Welcome to the HSA eCTD Portal Training Session!

- The recording and slides from today's session will be made available at a later date.
- Feel free to post your questions in the Zoom Q&A.
- We will be starting at 2.05pm.

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HSA eCTD Portal Training Session

28 May 2025

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Disclaimer

This presentation is intended to provide general guidance. Every effort has been made to ensure that the information is up-to-date and factual at the time of this session. For specific concerns or questions not covered by this presentation, companies may consult with HSA directly.

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Scope and Aims

- To communicate the purpose of the HSA eCTD Portal to industry stakeholders
- To provide training on how to use the HSA eCTD Portal for eCTD package transmissions to HSA

Note:

- This session will not cover HSA's eCTD Specification or how an eCTD package should be compiled

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Outline

Topic	Duration	Presenter
Singapore Submission Update	10 mins	Ms Lim Boon Kian, Deputy Director, Therapeutic Products Branch
Corppass Overview	5 mins	Mr Mahesh Guzuva, Project Manager, Information Management
eCTD Portal Demonstration	35 mins	Mr Eric Vestal, VRG Pte Ltd
Next Steps	5 mins	Ms Dai Weilu, Senior Regulatory Specialist, Therapeutic Products Branch
Questions & Answers	25 mins	All presenters
Closing Comments	2 mins	Ms Agnes Chan, Director, Therapeutic Products Branch

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Introduction

- There will be a Q&A session after all the presentations have been given.
- Questions will be answered live by the panelists.
- Please add your questions using the Q&A function in Zoom.
- If someone has asked a question that you also have, you may upvote it by clicking the thumbs up icon.
- You can also add a comment to an existing question if you would like to elaborate on it.

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Introduction

- Your feedback is important for us to better understand your needs regarding the use of the portal.
- A QR code leading to a feedback form will be provided at the end of this session. We welcome your honest feedback!

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SINGAPORE SUBMISSION UPDATE

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What is eCTD Submission Meant for?

- eCTD is a standard format for submission of dossiers, including responses to HSA

	eCTD	Non-eCTD
Regulatory application submitted to:	PRISM	PRISM
Regulatory outcome communicated via:	PRISM	PRISM
Dossier submitted via:	eCTD Portal (single zip file upload)	CD/DVD or EasiShare or PRISM
Dossier format:	ICH CTD only	ICH CTD or ASEAN CTD

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eCTD Pre-Submission Steps

For registration submissions:

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eCTD Pre-Submission Steps

For DMF submissions:

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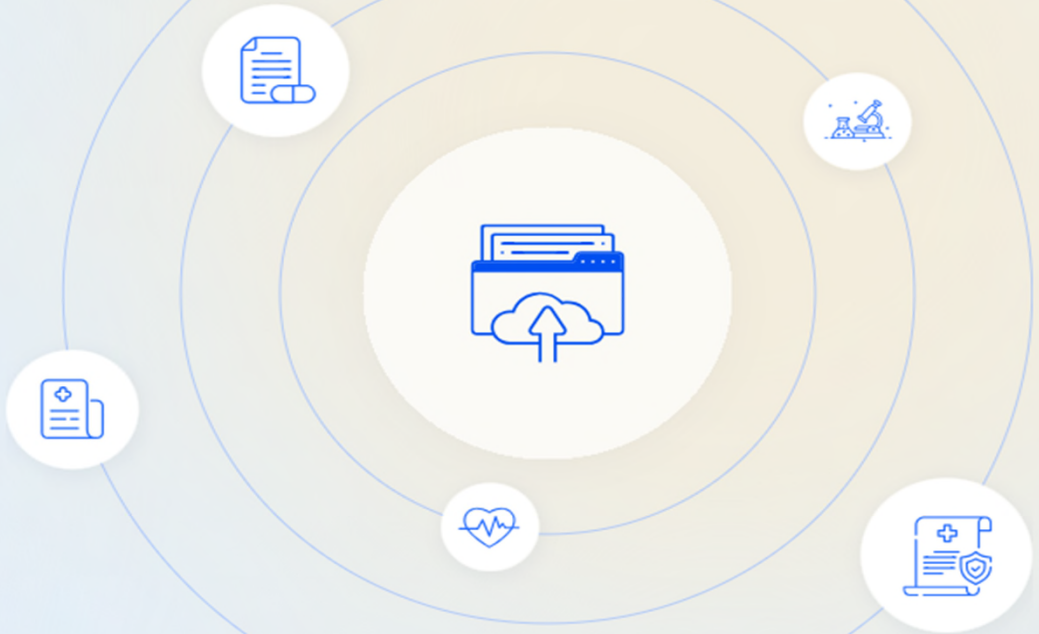
Package_Transmission_Guidelines

Welcome to SG-HSA eCTD Portal

Transmit package in eCTD format for product registration. To proceed, please log in with Corppass.

Log in with corppass

What is Corppass?



Getting Started

To learn more about submitting data in eCTD format and access the latest SG-HSA eCTD specification package, please visit the HSA eCTD webpage (click here)

Download User Guide

Click here to download User Guide.

Contact Us

If you encounter any technical issues with HSA eCTD Submission Portal, please contact our technical support team at eCTD_helpdesk@hsa.gov.sg.

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corppass

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corppass

- Corppass is the authorisation system for entities to manage digital service access of employees who need to perform business transactions on behalf of the entity.
- Corppass is a Whole-of-Government (WOG) service and is not managed by HSA
- Corppass is available for Singapore Registered Entities (both NRIC/FIN users and Foreign ID users) and Foreign Registered Entities.
- Entities that transact with the Government should register for and set up Corppass.

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Foreign Registered Entities

WHAT CAN YOU DO WITH CORPPASS?

CENTRALISE
Online access to over 200 digital services

CUSTOMISE
Digital service access of individual users within the entity

AUTHORISE
Third party service providers to transact on your behalf for selected digital services

GETTING STARTED ON CORPPASS

Check Documents Required

Identify Your Corppass Role

Register & Set Up Corppass

Note: For Foreign ID users, after successful account set up in Corppass, you will receive a new Singpass ID from Singpass via email. Follow the instructions to activate your new Singpass account. This will be a one-time process and is required to verify your identity whenever you want to transact with Government digital services.

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Corppass for Foreign Users

- Foreign users need to apply for Singpass Foreign User account (SFA) through Corppass or other SFA organisations
  - Register your details with the SFA organization
  - After successful verification of your details, the SFA organisation will pre-register your SFA
  - Singpass will provide your SFA details (Singpass User ID) via email
  - Follow the instructions in the email from Singpass to activate your SFA.

- Corppass admin can assign roles to foreign users with SFA similar to local users with Singpass

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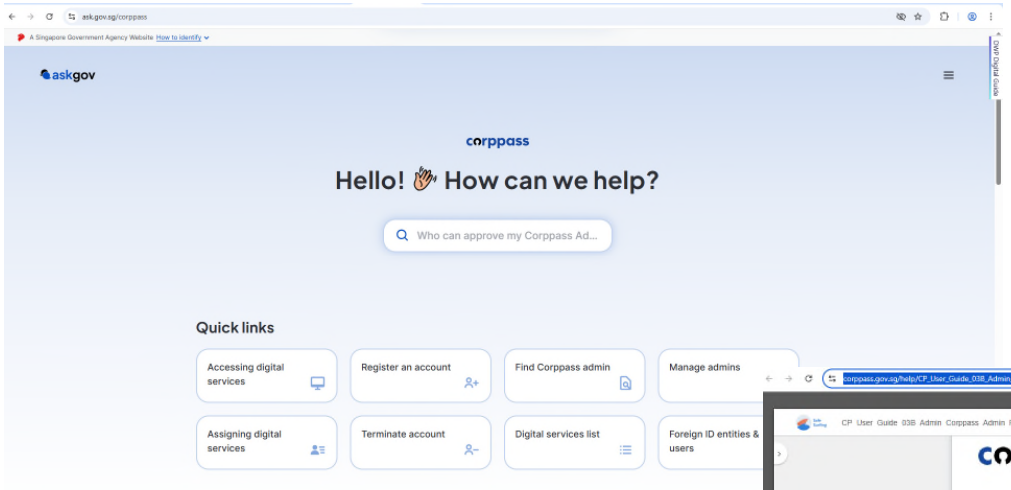
Corppass Help and Guides

https://ask.gov.sg/corppass



https://www.corppass.gov.sg/help/CP_User_Guide_03B_Admin_Corppass_Admin_Registration_Foreign_Entities.pdf

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eCTD PORTAL DEMONSTRATION

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Goals

1. Understand the **purpose** of the eCTD Portal

2. Review basic **concepts, requirements** and **constraints**

3. Hands-on, live demonstration so you can observe how easy it is to use, so that you will feel **comfortable** using it

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Purpose and Benefits

Purpose

- ✓ To transfer eCTD sequences to HSA for review

Key Benefits

- ✓ There is no cost to use the eCTD Portal
- ✓ Available to both local and International companies
- ✓ Operate 24/7 (excluding scheduled downtime)
- ✓ Interaction with HSA to transmit a sequence is not required
- ✓ Easy to use

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Key Concepts

Key Concepts

- ✓ Multiple users from the same company (Applicant) can use the Portal at the same time
- ✓ Each user is permitted a single session
- ✓ Each user can transmit only one package at a time
- ✓ Once submitted, the Sequence Package cannot be cancelled or recalled
- ✓ Cannot retrieve or download the package (i.e. the sequence) from the Portal

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To Transmit a Sequence

What you will need

1. Access to the internet via a standard web browser
2. Corppass account (Applicant)
3. An eCTD ID
4. A Package (a Package is not required to use the Portal)

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STEP 1 – The eCTD ID

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The eCTD ID – What, Why

What is an eCTD ID?

- A unique identifier issued by the eCTD Portal.
- It is linked to the company's Corppass login.

Why is an eCTD ID necessary?

- eCTD ID is the identifier for an eCTD Application submitted to HSA.
- Once utilized for a specific eCTD Application, it stays associated with that Application throughout the product's entire life cycle.

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The eCTD ID – Who, When, How

Who requires an eCTD ID?

Applicants who are preparing to submit a new drug application or a generic drug application to the HSA through eCTD submission.

- Applicants who plan to convert a non-eCTD application (ACTD or CTD) to eCTD.

When should you obtain an eCTD ID?

- Before the submission of the eCTD package, so that the eCTD ID can be included in the structure and envelope of the eCTD package.

How do you obtain an eCTD ID?

- Applicants request the eCTD ID through the eCTD Portal after logging in with Corppass.

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Demonstration

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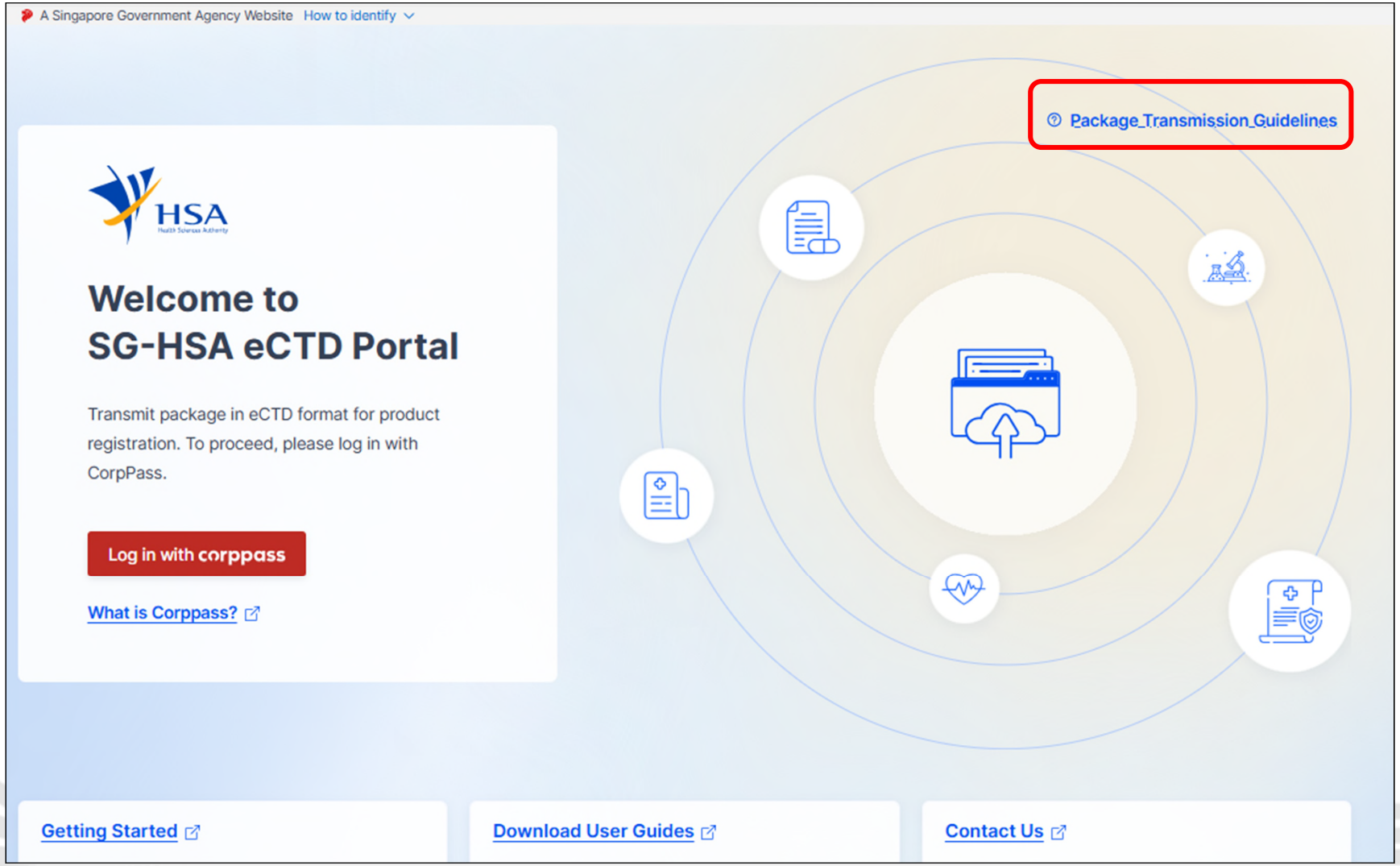
SG-HSA eCTD Portal



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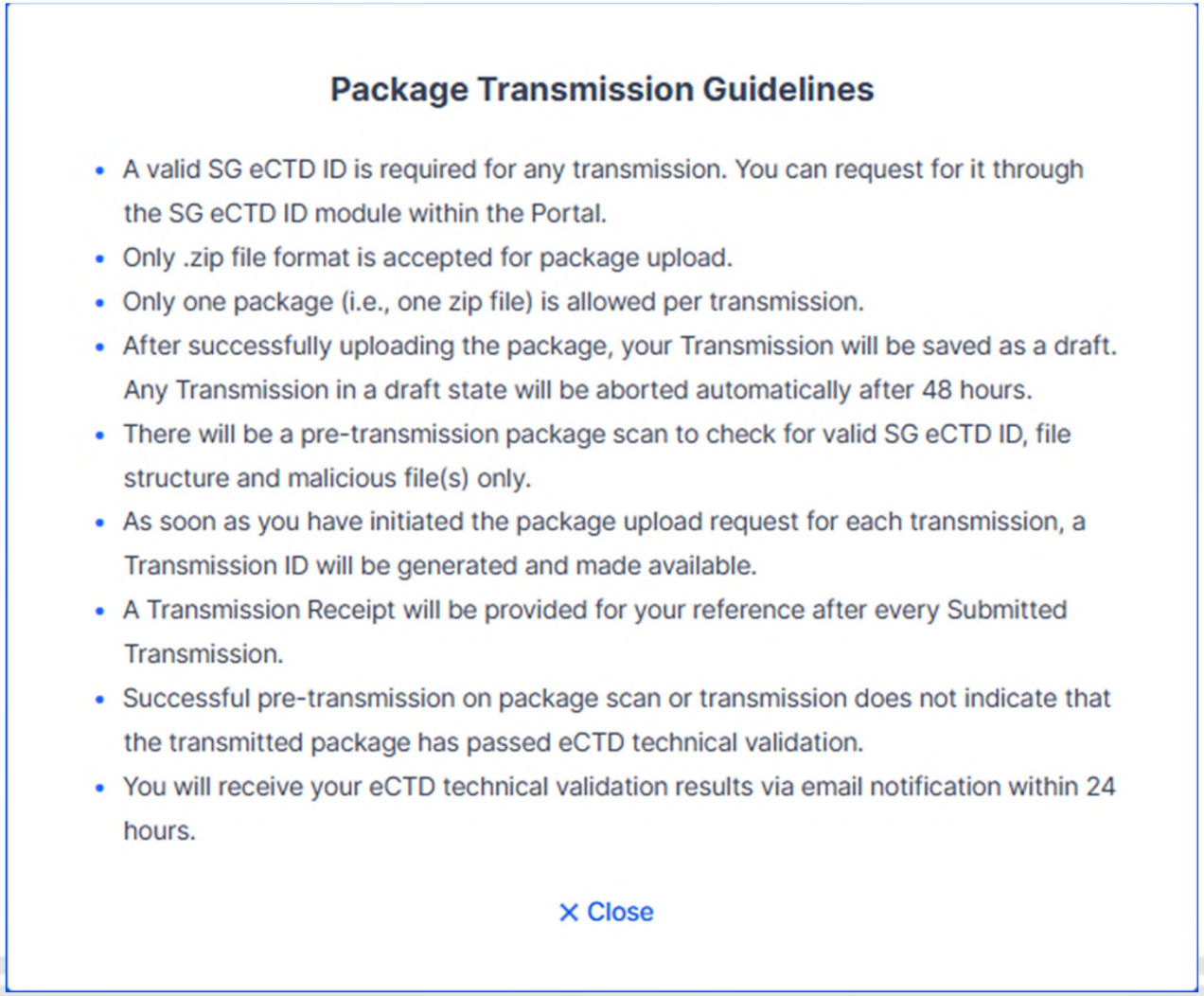
Package Transmission Guidelines



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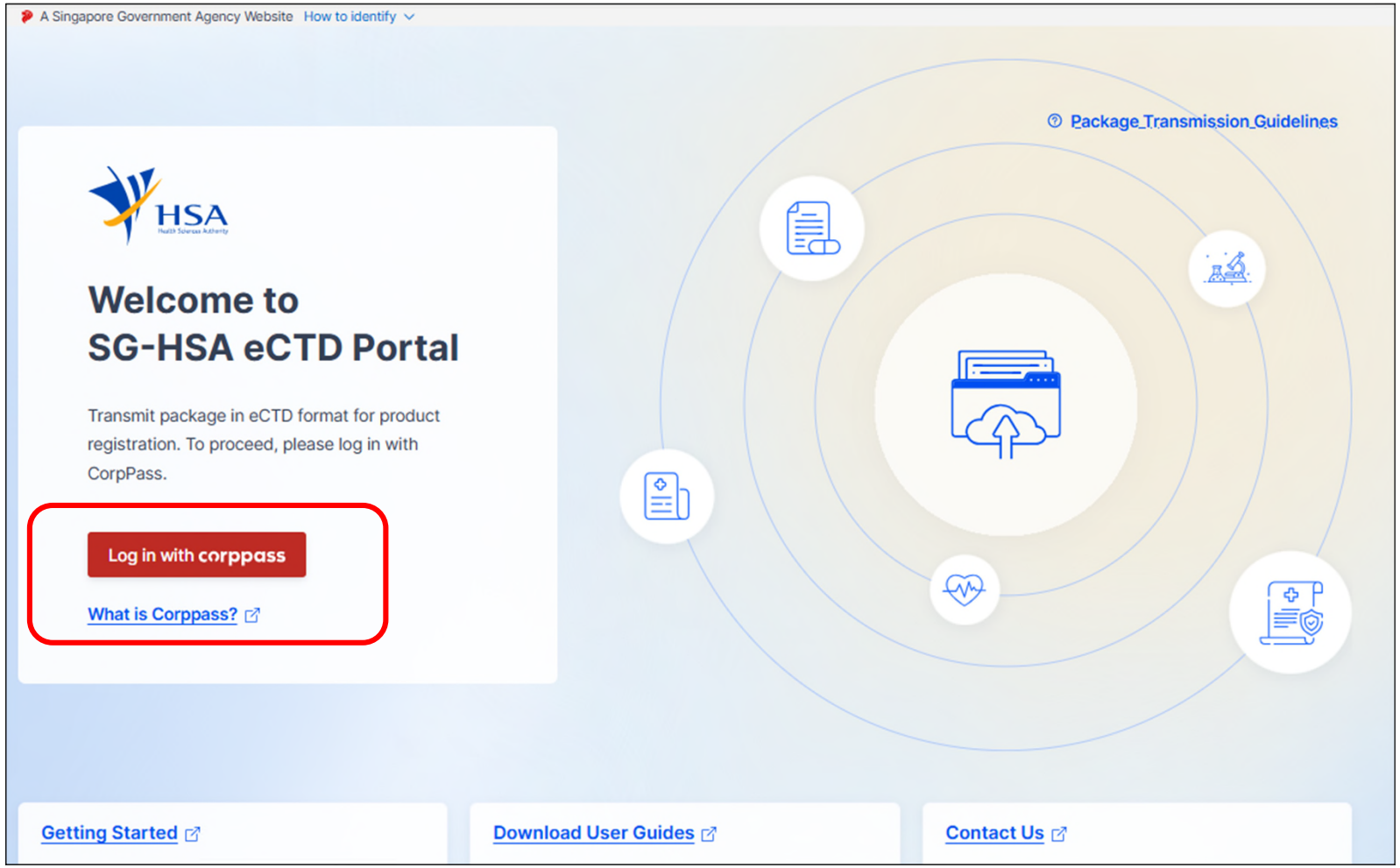
Log in with Corppass



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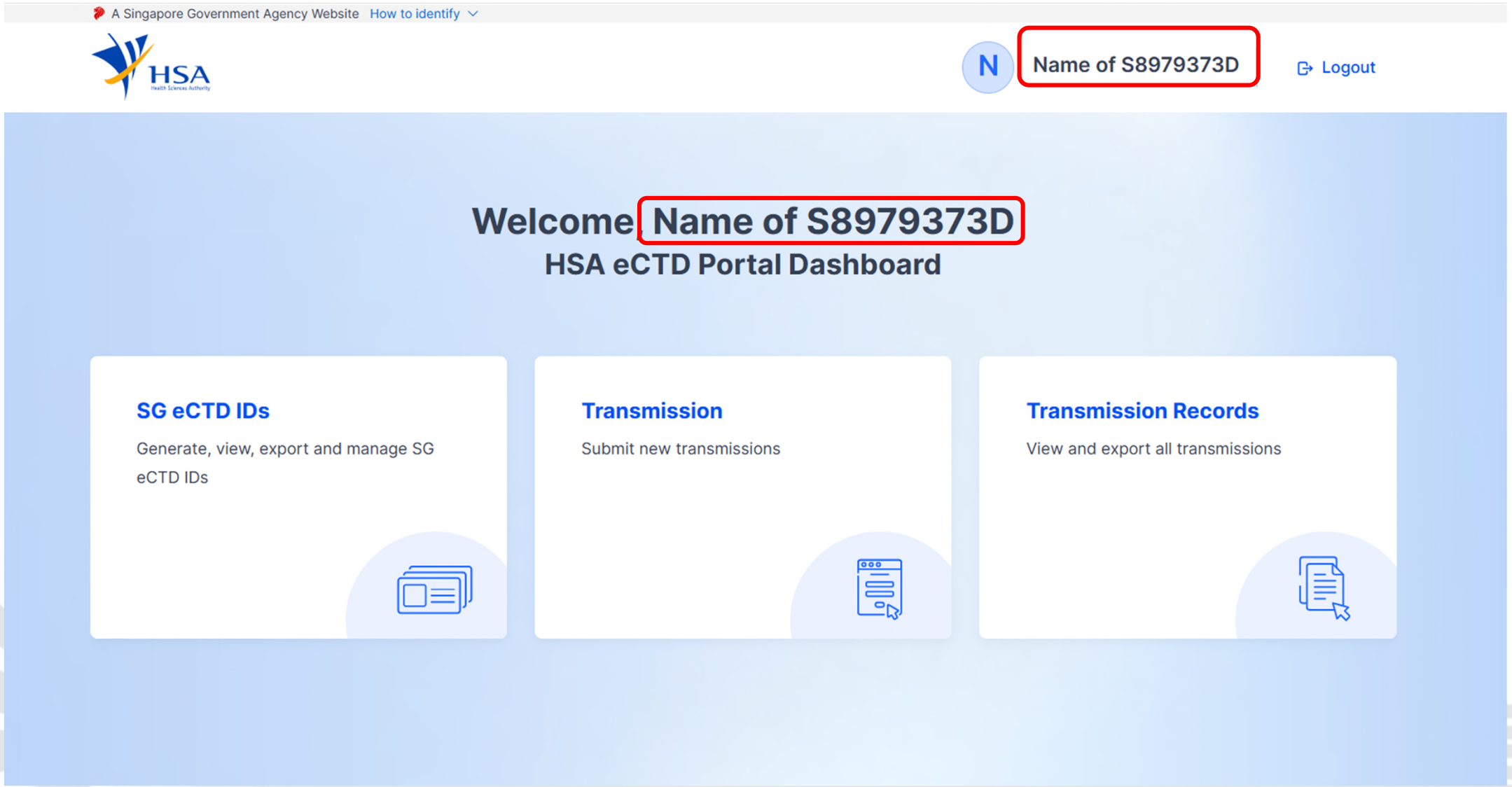
Dashboard



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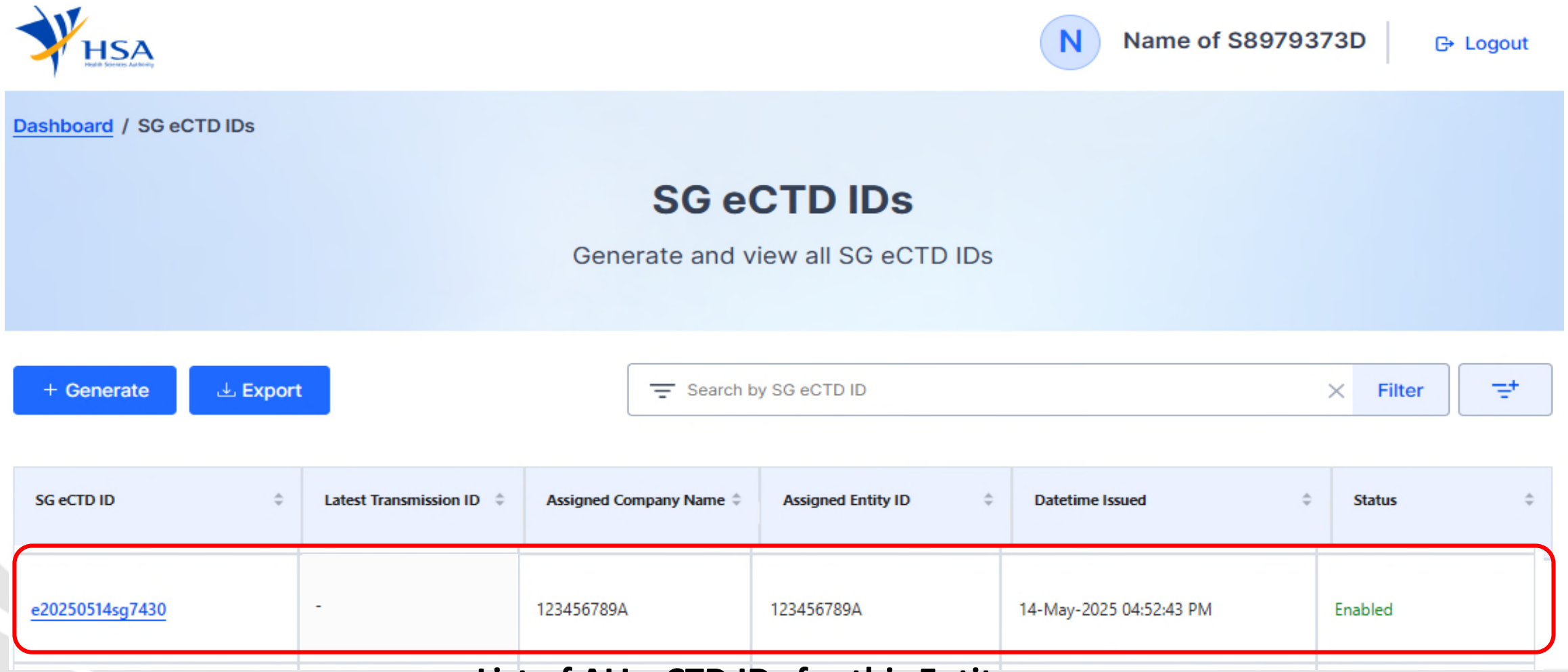
SG eCTD IDs



