

## RE-SUBMISSION OF BUSINESS AS USUAL (BAU) NEW MEDICINE APPLICATIONS AND VARIATIONS FROM 2018 and 2019

This document is intended to provide communication to applicants with regards to the re-submission of Business-As-Usual (BAU) applications received between 1 February 2018 and 31 July 2019. This will be a “living document” and will be updated.

### Document History

First Publication – Version 1	September 2021
Second Publication – Version 2	October 2021

**BOITUMELO SEMETE-MAKOKOTLELA**  
CHIEF EXECUTIVE OFFICER

## 1. INTRODUCTION

Reference is made to the “Submission of Business-As-Usual(BAU) Registration and Variation applications” communication of July 2019.

BAU adopted the new regulatory processes emanating from the Backlog Clearance Programme (BCP) pilot lessons and findings. BAU new medicine and variations applications received by SAHPRA between 1 February 2018 and 31 July 2019 that had to be re-compiled in line with the new regulatory requirements as published on the SAHPRA website and re-submitted for evaluation from 1 August 2021.

## 2. BAU Re-submissions

For all applications that were received by SAHPRA between 1 February 2018 and 31 July 2019 and were paid for – it must be noted that the electronic application must be submitted to SAHPRA by no later than **31 December 2021**.

This is for all applications where an application number was requested and/or payments have been made accordingly – related then to the period between 1 February 2018 and 31 July 2019, where there was no initial submission(s) or an initial submission was made but was not resubmitted as per communication from SAHPRA after the application was aligned with the new requirements.

For applications where the submission was already received – these will continue with the normal review process, where they have not yet been submitted/resubmitted to SAHPRA the following must be noted:

*Failure to submit the relevant new medicine applications that meets the requirements and in the accepted format by the deadline--*

- *may result in the funds being forfeited.*
- *consequently, should the applicant wish to pursue the registration of the relevant product(s) after the **31 December 2021** deadline, the applicant will be required to restart the registration process (request for a new application number, payment of the current fees, alignment to the current regulatory requirements etc.)*

**Please Note:** This communication only pertains to those BAU applications (**both new applications and variations alike**) made between 1 Feb 2018 and 31 Jul 2019, where the submission has not yet been completed.



---

**CHIEF EXECUTIVE OFFICER**