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

SAHPRA FINANCE

November 2020

GUIDELINE ON THE PAYMENT OF FEES TO SAHPRA

This guideline 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

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CHIEF EXECUTIVE OFFICER

1 Guideline on How to Process Payments

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

1.2 When applying for services, applicants are encouraged to download and first familiarise themselves with the following documents:

- Gazette Fee Schedule

  https://www.sahpra.org.za/wp-content/uploads/2020/01/992cfdc6SAHPRA_Fees_24.05.2019ExtractfromGovernmentGazette42474-5.pdf

- Applications Cover Page
- SAHPRA Fee Categorisation Guideline No. (Annexure A)

This will ensure that the appropriate fees are paid for the appropriate services.

1.3 Once the appropriate services have been identified, Applicants should then include on the Application Cover Page the services required and the reference used for the payment of the relevant fee as per the guideline: 17.05 SAHPRA Fee Categorisation Guideline.

1.4 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
- Fee payments may be transferred directly into the bank account of SAHPRA by electronic or manual deposit process.
- No cheque payments should be made.
- For administrative control purposes, it should be one payment per service required where it is practical to do so. If a bulk payment is made, the breakdown should be clear on the Applications Cover Page.

1.5 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 finance@sahpra.org.za to ensure timely processing:

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

1.6 Queries can be directed to finance@sahpra.org.za

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
30 October 2020	• Title and header of guideline amended to “Guideline on the payment of fees to SAHPRA”. • Footer stating “Banking Details of SAHPRA” removed • Links added for gazette fee schedule and applicant cover pages in section 1.2 • SAHPRA Fee Categorisation Guideline added as Annexure A on page 4 • Applications Cover Page template added as requirement • New terms/conditions added on section 1.4 • Contact details for queries updated on section 1.6	Version 5

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Annexure A

SAHPRA Fee Categorisation Guideline

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE
Health Products Authorisation	Human	Amendment of Entry in the Register	HUM REG	GLEDMARK	HUM REG GLEDMARK
Health Products Authorisation	Biological	Amendment of Entry in the Register	BIO REG	GLEDMARK	HUM REG GLEDMARK
Health Products Authorisation	Complementary	Amendment of Entry in the Register	CM REG	GLEDMARK	HUM REG GLEDMARK
Health Products Authorisation	Veterinary	Amendment of Entry in the Register	VET REG	GLEDMARK	VET REG GLEDMARK
Health Products Authorisation	Retention Fees	BIO Registration Retention	BIO RET	GLEDMARK	BIO RET GLEDMARK
Health Products Authorisation	New Applications Biological	Evaluation	BIO + APPLICATION NO.	NEUROGEN	BIO 540029 NEUROGEN
Health Products Authorisation	New Applications Complementary	Evaluation	CM + APPLICATION NO.	NEUROGEN	CM 550395 NEUROGEN
Health Products Authorisation	New Applications Human	Evaluation	HUM + APPLICATION NO.	NEUROGEN	HUM 540029 NEUROGEN
Health Products Authorisation	New Applications Veterinary	Evaluation	VT + APPLICATION NO.	NEUROGEN	VT 19/21 NEUROGEN
Health Products Authorisation	Retention Fees	HUMAN Registration Retention	HUM RET	GLEDMARK	HUM RET GLEDMARK
Health Products Authorisation	New Applications Biological	New Registration	BIO + APPLICATION NO.	NEUROGEN	BIO 564230 NEUROGEN
Health Products Authorisation	New Applications Complementary	New Registration	CM + APPLICATION NO.	NEUROGEN	CM 550395 NEUROGEN
Health Products Authorisation	New Applications Human	New Registration	HUM + APPLICATION NO.	NEUROGEN	CM 540488 NEUROGEN
Health Products Authorisation	New Applications VET	New Registration	VT + APPLICATION NO.	NEUROGEN	VT 19/34 NEUROGEN
Health Products Authorisation	Biological	Transfer of certificate of registration	BTRN + APPLICATION NO.	GLEDMARK	BTRN 564231 GLEDMARK
Health Products Authorisation	Complementary	Transfer of certificate of registration	CTRN + APPLICATION NO.	GLEDMARK	CTRN 557823 GLEDMARK
Health Products Authorisation	Human	Transfer of certificate of registration	HTRN+ APPLICATION NO.	GLEDMARK	HTRN 563212 GLEDMARK
Health Products Authorisation	Veterinary	Transfer of certificate of registration	VTRN+ APPLICATION NO.	GLEDMARK	VTRN 19/21 GLEDMARK
Health Products Authorisation	Retention Fees	VET Registration Retention	VET RET	GLEDMARK	VET RET GLEDMARK
Inspectorate	License Renewal	Exporter	INS RNW	REPAXEL	INS RNW REPAXEL
Inspectorate	License Renewal	Importer	INS RNW	REPAXEL	INS RNW REPAXEL
Inspectorate	License Renewal	Distribution	INS RNW	REPAXEL	INS RNW REPAXEL
Inspectorate	License Renewal	Wholesale	INS RNW	REPAXEL	INS RNW REPAXEL
Inspectorate	License Renewal	Manufacturer	INS RNW	REPAXEL	INS RNW REPAXEL
Inspectorate	New Licence	Distribution	INS NLIC	REPAXEL	INS NLIC REPAXEL
Inspectorate	New Licence	Export	INS NLIC	REPAXEL	INS NLIC REPAXEL
Inspectorate	New Licence	Import	INS NLIC	REPAXEL	INS NLIC REPAXEL
Inspectorate	New Licence	Wholesale	INS NLIC	REPAXEL	INS NLIC REPAXEL
Inspectorate	New Licence	Manufacturer	INS MAN	REPAXEL	INS MAN REPAXEL
Inspectorate	Retention Fees	Licence Retention	INS RET	REPAXEL	INS RET REPAXEL
Inspectorate	Licence Issuing	Distribution	INS LIC	BOTTA LABS	INS LIC BOTTA LABS
Inspectorate	Licence Issuing	Exporter	INS LIC	BOTTA LABS	INS LIC BOTTA LABS
Inspectorate	Licence Issuing	Importer	INS LIC	BOTTA LABS	INS LIC BOTTA LABS
Inspectorate	Licence Issuing	Manufacturer	INS LIC	BOTTA LABS	INS LIC BOTTA LABS

