South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

Certificate of Free Sale **15 November 2021**

APPLICATION FOR A CERTIFICATE OF FREE SALE FOR CATEGORY D MEDICINES (COMPLEMENTARY MEDICINES)

To all stakeholders

"Medicines Act" *means the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended.*

INTRODUCTION

1. A Certificate of Free Sale for Category D medicines (Complementary Medicines) issued by the South African Health Products Regulatory Authority (SAHPRA), serves as confirmation that the medicine meets the regulatory requirements of South Africa at the time of issue and that the product is freely available for purchase in South Africa.
2. A Certificate of Free Sale for Category D medicines may confirm whether the medicine is registered but is otherwise not an indication of quality, safety or efficacy of the medicine and may not be used for any other purpose than those stated in 1.
3. Certificates of Free Sale aim to meet the needs of the importing country. Before applying for a certificate, SAHPRA recommends that the applicant contact the relevant foreign government through their consulate to ascertain what information must be supplied to facilitate the export of the medicine to their country.
4. A Certificate of Free Sale for Category D medicines may be issued to:
   4.1. a holder of a licence in terms of section 22C(1)(*b*) of the Medicines Act to manufacture and export Category D medicines as identified on the appended Category D product lists;
   4.2. a manufacturer or exporter of *bona fide* Category D medicines before 31 July 2022, who is an applicant for a licence in terms of section 22C(1)(*b*) of the Medicines Act; or
   4.3. a manufacturer or exporter of *bona fide* Category D medicines before 30 April 2022 who does not yet hold a licence in terms of section 22C(1)(*b*) of the Medicines Act.
5. In the case of 4.1, the application for a Certificate of Free Sale may include multiple Category D medicines and multiple recipient countries will be valid for a maximum period of one year.
6. In the case of 4.2 and 4.3, the application for a Certificate of Free Sale may only be for single Category D medicines and multiple recipient countries.
7. Only Category D medicines in the sub-categories of either discipline-specific medicines or health supplements may be included in an application for a Certificate of Free Sale for Category D medicines.
8. The Certificate of Free Sale will be valid for a maximum period of one year and will be void should a medicine not be submitted for registration by the date specified in terms of any declaration made in terms of section 14(2) of the Medicines Act that a medicine is subject to registration.

REQUIRED INFORMATION

9. The following documents must be submitted as part of the application to SAHPRA for a Certificate of Free Sale:
   9.1. The completed Certificate of Free Sale for Category D Medicines online application form;
   9.2. A copy of the manufacturer's valid SAHPRA licence in terms of section 22C(1)(*b*) of the Medicines Act to manufacture Category D medicines;
   9.3. A copy of the exporter's valid SAHPRA licence in terms of section 22C(1)(*b*) of the Medicines Act to export Category D medicines;
   9.4. Cover letter on a company letterhead signed by the Responsible Pharmacist:
      9.4.1. of the applicant confirming the application for a Certificate of Free Sale; and
      9.4.2. of the prospective holder of certificate of registration of the medicine(s) in respect of which the application is being made, consenting to and confirming the application for a Certificate of Free Sale;
   9.5. Where applicable, the accompanying certificate of Good Manufacturing Practice (GMP);
   9.6. Details of the medicines to be exported including reference to any approved product listings and the relevant line items appended to the relevant SAHPRA licence; and
   9.7. Proof of payment.

SUBMISSION OF APPLICATION AND TIMELINES

10. Applications must be submitted online at www.sahpracm.org.za.
11. The fee for a Certificate of Free Sale is payable upon application and proof of payment must be submitted together with the completed application.

    Note: Fees may be updated from time to time. The onus is on the applicant to ensure that payment is made in line with the current fee structures, as published in the *Government Gazette*.
12. Payments should be made as per SAHPRA Guideline 17.02 for the direct transmission of fees payable to SAHPRA.
13. The applicant for a Category D Medicine Certificate of Free Sale application process will receive a response from SAHPRA within fifteen (15) working days from the date of submission of the application, provided that the application submitted is complete and meets the requirements.

INFORMATION APPEARING ON A CERTIFICATE OF FREE SALE

14. The following information will be included on the Certificate of Free Sale:
    - Name, site address and licence number of the manufacturer and the exporter concerned;
    - Details of medicine/s intended for export and listed in this application including
    - Medicine Name
    - Pack size (where relevant)
    - Category, Sub-category and class of medicine
    - Indication and associated SA risk classification
    - Registration status
    - Recipient Country/ies
    - Name and contact details of the Responsible Pharmacist
    - Any additional particulars required to facilitate the export of the listed Category D medicine to the relevant foreign government.

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