DEPARTMENT OF HEALTH

NO. 1018 **16 SEPTEMBER 2016**

MEDICINES AND RELATED SUBSTANCES ACT, 19 65 (ACT NO. 101 OF 1965, AS AMENDED)

(EXTENSION OF THE IMPLEMENTATION PERIOD OF THE INTERIM ADJUSTMENT OF THE SINGLE EXIT PRICE OF MEDICINES AND SCHEDULED SUBSTANCES [SEPA] FOR THE YEAR 2016)

I, DR A MOTSOALEDI, the Minister of Health, have 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) as amended, that the Single Exit Price (SEP) of Medicines and Scheduled Substances may be adjusted by up to a maximum of **2.90 %** of the Single Exit Price that was available as at 20 May 2016; regardless of how that SEP was arrived at. Submissions must be lodged no later than thirty days from the date of publication of this Notice.

All medicines and their related pack sizes approved with an effective date after 20 May 2016 are not eligible for interim SEPA 2016. An applicant may only submit once in this interim 2016 SEPA period.

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, 30 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: 2/8/2016

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 the products for which the applicant is not requesting an adjustment of the SEP.

MS MP MATSOSO
ACTING DIRECTOR-GENERAL: HEALTH
DATE: 12/8/2016

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

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

(THIS DOCUMENT IS PART OF THE IMPLEMENTATION EXTENTION NOTICE SIGNED BY THE MINISTER FOR THE INTERIM 2016 SEPA)

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. Failure to comply with any of the requirements and instructions in this document will result in the submission being considered incomplete.

CONTENTS

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, may forward submissions for the 2016 interim Single Exit Price Adjustment (SEPA). These submissions must also include;

i. Scheduled medicines for which no interim adjustment is required.

ii. Scheduled medicines for which no interim adjustment is applicable.

iii. Discontinued medicines (i.e. all the medicines for the applicant as they appear on the DoP)

(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 also 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 published on 13 January 2016. For a submission to be considered complete, **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, for the submission to be considered complete;

(c) For a submission to be considered complete, **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. Medicines with SEP effective on or after 20 May 2016 are not eligible for this interim adjustment;**

(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 is applicable only 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. Also, an applicant may not submit an interim SEP adjustment whilst a Regulation 9 application is in process;

(c) 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;

(d) Each submission must 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;

(e) 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;

(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. An interim SEPA submission will be null and void 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;

(g) All submissions for 2016 interim SEPA will be processed within 60 working days (excluding weekends and holidays) upon official receipt of the submission by the PEE Directorate of the Department. A submission is only considered received when the applicant is issued with an acknowledgement of receipt by a PEE official;

(h) The outcome of each interim SEPA submission will be communicated to the applicant as soon as the submission has been assessed;

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

(j) All correspondences concerning 2016 interim SEPA submission will only be communicated to the applicant of the medicines applied for as provided in this submission. It is the responsibility of the applicant to ensure that contact details provided in the submission are viable;

(k) 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 submissions with blank disc will be null and void;

(l) 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. Any Tab not fully completed will result in the submission being considered incomplete;

(m) The final date for submissions will be the date determined as per the Minister's notice of Extension;

(n) An applicant may only submit once for the 2016 interim SEPA. An applicant's portfolio may not be divided into multiple submissions;

(o) Where 2.90% adjustment is not requested or where the applicant did not adjust the SEP as per the extension notice signed by the Minister of Health, 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 the latest 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.

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. Queries are only attended to between 13h00 and 15h00 on working days (excluding public holidays and weekends). 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 RECIEPT

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 01January 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.

3.1.6 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.

3.1.7 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 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 mi;

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 20m I vial to be reconstituted with 10m I of diluents is 50].

The unit price must be represented as a numerical field and contents should be 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 INSTRUCTIONS FOR COMPLETING TAB 2 COLUMS:

- 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 of 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 AUSDollars, AUSDollar 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 CANDollars, CANDollar 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 NZDollars, NZDollar 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 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.

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 (template to be populated) should always be maintained in Arial font size 10. Applicants should only make use of spaces, 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 *(Responsible for this submission)*	
NUMBER OF MEDICINES IN THE SUBMISSION *(Also include medicines for which interim SEP adjustment is not requested, rows which contain multiple active ingredients should not be counted.)*	
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 at .....on 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 (The electronic version of any template referred on this document, for use by applicants can be accessed via www.mpr.gov.za)

TAB 1

2016 INTERIM SINGLE EXIT PRICE ADJUSTMENT TEMPLATE

Name of Applicant (as it appear no MCC Licensa):
Trade Name of Applicant (i.e. trading as):
Name of Contact Person:
Email address, telephone number and fax number of contact person above:

Applicant MCC Licence No	Applicant Name as Registered with MCC	MCC Medicine Registration No	Nappi Code	ATC 4 Code (WHO)	Schedule	Medicine Proprietary Name	Active Ingredients	Strength	Unit	Dosage Form	Pack Size	Quantity	SEP ON THE DATE OF SUBMISSION									REQUESTED INTERIM SEP ADJUSTMENT								THIS COLUMN IS FOR OFFICE USE ONLY
													Manufacturer Price	Logistics Fee	VAT	SEP	Unit Price	Effective Date	Status	Originator or Generic	Volume of Sales	Requested Manufacturer Price	Requested Logistics Fee	VAT on Request	Requested SEP	Requested Unit Price	Effective Date	
																					numerical field	numerical field	numerical field	numerical field	numerical field	numerical field	numerical field	
																						2 decimal places	2 decimal places	2 decimal places	2 decimal places	2 decimal places	2 decimal places	
																						no currency symbols	no currency symbols	no currency symbols	no currency symbols	no currency symbols	no currency symbols	
																						right indent	right indent	right indent	right indent	right indent	right indent