SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

SAHPRA
South African Health Products Regulatory Authority

LICENCE APPLICATION TO MANUFACTURE, IMPORT OR EXPORT MEDICINE & SCHEDULED SUBSTANCES

- An application form for the purpose of **obtaining** a licence **or renewing** a licence in terms of the provisions of the Medicines and Related Substance Act, 1965 Section 22C and 22D read together with Regulation 19 and 20 of the Act as the case may be.
- This form should be completed by or for each manufacturer of medicine who is not exempted from the requirement to hold a licence and who wishes to manufacture, import or export medicine or who wishes to renew their existing manufacture licence to manufacture, import or export medicine.
- Incomplete forms may be returned to the applicant. Please type or print in black pen. Any alterations must be initialled and dated. Application forms with white out will be returned. All required copies of certificates should be certified.
- The prescribed application fee for a licence must accompany any of these licence application forms. For amount, refer to the summary of fees and charges available on the SAHPRA website: www.sahpra.org.za
- The completed form should be emailed to:
  gmplicensing@sahpra.org.za
- The licence is the property of South African Health Products Regulatory Authority and must be returned upon demand. The licence remains valid for the period of five years from the date of issue unless otherwise suspended or revoked by South African Health Products Regulatory Authority.
- Licensing guidelines are available at the SAHPRA website: www.sahpra.org.za
- **Application for renewal of the licence must be submitted at least 180 days before expiry of the existing licence**..

Guidance notes & General information

Name of the proposed license holder

Full, legal name of licence applicant or owner of the business who wishes to manufacture, import or export medicine (must be full, *legally identifiable name* e.g. 'ABC Pty Ltd', 'Newcorp Ltd' trading as XYZ', 'Gillian Linda Smith trading as MNR). Spaces are provided for the following options. Please insert as applicable.

a) Name if sole individual trader
The individual's full name if trading as an individual trader

b) Name of corporation or company
If a corporation or company, the name of the registered corporation or company under the Companies Act and the **registration number** allocated by the Registrar of Companies.

c) Name if trading under other business name
The business name, or name under which you propose to trade for purposes of the Act [if different from (a) or (b)]

Declaration

This declaration seeks assurances that the requirements of Section 22C and 22D and Regulation 19 and 20 of the Act, as the case may be, have been satisfied and that the information provided in the application is current and correct at the time it was signed by the manufacturer, importer or exporter. The declaration in A (iii) is intended to establish whether a manufacturer has received a notice that its manufacturing operations do not comply with current acceptable quality assurance principles and good manufacturing practices as determined by South African Health Products Regulatory Authority. A penalty applies for false and misleading statements made in relation to this application.

Persons signing the declaration

Persons signing the declaration should be the manufacturer, or the manufacturer's duly appointed designee who is responsible to South African Health Products Regulatory Authority for compliance with the Act – refer Regulation 19 (1)(a)(iii).

Name	Full name
Position	The role in the organization e.g. Owner, Designee.

Site Master File

Part of the reporting aspects of the audit can be addressed by receiving information on related company details, e.g. details of the company's facilities, personnel structure and operating procedures including manufacturing activities, prior to audit.

It is expected that a Site Master File be prepared and submitted to the Inspectorate that should be in line with the guidelines on the preparation of a Site Master File, which can be obtained from the office of the Chief Executive Officer or the SAHPRA website at: www.sahpra.org.za.

Date of audit

Before a licence may be issued or renewed, the Inspectorate may have to conduct an audit of the company's manufacturing operations to assess conformity with the Good Manufacturing Principles as determined by South African Health Products Regulatory Authority. In order to schedule an audit, the applicant should indicate an approximate date by which they will be ready for an audit. If this date changes after the application is submitted the Inspectorate should be notified as soon as possible. The inspector assigned to undertake the audit will advise the manufacturer of the actual date of the audit approximately five working days beforehand.

Good Manufacturing Practices

Pursuant to the current GMP Guidelines, SAHPRA may determine written principles to be observed by a manufacturer of medicines or scheduled substances. These principles will primarily comprise the Guidelines on Good Manufacturing Practice (GMP). A copy of the current guidelines on GMP may be obtained by the manufacturer of medicines, biologicals or medical gas products from the office of the Chief Executive Officer or the website of SAHPRA:www.sahpra.org.za.

Note: If any of the details contained in this Application Form should change after this document has been signed, the Applicant will be obliged to submit an updated application form within 30 days, otherwise the Licence will automatically become null and void.

