What you need to know about **South African (SAHPRA) submissions**

Updates

- In 2013, the South African authority SAHPRA started accepting submissions in eCTD format for pharmaceuticals. They included an enhanced granularity in Modul 3.2.R which should be technically built with node extensions and subfolders.
- In 2019, SAHPRA introduced the additional “eSubmission” format, which will be accepted for a limited time. Currently it is not communicated how long this additional format will be accepted since SAHPRA currently reconsiders its eCTD roadmap.
- In 2020, SAHPRA updated section 3.2.R with new titles, but no update of the specification and eCTD structure. The previous titles can still be used in eCTD submission. We can guide you with the transitions in South African eCTD submissions.

Master File (APIMF)

APIMF number (Dossier ID) allocated after submission

Open and closed part

Request SAHPRA portal access for closed part

Document formatting

CTD compilation and publishing “eSubmission” format

Submission via e-mail
“eSubmission” validation and Submission

Pharmaceuticals and biologicals

Application number request before submission to SAHPRA

Document formatting

eCTD compilation and publishing

Conversion to eCTD format

Validation ZA Validation rules Submission (DVD/CD/USB)

Clinical Trial Application

Predetermined dates for submission and obtain proof of delivery

Contact CTU (Clinical Trials Unit) to inform about submission

Application form accompanied by the prescribed fee

Document formatting in PDF Communication via e-mail

CTC (Clinical Trials Committee) meeting to discuss reports

ASPHALION
Knowledge from experience

Asphalion can give you support in the following areas:

- Non-clinical and clinical development
- CMC
- Dossier writing
- Regulatory procedures
- Vigilance
- eSubmissions
- Data management

EXTEDO
eRegulatory Affairs

EXTEDO's Regulatory Solutions for South Africa:

- eCTDmanager: eCTD compilation and publishing for all South African submissions.
- eSUBmanager: Viewing and reviewing of archived and in-progress electronic submissions.
- eDOCSmanager: Manage all your regulatory documents in a secure document management system.
- SafetyEasy: Reporting and management of all serious and non-serious adverse events.

For further information, please contact: ectd@asphalion.com | info@extedo.com