

New Medicine Launch Form (Regulation 19)

ALL QUESTIONS ARE COMPULSORY

**In Terms of
Medicines and Related Substances Act, 101, 1965
Section 22G and its Regulations**

This submission form consists of 2 parts. The first part is on information and instructions for applicants and the second part is the actual application form that the applicant is required to complete. The application consists of 6 pages in total including the cover page.

PART I: Information and Instructions for Applicants

1. Applicants are required to:

- (a) Complete ALL sections of the form in the spaces provided as well as to complete the excel template with the title: "Template D New Medicine Launch". Where the applicant is unable to answer or does not have the requested information, this should be clearly stated on the form. All efforts made to obtain the requested information should be detailed on the form.
- (b) Keep the form in the original format and numbering. **Edits are not allowed.**

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

- (a) This form is not for re-launching medicines that were previously available on the market and may not be used for the amendment of medicine details.
- (b) This form is strictly for new medicines launched after 2004, following registration in terms of section 15 of the Medicines and Related Substances Act (No. 101 of 1965).
- (c) The information required in terms of this Regulations 19 form, must be furnished to the Director-General at least one month (30 working days) before the medicine is launched.
- (c) No manufacturer and/or importer is allowed to trade on the affected medicine, unless all the required information with regards to the medicine or scheduled substance is received and the official Single Exit Price launched.
- (d) It is compulsory to attach a certified copy of the applicant's SAHPRA/MCC License to Manufacture Medicines for this submission to be considered.
- (e) It is compulsory to attach a certified copy of the SAHPRA/MCC Medicine Registration Certificate for this submission to be considered.
- (f) It is compulsory to attach the original Professional Information (PI) and Patient Information Leaflet (PIL) of the medicine for which the submission is made, as approved by SAHPRA, for this submission to be considered.
- (g) Medicines launched after the close off period for SEPs are not eligible for the SEPA of the following year.

3. Lodgement of Submissions:

Submissions must be submitted electronically to the following address:

SEPupdates@health.gov.za

- For queries:

Telephone: (012) 395 8187/8181

E-mail: SEPupdates@health.gov.za

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

PART II: Submission Form

| | | | | |
|------|--|---------------------|--------------------------|--|
| 1.1. | Applicant Name: (As it appears on the SAHPRA/MCC Licence to Manufacture) | | | |
| 1.2. | Responsible Pharmacist: | | | |
| 1.3. | Applicant SAHPRA/MCC Registration No. (As it appears on the SAHPRA/MCC Licence to Manufacture) | | | |
| 1.4. | Nature of Business: (✓) | Manufacturer | <input type="checkbox"/> | |
| | | Importer | <input type="checkbox"/> | |
| 1.5. | Physical address: | | | |
| 1.6. | Postal address: | | | |
| 1.7. | Website address: | | | |
| 1.8. | Contact Person (1): | | | |
| | Name: | | | |
| | Position: | | | |
| | Phone number: | | | |
| | Fax number: | | | |
| | E-mail address: | | | |
| 1.9. | Contact Person (2): | | | |
| | Name: | | | |
| | Position: | | | |
| | Phone number: | | | |
| | Fax number: | | | |
| | E-mail address: | | | |

2. Proprietary Name, brand name or trade name under which the medicine or scheduled substance will be sold in the Republic (as it appears on the MCC/SAHPRA Medicine Registration Certificate).
3. SAHPRA/Medicines Control Council Registration number (as it appears on the MCC/SAHPRA Medicine Registration Certificate).
4. When registering with SAHPRA/MCC was the product registered as a generic or an originator/innovator?
5. The nature of its composition, including active ingredients and other ingredients.
6. The Single Exit Price (SEP) at which the medicine will be sold in South Africa.
7. The methodology used to determine the SEP and factors that influence the price at which the medicine will be sold.
8. The intended method and cost of distribution of the medicine or scheduled substance, including the details of the supply chain by which the medicine will be made available or accessible to users.
9. The nature of the disease or condition for which the medicine and scheduled substance will be used in South Africa.
10. The prevalence of the disease or condition as established by the applicant in South Africa.
11. Details of the efficacy, safety and cost-effectiveness of the medicine or scheduled substance compared to medicines or scheduled substances in the same therapeutic class.
12. Mark the appropriate box with an X: Is this medicine

| | |
|------------|--|
| Biological | |
| Biosimilar | |
| Neither | |

13. Note that the information provided in this question may be used to list this medicine on the “**Unreasonably Priced Medicine List**” If originator/innovator product answer (a) if not answer (b).

- (a) List the ex-manufacturer price i.e., the price less taxes, logistic fees, bonuses and discounts of this medicine in the countries listed in Table 1 below in relation to the SEP requested here. The price provided should be for the same pack size and quantity as the South African price. Where this is a difference, the applicant must describe the difference. The ex-manufacturer price must be provided in the original currency in which it is sold. Should the requested SEP be higher than in any of these markets provide reasons **AND** documentation to support this.

NOTE: All prices supplied must be the latest price. If the medicine is not available in this basket of countries (in Table 1 below), list ALL the international markets in which it is being sold & the prices as described above. **ALL** countries where the medicine is sold **MUST** be provided for the submission to be considered complete.

For all innovator products, provide the patent expiry date for the medicine in all the countries where the medicine is being sold.

Table1: List of countries where this medicine is available

| Medicine Name | Ex- Manufacturer Price in South Africa | Ex- Manufacturer Price in Canada | Ex- Manufacturer Price in Spain | Ex- Manufacturer Price in Australia | Ex- Manufacturer Price in New Zealand | Ex- Manufacturer Price in any other country where medicine is sold | Reasons for prices that are lower in other countries compared to the requested price in South Africa |
|---------------------------|---|---|--|--|--|---|---|
| | | | | | | | |
| Patent Expiry Date: | | | | | | | |

- (b) List the SEP for all existing competitors currently listed on the DoH Database of Medicine Prices (DoP). This list must be provided in the same format, containing all the fields as they appear on the DoP schedule. If there are no direct competitors, list the SEP for all medicines in the same therapeutic class.

NOTE: Failure to provide **ALL** competitors may result in the non approval of the submission.

14. Price at launch

14.1 What is the intended/target market for this medicine?

14.2 Is the requested SEP higher than the existing competitors?

Where yes, the applicant is required to explain the reasons for this higher price as well as to specify the intended and target market for the higher priced competitor being introduced and why that market would pay the higher price.

15. Was the medicine part of a patient access programme/compassionate use programme in South Africa?

16. Was the launched medicine made available under Section 21 of the Medicines and Related Substances Act 202 of 1965? If yes, indicate the Section 21 price?