List of ALL eCTD IDs for this Entity

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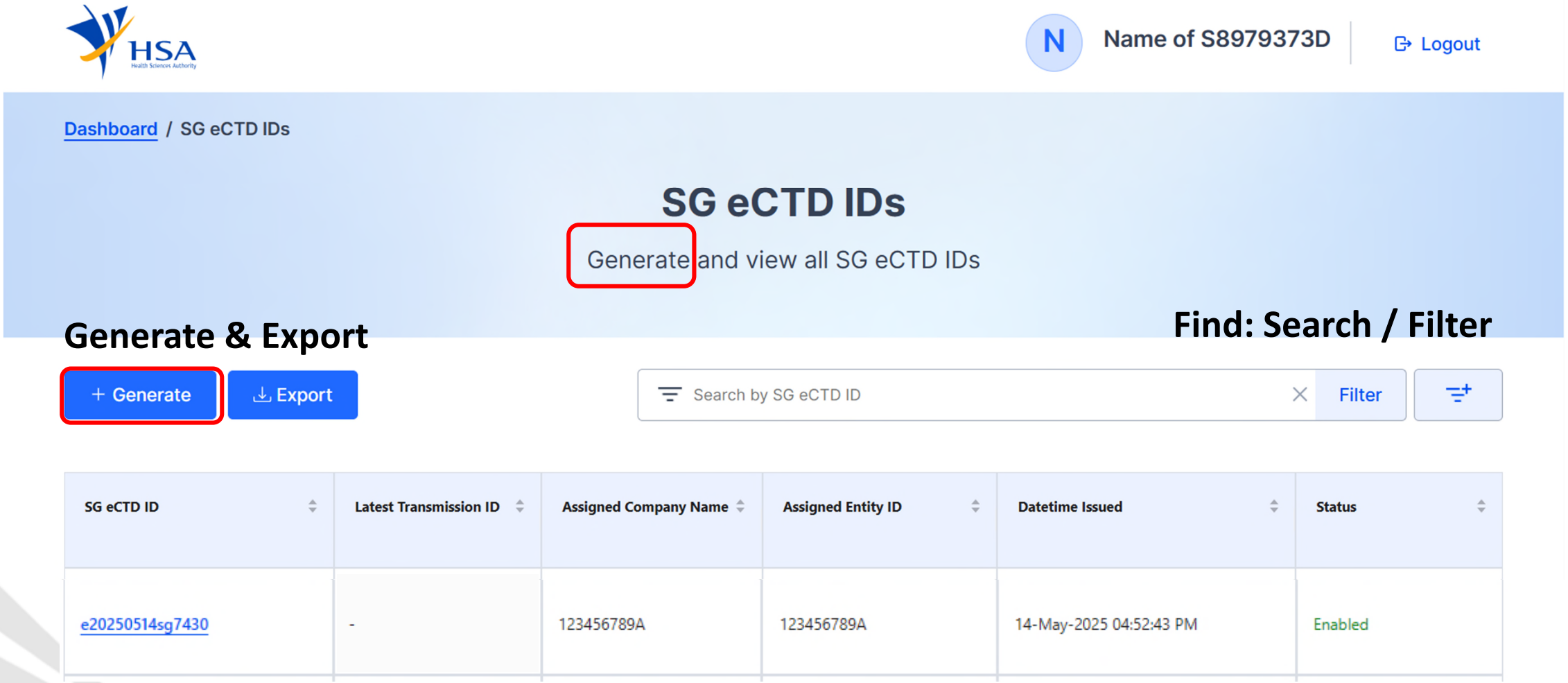
SG eCTD IDs



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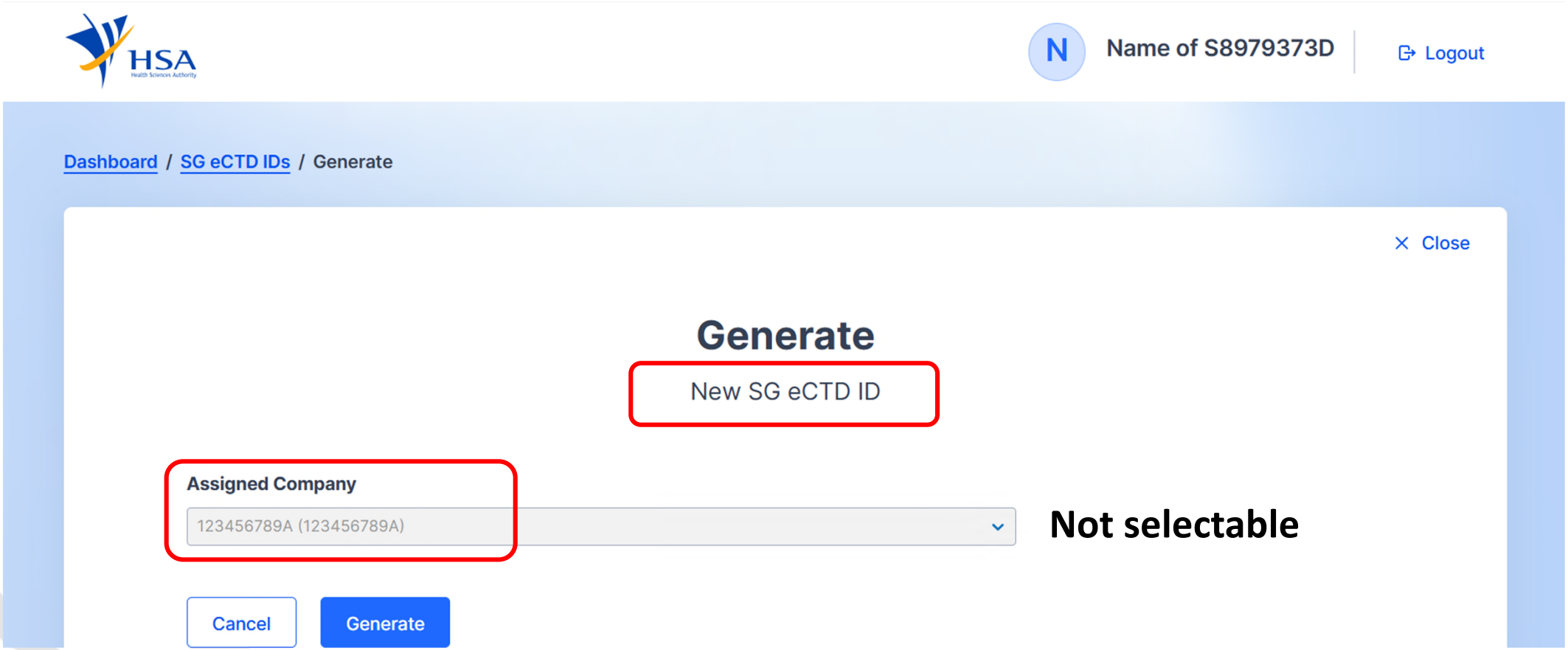
Generate eCTD ID



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New eCTD ID Generated (and Issued)

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Search eCTD ID

SG eCTD ID	Latest Transmission ID	Assigned Company Name	Assigned Entity ID	Datetime Issued	Status
e20250527sg7434	-	123456789A	123456789A	27-May-2025 03:57:50 PM	Enabled
e20250523sg7433	-	123456789A	123456789A	23-May-2025 04:39:36 PM	Enabled
e20250514sg7432	TID17490970397845876	123456789A	123456789A	14-May-2025 04:53:31 PM	Enabled
e20250514sg7431	TID17488132048395863	123456789A	123456789A	14-May-2025 04:53:24 PM	Enabled
e20250514sg7430	-	123456789A	123456789A	14-May-2025 04:52:43 PM	Enabled

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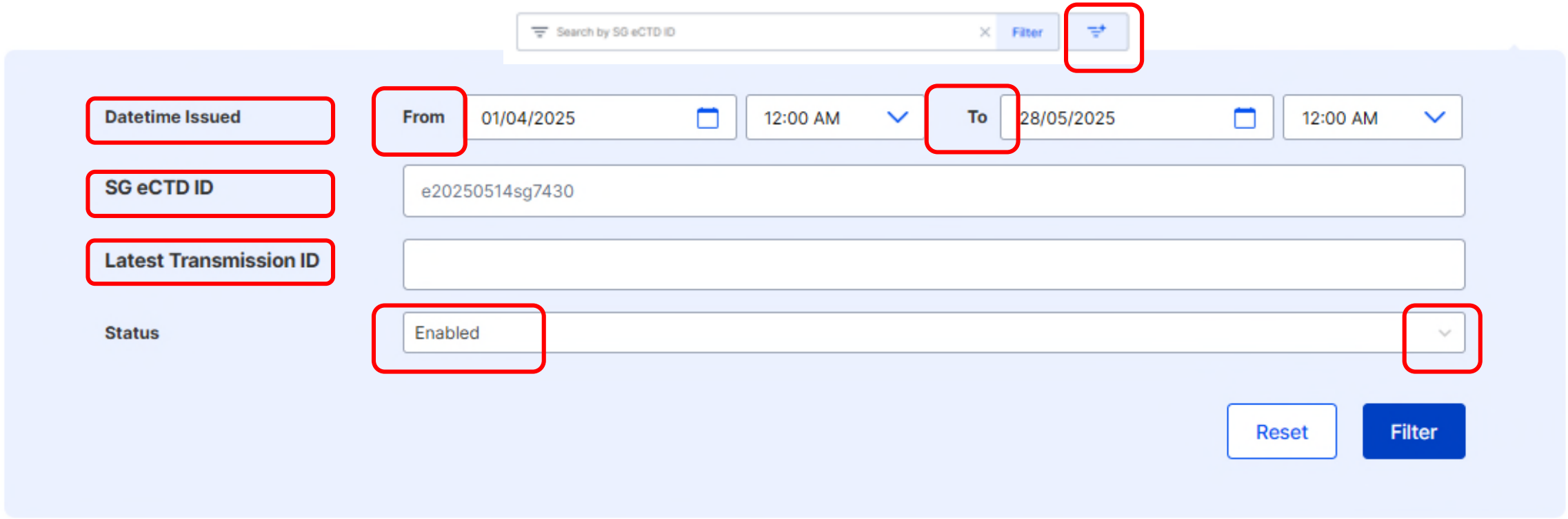
Search eCTD ID



SG eCTD ID	Latest Transmission ID	Assigned Company Name	Assigned Entity ID	Datetime Issued	Status
e20250514sg7430	-	123456789A	123456789A	14-May-2025 04:52:43 PM	Enabled

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End Demonstration

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Key Points – The eCTD ID

Reminders

- Required to file an eCTD application (sequences) with HSA.
- Issued by the eCTD Portal.
- One eCTD ID per eCTD Application.
- Once used for an Application, cannot change eCTD ID.
- eCTD IDs do not expire, but they can be disabled.

HSA Capability

- Can transfer an eCTD ID.
- Can disable an eCTD ID.

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STEP 2 – Prepare your eCTD Package

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eCTD Portal Terminology

eCTD Sequence (“Sequence”)

- An eCTD Sequence is one unit of an eCTD Application.
- A Sequence belongs to a Submission which belongs to an Application.
- Sequences are what are created by the Applicant and what are reviewed by HSA.

Submission Package (“Package”)

- A Package is what is filed through the Portal by the Applicant.
- The Package is a single eCTD Sequence nested under the Application Folder and stored in a ZIP format.

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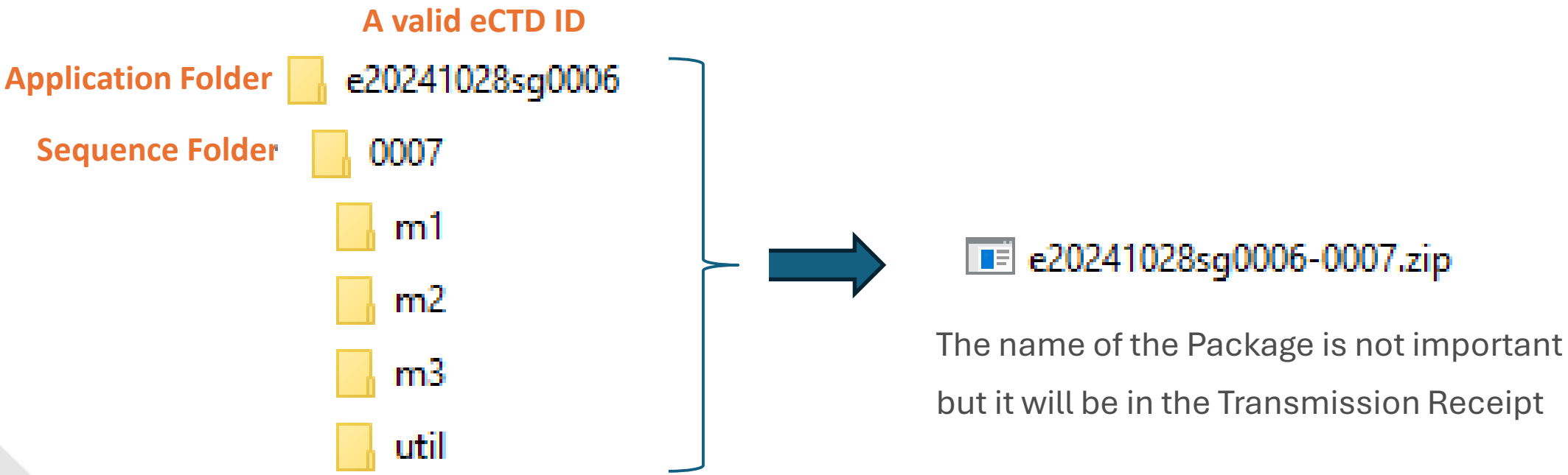
The Package

A **single eCTD Sequence** folder for a **single eCTD Application,** encapsulated as **ZIP file.**



