

DEPARTMENT OF HEALTH

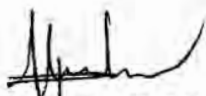
NO. 894

05 AUGUST 2016

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT NO. 101 OF 1965)**INFORMATION TO BE PROVIDED BY MANUFACTURERS AND OR IMPORTERS
OF MEDICINES AND SCHEDULED SUBSTANCES WHEN APPLYING FOR THE
INTERIM SINGLE EXIT PRICE ADJUSTMENT FOR 2016**

I, MS MP MATSOSO, 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 2016 Interim 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 presented as an electronic version (In Excel format on labelled compact disc) and hard copy. The submission should include information regarding the applicant's entire portfolio; including medicines for which the applicant is not requesting an interim adjustment of the SEP.

**MS MP MATSOSO****DIRECTOR-GENERAL: HEALTH**

DATE: 22/6/2016



health

Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMATION AND INSTRUCTIONS FOR THE INTERIM SINGLE EXIT PRICE ADJUSTMENT (SEPA) SUBMISSIONS FOR 2016

**(THIS DOCUMENT IS ONLY VALID FOR THE PERIOD 20 MAY
2016 AND 20 JUNE 2016)**

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the medicines for 2016 Interim SEP adjustment (SEPA) 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 period for receiving the interim SEPA submissions is from 20 May 2016 to 20 June 2016. Failure to comply with any of the requirements and instructions in this document will result in the submission being considered incomplete.

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1. ACRONYMS

CFO – Chief Financial Officer

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 notice as signed by the Minister of Health on the 16th May 2016, may forward submissions for the 2016 interim Single Exit Price Adjustment (SEPA) for medicines with SEP's as per the notice signed by the Minister of Health on 16th May 2016. . These submissions should also include;
 - i. scheduled medicines for which no interim adjustment is required
 - ii. no interim adjustment is applicable
 - iii. discontinued medicines.
- (b) There will be one submission per applicant for this 2016 interim SEPA. An applicant's portfolio may not be divided into multiple submissions.
- (c) The information contained in the published gazette with respect to the interim SEPA for 2016 should be read carefully.
- (d) Read carefully the information and instructions contained in this document before completing all tabs of the latest 2016 excel interim 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**).
- (g) Complete the checklist that is also annexed to this document (**Annexure C**).
- (h) Complete **all** sections of all tabs of the latest 2016 interim SEPA template in the fields provided (**Annexure D**).
- (i) Include a signed covering letter on a company letterhead, stating the purpose and motivation for this interim SEPA submission.
- (j) A complete submission which should include a fully completed interim SEPA template for 2016, annexure A, B, and C and a signed covering letter on the applicant's letterhead.

- (k) Ensure that all fields have been completed as per the final Annexure E Publication for each medicine.
- (l) Wherever the date is required, it should be stated in full (e.g. 14 March 2001).
- (m) Applicants are required to submit an electronic version of the submission on the interim SEPA template for 2016.

2.2 INTERIM SEPA SUBMISSION REQUIREMENTS

- (a) The submissions lodged in terms of these guidelines are solely for the purposes of 2016 interim 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) Applicants must take cognisance of the 4.80% SEPA approved in terms of gazette No. 39594 as on the published 13 January 2016. **ALL** sections of the 2016 interim SEPA template must be fully completed. A fully completed template must have all tabs or worksheets completed. Within each tab, all required fields must be completed for every medicine in the applicant's schedule as published.
- (c) **ALL** scheduled medicines that make up the applicant's portfolio on the date of the submission, **MUST** be presented in the interim SEPA template.
- (d) **ALL** SEP update submissions approved and communicated following the approval and communication of 2016 SEPA of 4.80% in terms of gazette No. 39594 published 13 January 2016 and before the date of the applicant's interim SEPA submission 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 documents may result in the reversal of the interim SEPA.
- (e) **ALL** medicines existing with SEP's effected on and or before 20 May 2016 must be included in the submission.
- (f) Only the rightful applicant 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 MCC approved and registered applicants whose manufacturing licences have not expired.

