

MEDICINE CONTROL COUNCIL (MCC)/SAHPRA

Contact Information

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As stated in Medicines and Related Substances Act ([MRSA 2008](#), [MRSA 2015](#), and [Proc20of201](#), as of June 1, 2017, the South African Health Products Regulatory Authority (SAHPRA) is established as the regulatory authority overseeing medicines and clinical research, replacing the Medicines Control Council (MCC). However, per [MRSA, 2015](#), the MCC will continue to perform the SAHPRA's functions until the date of the first meeting of the Board of SAHPRA.

SA GCP states that "All clinical trials of both **non-registered medicinal substances** and **new indications** of registered medicinal substances must be reviewed by the Medicines Control Council. The Medicines Control Council applies standards laid down by the Medicines and Related Substances Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines. The prescribing and dispensing of medicines is controlled through the determination of schedules for various medicines and substances.

Clinical trial applications are first looked at in terms of whether they fulfil MCC administrative requirements, before scientific review by a designated reviewer(s) who presents findings to the Clinical Trial Committee (CTC).

The CTC subsequently recommends if the application should be approved by the Council. This is also permission to import unregistered investigational products into South Africa

MCC Meeting Dates:

Refer to MCC Meeting date Schedule

Packages should be **couriered or hand delivered** and it is recommended to include an acknowledgment of **receipt**. Cover letters should indicate the trial title/number, submission date, site contact name and fax number, version of enclosed documents, and **reference** to any previous related correspondence (including the MCC reference number once assigned). Use the following codes on correspondence and place a copy of the cover letter on the outside of the package to indicate the type of submission:

CODE	SUBJECT
TGC	General Correspondence
TCA	Application to conduct Clinical Trial
TCV	Amendment of an existing clinical trail
TCR	Response to CTC comments
TAE	Report of adverse events arising from clinical trial
TUM	Application related to unregistered medicines

Fees:

It is recommended that proof of payment be **faxed** to the MCC finance department prior to delivering an application. Direct electronic payment should include a clear reference, e.g. the product application number or purpose of the payment. Proof of electronic payment / direct transfer must be submitted in a separate envelope attached to a copy of the covering letter of the relevant submission (s).

Refer to: Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) – Schedules – Fees Payable in terms of the Provisions of the Act (MRSA-Fees) (March 19September 1, 2015) Section: 5.

Payments should be sent to:

Account name: Medicines Control Council

Account type: Cheque Account

Account number: 40-5939-2080

Bank: ABSA

Bank Branch Code: 632005

Bank physical address: 240 Vermeulen Street, Pretoria 0001, South Africa

Swift Code: ABSAZAJJ

Initial Submission:

(Complete the CTF1 form V2. dated October 2017)

Compile the paper application using spaghetti clips with labelled section dividers, leaving documents unbound where possible (e.g. protocols and investigator brochures) so that the MCC can photocopy certain text if needed. Enclose electronic versions where indicated using labelled CD-ROM/diskettes in MS Word or Rich Text format.

- All application documents to be submitted in duplicate i.e. 2 submission packs with two CD-ROM electronic copies
- Additional 2 copies of the signed and completed application form

Submission Checklist:

- Cover sheet
- Completed Form CTF1 – Application to Conduct Clinical Trials
- Protocol
- Patient Information Leaflet(s) (PILs) and informed consent form(s) (ICFs)
- Standardized MCC contact details to be added to PILs
- Investigator's brochure (IB) and /or all Professional Information i.e. package insert(s)
- Investigator's curriculum vitae(s)(CVs) in MCC format
- Signed declaration(s) by investigators
- GCP Certificates (not more than 3 years old) or Proof of registration
- Workload Forms for Investigators
- Proof of Registration with Professional Statutory Body
- Regional monitor's MCC CV and declaration
- Signed joint financial declaration by sponsor and national principal investigator (PI)
- Signed Declaration by Applicant and National Principal Investigator
- Certificate(s) of analysis (may be submitted with ethics approval letter)
- Indemnity/insurance certificate and/or proof of malpractice insurance of trialist(s)
- Active Insurance Certificate for Clinical Trial
- Proof of Sponsor Indemnification for Investigators and Trial Site
- Proof of Application to Register the Trial on the South African National Clinical Trials Register

- Ethics approval or copy of letter submitted to EC
- Copy or copies of recruitment advertisement(s)) and Questionnaires (if applicable)
- Financial declaration (sponsor/national PI)

Ensure that protocols, investigator brochures, PIL and consent form are version and date controlled. Once administrative issues have been resolved, the MCC reviewer(s) will be sent the application. The review will usually be presented at the next CTC meeting.

Once the CTC has considered the application a fax/email will be sent to the investigator's contact person within approximately 2 weeks indicating:

Phase IV Clinical trials

Application form (6.24 Notification of Phase IV dated May 2017) is intended for applicants to notify the Medicines Control Council (MCC) of intention to undertake a phase IV clinical study of an approved medication within its approved dosage, formulation and indication.

Submission Checklist

- Cover letter
- Completed form
- MCC approved professional information (package inserts) for medication being investigated
- Copy of application letter to Ethics Committee/ Ethics Committee approval
- Protocol
- Patient Information Leaflet/informed consent document (PIL/ICON)

1a	Approval
1b	Ethics Committee Outstanding Approval
2a	Outstanding Issues which can be dealt with "in-house"
2b	Outstanding Issues which must be checked by the original reviewer
3	Original reviewer to report back to full committee
4	Referral for specialist opinion
5	Rejection of application and requires full resubmission if to be reconsidered
6	Rejection because of missing components

Submissions satisfying 1-2b will then be reviewed at the next available Medicine Control Council meeting after which a faxed/emailed response will be sent listing whether the application has been approved or rejected.

Response to CTC Comments:

The MCC allows 7 days in which to respond to comments in two hard and one electronic copy. Be careful about amending the protocol at this point, as changes that are in addition to those addressing the MCC review may be rejected.

Email address for Responses to new clinical Trial Applications and related queries

CTCResponses@health.gov.za

Amendment of Existing Clinical Trials:

(Complete the CTF2 form)

Email address for Protocol Amendments, Responses to Amendments and related queries:

CTCAmendments@health.gov.za

Additional Investigators and Additional Sites:

(Complete the CTF3 Form)

Email address for additional investigators (PI-Sub I) and Additional Trial Sites and related queries:

CTCInvestigators&sites@health.gov.za

Reporting of Adverse Events arising from Clinical trials:

ARF1