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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

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GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 68 **31 January 2014**

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

(ANNUAL ADJUSTMENT OF THE SINGLE EXIT PRICE OF MEDICINES AND SCHEDULED SUBSTANCES [SEPA] FOR THE YEAR 2014)

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), that the Single Exit Price (SEP) of Medicines and Scheduled Substances may only be submitted for the first time in 2014 from 31 January 2014 and by no later than 01 April 2014 to a maximum of **5.82%** of the Single Exit Price that was available as at 20 December 2013. The final date for resubmissions will be 19 May 2014.

All products and related pack sizes introduced after 20 December 2013 are not eligible for SEPA 2014. An applicant may only submit once in the 2014 cycle unless a resubmission is made for a previous incomplete submission.

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 under Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances.

DR A MOTSOALEDI, MP
MINISTER OF HEALTH
DATE: 29/1/2014

No. R. 69 **31 January 2014**

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 2014)

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 when applying for the SEP adjustment for 2014 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 provided for in electronic (Excel with an xls filename extension on labeled compact disc) and hard copy. The submission should include information regarding the applicant's entire portfolio; this includes products for which the applicant is not applying for an increase.

MS MP MATSOSO

DIRECTOR-GENERAL: HEALTH

DATE: 23/1/2014

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMATION AND INSTRUCTIONS FOR THE SINGLE EXIT PRICE ADJUSTMENT (SEPA) SUBMISSIONS FOR 2014

PREAMBLE

This document provides information and instructions on how to present the required information when communicating the SEP adjustment for medicines for 2014 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 will result in the submission not complying with the prescripts of the instruction document.

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1. ACRONYMS

CFO – Chief Financial Officer

DoP – Database of Single Exit Prices

MCC – Medicines Control Council

MPR – Medicine Pricing Registry

NAPP – 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) Read carefully the information contained in the published gazette with respect to the SEP adjustment for 2014.

(b) Read carefully the information and instructions contained in this document before completing the latest excel SEPA template which is available on the website www.mpr.gov.za (where is it exactly).

(c) Complete the information required in the cover page (**Annexure A**).

(d) Sign the declaration annexed to this document (**Annexure B**).

(e) Fill in the checklist that is also annexed to this document (**Annexure C**).

(f) Complete **all** sections of the latest template in the fields provided (**Annexure D**).

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

(h) Send a fully completed submission which should include a fully completed latest SEPA template on the latest excel spreadsheet, annexure A, B and C and a signed covering letter on the applicant's letterhead.

(i) Ensure that all fields have been completed and all the necessary supporting documentation has been included with the submission before submitting it to the Directorate: PEE of the National Department of Health.

(j) Express the full date (e.g. 14 March 2001) wherever the date is required.

(k) All applicants are required to submit an electronic version of the submitted latest excel SEPA template.

2.2 SUBMISSION REQUIREMENTS

(a) All sections of the SEPA 2014 template must be fully completed.

(b) **ALL** scheduled medicines that make up the applicant's portfolio on the date of submission **MUST** be presented in the latest SEPA template.

(c) The licensed applicant for the medicine or scheduled substance concerned lodges the submission as per the MCC manufacturing license and medicines registration certificate. Submissions will not be accepted from persons other than the applicant of the medicine concerned with MCC.

2.3 NOTES FOR APPLICANTS

(a) The 2014 Single Exit Price Adjustment (SEPA) concerns SEPs that are applicable as on 20 December 2013, regardless of how these SEPs were arrived at. The schedule of 20 December 2013 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 20 December 2013*.

(b) There can only be one SEP submission launched at any given point in time. The applicant cannot submit for SEP Updates whilst the submission for SEPA is still in process. Similarly, the applicant cannot submit a SEPA

whilst the submission for an SEP update is still in process. In an event where the applicant has already launched an SEP Update submission, any SEPA submission made will be withdrawn by the PEE Directorate.

(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 products, including discontinued products. Discontinued products should be indicated as such, as per the DoP under the status column.

(e) All products presented on the template for SEPA must be unit priced. When computing unit prices for your products, the resulting SEPs should not exceed the maximum allowable SEP after the adjustment on the SEP that existed on 20 December 2013 (i.e. SEP applicable as of 20 December 2013 + 5.82%).

(f) A medicine with multiple pack sizes is required by law to be unit priced.

(g) Where a new pack size is introduced after 20 December 2013, 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 20 December 2013. (Note that the launched products are part of the portfolio on the date of submission and they should be unit priced with their related pack sizes.

(h) All submissions for SEPA will be processed within 30 working days (excluding weekends and holidays) of receipt of the application 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 products applied for.

(l) The 2014 SEPA excel template, electronic version submitted should have a file name extension xls only. Submissions with 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 or improper.

(m) SEPA can only be submitted on the published latest SEPA 2014 template. **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 2014 SEPA cycle. This does not apply to resubmissions (see point o below)

i. A zero percent SEPA will be received accepted and approved as such. The applicant may not at a later stage resubmit a different SEPA request for the same product.

ii. Where no adjustment is requested, the existing SEP will be applicable for the balance of the 2014 SEPA cycle. The SEPA cycle is the period between two consecutive SEPA announcements by the Minister of Health.

iii. An applicant's portfolio may not be divided into multiple submissions.

iv. 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 will only be reviewed for products that were previously not approved. However all SEP submissions requirements as stated in this document must apply.

