

Doc Number: GLF-XX-ZZA	ANNEXURE D CONSOLIDATED VARIATIONS GUIDELINE (NAMES AND SCHEDULING)	 Effective date: 30 September 2025
Revision: 1.0		

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SCOPE

This annexure contains details on the specific categories and codes for variations specific to the safety and efficacy of registered medicines. This guideline is relevant only to submissions made for variations affecting the safety and efficacy of orthodox human medicines. It does not include veterinary, biological, and complementary medicines.

Variations applications are categorized as below SAHPRA codes for the Names and Scheduling unit:

- Proprietary name change: Type IB - Code N.S.1 a-d
- Rescheduling application: Type II – Code N.S.2 a-d
- Authorized Prescribers Amendment: Type II – Code N.S.3. a

N.B. All Names and Scheduling Type IB and Type II applications require regulatory approval prior to implementation.

1. PROPRIETARY NAME CHANGE

SAHPRA Classification	Type IB	SAHPRA Code	N.S.1.a- N.S.1.d
Code description	A Change in the proprietary name of a registered medicine or substance: a) Change in the proprietary name of a registered medicine or substance - Human Medicines b) Change in the proprietary name of a registered medicine or substance - Veterinary Medicines c) Change in the proprietary name of a registered medicine or substance – Complementary Medicines, Human d) Change in the proprietary name of a registered medicine –Complementary Medicines, Veterinary		
Details	A change in the product name of a registered product to ensure that any changes are in line with current Names and Scheduling policies. The application letter of the proprietary name change applications should be addressed to the Names and Scheduling unit. Applicants are to submit a resolution letter (for local sites), certificate of GMP compliance and, a manufacturing license issued within the last 3 years by		

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	<p>SAHPRA or an authority in which a GMP MRA with SAHPRA exists (i.e., a PIC/S member state, Zazibona work-sharing agreement or WHO PQ)</p> <p>If there has been a transfer of applicancy, the new applicant must provide proof that they hold all the rights pertaining to that particular dossier. A signed letter from the responsible pharmacist acknowledging that all rights to the dossier have been ceded to the new applicant must be included.</p> <p>The timeline for Type IB proprietary name change applications is 100 working days.</p> <p>N.B. All proprietary name changes (Type IB) applications require regulatory approval prior to implementation.</p>
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2. RESCHEDULING APPLICATIONS

	SAHPRA Classification	Type II	SAHPRA Code	N.S.2.a - N.S.2.d
Code description		A Change in the scheduling status of a registered medicine or substance: a) Change in the scheduling status of a registered medicine or substance - Human Medicines b) Change in the scheduling status of a registered medicine or substance - Veterinary Medicines c) Change in the scheduling status of a registered medicine or substance - Complementary Medicines, Human d) Change in the scheduling status of a registered medicine or substance - Complementary Medicines, Veterinary		
Details		A rescheduling of a registered medicine or scheduled substance to ensure that any changes are in line with current naming and scheduling policies. The timeline for Rescheduling Type II variation applications is 250 working days. N.B. All rescheduling (Type II) applications require regulatory approval from SAHPRA and are only implementable after the Government Gazette has been published with the updated Schedules.		

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3. AUTHORIZED PRESCRIBERS AMENDMENT

SAHPRA Classification	Type II	SAHPRA Code	N.S.3.a
Code description	a) Amending the Schedules of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) to allow prescription rights to authorised health professionals, other than medical practitioners or dentists, in accordance with the provisions of section 22A of the Act.		
Details	<p>Amendments to the Schedules with the objective of specifying substances to be made available for prescription by designated categories of health professionals, other than medical practitioners or dentists, as provided for by section 22A of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).</p> <p>The timeline for Authorized Prescribers Amendment Type II variation applications, which serve as a request made to SAHPRA, is 250 working days.</p> <p>N.B. All Authorized Prescribers Amendment (Type II) applications require regulatory approval from SAHPRA and are only implementable after the Government Gazette has been published with the updated Schedules.</p>		