

SHARE for Medical Devices

Industry Briefing Session 21 May 2025

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority



Agenda

What is SHARE?

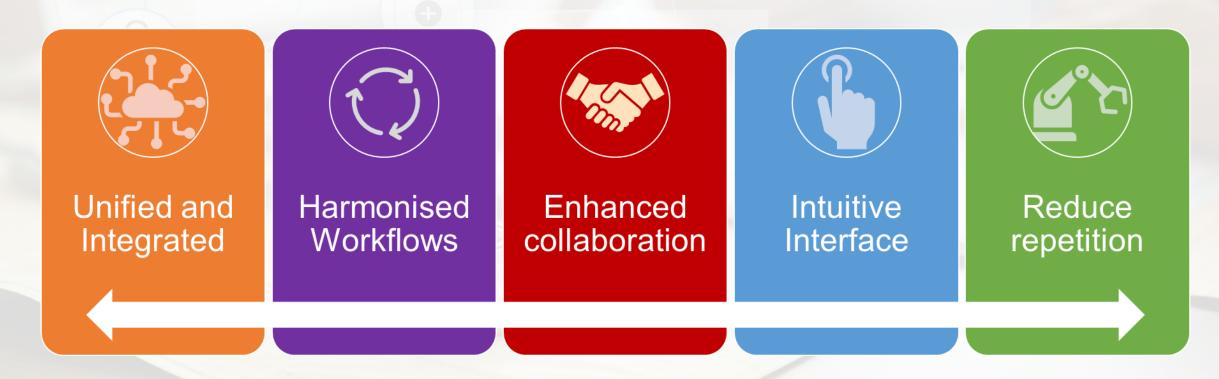
Key changes

"Quick Start" Guide

What's next?



VISION: To develop a unified and integrated platform that enables regulators, businesses, industry partners and general public to collaborate efficiently by synergising health product regulatory related services through product lifecycle to facilitate access to safe health products in Singapore





Key Changes



Class A Product Notifications

In MEDICS

- Submitted as part of Dealer Licence application or Amendment as a single excel sheet
- Free Sale Certificate application for Class A through FormSG

Only allows adding new lines to the excel, resulting in 'dirty' data

Excel sheet frequently gets rejected by system

In SHARE

- Submitted independently as a "Product Notification" application
- Free Sale Certificate application for Class A through SHARE

Allows amendment of existing notified Class A products

Alternative ways to key in product information



Third Party Entity Access

In MEDICS

 Applicant need to separately request for HSA Pin on behalf of the 3rd party company

Additional effort to submit
HSA Pin authorization
form with supporting
document, processing
time required, leading to
delay in responding to
questions

In SHARE

 Applicant can directly request 3rd party access for the query raised through SHARE

No need for HSA Pin, saves effort and processing time



Importer assignment by Registrant

In MEDICS

 Registrant will add authorized importer and wholesaler to a device listing via "Assignment of importer wholesaler ship and management of view access to importer wholesaler"

No acknowledgment required by Importer which sometimes results in confusion, wrong tagging

In SHARE

- Importer (under a different UEN) to accept the tagging assignment by Registrant.
- No need to assign authorized Wholesaler for the device listing

Importer to acknowledge and accept the tagging by Registrant ensures correct assignment



Export Certificate

In MEDICS

 Submit "Notification for Export" before submitting Export Certificate application.

In SHARE

 Export Certificate application submitted directly

Additional effort to submit twice for the same certificate

No need for "Notification for Export", saves effort and processing time



Fulfilment of Approval Conditions (FoAC)

In MEDICS

- No reminders
- Offline submission via email from applicant to HSA

Hard to track due
date and
submission history,
often leading to
overdue conditions

In SHARE

- Company users will be able to tracked their approval conditions and submit FoAC applications directly
- Closer to due date, system will send reminders to applicant on the pending task

Easier to track pending conditions that require action



Auto-Retention of Product listings for companies with GIRO arrangement

In MEDICS

 Auto-retention for registered products are triggered 1 day after device retention due date

In SHARE

 Auto-retention for registered products to be triggered 30 days before device retention due date

Product listing autoretention has a different timeline from Dealer's Licence auto-renewal, causes confusion Timeline to trigger autoretention for products to be aligned with Dealer's Licences auto-renewal @ T-30 days.



Cancellation

In MEDICS

 Cancellation effective immediately upon approval

In SHARE

Applicants can define a future effective cancellation date

Companies have to wait till the specific dates and time their cancellation submission; missed submissions result in unintended auto-retention

Companies can submit cancellation applications in advance and specify the effective cancellation date.



Online Payment (for New Product Registration)

In MEDICS

 Full payment of all related fees (application fee + evaluation fee) up front during submission

to change in application details in course of review needs to be handled manually

In SHARE

- Online payments for New Product Registration will be triggered at these timepoints:
 - ✓ Application fee upon submission
 - ✓ Evaluation fee upon confirmation of evaluation route

Eliminate hassle to make payment or refunds outside of the system

This aligns with triggers for payment via GIRO



Companies with GIRO arrangement

In MEDICS

 For companies with existing GIRO arrangement with HSA, payment mode is defaulted to GIRO; no online payment option

In SHARE

Companies can choose their preferred payment mode at <u>point of submission</u>

Companies are unable to choose to pay via online payment even for urgent cases.

Facilitate expedited processing of time sensitive cases



Quick Start to SHARE



Quick Start to SHARE

Setting up Access & Company Information

Submitting a new application

Input Requests

Checking status of application

Retrieving list of approved products and licences



Corppass Setup Logging into SHARE

Company Address Book



Corppass Setup

- Corppass Admin to access Corppass
- Grant access to the following e-service to company users:

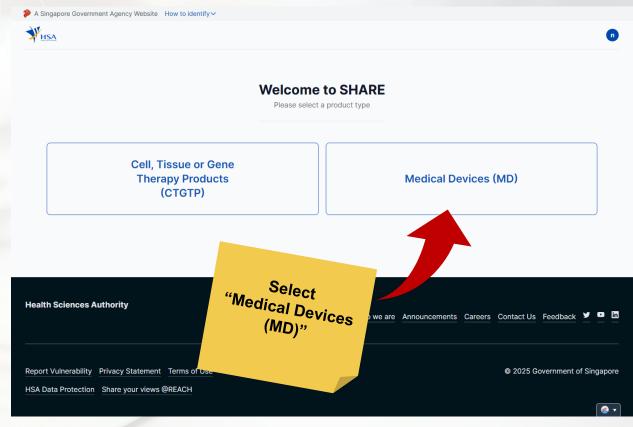
HSA E-SERVICES: SINGAPORE HEALTH PRODUCT ACCESS AND REGULATION E-SYSTEM (SHARE)

No more CRIS account and Registrant licence



Logging into SHARE

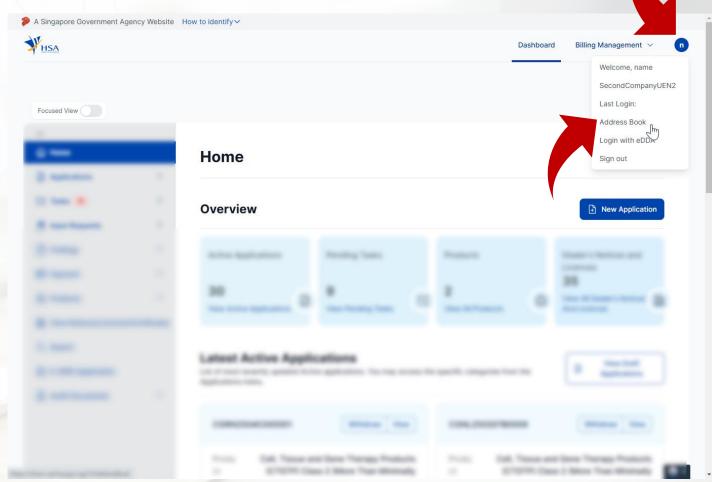






Company Address Book

- Email notifications for all applications relating to this UEN will be sent to this list
- Similar to Registrant contact in MEDICS





Submitting a new application

"New Application"

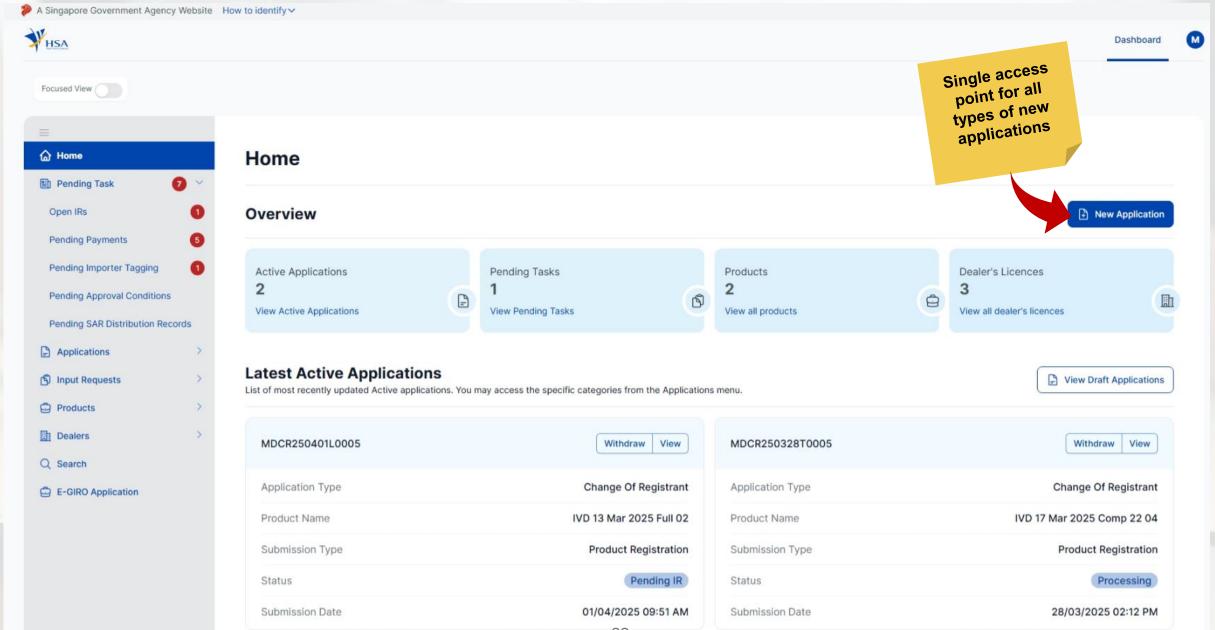
Dossier requirements and upload

Company contacts, applicant information and notification emails



"New Application"







A Singapore Government Agency Website How to identify >



New Application - Getting Started

Focused View

1. Details

2. Checklist

Details

Instruction for this page

Please select the required product type and submission type for your application



Application Type

Cancel this application and go back to Dashboard





Product Notification

Select Submission Type

Product Registration

Dealer's Licence

Special Access Route

Export Certificate

Free Sale Certificate



Dashboard

Select relevant options relating to your

submission



Dossier Requirements & Upload



New Application - Getting Started



Checklist

Dossier Format

Instruction for this page

Review your selections and prepare for your application.

 Product Type
 Medical Devices

 Submission Type
 Product Registration

 Application Type
 New

 Device Type
 General Medical Device

ASEAN CSDT

X

Based on your selection, your application process will take approximately 30 minutes

Please review the instructions to ensure a timely completion of the process.

You are about to start the application for a Product Registration of a Class B/C/D Medical Device to obtain marketing clearance for its import and supply in Singapore.

Please note that only medical device dealers who have been licensed by HSA can engage in the manufacture, import and/or wholesale of medical devices in Singapore. To apply for an Importer's, Wholesaler's Licence, please submit a Dealer's Licence application.

If your medical device is a Class A Medical Device, please submit a Product Notification application instead of this Product Registration application.

Please refer to the following guidance document for more information on medical device risk classification:

- GN-13 Guidance on the Risk Classification of General Medical Devices
- GN-14 Guidance on the Risk Classification of In Vitro Diagnostic Medical Devices

Submission Instructions

In this application, you would need to provide the following information:

 Each application is for registration of only one SINGLE medical device, or medical device FAMILY, or medical device SYSTEM or GROUP, or TEST KIT for IVD.

Please refer to the following guidance document for more information:

- GN-12 Guidance on Grouping of Medical Devices for Product Registration
- The softcopy of the supporting documents must be prepared in the ASEAN CSDT format. Please refer to the following guidance documents for more information:
 - 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
 - E-Submission Guide for General Medical Devices for ASEAN CSDT based Submissions
 - GN-18 Guidance on Preparation of a Product Registration Submission for IVD MD using the ASEAN CSDT
 - E-Submission Guide for IVD MD for ASEAN CSDT based Submissions

For more information, please visit our website

Change Product or Submission Type

< Back

Checklist-Documentary Requirements

i.e. CSDI

View the files applicable for the submission based on previous selections

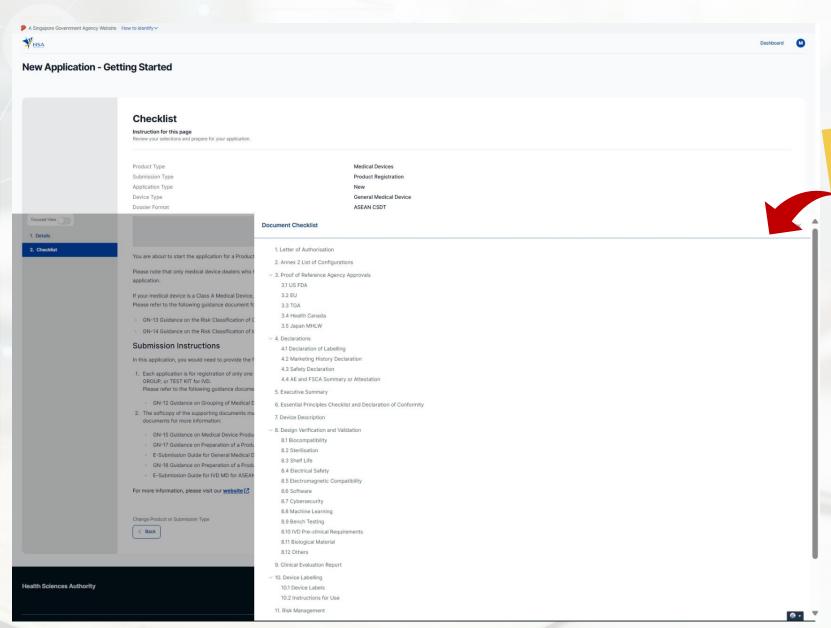


You will not be able to change your Product or Submission type after this page

Create Application 🕒

View Checklist

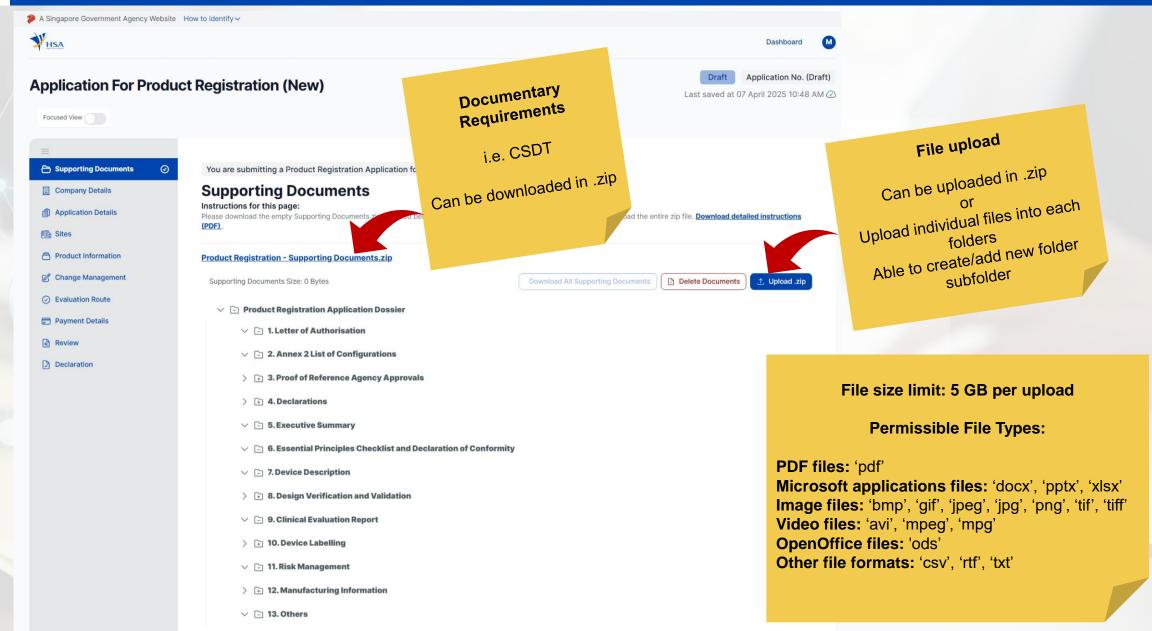




Document checklist specific for submission and application type

e.g. CSDT document checklist displayed for a New Product Registration of GMD

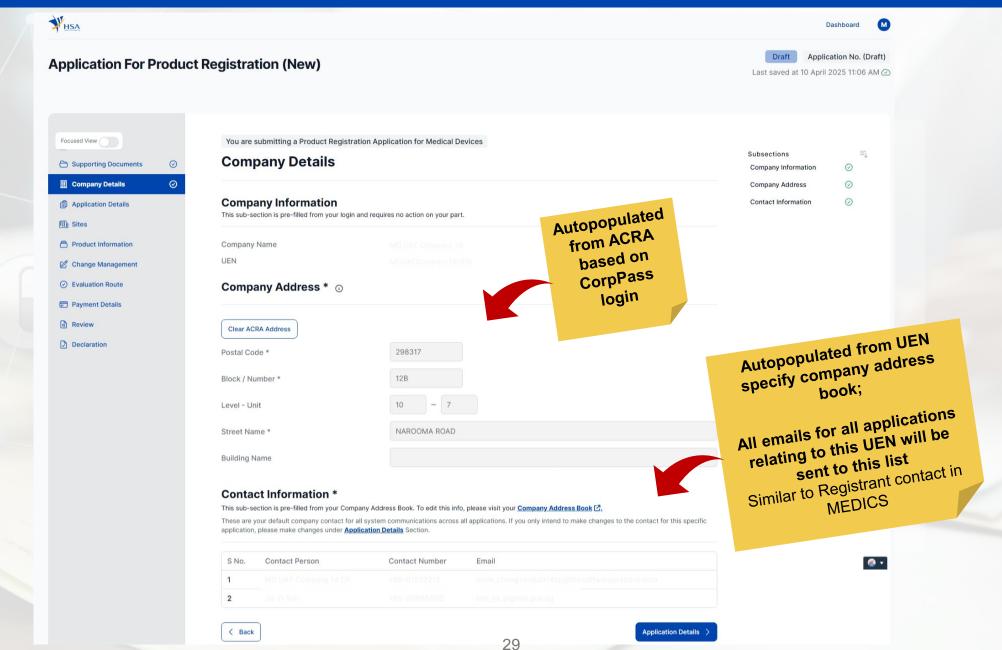






Company contacts, applicant information and notification emails







Application No. (Draft) **Application For Product Registration (New)** Last saved at 10 April 2025 11:33 AM @ Focused View 0 Supporting Documents You are submitting a Product Registration Application for Medical Devices **Applicant Name and** Subsections **Application Details** Company Details 0 Application Information Application Details Designation Main Applicant Information (2) Sites Application Information o Notification Emails Anyone with CorpPass login This sub-section is pre-filled from your initial selection and cannot be edited. Product Information for this UEN will be able to Change Management view, edit and submit this Medical Devices Product Type Submission Type Product Registration application; no CRIS Evaluation Route Application Type Payment Details management. Device Type General Medical Device Review Main Applicant Information * Declaration MD UAT Company 14 User 01 List of emails receiving notifications Applicant Name (as in NRIC/FIN) * specific to this application Designation * Regulatory Affairs specialist Similar to Applicant Info in MEDICS Notification Emails * 0 Please include your contact details in this section, and additional contacts if required. All notifications regarding this application will be sent to the persons listed below and contact No limit to number of emails to be added; recommended for companies to include Notification Email 1 their covering colleagues in this list Contact Person Mr Tan Contact Number +65-66666666 Email tan@gmail.com Notification Email 2 Contact Person Ms Teo Contact Number +65-88888888 € 🔻 teo@gmail.com Email



