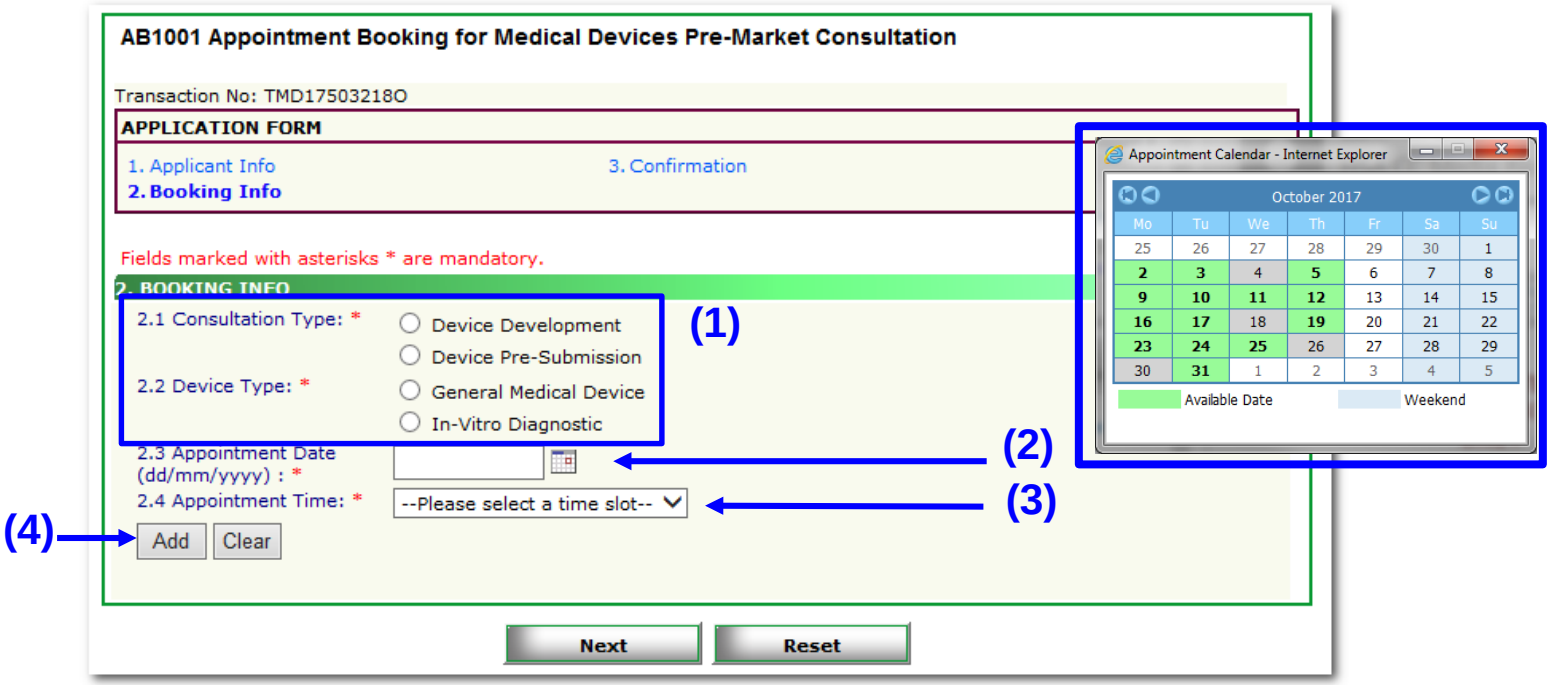
Step 1: Appointment Booking

1. APPLICANT INFO - Enter your particulars and contact details and click “Next”



Step 1: Appointment Booking

2. BOOKING INFO

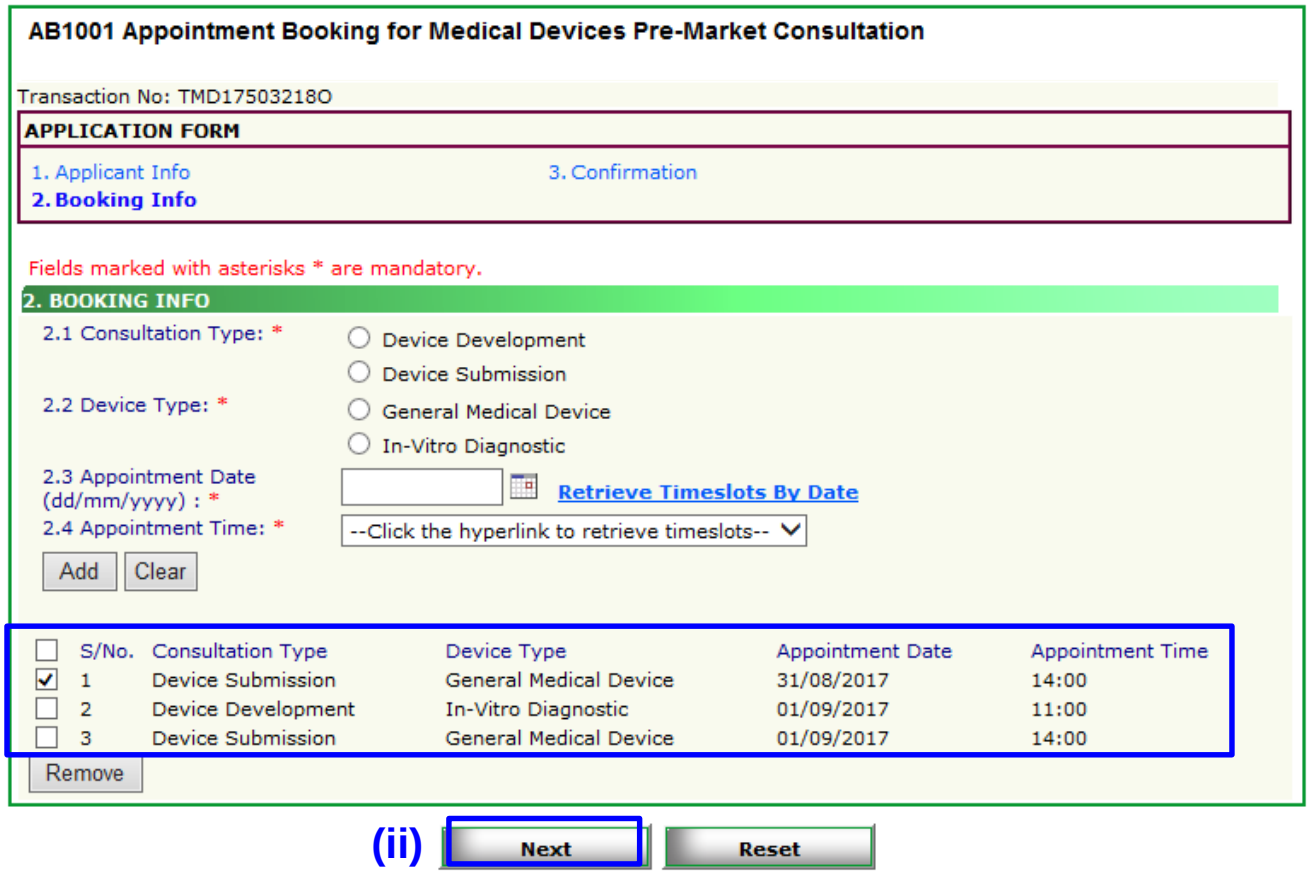


(1) Select Consultation Type and Device Type
(2) Select preferred appointment date based on availability
(3) Select preferred timeslot
(4) Add booking

For **multiple** bookings in a single application, repeat steps (1) to (4)

