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GUIDELINE ON CO-APPLICANCY

This guideline is intended to provide guidance to applicants who intend to submit an application as co-applicants for a medicinal product. It represents the South African Health Products Regulatory Authority (SAHPRA) current thinking on managing applications for registration where there is more than one applicant who is jointly accountable for ensuring the overall quality, safety and efficacy of the medicinal product. 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 will be of the required quality, safety and efficacy. It is important that applicants adhere to the 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

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Contents

Document History.....	1
Glossary	3
1. INTRODUCTION	4
1.1 Purpose.....	4
1.2 Scope	4
2. LEGAL PROVISION.....	4
3. REQUIREMENTS FOR APPLICATION FOR REGISTRATION AS CO-APPLICANTS	4
4. REFERENCES.....	7
5. VALIDITY	8

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Glossary

Abbreviation/ Term	Meaning
Medicines Act	Medicines and Related Substances Act, Act 101 of 1965, as amended
Co-Applicancy	Refers to where applicants share the responsibility of regulatory oversight of a medicinal product intended to be registered
HCR	The holder of the certificate of registration, which means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine, including quality and safety and compliance with conditions of registration, in line with the regulations of the Medicines and Related Substances Act, Act 101 of 1965, as amended
Primary Applicant	The Applicant that will be responsible as the Holder of Certificate of Registration
Secondary Applicant	The Applicant that is the secondary partner in the Co-Applicancy. Responsibilities and accountabilities to SAHPRA are determined in the pre-requisite Contract of Co-Applicancy
Pre-requisite contract of Co-Applicancy	Contract that is required to be signed by the co-applicants detailing their roles and responsibilities that they will undertake in ensuring compliance with the requirements in terms of Quality, Safety and efficacy of the product and that there is joint accountability by the applicants and of which SAHPRA will use to ensure compliance. Without this contract a request for Co-Applicancy will not be considered (refer to paragraph 3.2.2.5)
HPA	Health Products Authorization

1. INTRODUCTION

The Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended), 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 be jointly responsible for oversight of quality, safety and efficacy of a product intended for registration.

1.1 Purpose

To provide guidance to applicants who intend to be jointly responsible for oversight of quality, safety and efficacy of a product intended for registration.

1.2 Scope

A 'co-applicancy' is possible where applicants undertake to jointly provide the required data as prescribed in guidelines for registration and who would through a contract as a condition for submission of co-applicancy indicate the area of oversight and responsibility undertaken by the applicants in terms of fulfilling the overall regulatory requirements.

Therefore, the scope would encompass new registrations of products which are of public health need and/or improve access to a particular treatment; and which may have limitations in respect of a single applicant not being able to ensure the oversight of quality, safety and efficacy by themselves and whereby this can be provided jointly in a co-applicancy situation.

SAHPRA reserves the right to decide regarding whether the product satisfies a public health need.

This guideline excludes applicants who are not domicile in South Africa.

2. LEGAL PROVISION

The final decision to register a medicine will reside with the South African Health Products Regulatory Authority (SAHPRA) under applicable conditions of registration in terms of section 15(7) of the Medicines and Related Substances Act 1965 (Act 101 of 1965, as amended). The Act further references applicant which may be singular or plural to a product.

The co-applicancy of a medicine must only be applied for as outlined in the guidance.

3. REQUIREMENTS FOR APPLICATION FOR REGISTRATION AS CO-APPLICANTS

3.1 The principles or premise for submission of a co-applicant registration would be that:

- Registration requirements are as per Section 15 of the Act and all relevant guidelines in terms of the submission for registration and should be complied with.
- Applicants will have a pre-submission meeting with SAHPRA defining the rationale for proposing co-applicancy, the contents of the *pre-requisite contract* with the applicants concerned reflecting the submission of data by the applicants jointly or separately, the responsibility in respect of oversight of areas pertaining to safety, efficacy and quality.
- SAHPRA will consider the merits of such a co-applicancy in terms of its mandate.
- Any changes to the contract in terms of applicants and content that would alter the ongoing oversight of quality, safety and efficacy would require a new registration to be submitted as the primary basis for registration.
- Whilst the co-applicancy enables flexibility and sharing of responsibility for product safety, quality and efficacy, the premise as outlined in terms of the responsibility of each applicant remains binding throughout the registration.
- The primary applicant is responsible for fulfilling the conditions of registration, supported by the secondary applicant.

3.2 Submission Requirements includes the following:

3.2.1 The new medicine application form in eCTD format.

3.2.2 The pre-requisite co-applicancy contract:

3.2.2.1 This is a contract that the co-applicants will complete as a pre-requisite for application for co-applicancy.

3.2.2.2 That the applicants under consideration are compliant with requirements of Section 22C(1)(b) in terms of being appropriately licensed.

3.2.2.3 This contract shall include:

- details of each applicant
- the roles and responsibilities of each applicant in the agreement

- the relevant data sections submitted by each applicant should be defined and must collectively comply with the requirements of the application
- and that both applicants comply with section 15 and the relevant regulations

3.2.2.4 Of the co-applicants listed, there will be one holder of certificate of registration (the primary applicant) and will be documented in this contract.

The co-applicancy must be for a product that has been registered in South Africa by the secondary applicant.

NOTE: That one of the conditions of registration is that this contract exists and continues to be maintained. If there is a discontinuation, lapse of contract or significant changes which will alter the ongoing oversight of quality, safety and efficacy of the products it would result in de-registration/cancellation of registration of the product.

3.2.3 Pre-submission meeting:

3.2.3.1 Applicants intending to make an application must request for a pre-submission meeting through HPA.

3.2.3.2 The information about the intended applicants, the application form with provisional contract as well as the presentation slide deck by applicants should be provided to SAHPRA when requesting a pre-submission meeting.

3.2.3.3 The applicant will provide a detailed presentation on how the submission will be made and the relevant sections of data to be provided by each applicant. The oversight provided in terms of lifecycle management, possible recall, pharmacovigilance matters should be addressed, as well as how information will be shared with SAHPRA.

3.2.3.4 Indicate who will be the primary applicant /holder of certificate of registration and who will be the secondary applicant. The names of both applicants will be reflected in the registration certificate.

3.2.3.5 Declarations from each of the co-applicants to SAHPRA that they undertake the regulatory oversight and responsibility for the identified sections of product quality, safety and efficacy.

- 3.2.4 Technical requirements for Quality, Safety and Efficacy and note:
- 3.2.4.1 That the technical requirements for the product as defined in specific product guidelines will apply as in the case on a single applicant.
 - 3.2.4.2 That the co-applicants would be jointly accountable for the data supplied and the regulatory oversight as defined in the pre-requisite co-applicancy contract
 - 3.2.4.3 In matters relating to the clinical aspects of a co-applicant 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 (and official contact) is contractually responsible for submission of Modules 1, 4, and/or 5 of the eCTD. Where clinical queries arise during evaluation, these will be directed to the responsible applicant entity. Any final approvals or rejections will be communicated with the co-applicant entity as relevant.
- 3.2.5 Submission upload onto FTP:
- 3.2.5.1 As there may be separate submission of information permitted by the agreement, it may be required that the two applicants submit the information separately via the FTP.
- 3.3 Contract of co-applicancy of registration of medicines must address an identified public health need; and / or improve access to a particular treatment whilst ensuring SAHPRA required safety; quality and efficacy.
- 3.4 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.
- 3.5 Legal requirements- Pre-requisite co-applicancy contract defining the roles and responsibilities of the co-applicants.
- 3.6 Disclaimer: Whilst every effort will be made to avoid accidental disclosure, SAHPRA will not be held liable for managing IP information.
- 3.7 Communication to co-applicants- This can be determined from the pre-requisite contract such that SAHPRA is able to communicate with the relevant co-applicant.

4. REFERENCES

The following related documents are referenced:

- 4.1 Medicines and Related Substances Act 101 of 1965 (as amended).
- 4.2 All relevant Guidelines for product registration applied for.

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision. It will be reviewed on this timeframe or as and when required.

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