**[To be printed on the letterhead of the proposed Holder of the Certificate of Registration]**

[Date]

**Definition**

**For the purpose of this declaration:**

**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.

**To be completed by the applicant and printed on a Company Letterhead:**

|  |  |
| --- | --- |
| Details of The Clone/Replica | Details of The Holder of Certificate of Registration |
| Application for the clone/replica [Insert application number here] [Insert proposed proprietary name here] | [Insert registration number of the innovator/generic product] [Insert proprietary name of the innovator/generic product here] |
| Date of submission  | Date of registration |
| [Next clone/replica] |  |

I, [Insert name here], [Insert position here] at [Insert full company legal name here], hereby confirm the following for application [Insert clone/replica application number here] submitted to the South African Health Products Regulatory Authority (SAHPRA) on [Insert date of submission here]:

The information and documentation provided in support of this application for registration is identical at the time of registration to the SAHPRA registered innovator/generic product except for the name and application number.

NOTE: ANY CONTRAVENTION OF THE ACT WILL BE DEALT WITH AS PER SECTIONS 29 (OFFENCES) AND 30 (PENALTIES) OF ACT 101 OF 1965, AS AMENDED.

Full name of Responsible Pharmacist, job title, company details, email address, telephone number to be completed below.

Declaration (To be completed in the presence of a Commissioner of Oaths)

I………………………………………………………………………………………………….

Job title……………………………………………………………………..

Company name……………………………………………………………………..

Company address ……………………………………………………………………..

Email address……………………………………………………………………..

Tel ……………………….. (w) ……………………………(cell)

Declare under oath in English

……………………………………………………………………………………………………… ……………………………………………………………………………………………………………………… ………………………………………………………………………………………………………………

I understand the contents of this declaration and I consider the prescribed oath as legally binding.

Place: ………………………………….. Date: ………………………..

Time: ……………………………………

Signature: ………………………………………

I certify that the above statement was made and signed before me and that the deponent has acknowledged that he/she understands the content of the statement.

At: …………………………………on …………………day of…………………year…………….

………………………………………………..

Commissioner of Oaths (Details to be provided on physical and postal address e.g. stamp of police station)

………………………………………………….

Force number/Rank/Name - print