MEDICINES CONTROL COUNCIL

GUIDELINE FOR PARALLEL IMPORTATION OF MEDICINES IN SOUTH AFRICA

This document has been prepared to serve as a recommendation to applicants wishing to submit applications for a permit to parallel-import medicines. It represents the Medicines Control Council's current thinking on access to safe and quality medicines that are cost effective. It is not intended as an exclusive approach. Council reserves the right to request additional information to establish the safety, quality and efficacy of a medicine and to make amendments in keeping with current knowledge at the time of consideration of data accompanying applications for a permit or for amendment of the registration of a parallel imported medicine. The MCC is committed to ensure that all medicines gaining market approval will be of the required quality, safety and efficacy. It is important for applicants to adhere to the administrative requirements of the MCC to avoid delays in the processing of applications.

These guidelines should be read in conjunction with Regulation 7 of the Medicines and Related Substances Act No. 101 of 1965, as amended.

REGISTRAR OF MEDICINES
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DATE:

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1. INTRODUCTION

Medicines form a critical part of an effective healthcare system. The challenge facing most health departments today is to provide the public access to medicines that are of good quality, safety and efficacy and that are economically affordable. This is in fact one of the key objectives of the South African National Drug Policy which has also assumed special importance in the face of the HIV/AIDS pandemic and other related emerging and opportunistic infections.

2. BACKGROUND

An important component of the transformation process of the healthcare services in South Africa is its expansion to reach even the most remote part of the country to ensure that all people, particularly those previously disadvantaged, have access to good quality healthcare. This key objective is, however, being constrained by the escalating costs of services, facilities and medicines. In an attempt to address the issue, the South African government introduced the Medicines and Related Substance Control Amendment Act in 1997 (Act No. 90 of 1997) as a means to facilitate, among other things, access to affordable medicines by all. This Act allows for the importation and registration of medicines which are under patent, are already registered in South Africa, and which originate from any site of manufacture approved by Council, regardless of any existing patent rights.

3. LEGISLATIVE PROVISIONS

The Minister of Health is empowered by section 15C of the Medicines and Related Substances Control Act of 1965, as amended (Act No. 101 of 1965), to prescribe the conditions on which any patented medicine may be parallel imported into South Africa regardless of the provisions of the Patents Act, 1978 (Act 57 of 1978). A parallel imported medicine must have the same formulation, meet the same quality standards and is intended to have the same proprietary name as the medicine already available and registered in South Africa. In addition, any person or company, other than the person or company that is the holder of the registration certificate of that medicine, may import such a medicine. It may also be obtained from any manufacturing site used by the original manufacturer and which is approved by Council in accordance with the current technical requirements.

Thus, to procure a cost-effective or less expensive medicine than the one already registered and available in the Republic, the Minister may authorise, through a permit, the importation of the same medicine manufactured by, or on behalf of, the approved manufacturer from any other country and the restrictions imposed by the Patent Act shall not apply.

Parallel importation is defines in the Regulations as

"the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of the patentee in respect of such medicine"

The expressions "*parallel importer*", "*parallel imported medicine(s)", "parallel imported", "to parallel import", "to be parallel imported"* and "*parallel importation permit*" shall have the corresponding meanings to 'parallel importation'.

4. CONDITIONS FOR PARALLEL IMPORTATION OF A MEDICINES

4.1 Any patented medicine may be imported in terms of Section 15C and Regulation 7 of the Act if it is already registered in South Africa.

4.2 A person or company that wishes to import a patented medicine must apply to the Minister of Health for a permit to parallel import a medicine.

4.3 The holder of a certificate of registration for a medicine in South Africa shall not be entitled to prevent its importation into South Africa, nor its sale, on account of such registration or on account of the existence of a patent on such a medicine.

4.4 The parallel importer shall be responsible and liable for the parallel imported medicines, for example, in the event of a recall or adverse event, and must notify the Council of these situations.

4.5 The parallel importer shall be liable for destruction of any expired, parallel imported medicines still remaining on stock after the expiry date, whether during the duration of the permit or after the parallel importation permit has expired.

5. PROCEDURE FOR OBTAINING A PERMIT TO PARALLEL IMPORT MEDICINES

5.1 The application for a permit to parallel import a medicine must be submitted to the office of the Minister of Health. The application must be accompanied by the following:

i) Written confirmation of the lowest price at which the medicine is currently sold by the holder of the certificate of registration in South Africa dated not more than one month before the date of submission of the application for a parallel import permit;
ii) The price at which the parallel imported medicine will be sold in South Africa by the importer;
iii) A declaration by the importer that the medicine to be imported is a medicine under patent in South Africa;

iv) The prescribed application fee;

v) A certified copy of his or her identity document, or in the case of a juristic person, a certificate of registration as such in the Republic;

vi) A certified copy of his, her or its registration in terms of the Pharmacy Act, 1974, where applicable;

vii) A certified copy of the licence in respect of the premises in terms of: -

a) Section 19 of the Customs and Excise Act, 1964 (Act No. 91 of 1964); and

b) Section 22 of the Pharmacy Act, 1974;

viii) An undertaking that he, she or it will ensure the continued safety, efficacy and quality of the medicine; and

ix) Any other information the Minister may require.

5.2 The Minister may, upon consideration, approve with or without conditions, or reject, such an application.

5.3 If a permit is issued, it shall be valid for a period of 24 months.

5.4 The permit holder must, at least three months before the expiry date, apply to the Minister for its renewal in accordance with the procedure prescribed by the Minister.

