



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



INFORMATION AND INSTRUCTIONS FOR THE 2023 TOP-UP SINGLE EXIT PRICE INCREASE (TU-SEPI) SUBMISSIONS

**ALL TU-SEPI 2023 SUBMISSIONS MUST BE SUBMITTED
ELECTRONICALLY VIA EMAIL ADDRESS
SEPUPDATES@HEALTH.GOV.ZA WITH ALL SUPPORTING
DOCUMENTS SAVED ON A ZIPPED FOLDER**

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the 2023 Top-up SEP Increase (tu-SEPI) for medicines prices adjusted in terms of Section 22G of Medicines and Related Substances Act (101 of 1965) as amended, and Regulation 8(1) of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances. The applicants are required to comply with all the requirements and instructions in this document, failure to do so will result in the submission being considered incomplete. Incomplete submissions shall be regarded as ineligible for processing based on non-compliance with the requirements of these guidelines. These guidelines must be read together with the relevant sections of the Medicines Pricing regulations.

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 – Package Insert

SAHPRA – South African Health Products Regulatory Authority

SEP – Single Exit Price

SEPI – Single Exit Price Increase

TU-SEPI – Top-Up Single Exit Price Increase

VAT – Value Added Tax

WHO ATC – World Health Organisation Anatomical Therapeutic Chemical

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 their related pack sizes.
- (b) The following medicines are **NOT** legible for 2023 tu-SEPI but, they must be included with the row order as of 17th July 2023 DOP maintained:
 - i. Scheduled medicines for which 0% SEPA was effected in terms of the Minister's signed Notice of 23 December 2022 as published, was implemented.
 - ii. Scheduled medicines for which 2023 SEPA effected in terms of the Minister's signed Notice of 23 December 2022 as published, was not implemented for whatever reason(s).
 - iii. Discontinued medicines
 - iv. Medicines that took a permanent or non-permanent SEP reduction following the SEPI implementation that was made in terms of the Minister's signed Notice of 23 December 2022 as published.

NB: In cases where the medicine is not available on the 17th July 2023 database and the SEP of the medicine was adjusted in terms of the Minister's signed Notice of 23 December 2022 as published, the applicant must submit proof that the medicine was previously allocated an official Single Exit Price in terms of 2023 SEPA. Applicants must note that medicines falling in the category of medicines described under 2.1 (b) i. to iv. are **not eligible for 2023 tu-SEPI**.

- (c) The information contained in the published gazette with respect to the tu-2023 SEPI should be read carefully and the contents thereof must be complied with as required.

- (d) The dates and timelines with respect to the implementation period for 2023 tu-SEPI must be read carefully and complied with as required and the dates are as follows:
- i. **17 July 2023** – base Single Exit Prices, reference DOP
 - ii. **18 August 2023** – First day of receiving tu-SEPI submissions.
 - iii. **01 September 2023** - Last day of receiving tu-SEPI first-time submissions.
 - iv. **18 September 2023** – Last day of receiving tu-SEPI resubmissions.
- (e) Read carefully the information and instructions contained in this document before completing all the fields of Tab 1 of the latest 2023 excel tu-SEPI template which is available on the website www.mpr.gov.za or departmental website <https://www.health.gov.za/nhi/>.
- (f) Provide the required information on the cover page (**Annexure A**).
- (g) Sign the declaration annexed to this document (**Annexure B**).
- NB: No information appearing on the submission shall be changed post facto if the declaration form is found to be completed and signed by all the relevant officials responsible for lodging the 2023 tu-SEPI submission.**
- (h) Complete the checklist that is also annexed to this document (**Annexure C**).
- (i) Complete **all** sections of Tab 1 of the latest 2023 tu-SEPI template in the fields provided (**Annexure D**).
- (j) Include a signed covering letter on a company letterhead, stating the purpose of your submission, with every submission or re-submission where applicable.
- (k) A complete submission should include a fully completed latest tu-SEPI template for 2023, annexure A, B, C and D (A fully completed tu-SEPI template) and a signed covering letter on the applicant's letterhead.
- (l) Ensure all the SEPI template fields are completed in full and the base Single Exit Prices, to be used as a reference for Increase purposes are those which were applicable on 17th July 2023 and that they have an effective date of 17th July 2023 or earlier. The base SEP's for each submitted medicine must be verified as correct and that it is appropriate for the relevant medicine prior to lodging the submission.
- (m) Ensure that all fields have been completed as per DoP of 17th July 2023.
- NB: All the applicants must verify the correctness of the information which appears under the tu-SEPI template excel spreadsheet Tab 1 column titled (Originator or Generic). Should this information be declared incorrect after the 2023 tu-SEPI implementation process, the applicant will be required to provide evidence to support their claims i.e. should the column details be changed at a later stage after 17th July 2023.**
- (n) Wherever the date is required, it should be stated in full (e.g. 18 August 2023)
- (o) Applicants are required to submit **ONLY** the electronic version of the entire submission via e-mail:

- 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 Notice of 23 December 2022 as published must also be listed on this excel spreadsheet in the same format as that of the reference DoP.

- (p) Applicants must ensure that all relevant documents such as the covering letter and the declaration Form in Annexure B are signed prior to lodging the submission.
- (q) The responsible officials sign the declaration Form (Annexure B) to verify and certify that the submission is complete and that the information contained in the submission is true, correct error-free, and every aspect of the 2023 tu-SEPI gazette and its guidelines are complied with in totality as prescribed.
- (r) The signed declaration Form (Annexure B) also confirms that the submission in its entirety has been checked by all the persons whose signatures are appended under Annexure B, in addition to the person responsible for compiling the submission.

2.2 TU-SEPI SUBMISSION REQUIREMENT

- (a) The submissions lodged in terms of these guidelines are solely for the purpose of 2023 tu-SEPI. For other medicine details amendments, applicants must use Template G of the SEP updates as published either on websites: www.mpr.gov.za or <https://www.health.gov.za/nhi/> or emailed to sepupdates@health.gov.za
- (b) For a submission to be considered complete, **ALL** sections of the 2023 tu-SEPI template, inclusive of all excel spreadsheet fields, must be fully completed. A fully completed template must have Tab 1 and all its fields completed. All the required fields within Tab 1 must be completed for every medicine whose 2023 SEPA was implemented and published on DoP of 17th July 2023.
- (c) Only the rightful applicant as recorded on the DoP of 17th July 2023 for the medicine as per the SAHPRA (formerly MCC) manufacturing license and MCC / SAHPRA medicines registration certificate must lodge the submission for the medicine(s) concerned.
- (d) Only those applicants whose manufacturing licenses have not expired may submit 2023 tu-SEPI submissions.

- (e) In cases where an applicant name change occurred after the 17th July 2023 but before lodging the 2023 tu-SEPI submission, only the applicant whose applicant name is reflected on the DoP of 17th July 2023 shall be considered for purposes of the 2023 tu-SEPI submissions.

