

eCTD submissions

Submit documents in a standardised electronic format for therapeutic product registration.

eCTD format officially accepted for regulatory dossier submission

HSA is pleased to announce that electronic Common Technical Document (eCTD) format will be officially accepted for regulatory dossier submission with effect from 1 April 2026.

Companies may submit eCTD packages for actual dossiers through the eCTD portal using SG-HSA eCTD version 1.1, which serves as the official standard for all eCTD submissions. The technical files for defined lists, document matrix and submission type matrix are available online for real-time access and validation, along with an updated sg-regional stylesheet.

Companies may continue with their current non-eCTD submission modes but are strongly encouraged to transition to eCTD. HSA will provide advance notice before any subsequent phases of the roll-out.

[LOGIN TO ECTD PORTAL](#)

Please click [here](#) for other eCTD resources.

eCTD (electronic common technical document) is the standard structured format for the electronic transfer of regulatory information related to therapeutic products from industry to health authorities. eCTD submissions minimise the need for using storage media such as CD/DVD ROMs for dossier submissions. It also allows better product life cycle management for both industry and HSA.

HSA will adopt a phased approach for eCTD implementation for therapeutic product submissions based on [ICH eCTD specification 3.2.2](#).

The use of eCTD for dossier submission will be on a voluntary basis. The initial launch will be open to new drug applications, generic drug applications and their corresponding Drug Master File (DMF) submissions

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eCTD specification package v1.1

The latest version of the SG-HSA Specification package must be used for eCTD submissions to HSA upon implementation.

Click [here](#) for the Summary of Changes for SG-eCTD v1.1



The package includes the following:

- [SG-HSA eCTD Specifications v1.1](#)
- [SG-HSA eCTD Validation Criteria v1.1](#)
- [Defined lists](#)
 - [Application Type](#)
 - [Contact Type](#)
 - [Product Type](#)

- [Submission Type](#)
- [Sequence Type](#)
- Validation matrices
 - [Submission type Matrix \(PDF\)](#)
 - [Document type Matrix \(PDF\)](#)
- Technical files (Regional SG-HSA Module 1 Schema and supporting schemas) util.zip
- Sample eCTD submissions

Download the package as a zip file: [eCTD package v1.1](#)

⊖ eCTD specification package 1.0

- [SG-HSA eCTD Specifications v1.0](#) 
- [SG-HSA eCTD Validation Criteria v1.0](#) 

Resources for Industry

⊖ Choosing an eCTD software vendor

Selecting the right eCTD vendor is essential for efficient regulatory documentation management and submission. Some key factors to consider include:

- **Compliance and Standards:** Ensure the vendor's software complies with regulatory standards, including ICH specifications for eCTD.
- **User-Friendly Interface:** An intuitive, easy-to-navigate interface enhances efficiency in document management and submission processes.
- **Technical Support and Training:** Evaluate the vendor's support services and training resources.
- **Integration Capabilities:** Check if the software can integrate with existing systems.
- **Scalability:** Assess if the solution can accommodate increasing document volumes and adapt to new regulatory requirements.
- **Security and Data Protection:** Ensure the vendor has robust security measures to protect sensitive data and maintain data integrity.
- **Cost:** Evaluate the overall cost-effectiveness of the software
- **Reputation and Experience:** Consider the vendor's reputation and experience in regulatory submissions among major regulatory agencies.
- **Trial and Demo:** Request a demo or trial period to assess how well the software meets your needs. Sample submissions provided in this website may be used for demo/trial purposes.

⊖ HSA eCTD Portal Training

- [Training video](#) and [Presentation slides](#)  **6330 KB** for HSA eCTD Portal training
- [eCTD Portal User Manual](#)

⊖ Q&A document

- [SG-HSA eCTD_Questions and Answers](#) (updated March 26)

⊖ Summary of Envelope Requirements

- [HSA Summary of Envelope Requirements](#)

⊖ Updates

- [eCTD officially accepted for regulatory dossier submission \(1 April 2026\)](#)
- [Update of SG eCTD version 1.1](#)
- [Launch of eCTD portal for test submissions \(30 Sep 25\)](#)
- [Release of eCTD version 1.0 \(25 Sep 24\)](#)
- [Post-industry consultation update \(11 Dec 23\)](#)
- [Industry consultation notice \(2 May 23\)](#)
- [Notice to Industry \(17 Apr 23\)](#)

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