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

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GUIDELINE ON CO-APPLICANCY

This guideline is intended to provide guidance to applicants who intend to apply as co-applicants for the registration of a medicine. It represents the current thinking of the South African Health Products Regulatory Authority (SAHPRA) on managing applications for registration where there is more than one applicant who is jointly accountable for the overall quality, safety and efficacy of a medicine. SAHPRA reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The SAHPRA is committed to ensure that all registered medicines are of the required quality, safety, and efficacy. It is important that applicants adhere to administrative requirements to avoid delays in the processing and evaluation of applications. Guidelines and application forms are available from the office of the Chief Executive Officer and the website.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue	July 2024

DR BOITUMELO SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER

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Glossary

Abbreviation/ Term	Meaning
Co-applicancy	Where two applicants apply jointly as co-applicants for the registration of a medicine and are considered to have shared responsibility for regulatory oversight of such medicine once registered.
HCR	Holder of certificate of registration.
Medicines Act	Medicines and Related Substances Act 101 of 1965.
Co-applicancy contract	A contract that is required to be signed by two applicants who apply jointly as co-applicants for the registration of a medicine stating: (a) their roles, responsibility and accountability in ensuring compliance with requirements in terms of quality, safety, and efficacy of the medicine for which such application is made; (b) any terms of confidentiality between the co-applicants; and (c) that the co-applicants are jointly accountable.
Primary Applicant	The applicant who will be responsible as the holder of the certificate of registration (HCR).
Secondary Applicant	An applicant who is the secondary applicant as per the co-applicancy contract .

1. INTRODUCTION

The Medicines and Related Substances Act 101 of 1965 (the Medicines Act), makes provision for the registration of medicines based on safety, efficacy, and quality. This document outlines the process to be followed by applicants who intend to submit an application for registration as co-applicants and be jointly responsible and accountable for oversight of the quality, safety, and efficacy of a medicine for which an application for registration is made.

1.1 Purpose

To guide applicants who intend to apply jointly as co-applicants for the registration of a medicine.

1.2 Scope

A co-applicancy is possible where applicants who are legally separate entities undertake to jointly provide the data as required in guidelines for registration of a medicine and who, through a co-applicancy contract, indicate the areas of oversight and responsibility undertaken by the applicants in fulfilling overall regulatory requirements.

This approach applies only to new applications for registration of a medicine that meets a public health need, and where there may be limitations with respect to a single applicant being able to provide oversight of quality, safety, and efficacy and where this can be provided by a co-applicancy.

2. LEGAL PROVISIONS

The Medicines Act references the term “applicant”, which may be interpreted as referring to a single applicant or more than one applicant.

If the South African Health Products Regulatory Authority (SAHPRA) is satisfied that a medicine should be registered in terms of section 13(3)(*a*) of the Medicines Act, the Authority may register the medicine subject to conditions it may determine in terms of section 15(6) of the Medicines Act.

A co-applicancy may only proceed in the manner outlined in this guideline.

3. REQUIREMENTS FOR APPLICATION FOR REGISTRATION OF A MEDICINE AS CO-APPLICANTS

3.1 The **principles relating to such an application** are as follows:

3.1.1 Registration requirements as per section 15(6) of the Act and regulation 16 of the General Regulations published in terms of the Act, and all relevant guidelines relating to the submission of an application for registration of medicine must be met.

3.1.2 Co-applicants must be separate legal entities domiciled in South Africa and entitled to apply for registration of a medicine.

3.1.3 Applicants must have agreed by means of a written co-applicancy contract to share stipulated responsibilities.

3.1.4 The responsibility of each applicant as provided in the co-applicancy contract remains binding throughout the period of registration of the medicine for which application for registration is made.

3.1.5 Both applicants are responsible for fulfilling the conditions of registration. As stipulated in the co-applicancy contract.

3.1.6 Applicants must request a pre-submission meeting with SAHPRA. In preparation for this meeting, applicants must submit documentation providing the rationale for proposing co-applicancy as well as the draft co-applicancy contract

3.1.7 SAHPRA will consider the merits of such applications on a case-by-case basis.

3.2 Requirements for **submission of a co-applicancy application** include:

3.2.1 The application form: Module 1.2.1 (stating the primary and secondary applicants)

- details of each applicant;
- the roles and responsibilities of each applicant;
- which of the relevant data sections in the application for registration are to be submitted by each of the applicants;

- a commitment that both applicants shall collectively comply with the requirements of the application; and

- a commitment that both applicants shall comply with all relevant provisions of the Medicines Act and General Regulations made in terms of the Medicines Act.

3.2.2 The co-applicancy contract which must:

- be completed and supplied to SAHPRA as a pre-requisite for application for co-applicancy;

- stipulate that both the primary and secondary applicant are appropriately licensed in terms of section 22C(1)(b) of the Medicines Act;

- include details of the submission of data by the applicants jointly or separately, and the responsibility in respect of oversight of areas pertaining to safety, efficacy, and quality of the medicine for which an application for registration is submitted;

- specify the primary applicant, which will be the holder of the certificate of registration;

- include that as a condition of registration all applicants will be held responsible for the areas identified, and that the validity of the registration is contingent on the continued existence and agreement of both parties as per the contract on record with SAHPRA. Further that if, for any reason, this condition is not adhered to, including but not limited to, a discontinuation, lapse of contract or significant changes which will alter the ongoing oversight of quality, safety, and efficacy of the product it could result in cancellation of the registration of the product in terms of section 16 of the Medicines Act.

3.2.3 Pre-submission meeting

- Applicants intending to make an application must request a pre-submission meeting with the SAHPRA Health Products Authorisation unit.

- Information about the intended applicants, the application form (Module 1.2.1) with the draft co-applicancy contract, as well as a presentation prepared by the applicants outlining the proposed application should be provided to SAHPRA when requesting a pre-submission meeting.

- The presentation referred to above must include how the submission will be made and the relevant sections of data to be provided by each applicant. The oversight to be provided in terms

of lifecycle management, recall, and pharmacovigilance matters should also be addressed, as well as how information will be shared with SAHPRA.

- The applicants must indicate which will be the primary applicant (holder of the certificate of registration), and which will be the secondary applicant. The names of both applicants will be reflected on the registration certificate.

- The details of the primary applicant must appear on the labelling.

- Declarations from each of the applicants to SAHPRA that they undertake to comply with regulatory oversight and take responsibility for the identified aspects of product in relation to its quality, safety, and efficacy.

3.2.4 Technical requirements for quality, safety, and efficacy

- Note that the technical requirements for the product as defined in specific product guidelines will apply as in the case of a single applicant.

- The co- applicants shall be jointly accountable for the data supplied and the regulatory oversight as defined in the co-applicancy contract.

- In matters relating to the quality and clinical aspects of a co-applicancy submission, and where such responsibilities have been contractually divided, SAHPRA will expect a clear indication, in the relevant part of the dossier, of which applicant (with an official contact) is contractually responsible for submission of Modules 1, 4, and/or 5 of the eCTD. Where queries arise during evaluation, these will be directed to the applicant responsible for that aspect. Any final approvals or rejections will be communicated to the relevant co-applicant.

3.2.5 Submission upload onto IT Portal

- As there may be separate submissions of information permitted by the agreement between the co-applicants, it may be required that the applicants submit the information separately by means of the relevant IT portal.

4 CONDITIONS OF REGISTRATION

4.1 Any changes to the co-applicancy contract in terms of applicants and content that would alter the ongoing oversight of quality, safety, and efficacy should be submitted to SAHPRA for review and may require a new application for registration to be submitted. Furthermore, a registration of a product which was based on a co-applicancy cannot be transferred.

4.2 Declarations by each applicant with respect to their responsibilities and that they will be held accountable within the accepted timelines for information or action as requested by SAHPRA.

Disclaimer: Whilst every effort will be made to avoid accidental disclosure, SAHPRA will not be held liable for managing intellectual property information relevant to the medicinal product that is the subject of a co-applicancy.

5 REFERENCES

The following related documents are referenced:

5.1 Medicines and Related Substances Act 101 of 1965.

5.2 All relevant Guidelines for product registration applied for.

6 VALIDITY

This guideline is valid for a period of five years from the effective date of revision. It will be reviewed in accordance with this timeframe, or as and when required.