The name of the Package is not important

but it will be in the Transmission Receipt

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STEP 3 – Transmission

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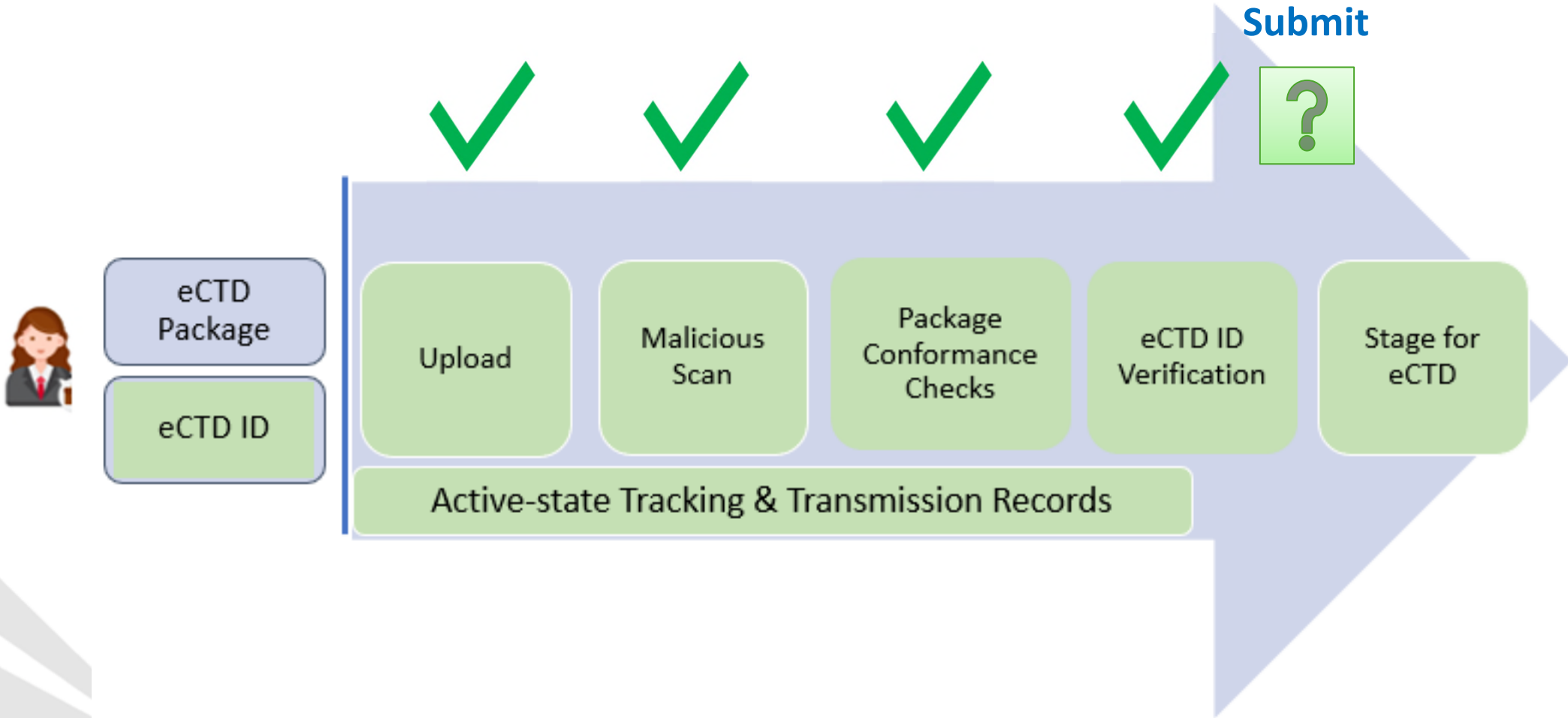
Portal - A Series of Checks



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Transmission Expectations

Expected of Applicant in advance of transmitting a Sequence to HSA for review

1. Use of a valid eCTD ID.
2. Malicious Scan.
3. Complete eCTD Validation.

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Key Points - Transmission

- ✓ You can replace the Package as many times as needed.
- ✓ All Packages will go through the *Package Checks* process.
- ✓ You can leave a Package Pending for Submission for 48-hours.
- ✓ You can Abort a Transmission at any time prior to Submitting.
- ✓ You must explicitly Submit the Package after all Package Checks by the Portal have completed.
- ✓ Once submitted, the Transmission cannot be cancelled.
- ✓ You cannot retrieve your Package from the Portal

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Demonstration

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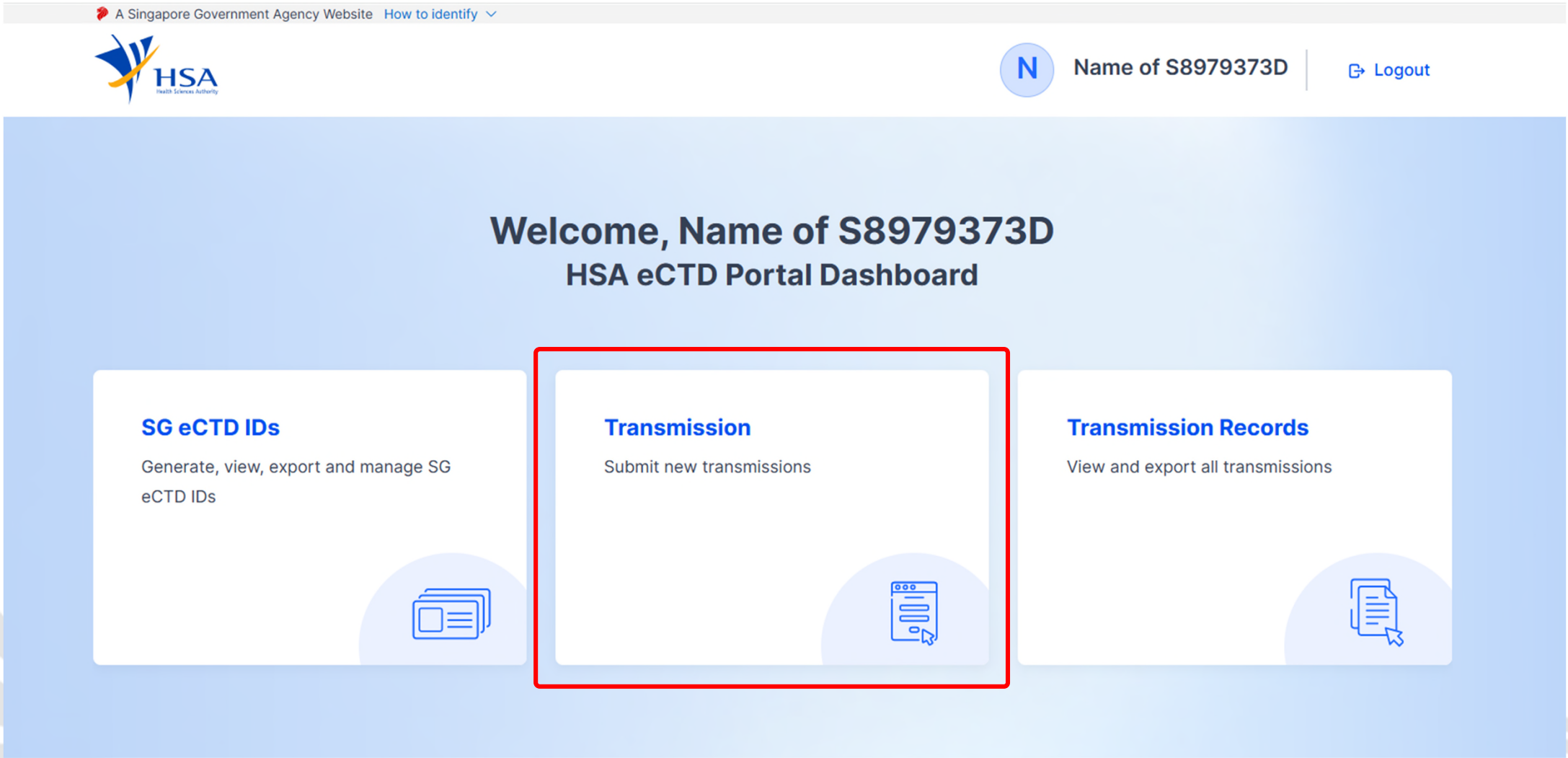
Transmission



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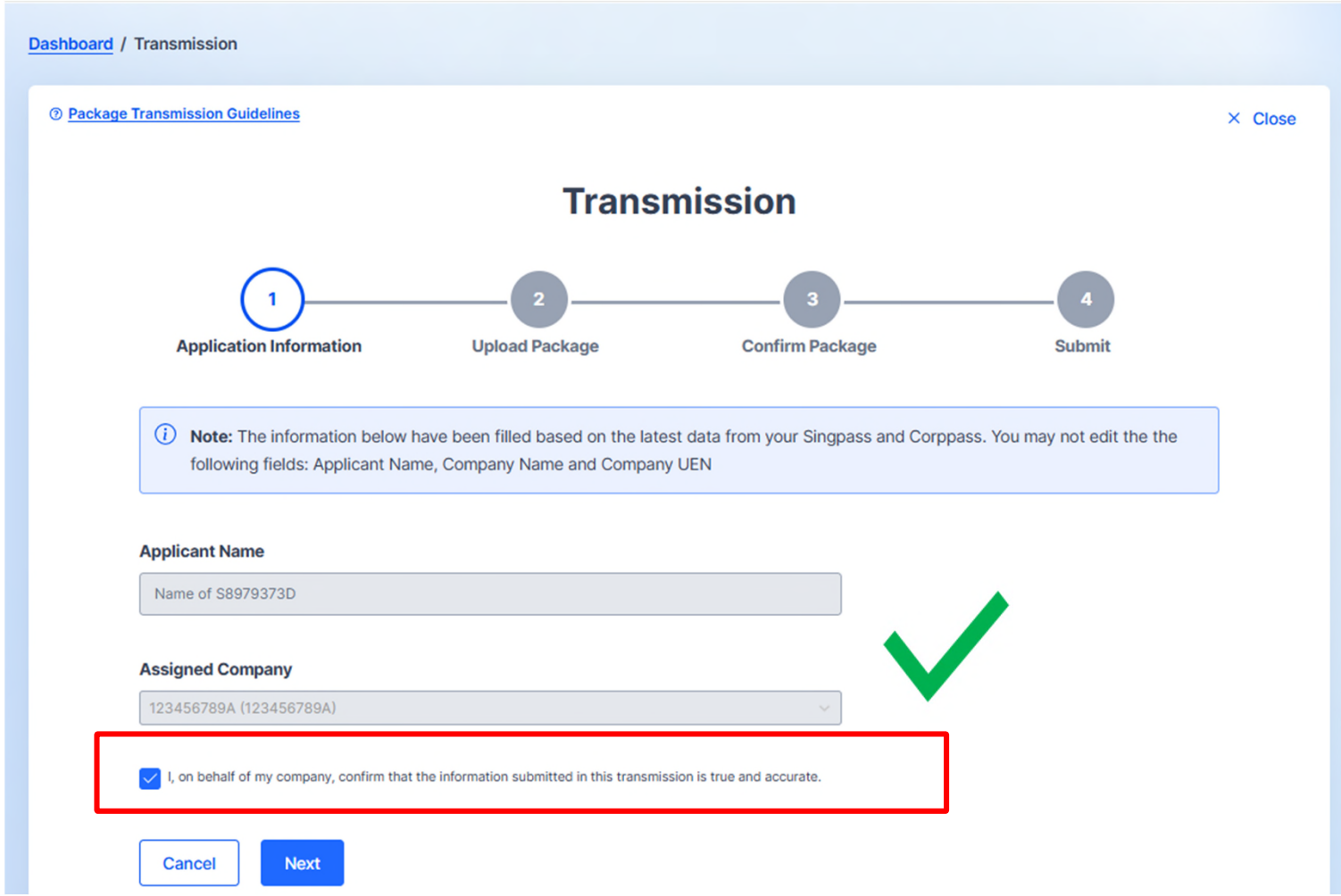
Transmission – Step 1



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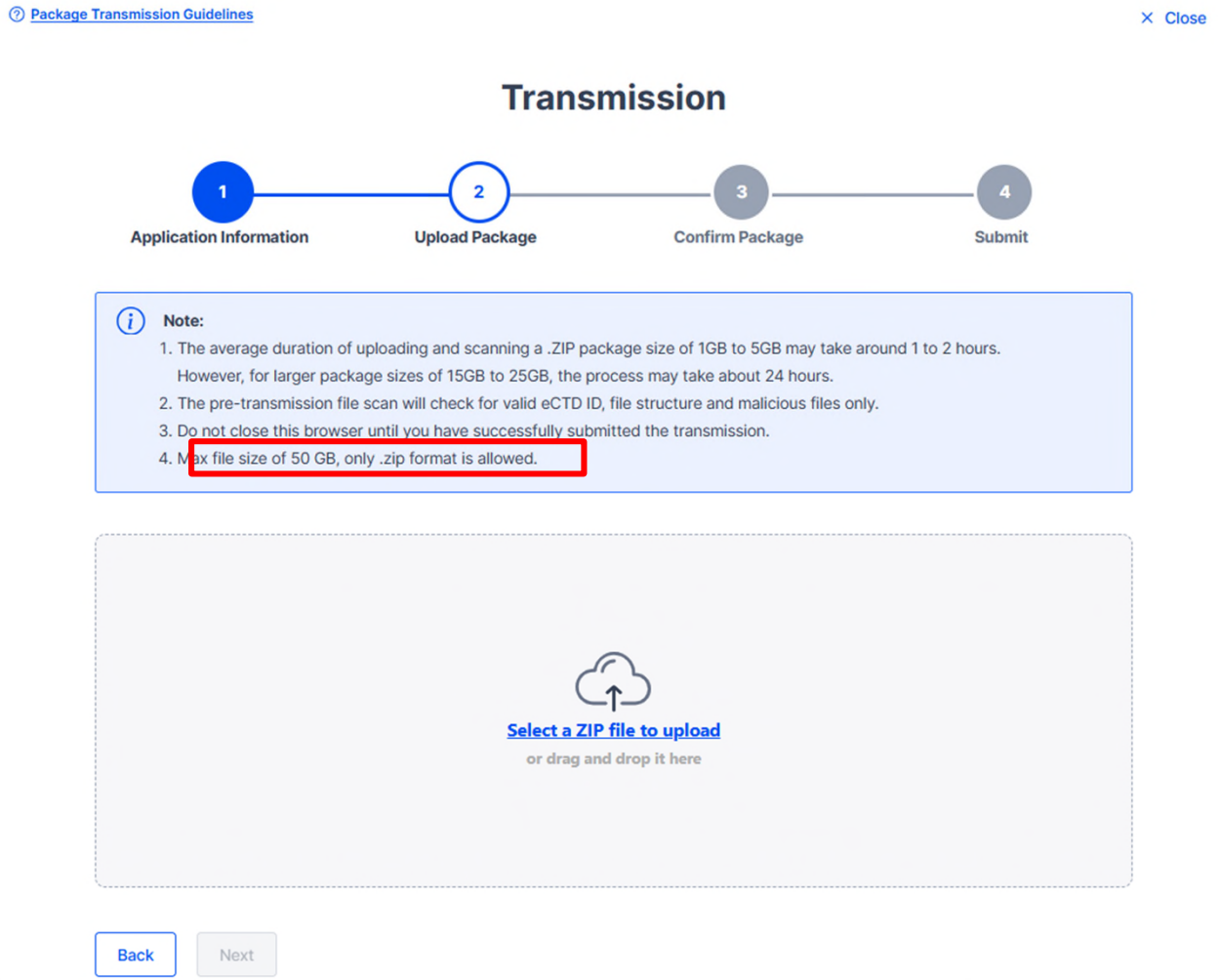
Transmission – Step 2