5.5 The Minister may, at any time and on good cause shown, cancel the permit to import any medicine.

6. PROCEDURE FOR OBTAINING REGISTRATION OF A MEDICINE THAT IS TO BE PARALLEL IMPORTED

6.1 After being issued with a permit to import a medicine, the importer must apply to Council for: -

i) Authorisation to import a sample of the medicine to be submitted together with the application for registration of the medicine; and

ii) Registration of the medicine, using Form MRF 1 (provided by the Registrar of Medicines).

6.2 An application for the registration of a parallel-imported medicine must be accompanied by the following:

i) Copies of the package insert and patient information leaflet, where available, which must be translated into English and verified;

ii) An appropriately labelled sample of the medicine in accordance with the requirements of Regulation 8 or Regulation 48;

iii) Information on the exporter, stating whether it is a manufacturer, packer, re-packer, wholesaler or broker;

iv) A cGMP Certificate from a recognised authority, which must be specific for the manufacturer, packer, re-packer, laboratory, distributor, wholesaler or broker of the imported medicine;

v) Real-time stability data for the duration of shelf-life using a stability-indicating method for the active pharmaceutical ingredient, according to the requirements of the Guideline for Stability Studies – Addendum 4;

vi) Comparative dissolution data against the MCC-approved product (same formulation, same name, same dosage form, etc.) that has been procured in South Africa, in terms of the requirements for proof of efficacy (Also Refer to the Guidelines on Dissolution Testing) and using f_2 values.

6.3 The following is the minimum information required for the registration of a parallel imported medicine:

i) Administrative Data (section A and B).

ii) Parts 1A, 1B and 1C.

iii) Part 2B.

iv) Part 2D for repackaged medicines and if the packaging material is different from that used by the patent holder.

v) Part 2E (b) (i) and (c); for repackaged medicines only.

vi) Part 2F (a), (b), (d) and (e).

vii) Part 2G for repackaged medicines only.

6.4 Council will only consider approval of registration of the medicine if the importer has: -

i) been issued with a permit to parallel import the medicine;

ii) a registered office in South Africa;

iii) a storage facility approved by Council for such medicine;

iv) a responsible pharmacist as required in terms of the Pharmacy Act, 1974 (Act No. 54 of 1974);

v) undertaken to be responsible for ensuring that such medicine meets the safety, quality and efficacy standards as determined by Council and accepts liability for any consequences arising from the distribution and use of the medicine;

vi) in place recall procedures as determined by Council,

vii) complied with any other conditions as Council may determine; and

viii) an MCC-approved manufacturing site in the case where the imported medicine is to be repackaged.

6.5 The parallel importer may proceed with the sale of the medicine only after the medicine has been registered.

7. REGISTRATION OF MEDICINES TO BE PARALLEL IMPORTED

7.1 The evaluation and registration of medicines intended for importation will follow the same procedure as provided for in Section 15 of the Act and as prescribed in the regulations, except as specified under item 6.3 above.

7.2 Council may impose any conditions necessary for the registration of the medicine.

7.3 The Registrar shall keep a separate register for parallel imported medicines.

8. CANCELLATION OF REGISTRATION OF PARALLEL IMPORTED MEDICINES

Council may, on good cause shown and in consultation with the Minister, cancel the registration of any parallel imported medicine.

9. INFORMATION TO BE PROVIDED TO THE PATENT HOLDER OR HOLDER OR THE CERTIFICATE OF REGISTRATION

The importer must, within 30 days after registration of the medicine, inform the patent holder or the holder of the certificate of registration in South Africa, of this fact and submit a copy of the letter to the Registrar.

10. IMPORTATION OF MEDICINES

10.1 The parallel importer must inform the holder of the certificate of registration at least four weeks prior to importation, on a form determined by Council, of his or her intention to parallel-import the medicine. The requirements for post-importation identification and testing of medicines, as described in Addendum 2 of the *Guidelines for the Registration of Medicines in South Africa,* will apply.

10.2 The parallel importer may not manufacture or re-export any medicine registered in South Africa as a parallel imported medicine.

11. REPACKAGING AND RELABELING OF PARALLEL-IMPORTED MEDICINES

11.1 Where the medicine is to be repackaged in South Africa after importation, this must be done at a site approved and licensed by the Council for this purpose.

11.2 The medicine must be labelled, packaged and have a package insert and patient information leaflet as prescribed in terms of regulations 8, 9 and 10.

11.3 The parallel importer may use the proprietary name approved in South Africa as well as any trade marks applicable to the medicine in order to ensure the public health interests.

11.4 The words “Parallel imported medicine” or the abbreviation “PIM” must be included on the label of each distribution pack.

11.5 The batch numbers of repackaged medicines must be identical to those of the original medicines and all original packaging material must be destroyed.

12 INFORMATION TO BE PROVIDED TO THE MEDICINES CONTROL COUNCIL

The following information must be supplied to Council by the parallel importer:

12.1 Any change in the conditions under which the medicine was registered;

12.2 Any adverse drug reactions or events arising from the use of the medicine;

12.3 Any report of risks associated with the medicine that may affect its quality, safety or efficacy.

13. TRANSFER OF CERTIFICATE OF REGISTRATION

A certificate of registration for an imported medicine may only be transferred to another person or company with the approval of the Minister.

14. AMENDMENTS TO THE DETAILS OF A PARALLEL IMPORTED MEDICINE

The importer must apply to Council on form PIF 1, available from the office of the Registrar, for approval of any change in the conditions of registration of an imported medicine or change in the storage conditions or change in any of the particulars of the medicine.

15. FEES PAYABLE

An applicant for the registration of a medicine to be parallel imported shall pay an application fee and a registration fee as determined by Council.

16. FORMS TO BE COMPLETED

The following forms, obtainable from the office of the Registrar, must be completed in respect of an application for amendment to the details of a parallel imported medicine and for informing the patent holder of the intention of the parallel importer to import a medicine, respectively: PIF 1 and PIF 2.