 

**2024 REGULATION 9 APPLICATION FORM**

## Application for the increase of the Single Exit Price of a Medicine or Scheduled Substance in terms of Regulation Nine of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances of the Medicines Act, 1965 (Act 101 of 1965)

## SECTION 22G

|  |
| --- |
| ***TO BE COMPLETED BY APPLICANT*** |
| **APPLICANT NAME** |  |
| **PROPRIETARY NAME AND PACK SIZE OF MEDICINE** |  |
| **DATE OF APPLICATION** |  |

|  |
| --- |
| ***FOR OFFICE USE ONLY*** |
| **Date received: (dd/mm/yyyy)** |  |
| **Received by:** | **…………………..** |

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PART I: GENERAL INFORMATION AND INSTRUCTIONS FOR APPLICANTS

1. Important considerations
	1. **This application shall only be considered if-**
2. the application is compliant with the requirements set out in terms of Regulation 9 of the Regulations Relating to a Transparent Pricing System for medicines and Scheduled Substances;
3. the application is based on exceptional circumstances which are fully substantiated and supported with certified and verifiable evidence for each of the claims forming the basis of the application;
4. an application for the annual price adjustment up to the amount published by the Minister for the same year has been approved in terms of Regulation 8 by the Department of Health (DOH) for the medicine concerned.
5. all sections of the application form have been fully completed;
6. the application is lodged by the MCC/SAHPRA registered applicant of the medicine concerned as depicted on the MCC/SAHPRA Medicine Registration Certificate and the DoP. It is the applicant’s responsibility to ensure the DoP reflects the applicant correctly.
7. an application is made for an individual or single medicine only. To be considered complete, the application must contain all the required documentation. All the documents must be clearly labelled.
8. the documents and information supplied must be readable and have no password protection for ANY files. Applications with files that cannot be viewed will be closed and the applicant will be informed.
9. the application form must remain in the original word format (doc or docx file extension). This must not be password protected. The applicant may include a pdf copy.
10. where an application is made for a medicine with more than one related pack size, applicants are required to use only one pack size for the purposes of lodging the application; unless specifically required to include other pack sizes due to the nature of the application. Medicines with related pack sizes must share the same unit price. The related pack sizes must be indicated elsewhere in the application.
11. Should an applicant wish to submit large files or submit in a zip folder, it is the applicant’s responsibility to ensure that these files are accessible.
	1. **Applicants are further required to note that-**
12. any medicine considered not to be eligible for SEPA in terms of Regulation 8 in the current SEPA cycle may also not apply for an SEP increase in terms of Regulation 9 in the current cycle;
13. all medicines whose prices were launched after the date on which the SEPA for the next cycle is applicable, such medicines shall not be eligible for price increases in terms of Regulation 9. This also applies to all medicines whose prices were launched after the date when medicines price amendment is not allowed as announced in anticipation for the new SEPA for the forthcoming year;
14. an applicant may not apply for a Regulation 9 increase on a medicine already approved for a Regulation 9 increase in the current annual SEPA cycle or where an SEP is effective in the current SEPA cycle.
15. while a Regulation 9 application is in process, an applicant may not make a SEPA submission, until the Regulation 9 application is concluded and a decision communicated to the applicant. The Regulation nine process is deemed to be concluded once the applicant has responded in writing to the Minister’s communication. Where the Minister granted approval in terms of Regulation 9 application, the applicant must have received the effective date and effected the Single Exit Price (SEP) in the market, prior to lodging any subsequent application or submission.
16. An applicant may, on written notice, request for the withdrawal of any Regulation 9 application in process at any point in time. A reason for withdrawal should be provided.
17. Arrangement of Part II of the application form
18. **Section 1-** Applicant details
19. **Section 2 -** Medicine or scheduled substance details
20. **Section 3 -** Justification of exceptional price increase
21. **Section 4-** Declaration
22. **Annexure A** Checklist
23. What is required from the Applicants
24. Complete ALL sections of the latest Regulation 9 form as required in the spaces provided. Extra space can be created where necessary (e.g. you are allowed to insert new rows for the tables provided in the form). However, applicants are not allowed to modify the format of the form, by for example, introducing new fields (i.e. columns) of information that is not requested in terms of this form; altering numbering or removing requirements.
25. Provide a separate list of supporting documentation, in line with the motivation that has been submitted as part of this application;
26. Ensure that the application is compliant in terms of all the requirements as set out under Regulation 9 of the Regulations Relating to a Transparent Pricing System for Medicines and Scheduled Substances;
27. Provide certified evidence as proof of the claims used to support the exceptional circumstances of the application;
28. Provide certified copies of proof of registration in South Africa, of the original Package Insert (PI) approved by the Medicines Control Council (MCC/SAHPRA) and the applicants Licence to Manufacture;
29. Fill in the checklist that is attached to this application form and ensure that all sections have been completed and all the necessary information has been attached to the application form before submitting the application to the Directorate: Pharmaceutical Economic Evaluations (DPEE);
