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

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REQUESTS: Existing Category D (Complementary Medicines) Registration Applications

COMPLEMENTARY MEDICINES APPLICATIONS SUBMITTED FOR REGISTRATION

To all stakeholders

Category D Medicines (Complementary Medicines) has been established in the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). Medicines compliant with the prescribed definition for this category are included in Guidance on progression to regulatory compliance by way of the SAHPRA Guideline 7.02.

A prioritisation of the regulatory pathway for Category D medicines includes the licensing of manufacturers, wholesalers, distributors, importers and exporters in terms of section 22C(1)(*b*) of the Medicines and Related Act, 1965 (Act 101 of 1965). The online SAHPRA CM platform was developed to support matters relevant to the regulatory compliance of CMs and was made available by the Authority on 17 February 2020.

With respect to medicine registration, the Authority (as per Guideline 7.02) recognises that applications for registration already submitted may have undergone fundamental changes due to a variety of reasons including, but not limited to, updated quality data, amended clinical evidence or updated indications. As such, the SAHPRA hereby provide for a process by which applicants may, at their choosing, request that applicants may request that qualifying applications be provided an opportunity to be requested to be updated or revised the data set", effectively suspending the relevant review subject to the conditions indicated below and to re-submit the updated files in the manner directed when approved, which will replace the previous versions of the application with SAHPRA. In addition, to assimilate existing application information into an electronic management system, information is requested from all applicants regarding current applications for registration, their current status and preferred administrative course as a result of the withdrawal opportunity.

SAHPRA therefore advises all applicants with applications for medicine registration to visit www.sahpracm.org.za – Applications – Medicines – Request: Existing Cat D (CM) Registration Applications, where:

1. Applicants will be requested to supply at least the following information:
    a. Name of Applicant (proposed Holder of Certificate of Registration)
    b. Name of Medicine
    c. Application number
    d. Date of application
    e. Categorisation of medicine (latest standing including Category, Sub-category, Class or Discipline)
    f. Indication and risk classification of the medicine

g. Whether the application was submitted in response to any registration deadline that may previously have been prescribed.
h. Status of application
    i. Screening outcome and date
    ii. Stage of evaluation (optional: dates and upload of communications received)
i. Name of Manufacturer(s) or Importer(s) and licensing status
j. Signed letterhead by Responsible Pharmacist requesting selected action (as per item 2) including any relevant motivation for the requested action.
k. Proof of payment(s) made in respect of the applications

2. Based on the information submitted, specific guidance or options will be presented for consideration, including:
    a. Proceeding with review: subject to all fees including screening and application fees having been paid and, where requested, supply of the documentation in electronic format as prescribed.
    b. Temporary suspension of application review to update or revise the data set: subject to all fees including screening and application fees having been paid and withdrawn for a period not exceeding 12 months. Supply of the updated documentation in electronic format as prescribed
    c. Withdrawal of the application: subject to forfeiture of any fees already paid.
3. Apart from guidance supplied at the point of entry, any request will be verified and individually reviewed based on the information supplied and status of the application and status updated and/or communication sent to the applicant.
4. This request will be available until **31 January 2022**.
5. Any application for which information is not received will thereafter continue to be screened and/or evaluated provided that the relevant application fees have been paid pending any further communication to the applicant. These applications will not be available for tracking through the online portal.
6. Applications will be prioritised for continued review based on status of the application, date of submission as well as licensing status of the relevant manufacturer(s) and importer(s).
7. Any application retained in the review process shall continue to be reviewed until a regulatory decision is made and cannot be requested to be revised outside of the review process after the request period has ended.

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