SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

SECTION 21 APPLICATION

SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY'S RESPONSIBILITIES AND LIABILITY WHEN PERFORMING ITS FUNCTION IN TERMS OF SECTION 21 OF ACT 101 OF 1965

In terms of this Section the Authority may authorize the sale of unregistered orthodox medicine, complementary medicine, and veterinary medicine or device for certain purposes.

21. (1) The authority may in writing authorize any person to sell during a specified period to any specified person or institution a specified quantity of orthodox medicine, complementary medicine, veterinary medicine or device, which is not registered.
21. (2) Any orthodox medicine, complementary medicine, veterinary medicine or device sold in pursuant to any authorization under sub-section (1) and in such a manner and during such period as the Authority may in writing determine.
21. (3) Authority may at any time by notice in writing withdraw the authorization granted in terms of sub-section (1) if effect is not given to any determination made in terms of sub-section (2)

An applicant who wishes to sell an unregistered medicine must be fully informed and be able to respond if his request is not successful.

Section 21 mandates the Authority to approve the use of unregistered medicine. The Authority, therefore, is required to address the following requirements of Section 21.

- Authorise sales
- Specify the period of sale
- Specify the purchaser or institution
- Specify the quantity of medicine
- Determine the purpose for the use of such medicine
- Determine the manner of use
- Determine the period of use
- Withdrawal of the authority to sell or use

THE AUTHORISATION OF THE USE OF UNREGISTERED MEDICINE UNDER SECTION 21 OF ACT 101 OF 1965

1 Objective

The objective of Section 21 of this policy is to determine how an unregistered medicine can be authorized under Section 21.

2 Responsibility

The Authority shall delegate the administration of the control of the execution to the appropriate qualified person (Clinical Pharmacologist or Medicine Control Officer)

3 Source document

Section 21 of Act 101 of 1965

4 Policy

4.1 The Authority shall in writing authorize any person to sell during a specified period up to (six months) to any specified person or institution a specified quantity of any medicine, which is not registered.

4.2 All applicants must submit the following information:

(a) Name, street address and telephone number of the applicant/medical practitioner
(b) Registration number of the prescriber
(c) Name and address of the patient
(d) Diagnosis of the patient
(e) Dose, frequency and route of administration of the product
(f) Number and frequency of repeats
(g) Concomitant medication
(h) Name and (Generic) of the product
(i) Motivation why an unregistered product is to be used
(j) Reasons for not using similar registered product/current regimen
(k) Urgent applications can be handled by telephone in case of an emergency but the above mentioned information must be supplied before an authorization number is supplied. A telephonic request must be followed up in writing within 48 hours.

4.3 Requests can only be repeated after a follow-up reports have been submitted to the supplier and the Authority.

4.4 In case of long term treatment a follow-up report must be submitted every six months. A new authorization number must be obtained every six months.

4.5 The officer designated must confirm the authorization in writing.

4.6 The patient must be fully informed that the drug is not registered with the authority.

4.7 The patient must be fully informed about the possible benefits and risks of the product.

4.8 The patient must sign the informed consent. In case of a minor the parent or guardian must sign the informed consent.

4.9 If approved, the product shall only be used for the treatment of the patient in such a manner and for the approved period only. No other patient may receive the authorized unregistered medicine.

4.10 All adverse events or unexpected events must be reported to the Authority.

4.11 At the termination of treatment a full case report shall be submitted to the Authority.

4.12 The Authority shall in writing withdraw any such authorization.

4.13 All unused unregistered products shall be returned to the supplier for disposal according to the requirements of the Authority.

4.14 Information about the basic efficacy, safety and quality about the product must be supplied to the authority.

4.15 Where the product is used for the clinical trial, the MBR1 form must include the formula of the final product in terms of a dosage unit:

a) Specifications of the final product namely *viz* the name of the specification, limits of criteria of acceptance of all physical, chemical and where applicable microbial parameters.

b) The laboratory responsible for the final lot release locally. At least an identification and assay must be done if the product is imported.

c) Stability data derived from the product stored at room temperature (at least nine months), and elevated conditions (three months) in tabulated form. The date of manufacture, batch number, batch size and container must be stated.

