No. R. 75 **4 February 2015**

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

INFORMATION TO BE PROVIDED BY MANUFACTURERS AND OR IMPORTERS OF MEDICINES AND SCHEDULED SUBSTANCES WHEN APPLYING FOR THE SINGLE EXIT PRICE ADJUSTMENT FOR 2015

I, DR T CARTER, Acting 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 2015 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 (Excel with an xls filename extension 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.

DR T CARTER
ACTING DIRECTOR-GENERAL: HEALTH
DATE: 28/1/2015

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMATION AND INSTRUCTIONS FOR THE SINGLE EXIT PRICE ADJUSTMENT (SEPA) SUBMISSIONS FOR 2015

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the SEP adjustment (SEPA) for medicines for 2015 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, are required to forward submissions on the Single Exit Price Adjustment (SEPA) for 2015 for all scheduled medicines appearing on the Database of Medicines Prices (DoP) published on 23 December 2014. These submissions should also include scheduled medicines for which no adjustment is required.

(b) The information contained in the published gazette with respect to the SEPA for 2015 should be read carefully

(c) Read carefully the information and instructions contained in this document before completing all tabs of the latest 2015 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 (**Annexure B**).

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

(g) Complete **all** sections of all tabs of the latest 2015 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 which should include a fully completed latest SEPA template for 2015, annexure A, B, and C and a signed covering letter on the applicant's letterhead.

(j) Ensure that all fields have been completed as per DoP of 23 December 2014.

(k) Wherever the date is required, it should be stated in full (e.g. 14 March 2001).

(l) Applicants are required to submit an electronic version of the submission for SEPA on the latest SEPA template for 2015.

2.2 SUBMISSION REQUIREMENTS

(a) This submission is solely for the purposes of adjusting the SEP. For other medicine details amendments, applicants must use Template G of the SEP updates as published on the website: www.mpr.gov.za

(b) **ALL** sections of the 2015 SEPA template must be fully completed. A fully completed template will 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 on DoP of 23 December 2014.

(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** SEP update submissions received between 12 January 2015 and the date of the applicant's 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 SEPA.

(e) 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 applicants.

2.3 NOTES FOR APPLICANTS

(a) The 2015 SEPA concerns SEPs that are applicable as on 23 December 2014, regardless of how these SEPs were arrived at. The schedule of 23 December 2014 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 23 December 2014*.

(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, updates 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 already launched an SEP Update submission, the applicant will be required to indicate in writing withdrawal of either the SEPA submission or Regulation 9 application which is already in process.

(c) Should the applicant wish to re-submit an SEPA communication, following a withdrawal, a new submission will be required (see 2.1 (h)).

(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 discontinued medicines.

(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 23 December 2014 (i.e. SEP applicable as of 23 December 2014 + 7.50%).

(f) All medicines including those with multiple pack sizes are required by law to be unit priced.

(g) Where a new pack size is introduced after 23 December 2014, 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 23 December 2014. (Note that the newly launched medicines 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 30 working days (excluding weekends and holidays) upon receipt of the submission by the PEE Directorate.

(i) The outcome of each submission will be communicated to the applicant as soon as the PEE Directorate has assessed the submission.

(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 concerning a submission will only be communicated to the applicant of the medicines applied for.

(l) The electronic version of the submitted 2015 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 be considered incomplete and unacceptable.

(m) SEPA can only be submitted on the published latest SEPA template for 2015. **ANY** modification to the template will result in the submission not being accepted. This also applies to resubmissions.

(n) An applicant may only submit once in the 2015 SEPA cycle. This does not apply to resubmissions (see point (o) below)

(i) Where no adjustment is requested, the existing SEP will be applicable for the 2015 SEPA cycle. The SEPA cycle is the period

between two consecutive SEPA announcements by the Minister of Health.

(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 that cycle.

