



COMMUNICATION TO STAKEHOLDERS

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SAHPRA Engagement Portal – Launch Update

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Version 11	24 February 2025	
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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.

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- Dr Alfred Kgasi Dr Chevon Clark Dr Johanna Gouws Dr Tobeka Boltina
- Ms Mmatebogo Nkoenyane Mr Anthony Ngcezula Mr Rajesh Mahabeer
 - Mr Nkosenhle Ngongoma
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- Type IB evaluation changes submission will limit to two (2) evaluation changes in one submission. And, to also note clearly that this is per strength.
- For Type II the eCTD submission requirement of 1 Type II will remain.

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

In	e current calculation module and pro	posed ca			Daule Str	ucu	ure i	s set ou	Lbelow
				URRENT				m Module	
			calcula	tion Module			until n	ew Gazette	
Type IA Scenario									
	Sumbission 1 per Application number (i.e. per strength)	(Q) B.II.d.1.c	R	3 500.00					
		(Q) B.II.d.1.d	R	3 500.00				0.500.00	
		(Q) B.II.d.2.a	R	3 500.00	D 105	20.00	R	3 500.00	D 2 500 00
	Combined and Application and the Company of the Com	(0) D II 1 0 1	_	2 500 00	R 1050	00.00			R 3 500.00
	Sumbission 2 per Application number (i.e. per strength)	(Q) B.II.d.2.d	R	3 500.00					
		(Q) B.II.d.N1.b		3 500.00			_	2 500 00	
		(Q) B.II.d.N1.c	R	3 500.00	R 1050	00.00	R	3 500.00	R 3 500.00
	Sumbission 3 per Application number (i.e. per strength)	(Q) B.II.e.1.a.3.	R	3 500.00	K 1050	30.00	R	3 500.00	R 3 500.00
	Sumbission 3 per Application number (i.e. per strength)	(Q) B.II.e. I.a.s.	. K	3 300.00	R 350	00.00	K	3 300.00	R 3 500.00
					K 330	30.00			K 3 300.00
	Same fee will apply for second strength and third strength etc.								
	same ree will apply for second strength and thind strength etc.								
			CI	URRENT			Interir	m Module	
				tion Module				ew Gazette	
Гуре IB Scenario									
	Sumbission 1 per Application number (i.e. per strength)	A.3	R	5 600.00					
		A.4	R	5 600.00			R	5 600.00	
					R 11 20	00.00			R 5 600.00
	Sumbission 2 per Application number (i.e. per strength)	A.7	R	5 600.00					
		B.I.a.1.a	R	5 600.00			R	5 600.00	
					R 11 20	00.00			R 5 600.00
	Sumbission 3 per Application number (i.e. per strength)		R	5 600.00			R	5 600.00	
		B.I.a.1.h			R 560	00.00			R 5 600.00
	Same fee will apply for second strength and third strength etc.								
				URRENT				m Module	
Tuna II Caanaria			caicuia	tion Module			untii n	ew Gazette	
Type II Scenario	Sumbission 1 per Application number (i.e. per strength)	B.II.e.7.c	R	13 800.00					
	Sumbission i per Application number (i.e. per strength)	B.II.e. 7.0	K	13 800.00			R	13 800.00	
					R 1380	00.00	IX.	13 600.00	R 13 800.00
					K 100	50.00			K 15 000.00
			CI	URRENT			Interir	m Module	
				tion Module				ew Gazette	
Related Variation	s submission								
	Sumbission 1 per Application number (i.e. per strength) -								
	applying the bundling rule of 3 Type IA, 2 Type IB and 1 Type II								
	per submission	(Q) B.II.d.1.c	R	3 500.00			R	3 500.00	
		(Q) B.II.d.1.d	R	3 500.00			-		
		(Q) B.II.d.2.a	R	3 500.00					
		A.7	R	5 600.00			R	5 600.00	
		B.I.a.1.a	R	5 600.00					
		B.II.e.7.c	R	13 800.00			R	13 800.00	
			R	35 500.00			R	22 900.00	

[•] Dr Alfred Kgasi • Dr Chevon Clark • Dr Johanna Gouws • Dr Tobeka Boltina

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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

Regnecke

Chief Operating Officer

SAHPRA

Date: 06 August 2025

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