

COMMUNICATION TO STAKEHOLDERS

Issue No.: HPA16-2025/26

06 August 2025

SAHPRA Engagement Portal – Launch Update

DOCUMENT HISTORY

First Publication – Version 1	06 March 2024
Version 2	26 April 2024
Version 3	26 April 2024
Version 4	27 May 2024
Version 5	08 July 2024
Version 6	25 September 2024
Version 7	24 October 2024
Version 8	28 October 2024
Version 9	16 January 2025
Version 10	22 January 2025
Version 11	24 February 2025
Version 12	11 March 2025
Version 13	12 June 2025
Version 14	18 July 2025
Version 15	06 August 2025

INTRODUCTION

Dear Applicants,

Following the communication and internal engagement on the interpretation of the Fees Gazette for Variation fees, the South African Health Products Regulatory Authority (SAHPRA) will apply the following calculation approach on fees to allow the new fee gazette to then adequately granulate the position on individual evaluation requests and bundled related submissions, going forward.

- The Type IA and IAIN submissions will limit three (3) evaluation changes in one submission.

- The current calculation module and proposed calculation module structure is set out below :

• **Chairperson: Dr Thapelo Motshudi • Vice-Chairperson: Prof Glenda Gray**
• **Dr Alfred Kgasi • Dr Chevon Clark • Dr Johanna Gouws • Dr Tobeka Boltina**
• **Ms Mmatebogo Nkoenyane • Mr Anthony Ngcezula • Mr Rajesh Mahabeer**
• **Mr Nkosenhle Ngongoma • Mr Moses Moselekwa**
CEO: Dr Boitumelo Semete-Makokotlela

Next Steps

- a) The calculation module development change has been requested, and this will be deployed into production on 22 August 2025.
- b) If you have an urgent submission, you can proceed to process payment based on the current calculated fee, and this will be included in the credit process that will assess all transactions between 1 April 2025 and 22 August 2025.
- c) SAHPRA's Finance Unit will reconcile transactions for variations submissions made from 1 April 2025 to date and will engage applicants between August – October in a phased manner to process credits where it is relevant.
- d) *Do not submit any requests to SAHPRA's Finance Unit – you will be contacted with the credit details in due course.***
- e) The new Fee Gazette input is being provided to the Finance Unit to ensure any ambiguity going forward is eliminated and a clear and simplified fee structure is then included in the new Gazette – aligned with other reference National Regulatory Authority fee structure approaches.

Regards,




Christelna Reynecke

Chief Operating Officer

SAHPRA

Date: 06 August 2025