(o) Resubmissions;

i. Will only be reviewed for medicines who's SEPs were previously not approved.

ii. All the requirements for the SEP submissions as stated in this document shall be applicable, except resubmissions which must contain only medicines listed in the Not-Approved sheet of Annexure E communicated to the applicant in response to the initial submission.

iii. Must only be on the 2015 SEPA template.

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 2015 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:

2015 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

For any enquiries regarding SEPA for 2015, you may contact Ms Matshidiso Marokane at (012) 395 8187/8181 or by e-mail at sepupdates@health.gov.za Queries are only taken on Mondays to Fridays 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.

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 2015 SEPA template;

(c) Completed annexure A;

(d) Completed annexure B and

(e) Completed annexure C

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.

3. HOW TO COMPLETE TEMPLATE COLUMNS

3.1 SEPA 2015 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 23 December 2014 for all medicines that sought SEPA for 2015. All the information and the formats must remain as it appears on the DoP of 23 December 2014.

- 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 23 DECEMBER 2014
- LOGISTICS FEES AS AT 23 DECEMBER 2014
- VAT
- SEP AS AT 23 DECEMBER 2014
- UNIT PRICE AS AT 23 DECEMBER 2014
- 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 2014 to 31 December 2014. 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 diving 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 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 2015 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 23 DECEMBER 2014
- LOGISTICS FEES AS AT 23 DECEMBER 2014
- VAT
- SEP AS AT 23 DECEMBER 2014
- UNIT PRICE AS AT 23 DECEMBER 2014
- EFFECTIVE DATE
- STATUS
- ORIGINATOR OR GENERIC

The details must be copied from the 23 December 2014 DoP for all the medicines for the applicant. All details, formatting and raw order must remain as it appears on DoP of 23 December 2014. Information provided by the applicant will be processed as the true reflection of the applicant's portfolio and published as such.

3.2.2 For all medicines that are labelled originator, the following columns must be completed; Closest Australian Pack Size, Australian Manufacturer Price in AUSDollars, AUSDollar Exchange Rates, Australian Price in Rands, Closest

Canada Pack Size, Canada Manufacturer Price in CANDollars, CANDollar Exchange Rates, CAN Price in Rands, Closest New-Zealand Pack Size, New-Zealand Manufacturer Price in NZDollars, NZDollar Exchange Rates, New-Zealand Price in Rands, Closest Spain Pack Size, Spain Manufacturer Price in EURO, EURO Exchange Rates, Spain Price in Rands, Closest Alternate Country Pack Size, Manufacturer Price alternate currency , Alternate Currency Exchange Rates, Alternate Country Price in Rands. 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.

3.2.4 The exchange rate will be the average over the 12 month period (i.e. 01 January 2014 to 31 December 2014). This value will be published in the template for consistency.

NOTE: The document should always be maintained in Arial 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 *As it appears on the MCC license*	
CONTACT 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 LINE ITEMS BEING RESUBMITTED FOR REVIEW *(Indicate the resubmitted items as such on the status column in the latest template)*	

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 2015 SEPA information and instruction document.
2. I have followed the instructions contained in the 2015 information and instruction document in completing the SEPA template.
3. I have correctly calculated unit pricing for all medicines in the applicant's portfolio.
4. I have requested only the SEPA and not any other medicine details amendments for the scheduled medicines in the applicant's portfolio.
5. I have enclosed a signed covering letter on the company letterhead, stating the purpose of this submission.
6. The information supplied in this submission is true and correct. (NB: please provide proof of authorization to sign on behalf of the company)

SIGNATURE (DEPONENT)

1. **.....(CFO)**
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..... 2015 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 2015 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 2015 template?		

HAVE YOU:	YES	NO
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)?		

NOTE: *If any of the answer(s) to the question(s) above is* ***NO****, the application will be considered* ***INCOMPLETE.***

4.4 ANNEXURE D: SEPA 2015 TEMPLATE

See Excel Template attached with two tabs: tab one and tab two.

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