DEPARTMENT OF HEALTH

NO. 5731 **27 December 2024**

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)

ANNUAL SINGLE EXIT PRICE ADJUSTMENT [SEPA] OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2025

I, DR A MOATSOLEDI, the Minister of Health, has determined on recommendation of the Pricing Committee, in terms of Regulation 8(1) of the Regulations relating to a Transparent Pricing System for Medicines and Scheduled Substances published in terms of the Medicines and Related Substances Act, (Act 101 of 1965), that the Single Exit Price (SEP) of Medicines and Scheduled Substances may be adjusted by not greater than **5.25%** of the SEP of medicines and their related pack sizes that was available as at 20th December 2024 regardless of how that SEP was arrived at in the 2024 cycle. Applications for adjustments of the SEP may only be submitted for the first time in 2025 from 06th January 2025 and by no later than 14th February 2025.

All medicines and their related pack sizes with SEP approved with an effective date later than 20th December 2024 are not eligible for SEPA 2025. An applicant may only submit once in the 2025 cycle unless a re-submission is made for eligible medicines that have not been previously approved for an adjustment in 2025 period in which an application was made. The final date for re-submissions will be 14th March 2025

An adjustment in the Single Exit Price in terms of this Notice may only be implemented by the manufacturer or importer of the relevant medicine or scheduled substance, no later than 32 working days after the date that the manufacturer or importer has communicated the information requested by the Director-General in terms of the Notice published in terms of Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled substances.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 17/11/2024

MEDICINES AND RELATED SUBSTANCES ACT, (ACT NO. 101 OF 1965)

INFORMATION TO BE PROVIDED BY MANUFACTURERS AND OR IMPORTERS OF MEDICINES AND SCHEDULED SUBSTANCES WHEN APPLYING FOR THE SINGLE EXIT PRICE ADJUSTMENT FOR 2025

I, DR SSS BUTHELEZI, Director-General, have determined in accordance with Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances published in Government Gazette number 28214 of 11 November 2005, that the information required in the submissions for the 2025 SEP adjustment as determined by the Minister be submitted to the Directorate: Pharmaceutical Economic Evaluation (PEE) within the National Department of Health by a manufacturer or importer of the medicine or scheduled substance, who is the applicant of the medicine, in accordance to the information and instruction document appended to this Notice.

Such information should be submitted electronically to sepupdates@health.gov.za The submission should include information containing the applicant's entire portfolio; including the medicines for which the applicant is not requesting an adjustment of the SEP.

DR SSS BUTHELEZI
DIRECTOR-GENERAL: HEALTH
DATE: 19.11.2024

2025 SEPA INFORMATION AND INSTRUCTIONS DOCUMENT

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

2030 NDP

INFORMATION AND INSTRUCTIONS FOR THE 2025 SINGLE EXIT PRICE ADJUSTMENT (SEPA) SUBMISSIONS

ALL 2025 SEPA SUBMISSIONS MUST BE SUBMITTED ELECTRONICALLY VIA EMAIL ADDRESS sepupdates@health.gov.za WITH ALL SUPPORTING DOCUMENTS SAVED ON A ZIPPED FOLDER

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2025 SEPA INFORMATION AND INSTRUCTIONS DOCUMENT

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the 2025 SEP adjustment (SEPA) 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 on the basis of non-compliance with the requirements of these guidelines. These guidelines must be read together with the relevant sections of the Medicines Pricing regulations.