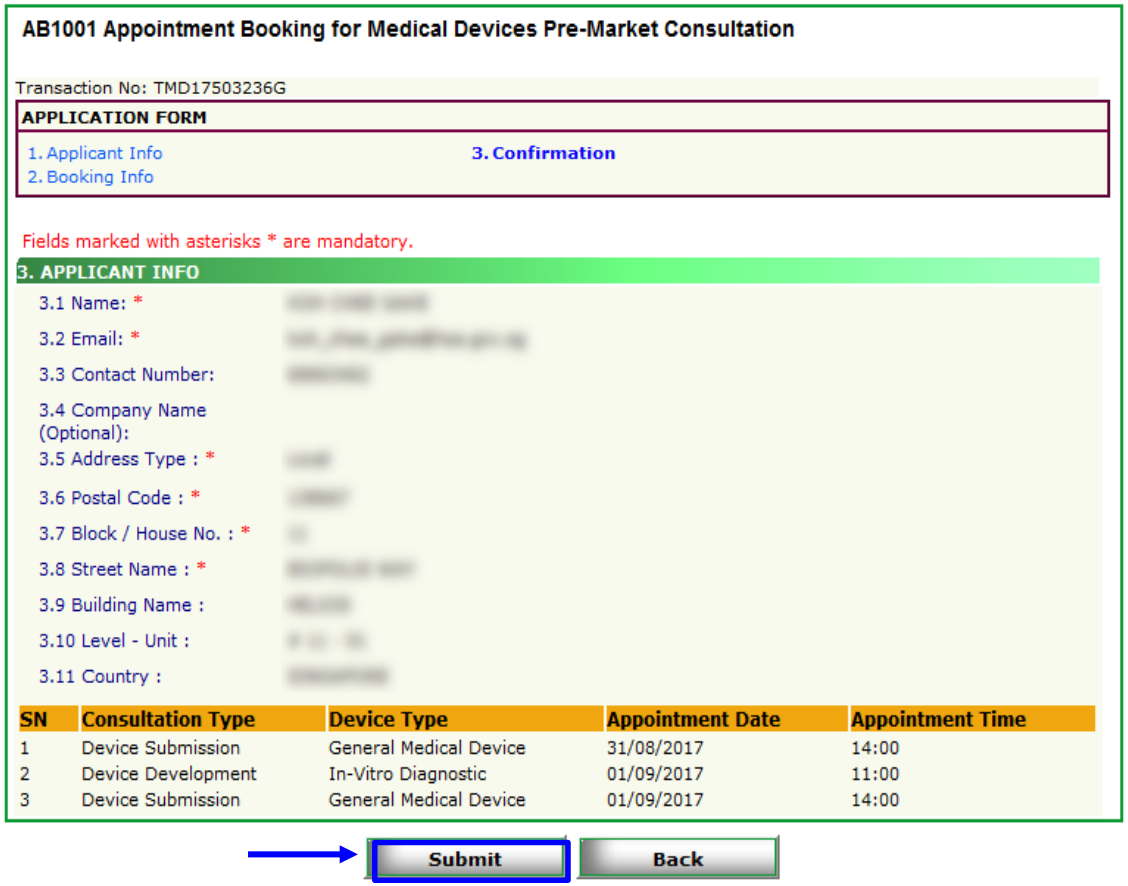
Step 1: Appointment Booking

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”.



AB1001 Appointment Booking for Medical Devices Pre-Market Consultation

Transaction No: TMD17503236G

APPLICATION FORM

1. Applicant Info
2. Booking Info
3. **Confirmation**

Fields marked with asterisks * are mandatory.

3. APPLICANT INFO

3.1 Name: *
3.2 Email: *
3.3 Contact Number:
3.4 Company Name (Optional):
3.5 Address Type : *
3.6 Postal Code : *
3.7 Block / House No. : *
3.8 Street Name : *
3.9 Building Name :
3.10 Level - Unit :
3.11 Country :

SN	Consultation Type	Device Type	Appointment Date	Appointment Time
1	Device Submission	General Medical Device	31/08/2017	14:00
2	Device Development	In-Vitro Diagnostic	01/09/2017	11:00
3	Device Submission	General Medical Device	01/09/2017	14:00

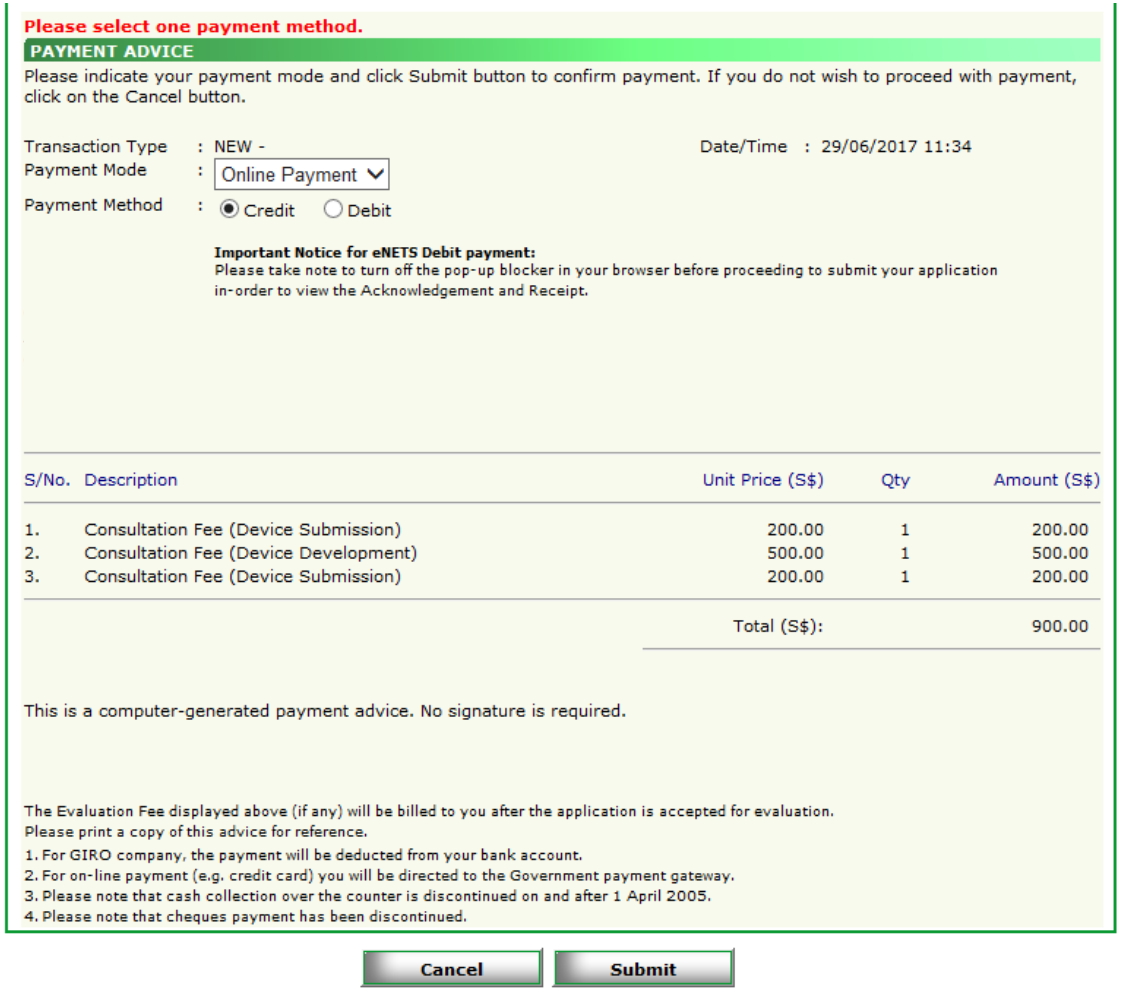
Submit | Back

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.

