# SECTION 21 – PATIENT INTAKE FORM

## 1. Section 21's:

Before any medicine can be sold in South Africa, it must be approved by the South African Health Products Regulatory Authority (SAHPRA), who certifies that the medicine is safe, of good quality and is effective.

Unless the medicine has gone through these processes, it cannot be on the shelves for sale. In exceptional circumstances, SAHPRA may permit access to unregistered medicines. This exception is permitted by section 21 of the Medicines and Related Substances Act, 101 of 1965 through a process that is commonly referred to as "a section 21 application".

## 2. Dispensing of Medicinal Cannabis:

Under the Medicines Act, medical practitioners can apply to SAHPRA for permission to access and prescribe unregistered medicines – including cannabis – for their patients in certain exceptional circumstances. The only means by which a patient will be able to obtain Medicinal Cannabis in South Africa is through a medical practitioner who holds the relevant license to prescribe it, which license is obtained from SAHPRA.

A Pharmacist registered accordingly with the relevant Pharmacy Council are able to provide medicinal cannabis when provided with a legitimate prescription from a medical practitioner. Medicinal Cannabis products may thus be made available to specific patients under medical supervision and through legal channels as confirmed by SAHPRA in the guideline document in this regard.

## 3. Supporting Documents Required:

- Notification of Payment
- Copy of ID

**PARTICULARS OF PATIENT**

| | |
|---|---|
| Title | |
| Full Names | |
| Surname | |
| ID Number | |
| Age | |
| Gender | |
| Weight (kg) | |
| Height (cm) | |
| Occupation | |
| Residential Address | |
| | |
| Postal Address | |
| | |
| Telephone (work) # | |
| Cellphone # | |

---

Diagnosis — *Full Description including the severity, staging and prognosis applicable:*

*Example: Chronic Pain, Anxiety, Epilepsy, Fibromyalgia*

---

1. Details of current treatment regimen for the above diagnosis. Include medicinal, surgical and other treatment:

   ***Example:*** *Aspirin, Ibuprofen, Naproxen, Serotonin and Norepinephrine.*

2. Do you suffer from any other conditions not yet mentioned? If yes, please specify as well as current treatment.

   ***Example:*** *High Blood Pressure, Cholesterol, Diabetes etc.*

3. Do you smoke Cannabis? (Please circle your answer) Yes ☐ No ☐

4. Do you use Cannabis in any other form? (Please circle your answer): Yes ☐ No ☐

   Specify:

## INFORMED CONSENT FORM:

I, _____ (full names and surname) voluntarily agree to be treated with a medication namely ***< 1% Delta-9-Tetrahydrocannabinol*** which is not registered in South Africa.

I confirm that I have been fully informed and my questions answered about my disease (for which a section 21 application is being made), its cause, severity, prognosis, available (in South Africa) registered treatment options 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 South Africa 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 SAHPRA.
- the medication will only be supplied to and used by and on me once specific approval has been obtained from SAHPRA.
- appropriate measures will be taken to prevent, monitor and manage the unwanted effects on me of the unregistered medication.
- use of the unregistered medication on and by me is for managing my disease and not for medical research.
- I will be free stop using the medication at any time and that I will inform my (treating) doctor accordingly.

**Date:** _____

**Full Names of patient/guardian:** _____

**Signature of patient/Guardian:** _____

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 doctor, 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 (in South Africa) registered treatment options 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, effectiveness 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 doctor) 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 that 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: _____