SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

LICENCE APPLICATION TO CULTIVATE, MANUFACTURE OR IMPORT CANNABIS FOR MEDICINAL PURPOSES

- 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 to be read in conjunction with Regulation 23 and 24 of the Act.

- This form should be completed by or for each manufacturer of Cannabis who is not exempted from the requirement to hold a licence and who wishes to cultivate, manufacture or import or who wishes to renew their existing licence to cultivate, manufacture or import.

- Incomplete forms may be returned to the Applicant. Please type or print in black ink. 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 or proof of payment for a licence must accompany the licence application forms. For amount, refer to the fees payable as published in the Government Gazette and published on the SAHPRA website, also available from the office of the CEO of SAHPRA.

  Note: Cheques should be made payable to **"South African Health Products Regulatory Authority"**

- The completed form should be sent to:

  Chief Executive Officer of SAHPRA
  South African Health Products Regulatory Authority
  Private Bag x828
  Pretoria
  0001

- The licence is the property of the South African Health Products Regulatory Authority (SAHPRA) 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 the South African Health Products Regulatory Authority (SAHPRA).

- Licensing guidelines are available at the South African Health Products Regulatory Authority's website: https://www.sahpra.org.za/

- After five years the applicants licensed to cultivate, manufacture, import or export, as the case may be, need to renew their licence.

Guidance Notes & General information

Definitions and Acronyms

DALRRD – Department of Agriculture, Land Reform and Rural Development

GAP – Good Agricultural Practices

GMP – Good Manufacturing Practices

SAHPRA – South African Health Products Regulatory Authority

Structure of the License Application

The application form comprises of 5 parts:

- PART A General Information
- PART B Site Information
- PART C List of Activities
- PART D Personnel Information
- PART E Declaration

PART A GENERAL INFORMATION

Section 1.1, 1.2. 1.3 – Application Type, Applicant Details, Business Registrations

The type of application must be specified i.e. is the application for a new licence or a renewal of a licence. The SAHPRA licence number is required if the application is for a renewal.

The applicant name and contact details are required. The full, legal name of the applicant must be filled in.

Current or previous business registrations with either the Department of Health or the Department of Agriculture, Land Reform and Rural Development must be disclosed.

Section 2.1, 2.2 – Business Details, Address

The full, legal name of the owner of the business as well as the registered company name e.g. ABC Pty Ltd', 'Newcorp Ltd' trading as XYZ', 'Gillian Linda Smith trading as MNR, must be filled in. If applicable, the company or corporation registration number issued by the Registrar of Companies must also be filled in. A certified copy of the company or corporation registration certificate must also accompany the application.

Section 2.1 of the application provides for the following options. Complete only that which is applicable to you.

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)]

Section 2.2 requires the business address or where communication from SAHPRA should be directed.

PART B SITE INFORMATION

All information related to the site of cultivation, manufacturing and/ or packaging of cannabis is required in this section. Separate forms are required for each site where cultivation, manufacturing and/ or packaging of cannabis is conducted.

Section 3.1, 3.2 and 3.3 – Site Details, Site Address and Site Location Coordinates

The legal site name, address and location coordinates must be completed. The location coordinates are required for cultivation applications only.

Section 3.4 – Documentation Enclosed

If the applicant of the licence or owner of the company does not own the cultivation, manufacturing or packaging site, documents related to the use of the land/ site must be included in the application e.g. lease agreement
In addition, police clearance certificates and certified copies of the identity documents of the business owners must be included in the application.

