SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

27 June 2019

BACKLOG CLEARANCE PROGRAM NEWSLETTER

Dear industry partners,

The launch of the Backlog Clearance Program is rapidly approaching! Thanks to your ongoing engagement and our teams' hard work, we have reached some key milestones over the past month. Please see below an update on nine key aspects of the Backlog Clearance Program.

1. Application survey and resubmission windows

On 15 May 2019, SAHPRA published the comprehensive list of new registration applications that will be evaluated as part of the Backlog Clearance Program. We opened a two-week query period and are currently finalising our responses to those queries. Please note that once we have addressed all queries, the new registrations backlog database will be deemed final. Having an accurate database is key to the successful resubmission of applications, as we will be checking that each application is resubmitted within the applicable window, and with the correct application number.

We have also contacted applicants regarding pending and approved Transfers of Applicancy listed in their backlog Application Surveys. Thank you to those applicants who have responded promptly with the required documentation. Please note that SAHPRA, at its discretion, may choose to open a submission period for additional Transfers of Applicancy at a later point in the Backlog Clearance Program. Requests for transfers received outside of this period will not be considered.

In addition, we have created the overall structure of resubmission windows for the Backlog Clearance Program. This prioritises unmet public health need, but is also designed to be pragmatic, given the size of SAHPRA's inherited backlog and the rapid timeframe in which it is to be cleared.

As previously communicated, resubmission windows will be prioritised by therapeutic area / types of medicines. We are pleased to have announced the first resubmission window:

- HIV
- TB
- Hepatitis
- Vaccines

Please refer to our announcement from 20 June 2019 entitled *"Backlog Clearance Program: First resubmission window"* for more information.

Over the coming weeks, we will finalise all remaining resubmission windows, including the allocation of APIs per window, through rigorous internal review and consultation with the

National Department of Health. Sufficient time will be provided to industry to consolidate, update, and resubmit their applications.

2. Guidelines and industry engagement

Thank you for the comments received on the second tranche of draft documents published in May. Despite the tight deadline, industry provided considerable insight, and it is much appreciated. By early July, SAHPRA will publish final versions of the documents. Following this, SAHPRA will hold an industry workshop to discuss any remaining operational questions you may have. Further details will be provided. Please ensure that your organisations are able to provide additional internal training to ensure your resubmitted applications are compliant with new documents and standards.

3. European Medicines Agency (EMA) Decentralised Procedure

SAHPRA is pleased to announce that the EMA Decentralised Procedure has been added to the list of recognised regulatory authorities' procedures for reliance-based evaluations. The inclusion of the Decentralised Procedure will enable the use of reliance for many more generic applications.

4. Publication of PIs and PILs on SAHPRA website

As previously announced, SAHPRA is implementing new processes to facilitate publication of latest-approved Professional Information (PI) and Patient Information Leaflets (PILs) for South African medicines on the SAHPRA website. This is expected to provide broad benefits, particularly the enablement of informed clinical treatment for the South African public. SAHPRA has started to contact the first companies to update the PI/PILs of priority innovator medicines to the latest EMA format (as per SAHPRA's draft PI/PIL guidelines). We appreciate the support shown so far for this important project, and look forward to timely responses from innovator companies. For more information on this topic, please refer to our communication from 14 June 2019 entitled *"Publication of South African PIs and PILs on the SAHPRA website to enhance public access to medicines information"*.

5. GMP inspection update

As you will recall, SAHPRA conducted a GMP survey to record up-to-date information on South African manufacturing sites and associated approvals. Companies were required to submit this survey by 25 January 2019 along with the Application Survey and an applicant declaration. The objectives of this survey were to enable SAHPRA to provide preliminary GMP approval to applications prior to allocation and develop a work plan of which manufacturing sites require inspection as part of the Backlog Clearance Program. Based on the survey results, SAHPRA has designed a revised inspection schedule.

Unfortunately, not all companies submitted completed surveys, and we would like to reiterate the importance of providing SAHPRA with the GMP status of sites relevant to backlog applications. SAHPRA's redesigned evaluation processes require GMP approval for the relevant site(s) to be obtained prior to resubmission of applications. If this is not the case, your application may be rejected upon screening. If you have applications in the new registration backlog, and did not submit a completed GMP survey, please email backlog@sahpra.org.za by 5pm on 1 July 2019 and further instructions will be provided as to what data need to be

submitted.

6. New variations process

Last week, SAHPRA released the Overview Survey for Type II variations, to enable our work-planning for backlog variation applications requiring evaluation. The deadline for completion of the Overview Survey is 3 July 2019. Please reach out to backlog@sahpra.org.za if you did not receive the survey and have variation application(s) in the backlog. We are also making good progress regarding the digital variations portal for Type IA and IB backlog applications, and will communicate next steps once the portal is up and running.

7. Variation certificates

SAHPRA's re-engineered variation certification process continues to progress efficiently, and we have cleared over 1 000 variation certificates! This great accomplishment highlights the potential of re-engineered processes and new levels of partnership with applicants.

8. Project Starburst

Project Starburst is continuing steadily. To date, 76 products have been registered, with an additional 7 applications ready to be registered. The aim is to complete all Starburst applications by mid-July.

As communicated previously, we will **not** be contacting applicants regarding the inclusion of their application for Project Starburst. Over 50% of the ~500 applications received for Starburst were ineligible, and we do not have the capacity to reply to each unsuccessful application. If your application was successful, you will receive an evaluation query or final recommendation from us by mid-July. If not, your application will need to be resubmitted as part of the Backlog Clearance Program.

9. Recruitment for the Backlog Clearance Team

We had an overwhelming response to the positions advertised for the Backlog Clearance Program. Interviews with short-listed candidates commenced last week, and will conclude by mid-July. Over the next two months we will onboard and train successful candidates, to ensure a strong staff complement for the launch of the Backlog Clearance Program in August.

Concluding notes

We have reached several key milestones over the past month, with more to come before the Backlog Clearance Program's go-live in August. As always, we appreciate your ongoing engagement and support over this time.

Yours faithfully

Davis Mahlatji
HEAD, BACKLOG CLEARANCE PROGRAM