2025 SEPA INFORMATION AND INSTRUCTIONS DOCUMENT

1. ACRONYMS

CFO – Chief Financial Officer
DoH – Department of Health
DoP – Database of Single Exit Prices
MCC – Medicines Control Council
MPR – Medicine Pricing Registry
NAPPI – National Pharmaceutical Product Interface
NDoH – National Department of Health
PEE – Pharmaceutical Economic Evaluations
PI – Package Insert
SAHPRA – South African Health Products Regulatory Authority
SEP – Single Exit Price
SEPA – Single Exit Price Adjustment
VAT – Value Added Tax
WHO ATC – World Health Organisation Anatomical Therapeutic Chemical

2025 SEPA INFORMATION AND INSTRUCTIONS DOCUMENT

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, may forward submissions for the Single Exit Price Adjustment (SEPA) for 2025 for all scheduled medicines appearing on the Database of Medicines Prices (DoP) published on 20th December 2024.

The medicines that form part of the applicant's portfolio that do not appear on the DoP of 20th December 2024 must be included at the bottom of tab 1 of the excel spreadsheet as part of the 2025 SEPA submission and the supporting evidence in the form of a communicated email that had a signed letter of approval and its associated excel spreadsheet both reflecting the effective date of the approved Single Exit Price (SEP) must be provided for such medicines as confirmation that the medicines were previously processed and allocated an official SEP by the department of Health.

a) The following medicines are legible for 2025 SEPA implementation:
    i. Medicines whose SEP's were approved for implementation on or before the 20th December 2024
b) The following medicines are **NOT** legible for 2025 SEPA implementation:
    i. Medicines for which 2025 SEPA adjustment is not applicable
    ii. Medicines for which 2025 SEPA implementation is not required
    iii. Discontinued medicines
    iv. Medicines whose SEP's were approved for implementation after the 20th December 2024.

NB: Applicants must note that medicines that are **NOT** eligible for 2025 SEPA implementation under 2.1 (b) must still be included in the submission for 2025 SEPA implementation under tab 1.

c) The information contained in the published gazette with respect to the 2025 SEPA should be read carefully and the contents thereof must be complied with as required.
d) The dates and timelines contained in the published gazette with respect to the implementation period for 2025 SEPA must be read carefully and complied with as required and the dates are as follows:
    i. 20 December 2024 – reference Dop base SEP's for applying 2025 SEPA
    ii. 06 January 2025 – First day of receiving 2025 SEPA submissions
    iii. 14 February 2025 – Last day of receiving 2025 first time SEPA submissions
    iv. 14 March 2025 - Last day of receiving 2025 SEPA resubmissions.

2025 SEPA INFORMATION AND INSTRUCTIONS DOCUMENT

e) Read carefully the information and instructions contained in this document before completing all the fields of both tabs (Tab 1 and Tab 2) of the latest 2025 excel SEPA template which is available on the website https://www.health.gov.za/nhi/.
NB: A submission, which has been signed off by the Chief Financial Officer is presumed to be free from calculation errors. Similarly, a submission, which has been signed off by the Responsible Pharmacist is presumed to be free from any errors which are regulatory in nature (see Annexure B).

f) Provide the required information on the cover page (**Annexure A**).

g) Sign the declaration annexed to this document (**Annexure B**).
NB: Do NOT amend the declaration form AND 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 2025 SEPA submission.

h) Complete the checklist that is also annexed to this document (**Annexure C**).

i) Complete **all** sections of **all** tabs (Tab 1 and Tab 2) of the latest 2025 SEPA 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 SEPA template for 2025, annexure A, B, C and D (A fully completed SEPA template) and a signed covering letter on the applicant's letterhead.

l) Ensure all the SEPA template fields are completed in full and the base Single Exit Prices, to be used as a reference for adjustment purposes are those which were applicable on 20th December 2024 and that they have an effective date of 20th December 2024 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 20th December 2024.
NB: All the applicants must verify the correctness of the information which appears under the SEPA template excel spreadsheet Tab 1 column titled (Originator or Generic). Should this information be declared incorrect after the 2025 SEPA 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 20th December 2024.

n) Wherever the date is required, it should be stated in full (e.g. 14 March 2025).

o) Applicants are required to submit **ONLY** the electronic version of the entire submission via e-mail and the submission must include:
   i. Signed cover letter on the official letter head of the applicant;
   ii. Completed latest 2025 SEPA template;
   iii. Completed Annexure A;
   iv. Completed Annexure B;

v. Completed Annexure C;
vi. Completed Annexure D (A fully completed latest 2025 SEPA template) and
vii. Supporting documents where applicable.