Section 3.5 – Site Master File (SMF)

A SMF must accompany the licence application.
The Site Master File is prepared by the cultivator, manufacturer and or importer, as the case may be and contains specific information on the site and related company details i.e. facilities, personnel structure, quality assurance, and the production and/or quality control of all activities carried out. If only part of the operation is carried out on the site, a Site Master File need only describe those operations, e.g. analysis, packaging, etc.
When submitted to a regulatory authority, the SMF provides information on the cultivators, manufacturers or importers operations and procedures that can be useful in the efficient planning and undertaking of an inspection.
The SMF must be prepared in line with the 4.08 Guidelines for the Preparation of a Site Master File, which can be accessed via the SAHPRA website at: https://www.sahpra.org.za

Section 4 – Responsible Person

The responsible person for the site must be named and contact details must be filled. If the responsible person is a pharmacist, the South African Pharmacy Council registration number must be included.

Section 5 – Site Usage

A brief description of the any other activities carried out on the site. This covers both pharmaceutical and non-pharmaceutical activities.

Section 6 – **Activities at Site**
Indicate activities conducted on site, to allow for the regulator to determine the parameters of the licence. Only those activities that are applicable to the site should be indicated.

Sub-section A – Complete if cultivation activities are conducted. Indicate the cannabis seed type detailing the species to be cultivated and the proposed area for cultivation.

Sub-section B – Complete if manufacturing activities (including processing, extracting) are conducted on site. Indicate specifically the manufacturing activities conducted i.e. extraction from the cannabis plant, manufacture of a cannabis-containing pharmaceutical.

Sub-section C – Complete if packaging activities are conducted on-site. Indicate specifically if the packaging relates to the packaging of the herbal cannabis material, the final pharmaceutical product or cannabis seeds.

Section 7 – Analytical Testing Sites
The information and details related to the analytical testing site is required in this section. The testing site could be the same as, or different from the cultivating, manufacturing or packaging site. Analytical testing refers to the analysis or testing of the starting materials, intermediates, bulk and finished product and packaging materials.
Sub-section 7.3 – Indicate analytical activities conducted on-site.

Section 8 – Storage and Handling of Harvest Materials
Only information related to harvested material or herbal cannabis products must be included in this section.

Sub-section 8.1, 8.2, 8.3 – Site Name, Site Address, Contact Person
The site, address and contact person related to the site at which the harvested material is stored is required. The storage site could be the same as, or different to the cultivating, manufacturing or packaging site.

Sub-section 8.4 – Site Usage
If the storage site is used for purposes other than the distribution of cannabis, this must be disclosed.

Sub-section 8.5 – Equipment and Facilities on Site
A brief description of the facilities available for storage and distribution of harvested material and herbal cannabis products must be included, if not already included in the SMF.
A brief description of the major equipment available for storage and distribution of harvested material and herbal cannabis products must be included, if not already included in the SMF.

Sub-section 8.6 – Activities Relating to Import/ Export
Any import or export of medicines by the applicant must be disclosed.

Section 9 – Storage and Handling of Finished Product Materials
Only information related to finished cannabis-containing medicines must be included in this section.

Sub-section 9.1, 9.2, 9.3 – Site Name, Site Address, Contact Person
The site, address and contact person related to the site at which the finished cannabis-containing medicines is stored is required. The storage site could be the same as, or different to the cultivating, manufacturing or packaging site.

Sub-section 9.4 – Site Usage
If the storage site is used for purposes other than the distribution of the finished cannabis-containing medicines, this must be disclosed.

Sub-section 9.5 – Equipment and Facilities on Site
A brief description of the facilities available for storage and distribution of finished cannabis-containing medicines must be included, if not already included in the SMF.
A brief description of the major equipment available for storage and distribution of finished cannabis-containing medicines must be included, if not already included in the SMF.

Sub-section 9.6 – Activities Relating to Import/ Export
Any import or export of medicines by the applicant must be disclosed.

PART C LIST OF ACTIVITIES

Section 10.1, 10,2. 10.3, 10.4, 10.5
Indicate activities conducted on site on the matrix provided. Only those activities that are applicable to the site should be indicated.

PART D PERSONNEL INFORMATION

This section should only be completed if the site is conducting activities related to the manufacturing or import of pharmaceutical cannabis products.
Information on key personnel in quality assurance, including production and quality control, and on the nominated responsible pharmacist, is included here. An organisation chart or organogram showing the arrangements for quality assurance and reporting structures should be included in the SMF.