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE
Inspectorate	Licence Issuing	Wholesale	INS LIC	BOTTA LABS	INS LIC BOTTA LABS
Inspectorate	Inspections	Local Good Wholesale Practice (Est based on Max 16 hrs)	GWP xxxxxxxxxxx	EXTRAZENEC	GWP 134/2019/PSI
Inspectorate	Certificates	Certificate of Pharmaceutical Product	PHARM CERT	RANDBINDO	PHARM CERT AUROB
Inspectorate	Certificates	GMP Certificate	GMP CERT	RANDBINDO	GMP CERT RANDBINDO
Inspectorate	Evaluation Review	Once Off Deviations	INS DEV	RANDBINDO	INS DEV RANDBINDO
Inspectorate	Evaluation Review	Post Importation Testing Exemption	INS PITE	RANDBINDO	INS PITE RANDBINDO
Inspectorate	Inspections	Desktop Review	INS DESK	RANDBINDO	INS DESK RANDBINDO
Inspectorate	Licence Amendment	Distribution	INS AMD	RANDBINDO	INS AMD RANDBINDO
Inspectorate	Licence Amendment	Exporter	INS AMD	RANDBINDO	INS AMD RANDBINDO
Inspectorate	Licence Amendment	Importer	INS AMD	RANDBINDO	INS AMD RANDBINDO
Inspectorate	Licence Amendment	Manufacturer	INS AMD	RANDBINDO	INS AMD RANDBINDO
Inspectorate	Licence Amendment	Wholesale	INS AMD	RANDBINDO	INS AMD RANDBINDO
Regulatory Compliance	Regulatory Compliance	Cannabis Inspections	CANINP	CANNIBUS ASSOCIATION	CANINP CANNIBUS ASSO
Regulatory Compliance	Regulatory Compliance	Export Permit	LEU NO	JACKSON & JACKSON	LEU NO 3169/2019
Regulatory Compliance	Regulatory Compliance	Export Authorisation	LEU NO	JACKSON & JACKSON	LEU NO 3349/2019
Regulatory Compliance	Regulatory Compliance	Import Authorisation	LEU NO	JACKSON & JACKSON	LEU NO 3349/2012
Regulatory Compliance	Regulatory Compliance	Import permit	LEU NO	JACKSON & JACKSON	LEU NO 2249/2019
Regulatory Compliance	Regulatory Compliance	Manufacturing Permits	LEU NO	JACKSON & JACKSON	LEU NO 3349/2019
Regulatory Compliance	Regulatory Compliance	Possessions	S22A	POL	S22A POL
Regulatory Compliance	New Licence	Cannabis Applications	CAN APP	VETAV	CAN APP VETAV
Inspectorate	Inspections	Local Good Clinical Practice	GCP xxxxxxxxxxx	PILMED	GCP 196/2020/PSI
Inspectorate	Inspections	Local Good Manufacturing Practice (Est based on Max 40 hrs)	GMP xxxxxxxxxxx	PILMED	GMP 396/2019/PSI
Inspectorate	Inspections	International Good Clinical Practice (Est based on Max 32 hrs)	GCP xxxxxxxxxxx	CLYDUS	GCP 196/2019/PSI
Inspectorate	Inspections	International Good Manufacturing Practice	GMP xxxxxxxxxxx	CLYDUS	GMP 136/2019/PSI
Complementary	Licence Amendment	Manufacturer	CM AMD	BOTTA LABS	CM AMD BOTTA LABS
Complementary	Licence Amendment	Wholesale	CM AMD	BOTTA LABS	CM AMD BOTTA LABS
Biological Medicines	Evaluation Review	Post Importation Testing Exemption	BIO PITE	ADHOC	BIO PITE ADHOC
Biological Medicines	Evaluation Review	Once Off Deviations	BIO DEV	ADHOC	BIO DEV ADHOC
Biological Medicines	NCL Lot Release	NCL Lot Release	NCL	ADHOC	NCL ADHOC
Biological Medicines	Post Registration Amendments	Type 1A	BIO T1	ADHOC	BIO T1 ADHOC
Biological Medicines	Post Registration Amendments	Type II Level 3	BIO T2	ADHOC	BIO T2 ADHOC
Biological Medicines	Post Registration Amendments	Type 1B	BIO T1	ADHOC	BIO T1 ADHOC
Biological Medicines	Post Registration Amendments	Type II Level 2	BIO T2	ADHOC	BIO T2 ADHOC
Biological Medicines	Post Registration Amendments	Type II Level 1	BIO T2	ADHOC	BIO T2 ADHOC
Complementary	Evaluation Review	Once Off Deviations	CM DEV	ADHOC	CM DEV ADHOC
Complementary	Inspections	Desktop Review	CM DESK	ADHOC	CM DESK ADHOC
Complementary	Licence Amendment	Distribution	CM AMD	ADHOC	CM AMD ADHOC
Complementary	Licence Amendment	Exporter	CM AMD	ADHOC	CM AMD ADHOC
Complementary	Licence Amendment	Importer	CM AMD	ADHOC	CM AMD ADHOC
Veterinary	Section 21	Use Of Unregistered Medicine	VETS21	DR Banks	VETS21 Dr Banks
Human	Section 21	Use Of Unregistered Medicine	HUMS21	Dr Ndlovu	HUMS21 Dr Ndlovu
Complementary	Section 21	Use Of Unregistered Medicine	CMS21	Dr Williams	CMS21 Dr Williams
Complementary	Licence Issuing	Distribution	CM LIC	NEATCARE	CM LIC NEATCARE
Complementary	Licence Issuing	Exporter	CM LIC	NEATCARE	CM LIC NEATCARE

