SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

Issue No.: CLINPR03-2024/25

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PHENYLEPHRINE - LACK OF EFFECTIVENESS OF ORAL PREPARATIONS AS NASAL DECONGESTANT

INTRODUCTION

This document is intended to communicate with the Holders of Certificates of Registration (HCRs) of orally administered phenylephrine-containing medicines.

Following the communication issued to stakeholders on 30 July 2024 regarding the ineffectiveness of oral phenylephrine preparations as nasal decongestants, HCRs for orally administered phenylephrine-containing medicines were given 90 days to respond, as outlined in the communication.

The Authority made the following recommendations:

- All phenylephrine-containing orally administered medicines that are not currently registered should be submitted for registration within 90 days of receiving this recommendation.
- All HCRs for orally administered phenylephrine-containing medicines should provide comments on the ongoing benefit/risk profile of their products, supported by relevant data, within 90 days of receiving this recommendation.

Subsequently, SAHPRA convened an Advisory Clinical Committee meeting on 25 November 2024 to discuss the limited responses received from HCRs following the recent communication. **The Committee concluded:**

- The majority of HCRs failed to respond within the specified timeframe.
- The few responses that were received were deemed inadequate and unsatisfactory, as the existing scientific data does not support the effectiveness of the recommended dosage of orally administered phenylephrine as a nasal decongestant.

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Consequently, the Authority is requesting that all HCRs of orally administered phenylephrine-containing medicines provide feedback by **31 March 2025** regarding the Authority's intent to classify these medicines as undesirable due to concerns about their efficacy.

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