Government Gazette
Staatskoerant

REPUBLIC OF SOUTH AFRICA
REPUBLIEK VAN SUID-AFRIKA

Regulation Gazette **No. 9665** *Regulasiekoerant*

Vol. 559 **Pretoria, 19 January Januarie 2012** **No. 34959**

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

CONTENTS • INHOUD

No.		*Page No.*	*Gazette No.*
	GOVERNMENT NOTICES		
Health, Department of			
Government Notices			
R. 47	Medicines and Related Substances Act (101/1965): Regulations: Transparent pricing system for medicines and scheduled substances: (Single exit price adjustment for the year 2012)	3	34959
R. 48	do.: do.: do.: Information to be provided by manufacturers and or importers of medicines and related substances for the single exit price adjustment for the year 2012	4	34959

GOVERNMENT NOTICES

DEPARTMENT OF HEALTH

No. R. 47 **19 January 2012**

MEDICINES AND RELATED SUBSTANCES ACT (101 of 1965)

REGULATIONS RELATING TO A TRANSPARENT PRICING SYSTEM FOR MEDICINES AND SCHEDULED SUBSTANCES:

(SINGLE EXIT PRICE ADJUSTMENT FOR THE YEAR 2012)

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, 1965 (Act101 of 1965), that the Single Exit Price (SEP) of medicines and scheduled substances may only be applied for from 03 January 2012 and by no later than 30 March 2012, to a maximum of 2.14% of the Single Exit Price that was applicable as at 09 December 2011.

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 required 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: 4/1/2012

No. R. 48 **19 January 2012**

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 RELATED SUBSTANCES FOR THE SINGLE EXIT PRICE ADJUSTMENT FOR THE YEAR 2012

I, Ms MP Matsoso, Director-General: Health, have determined in accordance with Regulation 21 of the Regulations Relating to a Transparent Pricing System for Medicines and Related Substances published in Government Gazette Number 28214 of 11 November 2005 that the following information must 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.

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: 13/1/2012

2012 SINGLE EXIT PRICE ADJUSTMENT (SEPA) INFORMATION AND INSTRUCTION DOCUMENT

This document is for the 2012 SEPA in terms of Regulation 8 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances,

In relation to Section 22G of Medicines and Related Substances Act (101 of 1965)

TABLE OF CONTENTS: PAGE:

PART I: APPLICANT INFORMATION..... 2

1. Abbreviations..... 2
2. Applicants are required to..... 3
3. This application shall only be considered if.....3
4. Applicants are required to take note of the following.....3
5. Lodging of Applications.....5
6. Documents to be submitted.....5
7. Acknowledgement of Receipt.....5

PART II: INSTRUCTIONS FOR THE APPLICANT ON HOW TO COMPLETE 2012 SEP ADJUSTMENT TEMPLATE

SECTION 1: COMPLETING THE 2012 SEP ADJUSTMENT TEMPLATE 6

PART III: ANNEXURE A, B AND C

ANNEXURE A: COVER PAGE.....11
ANNEXURE B: DECLARATION.....12
ANNEXURE C: CHECKLIST.....13

1. **This document consist of III parts:**

PART I	**APPLICANT INFORMATION**
PART II	**INSTRUCTIONS FOR THE APPLICANT ON COMPLETING THE TEMPLATE:**
	• **SECTION 1:** HOW TO COMPLETE THE 2012 SEPA TEMPLATE
PART III	**ANNEXURE A**
	ANNEXURE B
	ANNEXURE C

PART I: APPLICANT INFORMATION

2. **Abbreviations**

CFO	Chief Financial Officer
MCC	Medicines Control Council
NAPPI	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

3. Applicants are required to:

a. Read carefully the information and instructions contained in the published gazette.
b. Read carefully the information and instructions contained in this document before completing the excel 2012 SEPA template.
c. Complete **all** sections of the template in the fields provided.
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. Include a signed covering letter on a company letterhead, stating the purpose of your submission, with every submission or re-submission where applicable.
g. Send a completed application i.e. filled-in excel SEPA template, annexure A, B and annexure C and signed covering letter.
h. 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.
i. Express the full date wherever date is required, see no. 18 of section 1 in PART II of this document.

4. This 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 application is lodged by the applicant of the medicine or scheduled substance concerned.