Section 11 – The Responsible Person
The personal information, relevant qualifications, relevant experience, address and contact details of the nominated responsible pharmacist (RP) must be completed. A signed declaration by the responsible pharmacist accepting the role as RP must also be completed.
A Responsible Pharmacist (RP) means a natural person who is a **pharmacist** and who is **responsible** to the South African **Pharmacy** Council for complying with all the provisions of the **Pharmacy** Act and other legislation applicable to services that specially pertain to the scope of practice of a **pharmacist**.

Section 12 – Production
The personal information, relevant qualifications, relevant experience, address and contact details of the nominated production head must be completed.

Section 13 – Quality Assurance/ Control
The personal information, relevant qualifications, relevant experience, address and contact details of the nominated Quality Assurance head must be completed.

Section 14 – Security
The personal information, relevant qualifications, relevant experience, address and contact details of the nominated security head must be completed.

Section 15 - Proposed Date of audit
Before a licence may be issued or renewed, SAHPRA may have to conduct an audit of the company's cultivating, manufacturing or importing operations to assess conformity with Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP) as determined by the DARDLR and SAHPRA respectively. 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 SAHPRA should be notified as soon as possible. The inspector

assigned to undertake the audit will advise the applicant of the actual date of the audit approximately five working days in advance.

GAP is a set of practices that addresses environmental, economic and social sustainability for on-farm processes and result in the safety and quality of agricultural products. Applicants are invited to the *WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants (http://apps.who.int/medicinedocs/pdf/s4928e/s4928e.pdf)* that address the requirements for good agriculture and collection practises when dealing with herbal products.

GMP describes a set of principles and procedures that when followed helps ensure that medicines and related substances are of high quality, safety and efficacy. Pursuant to the current GMP Guidelines, SAHPRA may determine written principles to be observed by a cultivator, manufacturer or importer of Cannabis. A copy of the current guidelines on GMP may be via the SAHPRA website https://www.sahpra.org.za.

PART E DECLARATION

This declaration seeks assurances that the requirements of Section 22C and 22D and Regulation 23 and 24 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 cultivator, manufacturer or importer. 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 the 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 cultivator, the manufacturer, or the cultivator/manufacturer's duly appointed designee who is responsible to SAHPRA for compliance with the Act – refer Regulation 23 (1)(c)(iii). The full name, signature, date and position within the organisation e.g. Owner, Designee must be completed.

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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.

PART A: GENERAL INFORMATION

1.1 APPLICATION TYPE			
☒	New		
☐	Renew	SAHPRA Licence Number:	

1.2 APPLICANT DETAILS	
Title	Ms
Full Name	Black Widow
Telephone Number (Office)	013 456 7899
Mobile Number	084 557 7890
Fax Number	N/A
E-Mail Address	Blackwidow@cannabis.com

1.3 BUSINESS REGISTRATIONS			
1.3.1	Is the business registered with the National Department of Health as a Manufacturing Facility?	☐ ☒	Yes No
1.3.2	Is the business registered with the National Department of Agriculture, Forestry and Fisheries as a Farming Facility?	☐ ☒	Yes No

2.1 BUSINESS DETAILS	
Name of individual / owner	Mr Blue Crane
Registered Company Name (if Corporation)	High Life (Pty) Ltd
Trading Name (if applicable)	N/A
Company or Corporation Registration number issued by Registrar of Companies	56/78/910/11

2.2 ADDRESS FOR COMMUNICATIONS	
Line 1	1234 meiring naude
Line 2	
Town/ City	Pretoria
Province	Gauteng
Postal code	0001

PART B: SITE INFORMATION

Note: Separate forms must be completed for each site where cultivation, manufacturing and/or packaging activities take place.