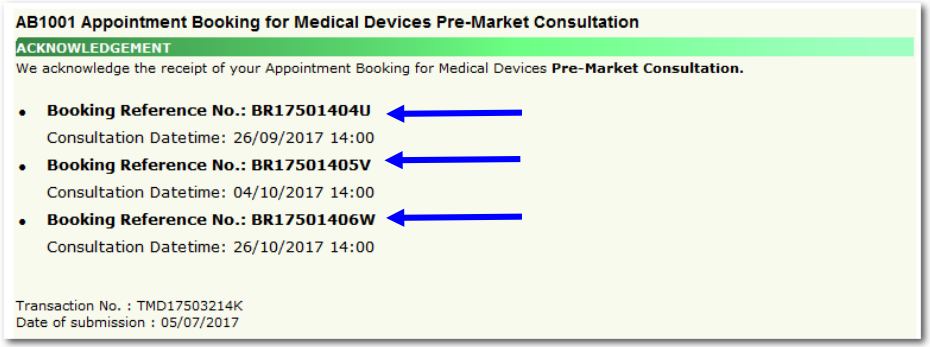
Step 1: Appointment Booking

Proceed to complete payment.



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.



AB1001 Appointment Booking for Medical Devices Pre-Market Consultation

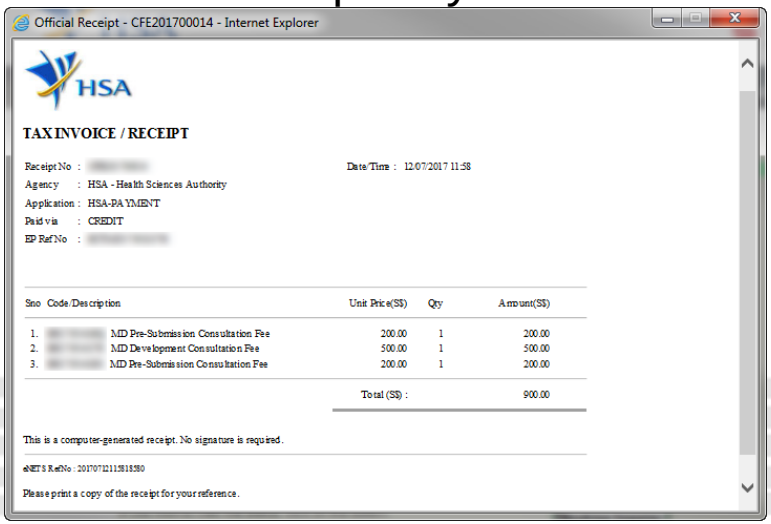
ACKNOWLEDGEMENT

We acknowledge the receipt of your Appointment Booking for Medical Devices **Pre-Market Consultation.**

- **Booking Reference No.: BR17501404U**
  Consultation Datetime: 26/09/2017 14:00
- **Booking Reference No.: BR17501405V**
  Consultation Datetime: 04/10/2017 14:00
- **Booking Reference No.: BR17501406W**
  Consultation Datetime: 26/10/2017 14:00

Transaction No. : TMD17503214K
Date of submission : 05/07/2017

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



Official Receipt - CFE201700014 - Internet Explorer

HSA

TAX INVOICE / RECEIPT

Receipt No : [redacted]
Date/Time : 12/07/2017 11:58
Agency : HSA - Health Sciences Authority
Application : HSA-PAYMENT
Paid via : CREDIT
EP Ref No : [redacted]

Sno	Code/Description	Unit Price(S$)	Qty	Amount(S$)
1.	[redacted] MD Pre-Submission Consultation Fee	200.00	1	200.00
2.	[redacted] MD Development Consultation Fee	500.00	1	500.00
3.	[redacted] MD Pre-Submission Consultation Fee	200.00	1	200.00
		Total (S$) :		900.00