GENERAL INFORMATION

1.1 NAME OF PROPOSED LICENCE HOLDER

NOTE: Manufacturers' Licences are granted to persons who, in the course of a business, manufacture, test and/or pack, import or export medicine or scheduled substances. This can include:
(i) A natural person, or
(ii) A legal person

1.2 LICENCE NUMBER (if known)

1.3 IS YOUR BUSINESS REGISTERED WITH THE SOUTH AFRICAN PHARMACY COUNCIL AS A MANUFACTURING PHARMACY?

YES	**NO**

Supply registration number and copy of certificate of recording

2.1 MANUFACTURER'S BUSINESS NAME

Name of individual	
Registered company name if Corporation	
Name if trading under other business name	
Company or Corporation Registration number issued by the registrar of Companies	

Has this site previously held any licence under the Medicines and Related Substances Act?

YES	**NO**

If YES, please attach details.

2.2 ADDRESS FOR COMMUNICATIONS

Town	**Postal Code**

3.1 LICENCE HOLDER CONTACT

Surname		**Initials**		**Title**	

Telephone number	
Fax number	
E-mail address	

3.2 SUPPLY REGISTRATION NUMBER AND COPY OF CERTIFICATE OF RECORDING OF PHARMACY OWNER WITH PHARMACY COUNCIL

SITE INFORMATION

Please complete separate forms for each site where manufacturing and/or packaging activities take place

4.1 SITE NAME

4.2 SITE ADDRESS

Town/City	**Postal Code**		
Has this site previously held any licence under the Act? If **YES** please attach details		**YES**	**NO**

4.3 SITE MASTER FILE (Tick the appropriate block)

Enclosed ☐ **Submitted before** ☐

Note: Before a licence audit is conducted manufacturers are required to submit a Site Master File. SMF previously submitted must not be older than **2 years**.

4.4 SITE MASTER FILE NUMBER (if known)

4.5 SUPPLY LICENCE NUMBER AND COPY OF LICENCE FOR THE PREMISES OBTAINED FROM THE DEPARTMENT OF HEALTH

	In operation prior to 2 May 2003	

5 SITE CONTACT (RESPONSIBLE PHARMACIST)

Surname		**Initials**		**Title**	

Telephone number	
Fax number	
E-mail address	

6 SITE USAGE

Describe below any other activities on this site which are not connected with medicine.

7 ACTIVITIES AT SITE

If the Licence is for Packaging **only**, go to section 12.
Filling of sterile products is classified as manufacture not as packaging.
Please tick **MP** (Manufacture, Testing and Packaging) or **M** (Manufacture and Testing only) as appropriate for each category of production.

8 STERILE PRODUCTS

A.1 **Large volume (100 ml or more) sterile liquid** dosage forms (including large volume parenteral and irrigation solutions):

		MP	M
A.1.1	Aseptically prepared		
A.1.2	Terminally sterilised products		

A.2 **Small volume (<100 ml) sterile liquid** dosage forms (including small volume parenterals and eye drops):

		MP	M
A.2.1	Aseptically prepared		
A.2.2	Terminally sterilised		

A.3 **Semi-solid sterile** dosage forms including creams and ointments:

		MP	M
A.3.1	Aseptically prepared		

Specify dosage form(s) below:

		MP	M
A.3.2	Terminally sterilised		

Specify dosage form(s) and sterilisation method below:

A.4 Solid sterile dosage forms:

		MP	M
A.4.1	Solid fill (including powders for reconstitution)		
A.4.2	Freeze-dried (lyophilised)		

A.5 Other sterile products: MP M

Specify dosage form and sterilisation method:

9 NON-STERILE PRODUCTS

B.1 Unit and multi-dose non-sterile liquids:

		MP	M
B.1.1	Internal		
B.1.2	External		
B.1.3	Aerosols (pressurised)		

B.2 Semi-solid and other liquid non-sterile dosage forms:

Please specify below:

B.3 Solid non-sterile dosage forms:

			MP	M
B.3.1	Unit-dose forms:	tablets		
		capsules, hard gelatin		
		capsules, soft gelatin		
		suppositories/pessaries		
B.3.2	Multi-dose forms (including powders and granules)			
B.3.3	Other solid non-sterile dosage forms:			

Specify below:

B.4 Medical Gases MP M

10 BIOLOGICALS

produced or handled and appearing in the finished product

		MP	M
C.1	Vaccines		
C.2	Sera and other immunologicals		
C.3	Blood and other blood products		
C.4	Other biologicals, please specify below:		

11 OTHER ACTIVE INGREDIENTS

appearing in the finished product

11.1	Potentially hazardous	MP	M
D.1	Penicillins		
D.2	Cephalosporins		
D.3	Hormones		
D.4	Cytostatics / cytotoxics		
D.5	Others, please specify below:		

11.2	Miscellaneous	MP	M
D.6	Radio-active materials		
D.7	Complementary medicines		

12 PACKAGING ONLY

Filling of sterile products is classified as manufacture, not as packaging.
Please tick the boxes as appropriate.

