

Doc Number: GLF-XX-ZZA	ANNEXURE A HEALTH PRODUCTS AUTHORISATION (CV)	 South African Health Products Regulatory Authority
Revision: 1.0		Effective date: 30 September 2025

Certificate variations must be applied for within 30 working days after the approval letters are received from the relevant units (Naming and Scheduling and Inspectorate), for which the required changes are to be made on the revised registration certificate.

This section covers the variation codes and supporting data for HPA Certificate Variations related changes of human, biological and veterinary medicines.

Code-related exceptions

Exception type	Addition	SAHPRA code	CV.0.1
EMA classification	N/A	SAHPRA classification	Type IA
Code description	Certificate Variation: Application for a Transfer of Holder of Certificate of Registration (ToHCR) for a registered medicine		
Details	New code introduced allowing issuing of the revised registration certificate/Old medicine letter. Applicants to effect changes in the Holder of Certificate of Registration (i.e., change in product ownership). Note that ToHCRs do not apply for medicines that have yet to be registered. Applications will be assessed on a case-by-case basis to confirm where such changes are warranted.		

Exception type	Addition	SAHPRA code	CV.0.2
EMA classification	N/A	SAHPRA classification	Type IA
Code description	Certificate Variation: Change in the proprietary name of the authorised medicine - certification		
Details	Applicants are to submit the SAHPRA name change approval letter, a resolution letter (for local sites), certificate of GMP compliance and a manufacturing license issued within the last three (3) years by 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).		

Exception type	Addition	SAHPRA code	CV.0.3
EMA classification	N/A	SAHPRA classification	Type IA
Code description	Certificate Variation: Other		
Details	New code introduced allowing issuing of the revised registration certificate/old medicine letter for exceptional instances where the revised		

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	registration certificate is required, e.g., de-linking the duplicate registration number from the master, corrections.
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In addition to any requirements set out in 2.24 Guidance for the submission of the South Africa CTD/eCTD – General & Module 1, Certificate Variations require the following document:

Table 1: List of key documentation/data required for certificate variation applications

Description of Change	Conditions to be Fulfilled	Supporting Data	Amendment Type
CV.0.1 Certificate Variation: Transfer of Applicancy			
Application for a Transfer of Holder of Certificate of Registration (ToHCR) for a registered medicine	None	1-12	IA
CV.0.2 Certificate Variation: Proprietary Name Change			
Application for a Transfer of Holder of Registration (ToHCR) for a registered medicine	None	1-12	IA
CV.0.3 Certificate Variation: Other			
Issuing of the revised registration certificate/old medicine letter for exceptional instances	None	1-3,6-11	IA
Conditions			
<ol style="list-style-type: none"> There must be no open variations that affect the revised registration certificate/old medicine letter. No other changes that have not yet been approved may be submitted with the Transfer of Applicancy variation. 			
Supporting Data			
<ol style="list-style-type: none"> Letter of application with (M1.0): <ul style="list-style-type: none"> Purpose of the variation(s) Description, Classification and Code of the Variation(s) (e.g., Type II – A.0.1) 			

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- SAHPRA Inspectorate Unit Approval Letter for the Transfer of Applicancy and
 - Naming approval Letter (for Code CV.02)
2. Application form (M1.2.1)
 3. Proof of payment for the variation application (M1.2.2.1)
 4. Electronic copy of the letter of cession from the current registered HCR
 5. Electronic copy of the letter of acceptance from the proposed HCR
 6. The current approved PI and PIL (M1.3.1.1 & M1.3.2)
 7. Amendment/variation schedule (M1.5.2.1)
 8. Medicine register details (M1.5.2.2.1)
 9. Current Registration Certificate with the variation summary appended (if applicable) (M1.5.2.2.2)
 10. Valid SAHPRA licence to manufacture, import or export medicines for the proposed HCR (M1.7.3)
 11. Current GMP certificates or manufacturing licences for all approved sites performing a function related to the product's manufacture, packer, FPRC, FPRR/Applicant (M1.7.3)