

COMMUNICATION TO STAKEHOLDERS

Issue No.: PV03-2025/26

29 October 2025

Request for Submission of Latest PSMF and Product/PV Resourcing Information

In line with **SAHPGL-CEM-PV-02_v2 (Pharmacovigilance System Guideline)**, subsection 5.5.5, which states: *“The Applicant/HCR should submit the PSMF electronically, within 14 calendar days after the receipt of the request from the Authority,”* SAHPRA hereby requests the following from **all** HCRs/Applicants:

1. Latest Pharmacovigilance System Master File (PSMF) (electronic copy), which must clearly:
 - indicate the total number of individuals working in the Pharmacovigilance department (in the relevant section/annexure), and
 - list all actively registered products and clearly indicate products that are *marketed* in the Republic of South Africa (RSA) (in the relevant section/annexure).
2. Timeline: Please submit the required documents within 14 (fourteen) calendar days by the 12th of November 2025.
3. Submission route: email to GVP@sahpra.org.za with subject: **“PSMF & Product/PV Resourcing – [Company Name]”**
4. For queries, contact:
 - SAHPRA PV Manager at mafora.matlala@sahpra.org.za
 - SAHPRA Inspectorate Manager at samu.motshitela@sahpra.org.za

Sincerely,

Boitumelo Semete-Makokotlela

SIGNIFLOW

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer (CEO)
SAHPRA