Input Requests

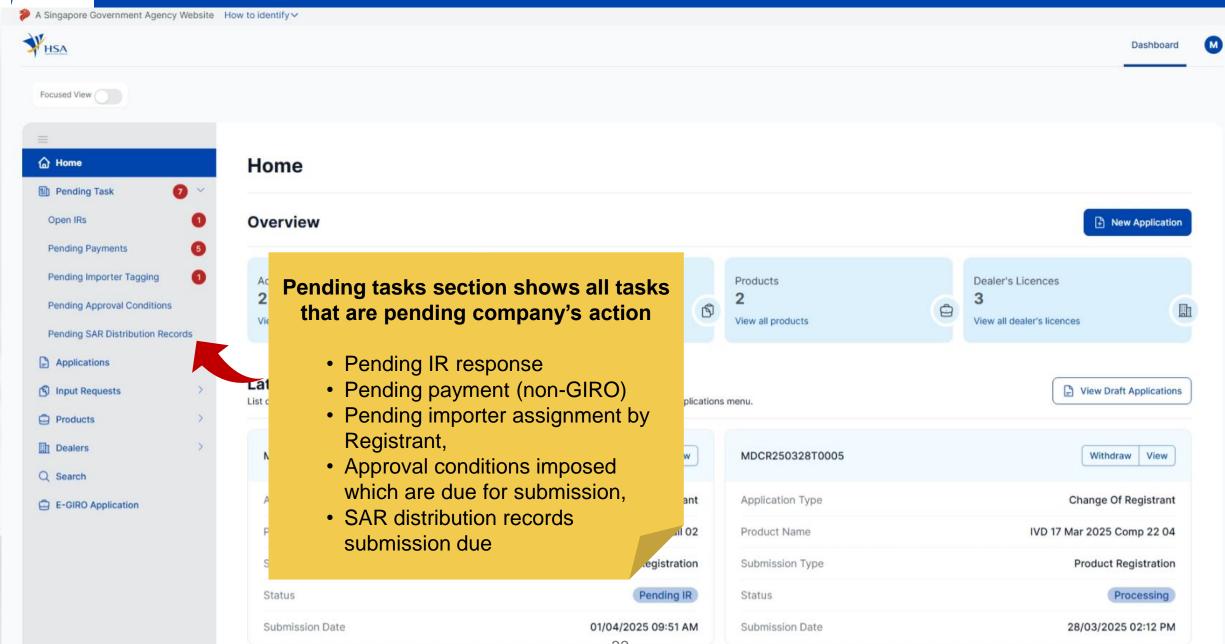
Open input requests on Dashboard

Input
Request
Status and
Extension

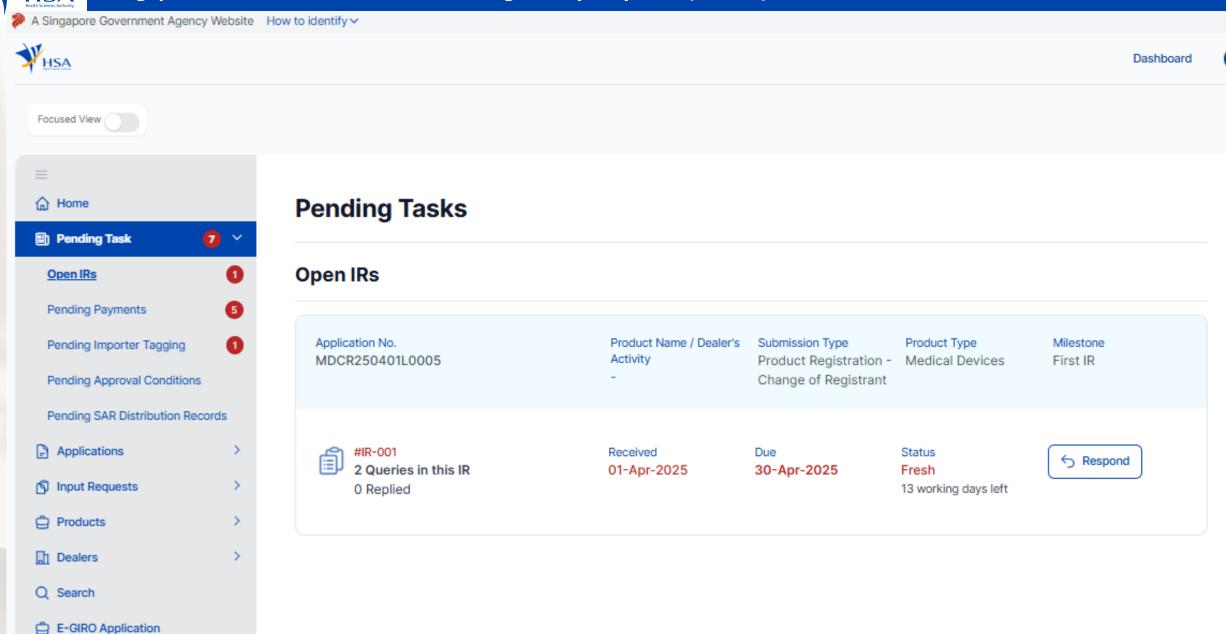


Open Input Requests on Dashboard





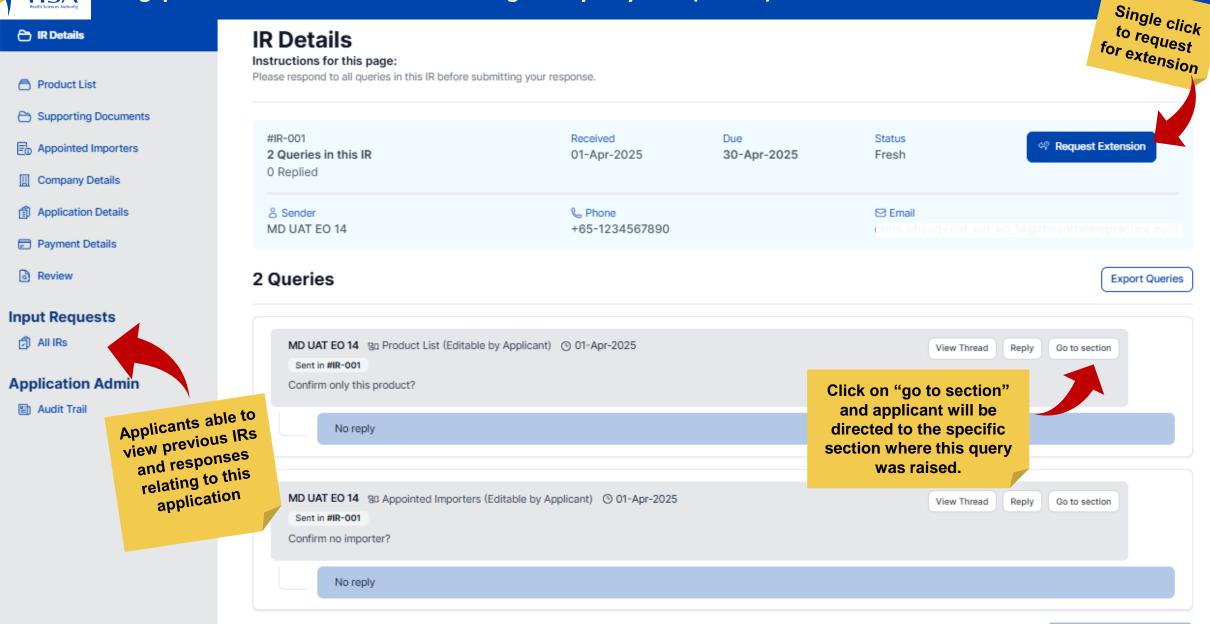




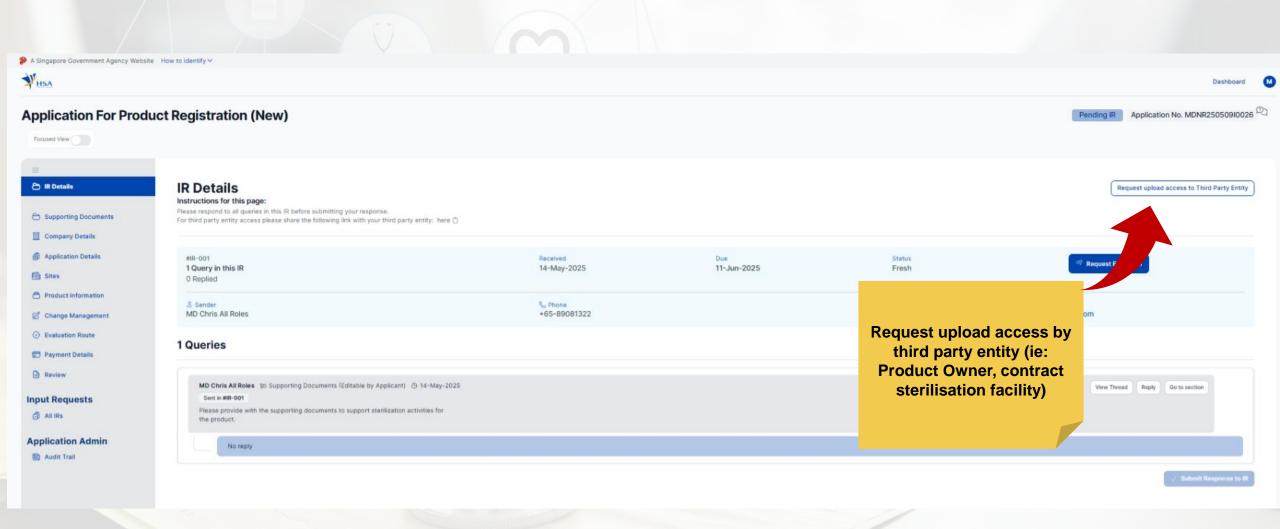


Input Request Status and Extension

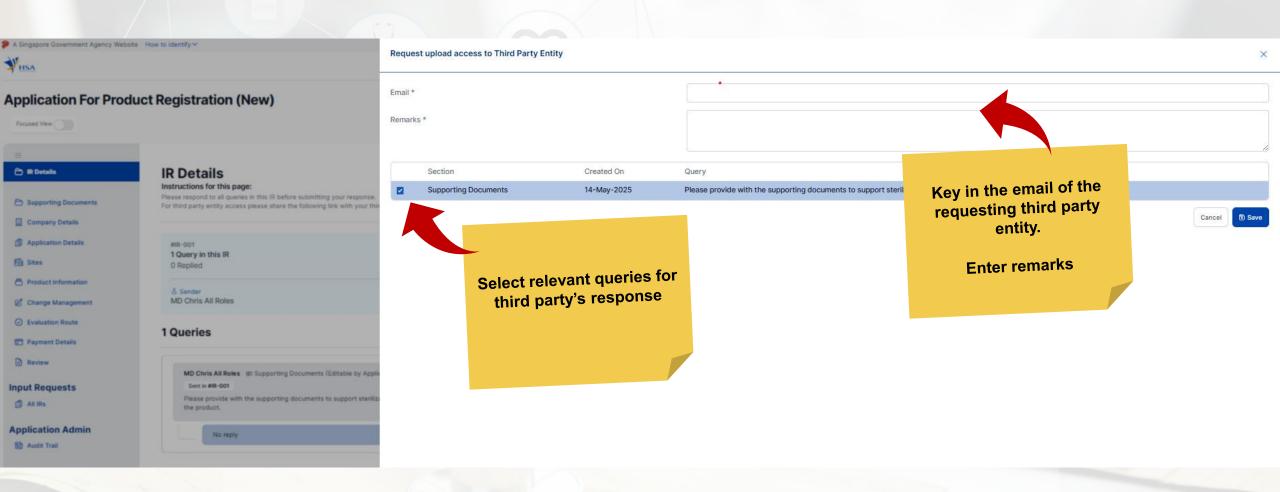














Checking status of applications

Draft Applications

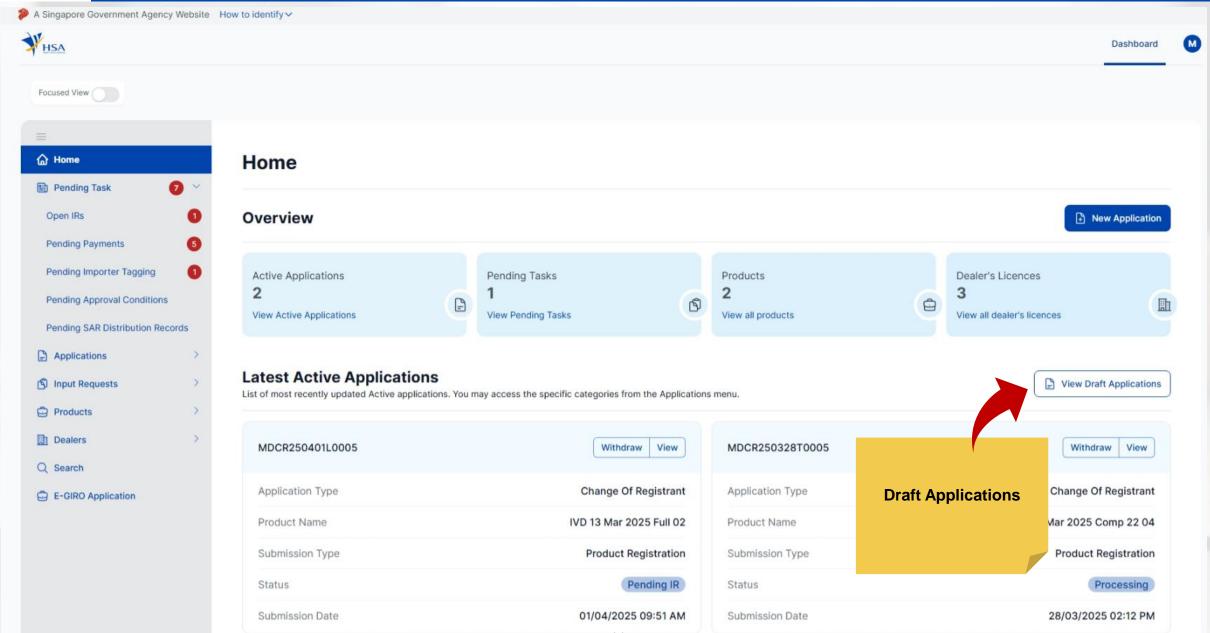
Pending Applications

Closed Applications

