



UPDATE ON SUBMISSION PROCEDURE FOR ALL SECTION 21 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.

As SAHPRA is currently housed within the National Department of Health in the Civitas building in Pretoria, its ability to execute its functions has been limited due to ongoing protest action about working conditions in the building. For this reason, SAHPRA is transforming its Section 21 processes to ensure ongoing provision of these services, which may be lifesaving.

The Authority has implemented a submission portal in order to address Section 21 re-authorisations as well as new applications.

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/R0IQCYZxMt6HOD3p1>

New applications

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>

Important:

1. We encourage all applicants who have not yet received feedback on their submissions to resubmit using the above links in order to ensure the fastest possible turnaround time.
2. SAHPRA will continue to maintain rigorous risk assurance standards for all Section 21 processes. In addition, patient confidentiality remains an ongoing priority.
3. What should be done with applications already faxed to the 086 number or e-mailed?
 - For new applications, please re-submit the online application via the online submission portal.
 - For re-authorisations, please re-submit your application via the online submission portal.