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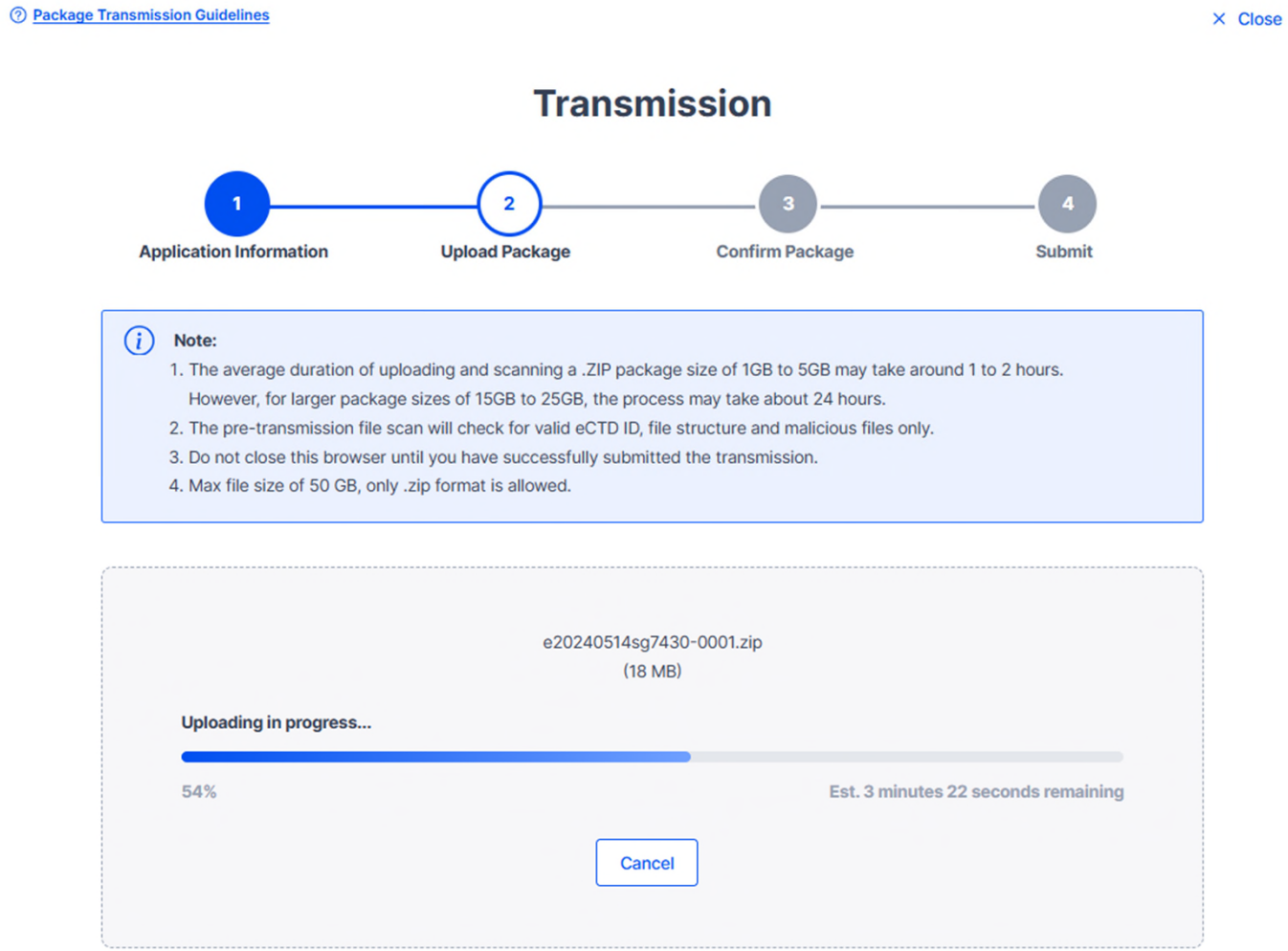
Transmission – Step 2



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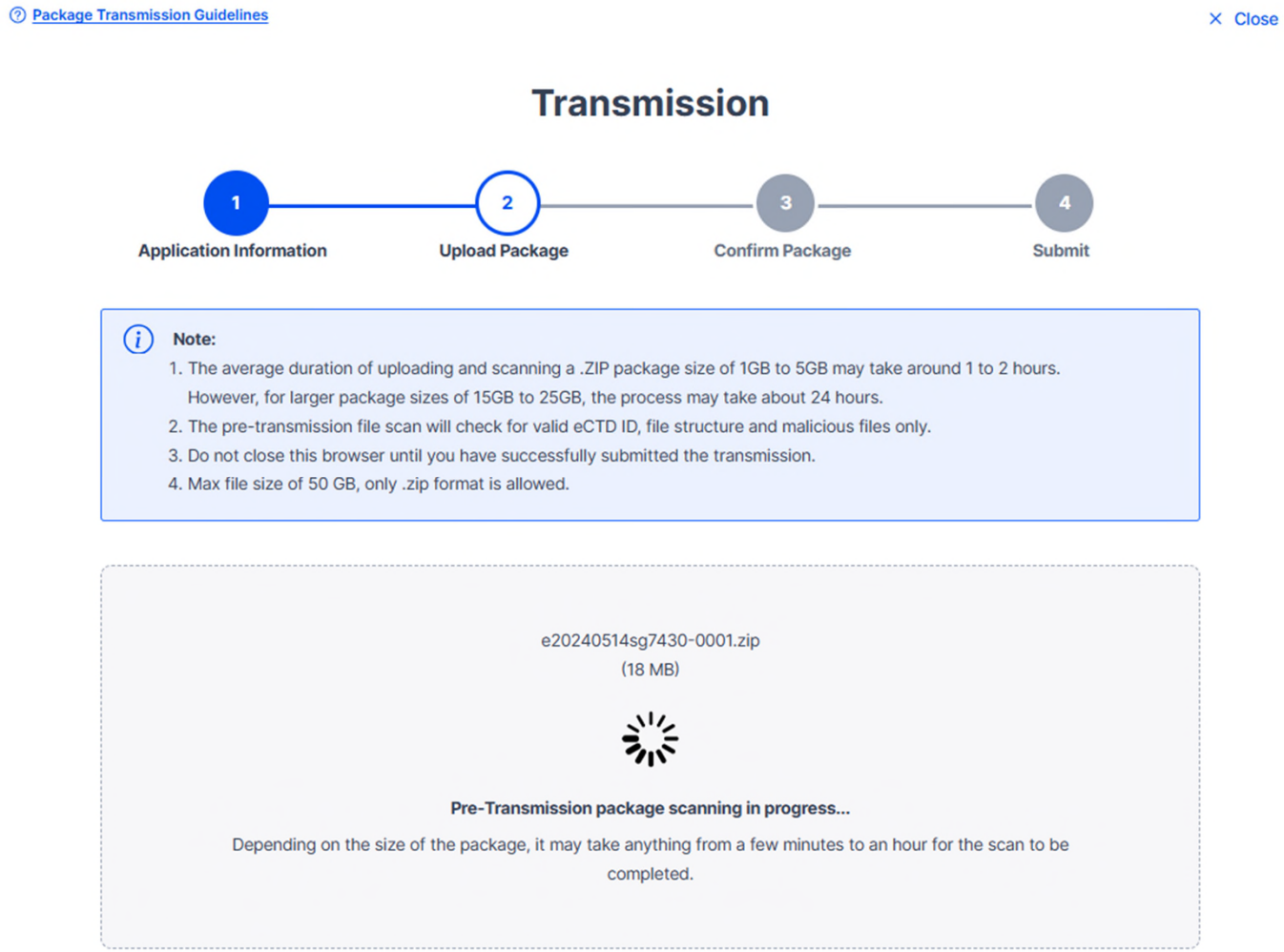
Transmission – Step 2



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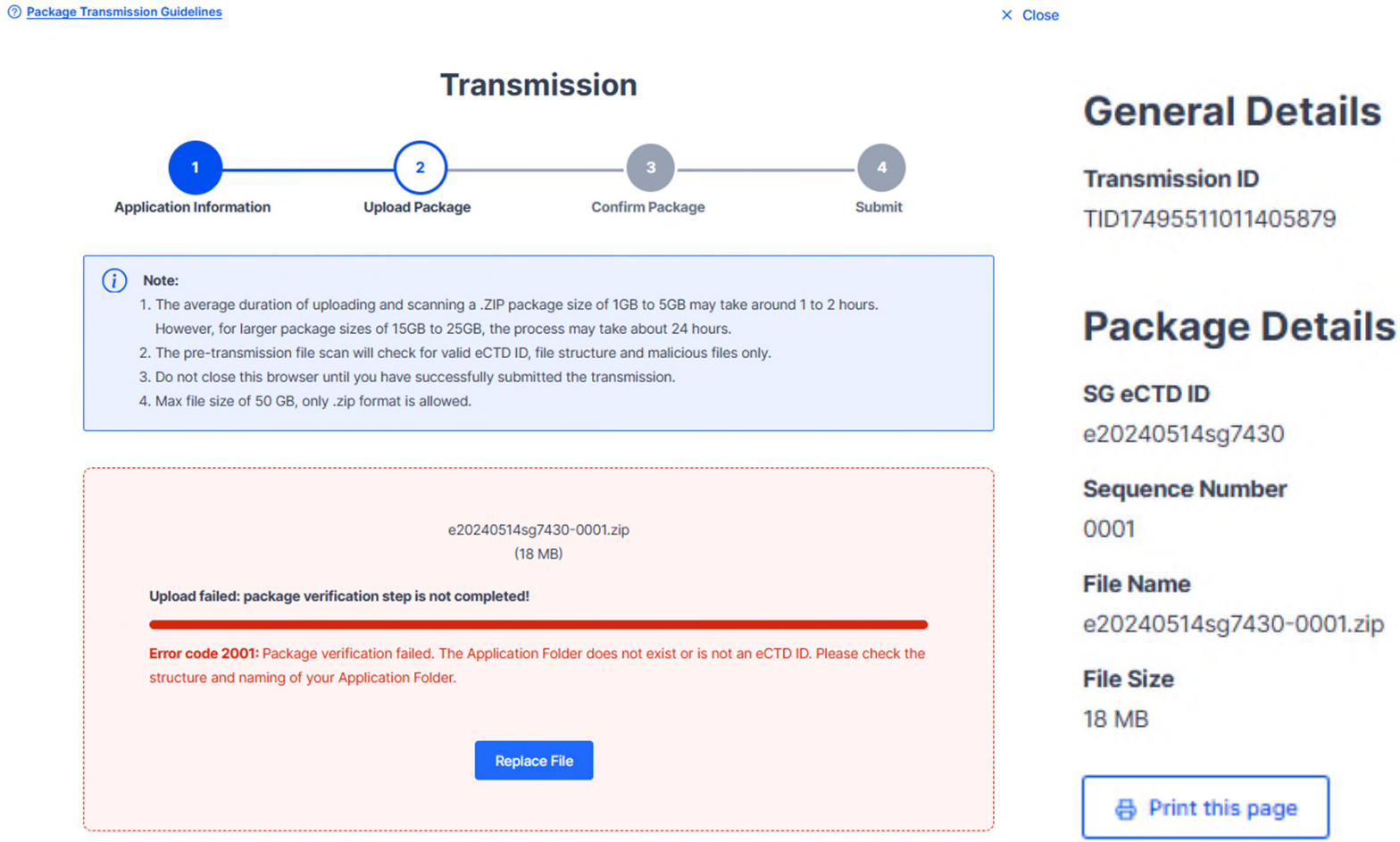
Portal: Transmission – Step 2

Example 1: Fail eCTD ID Verification



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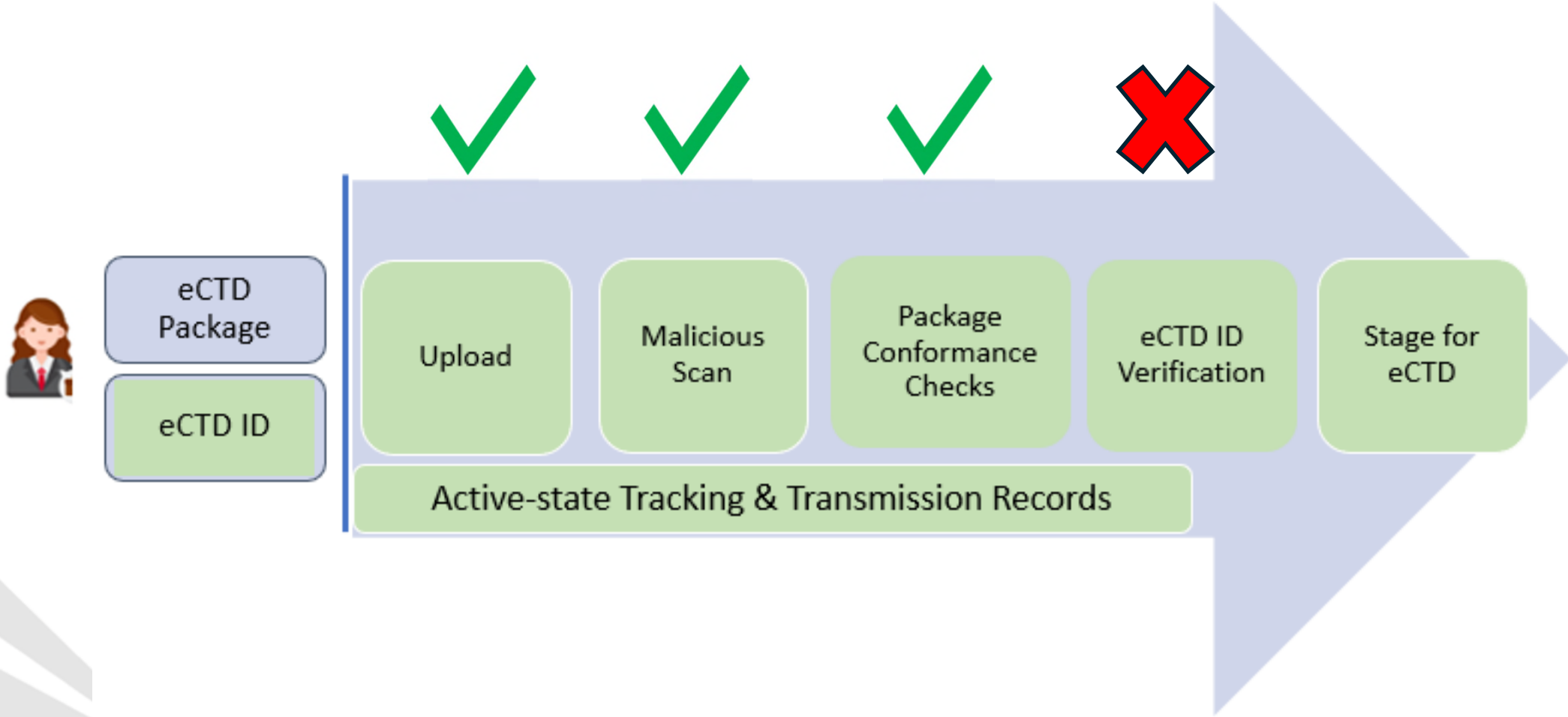
Portal: Fail eCTD Verification



