



SUBMISSION PROCEDURE FOR SECTION 21 RE-AUTHORISATIONS

To all Stakeholders

This South African Health Products Regulatory Authority (SAHPRA) communication serves to inform Section 21 applicants of *interim* submission arrangements to improve service delivery as pertains to Section 21 authorisations for the sale of unregistered orthodox medicines for human use in South Africa.

Re-authorisations

The Authority has implemented a submission portal in order to address the influx of urgent Section 21 re-authorisations. 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/aZ8LB9eOmck6lhPF3>

Currently this is for *re-applications* only and the system does not allow for new applications to be submitted.

New applications

Submit new applications strictly to section21@health.gov.za, with the subject line in the following format:
Dr A Healer | M Soap | cloxacillin

This is to enable fast processing of new applications.

Regrettably, any faxed applications to 086 274 3073 will not be processed until further notice.

You are requested not to send any application in more than once.

What should be done with applications already faxed to the 086 number?

- For new applications, please scan and e-mail as per **New applications** guideline above.
- For re-authorisations, please re-submit your application via the online submission portal.