

DIRECTOR GENERAL HEALTH REPUBLIC OF SOUTH AFRICA

PRETORIA
Private Bag X828, PRETORIA, 0001, Dr AB Xuma Building, 1112 Voortrekker Rd, Pretoria Townlands 351-JR, Pretoria, 0187, Tel (012) 395 8000
CAPE TOWN
P.O. Box 3875, CAPE TOWN, 8000, 103 Parliament Towers, Room 615, Plein Street, CAPE TOWN, 8000 Tel (021) 461 2040 Fax (021) 461 6864

To: All Licensed Pharmaceutical Manufacturers,
Importers of Medicines in South Africa (Applicants) and, or
Price File Managers

THE ANNUAL CLOSING OF THE 2024 RECEIPT OF THE SINGLE EXIT PRICE (SEP) SUBMISSIONS/APPLICATIONS MADE IN TERMS OF THE REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES

- 1. The above matter refers-
- 1.1 The National Department of Health's Pharmaceutical Economic Evaluations (PEE) Directorate hereby informs you that there will be no receipt or processing of any SEP updates submissions in terms of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances for the period 1st December 2024 to 06th January 2025 (including both dates). See Guidelines for SEP Updates on https://www.health.gov.za/nhi-pee/ for more details.
- 1.2 The categories of SEP update submissions affected by the close-off period include re-introduction of a medicine previously available in the market, introduction of the SEP for new pack size of an existing medicine, permanent and non-permanent SEP reductions, increase post SEP reduction (non-permanent), medicine SEP discontinuation, existing medicine details amendments and SEP increase post Regulation 9 SEP approval. New medicine launches are excluded.

- 1.3 The last date of receiving 2024 applications for the exceptional SEP increase made in terms of Regulation 9 of the Regulations is as per the Regulation 9 Guideline and exemptions applications made in terms of Section 36(2) of the Medicines and Related Substances Act, Act 101 of 1965 as amended was 30 September 2024.
- 2. For any further enquiries on this matter, contact the Directorate: Pharmaceutical Economic Evaluations on the email sepupdates@health.gov.za.

Yours faithfully

DR SSS BUTHELEZI

DIRECTOR-GENERAL: HEALTH ACTING

DATE: 14/11/2024.