South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

SAHPRA FINANCE May 2021

GUIDELINE ON THE PAYMENT OF FEES TO SAHPRA

This document has been prepared to serve as a guideline to enable the direct payment of fees into the bank account of SAHPRA and must be read together with the relevant Fees Regulations and the General Information guideline.

Version 1 - Date of release for publication	30 November 2005
Version 2 - Implementation date	13 July 2009
Version 2.1 – Amendment of fax number	October 2012
Version 3 – Change of bank account name to SAHPRA	November 2018
Version 4 – Alignment to SAHPRA template	March 2020
Version 5 – Implementation of Fee Categorisation	November 2020
Version 6 – Reference spacing and timeframes	May 2021
Version 7 – Electronic applications (SAHPRA Service Desk)	September 2022

Dr B Semete-Makokotlela

CHIEF EXECUTIVE OFFICER

1 Guideline on How to Process Payments

1.1 This guideline serves to only address the *processing of payments* for services and refunds. Guidelines for the *processing of service applications* can be found on https://www.sahpra.org.za/guidelines/ under each relevant section.

1.2 SAHPRA has embarked on a process to phase in an electronic application system through the SAHPRA Service Desk (Quantum) which will create unique reference numbers for the application and relevant payment. The SAHPRA Service Desk payment instructions and referencing should be followed for electronic applications processed thought his online application portal.

1.3 SAHPRA will communicate to industry when specific application workstreams will be processed through the SAHPRA Service Desk.

1.4 When applying for services, applicants are encouraged to first download and familiarise themselves with the following documents on the SAHPRA website:

- Gazette Fee Schedule
- Relevant Application Guideline
- Applicants Cover Page
- SAHPRA Fee Categorisation Guideline No.17.5 (Annexure A) to this guideline

1.5 This will ensure that the appropriate fees are paid for the appropriate services and that the required documents have been e-mailed to the appropriate unit(s).

1.6 Once the relevant services have been identified, applicants must then complete the Applicants Cover Page identifying the services required.

1.7 When making payments for identified services, the following are to be adhered to in ensuring efficient and effective allocation of payments:

- Payments are to be referenced in accordance with the SAHPRA Fee Categorisation Guideline (Annexure A) if the application is not process through the SAHPRA Service Desk (Quantum).
- If the applicable bank limits reference spacing, follow the sequence listed in Annexure A as far as the limitation allows. Spacing and dashes (/) may be omitted
- Fee payments may be transferred directly into the bank account of SAHPRA via an electronic or manual deposit process.
- No cheque payments will be accepted.
- For administrative control purposes, it should be one payment per service required. Therefore, no bulk payments for multiple services will be accepted.
- Payment should only be made once the application and required dossiers are ready for submission. Payments do not have to be made upon request of an application number. However, the applications and required dossiers should be submitted within a reasonable time upon receipt of an application number or as specified in the relevant application guideline.

1.8 As soon as the fee payment has been made, the following should be attached and sent via email to SAHPRA Finance at pop@sahpra.org.za and copy the relevant unit(s) processing the application:

- Proof of Payment (with SAHPRA References in Categorisation Guideline) from applicants' bank account.
- Applicants Cover Page

1.9 If the proof of payment has not been submitted, or no details to identify the payment reference as per this guideline and any further attempts to clear these payments fail after 12 months, any liability for SAHPRA to refund these payments will be forfeited.

1.10 If a payment has been received without an application, the applicant will be notified to submit the required application within 14 working days, failing which, the amount will be forfeited.

1.11 SAHPRA will consider special requests for extensions as outlined below:

- Requests for extensions to submit an application should be made to the relevant unit(s) processing the applications before the expiry of the 14-working day period.
- Extensions will only be granted on exceptional cases where non-submission of an application could not be made due to unforeseen circumstances or technical reasons.
- A response on the extension requested will be provided within three (3) working days.

