Regulatory Updates on Therapeutic Product Registration (1 April 2026)

1. 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.

To support users in navigating the new system effectively, HSA has prepared the necessary resources, including the training presentation, Q&A document and a portal user manual.

In addition, HSA has updated the following guidance documents to include eCTD as a dossier submission option.

- Guidance on Therapeutic Product Registration in Singapore
- Appendix 2A: Application checklist (ICH CTD_NDA_GDA)
- Appendix 2B: Application Checklist (ICH CTD – MAV)
- Appendix 5: Target Processing Timeline
- Appendix 11: Guideline on Drug Master File

- Appendix 13: Guideline on MIV Applications for Chemical Therapeutic Products
- Appendix 14: Guideline on MIV Applications for Biological Therapeutic Products
- Appendix 17: Guideline on PRISM Submission

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.

Please visit the eCTD webpage to keep up to date with the latest eCTD developments.

2. Declaration of quality defects to ensure Chemistry, Manufacturing & Controls (CMC) dossier remains valid at the point of submission

To promote Good Submission Practice and better support applicants to ensure that the CMC dossier remains valid at the point of submission, applicants will be required to provide an official letter declaring that there are no known quality defects that would require amendment or updates to the submitted CMC package, with effect from 1 June 2026. This enhancement aims to minimise inadvertent submission of superseded technical data and improve regulatory efficiency.

Refer to Chapters C, D and E of the Guidance on Therapeutic Product Registration in Singapore for more information.

Industry member, Therapeutic Products

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