SHARE for Medical Devices

Industry Briefing Session

21 May 2025

Medical Devices Cluster
Health Products Regulation Group
Health Sciences Authority

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Agenda

- What is SHARE?
- Key changes
- “Quick Start” Guide
- What’s next?

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Key Changes

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Export Certificate

In MEDICS

- Submit “Notification for Export” before submitting Export Certificate application.

Additional effort to submit twice for the same certificate

In SHARE

- Export Certificate application submitted directly

No need for “Notification for Export”, saves effort and processing time

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

Product listing auto-retention has a different timeline from Dealer's Licence auto-renewal, causes confusion

In SHARE

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

Timeline to trigger auto-retention for products to be aligned with Dealer's Licences auto-renewal @ T-30 days.

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Cancellation

In MEDICS

- Cancellation effective immediately upon approval

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

In SHARE

- Applicants can define a future effective cancellation date

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Online Payment (for New Product Registration)

In MEDICS

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

Fee adjustments due 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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Companies with GIRO arrangement

In MEDICS

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

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

In SHARE

- Companies can choose their preferred payment mode at point of submission

Facilitate expedited processing of time sensitive cases

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Quick Start to SHARE

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Setting up access & company information

Corppass Setup

Logging into SHARE

Company Address Book

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Setting up access & company information

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)

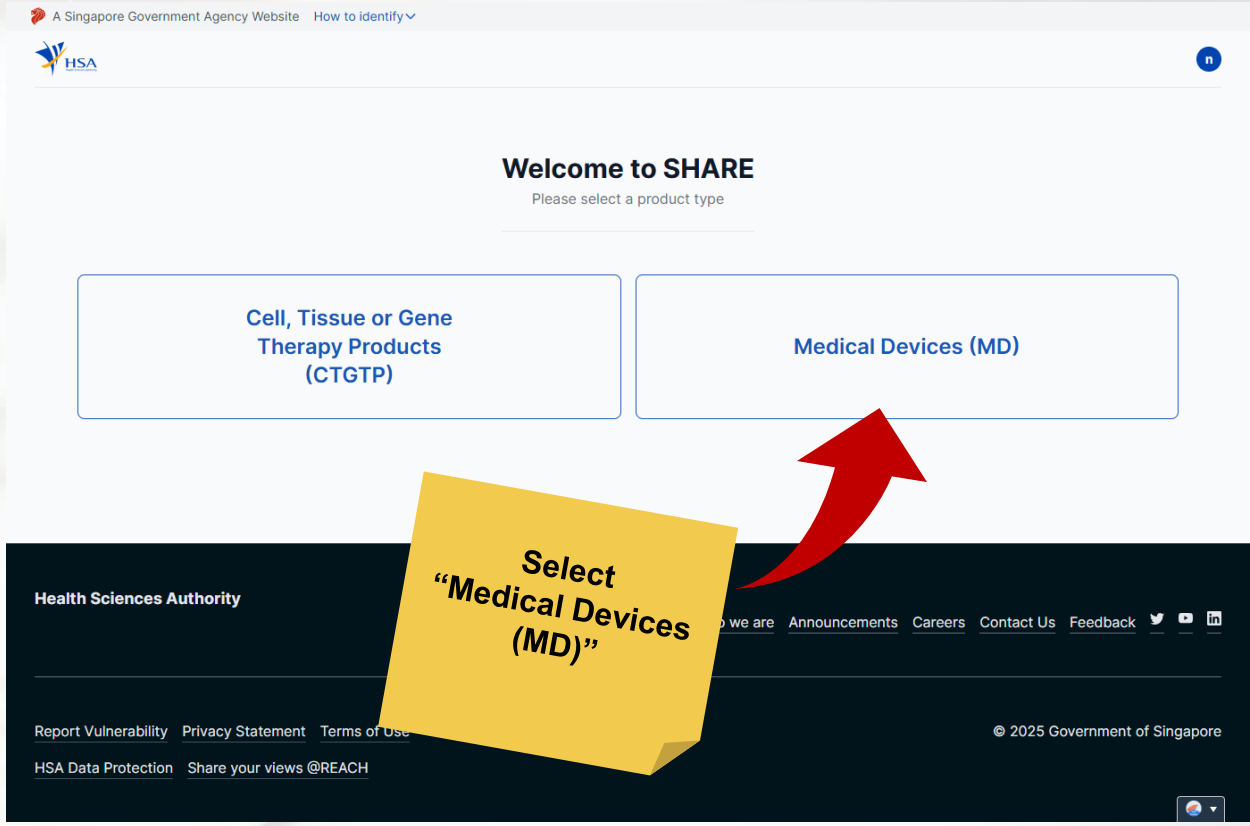
No more CRIS account and Registrant licence

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Setting up access & company information

Logging into SHARE



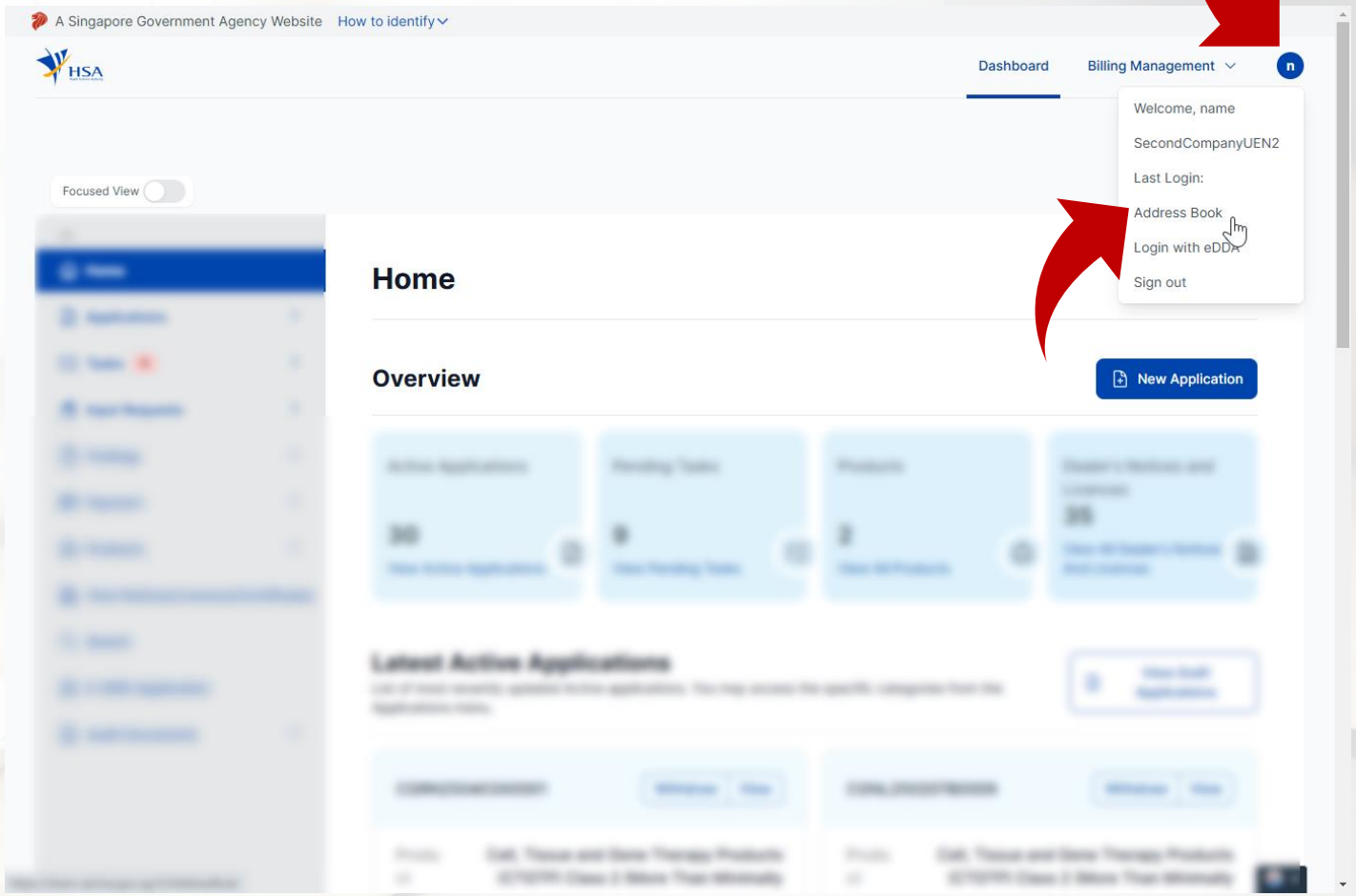
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Setting up access & company information

Company Address Book

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



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Submitting a new application

"New Application"

