SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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Request for Priority Review of New Medicines and only Type II Variation Applications

Document History

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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 accessibility and availability of medicines. The following criteria will be considered for priority review of medicines:

- That address an unmet clinical need, a disease or condition for which there are no registered treatment(s) in the South African Market;
- For Public health and animal health emergency refer to the guideline: Availability of medicines for use in a Public Health Emergency (PHE)-(SAHPGL-PEM-01);

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- For a limited target disease for a patient population (Orphan disease), refer to Waivers from certain medicine registration requirements – (SAHPGL-CEM-S21-01);
- In the event of national priorities guided by the National Department of Health (NDoH) or
- For registered products where security of supply is a concern, as guided by the NDoH or the 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.

an interchangeable multi-source (generic) medicine or biosimilar medicine meeting one or more of

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the criteria in point 1 above.

A major variation (type II) to a registered product, only in cases where the priority approval/ assessment of the variation is necessary to ensure the continued supply of the product to address a public health need.

3. Priority Review Process

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

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

- a formal request letter with a motivation for the priority review.
- The motivation for the priority review should clearly indicate which criteria/ requirements are met as stated in (**1)** and **(2)** above and should be clearly explained.
- Applicable to Post- Registration Variation submissions only: A description of the variations to be applied for and proposed submission sequence (e.g. 0000, 0001 etc.) must be provided Refer to Table 1 below

Table 1

Proposed eCTD eSub sequence	**0001**	
Variation Classification	**Variation Code**	**Description of variation**
Type II	B.II.d.1.e Change outside the approved specification limits range	Widening of specification of water content from NMT 2.0% to NMT 3.0%
Type II	…..	…….

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The documentation will be screened to ensure that the correct criteria/ requirements have been used in the motivation. If the motivation does not include the criteria/ requirements as stated in (**1)** and **(2)** above, the priority review request will not be considered.

Type I variation applications **will not** be considered for priority review due to the short timelines for implementation.

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.
- Outcome letters will be communicated to the applicants once the minutes for the previous meeting have been ratified.

Once approval is granted for priority review requests where the application has not been submitted to SAHPRA, the application should be submitted within thirty (30) working days of receipt of the letter.

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.

6. Timelines

The following regarding the relevant timelines refers:

- the timelines refer to the time spent with SAHPRA (i.e exclude time spent with the applicant)
- the timelines indicate the review timelines from the date of receipt of a complete application

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- the timelines do not include the time spent when a site inspection is required by SAHPRA
- timelines do not apply for rolling review applications

	Type	Review Timeline/ Working Days
Variations	Post-Reg Quality Type II	90
	Post-Reg Biologicals Type II	90
	Post-Reg Clinical Type II	90
New Medicines	Public Health Emergency (PHE) products	90
	Priority New Chemical Entities (NCEs)	180
	Priority Generic medicines	180