2.3 NOTES FOR APPLICANTS

- (a) The submission of 2023 tu-SEPI is not obligatory. The eligible applicants are not compelled to compile and submit 2023 tu-SEPI submissions.
- (b) The 2023 tu-SEPI is only applicable on the medicines with a SEP that was adjusted in terms of the Minister's signed Notice of 23 December 2022 as published and were already effective on the 17th July 2023.
- (c) Applicants must note that in terms of the Medicines Pricing Regulations, there shall only be one SEP at any given point in time.
- (d) Applicants are advised to compile their own list of reference medicine SEPs to enable the verification of prices during tu-SEPI implementation. The schedule of 17th July 2023 may be found on www.mpr.gov.za or <https://www.health.gov.za/nhi/> under "Published Documents", click database of medicine prices. Click on the excel spreadsheet titled *database of medicine prices 17th July 2023*. The reference database may be published on the NDoH website <https://www.health.gov.za/nhi/>.
- (e) There can only be one SEP submission launched at any given point in time. The applicant cannot request for an update on the SEP or lodge a Regulation 9 application, whilst the submission for tu-SEPI is still in process. Similarly, the applicant cannot submit a tu-SEPI or Regulation 9 application whilst the submission for an SEP update is still in process. In an event where the applicant has made a tu-SEPI submission and any other SEP submissions and/or a Regulation 9 application the tu-SEPI will not be considered. Should the applicant wish to re-submit, a new submission may be made once the other outstanding SEP submissions and/or Regulation 9 applications have been concluded.
- (f) **The row order of all the applicant's medicines, as they appear on the DoP of 17th July 2023 must be maintained.** Any medicines not appearing on the 17th July 2023 list but are eligible for 2023 tu-SEPI should appear at the bottom of the 2023 tu-SEPI template in an alphabetical order. Supporting documents in the form of Annexure E excel spreadsheet that shows that the medicine was previously approved for 2023 SEPI must be provided.
- (g) All medicines with related pack sizes that are presented on the template for 2023 tu-SEPI must be unit priced. When computing the unit prices, the resulting SEPs should not exceed the maximum allowable SEP after the Increase on the SEP that existed on 17th July 2023

(i.e. SEP applicable as of 17th July 2023 + maximum allowable tu-SEPI % as per the Minister's Notice).

- (h) All medicines including those with multiple pack sizes are required by law to be unit priced i.e. all same ingredient and dosage form medicines with related pack sizes must have the same unit price. Non-compliance with unit pricing will result in the entire submission not being considered.
- (i) Where a new pack size is introduced after 17th July 2023 and before the date of lodging of 2023 tu-SEPI, it is expected that this will result in a unit price that is no greater than the unit price that existed on its related pack sizes on 17th July 2023. (Note that the newly introduced pack sizes for medicines whose related pack sizes were approved for 2023 SEPI should be included in the submission for 2023 tu-SEPI and should also be unit priced with their related pack sizes).
- (j) All submissions for tu-SEPI will be processed within 32 working days (excluding weekends and holidays) upon receipt of the submission by the PEE Directorate of the Department.
- (k) The outcome of each processed submission will be communicated to the applicant within 32 working days of the date of your submission. Applicants are required to take note of this 2023 tu-SEPI implementation time frame prior to following up on a submission status.
- (l) All processes and approved SEPs will be communicated to submitting applicants, price file managers and all the stakeholders that are registered on the department of Health e-mailing list. The approved prices will be published on the website (www.mpr.gov.za) at a later stage.
- (m) All correspondence(s) concerning a submission will only be communicated to the applicant of the medicines applied for.
- (n) The electronic version of the submitted 2023 tu-SEPI template (Annexure D) **must be in excel (not pdf format) and should be saved with a file name extension "xls"**. Submissions containing password-protected documents and files in a version that is not accessible when using NDoH systems; such as those with the file extensions xlsx, docx and PDF, will not be considered.
- (o) 2023 tu-SEPI can only be submitted on the published latest tu-SEPI template for 2023 including Tab 1. **ANY** modification to the template will result in the entire submission not being considered. This also applies to re-submissions.
- (p) The final date for all 2023 tu-SEPI first submissions is 01st September 2023 and for resubmissions is 18th September 2023. No submission shall be reviewed outside of the dates that are stipulated in the 2023 tu-SEPI notice.