30. Complete the Declaration Document for Regulation 9 Application under Part 2, Section 4 below, Declaration. Note that the correct responsible persons must sign.
31. Read the guidelines on how to complete the application form before filling in the required information;
32. Furnish all additional information within the stipulated timeframes on the request or where no stipulation, within 30 days after request of additional information from the (DPEE). Failure to comply will render the application revoked for further processing;
33. **Regulation 9 applications shall not be accepted/received from the last working day of September every year**. Any applicant lodging an application on or close to this day must note that eligibility for the following year’s SEPA cannot be guaranteed;
34. Always use the latest version of the application form that can be obtained on the DoH website (<https://www.health.gov.za/nhi-pee/>);
35. There can only be one SEP submission launched at any given point in time. The applicant cannot request for an update on the SEP, Regulation 9, or updates whilst the submission for SEPA is still in process. SEP Updates are inclusive of SEPA and any other application made in terms of Regulation 9 for the same medicine. Therefore, 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 lodged 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.
36. Applicants are required to take note of the following:
37. Applications will be assessed within 180 working days from the date of submission and receipt of the application by DPEE (this does not include days where information requested from applicants is begin waited on);
38. The outcome of each application will be communicated to the applicant by the DPEE as soon as the Pricing Committee has made a recommendation on an application and the Minister has made a final decision;
39. A recommendation for approval of the price adjustment by the Pricing Committee may not prevent the Minister from adopting a different decision;
40. All correspondence with regards to an application will only be communicated to the applicant registered with MCC/SAHPRA for the concerned medicine and no other third party. The necessary communication will be sent to the person nominated as the point of contact by the relevant applicant;
41. Only FULLY COMPLETED applications will be considered;
42. The applicant is responsible to ensure that the application submitted is complete and complies with ALL requirements. All applications will be reviewed and concluded in the state in which they are made.
43. The Application Form file size should not exceed 12mb. The application email in total should not exceed 15mb.
44. Password protected and files in a version that the DPEE is unable to access will be regarded as incomplete;
45. Where supporting evidence to the application is not supplied, the application will be considered incomplete;
46. Where an application is not clearly and accurately labelled and organized in relation to the application form, the application will be considered incomplete. This includes but is not limited to applications where documents are randomly put together in no sequence;
47. In cases where the applicant is requested to submit additional information or provide clarity on certain aspects of the application, the response must be provided within the stipulated time or withing 30 days of the date of such request where no time is stipulated. The application will be revoked in its entirety if all the requested information is not supplied within the required timeframe of such a request;
48. All information supplied by the applicant is treated as strictly confidential by the Pricing Committee, the Regulation 9 Task Team and the DPEE and such information will not be divulged to any third parties without prior written consent from the applicant;
49. Where supporting evidence provided as part of this application (e.g. invoices) is supplied from another company, the applicant must declare any relationship between themselves and the company supplying the documentation. This is required irrespective of the nature of the relationship (i.e. marketing, financial, etc.).
50. For the purposes of a Regulation 9 application, the application must only be lodged by the applicant in terms of Section 15 of the Medicine and Related Substances Act of the concerned medicine. The applicant must furnish a certified MCC/SAHPRA Medicine Registration Certificate to indicate that the submission is made by the applicant of the respective medicine for which an exceptional price increase is sought;
51. Applicants are required to ensure due diligence is followed when acquiring a medicine from another applicant. The due diligence process should ensure that all information related to production, finances and administration that may be required by the applicant to operate in the regulated environment is obtained or accessible to the new applicant.
52. Any recommendation and decision on a Regulation 9 application will be based on the information available to the Pricing Committee and Minister as made available by the applicant;
53. Should any new information surface with regards to an application, the Pricing Committee and Minister reserve the right to revise their recommendation and/or decision.
54. If an application is made for a medicine with more than one related pack size, applicants are required to use only one pack size for the purposes of lodging the application; unless specifically required to include other pack sizes due to the nature of the application. Medicines with related pack sizes must share the same unit price;
55. Note that for a medicine for which a Regulation 9 application has been lodged and processed, the final outcomes of the application once approved by the Minister will affect the unit price(s) of all related pack sizes, including those medicines with related pack sizes that were not included as part of this submission;
56. A medicine for which an increase of the SEP is requested in terms of Regualtion 9 must be unit priced.
57. The notification of price updates to all stakeholders e.g. price file vendors, remains the responsibility of NDoH.
58. Supporting evidence

Applicants are required to submit all the evidence linked to the claims made to support the requested new SEP. The calculations used to arrive at the requested SEP must also be submitted. This should include evidence and calculations used to support the increase/adjustments requested on the components of the SEP. A narrative on the calculations should be provided.

1. Timeline for evidence

The submitted evidence (e.g. invoices) in support of cost increments in respect of the Regulation 9 application, must not be older than 24 months from the effective date of the current/prevailing SEPA. The effective date of the current/prevailing SEPA is the first date when applicants are allowed to apply for the Single Exit Price Adjustment (SEPA) in respect of the current year as published by the Minister on an annual basis by Notice in the Government Gazette. This date must be used as a reference point to calculate 24 months age of the evidence used in the regulation 9 application. *For example, the effective date to implement or apply for the SEPA in 2024 is the 12th of January 2024. Therefore, all supporting evidence submitted with Regulation 9 applications in 2024, must not be dated earlier than 12 January 2022.*

1. Exchange rates

Invoices containing prices of goods purchased in foreign currency must be submitted as is with the price reflected in original currency. To translate foreign currency into South African Rands (ZAR), applicants must always use an average exchange rate calculated *over 12 months from the date of the submitted evidence*. *For example, if the date of the evidence used in the application is 15th June 2024, the exchange rate to be used in the calculation should be an average exchange rate from 16th June 2023 to 15th June 2024.*

In cases where the applicant used a spot rate, the Pricing Committee (PC) shall revise the calculation to reflect a Rand value re-calculated using a 12 months average exchange rate. The official source for the historical exchange rates is the Reserve Bank of South Africa.

1. Logistics Fee re-calculation

In cases where the Logistics fee is decreased or increased in the application, the applicant must submit old and new contracts entered into between themselves and the affected logistics service provider (s). In terms of Regulation 5(2)(f) of the Pricing Regulations (2005), the logistics fee must be determined by agreement between the provider of logistical services and the manufacturer or importer of the medicine concerned. Therefore, absence of evidence to suggest contractual changes in the logistics fee component may result in the rand value of the logistics fee component being kept unchanged to determine the appropriate SEP in respect of the Regulation 9 application in question. This will be regardless of any other adjustments that may have been made in other components of the SEP.

1. Closing date for lodging applications

NB: All applications made in terms of Regulation 9 of the Medicines and Related Substances Act 101 of 1965 (Medicines Act) must be submitted by no later than 30 September of each year (or the last working day in September each year). Applications received after this date shall not be considered. Any application lodged after this date will not be considered.

1. Acronyms

DOH Department of Health

DoP Database of Medicine Prices

DPEE Directorate: Pharmaceutical Economic Evaluations

MCC/SAHPRA Medicines Control Council/South African Health Products Regulatory Authority

NAPPI National Pharmaceutical Product Interface

NDoH National Department of Health

SEP Single Exit Price

SEPA Single Exit Price Adjustment

VAT Value Added Tax

VAT (Excl.) VAT Excluded

VAT (Incl.) VAT Included (VAT is 15%)

WHO ATC World Health Organisation Anatomical Therapeutic Classification

1. Lodging of Applications
2. Applications must be lodged **electronically** via email to: sepupdates@health.gov.za;
3. Every application should be on a new email. Do not reply to previous applications, submissions or queries. The Title of the application should contain details of the application.
4. A reference number shall be issued by NDoH upon receipt of the application. The applicant must use this number in all follow up correspondences with NDoH, including tracking of progress on the application;
5. No hard copies will be considered, under any circumstances;
6. Only one electronic copy must be supplied;
7. All the evidence supplied in the application form, must be **hyperlinked** in the electronic version of the application form;
8. Additional calculations (and related explanations) and any other supplementary information must be submitted as appendices which should be labelled properly;
9. Applications with supporting documents submitted mixed-up, not clearly labelled or in no sequence will not be considered.
10. Only one application per medicine, dosage form, and pack size must be submitted at any given point in time.
11. Where an applicant submits more than one application for a particular medicine, the applicant must indicate in writing which applications are to be withdrawn and why. This communication should clearly indicate which application should be considered.
12. For queries:

Telephone: 012 395 8184/8181

E-mail: sepupdates@health.gov.za

Queries are only taken on Mondays to Fridays between 13:00 and 15h00.

1. Applications will only be accepted between 09h00 and 12h00 Monday to Friday, excluding public holidays and weekends. Submissions must always be sent by email.
2. The cover letter which accompanies the application must beaddressed as follows:

The Director General of Health

c/o The Director: Pharmaceutical Economic Evaluations

Ms NM Mpanza

 National Department of Health

 Dr AB Xuma Building

 1112 Voortrekker Road,

 Pretoria Townlands 351-JR

 PRETORIA, 0187

1. Confirmation of acknowledgement of receipt of application(s)

A reference number confirming receipt of application by the DPEE of NDoH will be emailed to the sender of the electronic application. Allocation of a Reference number is not confirmation that the files submitted are accessible, that the application is complete or that the files meet the requirements as per this Application Form. If a Reference Number has not been issued within a week, the application has not been received. NDoH will not be held responsible for applications that were incorrectly submitted.

PART II: SPECIFIC INFORMATION ON THE APPLICATION

SECTION 1: APPLICANT DETAILS

|  |  |  |
| --- | --- | --- |
|  | **Applicant Name:***(As it appears on MCC/SAHPRA Medicine Registration Certificate and DoP)* |  |
|  | **Applicant MCC/SAHPRA License Number:** (***Note*** *MCC/SAHPRA/ Licence must be attached as proof)* |  |
|  | **Nature of Business** *(As classified in MCC/SAHPRA register**(Tick the appropriate box(✓))* | **Manufacturer** |  |  |
| **Importer** |  |
|  | **Physical Address** |  |
|  |  |  |
|  |
|  |
|  | **Postal Address** |  |
|  |  |  |
|  |
|  |
|  | **Website Address** *(Where applicable)* |  |
|  | **Main Reason(s) for Lodging this Application:***(State briefly)* |  |
|  |  |  |
|  |
|  |
|  | **Main Contact Person of Applicant (1)** |
|  | **Name:** |  |
| **Designation:** |  |
| **Phone Number:** |  |
| **Fax Number:** |  |
| **E-mail Address:** |  |
|  | **Alternative Contact Person of Applicant (2)** |
|  | **Name:** |  |
| **Designation:** |  |
| **Phone Number:** |  |
| **Fax number:** |  |
| **E-mail Address:** |  |

Supporting evidence included must be hyperlinked to the points referred to on this application form.

SECTION 2: MEDICINE OR SCHEDULED SUBSTANCE DETAILS

Medicine and Pricing Information

|  |  |  |
| --- | --- | --- |
|  | **Medicine Proprietary Name:** *(As it appears on MCC/SAHPRA certificate & DoP)* |  |
|  | **Nappi Code:** |  |
|  | **Medicine MCC/SAHPRA Registration Number:***(As it appears on MCC/SAHPRA certificate)* |  |
|  | **Registered Indications:** |  |
|  | **WHO ATC Classification:** *(Level 4)* |  |
|  | **Active Ingredient(s):***(As it appears on the MCC/SAHPRA medicine registration certificate)* |  |
|  | **Dosage Form:** |  |
|  | **Strength:** |  |
|  | **Pack Size:** |  |
|  | **Quantity** |  |
|  | **Tender Price (ZAR):***(If medicine is also sold through government tender)* |  |
|  | **Annual Sales Volume (Tender):** *(For the 12 months with respect to financial year)* |  |
|  | **Annual Sales Volume (SEP):** *(For past 12 months with respect to financial year)* |  |
|  | **Current Pricing Information** |  |
|  | 1. **Ex-Manufacturer Price (ZAR):**

