IMDRF International Medical Device Regulators Forum

Regulatory Updates
Health Sciences Authority
Singapore

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Background

Pre-market Consultation (PMC) Scheme

- Medical Device Development Consultation
- Medical Device Pre-submission Consultation

Priority Review Scheme

- Qualification Criteria
- Priority Review Scheme Routes

Background

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

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

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Support innovation and device development

MEDICAL DEVICE PRE-MARKET CONSULTATION (PMC) SCHEME

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Pre-Market Consul

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.

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

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

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

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

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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	✓			

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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.

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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 2**

Qualification Criteria

1 **Falls under one of the 5 healthcare specific area**

- Cancer
- Diabetes
- Ophthalmologic diseases
- Cardiovascular diseases
- Infectious diseases

2 **Designed / validated to address 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/ therapeutic products are not eligible for the Priority Review Scheme.*

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

Upcoming Documents

- Update to the Guidance on Preparation of the ASEAN CSDT* for Medical Devices and In Vitro Diagnostics (IVDs)

- Registration and listing of IVD analysers and instruments

**** Common Submission Dossier Template***

Thank you!