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DEPARTMENT OF HEALTH

NO. 267 **26 March 2021**

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

ANNUAL SINGLE EXIT PRICE ADJUSTMENT [SEPA] OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2021

I, DR ZL MKHIZE, 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 **3.68%** of the SEP of medicines and their related pack sizes that was available as at 21st December 2020 regardless of how that SEP was arrived at for the 2020 cycle. Applications for adjustments of the SEP may only be submitted for the first time in 2021 from 11th January 2021 and by no later than 22nd February 2021.

All medicines and their related pack sizes with SEP approved with an effective date later than 21st December 2020 are not eligible for SEPA 2021. An applicant may only submit once in the 2021 cycle unless a resubmission is made for eligible medicines that have not been previously approved for an adjustment in 2021 period in which an application was made.The final date for resubmissions will be 08th March 2021.

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 ZL MKHIZE, MP
MINISTER OF HEALTH
DATE: 26/01/2021

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMATION AND INSTRUCTIONS FOR THE 2021 SINGLE EXIT PRICE ADJUSTMENT (SEPA) SUBMISSIONS

ALL SEPA 2021 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 2021 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 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.

This gazette is also available free online at **www.gpwonline.co.za**

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
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

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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 2021 for all scheduled medicines appearing on the Database of Medicines Prices (DoP) published on 21 December 2020. 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
iv. Medicines registered and allocated a Single Exit Price with an effective date which falls after the 21st of December 2020. These medicines must be added and listed at the bottom of tab 1 of the excel spreadsheet submitted as part of the 2021 SEPA submission.

i.e. the submitting applicant must submit all the medicines that form part of their portfolio even if some of the medicines do not appear on the Database of Prices (DoP) of 21st December 2020. For these additional items, the applicant must include all the supporting evidence (the communicated email and excel spreadsheet together with a letter of approval where the effective date of the approved SEP is indicated) which suggests that the medicines were previously processed and allocated a Single Exit Price by the department of Health.

NB: In cases where the medicine is not available on the 21 December 2020 database, the manufacturer must submit proof that the medicine was previously allocated an official Single Exit Price. The single Exit Prices approved on and before 21 December 2020 shall be eligible for the 2021 SEPA. Applicants must note that medicines falling in the category of medicines described under 2.1 (a) (iv) are **not eligible for 2021 SEPA**.

(b) The information contained in the published gazette with respect to the 2021 SEPA should be read carefully and the contents thereof must be complied with as required.

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(c) The dates and timelines contained in the published gazette with respect to the implementation period for 2021 SEPA must be read carefully and complied with as required.

(d) 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 2021 excel SEPA template which is available on the website www.mpr.gov.za .

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

(f) 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 2021 SEPA submission.

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

(h) Complete **all** sections of all tabs (Tab 1 and Tab 2) of the latest 2021 SEPA template in the fields provided (**Annexure D**).

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

(j) A complete submission should include a fully completed latest SEPA template for 2021, annexure A, B, C and D (A fully completed SEPA template) and a signed covering letter on the applicant's letterhead.

(k) 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 21 December 2020 and that they have an effective date of 21 December 2020 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.

(l) Ensure that all fields have been completed as per DoP of 21 December 2020.

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 2021 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 03 April 2021.

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

(n) Applicants are required to submit **ONLY** the electronic version of the entire submission on an appropriately labelled compact disc (See section 2.4 (a). The compact disc must include:

i. Signed cover letter on the official letter head of the applicant;
ii. Completed latest 2021 SEPA template;
iii. Completed annexure A;
iv. Completed annexure B;
v. Completed annexure C (A fully completed latest 2021 SEPA template) and
vi. Supporting documents where applicable

(o) 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.

(p) 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 2021 SEPA gazette its guidelines is complied with in totality as prescribed.

(q) 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 SEPA SUBMISSION REQUIREMENTS

(a) The submissions lodged in terms of these guidelines are solely for the purpose of 2021 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 2021 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 21 December 2020.

(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** the medicines (and their respective prices) that have an SEP update which was approved communicated and effected by the department in 2021, before the date of the applicant's 2021 SEPA submission, including those communicated to the applicant after the 21st December 2020, must be included in the 2021 SEPA submission. Both the letter

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and excel schedule received from the directorate Pharmaceutical Economic Evaluations Directorate must be submitted for this category of items.

(e) The information will serve as SEPA 2021 supporting documents and it will be used to verify the information that is included as part of the 2021 SEPA submission (on the 2021 SEPA excel templates i.e. Tab 1 and Tab 2) but which may not be appearing on the 21 December 2020 database. Failure to provide these supporting documents will render the 2021 SEPA submission incomplete. The requirement stated under d and e above also applies to all the re-submissions made by applicants.

(f) Only the rightful applicant as recorded on the DoP of 21st December 2020 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.

(g) Only those applicants whose manufacturing licenses have not expired may submit 2021 SEPA submissions.

(h) In cases where an applicant name change occurred after the 21st of December 2020 but before lodging the 2021 SEPA submission, only the applicant whose applicant name is reflected on the DoP of 21 December 2020 shall be considered for purposes of the 2021 SEPA submissions.