*(VAT Excl.)* |  |
| 1. Logistic Fee (ZAR):

*(VAT Excl. In rand value)* |  |
| 1. **VAT (ZAR):**

*[15% of (2.1.13(a) + 2.1.13(b)]* |  |
| 1. **SEP (ZAR):**

*[2.1.13(a) + 2.1.13(b) + 2.1.13(c)]* |  |
| 1. **Unit Price (ZAR):**
 |  |
|  | **New Pricing Information** |  |
|  | 1. **Ex-Manufacturer Price (ZAR):**

*(VAT Excl. From table 3.1.6)* |  |
| 1. Logistic Fee (ZAR):

*(VAT Excl. In rand value from table 3.1.6)* |  |
| 1. **VAT (ZAR):**

*(From table 3.1.6)* |  |
| 1. **SEP (ZAR):**

*(From table 3.1.6)* |  |
| 1. **Unit Price (ZAR):**

*(From table 3.1.6)* |  |
|  | **SEP Increase (ZAR):***(New SEP less Current SEP)* |  |
|  | **SEP Increase (%)** *[((New SEP less Current SEP)* ÷ *Current SEP)\*100]* |  |
|  | **Requested Ex-Manufacture Price (ZAR)** |  |
|  | **Has this medicine had a Regulation 9 application in the last 5 years?** If yes, provide details of date, approval and SEP.  |  |
|  | **Has the applicant presented evidence in this application that was previously used in a Regulation 9 application?** If yes provide details and reasons.  |  |

Supporting evidence included must be hyperlinked to the points referred to on this application form.

SECTION 3: JUSTIFICATION OF THE EXCEPTIONAL PRICE INCREASE

* 1. **In the tables, 3.1.1 through to 3.1.6 below provides a detailed breakdown of the cost of production. Also, indicate how the changes in costs necessitate an exceptional price increase. A narrative under each table may be inserted to further substantiate any claims relating to the costing item presented.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Raw Materials** | **Source/Supplier** | **Source Country** | **Supplier Unit Costs as per Evidence (e.g. Invoice)** | **Material Unit Costs used to Produce one Unit Output** | **Supporting Evidence? (Yes/No)** |
| **Current** | **New** | **Current** | **New** | **Current** | **New** |
| *Material 1* |  |  |  |  |  |  |  |  |
| *Material 2* |  |  |  |  |  |  |  |  |
| *Material 3* |  |  |  |  |  |  |  |  |
| *Material 4* |  |  |  |  |  |  |  |  |
| *Material 5* |  |  |  |  |  |  |  |  |
| *Material 6* |  |  |  |  |  |  |  |  |
| **SUBTOTAL 1** |  |  |  |

Table 3.1.1: Raw Material(s) Costs

If supporting evidence is included (i.e. if the answer is yes), please ***hyperlink*** the response to the referred evidence in question

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Packaging Materials** | **Source/Supplier** | **Source Country** | **Supplier Unit Costs as per Evidence (e.g. Invoice)** | **Materials Unit Costs used to Produce one Unit Output** | **Supporting Evidence? (Yes/No)** |
| **Current** | **New** | **Current** | **New** | **Current** | **New** |
| *Material 1* |  |  |  |  |  |  |  |  |
| *Material 2* |  |  |  |  |  |  |  |  |
| *Material 3* |  |  |  |  |  |  |  |  |
| *Material 4* |  |  |  |  |  |  |  |  |
| *Material 5* |  |  |  |  |  |  |  |  |
| *Material 6* |  |  |  |  |  |  |  |  |
| **SUBTOTAL 2** |  |  |  |

Table 3.1.2: Packaging Material(s) Costs

If supporting evidence is included ((i.e. if the answer is yes), please ***hyperlink*** the response to the referred evidence in question

Table 3.1.3: Manufacturing Overhead Costs

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Overhead Materials** | **Source/Supplier** | **Source Country** | **Supplier Unit Costs as per Evidence (e.g. Invoice)** | **Materials Unit Costs used to Produce one Unit Output** | **Supporting Evidence? (Yes/No)** |
| **Current** | **New** | **Current** | **New** | **Current** | **New** |
| *Material 1* |  |  |  |  |  |  |  |  |
| *Material 2* |  |  |  |  |  |  |  |  |
| *Material 3* |  |  |  |  |  |  |  |  |
| *Material 4* |  |  |  |  |  |  |  |  |
| *Material 5* |  |  |  |  |  |  |  |  |
| *Material 6* |  |  |  |  |  |  |  |  |
| **SUBTOTAL 3** |  |  |  |

If supporting evidence is included (i.e. if the answer is yes), please ***hyperlink*** the response to the referred evidence in question

|  |  |  |
| --- | --- | --- |
| **Input Labour Items** | **Input Labour Costs per Unit of Medicine Manufactured** | **Supporting Evidence? (Yes/No)** |
| **Current** | **New** | **Current** | **New** |
| *Item 1* |  |  |  |  |
| *Item 2* |  |  |  |  |
| *Item 3* |  |  |  |  |
| *Item 4* |  |  |  |  |
| *Item 5* |  |  |  |  |
| *Item 6* |  |  |  |  |
| **SUBTOTAL 4** |  |  |  |

Table 3.1.4: Direct Labour Costs

If supporting evidence is included (i.e. if the answer is yes), please ***hyperlink*** the response to the referred evidence in question

Table 3.1.5: Medicine Costs Reconciliation

|  |  |
| --- | --- |
| **Medicine Costs** | **Unit Medicine Costs**  |
| **Current** | **New** |
| ***SUBTOTAL 1 (Raw Materials)*** |  |  |
| ***SUBTOTAL 2 (Packaging Materials)*** |  |  |
| ***SUBTOTAL 3 (Overhead Materials)*** |  |  |
| ***SUBTOTAL 4 (Input Labour Items)*** |  |  |
| **TOTAL MEDICINE COSTS**  |  |  |

Table 3.1.6: Medicine Pricing Information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Pricing Items** | **Current** | **New** | **Requested** | **Differential Costs****(FOR OFFICE USE ONLY)** |
| ***Total Medicine Costs*** |  |  |  |  |
| ***Mark-up*** |  |  |  |  |
| ***Ex-Manufacturer Price (VAT Excl.)*** |  |  |  |  |
| ***Logistics Fee (VAT Excl.)*** |  |  |  |  |
| ***VAT*** |  |  |  |  |
| ***Single Exit Price*** |  |  |  |  |
| ***Unit Price*** |  |  |  |  |

***Guide on table 3.1.6-***

1. ***Total Medicine Costs:*** *Current and new total medicine costs must be transcribed from table 3.1.5*
2. ***Mark-up:***

* 1. ***Current Mark-up:*** *What the applicant is currently earning above the current total medicine costs and must be obtained as follows-*

$$\left[Ex-Manufacturer Price \left(VAT Excl.\right)from table 2.1.13(a) \right]- \left[Current Total Product Cost from table 3.1 6\right]$$

* 1. ***New Mark-up:*** *must be obtained as indicated below. However, any request for the adjustment of the resulting mark-up must be accompanied with the motivation-*

$$\frac{Current Markup}{Current Total Product Costs} ×New Total Product Costs $$

1. ***Ex-Manufacturer Price (VAT Excl.):*** *Total medicine costs added to the mark-up*
2. ***Logistics Fee (VAT Excl.):*** *Must remain the same. Any adjustment to the LF must be accompanied by a negotiated contract.*
3. ***VAT:*** *Must**represent 15% of the Ex-Manufacturer Price combined with the Logistics Fee*
4. ***Single Exit Price:*** *It is the sum of Ex-Manufacturer Price (VAT Excl.), Logistics Fee (VAT Excl.) and VAT*
	1. **Provide a list of supporting documentation used to justify the increase, which have been included in this application. The supporting documentation must be listed and attached as part of this application. List and provide the contact details of all the suppliers presented in tables 3.1.1, 3.1.2 and 3.1.3**