Dossier requirements and upload

Company contacts, applicant information and notification emails

All Rights Reserved, Health Sciences Authority

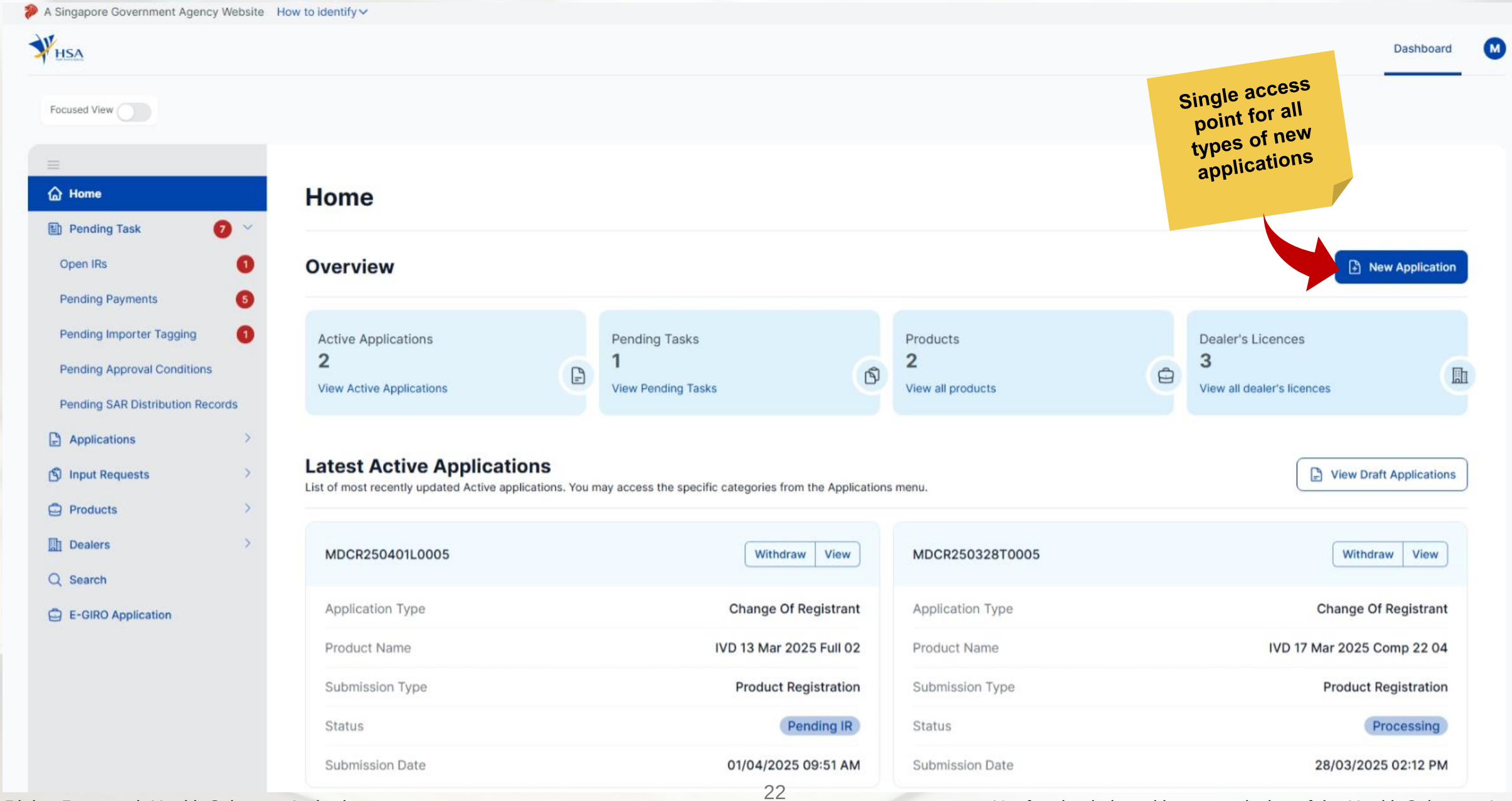
Not for circulation without permission of the Health Sciences Authority

“New Application”

All Rights Reserved, Health Sciences Authority

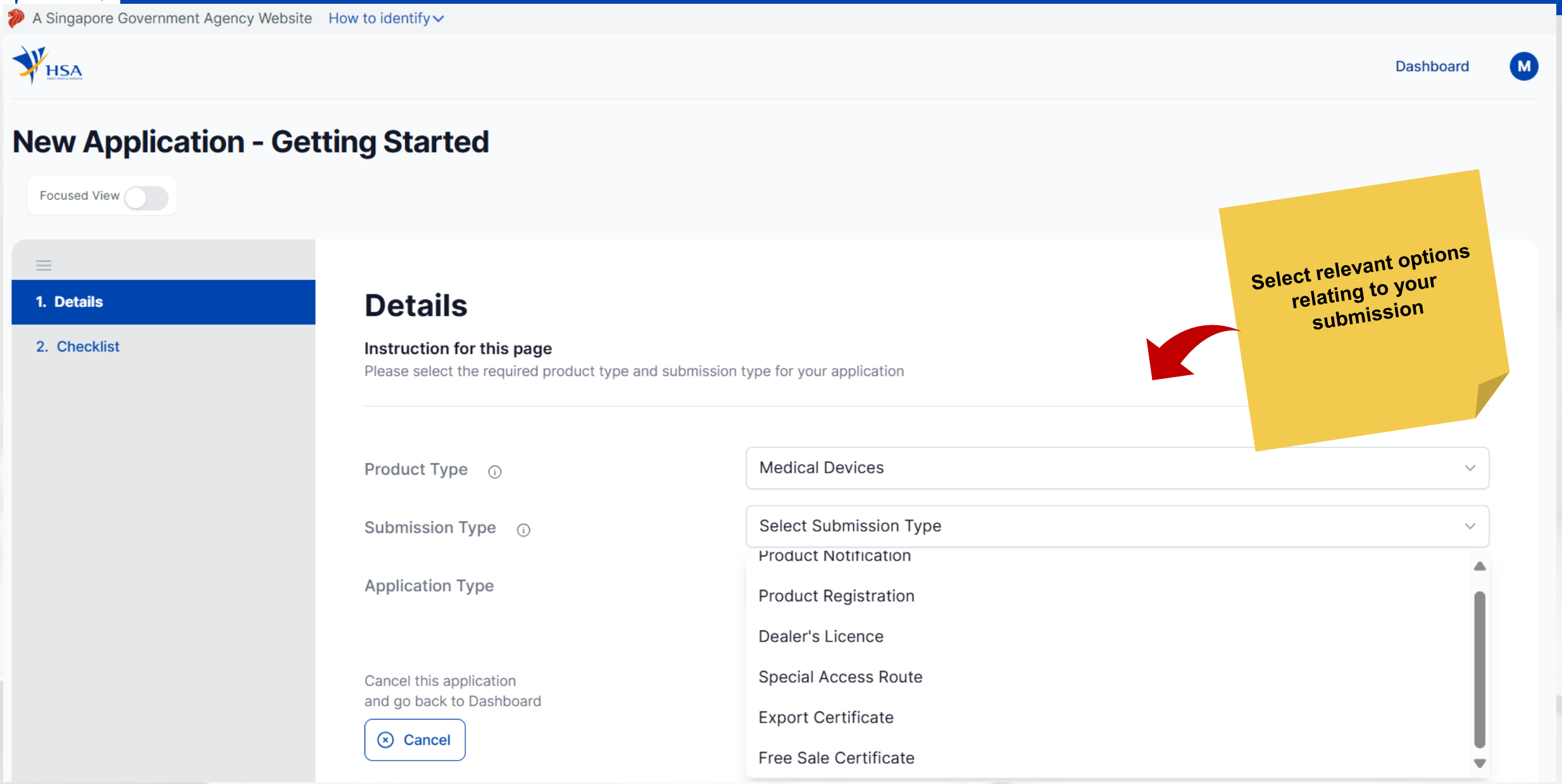
Not for circulation without permission of the Health Sciences Authority

Singapore Health Product Access and Regulatory E-System (SHARE)



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



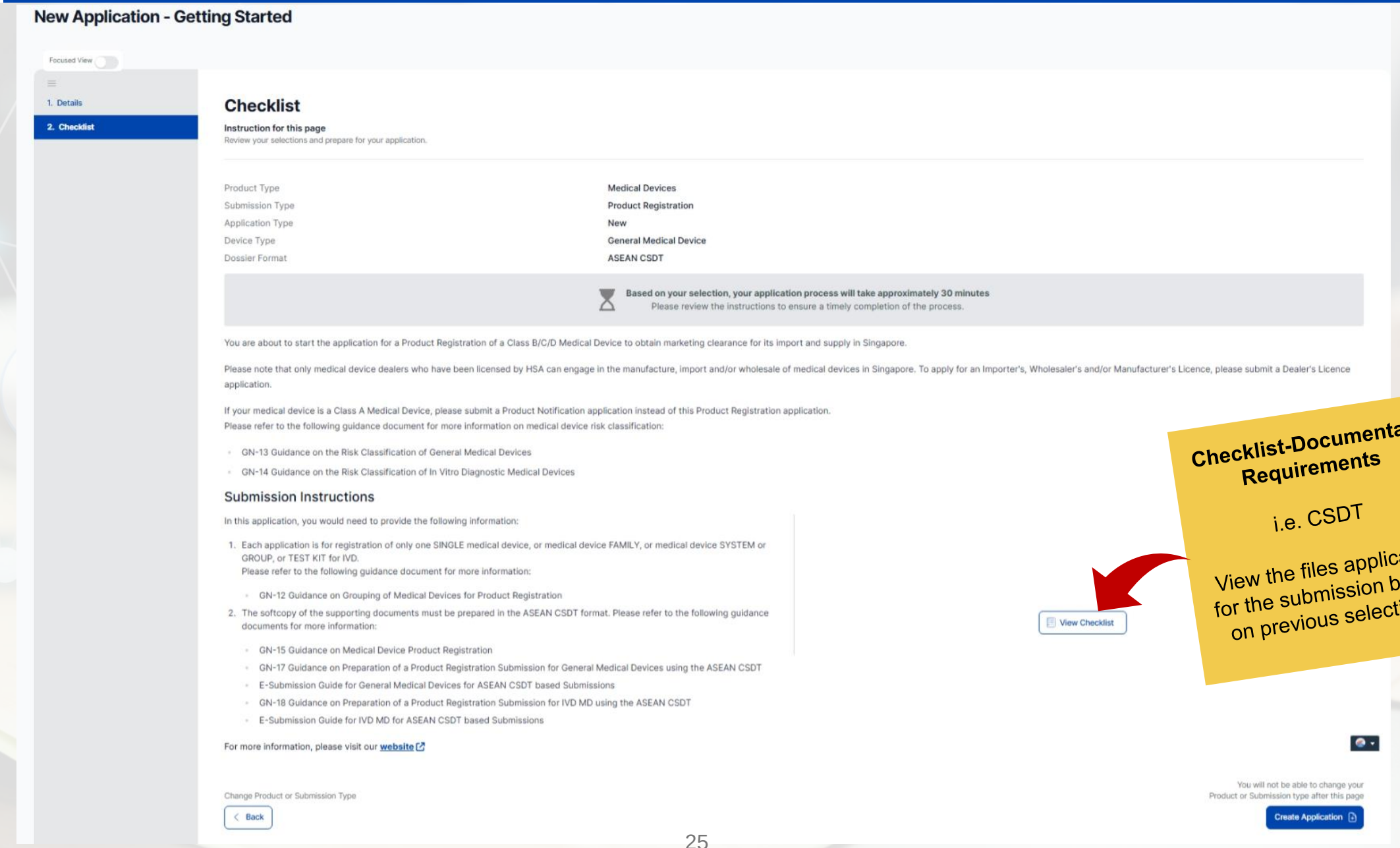
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Dossier Requirements & Upload