5. Applicants are required to take note of the following:

a. The 2012 Single Exit Price Adjustment (SEPA) concerns SEPs that are applicable as on 09 December 2011, regardless of how these SEPs were arrived at.

b. Each application should include all the applicants' scheduled products, including discontinued products.
c. Products with SEPs that are not unit priced where unit pricing is required, the applicant is required to unit price the SEPs of the products. In resolving this discrepancy, the resulting SEPs should not exceed the maximum allowable SEP (i.e. SEP applicable as of 09 December 2012 + X %).
d. The Directorate: PEE will endeavour to process applications within 30 working days of receipt of the application (this excludes weekends and holidays)
e. The outcome of each application will be communicated to the applicant as soon as the PEE Directorate has assessed an application.
f. All approved SEPs will be communicated to price file managers and published on the Department's website by the Pharmaceutical Economic Evaluations (PEE) Directorate.
g. All correspondence with regards to an application will only be communicated to the applicant of the products applied for.
h. Only **fully completed** applications will be considered.
i. The 2012 SEPA excel template submitted should have a file name extension xls. Password protected documents and files in a version that the PEE Directorate is unable to access (i.e. those with file extensions: xlsx and docx) will be regarded as incomplete and returned to the applicant.
j. The 2012 SEPA excel template must be completed, saved and returned in the same format as it was published.
k. Where the MCC medicine registration number, the scheduling status or other medicine details are missing on the published database of prices for 09 December 2011 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.

6. Lodging of Applications:

- Applications must be lodged electronically on compact disc and in hard copy.
- 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.
- Electronic copies and hardcopies of applications should be addressed to:

2012 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 queries:
Telephone: 012 395 8187/8181

E-mail: sepupdates@health.gov.za

Queries are only taken on Mondays to Fridays between 13:00h00 and 16:00h00.

- DoH will not be held responsible for applications that were not received and signed for by an official of the PEE unit, i.e. Mr Amos Rampheri or Ms Morongwa Modiba.

7. Acknowledgement

- On receipt of the submission an acknowledgement notice will be provided by the PEE Directorate official i.e Mr Amos Rampheri or Ms Morongwa Modiba.

8. Documents to be submitted by the applicant to warrant a complete application:

a. Signed cover letter on the applicants' letter head;

b. Completed 2012 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 FOR THE APPLICANT ON COMPLETING THE 2012 SEPA TEMPLATE

1. **10-digit applicant MCC License Number:** 10 digit number as provided by MCC. Although these are numbers the field is text in order to accommodate the zeros in the front. 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 no. 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 numerical field 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 will be the capital letter S. This will be immediately followed with the 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. Decimal spaces are separated by a decimal point (.) and not a comma (,). This column should be indented to the right.

10. **Unit** – This column represents the unit in which the strength is measured. 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. This column is a numeric field that should be indented to the left.

12. **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 PDF file named "Dosage_Form_Descriptions". This column should be indented to the left.

13. **Ex-Manufacturer Price (VAT exclusive) as at 09 December 2011**. This is the VAT exclusive manufacturer price of the product in South African Rands as at 09 December 2011. This is a numerical field to 2 decimal places, with no currency symbols. This column should be indented to the right.

14. **Logistics Fees (VAT exclusive) as at 09 December 2011**. 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.

15. **VAT** This column is the VAT on the sum of the 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.

16. **Single Exit Price (SEP) as at 09 December 2011**– 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.

17. **Unit price** – This is the unit price of the product. The unit price is the SEP divided by the pack size for solids. 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 number

of packs, then divided by the volume of the medicine in a container but not the size of the container. This is a numerical field to 2 decimal places with no currency symbols. This column should be indented to the right. For injections the unit price must be the price per ml of solution regardless of the volume of administration.

18. **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.

19. **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.

20. **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.

21. **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.

22. **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 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.

23. **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 number of vials, then divided by the number of mls 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 2012 SEPA information and instruction document.
2. I have followed the instructions contained in the 2012 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..... 2012 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 and 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.***

THE 2012 SEP ADJUSTMENT TEMPLATE:

THIS TEMPLATE CAN BE EXTRACTED FROM: www.mpr.gov.za

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

Applicants MCC Licence No	Applicant Name	Product MCC Registration No	Nappi Code	ATC 4	Schedule	Product Proprietary Name	Active Ingredients	Strength Unit		Pack Size	Dosage Form	Manufacturer Price	Logistics Fee	VAT	SEP	Unit Price	Effective Date	Status

Printed by and obtainable from the Government Printer, Bosman Street, Private Bag X85, Pretoria, 0001
Publications: Tel: (012) 334-4508, 334-4509, 334-4510
Advertisements: Tel: (012) 334-4673, 334-4674, 334-4504
Subscriptions: Tel: (012) 334-4735, 334-4736, 334-4737
Cape Town Branch: Tel: (021) 465-7531

Gedruk deur en verkrygbaar by die Staatsdrukker, Bosmanstraat, Privaatsak X85, Pretoria, 0001
Publikasies: Tel: (012) 334-4508, 334-4509, 334-4510
Advertensies: Tel: (012) 334-4673, 334-4674, 334-4504
Subskripsies: Tel: (012) 334-4735, 334-4736, 334-4737
Kaapstad-tak: Tel: (021) 465-7531