Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID AFRIKA

Vol. 643 | 23 January Januarie 2019 | No. 42183

ISSN 1682-5843

9 771682 584003 42183

Contents

DEPARTMENT OF HEALTH

NO. 27 **23 JANUARY 2019**

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

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES

(DISPENSING FEE TO BE CHARGED BY PERSONS LICENSED IN TERMS OF SECTION 22C (1) (a))

The Minister of Health has, on the recommendation of the Pricing Committee, in terms of Section 22G of the Medicine and Related Substances Act, 1965 (Act No. 101 of 1965) as amended, made the regulations in the schedule.

SCHEDULE

Definitions

1. In these regulations any word or expression to which a meaning has been assigned in the Act shall have such meaning and, unless the context indicates otherwise-

   "**the Regulations**" means the Regulations Relating to the Transparent Pricing System for Medicines and Scheduled Substances published under government Notice No. R1102 of November 2005 as amended.

Substitution of Regulation 12

2. The following regulation is hereby substituted for regulation 12 of the regulations:

"12. The appropriate dispensing fee as contemplated in section 22G of the Act to be charged by persons licensed in terms of section 22C (1) (a) of the Act must be calculated, exclusive of VAT, as follows:

(1) Where the single exit price of a medicine or scheduled substance is less than one hundred and twenty four rands (R124.00), the dispensing fee must not exceed 30% of the single exit price in respect of that medicine or scheduled substance;

(2) Where the single exit price of a medicine or scheduled substance is equal to or greater than one hundred and twenty four rands (R124.00), the dispensing fee must not exceed thirty seven rand and twenty cents (R37.20) in respect of that medicine or scheduled substance;

3. The provisions of sub-regulation 2 must be reviewed annually by the Minister after taking into account-

(a) the need to ensure the availability and affordability of quality medicines and scheduled substances in the Republic;

(b) annual inflation rates published periodically by Statistics South Africa;

(c) information supplied by persons licensed to dispense in terms of section 22C (1)(a) in accordance with guidelines determined by the Minister from time to time by Notice in the Gazette; and

(d) any other information the Minister may deem necessary to consider.

4. Persons Licensed to dispense in terms of section 22C (1) (a) must-

(a) by means of a clearly displayed notice in the dispensing practice, inform members of the public using the dispensing practice of the maximum fee structure used by such dispensing practice to determine the dispensing fee; and

(b) provide an invoice that in respect of each medicine clearly indicates the-

(i) dispensing fee charged; and

(ii) the single exit price;

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 9/11/2018

DEPARTMENT OF HEALTH

NO. 28 **23 JANUARY 2019**

MEDICINES AND RELATED SUBSTANCES ACT, (101 OF 1965)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES: DISPENSING FEE FOR PHARMACISTS

The Minister of Health has, on recommendation of the Pricing Committee, in terms of Section 22G (2) (b) of the Medicines and Related Substances Act, (No. 101 of 1965), made the regulations in the Schedule.

SCHEDULE

Definitions

1. In this schedule, "the Act" means the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965) and any word or expression to which a meaning has been assigned in the Act shall have such meaning, unless the context indicates otherwise-

   "**dispense"** means the supply of medicines based on a prescription to a patient or someone on behalf of the patient by a health professional authorized by law to supply medicines and includes-

   (a) the interpretation and evaluation of the prescription;

   (b) the selection, reconstitution, dilution, labelling, recording and the actual supply of the medicine;

(c) the provision of information and instructions to ensure safe and effective use of a medicine by a patient; and

(d) the provision of information as contemplated in section 22F (1)(a) of the Act.

"dispensing fee" means a fee determined in terms of these regulations, exclusive of Value Added Tax, that may be charged to dispense a medicine; and

"the Regulations" means the Regulations Relating to the Transparent Pricing System for Medicine and Scheduled Substances published in terms of Government Notice No. R1102 b of November 2005, as amended.

Amendment of Regulation 10

2. The following regulation is hereby substituted for Regulation 10 of the Regulations:

"10. (1) The appropriate dispensing fee as contemplated in Section 22G (2) (b) of the Act to be charged by a pharmacist, must be calculated as follows:

(a) where the single exit price of a medicine or scheduled substance is less than one hundred and nine rand and fifty six cents (R109.56),the dispensing fee shall not exceed R14.50 plus 46% of the single exit price in respect of that medicine or scheduled substance;

(b) where the single exit price of a medicine or scheduled substance is greater than or equal to one hundred and nine rand and fifty seven cents (R109.57, but less than two hundred and ninety two rand and twenty five cents (R292.25), the dispensing fee shall not exceed R27.75 plus 33% of the single exit price in respect of that medicine or scheduled substance;

(c) where the single exit price of a medicine or scheduled substance is greater than or equal to two hundred and ninety two rand and twenty six cents (R292.26), but less than one thousand and twenty two rand and ninety four cents (R1022.94), the dispensing fee shall not exceed R79.00 plus 15% of the Single Exit Price in respect of that medicine or scheduled substance;

(d) where the single exit price of a medicine or scheduled substance is greater than or equal to one thousand and twenty two rand and ninety five cents (R1022.95), the dispensing fee shall not exceed R182.00 plus 5% of the Single Exit Price in respect of that medicine or scheduled substance

This fee which is exclusive of VAT represents a maximum dispensing fee and does not preclude dispensers from charging a lower fee, either of which to be added to the SEP of a medicine or scheduled substance thus resulting in a final price to be paid by the consumer.

