ASPHALION
Knowledge from experience

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

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. The acceptance of eSubmission ended on 31th March, 2022.

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. In 2024, SAHPRA has enhanced the submission process via portal and updated the eCTD standard.

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 format
  - Submission Form via e-mail. APIMF document via SAHPRA submission portal.

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)
  - Submission via SAHPRA eCTD portal

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 can give you support in the following areas:

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