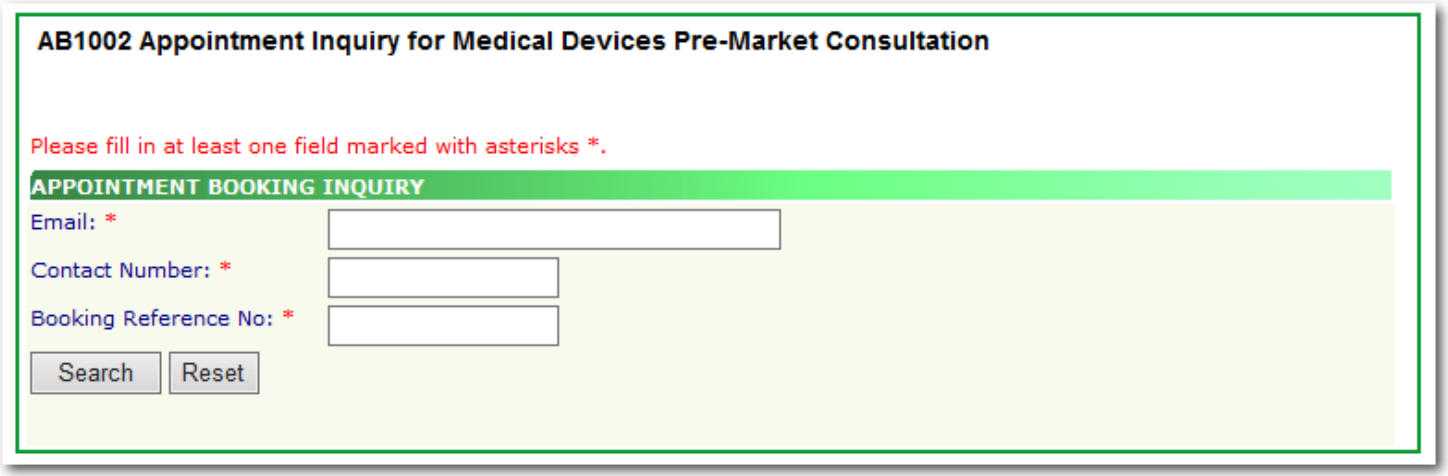
This is a computer-generated receipt. No signature is required.

eNETS RefNo : 20170712115818580

Please print a copy of the receipt for your reference.

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



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

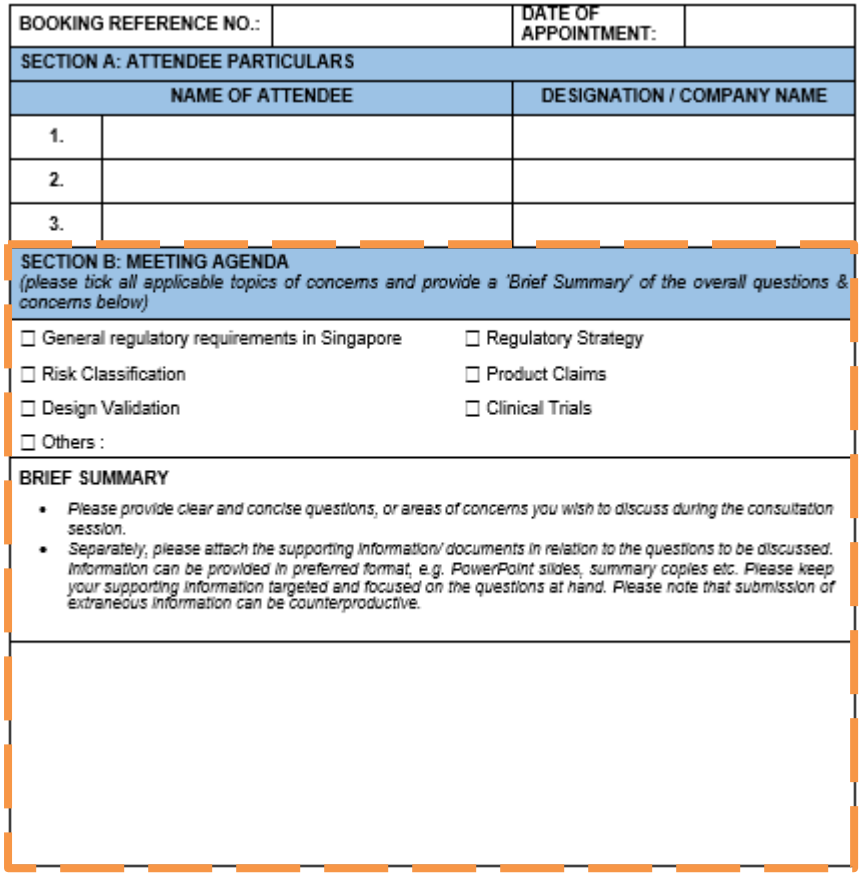
(a) **Medical Device Development Consultation Form**

- ✓ 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.*



BOOKING REFERENCE NO.:		DATE OF APPOINTMENT:	
SECTION A: ATTENDEE PARTICULARS			
NAME OF ATTENDEE		**DESIGNATION / COMPANY NAME**	
1.			
2.			
3.			

