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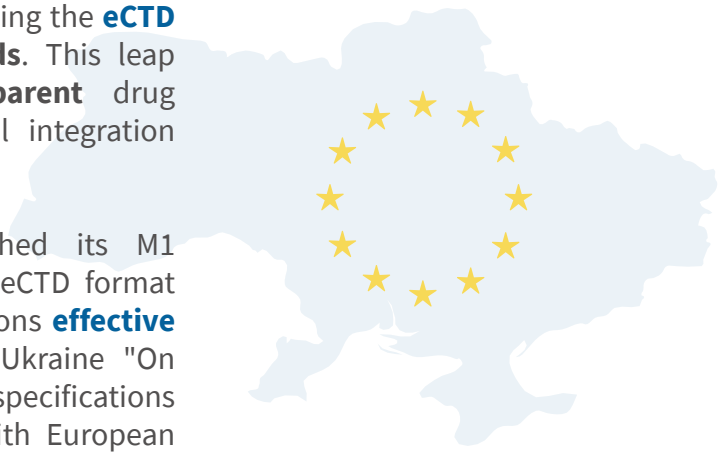
Ukraine: Embracing the eCTD Format

Ukraine is advancing its healthcare system by adopting the **eCTD format**, aligning closely with **European standards**. This leap forward promises more **efficient** and **transparent** drug registration processes, strengthening international integration and globalization efforts.



The Ukrainian Ministry of Health has published its M1 specifications and validation criteria, making the eCTD format **mandatory** for all **new drug registration** applications **effective August 18, 2025**, as stipulated by the Law of Ukraine "On Medicines" (July 28, 2022, No. 2469-IX). The v1.2 specifications and v1.0 validation criteria are mostly aligned with European standards.

Submissions can be made through the Applicant's Electronic Cabinet. While submitting a baseline is not mandatory, it is highly recommended for easier management of the medicinal product life cycle.

Stay ahead of the curve with ASPHALION's regulatory expertise, ensuring seamless and compliant submissions in Ukraine's evolving pharmaceutical landscape!

ASPHALION's Expert Regulatory Solutions for Ukraine:

- **eCTD Publishing**
- **Document Formatting**
- **Regulatory Consulting**
- **CMC & MW Dossier Writing**
- **Comprehensive Dossier Life-Cycle Management**