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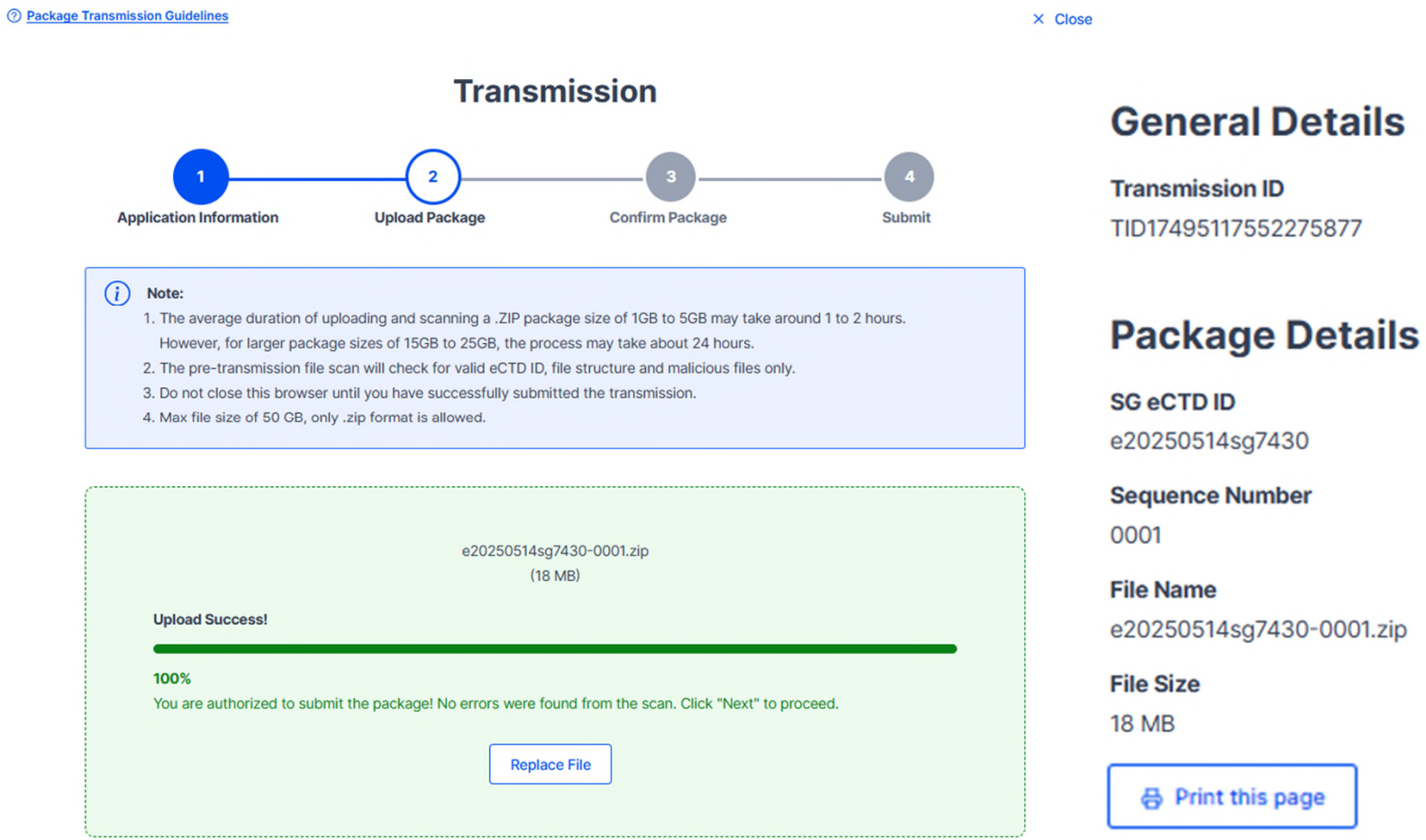
Portal: Transmission – Step 3

Example 2: Upload Success!



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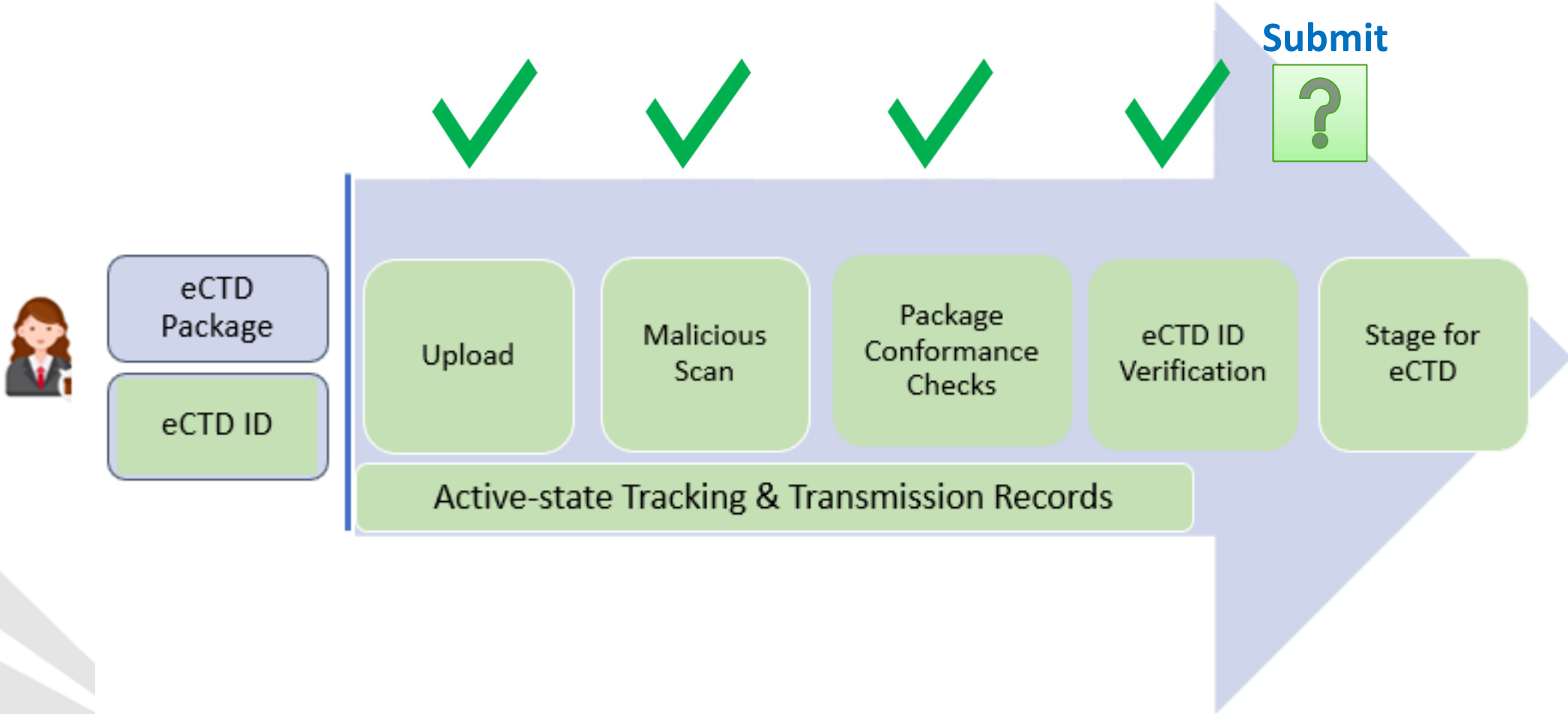
Portal: Fail Conformance Checks



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Portal: Transmission – Step 3

Example 3: Upload Success – Review & Confirm

GENERAL DETAILS

Transmission ID

TID17495117552275877

Application Information

Applicant Name

Name of S8979373D

Applicant Company

123456789A

Entity ID

123456789A

Submitted By

Name of S8979373D

Package Details

SG eCTD ID

e20250514sg7430

Sequence Number

0001

File Name

e20250514sg7430-0001.zip

File Size

18 MB

Back

Submit

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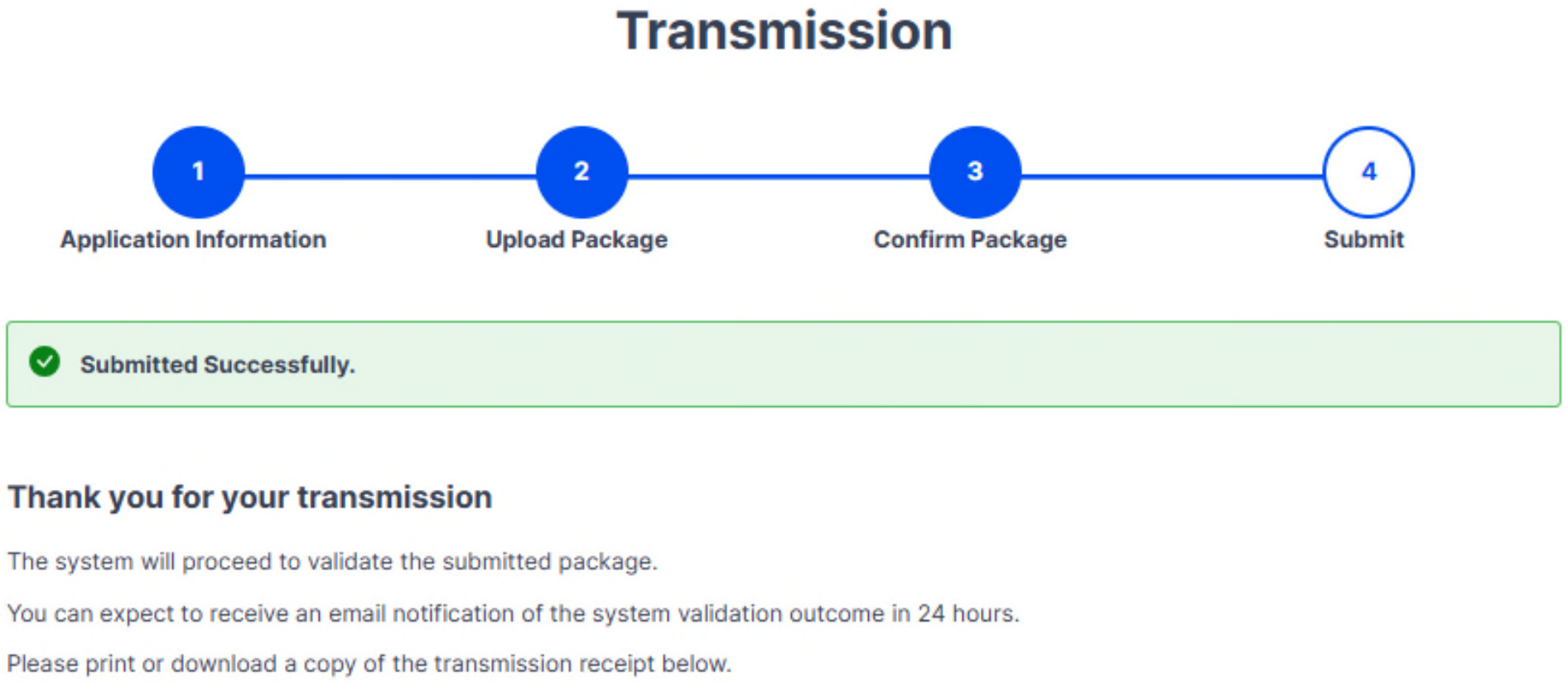
Portal: Transmission – Step 4

Example 3: Submit



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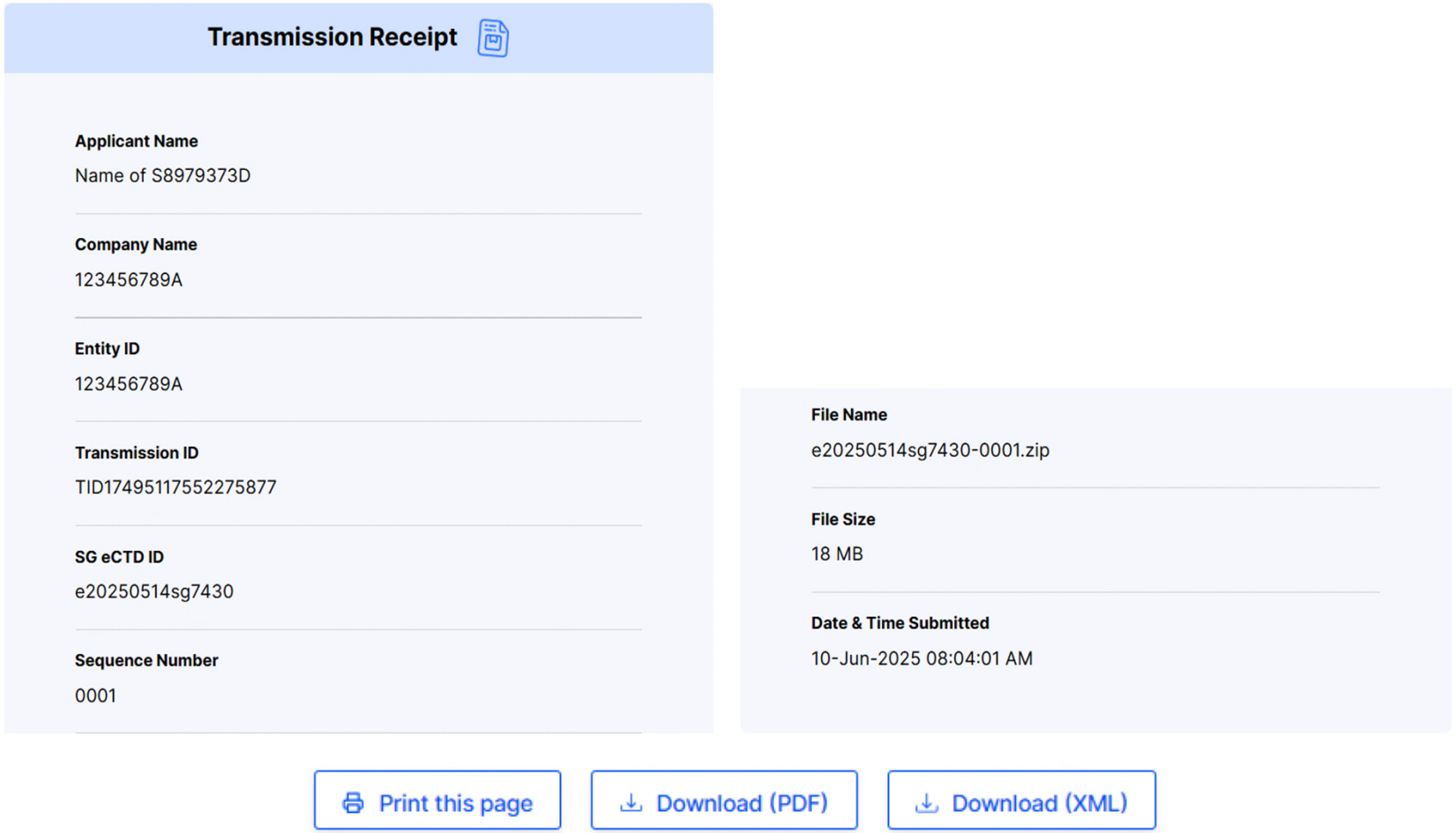
Portal: Transmission Receipt



