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  [ ] 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.

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
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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.

<table>
<thead>
<tr>
<th>Initial</th>
<th>Follow-up</th>
<th>Final</th>
</tr>
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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