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

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GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

No. 35 **22 January 2013**

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

(ANNUAL ADJUSTMENT OF THE SINGLE EXIT PRICE OF MEDICINES AND SCHEDULED SUBSTANCES FOR THE YEAR 2013)

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 under the Medicines and Related Substances Act, (Act 101 of 1965) as amended, that the Single Exit Price (SEP) of Medicines and Scheduled Substances may only be applied for from 02 January 2013 to 30 September 2013 to a maximum of 5.8% of the Single Exit Price schedule that was last published on 21 December 2012.

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: 11/1/2013

No. 36 **22 January 2013**

MEDICINES AND RELATED SUBSTANCES ACT (101 of 1965)
REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES:

INFORMATION TO BE PROVIDED BY MANUFACTURERS AND OR IMPORTERS OF MEDICINES AND SCHEDULED SUBSTANCES WHEN APPLYING FOR THE SINGLE EXIT PRICE ADJUSTMENT FOR 2013

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 2013 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 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 labelled 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: 14/01/2013

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

INFORMATION AND INSTRUCTIONS ON THE APPLICATION FOR THE SINGLE EXIT PRICE ADJUSTMENT (SEPA) FOR 2013

PREAMBLE

This document provides information and instructions on how to present the required information when applying for the SEP adjustment for medicines for 2013 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.

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ACRONYMS

CFO - Chief Financial Officer

MCC - Medicines Control Council

NAPP - National Pharmaceutical Product Interface

PEE - Pharmaceutical Economic Evaluations

SEP - Single Exit Price

SEPA - Single Exit Price Adjustment

VAT - Value Added Tax

VAT (Excl.) - VAT Excluded

VAT (Incl.) - VAT Included

WHO ATC - World Health Organisation Anatomical Therapeutic Chemical

ARRANGEMENT OF THE SECTIONS

PART I: APPLICANT DETAILS

1.1 Applicants are required to:

(a) Read carefully the information contained in the published gazette with respect to the SEP adjustment for 2013.
(b) Read carefully the information and instructions contained in this document before completing the excel SEPA template.
(c) Complete **all** sections of the template in the fields provided.
(d) Complete the information required in the cover page (**Annexure A**)
(e) Sign the declaration annexed to this document (**Annexure B**)
(f) Fill in the checklist that is also annexed to this document (**Annexure C**).
(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 application which should include a fully completed SEPA template on the excel spreadsheet, annexure A, B and C and a signed covering letter.
(i) Ensure that all fields have been completed and all the necessary supporting documentation has been included with the application before submitting it to the Directorate: Pharmaceutical Economic Evaluations (PEE) of the National Department of Health.
(j) Express the full date (e.g. 14 March 2001) wherever date is required and also refer to section 1 (18) in PART II of this document.

1.2 An application shall only be considered if:

(a) All sections of the Single Exit Price Adjustment (SEPA) template have been fully completed.
(b) **ALL** scheduled products that make up the applicants' portfolio are presented in the SEPA template.

(c) The licensed applicant for the medicine or scheduled substance concerned lodges the application as per the MCC manufacturing license and medicines registration certificate.

1.3 Applicants are required to take note of the following:

(a) The 2013 Single Exit Price Adjustment (SEPA) concerns SEPs that are applicable as on 21 December 2012, regardless of how these SEPs were arrived at.

(b) There can only be one SEP application in the system at any given point in time. The applicant cannot apply for SEP updates whilst the application for SEP adjustment is still in process. Similarly, the applicant cannot apply for SEP adjustment whilst the application for SEP update is still in process. In an event where the applicant has already launched an application for the SEP adjustment and the applicant wishes to launch an application for the SEP update, the SEP adjustment application must be withdraw in writing to the DPEE.

(c) Each application should include all the applicants' scheduled products, including discontinued products.

(d) All products presented on the template for SEPA and require unit pricing with related pack sizes must be unit priced. When computing unit prices for your products, the resulting SEPs should not exceed the maximum allowable SEP (i.e. SEP applicable as of 21 December 2012 + X %).

(e) All applications for the SEPA will be processed within 30 working days (excluding weekends and holidays) of receipt of the application by the DPEE

(f) The outcome of each application will be communicated to the applicant as soon as the DPEE has assessed an application.

(g) All approved SEPs will be communicated to price file managers and published on the Department's website by the DPEE.

