Existing pathways for innovative medical devices

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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.

Pre-Market 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

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.

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.

Priority Review Scheme

Qualification criteria

Medical devices* to be registered via FULL Evaluation Route

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

Supporting Digital Health Product Innovation

1. Immediate Registration Pathway for Standalone Software and Mobile Applications
This pathway was implemented in 2018 by leveraging the regulatory review and approval from our reference regulatory agencies in Australia, Canada, the European Union, Japan and the United States. This pathway allows immediate market access upon successful submission of a product registration application, while we perform a backend review to verify the qualification criteria are met and that these devices are safe and effective for use on our patients. More information on the various product registration pathways can be accessed in our Guidance on medical device product registration. [Click here]

2. Regulatory Guidelines for Telehealth Product
To help manufacturers, developers or importers of a digital health device to (i) determine if their device, software or app are regulated medical devices under HSA and (ii) understand the relevant regulatory requirements. [Click here]

3. Device Development Consultation Scheme
The purpose of the consultation is to provide medical device developers and/ or researchers with a platform to seek regulatory advice during various stages of the medical device development (e.g. device validation, clinical trial), in preparation for regulatory submission. [Click here]

4. Regulatory Guidelines for Software Medical Devices
This serves as a one stop reference on the regulatory requirements for management of software in medical devices throughout its entire life cycle. [Click here]

5. Artificial Intelligence (AI) in Healthcare Guidelines
Co-developed by MOH, HAS and Synapxe (previously known as IHiS) to provide a set of recommendations to encourage the safe development and implementation of AI-Medical Devices. [Click here]

Pandemic Special Access Route (PSAR)

Key features

- Designation of an emergency therapeutic product (ETP) or emergency medical device (EMD) by Minister contingent on the following criteria:
  - The need for the ETP or EMD to be used for the treatment, prevention or diagnosis of any potentially serious or life-threatening medical condition resulting from a civil defence emergency or infectious disease outbreak; and
  - HSA's (scientific) determination that the benefits of using the ETP or EMD outweigh the risks, both at the outset and on an ongoing basis. There is continued exercise of regulatory oversight through ongoing iterative review of safety and efficacy data which are made available over time

"civil defence emergency" means any fire, explosion, earthquake, oil spill, eruption, flood, storm, hazardous materials incident or other happening (whether or not attributable to an attack by an enemy or to any warlike act) that causes or may cause destruction of or damage to property or loss of life or injury or distress to persons or that in any way endangers the safety of the public in Singapore or in any part thereof;

Thank you

Contact information

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HSA's Engagement

- Mirxes, the company that developed the gastric cancer test based on miRNA worked with A*STAR DxD on the development of this IVD test

- DxD approached HSA as early as 2015 during the early phase of development of the test; HSA had provided scientific and regulatory advice throughout the development of this test from 2015 to 2018
    - Scientific advice on the design of the test kit
    - Designing the analytical validation studies for the test
    - Clinical study design and protocols
    - Regulatory advice on the appropriate intended purpose and developing the instructions for use for the test including precautions, contraindications etc.

- In Jan 2019, the GASTROClear test was submitted for evaluation and registration by MirXes under Priority Review for FULL evaluation
    - Registered by HSA in May 2019