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



Checklist-Documentary Requirements

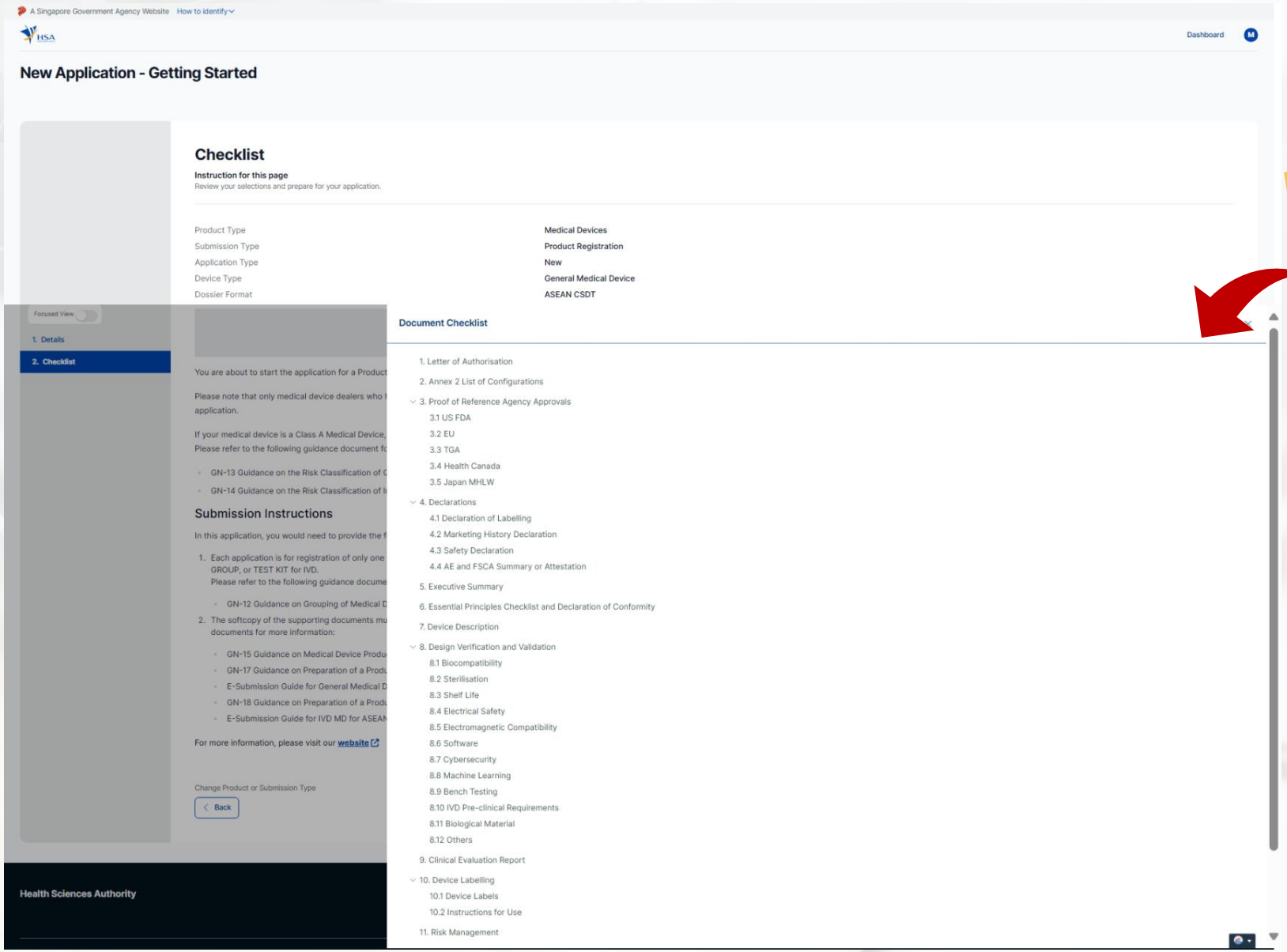
i.e. CSDT

View the files applicable for the submission based on previous selections

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Singapore Health Product Access and Regulatory E-System (SHARE)



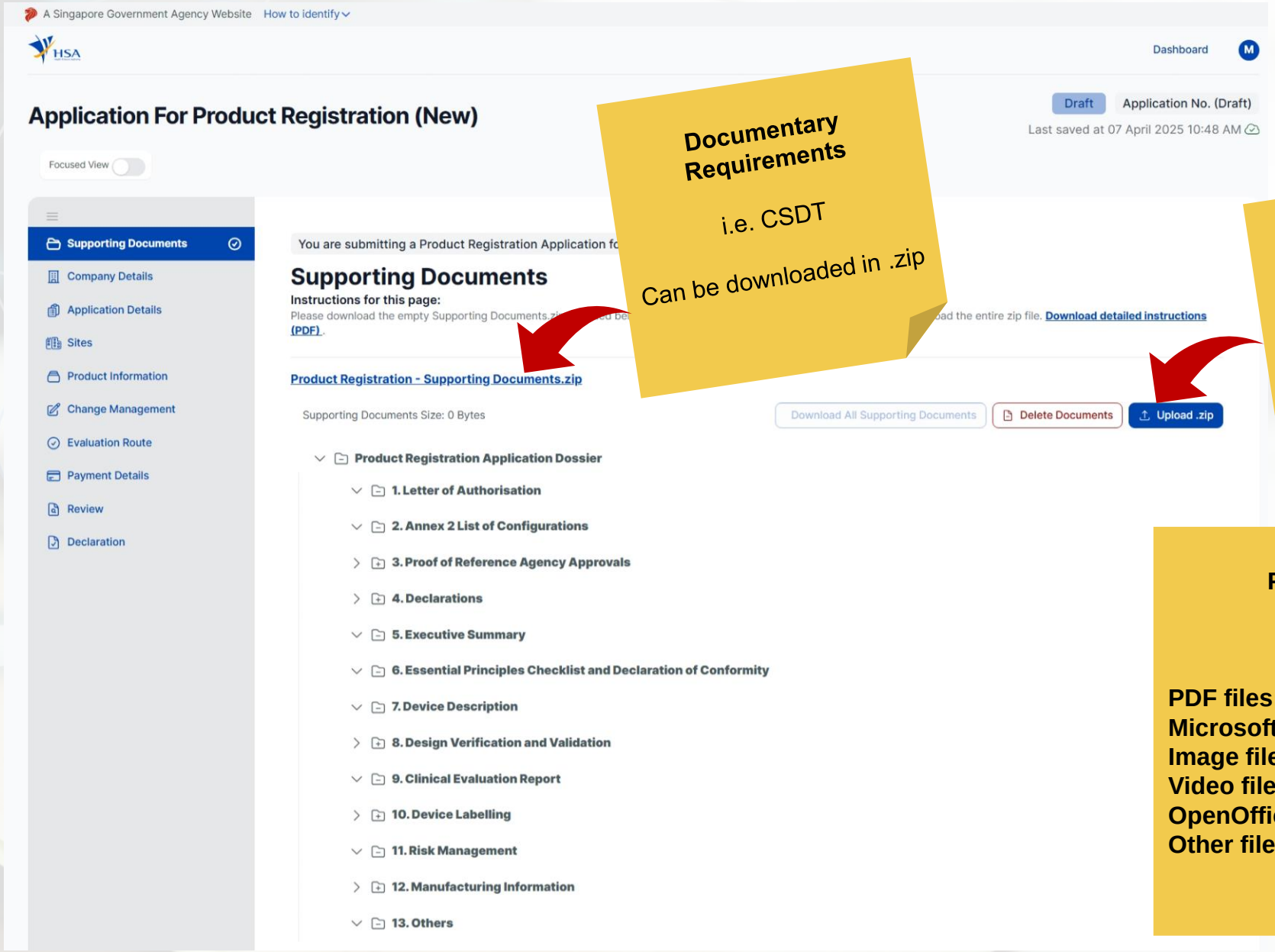
Document checklist specific for submission and application type

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Singapore Health Product Access and Regulatory E-System (SHARE)



Documentary Requirements

i.e. CSDT

Can be downloaded in .zip

File upload

Can be uploaded in .zip
or
Upload individual files into each folders
Able to create/add new folder subfolder

File size limit: 5 GB per upload

Permissible File Types:

PDF files: 'pdf'
Microsoft applications files: 'docx', 'pptx', 'xlsx'
Image files: 'bmp', 'gif', 'jpeg', 'jpg', 'png', 'tif', 'tiff'
Video files: 'avi', 'mpeg', 'mpg'
OpenOffice files: 'ods'
Other file formats: 'csv', 'rtf', 'txt'