(p) Where the MCC medicine registration number, the scheduling status or other medicine details are missing on the published database of prices on 20 December 2013, these fields should be completed in the submission and

accompanied by the MCC Licence to manufacture, MCC Medicine Registration Certificate and MCC approved Package Insert (PI).

(q) Where supporting evidence to the submission is not supplied, this submission will be considered incomplete and the applicant shall be informed of such.

2.4 LODGING OF SUBMISSIONS

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

(b) Each submission should be lodged on the latest SEPA excel template and must be accompanied by annexures of this document (annexure A, B & C) as well as the applicant's covering letter on the applicant's letterhead.

(c) Electronic copies and hardcopies of submissions should be addressed to:

2014 SEP Adjustment
The Director: Pharmaceutical Economic Evaluations (PEE)
ATT: Ms Ntobeko Mpanza
The National Department of Health
Room S2611 Civitas Building
Corner of Thabo Sehume Street and Struben Street
0001

For any enquiries regarding SEPA for 2014, 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 09h00 and 16h00. 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

The following documents are to be submitted by all SEPA applicants to ensure completeness of the submissions:

(a) Signed cover letter on the applicant's letter head;
(b) Completed 2014 SEPA excel template;
(c) Completed annexure A;
(d) Completed annexure B and
(e) Completed annexure C

Note: Where there are additions or amendments to existing medicine details, the following must accompany the complete submission:

(a) MCC Licence to manufacture;
(b) MCC Medicine Registration Certificate and
(c) MCC approved PI

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.

3. HOW TO COMPLETE TEMPLATE COLUMNS

3.1 APPLICANT MCC LICENCE NUMBER

10-digit number as provided by MCC. Format the column as follows: right click the input cell; select "format cell" on the appearing menu; click the tab "Number" and select "Custom" on the appearing list; on the field under "Type:", enter 10 zeros and click ok; then enter the license number as required. This column should be indented to the right. Ensure that the appropriate number of zeros is in the front of the licence number, as per the MCC Licence to Manufacture.

3.2 APPLICANT NAME AS REGISTERED WITH MCC

The name of the applicant for the product as described in the product MCC registration certificate. This column should be indented to the left.

3.3 MCC MEDICINE REGISTRATION NUMBER

The Registration number as provided by MCC in the MCC medicine registration certificate. This column should be indented to the left.

3.4 NAPPI CODE (9-digit)

This should be a 9 digit number (numerical format) with no decimals. These cells can be formatted by following this route: Right click, Format Cells, Number, and

Decimal Places (0). No dashes, spaces or any other characters should be used. This column should be indented to the right.

3.5 ATC 4 CODE (WHO)

As per WHO classification, this is the ATC 4 code that must be provided in 5 characters. To obtain ATC 4 Code for each active ingredient of a product, go to: www.whocc.no → Click on ATC/DDD index → Under the heading ATC/DDD index 2014 → use active ingredient of product to search for LEVEL 4 ATC code under name.

3.6 SCHEDULE

The schedule must be provided in 2 characters. The first character will be the capital letter S and immediately followed by a number representing the schedule, e.g. for the antibiotic Cefazolin which is schedule four, the representation in the schedule column will be written as S4. This will be as per the MCC approved PI. This column should be indented to the left.

3.7 MEDICINE PROPRIETARY NAME

This should be the product proprietary name as it appears on the MCC product registration certificate. This column should be indented to the left.

3.8 ACTIVE INGREDIENTS

This column should contain full names of all the active ingredients in the product, with each ingredient in a new row, no abbreviations should be used, e.g. Sodium Chloride and should not be represented by NaCl. The active ingredients should

be listed in decreasing order of concentration. The International Non-Proprietary name, as per WHO should be used. This column should be indented to the left.

3.9 STRENGTH

This column represents the numerical or quantum portion of the strength of the product, e.g. for paracetamol 20mg, the strength is 20. The number of decimals in this numerical field cannot be pre-determined, as it will depend on the product. A decimal point (.) and not a comma (,) should separate decimal places. This column should be indented to the right.

3.10 UNIT

This column represents the unit of measurement for the strength of the active ingredient(s). This is a text field, e.g. for Paracetamol 20mg, the unit is mg. This column should be indented to the left.

3.11 DOSAGE FORM

This is a 3 capital letter text field that describes the dosage form of the product. The 3 letters descriptions should be filled in as shown in the Dosage Form Abbreviation List (see www.mpr.gov.za). This column should be indented to the left.

3.12 PACK SIZE

This is the MCC approved pack size of the product, as published in the MCC approved PI. It should correspond with the SEP. This column is a numeric field that should be indented to the left.

3.13 QUANTITY

The number of packs as per 3.12 above.

3.14 MANUFACTURER PRICE AS AT 20 DECEMBER 2013

This is the VAT exclusive manufacturer price of the product in South African Rands as at 20 December 2013. This is a numerical field to 2 decimal places, with no currency symbols. This column should be indented to the right.

3.15 LOGISTICS FEES AS AT 20 DECEMBER 2013

This is the VAT exclusive logistics fees for the product in South African Rands. This is a numerical field to 2 decimal places, with no currency symbols. This column should be indented to the right.

3.16 VAT

This column is the VAT on the sum of the manufacturer price (as on 20 December 2013) plus the logistics fees (as on 20 December 2013). The VAT is currently 14%. This is a numerical field to 2 decimal places with no currency symbols. This column should be indented to the right.

3.17 SEP AS AT 20 DECEMBER 2013

This is the Single Exit Price for the product in South African Rands. It is the sum of the manufacturer price, the logistics fees and VAT. This is a numerical field to 2 decimal places with no currency symbols. This column should be indented to the right.

3.18 UNIT PRICE AS AT 20 DECEMBER 2013

(a) This is the price of a unit of the product, 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) Where products are packed in multiples 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 to 2 decimal places with no currency symbols. This column should be indented to the right.

3.19 EFFECTIVE DATE

This column is in the format DD MONTH YYYY. This implies it will be written as a full word date reflected as follows: 2 numerical digits for the date, the month in full and 4 numerical digits for the year in full. These cells can be

formatted by following this route: Right click, select Format Cells, Number, Date, Location (English South Africa) and Type (14 March 2001). This column should be indented to the right.

3.20 REQUESTED MANUFACTURER PRICE

This is the requested VAT exclusive manufacturer price of the product in South African Rands. This is a numerical field to 2 decimal places, with no currency symbols. This column should be indented to the right.

3.21 REQUESTED LOGISTICS FEE

This is the requested VAT exclusive logistics fee for the product in South African Rands. This is a numerical field to 2 decimal places, with no currency symbols. This column should be indented to the right.

3.22 VAT ON REQUESTED COMPONENTS

This column is the VAT on the sum of the requested manufacturer price plus the requested logistics fee. The VAT is currently 14%. This is a numerical field to 2 decimal places with no currency symbols. This column should be indented to the right.

3.23 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 to 2 decimal places with no currency symbols. This column should be indented to the right.

3.24 REQUESTED UNIT PRICE

This is the resulting unit price of the product. The unit price is the requested SEP divided by the pack size. See 3.18 above.

3.25 STATUS

This is marked Discontinued for products that have been discontinued as per the DoP.

3.26 ORIGINATOR OR GENERIC

This is marked as either Originator or Generic as per the DoP.

3.27 VOLUME OF SALES

This is the total quantity of sales of the particular product for the period 01 January 2013 to 31 December 2013.

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 LINE ITEMS IN THE SUBMISSION *(Also include products 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 2014 SEPA information and instruction document.
2. I have followed the instructions contained in the 2014 information and instruction document in completing the SEPA template.
3. I have corrected all unit pricing discrepancies in the applicant's portfolio.
4. I have enclosed a signed covering letter on the company letterhead, stating the purpose of this submission.
5. 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..... 2014 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 all the information in Section 2?		
b) Read, understood, and followed all the instructions in Section 3?		
c) Provided a signed covering letter on a company letterhead stating the purpose of the submission?		
d) Correctly completed the SEPA 2014 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 2014 TEMPLATE

See Excel Template attached

SINGLE EXIT PRICE ADJUSTMENT 2014 TEMPLATE

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

													SEP AS AT 20 DECEMBER 2013						REQUESTED SEP ADJUSTMENT					THIS COLUMN IS FOR OFFICE USE ONLY			
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	Manufacturer Price	Logistics Fee	VAT	SEP	Unit Price	Effective Date	Requested Manufacturer Price	Requested Logistics Fee	VAT on Request	Requested SEP	Requested Unit Price	Effective Date	Status	Originator or Generic	Volume of Sales
10 digits	As on MCC license	As on MCC certificate	9 digits	5 characters	2 characters	As on MCC certificate	As on MCC certificate	numerical field		3 character text, capital letters	numerical field	numerical field	numerical field	numerical field	numerical field	numerical field	numerical field	DD MONTH YYYY	numerical field	numerical field	numerical field	numerical field	numerical field		text field	text field	numerical field
					S3		Each active ingredient on a separate row.	The numerical portion of each active ingredient.	The unit in which the strength is measured.	As per dosage form abbreviation list			2 decimal places	2 decimal places	2 decimal places	2 decimal places	2 decimal places		2 decimal places	2 decimal places	2 decimal places	2 decimal places	2 decimal places		As per DoP	Either 1 of 2; originator or generic	for the period 01 January 2013 to 31 December 2013
													no currency symbols	no currency symbols	no currency symbols	no currency symbols	no currency symbols		no currency symbols	no currency symbols	no currency symbols	no currency symbols	no currency symbols				
right indent	left indent	left indent	right indent	left indent	left indent	left indent	left indent	right indent	left indent	left indent	right indent	right indent	right indent	right indent	right indent	right indent	right indent	left indent	right indent	right indent	right indent	right indent	right indent		left indent	left indent	right indent

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