3.1 SITE DETAILS	
Site Name	ABC Farm Holdings
Has this site previously held any licence under the Act?	☐ Yes (**Note:** If yes, please attach details) ☒ No
3.2 SITE ADDRESS	
Line 1	456 farm road
Line 2	
Town/ City	Muldersdrift
Province	Gauteng
Postal code	2568
3.3 SITE LOCATION COORDINATES	
Coordinates required for Cultivation purposes only	35°26'22.5"S 35°26'22.5"S

3.4 DOCUMENTS ENCLOSED	
Property Owners (if application)	☒ Yes ☒ No
Police clearance documents of business owner	☒ Yes ☐ No

3.5 SITE MASTER FILE (SMF)	
Note: Before a licence audit is conducted, manufacturers are required to submit a Site Master File. A SMF previously submitted must not be older than **2 years**.	
Is the SMF enclosed?	☒ Yes ☐ No
Has the SMF been submitted before?	☐ Yes ☒ No
SMF number (if known)	

4 SITE CONTACT (RESPONSIBLE PERSON)	
Title	Ms
Full Name	Black Widow
Identity number	8510201122345
South African Pharmacy Council Reg. No.	N/A
Telephone Number	013 456 7899
Mobile Number	084 557 7890
Fax Number	N/A
E-mail address	blackwidow@cannabis.com

5 SITE USAGE

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

- Sugar cane production

6	ACTIVITIES AT SITE
If the Licence is for **packaging only**, go to section B3. Please tick: **C** for (cultivation) or **MP** (Manufacture, Testing and Packaging) or **M** (Manufacture and Testing only) as appropriate for each category of production below.	

A	CULTIVATION	
A1.1	Types of seeds	Cannabis Sativa, Hybrid As per offtake agreement (See attachment)
A1.2	The area for growing	2 hectares (Greenhouse) See SMF

~~B~~	~~MANUFACTURING~~		~~C~~	~~MP~~	~~M~~
~~B1.1~~	~~Unit and multi dose liquids~~				
~~B1.1.1~~	~~Internal~~				
~~B1.1.2~~	~~External~~				
~~B1.1.3~~	~~Aerosols (pressurised)~~				
~~B1.2~~	~~Semi-solid & other liquid dosage forms~~ ~~Please specify below~~				
~~B1.3~~	~~Solid dosage forms~~				
~~B1.3.1~~	~~Unit dose forms:~~	~~Tablets~~			
		~~Capsules, hard gelatin~~			
		~~Capsules, soft gelatin~~			
		~~Suppositories/pessaries~~			
~~B1.3.2~~	~~Multi-dose forms (including powders and granules)~~				
~~B1.3.3~~	~~Other solid non-sterile dosage forms~~ ~~Please specify below~~				
~~B1.4~~	~~Other dosage forms~~				
	~~Veterinary premixes/ feed mills~~				

C	PACKAGING ONLY	
Filling of sterile products is classified as manufacturing, not as packaging. Please tick the appropriate boxes.		
C1	**Packaging activities**	**P**
C1.1	Filling of primary containers	X
C1.2	Labelling of primary containers	X
C1.3	~~Liquid dosage forms~~	
C1.4	~~Semi-solid dosage forms (including creams and ointments)~~	
C1.5	~~Solid dosage forms (including tablets and powders)~~	
C1.6	~~Other dosage forms, please specify below~~	

7	ANALYTICAL TESTING SITES	
This refers to the site(s) at which analysis or testing of starting materials, packaging materials, intermediate, bulk and finished products take place. This may also include one or more of the sites where manufacturing and/or packaging takes place.		
7.1	**Site name**	
XYZ laboratories (Pty) Ltd		
7.2	**Site address**	
	Line 1	457 lab road
	Line 2	
	Town/ City	Muldersdrift
	Province	Gauteng
	Postal code	2001
7.3	**TESTING ACTIVITIES AT THIS SITE**	
Please tick the appropriate boxes.		
D1	Chemical/ physical ☒	
D2	Microbiological/ sterility/ environmental/ LAL ☒	
D3	Pyrogens (rabbit test method) ☐	
D4	Stability testing ☐	
D5	Other, please specify	

