SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

2 October 2019

ANNOUNCEMENT ON REQUIREMENTS FOR NON-RESUBMISSION OF NEW REGISTRATION BACKLOG APPLICATIONS

Dear industry partners,

As you are aware from previous communication, SAHPRA requires the resubmission of **all** new registration backlog applications that were unregistered as of 1 August 2019, excluding pilot applications. Applications must be resubmitted in their designated resubmission window.

In an effort to expedite registrations, the Backlog Clearance Program will make **one** exception to the above rule. A new registration backlog application for which all approvals were received by 20 September 2019 will **not** need to be resubmitted, and will be registered through existing "business as usual" processes.

To clarify, final approvals from **all** units need to have been received by the applicant by 20 September 2019 (inclusive):

- Pharmaceutical and Analytical, **and**
- Clinical, **and**
- Naming, **and**
- Scheduling, **and**
- Inspectorate

The definition of each approval is as follows:

Pharmaceutical & Analytical: Official, signed approval letter stating that the Pharmaceutical and Analytical Committee has completed the evaluation of the product in terms of quality.

Clinical: Official, signed approval letter stating that the Clinical Committee has completed the evaluation of the Professional Information (PI) and Patient Information Leaflet (PIL) in terms of safety and efficacy, and that the PI and PIL have been forwarded to Operations and Administration.

Naming: Official, signed proprietary name council resolution stating that the proprietary name was found to be acceptable.

Scheduling: Official, signed scheduling recommendation with designated schedule listed.

Inspectorate: Compliant GMP certificate or final resolution letter from SAHPRA not older than 1 August 2016. Regrettably, sites with GMP certification from a PIC/S member, Recognised Regulatory Authority, or Zazibona will **not** automatically be considered an approval as this needs to be checked and confirmed during the evaluation process.

Please note that if **any** change has been made to the product which would invalidate even one of the aforementioned approvals, the application must be resubmitted. As biological medicines are excluded from the Backlog Clearance Program, this announcement does not apply to biological medicines.

For a product to qualify for non-resubmission, please submit all the aforementioned approvals and a signed declaration letter (Appendix 1 of this announcement) to backlog@sahpra.org.za by 10 October 2019. Please make the subject of your email "Non-resubmission: {Application number}". The Backlog Clearance Team will confirm that your submission

Kind regards,

DAVIS MAHLATJI

Head, Backlog Clearance Program

Appendix 1: Declaration for non-resubmission of a new registration backlog application

{Product name} **–** {Application number}

I, {Full name}, {Job title} at {Company's full legal name}, hereby confirm the following for application {Application number} for product {Proposed product name} originally submitted to the South African Health Products Regulatory Authority (SAHPRA) or the Medicines Control Council (MCC) on {Original submission date}:

- The information and documentation provided in support of this submission for registration is true and correct.
- All relevant approvals, in the form designated by SAHPRA, were received for this application by 20 September 2019.
- No changes have been made to the application approved by SAHPRA or the MCC which would impact the prior approvals.

If any of the above confirmations are found by SAHPRA to be incorrect and/or misleading, SAHPRA reserves the right to reject the application.

Full name of Responsible pharmacist / Person authorised to communicate with the authority:
Job title, company:
Email address:
Telephone number:

Signature:

Date: Place: