South African Health Products
Regulatory Authority
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Loftus Park
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Pretoria

Request for Priority Review of New Medicines and Variations Applications

This document is intended to provide communication to applicants wishing to request for priority review for new medicine and variation applications. This will be a "living document" and will be updated as required. This communication is an interim document. Kindly be advised that the information will be incorporated into the General Information Guideline at a later stage.

Document History

First Publication – Version 1	February 2022

1. INTRODUCTION

SAHPRA has a policy to make provision for priority review, for the assessment and registration of medicines that treat serious diseases and is of major public interest.

This policy is intended to provide priority review to facilitate greater accessibly and availability of medicines:

- That address an unmet clinical need in the South African Market (Novel/ Innovative medicine/ NCEs);
- That show a major therapeutic advantage in safety or efficacy to existing treatment options;
- For life threatening or seriously debilitating conditions;
- For Public health and animal health emergency;
- For a limited target disease for a patient population (Orphan disease);
- In the event of national priorities guided by the NDoH or
- Where security of supplies is a concern (guided by NDoH needs) and Department of Agriculture.

This policy applies to New Chemical Entities (NCE's), New Biological medicines, interchangeable multi-source(generic) medicines and Biosimilars for both new registrations and their lifecycle management.

2. Priority Review Pathway

The ***Priority Review Pathway*** makes provision for a truncated time frame of assessment and registration of vital and life-saving medicines, of which there is an unmet medical need in the South African market. This is performed by priority assessment of a complete dossier that provides evidence of maintaining the required high standards of quality, safety and efficacy as determined by the Act.

The ***Priority Review Pathway*** may be used in the following cases:

a new prescription medicine which contains:

- a chemical, biological or radiopharmaceutical active ingredient that has not previously been included in the Register; or
- a fixed combination of chemical, biological or radiopharmaceutical active ingredients, at least one of which has not previously been included in the Register.

an already registered prescription medicine with a new indication that contains:

- the same chemical, biological or radiopharmaceutical active ingredient (or fixed combination of such ingredients) as another prescription medicine included in the Register; and
- does not have the same indications as that other medicine.

3. Priority Review Process

Applicants are required to make a submission requesting priority review application via the designated email – priorityrequestnewmeds@sahpra.org.za and priorityrequestsvariations@sahpra.org.za

The following documentation should be submitted when requesting for priority review:

- a formal request letter
- motivation for the priority review should meet the requirements as stated in (**1)** and **(2)** above and should be clearly explained.

4. Priority Review Committee Meeting

Requests for priority review will be discussed by an internal special committee.

- For a positive outcome, a response letter will be issued with a priority number
    - The priority number should be included in all correspondence and in the file naming convention for the application.
- For a negative outcome, a non-approval letter will be issued.

5. Fees for Priority Review

SAHPRA intends on charging a fee for applications to be prioritised.

The appropriate fees for prioritised review will be gazetted.

The communication with updated information regarding the fees will be communicated in due course.