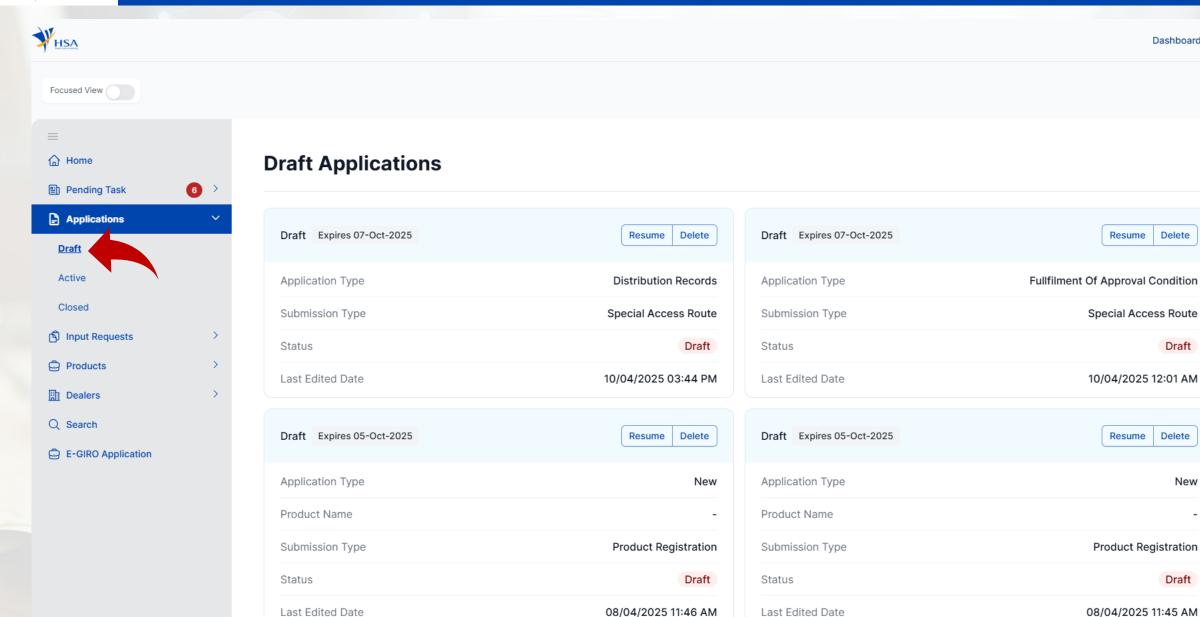


Draft Applications









Dashboard

Delete

Draft

Delete

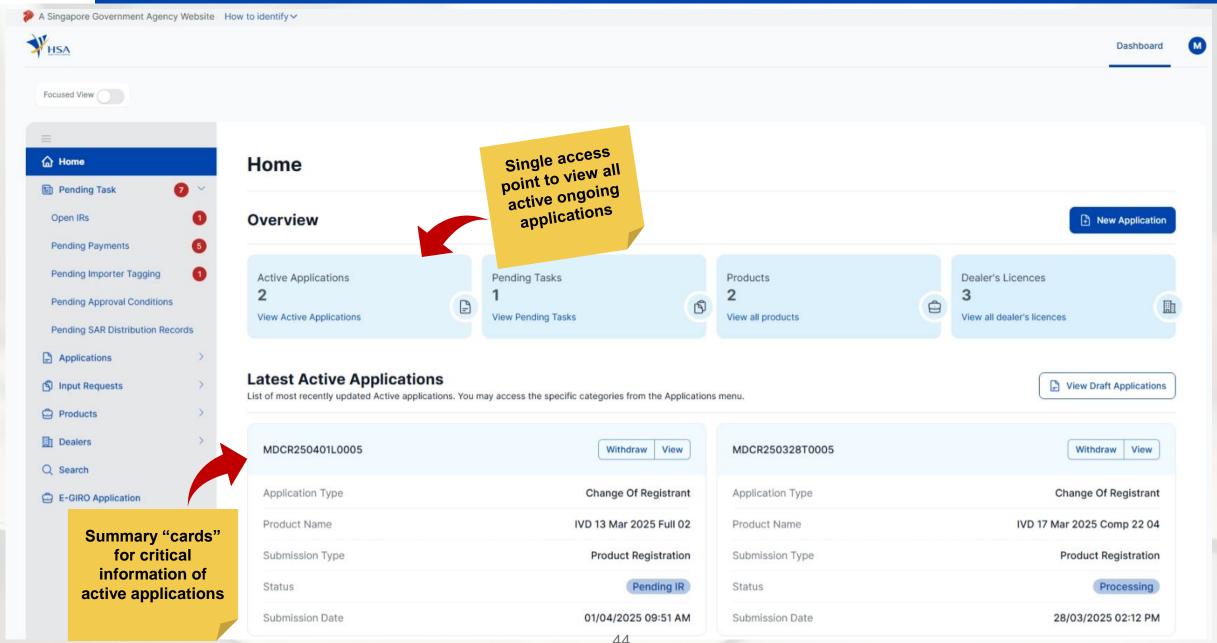
New

Draft

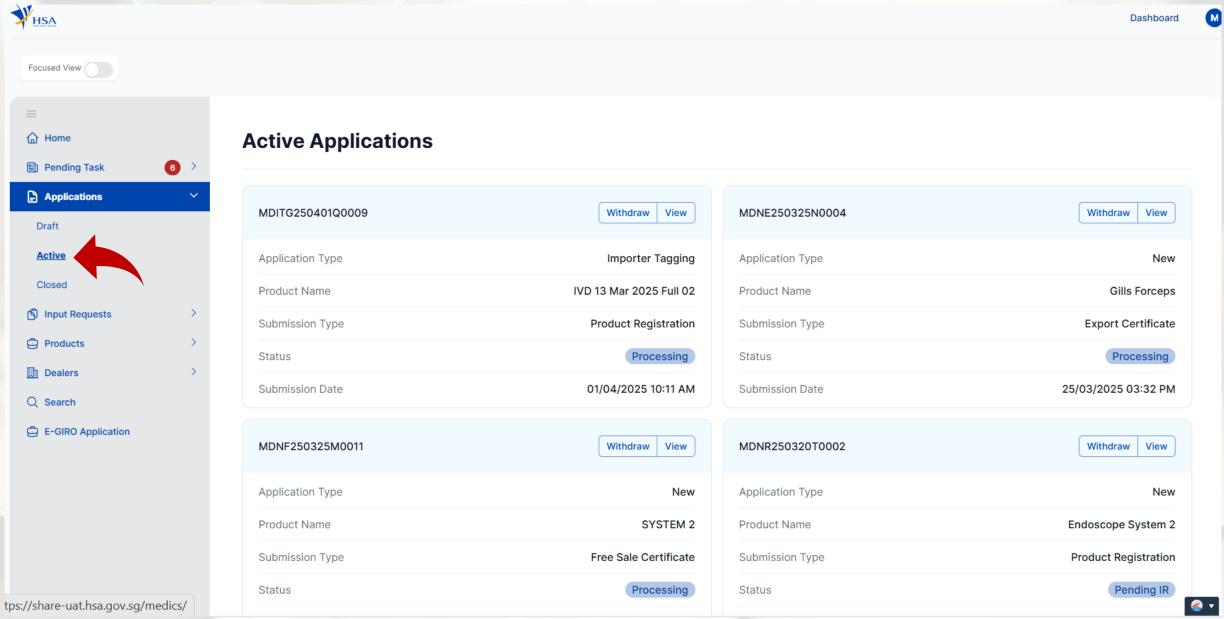


Active Applications





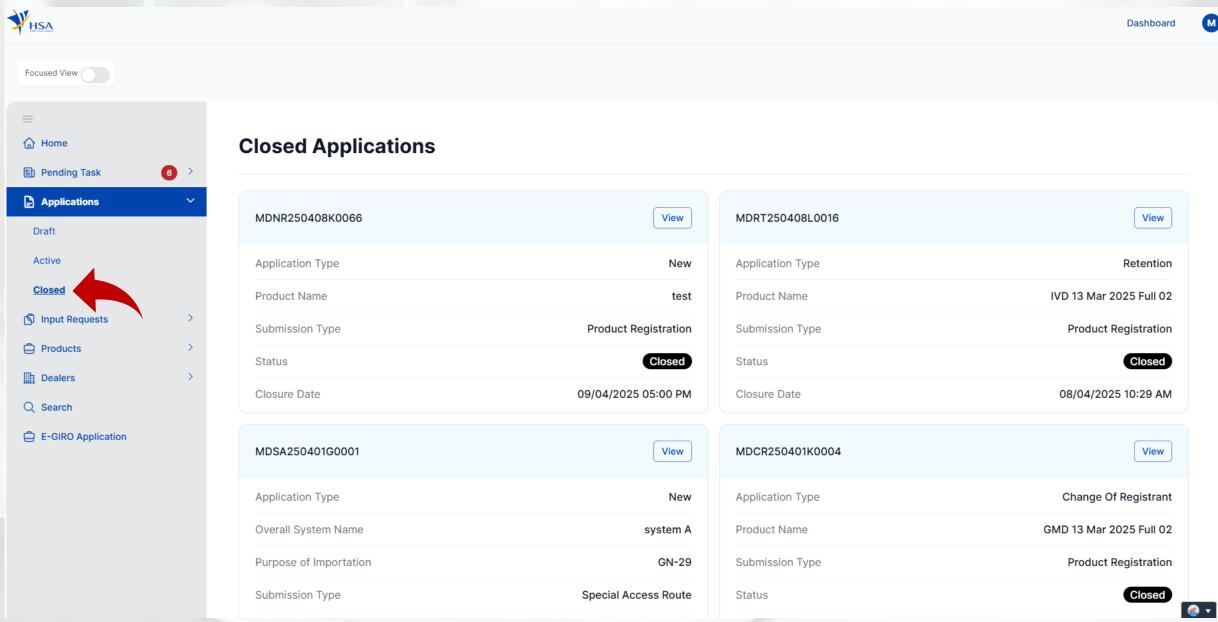






Closed Applications



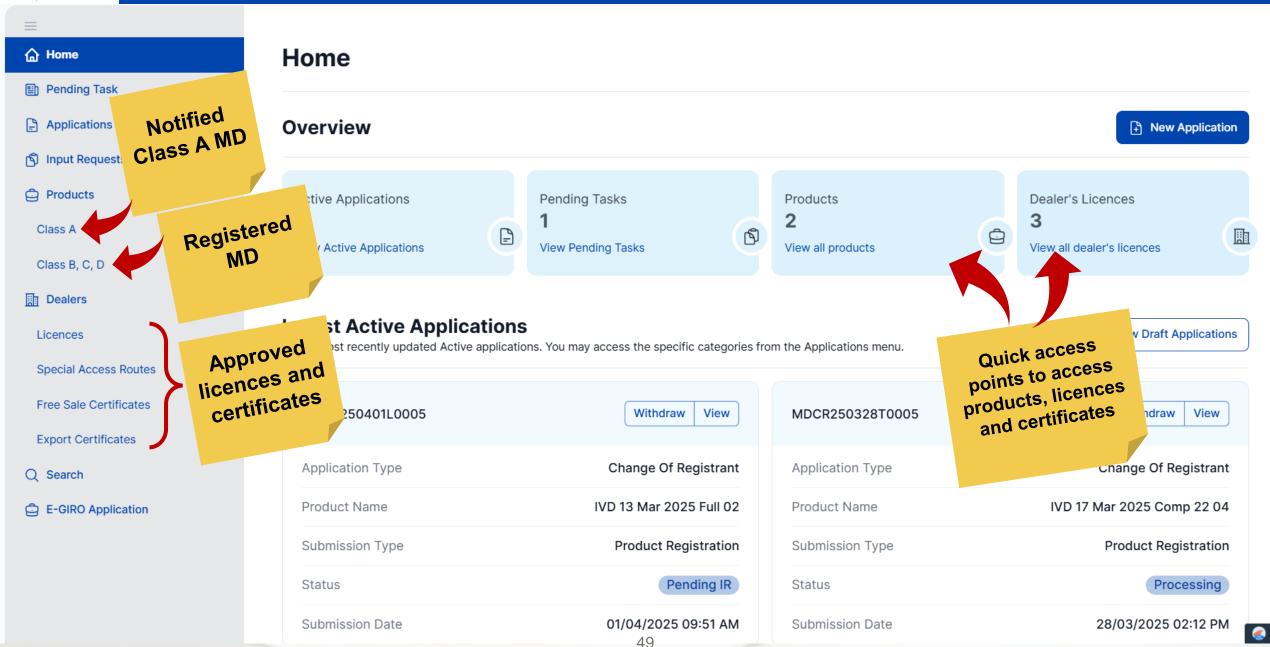




Retrieving list of products and licences

- Notified Class A products
- Approved Class B, Class C and Class D products
- Approved Dealer Licences, SAR and Certificates