SECTION B: MEETING AGENDA
(please tick all applicable topics of concerns and provide a 'Brief Summary' of the overall questions & concerns below)

☐ General regulatory requirements in Singapore	☐ Regulatory Strategy
☐ Risk Classification	☐ Product Claims
☐ Design Validation	☐ Clinical Trials
☐ Others :	

BRIEF SUMMARY

- *Please provide clear and concise questions, or areas of concerns you wish to discuss during the consultation session.*
- *Separately, please attach the supporting information/ documents in relation to the questions to be discussed. Information can be provided in preferred format, e.g. PowerPoint slides, summary copies etc. Please keep your supporting information targeted and focused on the questions at hand. Please note that submission of extraneous information can be counterproductive.*

Step 2: Document Submission

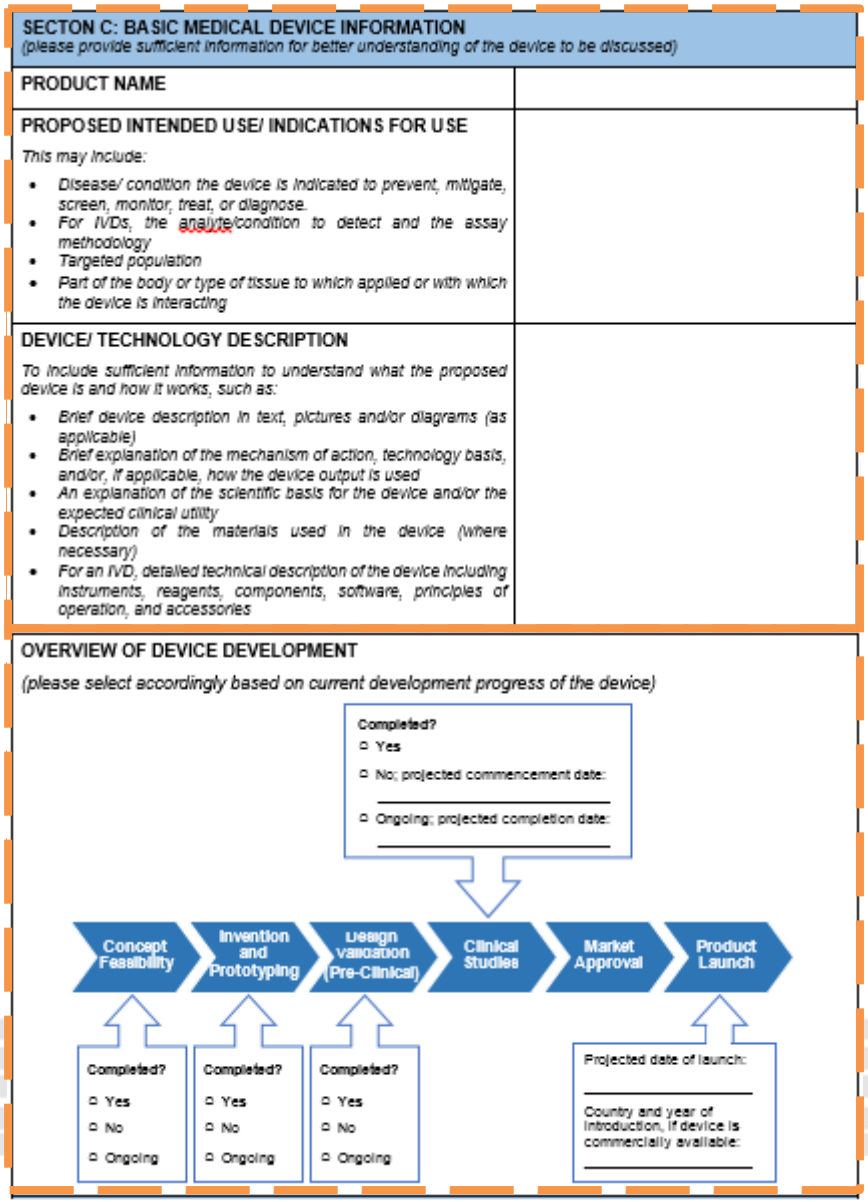
(a) **Medical Device Development Consultation Form**

- ✓ 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.*



SECTON C: BASIC MEDICAL DEVICE INFORMATION
(please provide sufficient information for better understanding of the device to be discussed)

PRODUCT NAME	
PROPOSED INTENDED USE/ INDICATIONS FOR USE *This may include:* • *Disease/ condition the device is indicated to prevent, mitigate, screen, monitor, treat, or diagnose.* • *For IVDs, the analyte/condition to detect and the assay methodology* • *Targeted population* • *Part of the body or type of tissue to which applied or with which the device is interacting*	
DEVICE/ TECHNOLOGY DESCRIPTION *To include sufficient information to understand what the proposed device is and how it works, such as:* • *Brief device description in text, pictures and/or diagrams (as applicable)* • *Brief explanation of the mechanism of action, technology basis, and/or, if applicable, how the device output is used* • *An explanation of the scientific basis for the device and/or the expected clinical utility* • *Description of the materials used in the device (where necessary)* • *For an IVD, detailed technical description of the device including instruments, reagents, components, software, principles of operation, and accessories*	

