

RE-SUBMISSION OF BUSINESS AS USUAL (BAU) NEW MEDICINE APPLICATIONS 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

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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 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 2019.

2. BAU Re-submissions

All applications that were received by SAHPRA between 1 February 2018 and 31 July 2019 and were paid for should be submitted to SAHPRA by no later than **30 November 2021**. This includes all payments that were made for new medicine applications 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.

Failure to submit the relevant new medicine applications 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 **30 November 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)



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