MEDICINES CONTROL COUNCIL

SECTION 21 APPLICATION FORM

Only to be used for orthodox/allopathic medicines for human use.

1. Fax completed form (i.e. pages 1 - 10), proof of payment of application fee (if applicable) and other relevant documents to **086 274 3073** or email to **section21@health.gov.za.**
2. For the current application fee payable kindly consult the Fees published on the MCC website under Publications http://www.mccza.com/Publications/Index/10 and refer to **Use of Unregistered Medicines - any other application except for the purpose of performing a clinical trial.**
3. Please consult the Key Contact section under "Contact the MCC" on the MCC website http://www.mccza.com/Contact/KeyContacts Clinical Evaluations & Trials, **Section 21 Orthodox Medicines for Human Use** for telephonic contact details to track the progress of your application.

For Office Use:

A. PARTICULARS OF THE APPLICANT (i.e. treating medical doctor/prescriber)

1. Title: _____

   Full Names and initials: _____

   Surname: _____

2. Health Professions Council (South Africa) Registration Number: _____

3. Registered qualifications: _____

   _____

4. Registered specialty under which you are currently practicing and treating the patient mentioned in section C below (e.g. general practitioner, paediatrician, physician, nephrologist, etc.) and designation:

   _____

5. Practice Number: _____

6. Registered Physical Address (where the patient records and/or the medicine may be inspected):

   _____

   _____

7. Postal Address: _____

   _____

8. Telephone no. (office hrs): _____

   Cellular Phone number: _____

9. Fax no. (office hrs) to communicate the outcome of this application:

   _____

10. E-mail address to communicate the outcome of this application:

    _____

11. Signature: _____ Date: _____

12. Official Stamp:

B. PARTICULARS OF PERSON, COMPANY, OR INSTITUTION IMPORTING THE UNREGISTERED MEDICINE

1. Category: Pharmacist Pharmaceutical Manufacturer Pharmaceutical Distributor Pharmaceutical Wholesaler Other: Specify

   _____

2. Registered Name of company: _____

   _____

3. Registration Number of company: _____

4. Physical Address (where the medicine and/or patient data may be inspected):

   _____

   _____

5. Postal Address:

   _____

   _____

Contact Person to answer queries about the unregistered medicine:

6. Title: _____

   Full Names and initials: _____

   Surname: _____

7. Registered Qualifications:

   _____

8. Professional Council you are registered with, e.g. SAPC: _____

   Registration Number: _____

9. Official designation: _____

10. Telephone number (office hours): _____

11. Fax number (office hours): _____

12. Cellular phone number: _____

13. E-mail address: _____

C. PARTICULARS OF THE PATIENT

1. Title: _____

   First Names: _____

   Surname: _____

2. Age: _____ Gender: _____ Weight: _____ Height: _____

3. Occupation: _____

4. Residential Address:

   _____

   _____

5. Postal Address (if different from above):

   _____

   _____

6. Telephone number (office hours): _____

7. Cellular phone number: _____

8. State the diagnosis &/or indication (the unmet medical need or a valid reason for the application to use the unregistered medication):

   _____

   _____

9. Full description of diagnosis including severity, staging and prognosis where applicable:

   _____

   _____

   _____

   _____

10. Details of current standard treatment regimen for the above diagnosis (C No. 8.). Include medicinal, surgical and other treatment.

    _____

    _____

    _____

    _____

11. Concomitant disease/s (brief description including severity, staging and prognosis where applicable):

    _____

    _____

    _____

12. Current treatment regimen/s for the above concomitant disease/s (C. 10)

    _____

    _____

    _____

    _____

13. Please specify which of, and the doses of the above treatment regimens (sections C 9 &11 above) that will be continued together with the unregistered medication/device.

_____

_____

_____

_____

14. Informed Consent obtained for the use of the unregistered medicine/device on the patient:
Yes or No

Please attach a completed valid informed consent form - Section E.

D. PARTICULARS OF THE UNREGISTERED MEDICINE FOR WHICH A SECTION 21 APPLICATION IS BEING MADE

1. Manufacturer: _____

2. Country of origin: _____

   Name of South African Subsidiary: _____

3. Generic Name (Active ingredient/s): _____

4. Trade Name: _____

5. **Specify formulation and quantity required:** (e.g. ampicillin 250 mg capsules, 1 000 capsules per month for 6 months = 6 000 capsules)

   _____

   _____

6. Is the medicine/device approved & registered for the intended use in other countries, including country of origin? Yes or No.
   If Yes, state which country it is registered in.
   What indication is it registered for? Is it an off-label indication for this patient?

   _____

   _____

   _____

   _____

7. Please provide documentary proof of the above (No. 6, e.g. medication leaflet, copy of publication in peer reviewed scientific publication)

   _____

   _____

   _____

8. Prescription and planned treatment regimen of the unregistered medicine/device for the above patient (Section C). (Dose, frequency, route and duration of administration)

   _____

   _____

   _____

   _____

9. Specify known adverse drug reactions (ADRs) to this medication, including interactions with concomitant disease/s and medication/s listed in sections C No's 11 & 12 above.

