Frequently Asked Questions
for a Section 21 (Orthodox Medicines for Human Use)
Please note that the information herein changes on a frequent basis. Please consult the latest version on the SAHPRA website to keep updated.

Q: What is a Section 21 authorisation?

A: The Section 21 Unit (Orthodox Medicines for Human Use) of the South African Health Products Authority (SAHPRA) processes and evaluates applications from applicants (treating practitioners) for access to unregistered medication within South Africa (SA). The applicant establishes whether there is a need for a certain medicine; if the orthodox medicine for human use is unregistered within South Africa, the applicant will submit a Section 21 application (Orthodox Medicines for Human Use).

The Section 21 application framework also allows for access to unregistered veterinary medicine and unregistered complementary medicines but the application procedures differ vastly for these unregistered medicines. It is important that the application is sent to the appropriate contact details for veterinary or complementary medicine Section 21 applications.

The legislative framework for access to unregistered is enabled by Section 21 of the Medicines and Related Substance Act, Act 101 of 1965, as amended:
21. Authority may authorise sale of unregistered medicines, medical devices or IVDs for certain purposes
(1) The Authority may in writing authorise any person to sell during a specified period to any specified person or institution a specified quantity of any particular medicine, medical device or IVD which is not registered.
(2) Any medicine, medical device or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.
(3) The Authority may at any time by notice in writing withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

A Section 21 application for Orthodox Medicines for Human Use is processed and evaluated by staff in the Section 21 Unit of the South African Health Products Regulatory Authority (SAHPRA), which operates within the terms set out in Section 21 of the Medicines and Related Substances Act 101 of 1965.
This is read together with Regulation 29 of the General Medicines Regulations:
AUTHORISATION OF SALE OF AN UNREGISTERED MEDICINE FOR CERTAIN PURPOSES
Regulation 29
(1) Subject to the provision of information, requirements and conditions as determined by the Authority, a person desiring to sell an unregistered medicine subject to registration in terms of section 14 of the Act, for purposes other than a clinical trial, shall apply to the Authority, on an application form obtainable from the office of the Chief Executive Officer, for authorisation in terms of section 21 of the Act to sell such a medicine.

(2) An application referred to in subregulation (1) must be accompanied by the prescribed fee and must contain at least the following information—
(a) duly completed application form;
(b) product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data and where applicable, human or animal pharmacological and clinical data with the medicine concerned;
(c) witnessed informed consent document, where applicable;
(d) details of registration or pending registration of the medicine with any other regulatory authority, if available;
(e) evidence of compliance of the manufacturer of the medicine with Good Manufacturing Practice standards as determined by the Authority;
(f) reasons why a South African registered medicine cannot be used; and
(g) any other information as may be required by the Authority.
(3) The person under whose supervision the unregistered medicine or substance is prescribed shall submit to the Authority—
(a) any adverse event report;
(b) progress reports after every six months from the date following commencement of the use of the unregistered medicine; and
(c) progress report 30 days after the completion or termination of the use of the medicine.
(4) The Authority may—
(a) impose any additional conditions;
(b) request additional information;
(c) inspect the site where the unregistered medicine is manufactured, stored or administered; or
(d) withdraw the authorisation to treat the patient or animal,
if the Authority is of the opinion that the safety of any patient or animal is compromised, that the scientific reasons for administering the unregistered medicine have changed or for any other reason as determined by the Authority.
(5) A medicine referred to in subregulation (1) shall be properly labelled and the package shall sufficiently identify the information as per the provisions of regulation 12(5)(c).

Q: What are the contact details of the Section 21(Orthodox Medicines for Human Use) unit?

A: Tel: 012 842 7600/ 072 134 4546/ 063 771 8906
E-mail address: section21@sahpra.org.za

Q: How do I apply for Section 21(Orthodox Medicines for Human Use) authorisation?

A: SAHPRA has implemented a submission portal in order to address Section 21 re-authorisations as well as new applications for Orthodox Medicines for Human Use only.

<u>New applications for Orthodox Medicines for Human Use:</u>

A new process has now been implemented for new applications. This requires an online form submission by applicants and provides a largely automated process.

The following link can be used to access the new process:
https://goo.gl/forms/RcM1Kbh6Q9tEUy5Z2

Re-authorisations for Orthodox Medicines for Human Use:

Re-authorisations imply that an authorisation was issued approximately 6 (six) months previously, which is close to expiry or recently expired, and that a new authorisation is required for ongoing treatment.
Applicants should submit all re-applications via the following link:
https://goo.gl/forms/R0IQCYZxMt6HOD3p1

It is also important to email the proof of payment to section21@sahpra.org.za in the manner specified below:
Send the Proof Of Payment to section21@sahpra.org.za with "Subject" parameter stating Proof of Payment.
The contents of the email must stipulate the doctor's name, patient name/bulk stock, unregistered medicine proprietary name and date and time of online application.
Please note that this is only for Section 21(Orthodox Medicines for Human Use) applications.
Other crucial supporting documents for online applications for orthodox medicines for human use, including but not limited to, informed consent, package insert, product information, must be emailed to: section21@sahpra.org.za. Please note that this is only for Section 21(Orthodox Medicines for Human Use) applications.