2.3 NOTES FOR APPLICANTS

- (a) The 2016 interim SEPA in terms of the notice signed by the Minister of Health on the 16 May 2016 is applicable to the medicines with an effective date no later than 20th May 2016.
- (b) 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 Regulation 9, whilst the submission for interim SEPA is still in process. Similarly, the applicant cannot submit interim SEPA or Regulation 9 application whilst the submission for an SEP update is still in process. In an event where the applicant has made an interim SEPA submission and any other SEP update submissions and/or a Regulation 9 application the interim SEPA submission will become null and void.
- (c) 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. Interim SEPA will not be allowed on discontinued medicines.
- (d) It is the applicant's responsibility to ensure that all medicines presented on the template for 2016 interim SEPA are unit priced. When computing the unit prices, the resulting SEPs should not exceed the maximum allowable SEP after the interim adjustment.
- (e) 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. An interim SEPA submission will be considered non-compliant in its entirety should the applicant not comply with unit pricing. This non-compliance of the submission is factual even if a single medicine is not unit priced with its related pack size(s). This will render the entire submission null and void.

- (f) All submissions for 2016 interim SEPA will be processed within 60 working days (excluding weekends and holidays) upon receipt of the submission by the PEE Directorate of the Department.
- (g) The outcome of each interim SEPA submission will be communicated to the applicant as soon as the submission has been assessed.
- (h) All approved SEPs will be communicated to price file managers and published on the website (www.mpr.gov.za) by the PEE Directorate.
- (i) All correspondences concerning 2016 interim SEPA submission will only be communicated to the applicant of the medicines applied for as provided in this submission.
- (j) The electronic version of the submitted 2016 interim SEPA template should be saved as an excel file. Submissions containing password-protected documents and files in a version that the PEE Directorate is unable to access such as PDF will be considered incomplete and unacceptable. 2016 interim SEPA submission with blank disc will be null and void.
- (k) Interim SEPA can only be submitted on the published latest interim SEPA template for 2016 including both Tab 1 and 2. **ANY** modification to the template will result in the submission not being accepted.
- (l) The final date for resubmissions will be 30 June 2016. Resubmissions will be reviewed for medicines that were not approved in the previous submissions.
- (m) An applicant may only submit once for the 2016 interim SEPA. An applicant's portfolio may not be divided into multiple submissions.
- (n) Where 2.90% adjustment is not requested or where the applicant did not adjust the SEP as per the notice signed by the Minister of Health on the 16th May 2016, the official SEP shall default to the SEP which was approved in terms of the government gazette No. 39594 published on the 13th January 2016. The medicines introduced post the approval in terms government gazette No. 39594 published on the 13th January 2016 which did not apply for this interim adjustment shall remain at their SEP provided the effective date occurred prior 20 May 2016.

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 2016 interim 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) No e-mail submissions will be accepted.
- (d) Electronic copies and hardcopies of the submissions **MUST** be addressed to:

2016 Interim SEPA

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 interim SEPA for 2016, you may contact Ms Oumakie Mabusela at (012) 395 8181 after 13h00 or by e-mail at sepupdates@health.gov.za.

Queries are only attended to during working days excluding public holidays and weekends between 13h00 and 15h00. 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.

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

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 2016 interim SEPA template (both Tab1 and Tab2);
- (c) Completed annexure A;
- (d) Completed annexure B and
- (e) Completed annexure C

2.6 ACKNOWLEDGMENT OF RECEIPT

Upon receipt of a submission, an acknowledgement notice will be provided to the representative of the applicant by the PEE Directorate official. All applicants must retain their acknowledgement notice, for reference purposes. Duplicates and copies will not be provided by the PEE Directorate.

3. HOW TO COMPLETE TEMPLATE COLUMNS

3.1 2016 INTERIM SEPA TEMPLATE TAB 1

3.1.1 For the information required in the 2016 interim SEPA template, the format of all fields must be in keeping with the latest published DoP. Failure to comply will render your submission null and void.

- 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 20 MAY 2016
- LOGISTICS FEES AS AT 20 MAY 2016
- VAT
- SEP AS AT 20 MAY 2016
- UNIT PRICE AS AT 20 MAY 2016
- 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 2015 to 31 December 2015. Where the medicine is not being sold this should be indicated.