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End Demonstration

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Review Transmission

Step 1 – Review Applicant Information / Accept "True and Accurate"

Step 2 – Upload (and Check) the Package

a) Malicious Scan – Pass / Fail

b) Package Conformance – Pass / Fail

c) eCTD ID Verification Check – Pass / Fail

If any checks Fail, the Package must be replaced or the Transmission Cancelled

Step 3 – Confirm Package

Step 4 – Submit Package

Transmission Receipt

Staged for the eCTD System

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The Transmission Receipt

- ✓ After Submitting, you can download a Transmission Receipt, or you can retrieve it later.
- ✓ Transmission Receipt includes:
  - Applicant Name (i.e. Submitted by)
  - Applicant Company Name, Entity ID
  - Transmission ID (TID …)
  - SG eCTD ID and Sequence Number
  - Package File Name and File Size
  - Date-time Submitted
- ✓ The Transmission Receipt is not the official date-time receipt by HSA. It is evidence of transmission, useful for your internal records and communication with HSA, if needed. The official date-time receipt for HSA is when the Sequence passes eCTD Validation.

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STEP 4 – Transmission Records

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Transmission Records

The Transmission Records Module provides visibility to both active and prior Transmissions

- ✓ The current status of any active Transmission.
- ✓ Log of all Transmissions by your company.
- ✓ Across all eCTD IDs assigned to your company.
- ✓ For each Transmission (Submitted or not), it provides access to Transmission record.
- ✓ For all Submitted Transmissions, it provides access to the Transmission Receipt.

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Demonstration

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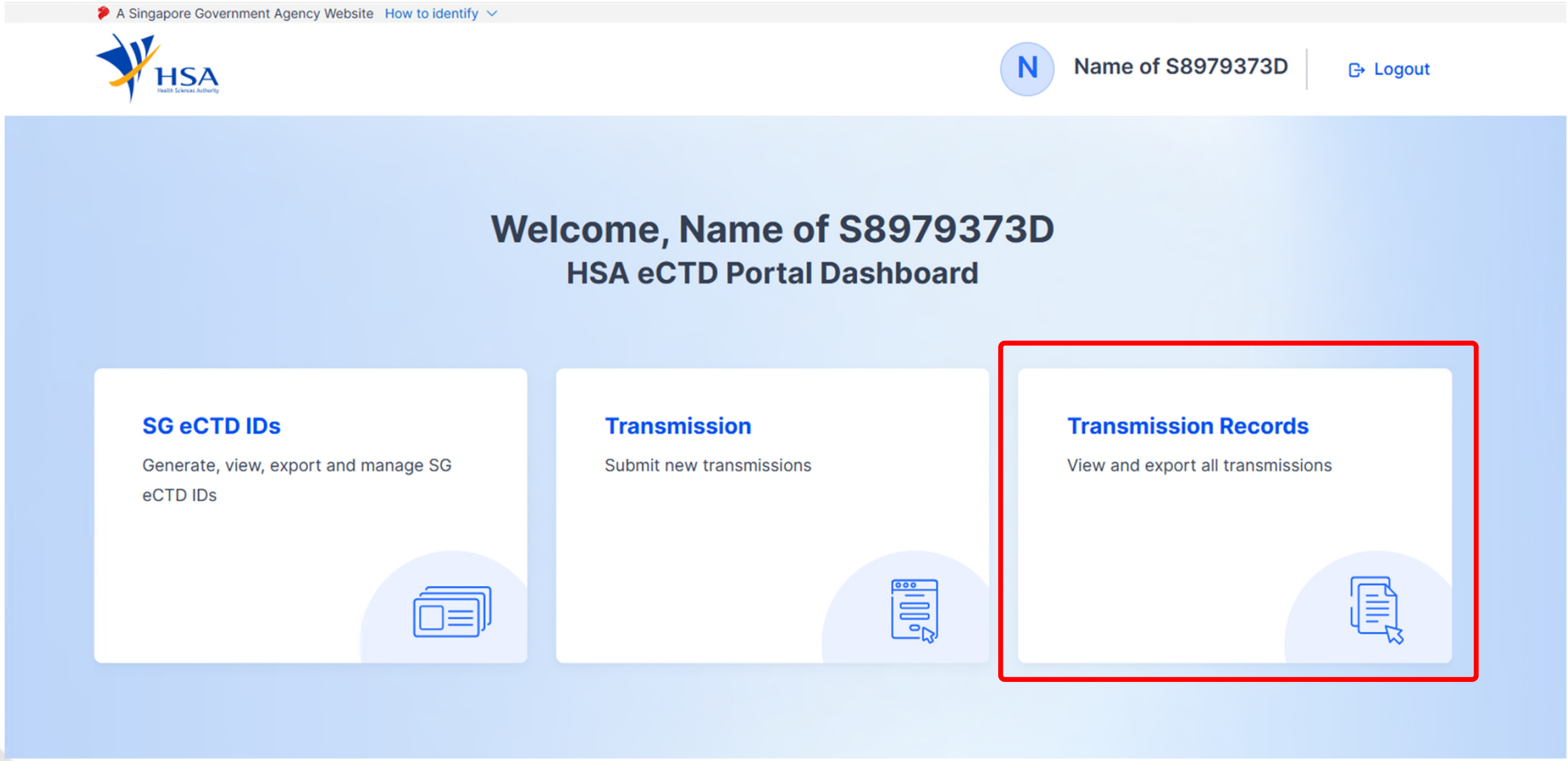
Transmission Records



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Transmission Records

Export

Filter by Transmission ID

Filter

Transmission ID	SG eCTD ID	Sequence Number	Company Name	Entity ID	Applicant Name	Status	Datetime Submitted	Status Last Updated
TID17495117552275877	e20250514sg7430	0001	123456789A	123456789A	Name of S8979373D	Routing to eCTD System	10-Jun-2025 08:04:01 AM	10-Jun-2025 08:04:01 AM
TID17490970397845876	e20250514sg7432	0001	123456789A	123456789A	Name of S8979373D	Duplicate Sequence	05-Jun-2025 12:20:57 PM	05-Jun-2025 01:01:03 PM
TID17488159590625864	e20250514sg7432	0001	123456789A	123456789A	Name of S8979373D	Passed Validation	02-Jun-2025 06:14:50 AM	02-Jun-2025 06:19:42 AM
TID17488132048395863	e20250514sg7431	0001	123456789A	123456789A	Name of S8979373D	Passed Validation	02-Jun-2025 05:27:48 AM	02-Jun-2025 05:34:49 AM

A

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SG eCTD ID Details

Transmissions by eCTD ID

A

SG eCTD ID Details

Assigned Company Name

123456789A

Assigned Entity ID

123456789A

Datetime Issued

14-May-2025 04:52:43 PM

Status

Enabled

Transmission IDs

Transmission ID	Status	Datetime Submitted
TID17495117552275877	Routing to eCTD System	10-Jun-2025 08:04:01 AM

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Transmission Detailed Information

Example of transmission passed validation

Time	Status	Description
03-Jun-2025 09:10:55 AM	Passed Validation	The package has passed eCTD technical validation.
03-Jun-2025 09:10:03 AM	Pending Validation	The package has successfully been downloaded to the eCTD system and unpacked. The system will now perform the technical validation.
03-Jun-2025 09:04:03 AM	Processing Package in eCTD System	The package has successfully been routed to the eCTD System and is currently undergoing processing.
03-Jun-2025 08:57:28 AM	Routing to eCTD System	The package is now available to the eCTD system for routing.
03-Jun-2025 08:57:28 AM	Submitted Transmission	The Transmission has been submitted.
03-Jun-2025 08:55:51 AM	Pending Submission	The package check has successfully been completed and passed with no error found. The System is currently pending the Authorised User to submit the Transmission.

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Transmission Detailed Information

Example of transmission failed package check

Time	Status	Description
15-Apr-2025 06:00:44 AM	Aborted Transmission	The Transmission has been aborted.
15-Apr-2025 05:54:26 AM	Failed Package Check	Permission-related, 2001, Package verification failed. The Application Folder does not exist or is not an eCTD ID. Please check the structure and naming of your Application Folder.
15-Apr-2025 05:54:18 AM	Pending Package Check	The package malicious scan has successfully been completed and passed with no error found. The System will now perform the package check.
15-Apr-2025 05:54:01 AM	Pending Package Malicious Scan	The upload has successfully been completed. The system will now perform the package malicious scan.
15-Apr-2025 05:53:53 AM	Pending Package Upload	The Transmission has been initiated and is pending the Authorised User to upload a package.

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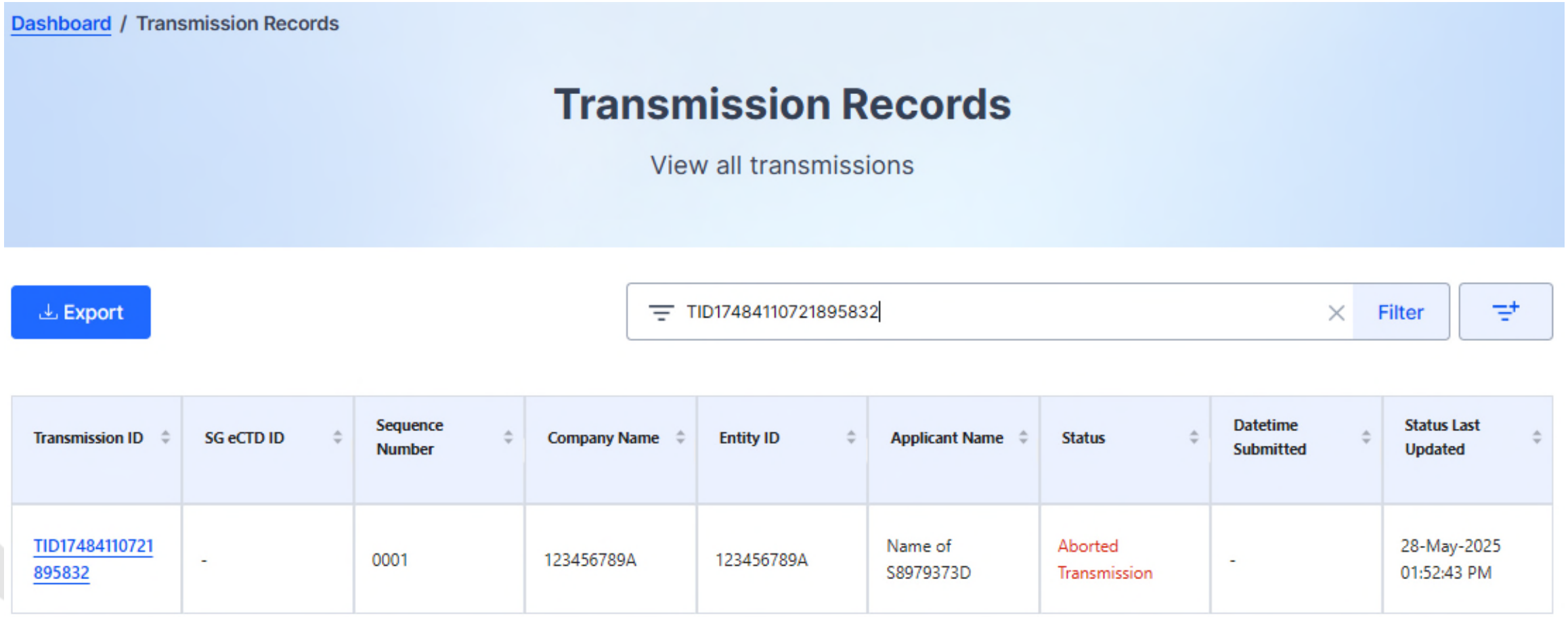
Search by Transmission ID