4.16 The CEO, when the Authority is not sitting, refer as far as possible all matters and report thereon to the next meeting of Council.

4.17 An exemption will be given for investigational and comparator medicines which:

a) are new chemical entities

b) are new or different dose forms, delivery systems and formulations of established medicines, which

c) does not have consent to be sold in the Republic of South Africa

The Authority may grant the approval after receiving approval from an accredited ethics committee for the study protocol and the justification and validity of the study protocol.

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

1. Title: First Names: 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 number (office hours): Cellular Phone number:
9. Fax number (office hours):
10. Email address:
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:

6. Contact Person: Title: First Names: Surname:

7. Registered Qualifications:

8. HPC (S.A.) Registration Number:

9. Official designation:

10. Telephone number (office hours):

11. Fax number (office hours):

12. Cellular phone number:

13. Email address:

C. PARTICULARS OF THE PATIENT

1. Title: First Names: Surname:

2. Age: Gender: Weight: Height:

3. Occupation:

4. Residential Address:

5. Work or postal Address:

6. Telephone number (office hours):

7. Cellular phone number:

8. Diagnosis (Reason for the application to use unregistered medication; full description including severity, staging and prognosis where applicable)

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

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

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

12. Please specify which of, and the doses of the above treatment regimens (sections C 9 &12 above) that will be continued together with the unregistered medication/device.

13. 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.

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:

4. Trade Name:

5. 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

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. Clearly state reasons for not using a similar available registered (in S.A.) medication/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 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:

F. PROGRESS REPORT FORM **Initial** **Follow-up** **Final**

F. 1. Particulars of the Treating Doctor/Pharmacist:

Title: Initials: Surname:

E-mail Address: Telephone no.: Fax No.:

Postal Address:

F. 2. Patient Particulars:

Title: Initials: Surname:

Age: Gender: Weight: Height:

Phone no.: Cell no.:

F. 3. Particulars of the unregistered Medication:

MCC Section 21 Approval No.:

Disease for which the unregistered medicine was used:

Generic Name of the Medicine: Trade Name:

Dosage that has been 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

F. 4. Outcome of treatment

F. 4.1 Therapeutic effect

Excellent Good Satisfactory No effect Not assessed

Brief description/comments:

_____

_____

_____

_____

F 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

_____

_____

_____

_____

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

SECTION 21 APPLICATION FEES

To all Section 21 applicants:

Please note that as from 07 November 2012, an application fee of R330 **per named patient** is payable before your application is evaluated. This is in accordance with Government Regulation Gazette Vol. 569, No. 35857 regarding fees payable to the CEO in terms of the Medicines and Related substances Act, 1965 (Act 101 of 1965) as amended.

Should you require **emergency stock** please state the following in your application:
1) Exact quantity of emergency stock required for the next six-month period.
2) Dosage per patient.
3) Exact number of patients you intend treating with emergency stock (i.e. Quantity in question 1 divided by dosage in question 2).

The total fee payable for emergency stock is **R330** multiplied by the **exact number of patients** you intend treating with emergency stock.

Please note that only cheques made out to the SAHPRA are acceptable means of payment.

To speed up the approval process, please submit the cheque with your application to:

Bank details

Account name: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
Special name: The Medicines Control Council
Account type: Cheque / Current Account
Account number: 40-5939-2080
Bank: ABSA
Bank Branch Code: 632005
Bank physical address: 240 VERMEULEN STREET, PRETORIA, 0001, SOUTH AFRICA
Swift Code: ABSAZAJJ

Faxed applications will be processed only if proof of receipt of cheque by reception of SAHPRA is submitted with the application. Please state patients' names and/or numbers of patients and exact quantities of drugs required for that respective cheque payment.

Yours faithfully

CHIEF EXECUTIVE OFFICER
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY