*(The Letter of Access shall be drafted on the approved APIMF Holder’s Company letterhead)*

From APIMF holder on headed paper

The Chief Executive Officer

South African Health Products Regulatory Authority

[Include address as per SAHPRA website, https://www.sahpra.org.za/head-office/]

**Letter of access for SAHPRA, in reference to APIMF record [APIMF number, if allocated]**

Name of API: [Fill in here]

APIMF holder: [Fill in here]

The aforementioned APIMF holder hereby authorises the South African Health Products Regulatory Authority (SAHPRA) to refer to and review the aforementioned APIMF record in support of the following new registration application(s) or variation(s) submitted by [Name of applicant] on [planned date of submission]:

Name of product: [Fill in here]

Application number: [Fill in here]

The aforementioned APIMF holder commits to ensure batch-to-batch consistency and to inform [Name of applicant] and SAHPRA of any change in the APIMF.

The aforementioned APIMF holder is hereby informed of and accepts that SAHPRA may share the evaluation reports of the aforementioned APIMF record within the regulator.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature for the APIMF holder (above)