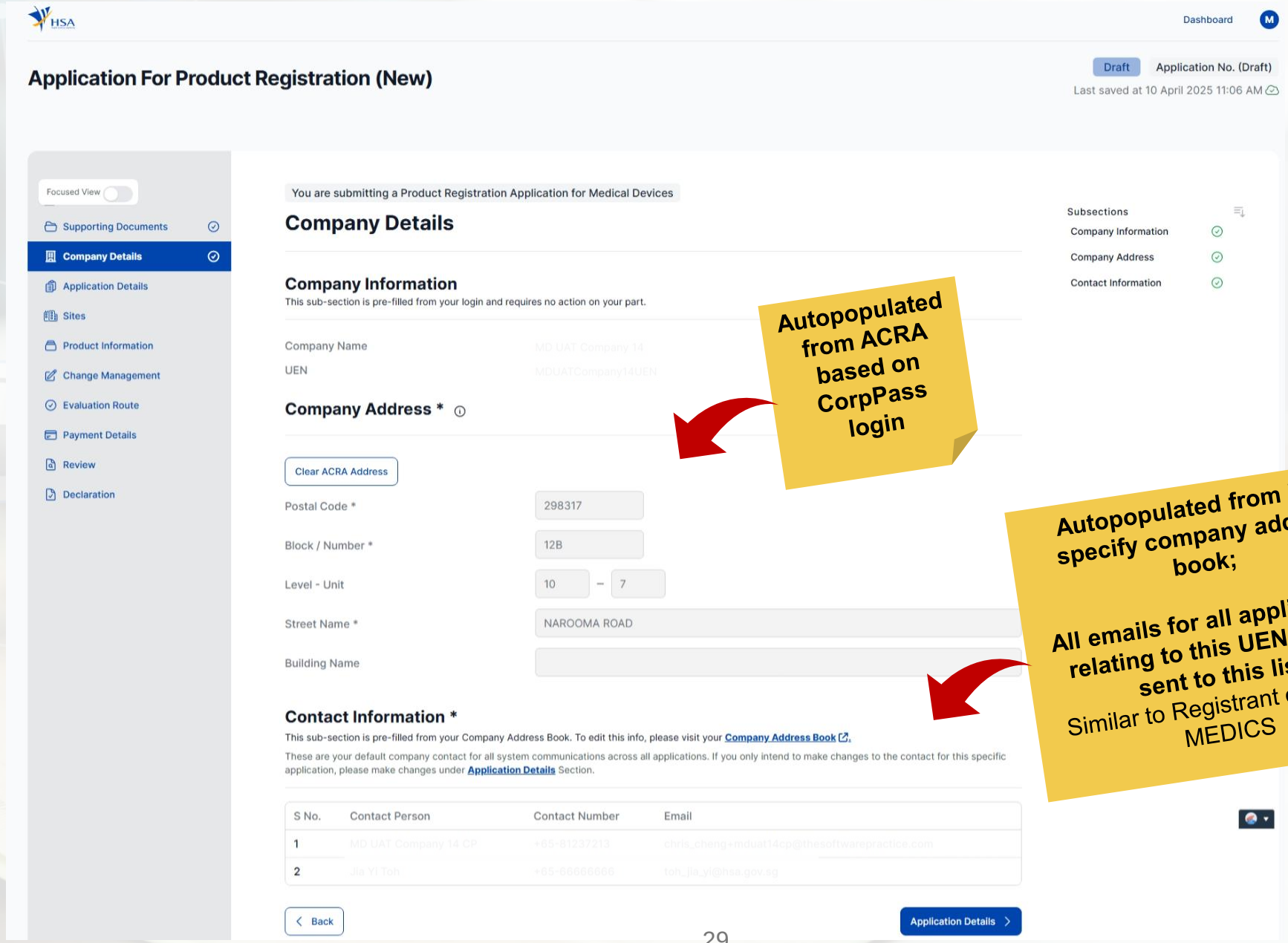
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Company contacts, applicant information and notification emails

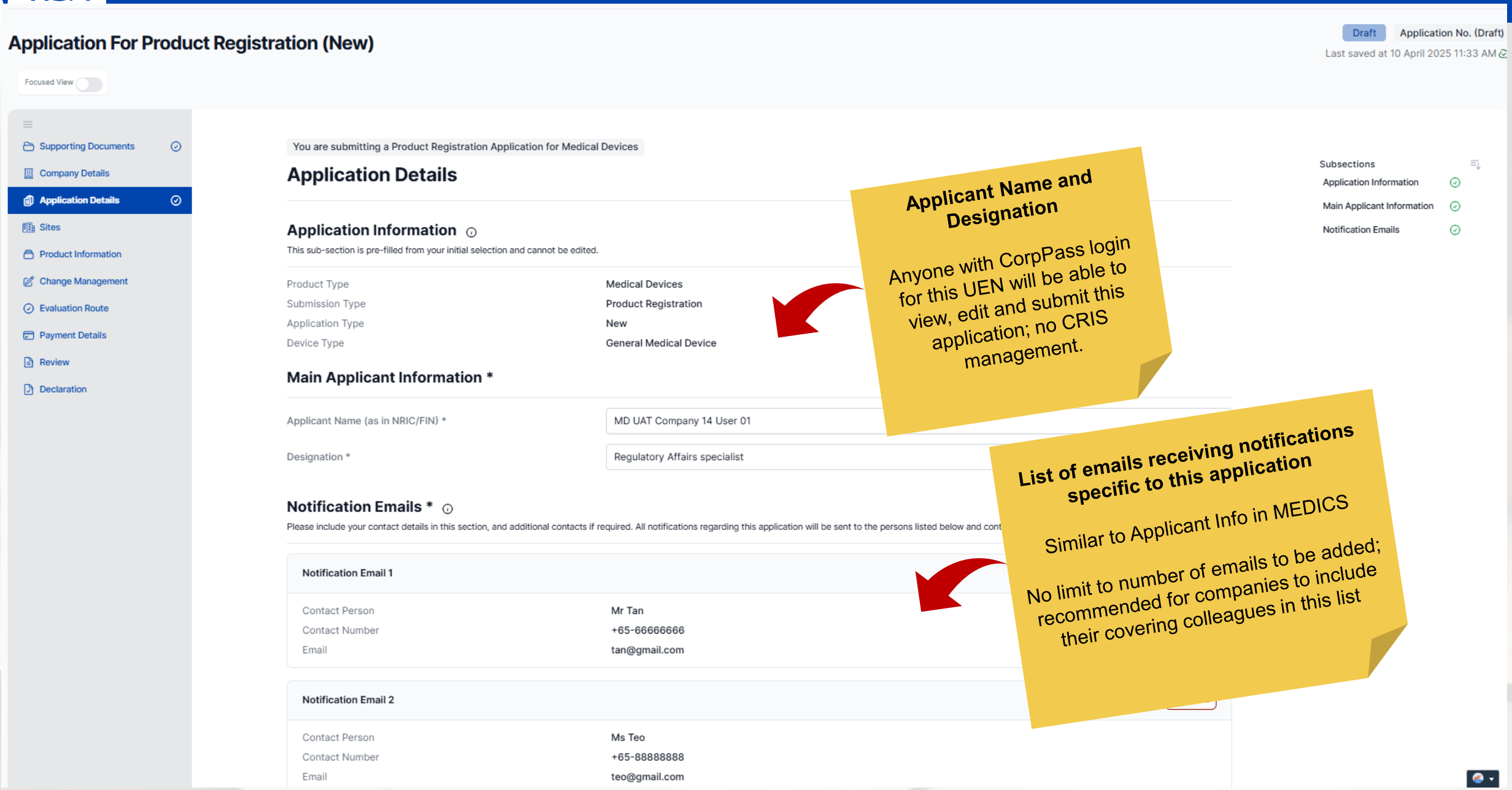
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Input Requests

Open input requests on Dashboard

Input Request Status and Extension

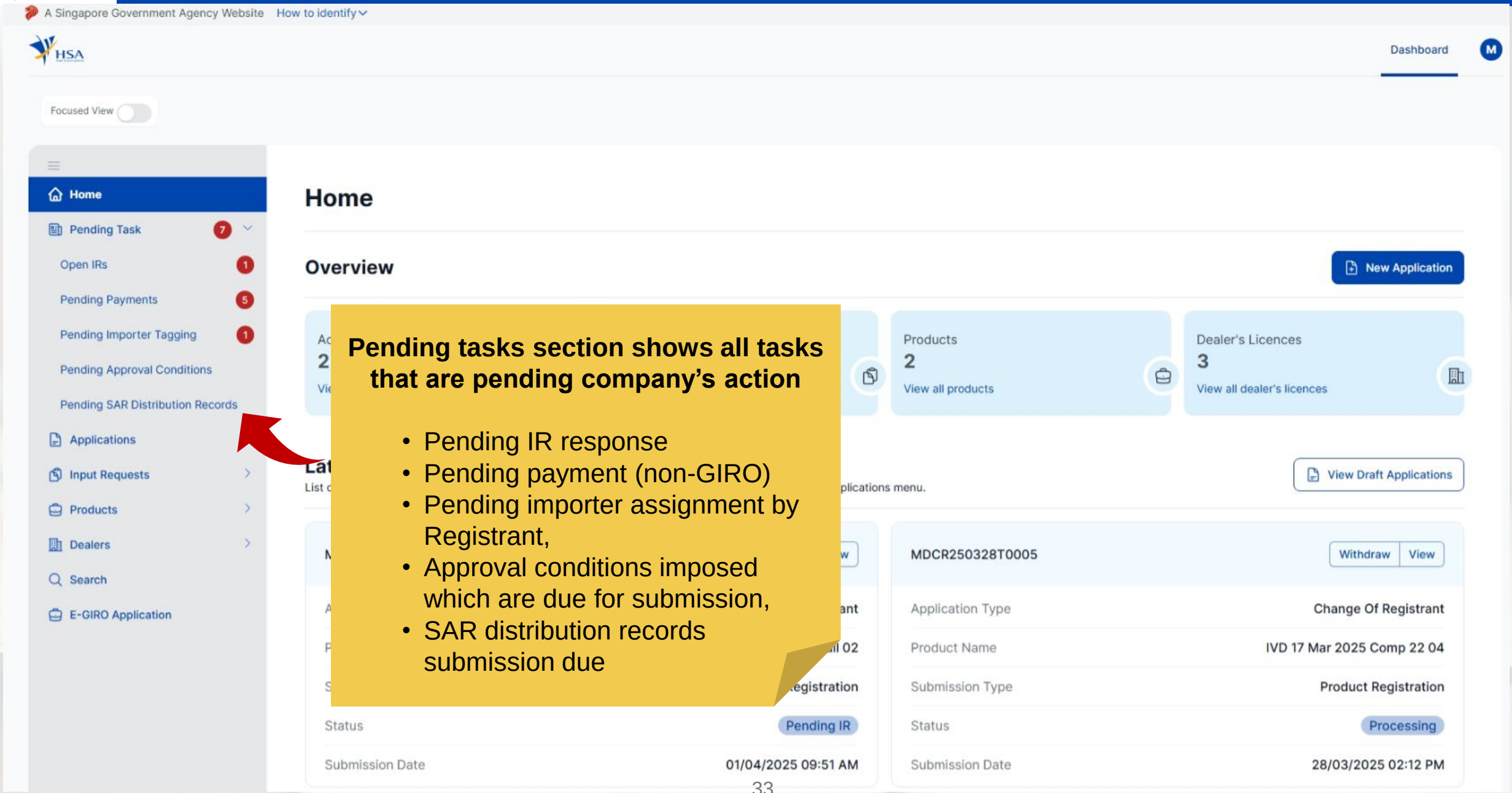
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Open Input Requests on Dashboard

