

DEPARTMENT OF HEALTH**NOTICE 3973 OF 2026**

**DIRECTOR GENERAL
HEALTH
REPUBLIC OF SOUTH AFRICA
PRETORIA
CAPE TOWN**

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

**CHANGE IN THE FORMAT 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 a change in the format of any SEP updates submissions made in terms of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances. See Guidelines for SEP Updates on <https://www.health.gov.za/nhi-pee/> for more details as well as updated templates and forms.
- 1.2 The categories of SEP update submissions affected by the change include new medicine launches, 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.

- 1.3 Included in the updates for 2026, is the inclusion of the Volume of Sales Column (VoS) for the preceding year. Applicants are advised that going forward this column is now a compulsory standard requirement. Any submission/application lacking this data will be deemed “incomplete” in terms of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances as related to Section 22G of the Medicines and Related Substances Act 101 of 1965. This update to the requirements in the submissions/applications has been necessitated by the increasing refusal by external data companies to provide data required to monitor trends and developments in the medicine supply chain, especially the private sector. Unreasonably high prices are charged to access the private sector pharmaceutical medicine utilization data.
- 1.4 The latest versions of the templates and forms will be effective with immediate effect as published on the National Department of Health website.
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

DATE: 11/02/2026