1.12 Requests for refunds should be submitted in line with Annexure B attached to this guideline.

1.13 Payment and pro forma invoice queries and requests can be directed to finance@sahpra.org.za or 012 501 0323

2 Bank details

Account name:	SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
Special name:	The Medicines Control Council
Account type:	Cheque/Current Account
Account number:	40-5939-2080
Bank:	ABSA
Bank Branch Code:	632005
Bank physical address:	240 VERMEULEN STREET, PRETORIA, 0001, SOUTH AFRICA
Swift Code:	ABSAZAJJ

3 Amendment History

Date	Reason for update	Version
May 2021	• Par. 1.5 • Par. 1.7 – 1.10	Version 6

	• Payment reference example update	
September 2021	• Par. 1.2 and 1.3 • Par. 1.7 • Reference to electronic applications through the SAHPRA Service Desk	

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Annexure A

SAHPRA Fee Categorisation Guideline No.17.5

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE (14 characters)
Health Products Authorisation	Human	Amendment of Entry in the Register	HU RG	GLEDMARK	HURG/GLEDMARK
Health Products Authorisation	Biological	Amendment of Entry in the Register	BI RG	GLEDMARK	BIRG/GLEDMARK
Health Products Authorisation	Complementary	Amendment of Entry in the Register	C RG	GLEDMARK	CMRG/GLEDMARK
Health Products Authorisation	Veterinary	Amendment of Entry in the Register	VT RG	GLEDMARK	VTRG/GLEDMARK
Health Products Authorisation	Retention Fees	BIO Registration Retention	BI RT	GLEDMARK	BIRT/GLEDMARK
Health Products Authorisation	New Applications Biological	Evaluation	BI + APPLICATION NO.	NEUROGEN	BI540029/NEURO
Health Products Authorisation	New Applications Complementary	Evaluation	CM + APPLICATION NO.	NEUROGEN	CM550395/NEURO
Health Products Authorisation	New Applications Human	Evaluation	HU + APPLICATION NO.	NEUROGEN	HU540029/NEURO
Health Products Authorisation	New Applications Veterinary	Evaluation	VT + APPLICATION NO.	NEUROGEN	VT19/21/NEUROG
Health Products Authorisation	Retention Fees	HUMAN Registration Retention	HU RT	GLEDMARK	HURT/GLEDMARK
Health Products Authorisation	New Applications Biological	New Registration	BI + APPLICATION NO.	NEUROGEN	BI564230/NEURO
