



SAPRAA Webinar

Names & Scheduling:

Processes and Procedures Refresher

Overview

1. Guidelines/Reference Documents For Names & Scheduling Applications
2. Guide On Rescheduling Applications
3. Guide On Proprietary Name Applications:
Important Factors To Consider For A Proposed Proprietary Name
4. Tips to Consider During Application Submissions
5. Questions

Guidelines/Reference Documents For N&S Applications

GOLD STANDARD

- SAHPGL-CEM-NS-01 Application for rescheduling of a substance or medicine
- SAHPGL-CEM-NS-02 Guideline to the scheduling of substances and medicine
- SAHPGL-CEM-NS-03 Guideline for proprietary names for medicines
- SAHPGL-CEM-NS-04 Scheduling of substances for prescribing by authorised prescribers other than medical practitioners or dentists
- Stem Book 2024 (guidance for proprietary names)
- Medicines And Related Substances Act, 1965 (Act 101 Of 1965) Consolidated Schedules
- SAHPRA's Registered Health Products Database (guidance for proprietary names)

OTHER

- 2.01 General Information Guideline

Guide On Rescheduling Applications

GOLD STANDARD GUIDELINE – For Rescheduling Applications

- SAHPGL-CEM-NS-01 Application for rescheduling of a substance or medicine
 - Purpose of the reschedule
 - Is there substantial information available to support the application

Other Guides

- SAHPGL-CEM-NS-02 Guideline to the scheduling of substances and medicine
- Medicines And Related Substances Act, 1965 (Act 101 Of 1965) Consolidated Schedules

Where to find these?

- <https://www.sahpra.org.za/document/application-for-rescheduling-of-a-substance-or-medicine/>
- <https://www.sahpra.org.za/document/guideline-to-the-scheduling-of-substances-and-medicines/>
- <https://www.sahpra.org.za/document/consolidated-schedules-6-september-2024/>

Guide On Rescheduling Applications

- **Processes for evaluating rescheduling applications**
 - Rigorous evaluations done by expert evaluators
 - Several rounds of review for rescheduling applications
 - Only two response cycles are permitted for addressing deficiencies identified
 - In the event of a reschedule approval to a lower schedule, a unique name and a separate registration dossier is required
 - Rescheduling applications that are approved are drafted in an amendment to the published Schedules, for consideration by the Minister of Health and publication in the Government Gazette

Guide On Proprietary Name Applications

GOLD STANDARD GUIDES – For Proposed Proprietary Names

- SAHPGL-CEM-NS-03 Guideline for proprietary names for medicines
- Stem Book 2024
- SAHPRA's Registered Health Products Database




Where to find these?

- <https://www.sahpra.org.za/document/guideline-for-proprietary-names-for-medicines/>
- <https://www.who.int/publications/i/item/9789240099388>
- <https://medapps.sahpra.org.za/>

Important Factors To Consider When Creating A Proprietary Name

- **Understanding the Guideline for proprietary names for medicines**
 - Is the proposed proprietary name unique or distinct? (not identical to popular names of people, places or items, not similar or identical in speech and writing to another existing proprietary name)
 - Does the proposed proprietary name contain more than 50% of the INN (in the order it appears)?
 - Does the proposed proprietary name contain a protect/prohibited WHO INN stem?
 - Is the proposed proprietary name misleading to the composition, the pharmacological action or the expected therapeutic effect?
 - Does the proposed proprietary name contain an unacceptable abbreviation or qualifier or symbol?
 - Does the proposed proprietary name contain an unacceptable company identifier or umbrella name?

Important Factors To Consider When Creating A Proprietary Name

- **Proposed proprietary names containing the company identifier with an INN**
- **Example**
 - ABC CETIRIZINE 10 
 - ABC CETIRIZINE 
 - CETIRIZINE 10 mg ABC 
- **The format should be: INN_Qualifier_Company Identifier**

Tips to Consider During Application Submissions

- ✓ Submit applications with as much details as possible (don't leave anything to be presumed)
- ✓ Emailed responses to queries cannot generate a re-evaluation (a formal response sequence is required)
- ✓ Emailed motivations/information cannot be used to re-evaluate a previous submission sequence
- ✓ Registration of a trade name will not be considered when assessing the acceptability of a proposed proprietary name for a medicine.
- ✓ More than three evaluation query rounds are not advised (encouraged to seek clarity via email or a Microsoft Teams meeting with the N&S unit to avoid reaching this stage)

Questions?

A large, teal-colored circular graphic with a rough, brushstroke-like texture. Inside the circle, the words "Thank you!" are written in a white, cursive script font.

Thank
you!