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

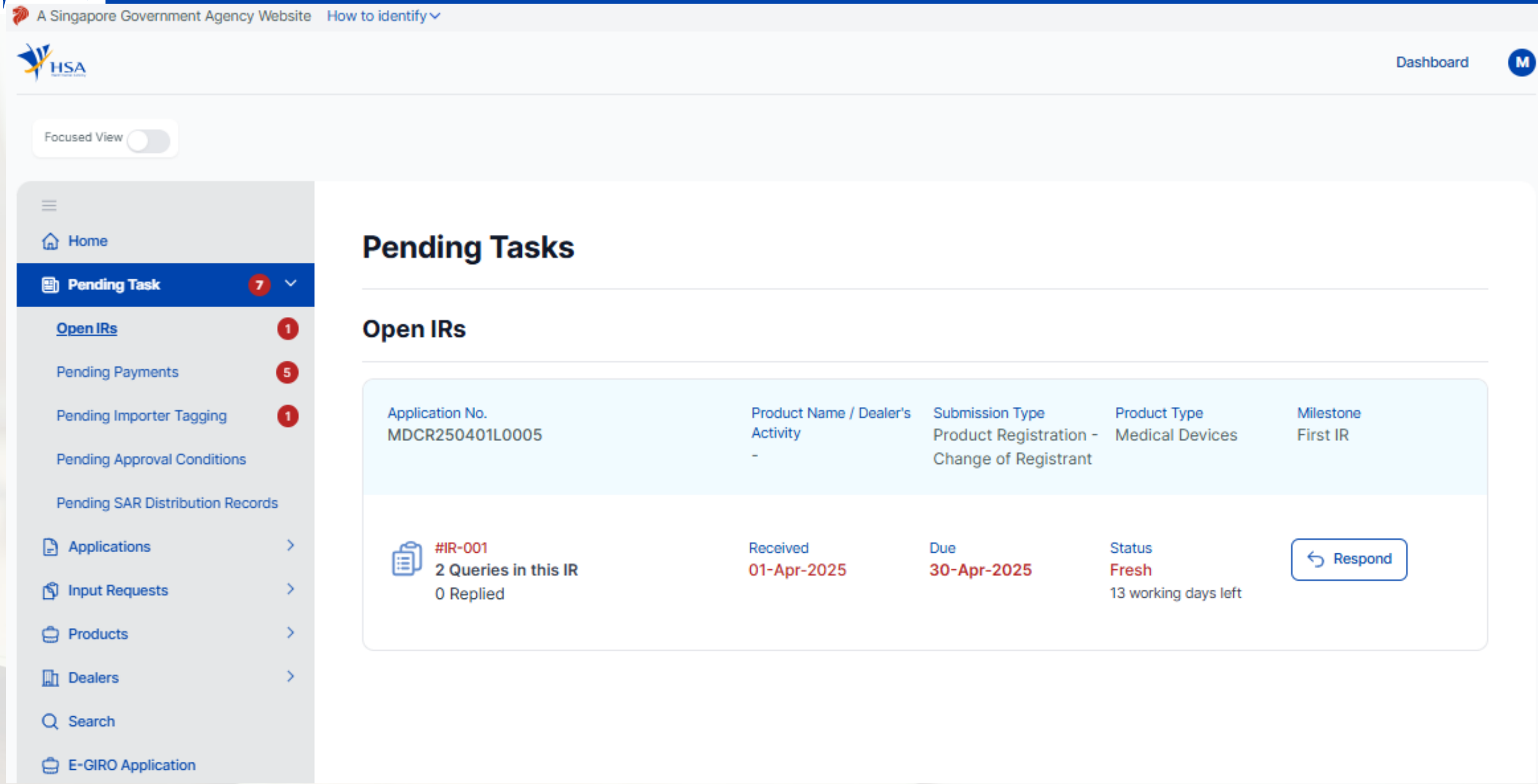


Pending tasks section shows all tasks that are pending company's action

- Pending IR response
- Pending payment (non-GIRO)
- Pending importer assignment by Registrant,
- Approval conditions imposed which are due for submission,
- SAR distribution records submission due

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



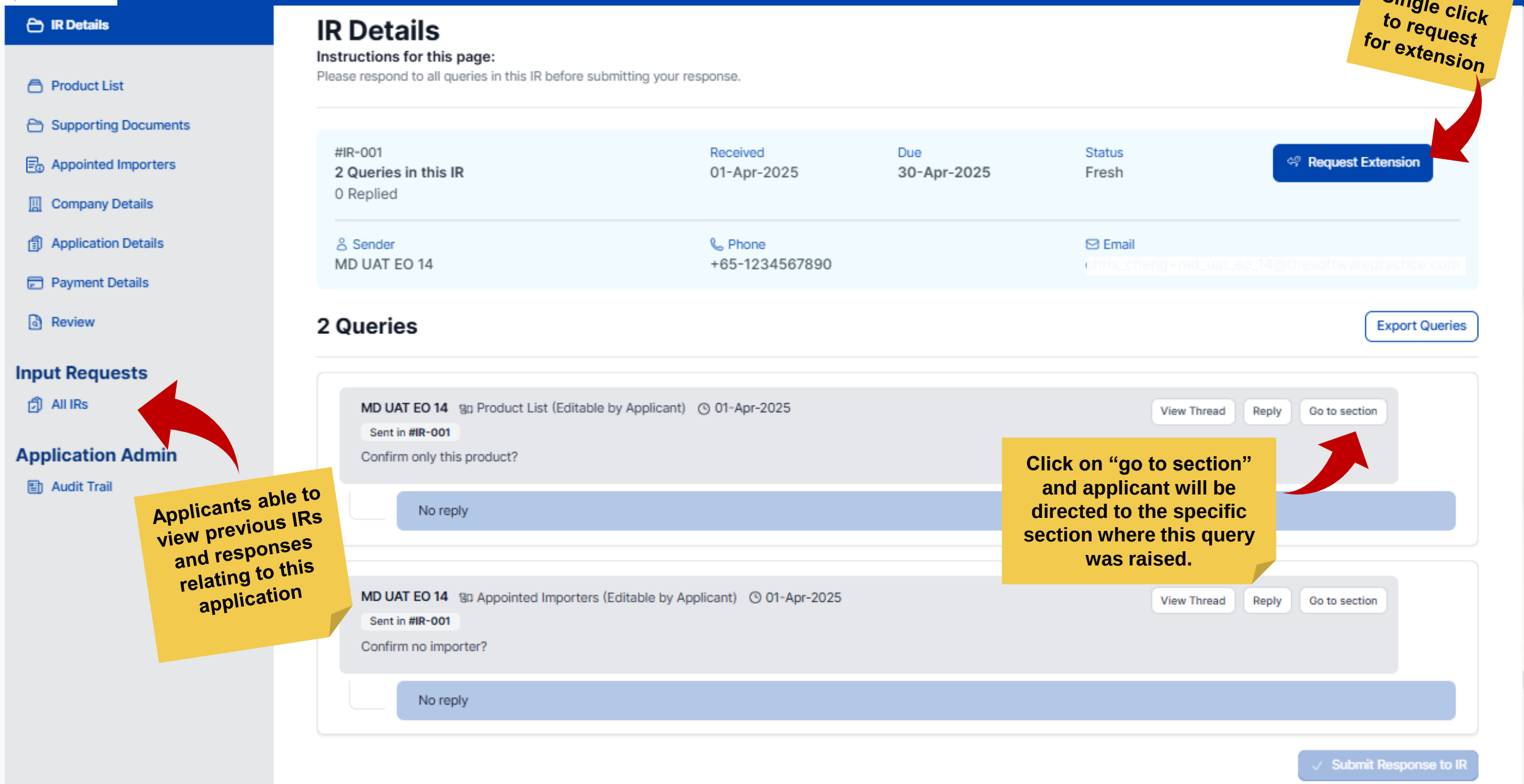
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Input Request Status and Extension

