SAHPRA
South African Health Products Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
402 Kirkness Street
Arcadia
0083

16 November 2020

Dear Industry Partners,

Re: Applications for Clones or Replicas and Supporting Documentation

SAHPRA has recently updated its policy regarding clones and replicas. For the purposes of this policy, the following definitions apply:

A clone is defined as an application submitted by the Innovator as a copy of its own product under a different proprietary name at any stage during the product life cycle.

A replica is defined as a copy of an already registered generic product, submitted by the same or by another applicant at any stage during the product life cycle.

This policy does not apply to duplicate or multiple applications, submitted at the same time in one application by the same applicant. Duplicate or multiple applications are governed by 2.40 Multiple submissions of the same application for registration with different proprietary names_May 2019_v4.

Based on the nature of the proposed processes, SAHPRA will require applicants to submit the following documents going forward:

A Clones & Replicas submitted by the same applicant

1. The original application upon which the clone or replica is based as sequence 0000 and the clone or replica application as sequence 0001
2. Declaration of Sameness for a clone or replica, signed by the applicant and endorsed by a commissioner of oaths in M1.*10 (amended template herewith included)*
3. Registration certificate for the registered product in M1.10
4. List of proposed proprietary names or any prior approvals for Naming & Scheduling received from the Authority in M1.0
5. PI/PIL with new proprietary name(s) and application number(s)
6. SCoRE Document

B Replica products submitted by a different applicant (the HCR is a different entity/company)

1. A complete application as sequence 0000
2. Declaration of Sameness for a clone or replica, signed by the applicant and endorsed by a commissioner of oaths in M1.10 *(amended template herewith included)*
3. Letter of Permission from applicant with registered product allowing second applicant to use their data *(template herewith included)*
4. Registration certificate for the registered product in M1.10
5. List of proposed proprietary names with proof of any prior approvals for Naming & Scheduling from the Authority

6. PI/PIL with new proprietary name(s) and application number(s) (for verification)
7. SCoRE Document

Should you have any questions, please feel free to contact us.

Yours sincerely,

Ms Portia Nkambule
Chief Regulatory Officer (CRO)
16 November 2020