

MEDICINES CONTROL COUNCIL



SECTION 21 APPLICATIONS FOR UNREGISTERED VETERINARY MEDICINES

This document has been prepared to serve as a recommendation to applicants wishing to submit applications for Section 21 exemptions for unregistered veterinary medicines. It represents the Medicines Control Council's current thinking on the safety, quality and efficacy of medicines. It is not intended as an exclusive approach. Council reserves the right to request for any additional information to establish the safety, quality and efficacy of a medicine and may make amendments in keeping with the knowledge which is current at the time of consideration of data accompanying applications for Section 21 exemptions for veterinary medicines. It is important for applicants to adhere to these requirements.

**REGISTRAR OF MEDICINES
MS M.P. MATSOSO**

VETERINARY SECTION 21 APPLICATION

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COUNCIL'S RESPONSIBILITIES AND LIABILITY WHEN PERFORMING ITS FUNCTION IN TERMS OF SECTION 21 OF ACT 101 OF 1965

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

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

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

Section 21 mandates Council to approve the use of unregistered medicine.

Council therefore, is required to address the following requirements of Section 21:

21(1)

- Authorise sales
- Specify the period of sale
- Specify the purchaser or institution
- Specify the quantity of medicine

21(2)

- Determine the purpose for the use of such a medicine
- Determine the manner of use
- Determine the period of use

21(3)

- Withdrawal of the authority to sell or use.

THE AUTHORISATION OF THE USE OF AN 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 authorised under Section 21.
2. Responsibility. Council shall delegate the administration of the control and execution to the appropriately qualified person (Clinical Pharmacologist or Medicine Control Officer).
3. Source document Section 21 of Act 101 of 1965.

4. Policy
- 4.1 Council shall in writing authorise any person to sell during a specific 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 (generic) of the unregistered product;
 - i) Motivation why an unregistered product is to be used;
 - j) Reason for not using a similar registered product/current regimen; and
 - k) Urgent applications can be handled by telephone in case of an emergency but the above-mentioned information must be supplied before an authorisation number is supplied. A telephonic request must be followed up in writing within 48 hours.
- 4.3 Request can only be repeated after follow-up reports have been submitted to the supplier and Council.
- 4.4 In case of long-term treatment, a follow-up report must be submitted every six months. A new authorisation number must be obtained every six months.
- 4.5 The officer designated must confirm the authorisation in writing.
- 4.6 The patient must be fully informed that the drug is not registered with the Medicines Control Council.
- 4.7 The patient must be fully informed about the possible benefits and risks of the product.
- 4.8 The patient must sign an informed consent. In the 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 authorised unregistered medicine.
- 4.10 All adverse events or unexpected events must be reported immediately to Council and the supplier.
- 4.11 At the termination of treatment, a full case report shall be submitted to Council.
- 4.12 Council may in writing withdraw any such authorisation.

- 4.13 All unused, unregistered products shall be returned to the supplier for disposal, according to the requirements of Council.
- 4.14 Information about the basic efficacy, safety and quality about the product must be supplied to Council.
- 4.15 Where the product is used for a clinical trial, the MRF1.0 form must include the formula of the final product in terms of a dosage unit.
- a) Specifications of a final product, namely 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 (9) months), and elevated condition (three (3) months) in tabulated form. The data of manufacture batch number, batch size and container must be stated.
- 4.16 The Registrar of medicines shall, when Council is not sitting, refer as far as possible, all matters and report thereon at 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 or formulations of established medicine; which
 - c) do not have consent to be sold in the Republic of South Africa.

The Medicines Control Council 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.

4.18 Copy of Authorisation Form

1. APPLICANT DETAILS

- a) Name
- b) Street Address
- c) Telephone number/Cell phone
- d) Fax number
- e) E-mail address
- f) Designation
- g) Qualification
- h) Registration number

2. PATIENT DETAILS

- a) Name
- b) Address
- c) Age
- d) Diagnosis
- e) Current regimen

3. DRUG / PRODUCT INFORMATION

- a) Generic name
- b) Trade name
- c) Indications
- d) Dose, route. Frequency and duration of administration
- e) Concomitant medication
- f) Has the product been approved for use in other countries?
- g) If approved, specify countries and conditions of authorisation
- h) If so specify major side effects of this product.

