SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

COMMUNICATION TO STAKEHOLDERS

Issue No.: CLINPR04-2025/26

28 May 2025

PHENYLEPHRINE - LACK OF EFFECTIVENESS OF ORAL PREPARATIONS AS NASAL DECONGESTANT

INTRODUCTION

This communication serves as an official update to the Holders of Certificates of Registration (HCRs) of orally administered phenylephrine-containing medicines.

Further to the Authority's prior communications dated 30 July 2024 regarding the lack of efficacy of orally administered phenylephrine as a nasal decongestant, and the subsequent request for submission of data supporting continued registration, the South African Health Products Regulatory Authority (SAHPRA) notes the limited and unsatisfactory responses received within the stipulated 90-day period.

The submissions were reviewed by the Advisory Clinical Committee, and it was concluded that:

- The majority of HCRs did not respond within the specified timeframe.
- The few responses received were considered inadequate, confirming that the available scientific data do not support the efficacy of the recommended dosage of orally administered phenylephrine as a nasal decongestant.

Subsequently, a second communication was shared with HCRs on 27 January 2025, requesting all HCRs of orally administered phenylephrine-containing medicines to provide feedback by 31 March 2025 regarding the Authority's intention to classify these medicines as undesirable due to concerns about their efficacy.

Following this, meetings were held between SAHPRA and several HCRs and/or their representatives to discuss the implications of the previous communications and the associated regulatory

SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Str
Arcadia
0083

requirements. During these engagements, stakeholders requested an extension to allow adequate time to gather and submit the necessary efficacy data.

In consideration of these requests, SAHPRA is granting a six (6) month extension to all HCRs of orally administered phenylephrine-containing medicines.

HCRs are required to submit the following by 15 November 2025:

- Clinical efficacy data specific to single-agent phenylephrine formulations; or
- A high-quality meta-analysis or systematic review that is compliant with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines, aligned to the indication in question for these products.

Submissions must include high-quality scientifically robust evidence, relevant to the claimed indications, and sufficient to support the ongoing benefit-risk profile of the product.

Failure to submit the required data within the specified period will result in regulatory actions due to a lack of demonstrated efficacy.

The Authority remains committed to evidence-based regulatory decision-making to ensure the safety, efficacy, and quality of health products available in South Africa.

Boitumelo Semete-Makokotlela

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer (CEO)
SAHPRA