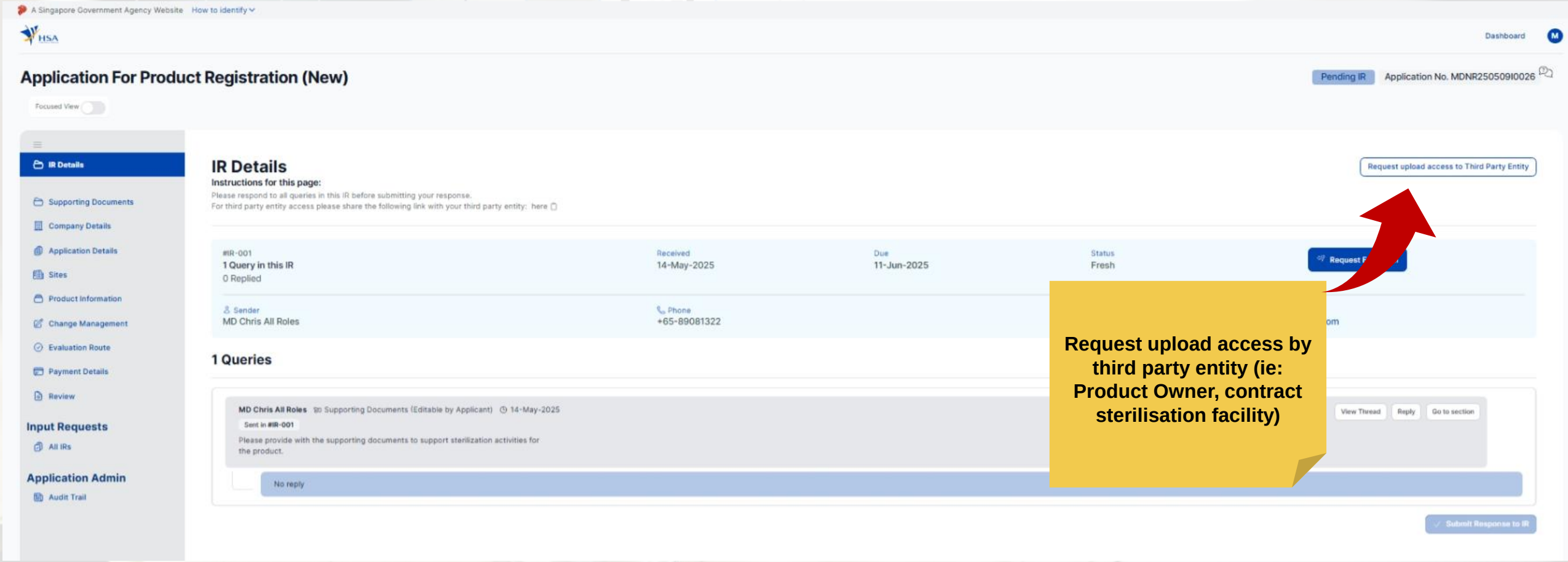
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



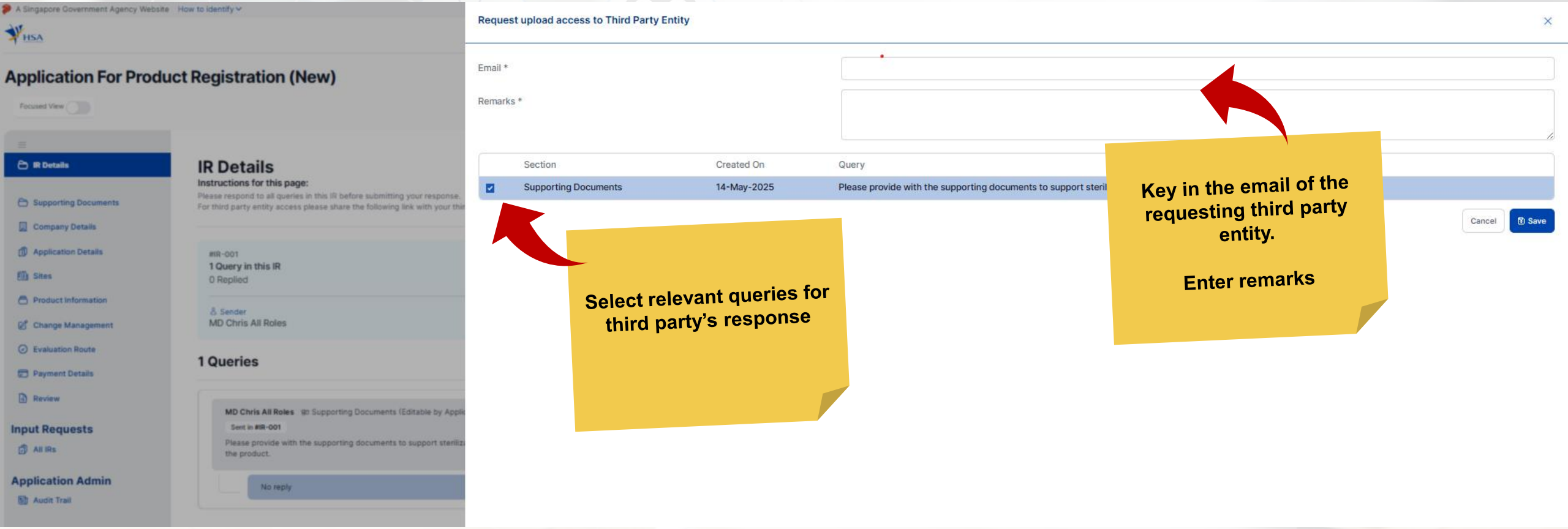
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Checking status of applications

Draft Applications

Pending Applications

Closed Applications

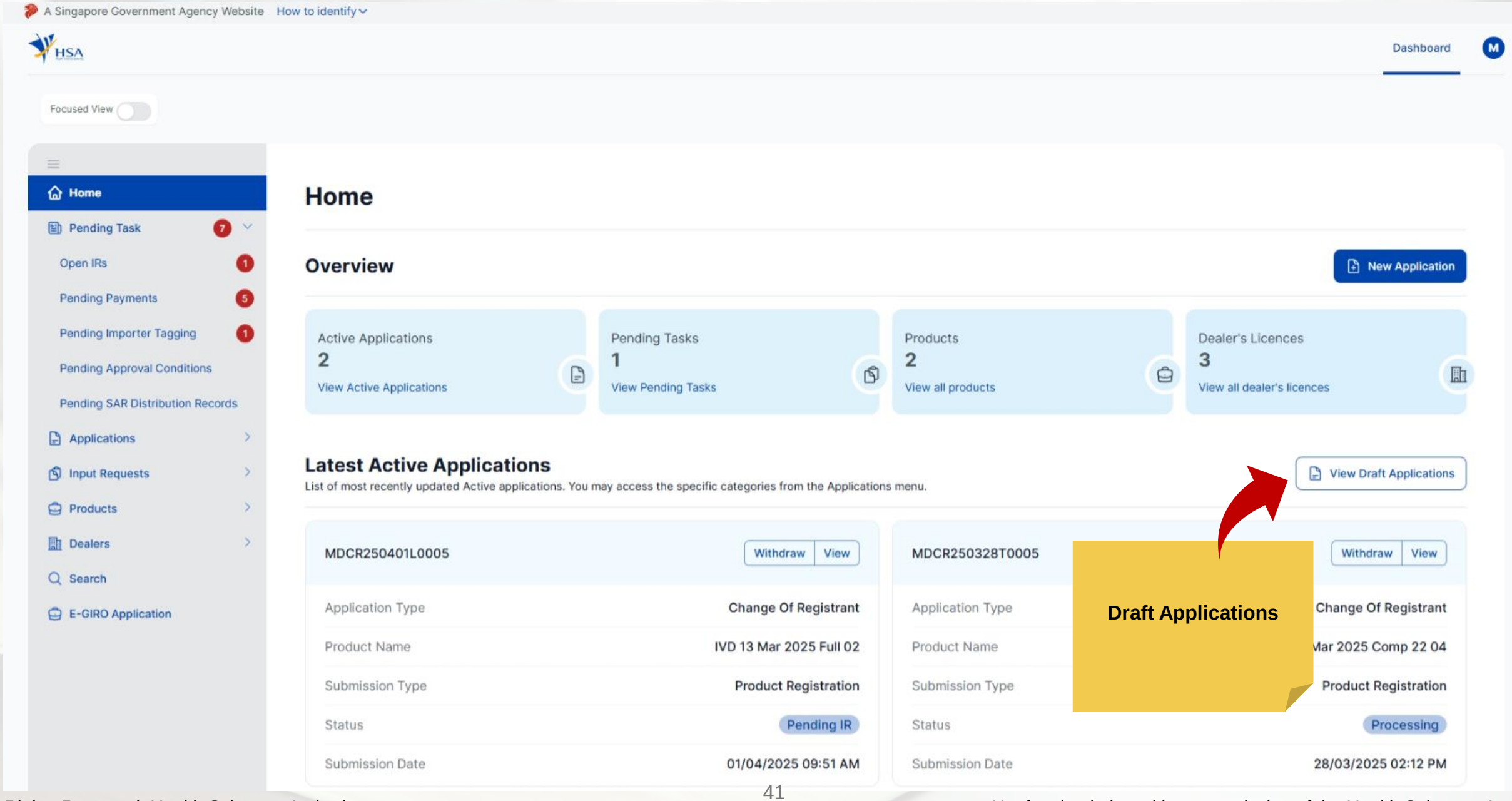
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Draft Applications