Q: Who can I contact regarding a Section 21 application to for a natural supplement / herbal medicine/complementary medicine?

A: The contact details for Section 21 for complementary medicines
Dr Kaizer Thembo
Tel: 012 842 7595/012 8427639/071 134 3709
Email: Kaizer.thembo@sahpra.org.za

Please do not submit a Section 21 application to for a natural supplement / herbal medicine/complementary medicine via the online system for Section 21(Orthodox Medicines for Human Use) authorisation.

Q: Who can I contact regarding a Section 21 application to for a veterinary medicine?

A: Dr Alice Sigobodhla
Tel: 012 842 7586 / 074 379 1178
Email: alice.sigobodhla@sahpra.org.za

Please do not submit a Section 21 application to for a veterinary medicine via the online system for Section 21(Orthodox Medicines for Human Use) authorisation.

Q: Who can I contact regarding a Section 21 application to for a medical device?

A: Ms Andrea Julsing Keyter
Tel:012 842 7585 / 082 062 2594
Email: andrea.julsing@sahpra.org.za

Please do not submit a Section 21 application to for a medical device via the online system for Section 21(Orthodox Medicines for Human Use) authorisation.

Q: Which contact details for the Section 21(Orthodox Medicines for Human Use) unit are now non-operational and must not be used?

A: Any contact detail not appearing in the afore-mentioned FAQ (***What are the contact details of the Section 21(Orthodox Medicines for Human Use) unit?)*** must not be used.
In addition, the Section 21(Orthodox Medicines for Human Use) unit no longer uses fax lines as a means of communication.
Landline and fax line numbers published prior to January 2019 must not be used.

Question: What is the Section 21 application fee?

A: R330

The latest fee can be obtained by referring to the Section on FEES on the SAHPRA website, www.sahpra.org.za.

Q: What are the banking details?

A: Account name: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
Account type: Cheque / Current Account
Account number:40-5939-2080
Bank: ABSA Bank
Branch Code:632005.

The latest banking detail can be obtained by referring to the Section on FEES on the SAHPRA website, www.sahpra.org.za.

Q: What do I write as beneficiary reference when doing payment for a Section 21(Orthodox Medicines for Human Use) application?

A: It is best to use the cell phone number of the person who will know the most about the application as beneficiary reference. This will allow ease of enquiry if the payment is probed. It is also important to email the proof of payment to section21@sahpra.org.za in the manner specified below. Please note that this is only for Section 21(Orthodox Medicines for Human Use) applications.

Q: Once I have made a payment for a Section 21(Orthodox Medicines for Human Use) application, where do I send the Proof Of Payment to?

A: Send the Proof Of Payment to section21@sahpra.org.za with “Subject” parameter stating Proof of Payment.
The contents of the email must stipulate the doctor’s name, patient name/bulk stock, unregistered medicine proprietary name and date and time of online application.
Please note that this is only for Section 21(Orthodox Medicines for Human Use) applications.

Q: What is the turnaround time for a Section 21 application for orthodox medicines for human use?

A: The turnaround time is 24-48 hours (on working days). There are in fact, cases, where this turnaround time, might be prolonged i.e. substances, unfamiliar medication which requires extensive research to be done by the evaluators.

Q: What do I do if the details on a Section 21 approval letter need to be changed?

A: It might be the case that certain details on a valid (six month) approval need to be amended, including but not limited to, changing the treating practitioner, change of importing company. In this case, please resubmit your application on the online portal with the amended details. The reason for re-submitting must be clearly mentioned in the re-submitted application.
However, if the approval is no longer valid (six months have elapsed since approval), the applicant must submit a re-authorisation with recent proof of payment details.

Q: What do I do when a SAHPRA-registered medicine is out of stock?

A: Obtain an out of stock letter from the supplier and submit it to the section 21 e-mail (section21@ sahpra.org.za), together with an online application.

Q: How long is a Section 21 authorisation valid?

A: It is valid for a Maximum of 6 (six) months unless otherwise stated.

Q: Who can apply for a Section 21?

A: A Treating Practitioner who may or may not belong to a health care facility (Institution) can apply.

Q: Can a patient apply for a Section 21 on their own?

A: No, a Treating Practitioner who takes full clinical responsibility (for monitoring safety, efficacy and quality of the unregistered medicine) must complete an online application.

Q: If a Medical Practitioner is the patient, can they apply for a section 21 on their own?

A: No, a Medical Practitioner other than the one who is a patient must apply for a section 21 authorisation**.**

Q: Can I hand deliver or email my application?

A: No hand deliveries will be accepted.

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Applicants should submit all re-applications via the following link:
https://goo.gl/forms/R0IQCYZxMt6HOD3p1

Supporting documents, including but not limited to, proof of payment and informed consent for online applications for orthodox medicines for human use should be sent by email to: section21@sahpra.org.za.

Q: Where can I get information on what medicine is registered by SAHPRA?

A: The Section 21(Orthodox Medicines for Human Use) unit is not in a position to provide this information. Please send an email enquiry to enquiries@sahpra.org.za. You will receive a written response to your enquiry.