   _____

   _____

   _____

   _____

10. Clearly outline how you intend preventing, monitoring for and managing the above ADRs

_____

_____

_____

_____

11. a. List all MCC-registered medicines for the unmet medical need mentioned in Section C, question 8 above.

    b. Clearly state reasons for **not using a similar MCC-registered medicine/device or treatment regimen** for the disease mentioned in section C No. 8 above.

_____

_____

_____

_____

12. Motivation for the use of the unregistered medication/device (do not repeat the indication and reasons listed in Sections C No. 8 & D No. 11).

_____

_____

_____

_____

13. Have you or any other person or institution applied to the MCC for the use of the same or other unregistered medicine/device for the same patient in the past? Yes or No.
If yes, specify and supply the MCC approval number.

_____

_____

_____

14. I hereby certify that:

- the use of this unregistered medication/device is purely for the management of the patient's disease and not research,
- data collected during treatment of the patient with the unregistered medication/device, may only be used for research after obtaining specific approval from the patient and the MCC, and that the MCC will be supplied with the results (published and unpublished) of such research
- a copy of this application form and consent form will be made available on request to the patient and any registered health care professional who may be involved in the treatment of the above patient.

Signed: (Applicant) _____ **Date:** _____

E. INFORMED CONSENT FORM

I, _____ **(full names of the patient)** voluntarily agree to be treated with a medication, namely _____ which is not registered in South Africa, _____ **(name of applicant, practice, hospital)** for _____ (**name of the disease**).

I confirm that I have been fully informed and my questions answered by _____ **(name of applicant, i.e. prescribing doctor)** about my disease (for which a section 21 application is being made), its cause, severity, prognosis, available registered treatment options in South Africa and the reasons for the current state of my illness and the unregistered medication and application to use a medication that is not registered in S.A., and that:

- the medication is not registered in South Africa, and that this implies that the quality, effectiveness and safety of this medication have not been verified by the Medicines Control Council (MCC) of South Africa (S.A.)
- the medication will only be supplied to, and used by and on me once specific approval has been obtained from the MCC of S.A.
- the medication _____ **(generic and trade names)** is approved for the treatment of _____ (**my disease**) in _____ **(name of the country from which the medication is to be imported)**, or (the medication is in an advanced stage of development [at least phase III trial] in South Africa and or _____ **(country of origin)** and that its quality, efficacy and safety are well documented and within legally and scientifically acceptable levels
- appropriate measures will be taken to prevent, monitor and manage the unwanted effects on me of the unregistered medication
- _____ **(name of applicant)** will comply with all regulations of the MCC, laws (S.A. and foreign) and conditions of approval of use of this unregistered medication/device and accordingly ensure continued availability and supply of the medication
- use of the unregistered medication on and by me is for managing my disease and not for medical research
- any information collected by _____ **(name of applicant)**, his/her employer, successor or any other person other than the MCC or its legal representative, may be used for research purposes upon receipt of specific written separate informed consent from me, my guardian or person responsible for my affairs after my death
- I will be free stop using the medication at any time and that I will inform my (treating) doctor accordingly.

Full Names of patient/guardian: _____

Signature of patient/Guardian: _____

Date: _____

Name of doctor (applicant): _____

Signature of doctor: _____

Date: _____

Name of witness: _____

Signature of witness: _____ **Date:** _____

F. PROGRESS REPORT FORM - Submit no later than 6 months after authorisation date or earlier if requested.

Initial **Follow-up** **Final**

1. Particulars of the Treating Doctor/Pharmacist:

Title: _____ Initials: _____ Surname: _____

E-mail Address: _____ Tel no: _____

Fax No: _____

Postal Address: _____

_____

2. Patient Particulars:

Title: _____ Initials: _____ Surname: _____

Age: _____ Gender: _____ Weight: _____ Height: _____

Phone no.: _____ Cell no.: _____

3. Particulars of the unregistered Medication:

MCC Section 21 Approval No:

Disease for which the unregistered medicine was used: _____

Generic Name: _____

Trade Name: _____

Dosage given to the patient: (Amount, Route, Frequency and Duration of administration):

_____

_____

Date of commencement of treatment with unregistered medicine: _____

Date last used: _____ or ongoing treatment

4. Outcome of treatment

4.1 Therapeutic effect

Excellent Good Satisfactory No effect Not assessed

Brief description/comments:

_____

_____

_____

_____

_____

4.2 Adverse drug reaction(ADR) to the unregistered medication

None or Present

If Present: local or systemic Severity: Mild Moderate Severe

Description of ADR including results of laboratory and/or other investigations and management

_____

_____

_____

_____

_____

4.3 Outcome of ADR: Resolved Ongoing Resulted in disability Resulted in death