(2) The provision of sub-regulation (1) must be reviewed annually by the Minister after taking into account-

(a) the need to ensure the availability and affordability of quality medicines and scheduled substances in the Republic;

(b) annual inflation rates published periodically by Statistics South Africa;

(c) information supplied by pharmacists in accordance with guidelines determined by the Minister from time to time by Notice in the Gazette; and

(d) any other information the Minister may deem necessary to consider.

(3) A pharmacist dispensing a medicine must-

(a) by means of a clearly displayed notice in the pharmacy, inform members of the public of the maximum fee structure used by such pharmacist to determine the dispensing fee; and

(b) provide an invoice in respect of each medicine which clearly indicates the-

(i) dispensing fee charged; and
(ii) single exit price.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 21/9/2018

DEPARTMENT OF HEALTH

NO. 29 **23 JANUARY 2019**

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

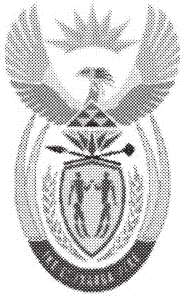
ANNUAL SINGLE EXIT PRICE ADJUSTMENT [SEPA] OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2019

I, DR A MOTSOALEDI, 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 to a maximum of **3.78%** of the SEP of medicines and their related pack sizes that was available as at 21st December 2018; regardless of how that SEP was arrived at for the 2018 cycle. Applications for adjustments of the SEP may only be submitted for the first time in 2019 from 11th January 2019 and by no later than 22nd February 2019.

All medicines and their related pack sizes with SEP approved with an effective date later than 21st December 2018 are not eligible for SEPA 2019. An applicant may only submit once in the 2019 cycle unless a resubmission is made for eligible medicines that have not been previously approved for an adjustment in 2019 period in which an application was made. The final date for resubmissions will be 01st March 2019.

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: 30/11/2018



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMATION AND INSTRUCTIONS FOR THE SINGLE EXIT PRICE ADJUSTMENT (SEPA) SUBMISSIONS FOR 2019

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the SEP adjustment (SEPA) for medicines for 2019 in terms of Section 22G of Medicines and Related Substances Act (101 of 1965) as amended, and Regulation 8 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances. Failure to comply with any of the requirements and instructions in this document will result in the submission being considered incomplete. Incomplete submissions shall be regarded as ineligible for processing on the basis on non compliance.

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
PEE – Pharmaceutical Economic Evaluations
PI – Package Insert
SEP – Single Exit Price
SEPA – Single Exit Price Adjustment
VAT – Value Added Tax
WHO ATC – World Health Organisation Anatomical Therapeutic Chemical

2. APPLICANT INFORMATION

2.1 APPLICANT REQUIREMENTS

(a) 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 2019 for all scheduled medicines appearing on the Database of Medicines Prices (DoP) published on 21 December 2018. These submissions should also include;

i. Scheduled medicines for which no adjustment is required,
ii. Scheduled medicines for which no adjustment is applicable and
iii. Discontinued medicines

i.e. all the medicines for the applicant as they appear on the DoP.

(b) The information contained in the published gazette with respect to the SEPA for 2019 should be read carefully and contents thereof complied with as required.

(c) 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 2019 excel SEPA template which is available on the website www.mpr.gov.za .

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

(e) Sign the declaration annexed to this document as an acknowledgement of the correctness of the contents of the submission (**Annexure B**).

(f) Complete the checklist that is also annexed to this document to confirm completeness of the submission (**Annexure C**).

(g) Complete **all** sections of all tabs of the latest 2019 SEPA template in the fields provided (**Annexure D**).

(h) Include a signed covering letter on a company letterhead, stating the purpose of your submission, with every submission or re-submission where applicable.

(i) A complete submission should include a fully completed latest SEPA template for 2019, annexure A, B, and C and a signed covering letter on the applicant's letterhead.

(j) Ensure that all fields have been completed and Single Exit Prices used for adjustment purposes are as per DoP of 21 December 2018.

(k) Wherever the date is required, it should be stated in full (e.g. 14 March 2020).