Health Products Authorisation	New Applications Complementary	New Registration	CM + APPLICATION NO.	NEUROGEN	CM550395/NEURO
Health Products Authorisation	New Applications Human	New Registration	HU + APPLICATION NO.	NEUROGEN	HU540488/NEURO
Health Products Authorisation	New Applications VET	New Registration	VT + APPLICATION NO.	NEUROGEN	VT19/34/NEUROG
Health Products Authorisation	Biological	Transfer of certificate of registration	BTR + APPLICATION NO.	GLEDMARK	BTR564231/GLED
Health Products Authorisation	Complementary	Transfer of certificate of registration	CTR + APPLICATION NO.	GLEDMARK	CTR557823/GLED
Health Products Authorisation	Human	Transfer of certificate of registration	HTR+ APPLICATION NO.	GLEDMARK	HTR563212/GLED
Health Products Authorisation	Veterinary	Transfer of certificate of registration	VTR+ APPLICATION NO.	GLEDMARK	VTR19/21/GLEDM
Health Products Authorisation	Retention Fees	VET Registration Retention	VT RT	GLEDMARK	VTRT/GLEDMARK
Inspectorate	License Renewal	Exporter	INS RN	REPAXEL	INSRN/REPAXEL
Inspectorate	License Renewal	Importer	INS RN	REPAXEL	INSRN/REPAXEL
Inspectorate	License Renewal	Distribution	INS RN	REPAXEL	INSRN/REPAXEL
Inspectorate	License Renewal	Wholesale	INS RN	REPAXEL	INSRN/REPAXEL
Inspectorate	License Renewal	Manufacturer	INS RN	REPAXEL	INSRN/REPAXEL
Inspectorate	New Licence	Distribution	INS NL	REPAXEL	INSNL/REPAXEL
Inspectorate	New Licence	Export	INS NL	REPAXEL	INSNL/REPAXEL
Inspectorate	New Licence	Import	INS NL	REPAXEL	INSNL/REPAXEL
Inspectorate	New Licence	Wholesale	INS NL	REPAXEL	INSNL/REPAXEL
Inspectorate	New Licence	Manufacturer	INS MN	REPAXEL	INSMN/REPAXEL
Inspectorate	Retention Fees	Licence Retention	INS RT	REPAXEL	INSRT/REPAXEL
Inspectorate	Licence Issuing	Distribution	INS LI	BOTTA LABS	INSLI/BOTTALAB
Inspectorate	Licence Issuing	Exporter	INS LI	BOTTA LABS	INSLI/BOTTALAB
Inspectorate	Licence Issuing	Importer	INS LI	BOTTA LABS	INSLI/BOTTALAB
Inspectorate	Licence Issuing	Manufacturer	INS LI	BOTTA LABS	INSLI/BOTTALAB
Inspectorate	Licence Issuing	Wholesale	INS LI	BOTTA LABS	INSLI/BOTTALAB
Inspectorate	Inspections	Local Good Wholesale Practice (Est based on Max 16 hrs)	W + Inspection No	EXTRAZENEC	W134/2019/PSI