4. MOTIVATION FOR THE USE OF UNAUTHORISED MEDICINE

5. REASON FOR NOT USING A SIMILAR REGISTERED PRODUCT OR CURRENT REGIMEN

6. PATIENT / GUARDIAN'S INFORMED CONSENT AND PROCEDURE

7. AUTHORISED BY:

8. AUTHORISATION NUMBER:

4.18 COPY OF AUTHORISATION FORM



Medicines Control Council

**APPLICATION FOR THE USE OF AN UNREGISTERED MEDICINE IN
TERMS OF SECTION 21 OF ACT 101 OF 1965**

1. APPLICANT DETAILS

- a) Name: _____
- b) Postal / street address: _____

- c) Telephone number / Cell phone: _____
- d) Fax number: _____
- e) E-mail address: _____
- f) Designation: _____
- g) Qualification: _____
- h) Registration number: _____

2. PATIENT DETAILS

- a) Name: _____
- b) Street address: _____

- c) Age: _____
- d) Diagnosis: _____
- e) Current regimen: _____

3. DRUG/PRODUCT INFORMATION

- a) Generic name: _____
- b) Trade name: _____
- c) Indication: _____
- d) Dose, route, frequency and duration of administration: _____

- e) Concomitant medication: _____

- f) Has the product been approved for use in other countries? _____
- g) If approved, specify countries and conditions of authorisation: _____

h) If so, specify major side effects of this product: _____

4. **MOTIVATION FOR THE USE OF UNAUTHORISED MEDICINE:** _____

5. **REASON FOR NOT USING A SIMILAR REGISTERED PRODUCT OR CURRENT REGIMENT:** _____

6. **PATIENT / GUARDIAN'S INFORMED CONSENT AND PROCEDURE (YES/NO)**

7. **PREVIOUS APPROVAL NUMBER (repeat) and six months progress report:**

8. **AUTHORISED BY:** _____

AUTHORISATION NUMBER: _____

DATE: _____

Annexure 1

GUIDELINES FOR SECTION 21 APPLICATIONS FOR VETERINARY MEDICINES

1. Enquiries for the acquisition of unregistered veterinary products may be made by fax, telephone and letter to the Secretariat of the Veterinary Clinical Committee (VCC).
2. Applications must be made on the specific application form for veterinary Section 21 applications as per Attachment 1 (Section 21 application form) and then faxed/ posted to the Secretariat of the VCC.
3. In the case of a Section 21 application for the use of the unregistered veterinary product in a clinical trial the protocol for the clinical trial to be conducted in South Africa must be attached to this application (see guidelines for clinical trials).
4. The Secretariat may request other information from the Applicant concerning the specific application. This application will only be processed further once this information has been forwarded to the Secretariat.
5. The Applicant may contact the Secretariat should the Applicant not receive any decision in respect of the application within five working days of having submitted the application.
6. The Secretariat shall inform the Applicant of the decision by letter and will attach a progress report form as per attachment 2. This progress report is to be completed by the applicant in due course (+/- 6 months). No further approvals will be given to the Applicant for the acquisition of a specific product if any progress reports are outstanding.
7. In the case of an emergency request (i.e. the patient has a life-threatening condition) for an unregistered medicine, the Secretariat may verbally supply the authorisation number to the Applicant. However, the written application for the unregistered medicine must be forwarded to the Secretariat within three days of this verbal authorisation.
7. Approval of Section 21 applications may be subject to the issuing of an import permit for products of animal origin in terms of the Animal Diseases Act 35 of 1984. This will be stated in the letter from the Secretariat to the Applicant.
8. The acquisition of certain products may be subject to other conditions with which the Applicant must comply. These will be stipulated in the authorisation letter.
9. The approval number quoted in the letter to the Applicant shall be derived in the following manner e.g. SP/40/2003 :SP = special permission ; 40 = fortieth application for approval ; 2003 = year of 2003.
11. The Applicant shall then obtain the unregistered medicine through the relevant veterinary supplier or directly from the Registration Holder of the product.

12. The application as well as the letter of approval must be tabled at the next VCC meeting for confirmation by the committee of the approval given as well as for information. The decision taken by the committee must be ratified at the next Council meeting.

CONTACT DETAILS FOR THE VETERINARY CLINICAL COMMITTEE SECRETARIAT:

National Dept. of Health
Sub – Directorate: Veterinary Medicines Unit - Code for Applications **RUM**
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Pretoria
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