



## **SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY**

31 October 2019

### **BACKLOG CLEARANCE PROGRAM NEWSLETTER**

Dear Industry Partners,

It has been a productive three months since the Backlog Clearance Program launched! Although there are areas requiring improvement, we are determined to be operating at scale by the end of the year. As always, we appreciate industry's commitment, exemplified by our weekly call with ITG's Backlog Working Group. Kindly see below an update on the progress to date, as well as some key developments to come.

#### **1. The Backlog Clearance Team**

SAHPRA's Backlog Clearance Team has been on-boarded and trained, with one additional member joining in November 2019. Our most recent new joiners, 4 technical screeners, commenced work earlier this month. The team to date is as follows:

- Project Management Office (PMO):
  - PMO Lead
  - 3 Assistant Managers
- 2 Evaluator Coordinators
- 5 Portfolio Coordinators
- 4 Technical Screeners
- 5 Admin Clerks

The Backlog Clearance Team is being supported by team leaders from "Business As Usual" (BAU). Weekly meetings with BAU representatives are being held to reflect on the progress of the Program, and to discuss roadblocks and key learnings.

By mid-November 2019, all ~60 external evaluators contracted to the Backlog Clearance Program would have been trained by their assigned units, and equipped to start working.

#### **2. New registration resubmissions**

Resubmission window 1 for new registration backlog applications opened on 1 August 2019 and closed on 30 September 2019. This window was for HIV, TB, Hepatitis, and high priority new chemical entity (NCE) applications. More than ~90% of the anticipated applications were received. Thank you to applicants for submitting timeously and making the first window a success! However, over half of applications received were submitted over the last 2 days of the resubmission window. Going forward, the Backlog Clearance Team would like to encourage applicants to resubmit earlier in the window, to avoid bottlenecks in processing.

Passing the applications through administrative screening, including upload to our cloud-based evaluation software, took longer than initially expected, due to technical difficulties. However, these issues have been resolved, and we expect a much quicker progression going forward. Positively, there was a limited number of administrative screening queries, suggesting that high quality dossiers are being submitted. Resubmission window 1 applications are now at different stages of processing, in preparation for evaluation.

Resubmission window 2 (Oncology, and medium priority NCE applications) opened on 1 October 2019, and applicants are reminded to submit qualifying applications by 31 October 2019.

Please note that from resubmission window 3 (4 November 2019 – 29 November 2019) onwards, the reception times will change from 09:00 – 12:00 to **09:00 – 15:00 from Monday to Thursday**. However, the backlog reception will still be closed on Fridays. This will help ensure that all new registration backlog applications are received by the backlog admin clerks, and not by BAU admin clerks. Applicants are reminded to please submit their new registration resubmissions (initial resubmission **and** subsequent responses) to the backlog reception desk (clearly sign-posted), and **not** to the BAU reception desk. Please ensure that your new registration resubmissions have “BACKLOG – NEW REGISTRATION” in large text on the cover page of the application. In addition, please ensure that new registration resubmissions for the Backlog Clearance Program, and subsequent responses, are stamped with the backlog-specific SAHPRA stamp, which states “BACKLOG”.

### **3. Digital Variations Portal**

As you are aware, the Digital Variations Portal will go live in two phases. The first phase will be the “soft launch”, where the Portal will be opened for previously submitted Type I variation applications for notification or evaluation to SAHPRA. Please note that only previously submitted Type C variations reclassified as Type I are included in the soft launch. The “soft launch” is expected to take place in early November after training takes place for Port Health.

Please see attached in this email *Communication to Applicants regarding Variations*, which includes detailed information regarding the submission of variations.

### **4. Update on Inspectorate Action Plan**

Currently, the Inspectorate Unit is progressing with its plan for ~40 sites which SAHPRA is aiming to inspect by the end of the year. The ~40 sites are mainly manufacturing sites and laboratories linked to new registration backlog applications in resubmission windows 1 and 2. To date, 25 sites in this plan have been inspected, 13 of which are soon to be finalised.

### **5. Updated Backlog Clearance Communication**

Please see the latest version (v4) of the Backlog Clearance Communication (BCC) in this email. Please note that the BCC has been edited to focus on new registration applications; please refer to SAHPRA’s *Communication to Applicants regarding Variations* for information on variation application submissions in the Backlog Clearance Program.

### **6. Website update**

Please note that SAHPRA is in the process of revamping our website. The objective is to have the new website up and running by mid-November 2019. All new and revised guidelines will be published, with obsolete guidelines removed. SAHPRA appreciates industry’s patience during the revamp process.

### **7. Concluding Notes**

We have reached several key milestones since “go live” of the Backlog Clearance Program, and look forward to many more. We will continue to provide regular progress updates over time and will continue to incorporate learnings and improvements to our processes along the way. We appreciate your ongoing engagement and support.

Yours faithfully

Davis Mahlatji

**HEAD, BACKLOG CLEARANCE PROGRAM**