(h) All correspondence concerning an application will only be communicated to the applicant of the products applied for.

(i) The 2013 SEPA excel template submitted should have a file name extension xls. Password protected documents and files in a version that the DPEE is unable to access such as those with the file extensions xlsx and docx, will be returned to the applicant.

(j) The 2013 SEPA excel template must be completed, saved and returned in the same format as it was published. You are not allowed to modify the template as published.

(k) Where the MCC medicine registration number, the scheduling status or other medicine details are missing on the published database of prices on 21 December 2012, these fields should be completed in the application and accompanied by MCC Licence to manufacture, MCC Medicine Registration Certificate and MCC approved Package Insert.

(l) Where supporting evidence to the application is not supplied, this application will be considered incomplete and the applicant shall be informed as such.

1.4 Lodging of applications

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

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

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

2013 SEP Adjustment
The Director: Pharmaceutical Economic Evaluations (PEE)
ATT: Ms Mahlogonolo Ledwaba
The National Department of Health
Room S2611 Civitas Building

Corner of Andries Street and Struben Street
0001

For any enquiries regarding the applications for SEPA for 2013, you can contact Mr Stanley Muthaphuli or 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 13:00h00 and 16:00h00. Please note that the DoH will not be held responsible for applications that were not received and signed for by an official of the PEE unit, i.e..

1.5 Acknowledgement

2. Upon receipt of the submission, an acknowledgement notice will be provided by the PEE Directorate official i.e. Mr Stanley Muthaphuli or Ms Matshidiso Marokane.

1.6 Documents to be submitted by the applicant to ensure the completeness of the application:

(a) Signed cover letter on the applicants' letter head;
(b) Completed 2013 SEPA excel template;
(c) Completed annexure A;
(d) Completed annexure B and
(e) Completed annexure C

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

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

PART II: INSTRUCTIONS ON HOW TO COMPLETE THE 2013 SEPA TEMPLATE

1. **10-digit applicant MCC License 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.

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

4. **9-digit NAPPI code in numerical format:** This should be a 9 digit number with no decimals. These cells can be formatted by following this route: 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.

5. **ATC 4 code as per WHO classification:** The ATC 4 code must be provided in 5 characters. To obtain ATC 4 Code for each active ingredient of a product, go to: www.whocc.no → ATC/DDD link → ATC/DDD index 2010→ use active ingredient of product to search for LEVEL 4 ATC code. This column should be indented to the left.

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, it will be written as S4. This column should be indented to the left.

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.

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 **not 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.

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.

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.

11. **Pack size** – This is the pack size of the product that should correspond with the SEP. For solid dosage forms, the pack size is the number of tablets or capsules in a pack and for liquid dosage forms, the pack size is the total volume of liquid contained in a pack. This column is a numeric field that should be indented to the left.

12. **Quantity –** This the number of packs

13. **The 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 attached document on the dosage form abbreviations (Annexure D). This column should be indented to the left.

14. **Ex-Manufacturer Price (VAT exclusive) as at 21 December 2012**. This is the VAT exclusive manufacturer price of the product in South African Rands as at 21 December 2012. This is a numerical field to 2 decimal places, with no currency symbols. This column should be indented to the right.

15. **Logistics Fees (VAT exclusive) as at 21 December 2012**. 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.

16. **VAT.** This column is the VAT on the sum of the ex-manufacturer price plus the logistics fees. 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.

17. **Single Exit Price (SEP) as at 21 December 2012**– 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.

18. **Unit price** – This is the unit price of the product. The unit price is the SEP divided by the pack size for solid dosage formulations. However, where the SEP reflects the number of packs for liquids e.g. vials, ampoules, pre-filled injections, solutions, syrups or suspensions the unit price per milliliter (ml) will be the SEP divided by the quantity, then divided by the volume of the medicine in the immediate container but not the size of the container. For injections, the unit price must be the price per ml of solution regardless of the volume of administration. This is a

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

19. **The effective date** 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: Format, Cells, Number, Date, Location (English South Africa) and Type (14 March 2001). This column should be indented to the right.

20. **Requested Ex-Manufacturer Price (VAT exclusive).** 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.

21. **Requested Logistics Fees (VAT exclusive).** This is the requested VAT exclusive aggregate/weighted average 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.