Table 3.2.1: List of Supporting Documentation Used to Justify the Increase

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Material Name** | **Supplier** | **Telephone Number** | **Address** | **Date of Supporting Evidence Included** |
| *Material 1* |  |  |  | **Current** | **New** |
| *Material 2* |  |  |  |  |  |
| *Material 3* |  |  |  |  |  |
| *Material 4* |  |  |  |  |  |
| *Material 5* |  |  |  |  |  |
| *Material 6* |  |  |  |  |  |
| *Material 7* |  |  |  |  |  |

* 1. **Provide a list of all therapeutic and generic equivalent medicines and their respective single exit prices for each of the medicines available in South Africa (List as it appears on the latest Database of Medicines Prices (DOP) published on the Department of Health’s website (**[**www.mpr.gov.za**](http://www.mpr.gov.za)**)**

Table 3.3.1: List of Competitors

1.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **MPN** | **API(s)** | **Strength** | **Unit** | **Dosage Form** | **Pack Size** | **EMP** | **LF** | **VAT** | **SEP** | **Unit Price** | **Sales Volume** |
|  |  |  |  |  |  |  |  |  |  |  |  |
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**Key**: MPN - Medicine Proprietary Name; API - Active Pharmaceutical Ingredient(s); EMP – Ex-Manufacturer Price; LF - Logistics Fee; VAT - Value Added Tax; SEP - Single Exit Price. The sales volume must be the previous annual sales of the medicine as per the latest DOP from ([www.mpr.gov.za](http://www.mpr.gov.za)) by the time when this application is made. Additional space (rows) can be added if there are more competitors than the space provided**.**

**(b)**

Where the applicant is requesting a price higher than that of the existing competitors, the applicant **must** explain this request as well as the intended market for the higher priced competitor.

Table 3.3.2: List of Other Existing Pack Sizes

The applicant must list all the other existing pack sizes for the Medicine Proprietary Name of the medicine being applied for.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Pack Size** | **Quantity** | **Dosage Form** | **Nappi Code** | **Tender Price** | **EMP** | **LF** | **VAT** | **SEP** | **Unit Price** | **Annual Volume of Tender Sales** | **Annual Volume of SEP Sales** |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
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**Key**: EMP – Ex-Manufacturer Price; LF - Logistics Fee; VAT - Value Added Tax; SEP - Single Exit Price. The sales volume must be the annual sales of the medicine for the year preceding the application, i.e. if the application is made in 2024, the volumes must be for 01 January 2023 to 31 December 2023. Additional space (rows) can be added if required**.**

Table 3.3.3: List of International Prices

This must be a list of the medicine price and sales volume in the listed international markets. The price must be supplied in the original currency of the country in which it is sold. If a price is not available in any of the markets listed below, then the price in ALL the markets where the medicine is being sold must be supplied.

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Country** | **MPN** | **Strength** | **Pack Size** | **Qty** | **Dosage Form** | **EMP** | **LF** | **VAT** | **Final Price** | **Unit Price** | **Sales Volume** |
| Australia |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Canada |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| New Zealand |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |
| Spain |  |  |  |  |  |  |  |  |  |  |  |
| Other(Provide details for all other countries where the medicine is available; create additional space where necessary) |  |  |  |  |  |  |  |  |  |  |  |

**Key**: MPN - Medicine Proprietary Name; Qty - Quantity; EMP – Ex Manufacturer Price; LF - Logistics Fee; VAT - Value Added Tax. The sales volume must be the annual sales of the medicine for the year preceding the application, i.e. if the application is made in 2024, the volumes must be for 01 January 2023 to 31 December 2023. Additional space (rows) can be added if required**.**

* 1. **Describe the impact on your business if the application is not approved.** (Provide supporting evidence and substantiate fully)
	2. **Describe the impact on access of the medicine in South Africa if the application is not approved?** (Provide supporting evidence and substantiate fully)
	3. **Describe any public interest issue(s) that should be taken into account when evaluating this application.**

SECTION 4: DECLARATION FOR REGULATION 9 APPLICATION

**Declaration Page 1 of 2**

I ……………………………………………., **(full name and surname)** in my capacity as………………………………, **(CEO/GM/CFO)** 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 “Regulation 9 Application Form” as available on <https://www.health.gov.za/nhi-pee/>; including all the information and instructions contained therein.
2. I have followed all the instructions contained in the Regulation 9 Application Form.
3. I confirm that all MCC/SAHPRA documentation submitted is the latest and most accurate and I have provided certified copies of original.
4. I confirm that in the *exceptional* case of requiring a Variation Certificate that the Responsible Pharmacist has submitted an affidavit confirming that the Variation Certificate submitted is the latest information from SAHPRA on the date of application and that the variation has **not** been disallowed by SAHPRA.
5. I confirm that all documentation submitted are certified copies of the original.
6. The application is free of calculation errors, and I have corrected all unit pricing discrepancies in the applicants’ portfolio.
7. I have enclosed a signed covering letter stating the purpose of this application.
8. The information supplied is true and correct. (NB: please provide proof of authorization to sign on behalf of company)
9. I declare that the relationship between the applicant company and any company supplying evidence for this application has been declared as required under Paragraph 4 of this Application Form. A declaration of relationship is provided for EACH company from which evidence is supplied. The declaration contains **all** details (commercial, financial, regulatory, subsidiary, etc) of the relationship between the company and the applicant.

**Declaration Page 2 of 2**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

 **FULL NAME SIGNATURE (DEPONENT)**

**WITNESSES (FULL NAMES AND SIGNATURE REQUIRED):**

1. **…………………………………. (CFO)**

**Name**

**…………………………………. (CFO)**

**Signature**

1. **………………………………… (Responsible Pharmacist)**

**Name**

**………………………………… (Responsible Pharmacist)**

**Signature**

*Note that any senior personnel acting on behalf of the CEO/MD/CFO may sign, provided that there is proof that he/she has the authority to sign on behalf of the CEO/MD/CFO and such proof must also be submitted. All copies of documentation should be certified copies of the original.*

The Deponent has acknowledged that he/she knows and understands the contents of this declaration, which was signed and sworn to before me at ……………….on this the…….day of…………………. 20.... and that the regulations contained in Government Gazette Notice No. R 1258 of 21 July 1972 (as amended) have been complied with.

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DEPONENT**

 **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ COMMISSIONER OF OATHS**

 **­­­­­­­­­­­­­­­­**

ANNEXURE A: CHECKLIST

1. REGULATION 9 APPLICATION

Mark the appropriate box (X)

**SECTION 1: APPLICANT DETAILS**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Have you answered all questions in Section 1? Have you used the latest version of the application form? |  |  |
| Have you enclosed a certified copy of the original license to act as a manufacturer/importer issued by MCC/SAHPRA? |  |  |
| Have you provided 2 contact persons for the applicant? |  |  |
| Have you stated the main reasons for making this application? |  |  |
| Have you declared the relationship between the applicant and the source of materials used as evidence in this application? |  |  |

**SECTION 2: MEDICINE OR SCHEDULED SUBSTANCE DETAILS**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Have you answered all questions in Section 2? |  |  |
| Have you supplied all prices correctly as requested in section 2? |  |  |
| Have you enclosed a certified copy of the original registration certificate for the medicine issued by MCC/SAHPRA? |  |  |
| Have you enclosed a certified copy of the original Package Insert approved by MCC/SAHPRA? |  |  |

**SECTION 3**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Have you provided a detailed breakdown of cost as required in 3.1? |  |  |
| Have you provided certified copies of all supporting evidence to substantiate 3.1? |  |  |
| Have you provided the SEP’s for all generic and therapeutic equivalent competitors as required in 3.5? |  |  |
| Have you listed and attached all supporting documentation as required in 3.2? |  |  |
| Have you tested all the hyperlinks of the electronic version of your submission to ensure that they are working properly? |  |  |
| Have you attached a clearly labelled appendix to show how evidence was translated into the requested SEP  |  |  |

**SECTION 4**

|  |  |  |
| --- | --- | --- |
|  | **YES** | **NO** |
| Have you signed the declaration as required, indicating that the information supplied is true and correct? |  |  |