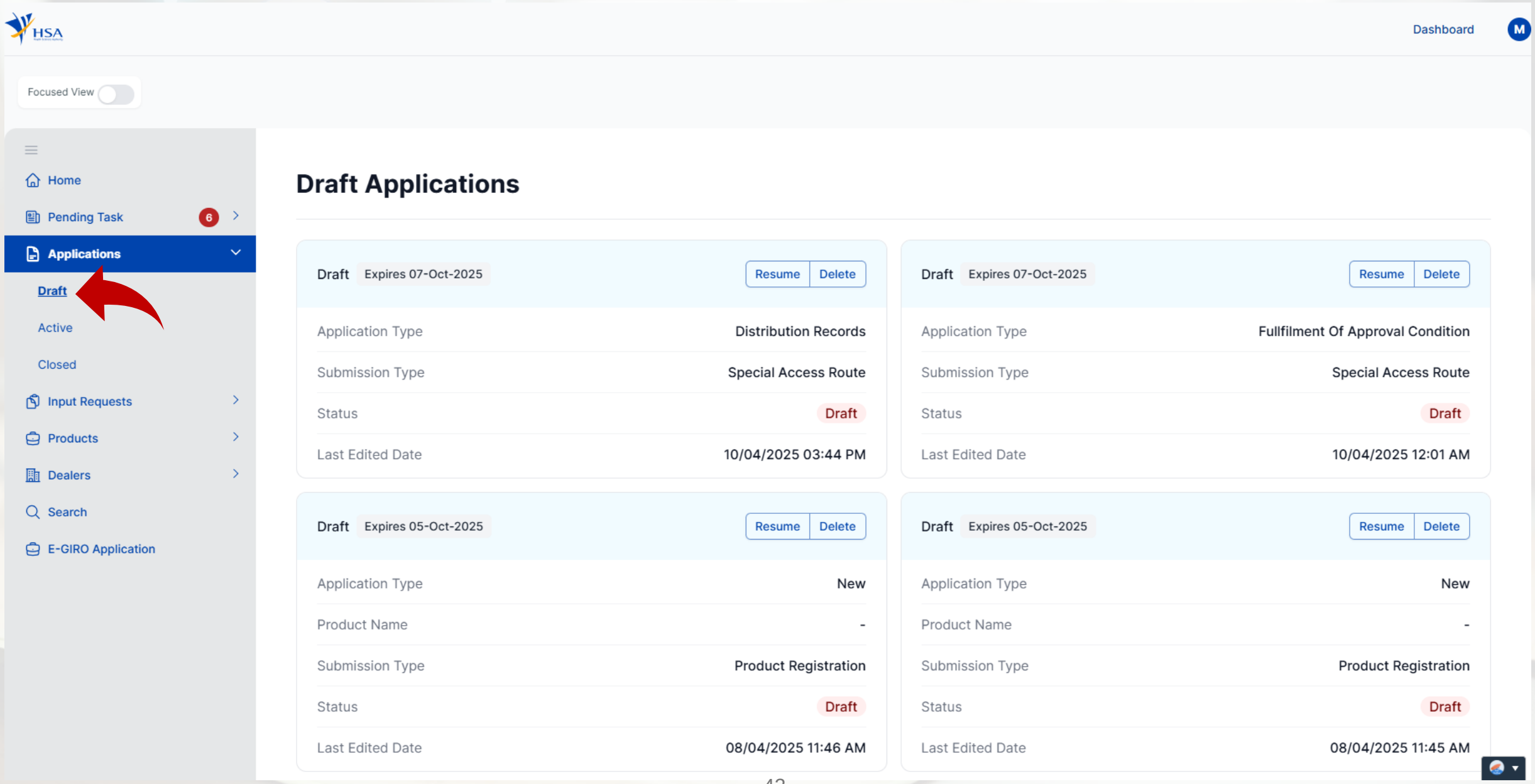
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

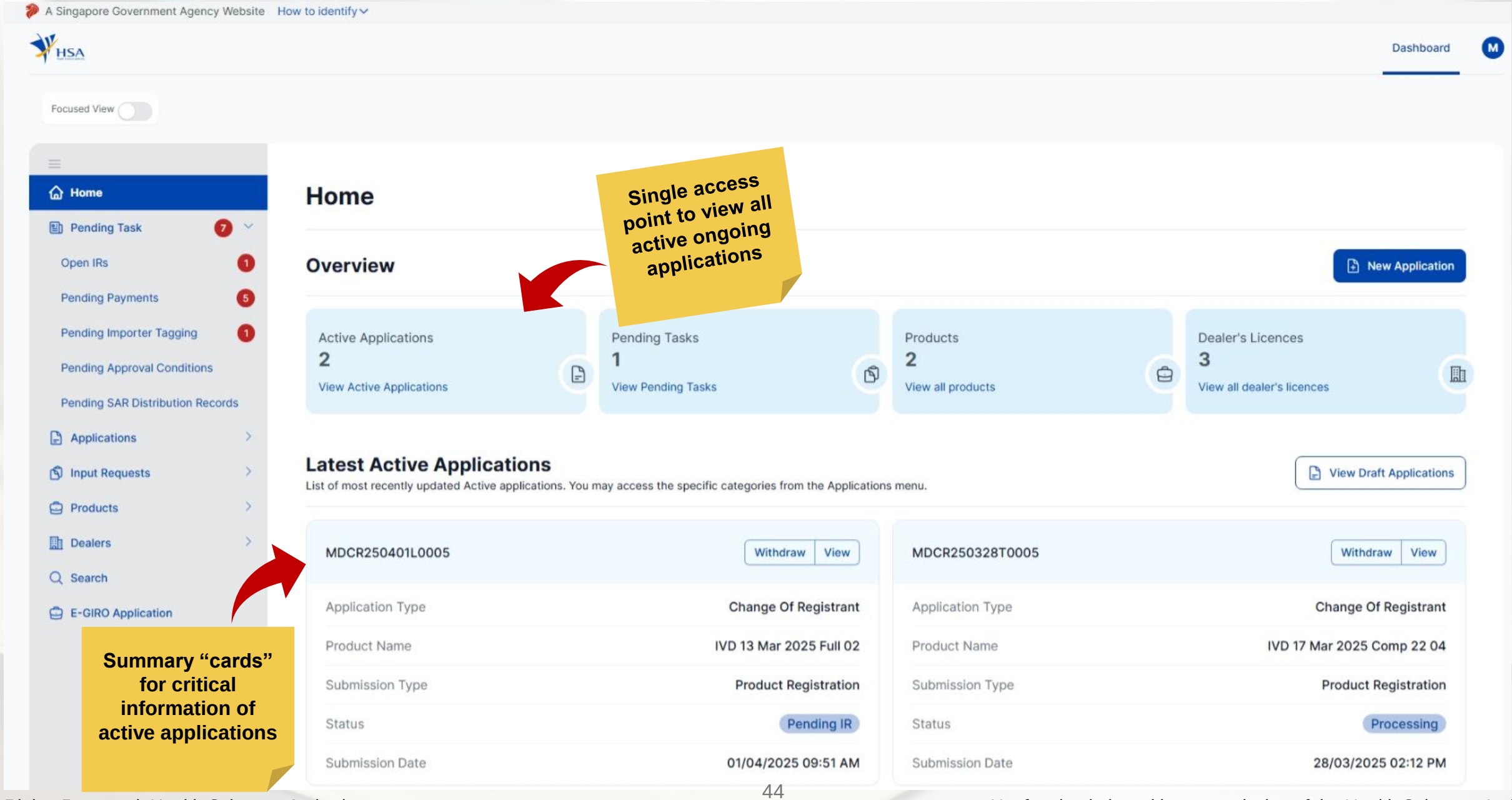
Not for circulation without permission of the Health Sciences Authority

Active Applications

All Rights Reserved, Health Sciences Authority

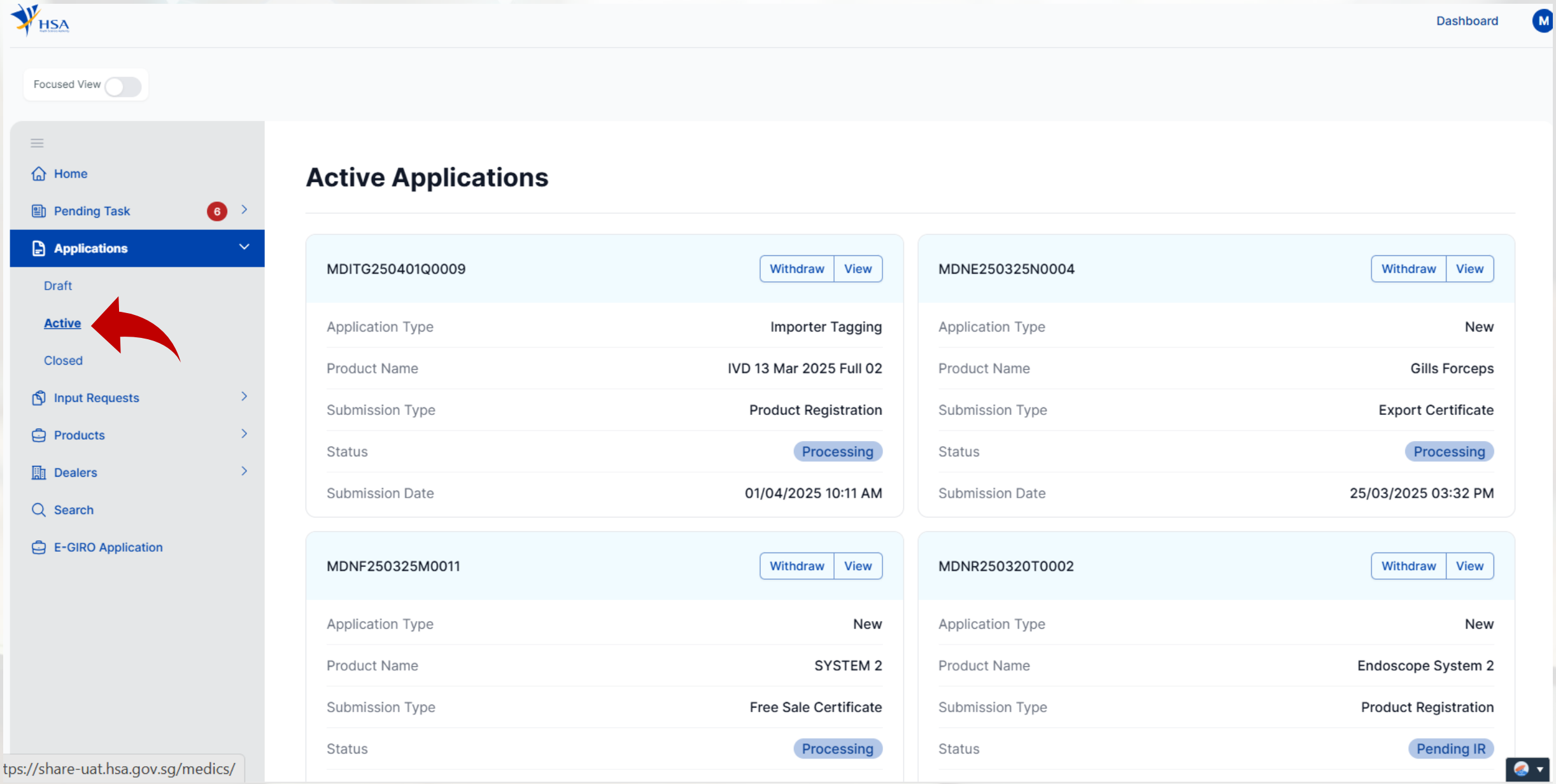
Not for circulation without permission of the Health Sciences Authority

Singapore Health Product Access and Regulatory E-System (SHARE)



All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



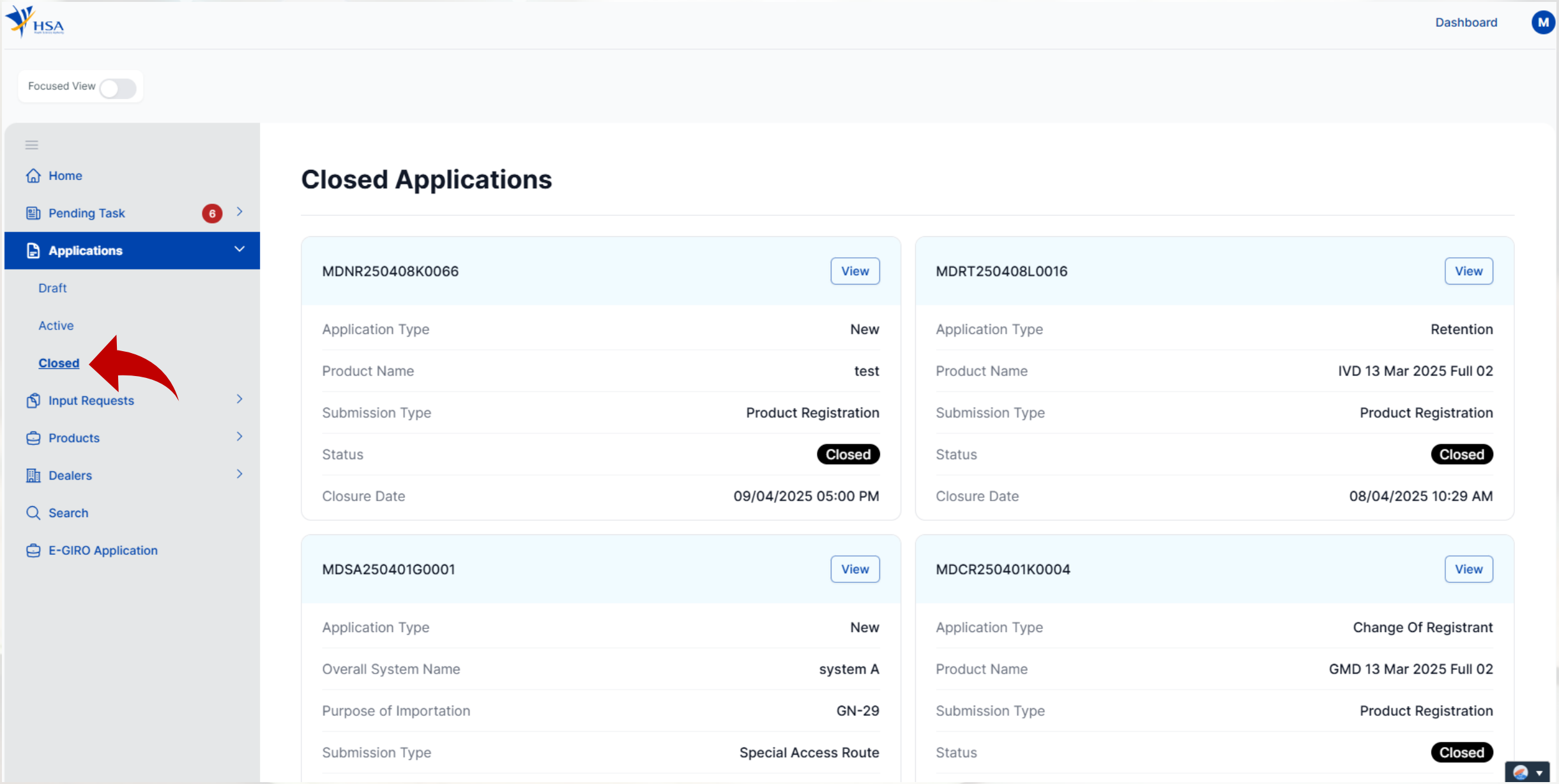
All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

Closed Applications

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority

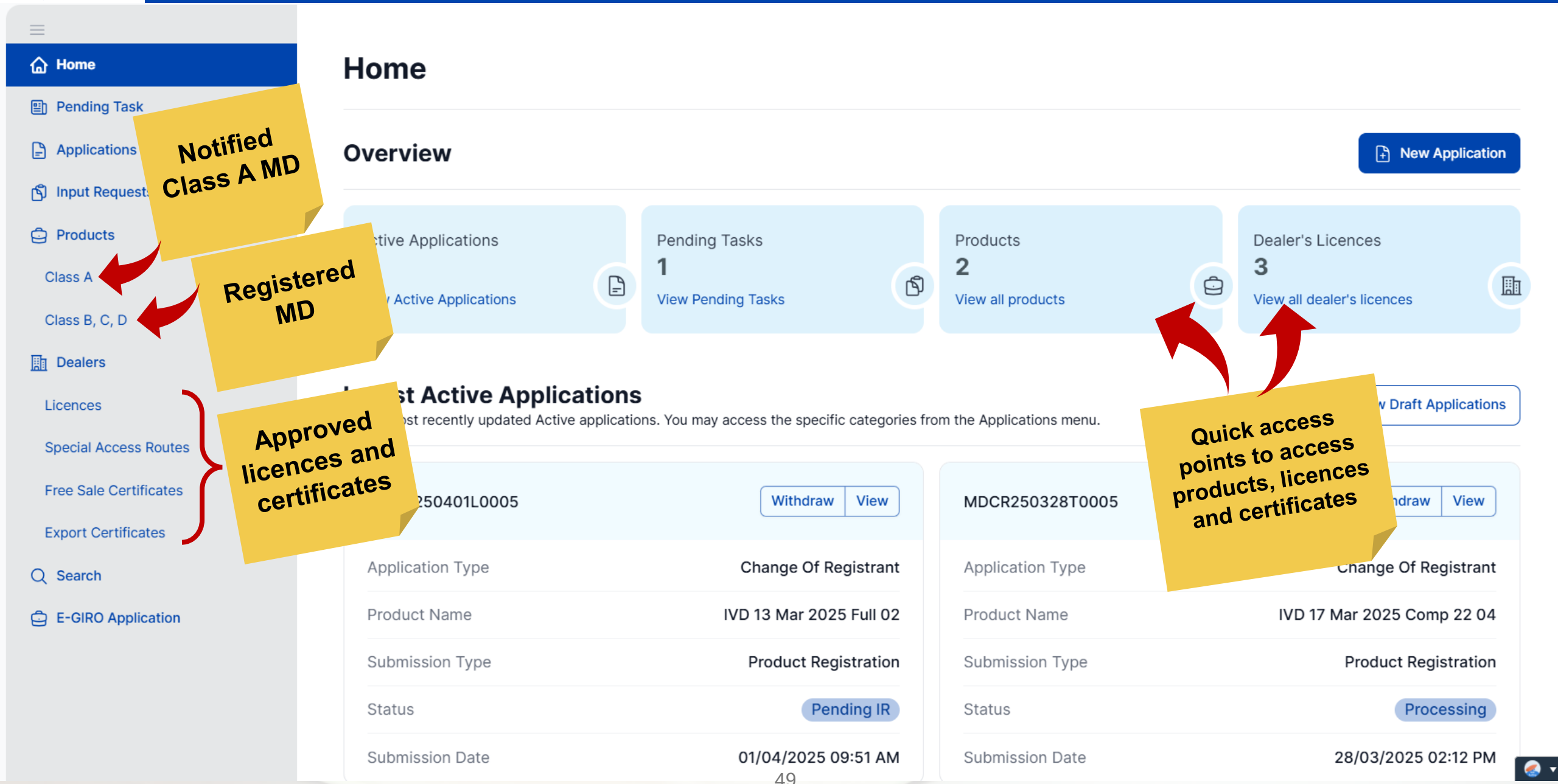
Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority



All Rights Reserved, Health Sciences Authority
Not for circulation without permission of the Health Sciences Authority

What's next?

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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.

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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		**No new submissions accepted**			**Submission on SHARE**
IR Response on MEDICS			**No IR Responses accepted**		

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority

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

All Rights Reserved, Health Sciences Authority

Not for circulation without permission of the Health Sciences Authority