22. **VAT** – This column is the VAT on the sum of the requested ex-manufacturer price plus the aggregate/weighted average 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.

23. **Requested Single Exit Price (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 aggregate/weighted average 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.

24. **New Unit Price** – this is the resulting unit price of the product. The unit price is the requested SEP divided by the pack size. However, where the SEP reflects the number of vials of an injection, the unit price per milliliter (ml) will be the SEP divided by the quantity, then divided by the volume of the medicine per vial. This is a numerical field to 2 decimal places with no currency symbols. This column should be indented to the right. For injections, the concentration determines unit prices. Injections with the same concentration should be unit priced regardless of the volume of the solution and or the size of the container. Vials and ampoules containing the same medicine of the similar concentration need not be unit priced.

NOTE: The document should always be maintained in Arial font size 10. There should be no unnecessary use of space, dashes or other characters.

PART III: ANNEXURE A, B AND C

ANNEXURE A: COVER PAGE

TO BE COMPLETED BY APPLICANT	
APPLICANT NAME *As it appears on MCC license*	
CONTACT PERSON *(Responsible for this application)*	
NUMBER OF LINE ITEMS IN THE APPLICATION *(Also include products for which SEP adjustment is not requested)*	

FOR OFFICE USE ONLY	
Date received: **(dd/month/yyyy)**	
Received by:	

ANNEXURE B: 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 2013 SEPA information and instruction document.
2. I have followed the instructions contained in the 2013 information and instruction document in completing the SEPA template.
3. I have corrected all unit pricing discrepancies in the applicants' portfolio.
4. I have enclosed a signed covering letter stating the purpose of this submission with the application.
5. The information supplied is true and correct. (NB: please provide proof of authorization to sign on behalf of 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..... 2013 and that the regulations contained in Government Gazette Notice No. R 1258 of 21 July 1972 (as amended) have been complied with.

COMMISSIONER OF OATHS

ANNEXURE C: CHECKLIST

Tick the appropriate box (√)

PART I and II

HAVE YOU:	YES	NO
Read and understood all the information in PART I?		
Read, understood, and followed all the instructions in PART II?		
Provided a signed covering letter on a company letterhead stating the purpose of the application with your application?		
Completed the SEPA template?		

PART III

HAVE YOU:	YES	NO
Completed the required fields of the covering page (Annexure A)?		
Signed the declaration as required, indicating that the information supplied with this application is true and correct (Annexure B)?		
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**.*

2013 SEPA TEMPLATE

NAME OF APPLICANT (As it appears on MCC license)	
TRADE NAME OF APPLICANT (i.e. trading as):	
NAME OF CONTACT PERSON:	
E-MAIL ADDRESS, TELEPHONE NO. AND FAX NO. OF CONTACT PERSON:	

													LAST NDoH-APPROVED SEP (Applicable on 21 December 2012)						**REQUESTED SEP INCREASE**					**THIS COLUMN IS**		
10-digit Applicant MCC License No.	**Applicant Name as registered with MCC**	**Medicine MCC Registration No.**	**9-digit NAPPI Code**	**ATC 4 Code. Should be 5 characters**	**2 character product Schedule as per MCC approved package insert**	**Medicine Proprietary Name as per MCC registration certificate**	**Active Ingredients as per MCC registration. Each active Ingredient on a separate row**	**Strength. The numerical portion of each active ingredient**	**Unit. The unit in which the strength is measured**	**Dosage Form**	**Product Pack Size**	**Quantity**	**Ex-Manufacturer Price as at 21 December 2012 (Excl VAT)**	**Logistics Fee as at 21 December 2012 (Excl VAT)**	**VAT(Value Added Tax) on the sum of the ex-Manufacturer Price and Logistics Fee as at 21 December 2012**	**Single Exit Price as at 21 December 2012 (Incl VAT)**	**Unit Price as at 21 December 2012**	**Last Effective Date of SEP (Full word date, should be on or before 21 December 2012**	**Requested Ex-manufacturers Price(Excl VAT)**	**Requested Logistics Fee (Excl VAT)**	**VAT(Value Added Tax) on the sum of the requested Ex-Manufacturer Price and Logistics Fees**	**Requested Single Exit Price (Incl VAT)**	**New Unit price**	**Effective Date (dd mm yyyy)**	**Originator or Generic**	**Volume of Sales**

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