(l) Applicants are required to submit both the hard copy and an electronic version of the entire submission for 2019 SEPA. This must include;

i. Signed cover letter on the official letter head of the applicant;
ii. Completed latest 2019 SEPA template;
iii. Completed annexure A;
iv. Completed annexure B;
v. Completed annexure C and
vi. Supporting documents where applicable

(m) Applicants are required to sign the declaration in Annexure B. The responsible officials, who are signing the declaration in Annexure B, certify that the information submitted is true, correct and error-free. The signed declaration in Annexure B, also confirms that the submission in its entirety has been checked by all the persons who's signatures are appended under Annexure B, in addition to the person responsible for compiling the submission.

2.2 SEPA SUBMISSION REQUIREMENTS

(a) The submissions lodged in terms of these guidelines are solely for the purpose of 2019 SEPA. For other medicine details amendments, applicants must use Template G of the SEP updates as published on the website: www.mpr.gov.za

(b) For a submission to be considered complete, **ALL** sections of the 2019 SEPA template, inclusive of all excel spreadsheet fields, must be fully completed. A fully completed template must have all tabs or worksheets and all the fields completed. Within each tab, all required fields must be completed for every medicine in the applicant's schedule and Single Exit Prices reflected shall be as published on DoP of 21 December 2018.

(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.

(d) **ALL** official SEP update submissions communicated and effected in 2019 by the department, before the date of the applicant's SEPA submission, including those communicated after 21 December 2018, must be included in the submission (this includes both the letter and the excel schedule from the Directorate: PEE to the applicant). Failure to provide these supporting documents will render the 2019 SEPA submission incomplete. This requirement is also applicable to any resubmission made.

(e) Only the rightful applicant as recorded on the DoP of 21 December 2018 for the medicine as per the MCC manufacturing license and MCC medicines registration certificate must

lodge the submission for the medicine(s) concerned. Submissions will not be accepted from persons other than these applicants whose manufacturing licences have not expired. In cases where an applicant name change occurred after 21 December 2018 but before lodging the 2019 SEPA submission, only the applicant name reflected on the DoP of 21 December 2018 shall be considered for purposes of this submission.

2.3 NOTES FOR APPLICANTS

(a) The 2019 SEPA is not obligatory. Applicants must note that they are not compelled to compile and lodge 2019 SEPA submissions.

(b) The 2019 SEPA concerns SEPs that are applicable as on 21 December 2018, regardless of how these SEPs were arrived at. This includes approved SEP's following a submission of a Non-Permanent SEP reduction. These non-permanent SEP's shall be regarded as permanent at the point of lodging the 2019 SEPA submission. In terms of the medicines pricing regulations, there shall only be one SEP at any given time.The schedule of 21 December 2018 is found on www.mpr.gov.za under "Published Documents", click database of medicine prices. Click on the excel spreadsheet titled *database of medicine prices 21 December 2018.*

(c) There can only be one SEP submission launched at any given point in time. The applicant must not request for an update on the SEP or lodge a Regulation 9 application, whilst the submission for SEPA is still in process. Similarly, the applicant cannot submit a SEPA or Regulation 9 application whilst the submission for an SEP update is still in process. In an event where the applicant has made a SEPA submission and any other SEP submissions and/or a Regulation 9 application the SEPA 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.

(d) 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. **The row order of all the applicant's medicines, as they appear on the DoP of 21 December 2018 must be maintained**. Any medicines not appearing on the 21 December 2018 list should appear at the bottom of the 2019 SEPA template in an alphabetical order.

(e) All medicines presented on the template for SEPA must be unit priced. When computing the unit prices, the resulting SEPs should not exceed the maximum allowable SEP after the adjustment on the SEP that existed on 21 December 2018 (i.e. SEP applicable as of 21 December 2018 + maximum allowable SEPA % as per the notice).

(f) 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.

(g) Where a new pack size is introduced after 21 December 2018, it is expected that this will result in a unit price that is no greater than the unit price that existed on pack sizes on 21 December 2018. (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).

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

(i) 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 time frame prior to following up on a submission status.

(j) All approved SEPs will be communicated to price file managers and published on the website (www.mpr.gov.za) by the PEE Directorate.

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

(l) The electronic version of the submitted 2019 SEPA template should be saved with a file name extension "xls". Submissions containing password-protected documents and files in a version that the PEE Directorate is unable to access such as those with the file extensions xlsx, docx and PDF will not be considered.

(m) SEPA can only be submitted on the published latest SEPA template for 2019 including both Tab 1 and 2. **ANY** modification to the template will result in the entire submission not being considered. This also applies to resubmissions.

(n) The final date for all 2019 SEPA submissions will be the date determined as per the Minister's notice.

(o) An applicant may only submit once in the 2018 SEPA cycle. This does not apply to resubmissions (see point (p) below)

(i) Where no adjustment is requested, the existing SEP will be applicable for the 2019 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 resubmit a different SEPA request for the same medicine. The submission of a SEPA and the approval thereof for the 2019 cycle implies any non permanent reduction is concluded.