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 2025 SEPA gazette its guidelines is 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. **NB: A submission, which has been signed off by the Chief Financial Officer is presumed to be free from calculation errors. Similarly, a submission, which has been signed off by the Responsible Pharmacist is presumed to be free from any errors which are regulatory in nature.**

2.2 SEPA SUBMISSION REQUIREMENTS

a) The submissions lodged in terms of these guidelines are solely for the purpose of 2025 SEPA. For other medicine details amendments, applicants must use Template G of the SEP updates as published on the website 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 2025 SEPA template, inclusive of all excel spreadsheet fields, must be fully completed. A fully completed template must have all tabs (Tab 1 and Tab 2) and all the fields of the relevant worksheets completed. Within each tab, all the required fields must be completed for every medicine in the applicant's schedule as published on DoP of 20th December 2024.

c) **ALL** scheduled medicines that make up the applicant's portfolio on the date of the submission, **MUST** be presented in the latest SEPA template i.e. completed Annexure D.

d) **ALL** the medicines (and their respective prices) that have an SEP update which was approved, communicated and effected by the department in 2025, before the date of the applicant's 2025 SEPA submission, including those communicated to the applicant after the 20th December 2024, must be included in the 2025 SEPA submission. Both the letter and excel schedule received from the Directorate: Pharmaceutical Economic Evaluations (PEE) must be submitted for this category of items. The information will serve as SEPA 2025 supporting documents and it will be used to verify the information that is included as part of the 2025 SEPA submission (on the 2025 SEPA excel templates i.e. Tab 1 and Tab 2) but which may not be appearing on the 20th December 2024 database. Failure to provide these supporting documents will render the 2025 SEPA submission incomplete.

e) Only the rightful applicant as recorded on the DoP of 20th December 2024 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.

f) Only those applicants whose manufacturing licenses have not expired may submit 2025 SEPA submissions.

g) In cases where an applicant name change occurred after the 20th December 2024 but before lodging the 2025 SEPA submission, only the applicant whose applicant name is reflected on the DoP of 20th December 2024 shall be considered for purposes of the 2025 SEPA submissions.

2.3 NOTES FOR APPLICANTS

a) The submission of 2025 SEPA is not obligatory. The eligible applicants are not compelled to compile and submit 2025 SEPA submissions.

b) The 2025 SEPA is only applicable on the medicines with a SEP that was already effective on the 20th December 2024, regardless of how these SEP's were arrived at. This includes the SEP approvals granted after a Non-Permanent Price Reduction submission. These non-permanent SEPs shall be regarded as permanent reductions at the point of lodging the 2025 SEPA submission.

c) Therefore, if the SEP of a medicine that appears on the 20th December 2024 database was arrived at after the applicant submitted a Template B submission, then such an SEP shall automatically become the SEP for applying 2025 SEPA on the first day of implementation of 2025 SEPA i.e. 06th January 2025.

d) Applicants must note that in terms of the Medicines Pricing Regulations, there shall only be one Single Exit Price at any given point in time.

e) Applicants are advised to compile their own list of reference medicine Single Exit Prices to enable the verification of prices during SEPA implementation. The schedule of 20th December 2024 may be found on the website https://www.health.gov.za/nhi/ under the folder for databases. Click on the excel spreadsheet titled *database of medicine prices 20th December 2024.*

f) An applicant can only have one SEP submission active at any given time. If the same medicine is involved in multiple SEP related submissions, only one will be processed and others will be deemed withdrawn. Applicants cannot request an update on an SEP of a medicine and its details or submit an application made in terms of Regulation 9 of the medicines pricing regulations,while the SEPU submission, which includes the same medicine(s) is still active and therefore under review. Likewise, the applicant cannot submit a new SEPA or Regulation 9 application if their SEPU submission containing the same medicine(s) is still being processed. If the applicant does not specify which

submission they wish to keep active, the latest submission will be treated as the active one, and any previous ones will be deemed automatically withdrawn. Applicants may choose to wait for all ongoing SEP submissions or Regulation 9 applications to be concluded before submitting a SEPA 2025 application. Submitting a new application before the conclusion of previous ones may nullify those pending applications.