2.3 NOTES FOR APPLICANTS

(a) The submission of 2021 SEPA is not obligatory. The eligible applicants are not compelled to compile and submit 2021 SEPA submissions.

(b) The 2021 SEPA is only applicable on the medicines with a Single Exit Price that was already effective on the 21st of December 2020, regardless of how these Single Exit Prices 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 2021 SEPA submission.

(c) Therefore, if the SEP of a medicine that appears on the 21 December 2020 database was arrived at after the applicant submitted a Template B submission, then such an SEP shall automatically become a permanent SEP at the beginning on the first day of implementation of 2021 SEPA i.e. 11 January 2021.

(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 21

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December 2020 may be 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 2020*.

(f) 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 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.

(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. **The row order of all the applicant's medicines, as they appear on the DoP of 21 December 2020 must be maintained**. Any medicines not appearing on the 21 December 2020 list should appear at the bottom of the 2021 SEPA template in an alphabetical order.

(h) All medicines with related pack sizes that are presented on the template for 2021 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 2020 (i.e. SEP applicable as of 21 December 2020 + maximum allowable SEPA % as per the notice).

(i) 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.

(j) Where a new pack size is introduced after 21 December 2020, 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 2020. (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).

(k) 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.

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(l) 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 2021 SEPA implementation time frame prior to following up on a submission status.

(m) 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 emailing list. The approved prices will be published on the website (www.mpr.gov.za) at a later stage.

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

(o) The electronic version of the submitted 2021 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.

(p) 2021 SEPA can only be submitted on the published latest SEPA template for 2021 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.

(q) The final date for all 2021 SEPA submissions will be those as determined in the Minister's 2021 SEPA notice. No submission shall be reviewed outside of the dates that are stipulated in the 2021 SEPA notice.

(r) An applicant may only submit once in the 2021 SEPA cycle. This does not apply to resubmissions (see point (s) below)

  (i) Where no adjustment is requested, the existing SEP will be applicable for the 2021 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 2021 cycle implies that previously approved non-permanent reductions automatically become permanent approvals at the end of the 2021 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 2021 cycle.

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(s) Resubmissions;

i. Resubmissions shall only be considered if submitted within the timelines stipulated in the 2021 SEPA notice.

ii. Will **only** be reviewed for medicines that had SEPs that were previously not adjusted in terms of the 2021 SEPA quantum, as a result of discrepancies identified in the first 2021 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 2021 SEPA template.

viii. Must only be on the 2021 SEPA template, by the close off date as specified by the Minister of Health and reflected in the 2021 SEPA notice.

2.4 LODGING OF SUBMISSIONS

(a) Submissions must be lodged electronically via the department of health email sepupdates@health.gov.za.

(b) The cover letter must reflect the following information:

(i) Applicant Name

(ii) 2021 SEPA Submission

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

(v) 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 2021 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.

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(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 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 2021.

(f) The 2021 SEPU email must be addressed to:

2021 SEP Adjustment
The Director: Pharmaceutical Economic Evaluations (PEE)
ATT: Ms Ntobeko Mpanza
The National Department of Health
Room S2610 Civitas Building
Corner of Thabo Sehume Street and Struben Street
0001

Email submissions must be made 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 2021 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 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 acknowledgement notice should be quoted in every communication made to NDoH by the applicant.

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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 2021 SEPA template with both Tab1 and Tab 2
(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 2020 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 21 December 2020.

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

3.1 SEPA 2021 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 2020 for all medicines that sought SEPA for 2021. All the information and formats and the order of medicines must remain as they appear on the DoP of 21 December 2020.

- APPLICANT MCC LICENCE NUMBER
- APPLICANT NAME AS REGISTERED WITH MCC
- MCC MEDICINE REGISTRATION NUMBER

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- 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 2020
- LOGISTICS FEES AS AT 21 December 2020
- VAT
- SEP AS AT 21 December 2020
- UNIT PRICE AS AT 21 December 2020
- 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 2020 to 31 December 2020. 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.

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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.

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(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 2021 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 2020
- LOGISTICS FEES AS AT 21 December 2020
- VAT
- SEP AS AT 21 December 2020

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- UNIT PRICE AS AT 21 December 2020
- EFFECTIVE DATE
- STATUS
- ORIGINATOR OR GENERIC

The details must be copied from the 21 December 2020 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP of 21 December 2020.

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 AUSDollars, 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 12-month period (i.e. 01 October 2019 to 30 September 2020. These values will be published in the template for consistency. The following are the for the conversion to Rands:
AUS$ 11.00003581

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CAN$ 12.05044106
NZD$ 10.36368898
EUR€ 18.18944400

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 / 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.)*	

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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 2021 SEPA information and instruction document.
2. I have followed the instructions contained in the 2021 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)

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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..... 2021 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

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4.3 ANNEXURE C: CHECKLIST

SEPA CHECKLIST

Tick the appropriate box (√)

HAVE YOU:	YES	NO
a) Read and understood the entire instruction document for 2021 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 2021 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 2021 TEMPLATE

See Excel Template Published in www.mpr.gov.za or www.doh.gov.za

DIRECTOR GENERAL HEALTH, MP
DR SSS BUTHELEZI
DATE:

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