MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

CO-PACKAGING OF MEDICINES

This guideline is intended to provide guidance to applicants regarding applications for registering co-packaged medicines. It represents the Medicines Control Council's current thinking on co-packaging of medicines. Council 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 MCC 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 Registrar of Medicines and the website.

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1 PURPOSE OF THIS GUIDELINE

To give guidance regarding applications for registration of co-packaged medicines.

2 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.

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 more than one medicine in 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 are 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 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.

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

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

4 LEGAL CONSIDERATIONS

4.1 The final decision to register a co-packaged medicine will reside with the Medicine Control Council (MCC) 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).

4.2 The co-packaged medicine must only be packaged in the style and format approved by the MCC.

5 UPDATE HISTORY

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April 2017	First version published for comment	v1.0 May 2017
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