The implementation timelines for SEPA 2025 are fixed, and cannot be changed without approval from the Minister of Health. All applicants must consider these SEPA 2025 timelines before making their 2025 SEP submission decisions.

I. 20 December 2024 – reference Dop base SEP's for applying 2025 SEPA
II. 06 January 2025 – First day of receiving 2025 SEPA submissions
III. 14 February 2025 – Last day of receiving 2025 first-time SEPA submissions
IV. 14 March 2025 - Last day of receiving 2025 SEPA resubmissions.

g) Each submission should include all the applicant's scheduled medicines, including discontinued medicines. Discontinued medicines should be indicated as such, as per the DoP under the status column. SEPA will not be allowed on officially declared discontinued medicines.
h) **The row order of all the applicant's medicines, as they appear on the DoP of 20th December 2024 must be maintained.**
i) Any medicines not appearing on the 20th December 2024 list should appear at the bottom of the 2025 SEPA template in an alphabetical order.
j) All medicines with related pack sizes that are presented on the template for 2025 SEPA must be unit priced unless the medicine/s are exempt by the Minister of Health from unit pricing subsequent to submitting an exemption request to the Pricing Committee. In the case of unit pricing exemption, the applicant must provide a signed and valid exemption letter by the Minister of Health. When computing the unit prices, the resulting SEPs should not exceed the maximum allowable SEP after the adjustment on the SEP that existed on 20th December 2024 (i.e. SEP applicable as of 20th December 2024 + maximum allowable SEPA % as per the Minister's Notice).
k) 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, unless the medicines are exempt by the Minister of Health from unit pricing subsequent to submitting an exemption request to the Pricing Committee and such exemption signed by the Minister of Health must be provided as supporting documentation. Non-compliance with unit pricing will result in the entire submission not being considered.

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l) Where a new pack size is introduced after 20th December 2024, it is expected that this will result in a unit price that is no greater than the unit price that existed on a related pack sizes on 20th December 2024 unless a related pack size has been exempt by the Minister of Health from unit pricing subsequent to submitting an exemption request to the Pricing Committee and such exemption signed by the Minister of Health must be provided as supporting documentation. (Note that the newly launched medicines and/or pack sizes should be included in the portfolio of medicines in the submission for SEPA and should also be unit priced with their related pack sizes).

m) All submissions for SEPA will be processed within 32 working days (excluding weekends and holidays) upon receipt of the submission by the Directorate: PEE of the National Department of Health (NDoH).

n) 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 2025 SEPA implementation time frame prior to following up on a submission status.

o) All processed and approved SEPs will be communicated to submitting applicants, price file managers and all the stakeholders that are registered on the Directorate: PEE of NDoH's emailing list. The approved prices will be published on the website https://www.health.gov.za/nhi/ at a later stage.

p) All correspondence(s) concerning a submission will only be communicated to the applicant of the medicines applied for.

q) The electronic version of the submitted 2025 SEPA 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.

r) 2025 SEPA can only be submitted on the published latest SEPA template for 2025 including both Tab 1 and Tab 2. **ANY** modification to the template will result in the entire submission not being considered. This also applies to re-submissions.

s) The final date for all 2025 SEPA submissions will be those as determined in the Minister's 2025 SEPA notice. No submission shall be received and reviewed outside of the dates that are stipulated in the 2025 SEPA notice.