OVERVIEW OF DEVICE DEVELOPMENT

(please select accordingly based on current development progress of the device)

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*

SECTION B: MEDICAL DEVICE DETAILS	
Name of Product Owner	
Name of Medical Device	
Medical Device Type	*Please select one:* ○ General Medical Device ○ In-Vitro Diagnostic Medical Device
Proposed Risk Classification	*Please select one:* ○ Class B (Low moderate risk) Based on Rule _____ ○ Class C (Moderate high risk) Based on Rule _____ ○ Class D (High risk) Based on Rule _____ *Reference documents:* • *GN-13: Guidance on the Risk Classification of General Medical Devices* • *GN-14: Guidance on the Risk Classification of In-Vitro Diagnostic Medical Devices*
Proposed Evaluation Route	*Please select one:* ○ Full ○ Abridged ○ Expedited ○ Immediate (For Class B Medical Devices only) *Reference documents:* • *GN-15: Guidance on Medical Device Product Registration*
Proposed Grouping Type	*Please select one:* ○ SINGLE ○ FAMILY ○ SYSTEM ○ TEST KIT ○ CLUSTER ○ DEVICE SPECIFIC (GN-12-2):_____ *Reference documents:* • *GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria* • *GN-12-2: Guidance on Grouping of Medical devices for Product Registration – Device Specific Grouping Criteria*

Step 2: Document Submission

Summary of Submission Requirements (Class B)

	Documentary Requirements	Full	Abridged	EBR-1 and EBR-2	IBR
1	Letter of Authorisation	✓	✓	✓	✓
2	Annex 2 List of Configurations	✓	✓	✓	✓
3	Proof of reference agency's approval(s)		✓	✓	✓
4	Proof of marketing history in the reference agencies' jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history			✓ Only required for EBR-1	✓
5	Declaration of no safety issues globally				✓
6	Executive Summary	✓	✓	✓	✓
7	Essential Principles Checklist and Declaration of Conformity	✓	✓	✓	
8	Device Description	✓	✓	✓	✓
9	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[1]	✓ Summary[2]	✓ Summary[2]	✓ Sterilisation validation for Sterile device only[3]
10	Clinical Evidence[4]	If applicable			
11	Proposed Device Labelling[4]	✓	✓	✓	✓
12	Risk Analysis	✓	If applicable		
13	Manufacturer Information (site's name and address)	✓	✓	✓	✓
14	Proof of QMS– Eg: ISO13485 Certificate, Conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169	✓	✓	✓	✓
15	Manufacturing Process – Flow Chart	✓			

Summary of Submission Requirements (Class C and D)

	Document Requirements	Full	Abridged	ECR-1 and ECR-2	EDR
1	Letter of Authorization	✓	✓	✓	✓
2	Annex 2 List of Configurations	✓	✓	✓	✓
3	Proof of reference agency's approval(s)		✓	✓	✓
4	Proof of marketing history in the reference agencies' jurisdictions e.g. invoice with date, proof of sale or a declaration on marketing history			✓ Only required for ECR-1	
5	Declaration of no safety issues globally				
6	Executive Summary	✓	✓	✓	✓
7	Essential Principles Checklist and Declaration of Conformity	✓	✓	✓	✓
8	Device Description	✓	✓	✓	✓
9	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[1]	✓ Summary[2]	✓ Summary[2]	✓ Summary[2]
10	Clinical Evidence	✓	✓	✓	✓
11	Proposed Device Labelling	✓	✓	✓	✓
12	Risk Analysis	✓	✓	✓	✓
13	Manufacturer Information (site's name and address)	✓	✓	✓	✓
14	Proof of QMS – E.g. ISO13485 certificate, conformity to US FDA Quality System Regulations or Japan MHLW Ordinance 169	✓	✓	✓	✓
15	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

Qualification Criteria

Medical devices* to be registered via FULL Evaluation Route → **Route 2**

1 Falls under 1 of the 5 healthcare focus area

- Cancer
- Diabetes
- Ophthalmic diseases
- Cardiovascular diseases
- Infectious diseases

+

2 Designed & validated to meet unmet clinical needs

Intended for a medical purpose with **no existing alternative** treatment or means of diagnosis

OR

Represents a breakthrough technology that provides a **clinically meaningful advantage** over existing legally marketed technology

→ **Route 1**

**** Class A and devices incorporating registrable medicinal products are not eligible for the Priority Review Scheme.***

Turn-Around-Time (TAT) & Fees

Risk Class	TAT (in working days)		Evaluation Fee ($)	
	Route 1 & 2		Route 1	Route 2
	25% reduction by mid 2018	**35%** reduction by end 2019	**15%** increase over current fee	**50%** increase over current fee
Class B (FULL)	120	105	4,100	5,300
Class C (FULL)	165	145	6,600	8,600
Class D (FULL)	235	205	13,200	17,100

Application Process

Selection to opt for the Priority Review Scheme can be performed while submitting your product registration application in MEDICS*, at:

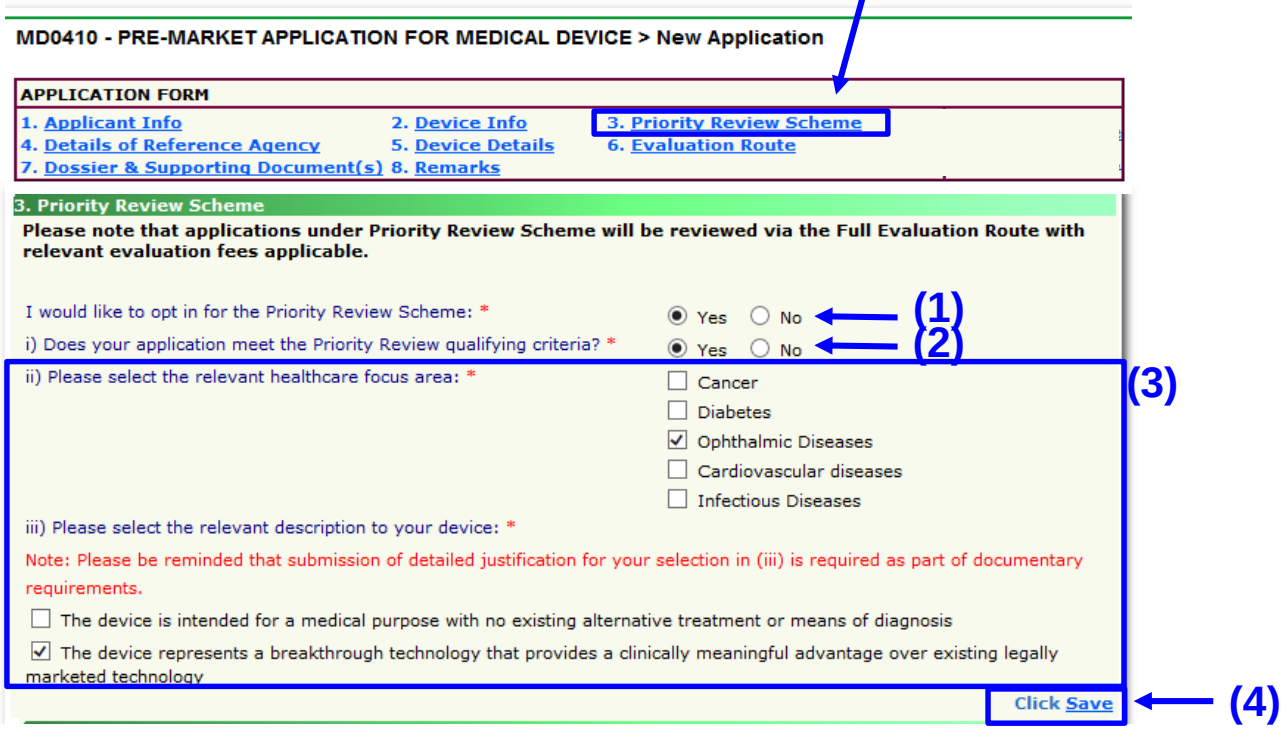
http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/MEDICS_e-Services.html

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.*

Application Process

Make the relevant selection under '3. Priority Review Scheme' section, in the Pre-Market Application form.



(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.

Document Requirements

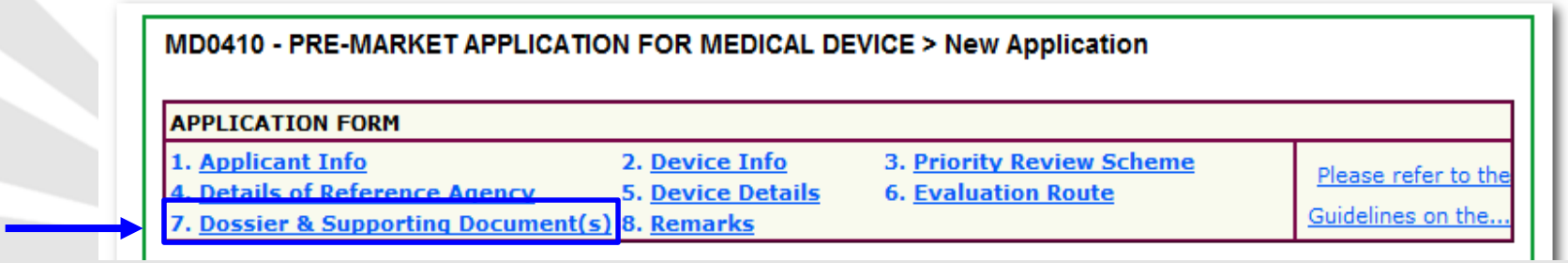
1) Submission requirements for **FULL Evaluation Route**.

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.



Review Process

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.

Timeline

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:

http://www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/Medical_Devices/Regulatory_Updates/md_initiatives.html

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