4.1 Have the Ethics Committee(s) responsible for each centre to which this amendment applies been notified?

4.2 List Ethics Committees

4.3 Date of application to Ethics Committee

4.4 Date of approval by Ethics Committee

I, the undersigned, agree to conduct / manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility to sign this form).

_____ _____

Applicant (local contact) Date

CTF 3

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

APPLICATION FOR ADDITIONAL INVESTIGATOR(S) OR CHANGE OF INVESTIGATOR(S) AND APPLICATION FOR ADDITIONAL SITES

MCC CLINICAL TRIALS SECTION TRACKING NUMBER FOR THIS CORRESPONDENCE:

REGISTRAR OF MEDICINES
APPLICATION FOR APPROVAL OF:

☐ **CHANGES IN INVESTIGATOR (S) AT APPROVED SITE (includes additional investigators)**
☐ **ADDITIONAL SITE (S)**

Protocol number, title and date

1. APPLICANT

1.1 Name/address/tel/fax number of Applicant wishing to conduct trial

1.2 Name/address/tel/fax number of CRO representing sponsor as Applicant or Local Sponsor Company details (if applicable)

1.3 Name, designation and qualifications of person representing the Applicant (***Local Contact Person for all further correspondence***)

1.4 National Coordinator name, address, tel/fax number

1.5 International Principal Investigator name, address, tel/fax number

1.6 Name of sponsor

2. TRIAL PARTICULARS **(original application)**

2.1 MCC Approval Number:

2.2 Date of Approval of original protocol:

2.3 Number of Investigators in South Africa already approved for this trial:

2.4 Number of sites in South Africa already approved for this trial:

2.5 Number of patients in South Africa already approved for this trial:

3. INVESTIGATOR DETAILS

3.1 Name and address of additional Investigator(s) / Changes to Investigators

3.2 For Investigators who have not previously been in clinical trials, proof of adequate training and experience to properly conduct the study must be provided.

3.3 Summarise other ongoing/planned studies at this site involving this investigator *(give details of indication, phase, study status, number of patients intended, number of patients already enrolled, whether the investigator is involved in research in a full-time or part-time capacity, and any other detail that may effect the capacity of the site at any one time)*

3.4 Details of Ethics Committee(s) who will approve investigator(s)

3.5 Date of application to Ethics Committee

3.6 Date of approval by Ethics Committee

3.7 Is CV for additional Investigator(s) attached (list)
YES ☐

3.8 Is the Declaration of Intent attached (list)
YES ☐

4. CAPACITY OF THE SITE

4.1 Describe how the site is structured so as to be able to take on the work for which this application is being made. (Give details of support staff, facilities, back up and any other relevant infrastructure)

5. RATIONALE FOR APPLICATION

5.1 Briefly explain the reason for the new investigator/s

I, the undersigned, agree to conduct / manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility to sign this form).

Applicant (local contact) Date

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

MEDICINE DONATIONS TO SOUTH AFRICA

This document has been prepared to serve as a guideline to applicants wishing to submit applications for the donation of medicines. It is not intended as an exclusive approach. Council reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine and may make amendments in keeping with the knowledge which is current at the time of consideration of data accompanying applications for the donation of medicines. The MCC is committed to ensure that all medicines available that are donated will be of the required quality, safety and efficacy. It is important for applicants to adhere to the administrative requirements to avoid delays in the processing of applications.

REGISTRAR OF MEDICINES
MS M.P. MATSOSO
DATE: 29/4/2003

INDEX

MEDICINE DONATIONS TO SOUTH AFRICA

1. INTRODUCTION

These guidelines aim to improve the quality of donations, not to hinder them. They are intended to serve as a base for national guidelines, to be reviewed, adapted and implemented by the government and organizations dealing with drug donations.

There are many different scenarios for medicines donations. They may take place in acute emergencies or as part of development aid in non-emergency situations. They may be corporate donations (i.e. direct or through private voluntary organisations), aid by governments, or donations aimed directly at single health facilities. Therefore, these guidelines aim to describe this common core of " Good Donations Practise."

Four core principles interlay the guidelines:

1. A drug donation should benefit the recipient to the maximum extent possible.

2. A donation should be given with full respect for the wishes and authority of the recipient and are supportive of existing government policies and administrative arrangements.

3. There should be no double standards in quality; if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

4. There should be effective communication between the donor and the recipient: donations should be based on an expressed need and should not be sent unannounced.

2. BACKGROUND

Over the last three or four decades in particular, there has been an enormous increase in our scientific knowledge about the mode of action, effects, and side effects of medicines. Medicines are not automatically beneficial, that they have to be used carefully and appropriately, and that some can do more harm than good, as a result more cautious and critical attitude towards medicines have been developed.

Subsequently, South African government or/and the Department of Health in particular recognises the need of appropriate curative services, hence it has developed essential drug list based on the health needs of the majority of the population and used as a foundation for medicine donations.

It suffice to say that the goal of the National Drug Policy is to ensure an adequate and reliable supply of safe, cost effective medicines of acceptable quality to all the citizens of South Africa and the national use of medicines by prescribers, dispensers and consumers.

3. THE LEGAL SITUATION

MEDICINE DONATIONS TO SOUTH AFRICA

In the Medicines and Related Substances Control Act, No 101 of 1965, South Africa has sophisticated legislation, which prohibits the use, sale, or supply of any medicine unless it has been evaluated in terms of its safety, quality and efficacy and has thereafter been registered.

Section 21 of the legislation does allow the Medicines Control Council to permit the use of unregistered medicines (which what donated medicines are) subject to such conditions as the Council may determine. As a consequence no donated medicines may be used unless the Council has specifically authorized its use. Application for the donation of medicine must be made to the Registrar of Medicines. In submitting an application the following information must be supplied: name, expiry date, batch number, package, site of manufacture, package insert, quantity, intended for and local recipient.

4. SELECTION OF MEDICINES

4.1 All medicine donations should be based on the health needs and disease pattern of the Republic of South Africa. Drugs should not be sent without prior consent by the recipient.

The purpose of this guideline is to stress the point that it is the prime responsibility of the recipient to specify their needs. It is intended to prevent unsolicited donations, and donations which arrive unannounced and unwanted. It also empowers the recipients to refuse unwanted gifts.

4.2 Donated medicines should not be sent without prior consent of the Medicines Control Council.

4.3 Donated medicines must appear on the Essential Drug List and must be compatible with overall Government Policy. Exception may be made on recommendation by the Medicines Control Council (MCC).

It further intends to ensure that medicine donations comply with the South African National Drug Policy and essential drugs programme. It aims at maximizing the positive impact of the donation, and prevents the donation of medicines, which are unnecessary and/or unknown in the recipient country.

Possible exceptions

An exception could be made for medicines needed in sudden outbreaks of uncommon or newly emerging diseases, since such medicines may not be approved for use in South Africa. Exceptions could also be made on the basis of a specific request by the Government of South Africa.

4.4 The presentation, strength and formulation should be similar to those used in South Africa.

Quality assurance and shelf life.

4.5 All donated medicines have to originate from a reliable source and comply with the

requirements in terms of quality standards, safety and efficacy, in both the donor and South Africa. All donated drugs must be accompanied by the relevant documentation that include a summarised application in terms of Regulation 15 (excluding the annexures as approved by the MCC), Registration certificate from the country of origin and a WHO GMP Certificate. All application for donated medicines must be reviewed by the MCC (through the MCC fast track procedure) before they can be released for distribution. The approval granted by the MCC for distribution will only be valid for a specific consignment applied for. ***(It should be re-iterated that the approval should NOT be regarded as a blank approval for additional importation / distribution of the same product).***

This provision prevents double standards: medicines of unacceptable quality in the donor country should not be donated to other countries. Donated medicines should be authorised for sale in the country of origin, and manufactured in accordance with international standards of Good Manufacturing Practice (GMP).

4.6 Medicines that had been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples shall not be accepted as donated medicines.

In South Africa re-issue of returned medicines is not permitted because their quality cannot be guaranteed. For that reason returned medicines should not be donated. In addition to quality issues, returned medicines are very difficult to manage at receiving end because of broken packages and small quantities involved.

4.7 All donated medicines should have a remaining shelf life of at least 12 months after arrival in South Africa.

Due to logistical problems limiting immediate distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision prevents the donation of medicines near their expiry date that could reach the patients after expiry.

Possible exceptions

Possible exception is those drugs that because of their physical properties are manufactured with a short shelf life of less than two years. Vaccine requires stringent conditions during storage and distribution. They should only be donated in close collaboration with the Directorate of Administration of Medicines- Department of Health.

Presentation, Packing and Labelling

4.8 All donated medicines must be labelled in at least English, and the label should contain at least the International Non-proprietary Name (INN, or generic name), batch number, expiry date, dosage form, strength, name and address of the manufacturer, quantity and storage conditions.

All donated medicines, including those under brand name should also be labelled with their International Non-proprietary Name. Training programmes in South Africa are based on the use of generic names. Receiving medicines under different and often unknown brand names and without the generic name can confuse health workers and constitutes a risk in therapeutic practice. In case of injections, the route of administration should be indicated.

4.9 Donated medicines should be presented in large quantity packaging units and hospital packs as used in South Africa.

Large quantity packs (e.g. containers of 1,000 tablets) are cheaper, and easier to transport. This provision prevents the donation of medicines in sample packages, which are not practical to manage.

4.10 Donated medicines must be packed in containers that comply with international shipping regulations and accompanied by a detailed packing list. Medicines should not be mixed with other supplies in the same carton. Transport conditions should be in accordance with the storage condition of the medicines.

This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations, as the identification and management of unmarked boxes with mixed medicines is very time and labour intensive. This provision specifically discourages donations of small quantities of mixed medicines.

4.11 Different medicines should not be packed together in one carton and medicines should not be mixed with other supplies.

Information and Management

4.12 The government of South Africa through the Directorate of Administration of Medicines (Department of Health) should be informed of all medicine donations that are considered, prepared or actually underway. Prior approval for the donation should be obtained from the Directorate Medicine Administration to avoid unnecessary delays at the port of entry. The information should extend to delivery dates, possible delays, port of entry, method of transport, and information as required in ports.

Detailed advance information on all medicine donations is essential to enable South Africa to plan for the receipt of the donation and to coordinate the donation with other sources of supply. The information should at least include: the type and quantities of donated medicines including their generic name, strength, dosage form, and the identity and contact address of the donor.

4.13 The declared value to South Africa of a medicine donation should be based upon the wholesale world- market price for its generic equivalent.

This provision is needed in South Africa to prevent medicine donations being priced

according to the retail price of the product in the donor country, which may lead to elevated overhead cost for import tax, clearance, and handling in South Africa. It may also result in a corresponding decrease in the public sector drug budget in South Africa. All costs of international and local transport, warehousing, port clearance, quality testing and appropriate storage and handling should be paid by the donor, unless specifically agreed otherwise with the South African Government in advance. Similarly, the cost of disposing of a medicine donation adjudged to be unsuitable should be borne by the donor.

These incidental costs can be quite prohibitive and erode the Department of Administration of Medicines (Department of Health) budget. On the other hand, if the donor makes the provisions for these costs, the benefits of the donation will be maximised.

5. CONTACT DETAILS:

Chief Directorate: Medicines Regulatory Affairs
Directorate: Inspectorate & Law Enforcement
Department of Health
Private Bag X828
Pretoria 0001
South Africa

Telephone: +27(12) 312 0000

Fax: +27(12) 312 3114

6. UPDATE HISTORY

Date	Reason for update	Version
February 1996	New	1996/1