- (q) An applicant may only submit once in the 2023 tu-SEPI cycle. This does not apply to resubmissions (see point (s) below)
 - i. An applicant's portfolio may not be divided into multiple submissions.
 - ii. The maximum allowable Increase may not be divided into multiple submissions. Should an applicant request less than the maximum published Increase, the balance will be forfeited for the 2023 cycle.
- (r) Resubmissions;
 - i. Resubmissions shall only be considered if submitted within the timelines stipulated in the 2023 tu-SEPI notice i.e on or before 18th September 2023.
 - ii. Will **only** be reviewed for medicines that had SEPs that were previously not adjusted in terms of the 2023 tu-SEPI quantum, because of discrepancies identified in the first 2023 tu-SEPI submission.
 - iii. All the requirements for the tu-SEPI submissions as stated in this document shall be applicable to re-submissions.
 - iv. A resubmission of the not-approved medicines may not be split into multiple re-submissions.
 - v. MUST contain ALL the medicines listed under the Not-Approved sheet of Annexure E which is communicated to the applicant in response to the initial submission.
 - vi. Resubmissions must contain only medicines listed in the Not-Approved sheet of Annexure E communicated to the applicant in response to the initial submission.
 - vii. Re-submissions must only be submitted on the official and latest 2023 tu-SEPI template.
 - viii. Must only be on the 2023 tu-SEPI template, by the close off date as specified by the Minister of Health and reflected in the 2023 tu-SEPI notice.

2.4 LODGING OF SUBMISSIONS

- (a) Submissions must be lodged electronically via the department of health email sepupdates@health.gov.za. No hard copies submissions will be considered.
- (b) The cover letter must reflect the following information:
 - (a) Applicant Name
 - (ii) 2023 tu-SEPI Submission
 - (i) Number of Medicines in TAB 1 of the submission template (e.g. Tab 1 = 50 medicines /75 line items)

- (c) Each submission **MUST** be lodged on the latest 2023 tu-SEPI template and must be accompanied by annexure A, B, C and D included in this document as well as the applicant's covering letter on the official letterhead of the applicant. All these documents must be saved on a zipped folder and submitted as such.
- (d) Where an applicant is uncertain about the contents of the submission being lodged, clarity must be solicited from the PEE directorate prior to lodging the submission and this must be done by no later than the closing dates for the lodging of the SEPI submissions. Queries relating to approved submissions that may contain information that was not corrected timeously will not be tolerated.
- (e) Only e-mail submissions will be accepted for tu-SEPI 2023.
- (f) The 2023 SEPI email must be addressed to:

2023 tu-SEP Increase

Director: Pharmaceutical Economic Evaluations (PEE)

ATT: Ms Ntobeko Mpanza

National Department of Health

Room C6-18A Dr A B Xuma Building

1112 Voortrekker Road, Pretoria Townlands 351 - JR

0001 Via sepupdates@health.gov.za.

Email submissions must be lodged between 09:00 and 12:00 Monday to Friday excluding public holidays. All submissions will be allocated a reference number and no late submissions will be considered. Where the reference number is not received within five (5) working days from the date of lodging the submission, the applicant must resubmit since their submission will not be reflecting on the list of submissions received by the department of Health.

For any enquiries regarding 2023 tu-SEPI implementation, you may contact Ms Mahlogonolo Ledwaba between 13:00 and 15:00 at (012) 395 8186 or by e-mail at Mahlogonolo.Ledwaba@health.gov.za and Frieda.Seete@health.gov.za at 012 395 8210 from Monday to Friday excluding public holidays.

All queries must include the reference number provided to the applicant as an acknowledgement of receipt of the tu-SEPI submission.

Note that the National Department of Health (NDoH) will not be held responsible for submissions that were incorrectly submitted. A reference number reflected on the acknowledgment notice should be quoted in every communication made to NDoH by the applicant.

2.5 DOCUMENTS TO BE SUBMITTED

Applicants are required to submit **all** the following documents to ensure completeness of the submissions:

- (a) Signed cover letter on the official letter head of the applicant; (The cover letter should include details of the number of medicines being submitted: see point 2.4 (b) above.
- (b) Completed latest 2023 SEPI template with Tab 1
- (c) Completed annexure A
- (d) Completed annexure B
- (e) Completed annexure C and
- (f) Completed Annexure D
- (g) Supporting documents where necessary, such as Annexure E of 2023 SEPA as approved and last communicated.

2.6 ACKNOWLEDGEMENT OF RECEIPT

Upon receipt of a submission, an acknowledgement notice will be provided to the representative of the applicant by the PEE Directorate official. All applicants should retain their acknowledgment notice, for reference purposes.

