

22 June 2021

BACKLOG CLEARANCE PROGRAMME – EXTENSION OF PROJECT

BACKGROUND

One of the critical priorities of the South African Health Products Regulatory Authority (SAHPRA), since its inception in February 2018, has been the clearance of the inherited backlog of new medicine registration and variation applications. At its formation, SAHPRA inherited a backlog of approximately ~16,000 applications (~50% new registration applications and ~50% variation applications).

In light of the above application backlog, SAHPRA set up a dedicated Backlog Clearance Programme with appropriately skilled staff whose sole focus was to clear these applications within a specified timeframe. The Programme went live on 01 August 2019 and the aim was to clear all backlog applications by end August 2021.

BACKLOG CLEARANCE PROGRAMME OUTPUTS TO DATE

As of May 2021, the Backlog Clearance Programme has cleared ~84% of the applications backlog through various mechanisms that included opt-out by applicants, sub-projects focusing on “low-hanging fruit” (Project Starburst & certification variations), clearing the variations applications, rejecting non-compliant applications and approving the re-submitted applications.

New Registration Applications:

A total of 3343 new registration applications (line items) were re-submitted in the Programme (after opt-outs from applicants). To date, 1140 new registration applications have been finalised (not accepted at screening/registered/rejected), with approximately 2200 still to be processed.

Variation Applications:

A total of 2800 variations to registration certificates were finalised during the Certification sub-project prior to the Go-Live of the project, while 2642 Type I variation codes have been finalised (approved/rejected) in the Programme. To date, 509 Type II variation codes have been approved; these were major variations requiring assessment and approval prior to implementation. Thus, in total, 5951 variations have been finalised. 253 Type II variation applications are still pending finalisation.

EXTENSION OF PROJECT

Over the latter part of the project, an increase in finalised new registration applications has been seen, as a result of greater leveraging of reliance practices, as well as optimisation of processes. Of all new registration applications finalised to date, 28% were done during the first 8 months of the project (February – September 2020), while 72% were concluded between October 2020 to the current date (i.e., the last 8 months), thus demonstrating that the processes that have recently been optimised are yielding positive results.

Therefore, in line with the current progress in the Programme, it is estimated that the project will extend to 31 March 2022 (end of 2021/2022 SAHPRA Financial Year).

As mentioned, 2200 new registration applications (equating to 945 master applications) & 253 Type II variation applications remain to be finalised. These will be processed utilising reliance practices insofar as it is possible to ensure expedited review of the remaining applications. The Backlog Clearance Unit has implemented both verified and abridged review for certain qualifying applications.

Furthermore, optimisation of the processes within the Backlog Clearance Programme remains an ongoing priority to ensure the deadline of end March 2022 will be met.

SAHPRA would like to thank all internal and external stakeholders who have assisted with the clearance of the application backlog and wish to ask for understanding and patience as we endeavour to finalise the project by 31 March 2022.

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