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE (14 characters)
Inspectorate	Certificates	Certificate of Pharmaceutical Product	PH CT	RANDBINDO	PHCT/RANDBINDO
Inspectorate	Certificates	GMP Certificate	GMP CT	RANDBINDO	GMPCT/RANDBIND
Inspectorate	Evaluation Review	Once Off Deviations	INS DV	RANDBINDO	INSDV/RANDBIND
Inspectorate	Evaluation Review	Post Importation Testing Exemption	INS PIT	RANDBINDO	INSPIT/RANDBIN
Inspectorate	Inspections	Desktop Review	INS DES	RANDBINDO	INSDES/RANDBIN
Inspectorate	Licence Amendment	Distribution	INS ADS	RANDBINDO	INSADS/RANDBIN
Inspectorate	Licence Amendment	Exporter	INS AEX	RANDBINDO	INSAEX/RANDBIN
Inspectorate	Licence Amendment	Importer	INS AIM	RANDBINDO	INSAIM/RANDBIN
Inspectorate	Licence Amendment	Manufacturer	INS AMA	RANDBINDO	INSAMA/RANDBIN
Inspectorate	Licence Amendment	Wholesale	INS AWH	RANDBINDO	INSAWH/RANDBIND
Regulatory Compliance	Regulatory Compliance	Cannabis Inspections	CANI	CANNIBUS ASSOCIATION	CANI/CANNIBUSA
Regulatory Compliance	Regulatory Compliance	Export Permit	LEU+number	JACKSON & JACKSON	LEU/3169/2019
Regulatory Compliance	Regulatory Compliance	Export Authorisation	LEU+number	JACKSON & JACKSON	LEU/3349/2019
Regulatory Compliance	Regulatory Compliance	Import Authorisation	LEU+number	JACKSON & JACKSON	LEU/3349/2012
Regulatory Compliance	Regulatory Compliance	Import permit	LEU+number	JACKSON & JACKSON	LEU/2249/2019
Regulatory Compliance	Regulatory Compliance	Manufacturing Permits	LEU+number	JACKSON & JACKSON	LEU/3349/2019
Regulatory Compliance	Regulatory Compliance	Possessions	S22A	POL	S22A/POL
Regulatory Compliance	New Licence	Cannabis Applications	CANA	VETAV	CANA/VETAV
Inspectorate	Inspections	Local Good Clinical Practice	C + Inspection No	PILMED	C196/2020/PSI
Inspectorate	Inspections	Local Good Manufacturing Practice	M + Inspection No	PILMED	M396/2019/PSI
Inspectorate	Inspections	International Good Clinical Practice	C + Inspection No	CLYDUS	C196/2019/PSI
Inspectorate	Inspections	International Good Manufacturing Practice	M + Inspection No	CLYDUS	M136/2019/PSI
Complementary	Licence Amendment	Manufacturer	CM AMA	BOTTA LABS	CMAMA/BOTTALAB
Complementary	Licence Amendment	Wholesale	CM AWH	BOTTA LABS	CMAWH/BOTTALAB
Biological Medicines	Evaluation Review	Post Importation Testing Exemption	BI PIT	ADHOC	BIPIT/ADHOC
Biological Medicines	Evaluation Review	Once Off Deviations	BI DV	ADHOC	BIDV/ADHOC
Biological Medicines	NCL Lot Release	NCL Lot Release	NCL	ADHOC	NCL/ADHOC
Biological Medicines	Post Registration Amendments	Type 1A	BI T1	ADHOC	BIT1/ADHOC
Biological Medicines	Post Registration Amendments	Type II Level 3	BI T2	ADHOC	BIT2/ADHOC
Biological Medicines	Post Registration Amendments	Type 1B	BI T1	ADHOC	BIT1/ADHOC
Biological Medicines	Post Registration Amendments	Type II Level 2	BI T2	ADHOC	BIT2/ADHOC
Biological Medicines	Post Registration Amendments	Type II Level 1	BI T2	ADHOC	BIT2/ADHOC
Complementary	Evaluation Review	Once Off Deviations	CM DV	ADHOC	CMDV/ADHOC
Complementary	Inspections	Desktop Review	CM DES	ADHOC	CMDES/ADHOC
Complementary	Licence Amendment	Distribution	CM ADS	ADHOC	CMADS/ADHOC
Complementary	Licence Amendment	Exporter	CM AEX	ADHOC	CMAEX/ADHOC
Complementary	Licence Amendment	Importer	CM AIM	ADHOC	CMAIM/ADHOC
Veterinary	Section 21	Use of Unregistered Medicine	VTS21	Dr A Banks	VTS21/ABANKS
Human	Section 21	Use of Unregistered Medicine	HMS21	Dr A Ndlovu	HMS21/ANDLOVU
Complementary	Section 21	Use of Unregistered Medicine	CMS21	Dr A Williams	CMS21/AWILLIAM
Complementary	Licence Issuing	Distribution	CM LI	NEATCARE	CMLI/NEATCARE
Complementary	Licence Issuing	Exporter	CM LI	NEATCARE	CMLI/NEATCARE
Complementary	Licence Issuing	Importer	CM LI	NEATCARE	CMLIC/NEATCARE
Complementary	Licence Issuing	Manufacturer	CM LI	NEATCARE	CMLIC/NEATCARE