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE
Complementary	Licence Issuing	Importer	CM LIC	NEATCARE	CM LIC NEATCARE
Complementary	Licence Issuing	Manufacturer	CM LIC	NEATCARE	CM LIC NEATCARE
Complementary	Licence Issuing	Wholesale	CM LIC	NEATCARE	CM LIC NEATCARE
Complementary	License Renewal	Exporter	CM RNW	NEATCARE	CM RNW NEATCARE
Complementary	License Renewal	Importer	CM RNW	NEATCARE	CM RNW NEATCARE
Complementary	License Renewal	Distribution	CM RNW	NEATCARE	CM RNW NEATCARE
Complementary	License Renewal	Wholesale	CM RNW	NEATCARE	CM RNW NEATCARE
Complementary	License Renewal	Manufacturer	CM RNW	NEATCARE	CM RNW NEATCARE
Complementary	New Licence	Distribution	CM NLIC	BANTAXY	CM NLIC BANTAXY
Complementary	New Licence	Export	CM NLIC	BANTAXY	CM NLIC BANTAXY
Complementary	New Licence	Import	CM NLIC	BANTAXY	CM NLIC BANTAXY
Complementary	New Licence	Wholesale	CM NLIC	BANTAXY	CM NLIC BANTAXY
Complementary	New Licence	Manufacturer	CM MAN	BANTAXY	CM MAN BANTAXY
Complementary	Retention Fees	Licence Retention	CM RET	BANTAXY	CM RET BANTAXY
Pharmaceutical and Analytical	Post Registration Amendments	Type 1A	P&A T1	VETAV	P&A T1 VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type II Level 3	P&A T2	VETAV	P&A T2 VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type 1B	P&A T1	VETAV	P&A T1 VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type II Level 2	P&A T2	VETAV	P&A T2 VETAV
Pharmaceutical and Analytical	Post Registration Amendments	Type II Level 1	P&A T2	VETAV	P&A T2 VETAV
Human	Clinical Trials	Protocol Amendments Administrative	HUM PAA	TABPHARM	HUM PAA TABPHARM
Human	Clinical Trials	Other Clinical Trials	HUM CLT	TABPHARM	HUM CLT TABPHARM
Human	Clinical Trials	Protocol Amendments Technical	HUM PAT	TABPHARM	HUM PAT TABPHARM
Human	Clinical Trials	Clinical Trials - Postgrad Study	HUM CLT	TABPHARM	HUM CLT TABPHARM
Human	Clinical Trials	Clinical Trials - Bioequivalence study	HUM CLT	TABPHARM	HUM CLT TABPHARM
Human	Clinical Trials	Clinical Trials - Industry	HUM CLT	TABPHARM	HUM CLT TABPHARM
Human	Post Registration Amendments	Type 1A	CLN T1	TABPHARM	CLN T1 TABPHARM
Human	Post Registration Amendments	Type II Level 3	CLN T2	TABPHARM	CLN T2 TABPHARM
Human	Post Registration Amendments	Type 1B	CLN T1	TABPHARM	CLN T1 TABPHARM
Human	Post Registration Amendments	Type II Level 2	CLN T2	TABPHARM	CLN T2 TABPHARM
Human	Post Registration Amendments	Type II Level 1	CLN T2	TABPHARM	CLN T2 TABPHARM
Veterinary	Clinical Trials	Other Clinical Trials	VET CLT	VIRCAB	VET CLT VIRCAB
Veterinary	Clinical Trials	Clinical Trials - Bioequivalence study	VET CLT	VIRCAB	VET CLT VIRCAB
Medical Devices	Certificates	Certificate of Free Sale	MD CERT	REPAXEL	MD CERT REPAXEL
Medical Devices	Clinical Trials	Clinical Trials - Industry	MD CLT	REPAXEL	MD CLT REPAXEL
Medical Devices	Clinical Trials	Clinical Trials - Postgrad Study	MD CLT	REPAXEL	MD CLT REPAXEL
Medical Devices	Inspections	Desktop Review	MD DESK	REPAXEL	MD DESK REPAXEL
Medical Devices	Evaluation Review	Once Off Deviations	MD DEV	REPAXEL	MD DEV REPAXEL
Medical Devices	Clinical Trials	Other Clinical Trials	MD CLT	REPAXEL	MD CLT REPAXEL
Medical Devices	Clinical Trials	Protocol Amendments Administrative	MD PAA	REPAXEL	MD PAA REPAXEL
Medical Devices	Clinical Trials	Protocol Amendments Technical	MD PAT	REPAXEL	MD PAT REPAXEL
Medical Devices	Registration	Administrative Amendment Class A, B, C and D	MD EVA	FGPHARMA	MD EVA FGPHARMA
Medical Devices	License Renewal	Distribution	MD RNW	FGPHARMA	MD RNW FGPHARMA
Medical Devices	New Licence	Distribution	MD NLIC	FGPHARMA	MD NLIC FGPHARMA
Medical Devices	New Licence	Export	MD NLIC	FGPHARMA	MD NLIC FGPHARMA

UNIT	CATEGORY	SUB-CATEGORY	ABBREVIATED CLASSIFICATION/PAYMENT REFERENCE	PAYING CLIENT EXAMPLE	PAYMENT REFERENCE EXAMPLE
Medical Devices	New Licence	Import	MD NLIC	FGPHARMA	MD NLIC FGPHARMA
Medical Devices	License Renewal	Importer	MD RNW	FGPHARMA	MD RNW FGPHARMA
Medical Devices	License Renewal	Manufacturer	MD RNW	FGPHARMA	MD RNW FGPHARMA
Medical Devices	New Licence	Manufacturer	MD MAN	FGPHARMA	MD MAN FGPHARMA
Medical Devices	License Renewal	Wholesale	MD RNW	FGPHARMA	MD RNW FGPHARMA
Medical Devices	New Licence	Wholesale	MD NLIC	FGPHARMA	MD NLIC FGPHARMA
Medical Devices	Licence Amendment	Distribution	MD AMD	PHARMAK	MD AMD PHARMAQ
Medical Devices	Licence Issuing	Distribution	MD LIC	PHARMAK	MD LIC PHARMAQ
Medical Devices	Licence Amendment	Exporter	MD AMD	PHARMAK	MD AMD PHARMAQ
Medical Devices	Licence Issuing	Exporter	MD LIC	PHARMAK	MD LIC PHARMAQ
Medical Devices	License Renewal	Exporter	MD RNW	PHARMAK	MD RNW PHARMAQ
Medical Devices	Licence Amendment	Importer	MD AMD	PHARMAK	MD AMD PHARMAQ
Medical Devices	Licence Issuing	Importer	MD LIC	PHARMAK	MD LIC PHARMAQ
Medical Devices	Licence Amendment	Manufacturer	MD AMD	PHARMAK	MD AMD PHARMAQ
Medical Devices	Licence Issuing	Manufacturer	MD LIC	PHARMAK	MD LIC PHARMAQ
Medical Devices	Licence Amendment	Wholesale	MD AMD	PHARMAK	MD AMD PHARMAQ
Medical Devices	Licence Issuing	Wholesale	MD LIC	PHARMAK	MD LIC PHARMAQ
Medical Devices	Registration	Evaluation Class A (low risk medical device)	MD EVA	VETAV	MD EVA VETAV
Medical Devices	Registration	Evaluation Class B (low to moderate risk medical device)	MD EVA	VETAV	MD EVA VETAV
Medical Devices	Registration	Evaluation Class C (moderate to high risk medical device)	MD EVA	VETAV	MD EVA VETAV
Medical Devices	Registration	Evaluation Class D (high risk medical device)	MD EVA	VETAV	MD EVA VETAV
Medical Devices	Retention Fees	Licence Retention	MD RET	VETAV	MD RET VETAV
Medical Devices	Retention Fees	Registration Retention	MD RET	VETAV	MD RET VETAV
Medical Devices	Registration	Request for Designation	MD EVA	VETAV	MD EVA VETAV
Medical Devices	Registration	Technical Amendment Class A and B	MD EVA	VETAV	MD EVA VETAV
Medical Devices	Registration	Technical Amendment Class C and D	MD EVA	VETAV	MD EVA VETAV