Singapore’s HSA starts accepting eCTD packages for regulatory dossier applications

Singapore – Pharma

Singapore's HSA formally accepts the electronic Common Technical Document (eCTD) format for therapeutic product dossier submissions from 1 April 2026. This regulatory change represents a key step toward the digital transformation of submission processes and closer alignment with international regulatory standards.

The transition to eCTD is expected to improve the consistency, transparency, and efficiency of regulatory reviews. While the new format will become officially accepted from the implementation date, HSA will allow a transition period during which existing submission methods may still be used.

Overall, this update reflects HSA’s ongoing efforts to modernize its regulatory framework and support a more streamlined and harmonized submission environment for the pharmaceutical industry.

Singapore HSA Accepts eCTD Format from 1 April 2026

The Health Sciences Authority (HSA) of Singapore has announced a major regulatory update for therapeutic product registrations: the official acceptance of the electronic Common Technical Document (eCTD) format for dossier submissions starting **1 April 2026**.

Shift to eCTD Submissions

From the effective date, companies will be able to submit regulatory dossiers in eCTD format via the HSA eCTD portal using **SG-HSA eCTD version 1.1**, which will serve as the national standard. This structured electronic format aligns with international regulatory practices and is expected to improve consistency, traceability, and efficiency in dossier review.

To support implementation, HSA has made available updated technical resources, including submission type matrices, document matrices, and an SG-regional stylesheet to ensure proper validation of submissions. Training materials, user guides, and Q&A documents are also provided to assist industry stakeholders in transitioning to the new system.

Gradual Transition Approach

While eCTD will be officially recognized, HSA will continue to accept non-eCTD submission formats for a transitional period. However, companies are strongly encouraged to begin adopting eCTD early, as future phases of implementation are expected to progressively move toward full digital standardization. Advance notice will be given before any further changes are introduced.

Updated Regulatory Requirements

In addition to the eCTD adoption, HSA has introduced updates affecting Chemistry, Manufacturing and Controls (CMC) documentation. A key new requirement ensures that CMC dossiers must be valid and up to date at the time of submission, reinforcing regulatory compliance and data integrity expectations.

Several guidance documents have also been revised to reflect these changes, including updates to registration guidelines, application checklists, and submission procedures across both chemical and biological therapeutic products.

Pharmaceutical companies are advised to begin preparing for the transition early to ensure readiness ahead of the 2026 implementation date.

Conclusion

The introduction of eCTD as an accepted submission format marks an important step in Singapore's ongoing regulatory modernization. Combined with strengthened CMC documentation requirements, these changes aim to enhance submission quality, streamline review processes, and align Singapore more closely with global regulatory standards.