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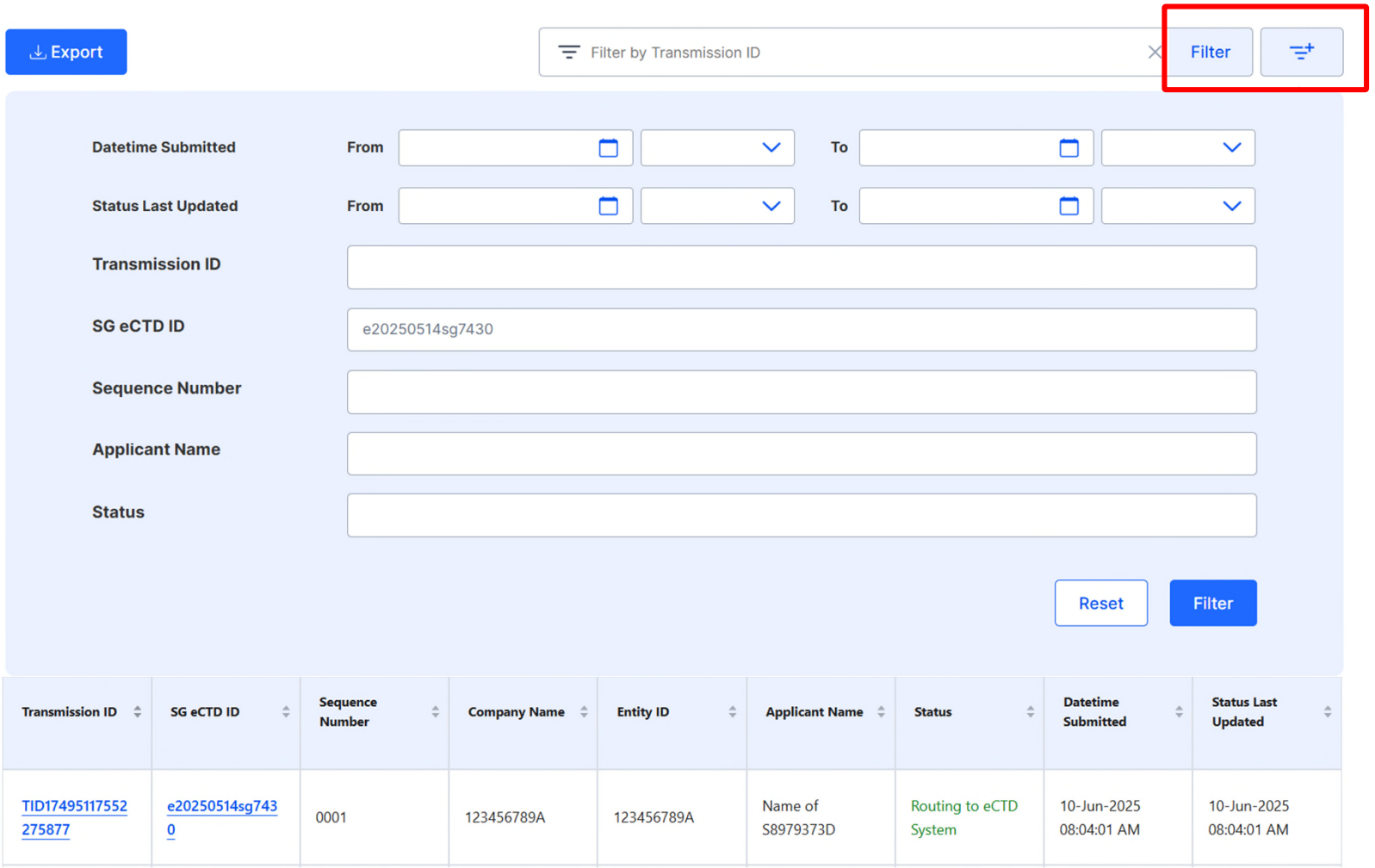
Search by eCTD ID



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End Demonstration

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STEP 5 – After Transmission

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eCTD Validation Outcome

Case: Passes Validation

- Sequence is accepted for Screening by HSA
- Portal End State will reflect Passed Validation
- Official date-time of receipt by HSA
- All Contacts in the Envelope / Administrative Information of the Sequence will receive an email notification that Sequence Passed eCTD Validation
- The eCTD Validation Report is not attached to the email

Case: Fails Validation

- The Sequence is not reviewed by HSA
- Portal End State will reflect Failed Validation
- All Contacts listed in the Envelope / Administrative Information of the Sequence will receive an email notification that the Sequence Failed, along with the Validation Report
- Applicant should correct the Sequence and transmit it through the Portal again.

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Key Points - eCTD Validation

Reminders - eCTD Validation and the Portal

- ✓ eCTD Validation Outcome is reported in the Portal.
- ✓ eCTD Validation is not completed by the Portal.
- ✓ The eCTD Validation Report is not available through the Portal.
- ✓ Portal users and the Contacts in the Envelope of a Sequence may be two different groups.
- ✓ The Portal does not send any emails. Email notification regarding Validation outcome are sent by the eCTD System.

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Example - Email to Sequence Contacts

From: HSA eCTD Systems Team
Subject: Sequence failed technical validation (e20250528sg0710 - 0051)

LORENZ Automator – Sequence Intake Process

Dear Applicant,

The following Sequence has failed the eCTD technical validation and is therefore rejected.

Application: e20250528sg0710 | Sequence 0051

Validation

Job Status: Completed

Validation Result

Information: 3; Warning: 0; Error: 3

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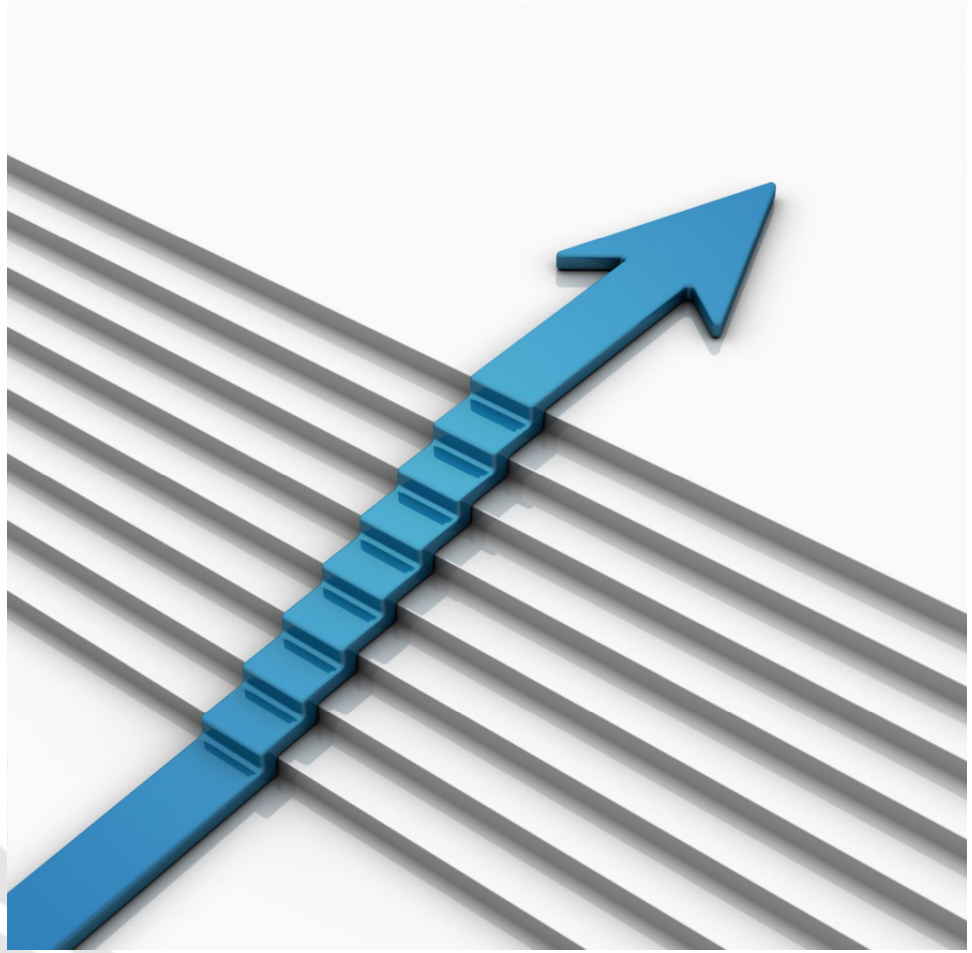

Next Steps in eCTD Implementation in Singapore

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eCTD Test Submission Period

The eCTD portal will launch Q3/Q4 2025 for test submission.

Please prepare test submission package following SG-eCTD Specification v1.0.

The test submission period will last for 6 months.

All information provided during test submission will not be reviewed and will be deleted as the end of test submission period.

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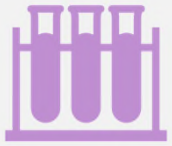
Dossier Submission in eCTD Format

Dossier in eCTD format will be accepted from Q2 2026.



The initial launch will be open to new drug applications, generic drug applications, drug master file submissions.

For companies interested in converting the current registered products to eCTD format, please refer to the guidance in SG-eCTD Specification.

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Question and Answers

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General Questions

What is the eCTD portal?

The eCTD portal is designed for the electronic transmission of eCTD packages and submissions.

Who can use the eCTD portal?

Both local and foreign users can use the eCTD portal as long as they have registered for Corppass and have been assigned the necessary roles.

Is Corppass required for using the eCTD portal?

Yes, Corppass is required for logging into the eCTD portal. Foreign users need to apply for a Singpass foreign user account (SFA) and be assigned roles within Corppass. Please refer to https://ask.gov.sg/corppass if you have any further questions on how to register for Corppass or SFA.

Is there a fee for applying for Corppass or SFA?

No, there is no fee for applying for Corppass or SFA.

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When will the eCTD submission be mandatory?

At initial launch, the use of the eCTD for dossier submission is optional. HSA will review the adoption rates, engage the industry for feedback and roll out the subsequent phases in the long run.

Can consultants submit eCTD packages through the portal on behalf of companies, including DMF submissions? What are the requirements?

Yes, consultants can submit eCTD packages, including DMF submissions, provided that:

- They are registered as authorised Corppass users
- The company's Corppass admin has granted them proper access
- They understand that their submissions are considered official company actions since they are acting as authorised representatives

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Technical Questions

What is the maximum size limit for a zip file in the eCTD portal?

The maximum size limit for a zip file is 50 GB.

Do companies need eCTD software for submitting packages?

Companies do not necessarily need eCTD software to compile eCTD packages as there are different options available which includes but not limited to commercial eCTD publishing software, in-house development team or regulatory service providers. For validating an eCTD package, there are different validation tools available as well.

How long does the eCTD validation process take?

The eCTD validation process typically completes within 24 hours.

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What happens if eCTD package verification fails?

The portal will provide error codes and details regarding the issue. Users can refer to the online manual for explanations of the error codes and troubleshooting guidance.

Can multiple users work simultaneously on the same eCTD ID?

Yes, multiple users can submit Sequences for different regulatory activities simultaneously under the same eCTD ID.

What are the recommended times for submitting an eCTD sequence?

Currently, we do not have data on peak submission times. Users are encouraged to submit as per their schedule during the test submission period.

What happens if there is a need to resubmit an updated part of the eCTD?

When updates are needed, companies should prepare a new sequence, include the corrected document and use the appropriate lifecycle operation to replace the incorrect document.

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Product and Submission Questions

Can foreign entities apply for NDAs?

No, NDA submissions in PRISM must be made through a local applicant. Foreign entities cannot apply directly.

What is the process for handling baseline submissions for products that are already registered?

When transitioning from non-eCTD to eCTD format, companies can submit baseline submissions by:

- Including a cover letter with an information summary
- Choosing to submit either a partial or complete baseline dossier
- Providing a declaration confirming no changes from the currently registered dossier

Are companies required to convert existing product registrations to eCTD format?

No, conversion is not mandatory as eCTD submission is currently optional for dossiers.

Is there a deadline for submitting baselines of already registered products?

No deadline has been set. Companies have the flexibility to convert their registered products to eCTD format at their own pace.

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How can companies provide proof of submission for stringent client requirements, i.e., detailed list of documents submitted?

The portal currently does not provide detailed breakdowns. Companies should provide additional details about their requirements for our review.

Why is it necessary to manually generate and tag the eCTD ID?

The manual generation and tagging of the eCTD ID is an essential part of the submission process because companies need to:

- Generate the eCTD ID at the start of the process
- Include this ID within the eCTD package
- Connect it to the corresponding PRISM application form.

Is it possible to customise the eCTD ID by adding tags or renaming it with our own reference, such as a product name?

No, this is not possible. You must use the eCTD ID exactly as it is generated by the HSA eCTD Portal. This original ID is essential for successful uploading of eCTD submissions and proper system validation processes.

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How do I link the eCTD ID to my PRISM form submission? Do I need to submit Module 1 documents in PRISM?

You may attach a document in the PRISM form under "CD Submission" indicating the use of the eCTD ID for the application. When using eCTD, you do not need to submit Module 1 documents in PRISM, as they will be included in your eCTD submission

How is the eCTD ID assigned to a specific product?

The company has the flexibility to determine which eCTD ID corresponds to which product. This association is established when the company includes the eCTD ID in the application envelope.

Will eCTD ID be disabled under certain scenarios?

Yes, eCTD ID will be disabled when the product registration or drug master file is cancelled.

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Can a company register the same product with different concentrations under one eCTD Application?

Companies can decide whether to submit under one eCTD application or use separate applications or different strengths.

The choice should be based on the company's product lifecycle management strategy.

After product approval, do we submit variation changes via PRISM or eCTD portal? Or we only submit the updated dossier when the variation is approved in PRISM?

The regulatory filing and approval process will remain in PRISM. Hence, the company should file the variation application in PRISM and submit the eCTD through the eCTD portal to support the variation application. There's no need to submit the dossier in PRISM when using eCTD.

Important note: Once you begin using eCTD for a product, all future submissions for that product must continue using the eCTD format. This is known as the "Once eCTD, always eCTD" principle.

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Are Drug Master File (DMF) holder and product registrants required to use the same eCTD ID to submit DMF documents?

No, separate eCTD IDs must be used. Here's how the submission process works:

For DMF holders:

- Submit both open and closed parts of the DMF directly through the portal
- Use their own unique eCTD ID

For product registrants (applicants):

- Include only the open part of the DMF within their module 1-5 dossiers
- Submit using a different eCTD ID from the DMF holder

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How can companies perform pilot submissions?

Companies can conduct pilot submissions by submitting actual dossiers during the designated test period. However, please note that these test submissions will not undergo regulatory review.

What is the benefit of using eCTD portal vs EasiShare portal?

The eCTD portal and EasiShare serve different purposes. The eCTD portal is HSA's dedicated platform for submitting dossiers in eCTD format, which offers advantages in providing a standardised electronic structure for submissions and enhances document organisation and management, allowing for more effective lifecycle management of submissions through its structured format.

EasiShare, on the other hand, simply serves as an electronic alternative to sending physical CD/DVDs when submitting non-eCTD dossiers.

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What is the purpose of the appendix 2A checklist submission when submitting using eCTD?

The appendix 2A checklist acts as a guidance tool for companies and helps ensure all required documentation is included in the application.

Is there any advantage of submitting eCTD e.g. shorter evaluation timelines?

The target processing timeline, as specified in Appendix 5 of Guidance on Therapeutic Product Registration in Singapore, is the same for applications using eCTD or non-eCTD format.

However, eCTD does offer other operational benefits:

- Better organisation and structure of submission documents
- More efficient lifecycle management of product information
- Improved tracking of changes across submissions
- Easier navigation of dossier contents for both industry and regulators
- Alignment with international standards for electronic submissions

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