(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 2018 cycle.

(p) Resubmissions;

i. Will only be reviewed for medicines who's SEPs were previously not adjusted in terms of the 2019 SEPA quantum, as a result of discrepancies identified in the first submission

ii. All the requirements for the SEP submissions as stated in this document shall be applicable to resubmissions.

iii. Resubmissions must contain only medicines listed in the Not-Approved sheet of Annexure E communicated to the applicant in response to the initial submission.

iv. The resubmissions process shall not be used to accommodate errors made by the applicants in their first 2019 SEPA submission.

v. Must only be on the 2019 SEPA template, by the close off date as specified by the Minister of Health and reflected in the SEPA notice.

2.4 LODGING OF SUBMISSIONS

(a) Submissions must be lodged electronically on a compact disc and hard copy.

(b) Each submission **MUST** be lodged on the latest 2019 SEPA template and must be accompanied by annexure A, B and C included in this document as well as the applicant's covering letter on the official letterhead of the applicant.

(c) Where an applicant is uncertain on a submission being made clarity must be sought from PEE.

(d) No e-mail submissions will be accepted.

(e) Spreadsheets must be submitted in excel format and not pdf.

(f) Electronic copies and hardcopies of the submissions **MUST** be addressed to:

2019 SEP Adjustment
The Director: Pharmaceutical Economic Evaluations (PEE)
ATT: Ms Ntobeko Mpanza
The National Department of Health
Room S0419 Civitas Building
Corner of Thabo Sehume Street and Struben Street
0001

And hand-delivered between 09:00 and 11:59 Monday to Friday excluding public holidays. For any enquiries regarding SEPA for 2019, you may contact Ms Mahlogonolo Ledwaba between 10:00 and 15:00 at (012) 395 8186 or by e-mail at Mahlogonolo.Ledwaba@health.gov.za from Monday to Friday excluding weekends and public holidays.

All queries must include the acknowledgement of receipt provided when the submission was made as well as any/all responses received by the applicant from DoH.

Note that the Department of Health will not be held responsible for submissions that were not received and signed for by the designated official of the PEE Directorate. A reference number reflected on the acknowledgement notice should be quoted in every communication.

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;
(b) Completed latest 2019 SEPA template
(c) Completed annexure A
(d) Completed annexure B
(e) Completed annexure C and
(f) Compact disc containing all of the above in the prescribed format

2.6 ACKNOWLEDGMENT OF RECIEPT

2.6.1 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 acknowledgement notice, for reference purposes.

3. HOW TO COMPLETE TEMPLATE COLUMNS

The details must be copied from the 21 December 2018 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 21 December 2018.

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

3.1 SEPA 2019 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 21 December 2018 for all medicines that sought SEPA for 2019. All the information and the formats must remain as it appears on the DoP of 21 December 2018.

- APPLICANT MCC LICENCE NUMBER
- APPLICANT NAME AS REGISTERED WITH MCC
- 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 21 DECEMBER 2018
- LOGISTICS FEES AS AT 21 DECEMBER 2018
- VAT
- SEP AS AT 21 DECEMBER 2018
- UNIT PRICE AS AT 21 DECEMBER 2018
- 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 2018 to 31 December 2018. 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 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 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.

3.2 SEPA 2019 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 MCC LICENCE NUMBER
- APPLICANT NAME AS REGISTERED WITH MCC
- 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 21 DECEMBER 2018
- LOGISTICS FEES AS AT 21 DECEMBER 2018
- VAT
- SEP AS AT 21 DECEMBER 2018
- UNIT PRICE AS AT 21 DECEMBER 2018
- EFFECTIVE DATE
- STATUS
- ORIGINATOR OR GENERIC

The details must be copied from the 21 December 2018 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 21 December 2018.

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,

AUSDollar 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 CANDollars, CANDollar 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 NZDollars, NZDollar 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 12month period (i.e. 01 October 2017 to 30 September 2018). These values will be published in the template for consistency. The following are the for the conversion to Rands:

AUS$:
CAN$:
NZD$:
EUR€:

NOTE: The template with Tab 1 and 2 must always be maintained in the font and format as it appears on DoP. 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 *As it appears on the MCC 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 2019 SEPA information and instruction document.
2. I have followed the instructions contained in the 2019 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)
7. The submission compiled and lodged does not contain any errors.

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…… 2019 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 2019 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 2019 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 be considered incomplete.*

4.4 ANNEXURE D: SEPA 2017 TEMPLATE

TAB 1 and TAB 2 will be uploaded on www.mpr.gov.za

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Contact Centre Tel: 012-748 6200. eMail: info.egazette@gpw.gov.za
Publications: Tel: (012) 748 6053, 748 6061, 748 6065