SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

1 August 2019

BACKLOG CLEARANCE PROGRAM NEWSLETTER

Dear Industry Partners,

After many months of preparation, I am pleased to announce that SAHPRA's Backlog Clearance Program is officially live! I know many of you have been working tirelessly over recent weeks preparing your new registration applications for resubmission. Thank you for your support and continued cooperation. I can assure you that we at SAHPRA have similarly been making every effort to ensure that we maintain our Backlog Clearance Program commitments to you and, most importantly, to the patients of South Africa. We would like to provide progress updates across all the work streams of the Program.

1. "Go live" preparation

~150 industry representatives attended the Backlog Clearance Program industry workshop on 23 July 2019, where we outlined progress to date and the operational details for the Program. This was followed by a comprehensive Q&A session. Based on the topics discussed, we have updated the Backlog Clearance Communication (BCC) and have attached the latest version to this newsletter. As highlighted at the workshop, the BCC is a live document which will be updated continually.

In terms of quick wins, SAHPRA continues to deliver with ~1,600 variation certificates signed to date by the Acting CEO. SAHPRA is on track to clear the variation certification backlog by the end of the year at the very latest, which will be an important milestone in the Backlog Clearance Program. Project Starburst has also now concluded. A total of 82 applications have been registered. Please see Appendix 1 of this newsletter for the list of all application numbers of products registered through Project Starburst. Please note that if your application number is not on this list, you will need to consolidate, update and resubmit the application in the appropriate resubmission window – even if you have received communication from SAHPRA in the interim. Please include all prior recommendations and approvals from SAHPRA, noting any updates or changes since the communication was received.

SAHPRA's new documents have also been published on our website, including:

- Clinical Guideline
- Professional Information and Patient Information Leaflet Guidelines
- Quality and Bioequivalence Guideline
- SCoRE document
- Variations Addendum
- eCTD and eSubmission guidelines
- eCTD and eSubmission new registration validation templates
- General Information Guideline

- SA Guide to GMP
- Backlog Clearance Communication (BCC)
- Quality & bioequivalence abridged and verified review templates

All documents (barring the BCC) apply to both backlog and BAU applications. SAHPRA will further publish a list of documents which have been replaced/are no longer applicable.

2. Streamlined processes

The Backlog Clearance Program reception is open for business! We are sharing premises with "business as usual" (BAU) at CSIR Building 38A. Please note that the backlog reception keeps different opening hours to the BAU reception. The backlog reception will be open from **9am – 12pm, Monday to Thursday**. If you try to submit an application outside of opening hours, it will not be accepted by any admin clerk, and SAHPRA will bear no responsibility for the application.

In addition, please ensure you are submitting your application in the correct resubmission window. For more information, please refer to the announcement from 8 July 2019. As a last resort, please email backlog@sahpra.org.za for confirmation of your resubmission window.

SAHPRA also wishes to correct any misunderstanding around batch processing by API. You will recall that initial analysis of the backlog revealed that 15 APIs comprise 16% of the new registrations backlog, each averaging 20 applicants. This provided a batch processing opportunity. This batch processing will take place at the time of allocation to evaluators within each resubmission window. Applications of high quality (requiring fewer queries) and with unredacted assessment reports from SAHPRA's recognised regulatory authorities/bodies will support streamlined evaluation processes. At the conclusion of evaluation, registration certificates will be released once a month, on a set day (to be determined) to facilitate pragmatic processes. All signed certificates ready for collection will be included on these days, regardless of API, therapeutic area or resubmission window.

3. Staffing for success

As of end July 2019, more than 110 interviews for the Backlog Clearance Team have been completed. Contracts are being finalised and signed, and we have started to onboard and train successful candidates. Backlog staff will be supported by team leaders from BAU, who will ensure SAHPRA remains "one regulator" throughout the duration of the Program, with quality, safety and efficacy standards upheld.

4. Digitally empowered

SAHPRA's rapid digitisation continues to gather momentum. Cloud-based application evaluation software has been deployed and is undergoing final testing. An internal workflow tracking tool for use by Portfolio Coordinators has been developed and is being finalised. An online, industry-facing tool will be used to allow applicants to track the status of their applications, thereby minimising unnecessary queries to SAHPRA. SAHPRA's new Digital Variations Portal is also in the development phase.

5. Variations

In summary, SAHPRA is adopting the EU Variations Classification Guideline in full, with specific exceptions detailed in the Variations Addendum. The Addendum (and associated processes) will be implemented across both the Backlog Clearance Program and BAU simultaneously. However, the Backlog Clearance Team will only handle registered products with a variation application submitted before 1 February 2018.

To determine products' eligibility for the Backlog Clearance Program, the Type II Deep Dive Survey was released today. The survey will facilitate work planning, and assist in the definition of the Type II resubmission windows of the Backlog Clearance Program. The survey can be accessed via the following link: https://www.113.vovici.net/se/13B2588B6375BAE5.

Applicants are requested to complete one survey for every master registered product which has at least one outstanding Type II variation application submitted *before* 1 February 2018 (i.e., for each product included in the variations backlog). As such, products which only have unfinalised Type II variations submitted *after* 01 February 2018 are outside the scope of this survey. The deadline for completion of all surveys is **13 September 2019**. We understand that a plethora of information has been requested from you in a short time period. However, it is critical that you dedicate sufficient capacity to completing the Deep Dive Survey in full.

Type II variation backlog applications will need to be resubmitted according to pre-defined resubmission windows. The dates of these resubmission windows will be communicated in due course. Three factors will be considered in structuring the resubmission windows:

- General prioritisiation by pharmacological classification / therapeutic area
- Stock-out status: products currently stocked-out or at risk of stock-out
- Tender status: unable to fill the requirements of a tender previously granted

The Digital Variations Portal will be used for all variation applications (across backlog and BAU). Development of the Portal is progressing, but we are not yet in a position to announce launch dates.

Concluding notes

There has been a recent increase in queries sent directly to SAHPRA's Board. Please refrain from contacting the Board for application queries. In future, before an application's resubmission, applicants with questions should review the latest version of the BCC or published guidelines. If their question remains, they should contact the Industry Task Group. Failing that, the team can be contacted at backlog@sahpra.org.za. If an application has already been submitted, the backlog application tracker should be the applicants' first point of call for status updates before contacting the assigned Portfolio Coordinator.

There is no doubt that we are entering an exciting new phase of the Backlog Clearance Program. We will continue to provide regular progress updates over time and will incorporate learnings and improvements to our processes along the way. Thank you for your understanding and continued support as we work to clear the backlog together.

Yours faithfully

Davis Mahlatji
HEAD, BACKLOG CLEARANCE PROGRAM

Appendix 1

Applications registered through Project Starburst
380328
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