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE (14 characters)
Complementary	Licence Issuing	Wholesale	CM LI	NEATCARE	CMLI/NEATCARE
Complementary	License Renewal	Exporter	CM RN	NEATCARE	CMRN/NEATCARE
Complementary	License Renewal	Importer	CM RN	NEATCARE	CMRN/NEATCARE
Complementary	License Renewal	Distribution	CM RN	NEATCARE	CMRN/NEATCARE
Complementary	License Renewal	Wholesale	CM RN	NEATCARE	CMRN/NEATCARE
Complementary	License Renewal	Manufacturer	CM RN	NEATCARE	CMRN/NEATCARE
Complementary	New Licence	Distribution	CM NLD	BANTAXY	CMNLD/BANTAXY
Complementary	New Licence	Export	CM NLE	BANTAXY	CMNLE/BANTAXY
Complementary	New Licence	Import	CM NLI	BANTAXY	CMNLI/BANTAXY
Complementary	New Licence	Wholesale	CM NLW	BANTAXY	CMNLI/BANTAXY
Complementary	New Licence	Manufacturer	CM NLM	BANTAXY	CMNLM/BANTAXY
Complementary	Retention Fees	Licence Retention	CM RT	BANTAXY	CMRT/BANTAXY
Pharmaceutical and Analytical	Post Registration Amendments	Type 1A	PA T1	VETAV	PAT1/VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type II Level 3	PA T2	VETAV	PAT2/VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type 1B	PA T1	VETAV	PAT1/VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type II Level 2	PA T2	VETAV	PAT2/VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type II Level 1	PA T2	VETAV	PAT2/VETAV
Human	Clinical Trials	Protocol Amendments Administrative	HU PAA	TABPHARM	HUPAA/TABPHARM
Human	Clinical Trials	Other Clinical Trials	HU CLT	TABPHARM	HUCLT/TABPHARM
Human	Clinical Trials	Protocol Amendments Technical	HM PAT	TABPHARM	HMPAT/TABPHARM
Human	Clinical Trials	Clinical Trials - Postgrad Study	HM PGS	TABPHARM	HMPGS/TABPHARM
Human	Clinical Trials	Clinical Trials - Bioequivalence study	HM BIS	TABPHARM	HMBIS/TABPHARM
Human	Clinical Trials	Clinical Trials - Industry	HM IND	TABPHARM	HMIND/TABPHARM
Human	Post Registration Amendments	Type 1A	CLN T1	TABPHARM	CLNT1/TABPHARM
Human	Post Registration Amendments	Type II Level 3	CLN T2	TABPHARM	CLNT2/TABPHARM
Human	Post Registration Amendments	Type 1B	CLN T1	TABPHARM	CLNT1/TABPHARM
Human	Post Registration Amendments	Type II Level 2	CLN T2	TABPHARM	CLNT2/TABPHARM
Human	Post Registration Amendments	Type II Level 1	CLN T2	TABPHARM	CLNT2/TABPHARM
Veterinary	Clinical Trials	Other Clinical Trials	VT CLT	VIRCAB	VTCLT/VIRCAB
Veterinary	Clinical Trials	Clinical Trials - Bioequivalence study	VT CLT	VIRCAB	VTCLT/VIRCAB
Medical Devices	Certificates	Certificate of Free Sale	MD CT	REPAXEL	MDCT/REPAXEL
Medical Devices	Clinical Trials	Clinical Trials - Industry	MD CTI	REPAXEL	MDCTI/REPAXEL
Medical Devices	Clinical Trials	Clinical Trials - Postgrad Study	MD PGS	REPAXEL	MDPGS/REPAXEL
Medical Devices	Inspections	Desktop Review	MD DES	REPAXEL	MDDES/REPAXEL
Medical Devices	Evaluation Review	Once Off Deviations	MD DV	REPAXEL	MDDV/REPAXEL
Medical Devices	Clinical Trials	Other Clinical Trials	MD CLT	REPAXEL	MDCLT/REPAXEL
Medical Devices	Clinical Trials	Protocol Amendments Administrative	MD PAA	REPAXEL	MDPAA/REPAXEL
Medical Devices	Clinical Trials	Protocol Amendments Technical	MD PAT	REPAXEL	MDPAT/REPAXEL
Medical Devices	Registration	Administrative Amendment Class A, B, C and D	MD EVA	FGPHARMA	MDEVA/FGPHARMA
Medical Devices	License Renewal	Distribution	MD RND	FGPHARMA	MDRND/FGPHARMA
Medical Devices	New Licence	Distribution	MD NLD	FGPHARMA	MDNLD/FGPHARMA
Medical Devices	New Licence	Export	MD NLE	FGPHARMA	MDNLE/FGPHARMA
Medical Devices	New Licence	Import	MD NLI	FGPHARMA	MDNLI/FGPHARMA
Medical Devices	License Renewal	Importer	MD RNI	FGPHARMA	MDRI/FGPHARMA

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE (14 characters)
Medical Devices	License Renewal	Manufacturer	MD RNM	FGPHARMA	MDRNM/FGPHARMA
Medical Devices	New Licence	Manufacturer	MD NLM	FGPHARMA	MDNLM/FGPHARMA
Medical Devices	License Renewal	Wholesale	MD RNW	FGPHARMA	MDRNW/FGPHARMA
Medical Devices	New Licence	Wholesale	MD NLW	FGPHARMA	MDNLW/FGPHARMA
Medical Devices	Licence Amendment	Distribution	MD DIS	PHARMAK	MDDIS/PHARMAK
Medical Devices	Licence Issuing	Distribution	MD LID	PHARMAK	MDLID/PHARMAK
Medical Devices	Licence Amendment	Exporter	MD EXP	PHARMAK	MDEXP/PHARMAK
Medical Devices	Licence Issuing	Exporter	MD LIE	PHARMAK	MDLIE/PHARMAK
Medical Devices	License Renewal	Exporter	MD RNE	PHARMAK	MDRNE/PHARMAK
Medical Devices	Licence Amendment	Importer	MD IMP	PHARMAK	MDIMP/PHARMAK
Medical Devices	Licence Issuing	Importer	MD LII	PHARMAK	MDLII/PHARMAK
Medical Devices	Licence Amendment	Manufacturer	MD MAN	PHARMAK	MDMAN/PHARMAK
Medical Devices	Licence Issuing	Manufacturer	MD LIM	PHARMAK	MDLIM/PHARMAK
Medical Devices	Licence Amendment	Wholesale	MD WHO	PHARMAK	MDWHO/PHARMAK
Medical Devices	Licence Issuing	Wholesale	MD LIW	PHARMAK	MDLIW/PHARMAK
Medical Devices	Registration	Evaluation Class A (low risk medical device)	MD EVA	VETAV	MDEVA/VETAV
Medical Devices	Registration	Evaluation Class B (low to moderate risk medical device)	MD EVB	VETAV	MDEVB/VETAV
Medical Devices	Registration	Evaluation Class C (moderate to high-risk medical device)	MD EVC	VETAV	MDEVC/VETAV
Medical Devices	Registration	Evaluation Class D (high risk medical device)	MD EVD	VETAV	MDEVD/VETAV
Medical Devices	Retention Fees	Licence Retention	MD RT	VETAV	MDRT/VETAV
Medical Devices	Retention Fees	Registration Retention	MD RT	VETAV	MDRT/VETAV
Medical Devices	Registration	Request for Designation	MD RD	VETAV	MDRD/VETAV
Medical Devices	Registration	Technical Amendment Class A and B	MD AA	VETAV	MDAA/VETAV
Medical Devices	Registration	Technical Amendment Class C and D	MD AB	VETAV	MDAB/VETAV

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Annexure B

Refund request by an applicant

For SAHPRA to process your refund you are required to provide the following information:

1. Letter from the company explaining the reason for the refund request
2. Proof of payment - (A letter from the bank is not acceptable)
3. Valid Tax Clearance Certificate
4. Banking details
5. Cipro Certificates and ID copies of directors [CK]

or

Refund request by an individual:

1. An affidavit or letter stating the reason for refund request
2. Certified copy of ID
3. Proof of payment
4. Banking details

Please **email refund applications** to finance@sahpra.org.za and copy the relevant unit processing the application.

Subject line: Marked "application for refund"

Queries:

	Name	Email	Contact number
Finance Manager:	Simphiwe Matsabe	Simphiwe.matsabe@sahpra.org.za	012 015 5474
Deputy Manager: Finance	Naazneen Babamia	Naazneen.babamia@sahpra.org.za	012 501 0323
Senior Accountant	Sydney Malongane	Sydney.Malongane@sahpra.org.za	012 501 0355
Senior Admin	Mashudu Mugagadeli	mugagadeli@sahpra.org.za	012 015 5422
Senior Admin	Phenyo Diale	boitshoko.diale@sahpra.org.za	012 015 5457