3. HOW TO COMPLETE TEMPLATE COLUMNS

The details must be copied from the 17th July 2023 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 17th July 2023

Failure to comply with the prescribed requirements under this section 3 below will result in the entire submission not being considered.

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
- 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 17 July 2023
- EFFECTIVE DATE
- STATUS
- ORIGINATOR OR GENERIC

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 the total volume of the medicine administered to a single patient is less than 1 ml.
- (b) For inhalers, where the pack size is described in the SAHPRA (formerly MCC) approved PI as doses or puffs the unit price will be for 1 dose or puff.
- (c) The unit price is the SEP divided by the pack size and then further divided by the quantity [the "quantity" represents the multiples in which the medicine is packed/the number of pack sizes e.g. for injections, the "quantity" for 50 vials containing 500mg powder for injection packed in 20ml vial to be reconstituted with 10ml of diluents is 50].

This is a numerical field displayed at decimal places with no currency symbols. This column should be indented to the right.

NOTE: The template with Tab 1 must always be maintained in the font and format as it appears on DoP of 17th July 2023. Applicants should only make use of space, dashes or any other characters if these are represented as such in official documentation.

4. ANNEXURES

4.1 ANNEXURE A: COVER PAGE

TO BE COMPLETED BY THE APPLICANT	
APPLICANT NAME <i>As it appears on the MCC / SAHPRA license</i>	
CONTACT PERSON Name: E-mail: Fax No: <i>(Person responsible for this submission)</i>	
NUMBER OF MEDICINES IN THE SUBMISSION <i>(Also include medicines for which SEP Increase is not requested, rows which contain multiple active ingredients should not be counted.)</i>	
NUMBER OF ROWS BEING SUBMITTED <i>(Rows which contain only active ingredients should also be counted.)</i>	

FOR OFFICE USE ONLY (as per acknowledgement notice)	
Date received: (dd/month/yyyy)	
Received by (Name and Surname):	
Signature:	

**4.2 ANNEXURE B: DECLARATION
SEPI DECLARATION**

I, (full name and surname) in my capacity as.....and having the authority to sign and enter into legally binding agreements on behalf of.....
(Name of applicant) hereby certify that:

1. I have read and understood the information and instructions contained in the 2023 tu-SEPI information and instruction document.
2. I have followed the instructions contained in the 2023 information and instruction document in completing the tu-SEPI template.
3. I have correctly calculated unit pricing for all medicines in the applicant's portfolio.
4. I have requested only the tu-SEPI and not any other medicine details amendments for the scheduled medicines in the applicant's portfolio.
5. I have enclosed a signed covering letter on the company letterhead, stating the purpose of this submission.
6. The information supplied in this submission is true and correct. (NB: please provide proof of authorization to sign on behalf of the company)

SIGNATURE (DEPONENT)

1.(CFO name and signature)
2.(Responsible Pharmacist name and signature)

The Deponent has acknowledged that he/she knows and understands the contents of this affidavit, which was signed and sworn to before me aton this the.....day of..... 2023 and that the regulations contained in Government Gazette Notice No. R 1258 of 21 July 1972 (as amended) has been complied with.

COMMISSIONER OF OATHS

4.3 ANNEXURE C: CHECKLIST

SEPI CHECKLIST

Tick the appropriate box (✓)

HAVE YOU:	YES	NO
a) Read and understood the entire instruction document for 2023 tu-SEPI?		
b) Read, understood, and followed all the instructions in Section 2 and Section 3?		
c) Provided a signed covering letter on a company letterhead stating the purpose of the submission?		
d) Correctly completed the 2023 tu-SEPI template?		
e) Completed the required fields of the covering page (Annexure A)?		
f) Signed the declaration as required, indicating that the information supplied with this application is true and correct (Annexure B)?		
g) Answered yes to all questions in this checklist (Annexure C)?		
h) There are no blanks on Tab 1		

NOTE: *If any of the answer(s) to the question(s) above is **NO**, the submission will not be considered.*

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