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What's next?



Timeline

Period	Activity	Comments	
21 May 2025	SHARE for MD Industry Briefing		
27 June 2025	Stop accepting NEW application submissions via MEDICS	IR responses still accepted for ongoing applications.	
4 July 2025	Stop any changes to applications in MEDICS, including IR responses by 5:00 PM	Any changes made to applications on MEDICS after this will NOT be migrated to SHARE.	
4 – 13 July 2025	Cut-over period	MEDICS will be completely taken down. No further access to MEDICS will be available after start of cut-over.	
14 July 2025	General Availability Go Live	Companies can submit NEW applications in SHARE For ongoing applications, pending IRs from MEDICS will be re-sent in SHARE.	



Timeline

MAY	JUNE	JULY			
21 May		27 June	4 July		14 July
Industry Briefing	Please complete any urgent submission before 27 June 2025	Stop New Submission	Stop IR Submission	(no MEDICS access)	SHARE Go-Live
	New submission on MEDICS IR Response on MEDICS	No new submissions accepted No IR Responses accepted			Submission on SHARE



What can you do now?

Before 27 June 2025

Submit all urgent applications on MEDICS

Before 4 July 2025

Respond to urgent Input Requests on MEDICS

Before 14 July

Grant user access to SHARE in CorpPass



Thank you

If you require SHARE technical support, please send a screenshot of the issue to: hsa_share_support@hsa.gov.sg

If you require clarification on submission requirements and timeline, please contact: hsa_md_info@hsa.gov.sg