



An online database of country-specific regulatory information



*Additional countries will be added based on NIAID's research priorities

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Overview
In accordance with the GRMRSa, the SA-GCPs, and G-Clin, the Medicines Control Council (MCC) is responsible for reviewing and approving all clinical trial applications for an unregistered medicine, and for any new indication or dosage regimen of a registered medicine. The scope of the MCC's assessment includes all clinical trials (Phases I-IV) and bioequivalence/bioavailability studies.

Clinical Trial Review Process
As indicated in the SA-GCPs, the Medicines Regulatory Authority (MRA) is secretariat to the MCC and coordinates the clinical trial application process. The MRA forwards all submitted clinical trial applications to the MCC's Clinical Trials Committee (CTC). The CTC committee, in turn, considers the scientific, medical, and ethical issues of the applications, and also ensures that the submissions provide proof of safety, quality, and efficacy of the investigational product for both unregistered and registered medicines. (See the **Clinical Trial Lifecycle topic, Submission Process subtopic** for detailed submission requirements.)

REQUIREMENTS
(1) (Regulation) **Medicines and Related Substances Act 101 of 1965 - General Regulations Made in Terms of the Medicines and Related Substances Act 101 of 1965, as Amended (GRMRSa)** (February 15, 2014)
Department of Health, Republic of South Africa
Relevant Section: Part 34 (1)
(2) (Guidance) **Guidelines for Good Practice in the Conduct of Clinical Trials With Human Participants in South Africa (2nd edition) (SA-GCPs)** (2006)
Department of Health, Republic of South Africa
Relevant Sections: 1.5.1, Appendices D and F
(3) (Guidance) **Clinical (Version 1) (G-Clin)** (December 2003)
Registrar of Medicines, Medicines Control Council, Department of Health, Republic of South Africa
Relevant Section: 3

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Links to Official Documents

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INFORMED CONSENT	South Africa ×	Brazil ×
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SPECIMENS	Import & Export	

Overview
A permit must also be obtained from the Department of Health (DOH) Director General to import or export biological substances. Both the Medicines Control Council (MCC) clinical trial approval letter and the DOH import/export permit must be included with each biological substance shipment.

DOH Application Requirements
Upon review of the import or export application, the Director-General will issue a permit or certificate authorizing the import or export request if he/she is satisfied that the submission meets all regulatory requirements. The permit will contain an expiration date for the approved biological substance(s).

General Import/Export Requirements for Biological Substances
Each biological substance to be imported into South Africa must be accompanied by a certificate from the supplier stating that the substance has been exported in terms of the originating country's applicable laws and regulations.

Overview
The sponsor or his/her designated contract research organization (CRO) must obtain approval from the Brazilian Health Surveillance Agency (Agência Nacional de Vigilância Sanitária) (ANVISA) to import human biological materials into Brazil.

The sponsor may apply for an import license at the same time that he/she submits the clinical trial application to ANVISA. The clinical trial application is referred to as the Drug Clinical Development Dossier (Dossier de Desenvolvimento Clínico de Medicamento (DDCM)). ANVISA's approval of the DDCM is known as a Special Notice/Bulletin or a Comunicado Especial (CE).

ANVISA issues a Special Bulletin (SB), a Specific Special Bulletin (SSB), or a Document for Importation of Product(s) under investigation by the DDCM. An SB is an authorizing document ANVISA issues upon review and approval of the DDCM and can be used for investigational product (IP) import/export requests; an SSB is an ANVISA document issued to permit the sponsor to import/export an IP while his/her DDCM is still awaiting review and is within ANVISA's 180-day