

1. **ACRONYMS**

CFO – Chief Financial Officer

DoH – Department of Health

NDoH- National Department of Health

DoP – Database of Single Exit Prices

MCC – Medicines Control Council

MPR – Medicine Pricing Registry

NAPPI – National Pharmaceutical Product Interface

PEE – Pharmaceutical Economic Evaluations

PI –

2. APPLICANT INFORMATION

2.1 APPLICANT REQUIREMENTS

All registered applicants for medicines sold in SA, who are eligible in terms of the notice as signed by the Minister of Health on the 25th July 2023, may forward submissions for the Top-up Single Exit Price Increase (tu-SEPI) for 2023 for all scheduled medicines appearing on the Database of Medicines Prices (DoP) published on 17th July 2023.

(a) The following medicines are legible for 2023 tu-SEPI;

- i. Scheduled medicines for which 2023 SEPA was effected in terms of the Minister's signed Notice of 23 December 2022 as published, has been implemented.
- ii. **Newly** introduced pack-sizes whose related pack sizes were approved for 2023 SEPA in terms of the Minister's signed Notice of 23 December 2022 as published.

Such medicines must be unit priced with t(t)e[(S)4(uc)-3(h)-8(me)3(d)-9(i)5(c)12 0 Qq0.00000912

(d)

- i. Signed cover letter on the official letter head of the applicant;
- ii. Completed latest 2023 tu-SEPI template;
- iii. Completed annexure A;
- iv. Completed annexure B;
- v. Completed annexure C;
- vi. Completed annexure D (A fully completed latest tu-2023 SEPI template) and
- vii. Supporting documents where applicable e.g., Annexure E; All medicines that were submitted and approved for the 3.28% SEPA in terms of the Minister's signed

Note that the National Department of Health (NDoH) will not be held responsible for submissions that were incorrectly submitted.

3.1 TU-SEPI 2023 TEMPLATE TAB 1

- 3.1.1 For the information required under the following listed columns labels (headings) in the Template, applicants are required to copy such information from the DoP published on 17th July 2023 for all medicines that were previously approved for 2023 SEPI and sought tu-SEPI for 2023. All the information and formats and the order of medicines must remain as they appear on the DoP of 17th July 2023.

APPLICANT SAHPRA/MCC LICENCE NUMBER

APPLICANT NAME AS REGISTERED WITH SAHPRA/MCC

SAHPRA/MCC MEDICINE REGISTRATION NUMBER

NAPPI CODE (9-digit)

ATC 4 CODE (WHO)

SCHEDULE

MEDICINE PROPRIETARY NAME

ACTIVE INGREDIENT

STRENGTH

UNIT

DOSAGE FORM

PACK SIZE

QUANTITY /F4 9.96 Tf 1 0 0 1 232.85 275.45 Tm 0 g 0 G [(ld1 Q q 0.00000912 0 612 792 re W* n E

MANUFACTURER PRICE AS AT 17 July 2023

LOGISTICS FEES AS AT 17 July 2023

VAT

SEP AS AT 17 July 2023

UNIT PRICE AS AT

3.1.2 REQUESTED MANUFACTURER PRICE

This is the requested Value Added Tax (VAT) exclusive manufacturer price of the medicine in South African Rands. This is a numerical field displayed at 2 decimal places, with no currency symbols. This column should be indented to the right.

3.1.3 REQUESTED LOGISTICS FEE

This is the requested VAT exclusive logistics fee for the medicine in South African Rands. This is a numerical field displayed at 2 decimal places, with no currency symbols. This column should be indented to the right.

3.1.4 VAT ON REQUESTED COMPONENTS

This column is the VAT component of the SEP, calculated at 15% to the sum of the requested manufacturer price and the requested logistics fee. This is a numerical field displayed at 2 decimal places with no currency symbols. This column should be indented to the right.

3.1.5 REQUESTED SEP

This is the requested Single Exit Price for the medicine in South African Rands. It is the sum of the requested ex-manufacturer price, the requested logistics fee and VAT. This is a numerical field displayed at 2 decimal places with no currency symbols. This column should be indented to the right.

3.1.6 REQUESTED UNIT PRICE

This is the resulting unit SEP of the medicine, considering its pack size and quantity of presentation as per the SAHPRA (formerly MCC) approved package insert (PI). The unit price should be obtained by; dividing the requested SEP by the pack size and then further divided by the quantity. This is the price of a unit of the medicine, e.g. one tablet, capsule, millilitre, gram, etc. The unit price as described in the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled substances (Section 22G of the Medicines and Related Substances Act) is the SEP

divided by the number of units of the product. Note that unit pricing applies to all medicines with the same proprietary name, strength and dosage form.

(a) For injections the unit price shall be calculated per ml of reconstituted volume, even where

4.4 ANNEXURE D: SEPI 2023 TEMPLATE

See Excel Template Published in www.mpr.gov.za or <https://www.health.gov.za/nhi/> and emailed to _sepupdates@health.gov.za