t) An applicant may only submit once in the 2025 SEPA cycle. This does not apply to resubmissions under point (u) below.

i. Where no adjustment is requested, the existing SEP will be applicable for the 2025 SEPA cycle. The SEPA cycle is the period between two consecutive SEPA announcements by the Minister of Health. The applicant may not at a later stage re-submit a different SEPA request for the same medicine. The SEPA submission and the approval thereof for the 2025 cycle

implies that previously approved non-permanent reductions automatically become the official SEP for applying 2025 SEPA at the end of the 2025 SEPA implementation cycle.

ii. An applicant's portfolio may not be divided into multiple submissions.

iii. The maximum allowable adjustment may not be divided into multiple submissions. Should an applicant request less than the maximum published adjustment, the balance will be forfeited for the 2025 cycle.

u) Resubmissions;

i. Resubmissions shall only be considered if submitted within the timelines stipulated in the 2025 SEPA notice.

ii. Will **only** be reviewed for medicines that had SEPs that were previously not adjusted in terms of the 2025 SEPA quantum, as a result of discrepancies identified in the first 2025 SEPA submission.

iii. All the requirements for the SEP 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 2025 SEPA template.

viii. Must only be on the 2025 SEPA template, by the close off date as specified by the Minister of Health and reflected in the 2024 SEPA notice.

2.4 LODGING OF SUBMISSIONS

a) Submissions must be lodged electronically via the department of health email sepupdates@health.gov.za. No hard copy submissions will be considered.

b) The cover letter must reflect the following information:

i. Applicant Name

ii. 2025 SEPA Submission

iii. Number of Medicines in TAB 1 of the submission template (e.g. Tab 1 = 50 medicines /75 line items

iv. Number of Medicines in TAB 2 of the submission template (e.g. Tab 2 = 10 medicines /15 line items- Tab 2 is for originator medicines.

c) Each submission **MUST** be lodged on the latest 2025 SEPA 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 2025 SEPA 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 SEPA 2025

f) Every submission must be on a new e-mail with the heading that is specific to the content i.e. 2025 SEPA submission.

g) The 2025 SEPA submission email via sepupdates@health.gov.za must be addressed to:

2025 SEP Adjustment
Attention: Director General _ National Department of Health
c/o Director: Pharmaceutical Economic Evaluations (PEE)
Dr Ntobeko Mpanza
National Department of Health
Room D1-16A Dr Xuma Building
1112 Voortrekker Road, Pretoria Townlands 351 - JR
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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 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 2025 SEPA 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 morongwa.mashaba@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 SEPA submission

Note that the Department of Health 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 annexure A
(c) Completed annexure B
(d) Completed annexure C and
(e) Completed annexure D or latest 2024 SEPA template with both Tab 1 and Tab 2
(f) Supporting documents where necessary

2.6 ACKNOWLEDGEMENT OF RECEIPT

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

3. HOW TO COMPLETE TEMPLATE COLUMNS

The details must be copied from the 20th December 2024 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 20th December 2024.

Failure to comply with the prescribed requirements under section 3.1 will result in the entire submission not being considered.

3.1 SEPA 2025 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 20th December 2024 for all medicines that sought 2025 SEPA. All the information and formats and the order of medicines must remain as they appear on the DoP of 20th December 2024.

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- 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 20th December 2024
- LOGISTICS FEES AS AT 20th December 2024
- VAT
- SEP AS AT 20th December 2024
- UNIT PRICE AS AT 20th December 2024
- EFFECTIVE DATE
- STATUS
- ORIGINATOR OR GENERIC

3.1.2 VOLUME OF SALES

This must be the total quantity of sales of each medicine for the period 01 January 2024 to 31 December 2024. Where the medicine is not being sold this should be indicated in the column. A blank will result in submission not being considered.

3.1.3 REQUESTED MANUFACTURER PRICE

This is the requested 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.