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 14% 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.

3.1.4 REQUESTED SEP

This is the requested Single Exit Price for the product 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.

3.1.5 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 divided and by the quantity of presentation

- 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 100ml of diluents is 50].

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

3.2 INTERIM SEPA 2016 TAB 2

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 20 MAY 2016
- LOGISTICS FEES AS AT 20 MAY 2016
- VAT
- SEP AS AT 20 MAY 2016
- UNIT PRICE AS AT 20 MAY 2016
- EFFECTIVE DATE
- STATUS
- ORIGINATOR OR GENERIC

The details must be copied from the 20 MAY 2016 DoP for all the medicines for the applicant. All details and formatting must remain as it appears on DoP 20 MAY 2016.

3.1.2 For all medicines that are labelled originator, the following columns must be completed; Closest Australian Pack Size, Related Australia Quantity, Australian Manufacturer Price in AU\$Dollars, AU\$Dollar Exchange Rates, Australian Price in Rands, AUS matching pack price 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, CAN matching pack price 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, NZ matching pack price in Rands, Comment on NZ Price Provided, Closest Spain Pack Size, Related Spain Quantity, Spain Manufacturer Price in EURO, EURO Exchange Rates, Spain Price in Rands, Spain matching pack price 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 Rands, Alternate Country matching pack price 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. Extra columns must be inserted for each alternate country.

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 1 OO'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.

For the columns "Country matching pack price in Rands" this should be the

price in Rands of the relevant Country price for the related South African pack size and quantity. An example will be provided in the template for demonstration purposes. The principle is that where a 30's pack size is available in South Africa, the international price calculated in Rands should be for the equivalent 30's pack size.

For the columns "Comment on Country Price Provided" -these columns should be used to put in all comment related to the price, pack size, quantity or any other field that may affect the comparisons of the price of the South African medicine with the price of the medicine in the comparator country.

- 3.2.4 The exchange rate will be the average over the 12 month period (i.e. 01 October 2015 to 30 September 2015). This value will be published in the template for consistency as specified below:

Australian Dollar (AUS\$)-9.4036

Canada (CAN\$)-9.7712

New Zealand (NZ\$) - 8. 7155

Spain (EURO€) - 13.7689

NOTE: The document should always be maintained in Aria/ font size 10.

There should be no unnecessary use of space, dashes or other characters.

4. ANNEXURES

4.1 ANNEXURE A: COVER PAGE

TO BE COMPLETED BY THE APPLICANT	
APPLICANT NAME <i>As it appears on the MCC license</i>	
CONTACT PERSON <i>(Responsible for this submission)</i>	

NUMBER OF MEDICINES IN THE SUBMISSION <i>(Also include medicines for which interim SEPA adjustment is not requested, rows which contain multiple active ingredients should not be counted.)</i>	
NUMBER OF LINE ITEMS BEING SUBMITTED FOR 2016 INTERIM SEPA	

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

4.2 ANNEXURE B:

2016 INTERIM 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 2016 interim SEPA information and instruction document.
2. I have followed the instructions contained in the interim 2016 information and instruction document in completing the interim SEPA template.
3. I have correctly calculated unit pricing for all medicines in the applicant's portfolio.
4. I have requested only the interim 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 and motivation for 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)
2.(Responsible Pharmacist)

The Deponent has acknowledged that he/she knows and understands the contents of this affidavit, which was signed and sworn to before me aton this the.....day of..... 2016 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:**2016 INTERIM SEPA CHECKLIST**

Tick the appropriate box (✓)

HAVE YOU:	YES	NO
a) Read and understood the entire instruction document for 2016 interim 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 and the motivation for this submission?		
d) Correctly completed the template for 2016 interim SEPA?		
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) Completed TAB 2 of the template?		

NOTE: If any of the answer(s) to the question(s) above is **NO**, the submission will be null and void.

4.4 ANNEXURE D: 2016 INTERIM SEPA TEMPLATE

See Excel Template attached, with Tab 1 and Tab 2

2016 EXTRAORDINARY SINGLE EXIT PRICE ADJUSTMENT TEMPLATE

[illegible]

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