South African Health Products
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17 February 2023

GUIDELINE ON CO-PACKAGING OF MEDICINES

This guideline is intended to provide guidance to applicants regarding applications for registering co-packaged medicines. It represents the South African Health Products Regulatory Authority (SAHPRA) current thinking on co-packaging of medicines. 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 https://www.sahpra.org.za.

Document History

Final Version	Reason for Amendment	Effective Date
1	First issue	February 2023

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1. INTRODUCTION

This guideline is intended to provide guidance to applicants regarding applications for registering co-packaged medicines. It represents the current thinking of the South African Health Products Regulatory Authority (SAHPRA) on co-packaging of medicines. 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. SAHPRA is committed to ensuring that all registered medicines will be of the required quality, safety and efficacy.

Definition of a co-packaged medicine: A 'co-packaged medicine' consists of more than one medicine presented under a single name (Proprietary Name) and in a single package, where the individual medicines are intended for simultaneous or sequential administration.

This scope of this policy document does not include the co-packaging of a medicine together with a medical device. If a medicine and a medical device are supplied together in the same package, or documentation for a medicine (including but not limited to the instructions for use) contains references to a particular medical device, the information about the device should also be submitted when applying for marketing authorization for the medicine.

2. LEGAL PROVISION

The final decision to register a co-packaged 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 co-packaged medicine must be packaged only in the style and format approved by the SAHPRA.

3. REQUIREMENTS FOR A CO-PACKAGED MEDICINE APPLICATION FOR REGISTRATION

3.1 The principles applicable to fixed-dose combination (FDC) medicine applications for registration are also applicable to co-packaged medicines applications.

3.2 Inclusion of each individual medicine in a co-packaged medicine containing more than one medicine should be based on valid therapeutic principles and acceptable clinical practice of using the individual medicines included in the co-packed medicine, simultaneously or sequentially, for the same indication and at the same doses that were approved for each individual medicine.

3.3 Co-packaged medicines must address an identified public health need and / or improve adherence to a particular treatment protocol and / or facilitate implementation of interventional programmes and / or have benefit for the treatment of a clearly-defined subset of patients.

3.4 Each individual medicine in a co-packaged medicine containing a different formulation and / or form of presentation, must be registered as an individual medicine for the same indication and at the same dose that is proposed in the co-packaged medicine application. The co-packed medicine must then also be registered separately. Whereas each individual medicine may have a different Schedule, based on the included active pharmaceutical ingredient (scheduled substance), the co-packaged medicine will be designated the higher or highest schedule of the included individual medicines.

3.5 Container closure system: The container closure system used to generate the stability data must be the same material and the same configuration as that of the co-packaged medicine. If stability data is not available in the same packaging configuration, then stability data generated from each component packaged separately in the proposed packaging material for marketing will be acceptable.

3.6 Shelf life: The individual components of the co-packaged medicine should have an approved shelf-life period. The shelf-life of the co-packaged medicine will take the shortest shelf-life of the individual component. The stability studies should be conducted under the same conditions for both the individual components and the co-packaged medicine.

3.7 The benefit-risk profile of the co-packaged medicine, administered simultaneously or sequentially, should not be different from the risk benefit profile when the individual medicines are administered simultaneously or sequentially.

3.8 There should be no pharmacokinetic interactions between the individual medicines included in a co-packaged medicine when given simultaneously or sequentially.

3.9 Co-packaging of medicines shall be performed in compliance with current Good Manufacturing Practice Guidelines.

4. REFERENCES

The following related document is referenced:

4.1 Related Guidelines

4.1.1 SAHPGL-CEM-PRE-02 Fixed Dose Combination Products (FDC Products) for HIV/AIDS, tuberculosis, and malaria

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.