3.1.4 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.

3.1.5 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.

3.1.6 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.

3.1.7 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.

(a) 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.

(b) 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.

(c) 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.

(d) 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 formats as it appears on Dop of 20th December 2024. Applicants should only make use of space, dashes or any other character if these are represented as such in official documentation.

3.2 SEPA 2025 TAB 2

Any blanks on Tab 2 will result in the submission not being considered. Where the medicine is a generic the applicant must comment. Where there is no price available the applicant must indicate this as well as measures taken to obtain the price. Proof of this communication must be supplied.

3.2.1 For the following columns:

- 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 20th December 2024
- LOGISTICS FEES AS AT 20th December 2024
- VAT
- SEP AS AT 20th December 2024
- UNIT PRICE AS AT 20th December 2024
- EFFECTIVE DATE
- STATUS

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- ORIGINATOR OR GENERIC

The details must be copied from the 20th December 2024 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 20th December 2024.

3.2.2 For all medicines that are labelled originator, the following columns must be completed; Closest Australian Pack Size, Related Australia Quantity, Australian Manufacturer Price in AUS Dollars, AUS Dollar Exchange Rates, Australian Price in Rands, Australian matching pack size in Rands, Comment on Australian Price Provided, Closest Canada Pack Size, Related Canada Quantity, Canada Manufacturer Price in CAN Dollars, CAN Dollar Exchange Rates, CAN Price in Rands, Canadian matching pack size in Rands, Comment on Canadian Price Provided, Closest New-Zealand Pack Size, Related NZ Quantity, New-Zealand Manufacturer Price in NZ Dollars, NZ Dollar Exchange Rates, New-Zealand Price in Rands, New Zealand matching pack size in Rands, Comment on New Zealand Price Provided, Closest Spain Pack Size, Related Spain Quantity, Spain Manufacturer Price in EURO, EURO Exchange Rates, Spain Price in Rands, Spanish matching pack size in Rands, Comment on Spanish Price Provided, Closest Alternate Country Pack Size, Related Alternate Country Quantity, Manufacturer Price alternate currency , Alternate Currency Exchange Rates, Alternate Country Price in Rand, Alternate Country matching pack size in Rands, Comment on Alternate Country Price Provided. Where a medicine does not have a comparator product from Australia, Canada, New Zealand & Spain **all** other countries where the medicine is being sold must be listed and provided as alternate countries.

3.2.3 Where the exact pack size does not exist in the international market, the closest pack size will be used e.g. if there is 30 pack size in South Africa and only 28's and 100's in Spain the 28 pack size will be used as the closest pack to 30's. The related quantity refers to the quantity in which the pack size of the medicine is being sold in that country and allows for a like comparison of the South African medicine.

3.2.4 The exchange rate will be the average over the 12-month period (i.e. 01 August 2023 to 31 July 2024. These values will be published in the template for consistency. The following are the for the conversion to Rands:
AUS$ 12,2542
CAN$ 13,2967
NZD$ 11,3121
EUR€ 20,2105

4. ANNEXURES

4.1 ANNEXURE A: COVER PAGE

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

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

4.2 ANNEXURE B: DECLARATION

SEPA 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 2025 SEPA information and instruction document.
2. I have followed the instructions contained in the 2025 information and instruction document in completing the SEPA template.
3. I have correctly calculated unit pricing for all medicines in the applicant's portfolio.
4. I have requested only the SEPA 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 at ……on this the……day of…… 2025 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

SEPA CHECKLIST

Tick the appropriate box (√)

HAVE YOU:	YES	NO
a) Read and understood the entire instruction document for 2025 SEPA?		
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 SEPA 2025 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 and Tab 2		

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

4.4 ANNEXURE D: SEPA 2025 TEMPLATE

See Excel Template Published on the website https://www.health.gov.za/nhi/ and emailed to sepupdates@health.gov.za