12.1	Packaging activities	P
E.1	Filling of primary containers	
E.2	Labelling of primary containers	

12 Packaging Only continued

12.2	**Dosage forms packed**	**P**
E.3	Liquid dosage forms	
E.4	Semi-solid dosage forms (including creams and ointments)	
E.5	Solid dosage forms (including tablets and powders)	
E.6	Medical gases	
E.7	Other dosage forms, please specify below:	

13 OTHER DOSAGE FORMS MANUFACTURED AND/OR PACKED

		MP	**M**
F.1	Veterinary premixes / feed mills		
F.2	Registerable wound dressings		
F.3	Registerable medical devices (e.g. intra-uterine device)		
F.4	Any other medicinal products not listed elsewhere in this application		

Please specify below:

14 OTHER SPECIFIC PROCESSES / ACTIVITIES

G.1	Form / fill / seal processes	
G.2	Strip and / or blister packing	
G.3	Packaging of parallel-imported products	
G.4	Manufacture and / or packaging for export	
G.5	Manufacturer as Sole Importer	
G.6	Sterilisation processes used (for products or components):	
G.6.1	Steam or steam / air	
G.6.2	Dry heat	
G.6.3	Irradiation / electron beam	
G.6.4	Biocidal gas / chemical	

15 ANALYTICAL TESTING SITES

This refers to the site(s) at which analysis or testing of starting materials, packaging materials, intermediate, bulk and finished products takes place. This may also include one or more of the sites where manufacture and/or packaging also takes place.

15.1 Site Name

15.2 Site Address

Town	**Postal code**

15.3 Testing activities at this site

H.1	Chemical / physical	
H.2	Microbiological / sterility / environmental / LAL	
H.3	Pyrogens (rabbit test method)	
H.4	Bioassay	
H.5	Stability testing	
H.6	Other, please specify:	

16 STORAGE AND HANDLING OF MATERIALS

Please complete separate forms for each site from which storage, distribution or other activities take place

16.1 Site Name

16.2 Site Address

Town	**Postal code**

16.3 Site Contact

Surname		**Initials**		**Title**	

Telephone number	
Fax number	
E-mail address	

16.4 Site Usage

Is this site used for distribution only (i.e. onward dispatch of ready packed orders)	**YES**	**NO**
or is this site used for other purposes	**YES**	**NO**

Please specify these other purposes (e.g. order receipt, invoicing, picking of orders, handling of goods returned from customers):

16.5 Facilities on site

Is the description of the facilities available for the storage and distribution of medicinal products detailed in the Site Master File?	**YES**	**NO**

If not, please provide a brief description (approximately 500 words) of the facilities available for the storage and distribution of medicinal products on a separate sheet of paper.

16.6 Equipment on site

Is a description of the major items of equipment other than transport available for the storage and distribution of medicinal products detailed in the Site Master File?	**YES**	**NO**

If not, please provide a brief description (approximately 500 words) of the equipment available for the storage and distribution of medicinal products on a separate sheet of paper. In particular please provide details of any refrigeration equipment available.

16.7 Activities of site relating to Import or Export

Are medicines Imported by the Applicant?	**YES**	**NO**
Are medicines Exported by the Applicant?	**YES**	**NO**

If yes, please provide a list of products being exported.

17 LIST OF ACTIVITIES

PLEASE SPECIFY THE ACTIVITIES TO BE PERFORMED AT THIS SITE IN ACCORDANCE WITH THE FOLLOWING MATRIX (Note: The entire matrix will be included on the actual license that will be issued)

17.1 MANUFACTURING ACTIVITIES	**YES**	**NO**
Sterile, Non-biological Manufacture (includes filling, but not cartoning or labelling)		
Large volume parenteral products		
Small volume parenteral products		
Other sterile dosage forms (please specify)		
Non-sterile Manufacture		
Tablets		
Capsules		
Liquids		
Semi-solids		
Suppositories		
Other non-sterile dosage forms (please specify)		
Biological Manufacture		
Vaccines		
Sera and other immunologicals		
Blood and other blood products		
Other biological products (please specify)		
Medical Gas Manufacture		
Radioactive Medicines Manufacture		
Complementary Medicines Manufacture		
17.2 PACKAGING ACTIVITIES		
Packaging of bulk product and labelling		
Re-labelling or redressing		
Cartoning or secondary packaging		
17.3 TESTING ACTIVITIES		
Analytical		
Microbiological		
Sterility		
Stability		
Animal		
Other (please specify)		
17.4 DISTRIBUTION ACTIVITIES		
Bulk distribution to wholesale pharmacies		
Fine distribution to retail pharmacies and other clients		
Export (please specify products exported on a separate list)		
Import		

17 List of Activities continued

17.5 MATERIALS HANDLED OR STORED AT THIS SITE	**YES**	**NO**
Penicillins		
Cephalosporins		
Hormones		
Cytostatics/Cytotoxics		
Bulk Pesticides, Herbicides or Rodenticides		
Potent Steroids		
Other potent, toxic, sensitising or hazardous materials (please specify)		

PERSONNEL INFORMATION

Guidance notes on nomination of personnel having control

The Medicines and Related Substance Act, 1965

The Act requires that the applicant shall identify the persons who will have and maintain control of the manufacture of medicine and scheduled substances. The Regulations to the Act require that changes be notified promptly to South African Health Products Regulatory

Relevant Qualifications

Relevant qualifications are those relevant to the manufacture of medicines and scheduled substances including those in related sciences and management.

Relevant Experience

Relevant experience is that relevant to the manufacture (including quality management) of medicines and scheduled substances involving comparable good manufacturing practice or experience, which the applicant believes should be taken into consideration as relevant.

All applications should include a relevant CV and each pharmacist nomination shall include a letter of appointment by the licence holder and a letter of acceptance.

18 THE RESPONSIBLE PHARMACIST

Please give the following details of the pharmacist who is to control the manufacture, import or export of medicines or scheduled substances in terms of the provisions of Regulation 19 of the Act.

18.1 Personal information

Surname	Given names	Position in Company	Pharmacy Council registration number

18.2 Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

18.3 Relevant experience (last job first)

Number of Years	Employer	Position Held

18.4 Business Address and Phone number

Tel. no.

Please submit a certified copy of the candidate's Registration Certificate from the SA Pharmacy Council with this application.

I confirm that the above particulars are to the best of my knowledge and belief accurate and true.

I agree to be nominated as the Pharmacist responsible for the manufacture, import or export of medicines or scheduled substances as detailed in this licence application.

Signed (responsible pharmacist): Date:

Signed (designee): Date:

19 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF PRODUCTION

19.1 Personal information

Surname	Given names	Position in Company

19.2 Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

19.3 Relevant experience (last job first)

Number of Years	Employer	Position Held

20 PERSON WHO WILL HAVE CONTROL OF QUALITY CONTROL / ASSURANCE

20.1 Personal information

Surname	Given names	Position in Company

20.2 Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

20.3 Relevant experience (last job first)

Number of Years	Employer	Position Held

21 PERSON(S) RESPONSIBLE FOR LIVING TISSUE CULTURES

21.1 Personal information

Surname	Given names	Position in Company

21.2 Relevant qualifications

Degree/Diploma	Field of Study	Institution	Year Graduated

21.3 Relevant experience (last job first)

Number of Years	Employer	Position Held

21 Person(s) responsible for living tissue cultures continued

Name and function of the person to whom he/she reports

22 PROPOSED DATE OF AUDIT

Approximate date when ready for audit

DECLARATION

Applicants should note that in terms of the provisions of the Medicines and Related Substance Act, 1965 it is an offence to make false and misleading statements in connection with an application for a licence to manufacture, import or export medicine or scheduled substances.

		Tick (✔) one box only in each case	
A.	I declare that:	Yes	No
(i)	The manufacturer had a licence revoked after being granted such a licence.		
(ii)	The manufacturer has been convicted of an offence against the Medicines and Related Substance Act, 1965 or a law of a state or territory relating to medicines or scheduled substances.		
(iii)	The manufacturer has received notification from SAHPRA on more than one occasion that the manufacturer has failed to observe Good Manufacturing Practices in connection with the manufacture of medicines or scheduled substances.		
(iv)	The information provided in this application is current and correct.		

If parts (i), (ii) or (iii) of the declaration were answered in the affirmative, details should be provided on additional pages.

Delete part (iii) of the declaration if it is not applicable.

B. I / We apply for the **granting / renewal** (*indicate by crossing out the non-applicable section*) of a Manufacturer's Licence to the proposed holder named in this application form in respect of the activities to which the application refers.

1. The licence to be subject to all the Standard Provisions applicable to Manufacturer's Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965.
2. The manufacturing operations are conducted only in accordance with the information set out in the application or furnished in connection with it.
3. I / We declare that we hold the relevant product registrations or are named on the relevant product registrations as manufacturers and / or packaging relating to the medicinal products we wish to manufacture and / or pack pursuant to this application.
4. To the best of my / our knowledge and belief the particulars I / we have given in this form are correct and complete.

The above declaration must be signed:

- in the case of a corporation or company by the designee / natural person who shall be responsible to SAHPRA for compliance with the Act.
- in the case of other enterprises by the owner.

Name	
Signature	
Position within Organization	
Date	

Note: This is a legal document. Any changes to the application once submitted must be made in writing detailing the requested variation and be signed by the authorized person above.