8 STORAGE AND HANDLING OF HARVEST MATERIALS	
8.1 SITE NAME	
ABC Farm Holdings	
8.2 SITE ADDRESS	
Line 1	456 farm road
Line 2	
Town/ City	Muldersdrift
Province	Gauteng
Postal code	2568
8.3 SITE CONTACT PERSON	
Title	Ms
Full name	Black Widow
Telephone number	013 456 7899
Mobile number	084 557 7890
Fax number	N/A
E-mail address	blackwidow@cannabis.com

8.4 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
If used for other purposes, please specify below Cultivation	

8.5 EQUIPMENT AND FACILITIES ON SITE	
Is a description of facilities available for the storage and distribution of medicinal products detailed in the Site Master File?	☒ Yes ☐ No
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 these descriptions are not included in the SMF, please provide brief descriptions (approximately 500 words each) of the facilities available and the equipment available for the storage and distribution of medicinal products on a separate sheet of paper.	

8.6 ACTIVITIES RELATING TO IMPORT/EXPORT	
Are medicines imported/exported by the Applicant?	☒ Yes ☐ No
If yes, please provide a list of products being imported/exported.	

9 STORAGE AND HANDLING OF FINISHED PRODUCT MATERIALS	
9.1 SITE NAME	
9.2 SITE ADDRESS	
Line 1	
Line 2	
Town/ City	
Province	
Postal code	
9.3 SITE CONTACT PERSON	
Title	
Full name	
Telephone number	
Mobile number	
Fax number	
E-mail address	
9.4 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
If used for other purposes, please specify below	
9.5 EQUIPMENT AND FACILITIES ON SITE	
Is a description of facilities available for the storage and distribution of medicinal products detailed in the Site Master File?	☐ Yes ☐ No
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 these descriptions are not included in the SMF, please provide brief descriptions (approximately 500 words each) of the facilities available and the equipment available for the storage and distribution of medicinal products on a separate sheet of paper.	
9.6 ACTIVITIES RELATING TO IMPORT/EXPORT	
Are medicines imported/exported by the Applicant?	☐ Yes ☐ No
If yes, please provide a list of products being imported/exported.	

PART C: LIST OF ACTIVITIES

10. Please specify the list of activities to be performed at this site in accordance with the following matrix. ***Note:*** *The entire matrix will be included on the actual licence that will be issued.*

		YES	NO
10.1	**CULTIVATION ACTIVITIES**		
	Storage of seeds	X	
	Growing of seeds	X	
10.2	**MANUFACTURING ACTIVITIES**		
	Sterile manufacturing (includes filling, but not cartoning or labelling)		X
	Large volume parenteral products		X
	Small volume parenteral products		X
	Other sterile dosage forms (please specify)		X
	Non-sterile Manufacturing		
	Tablets		X
	Capsules		X
	Liquids		X
	Semi-solids (Creams or ointments)		X
	Suppositories		X
	Other non-sterile dosage forms (please specify)		X
	Complementary Medicines Manufacturing		X
10.3	**PACKAGING ACTIVITIES**		
	Packaging of bulk product and labelling	X	
	Re-labelling or redressing		X
	Cartoning or secondary packaging		X
10.4	**TESTING ACTIVITIES**		
	Analytical	X	
	Microbiological	X	
	Sterility		X
	Stability		X
	Animal		X
	Other (please specify)		

10.5 DISTRIBUTION ACTIVITIES		
Bulk distribution to wholesale pharmacies		X
Fine distribution to retail pharmacies and other clients		X
Import		X
Export (please specify products exported on a separate list)		X

PART D: PERSONNEL INFORMATION

Guidance notes on nomination of responsible personnel

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 cultivation, manufacture or import medicinal Cannabis. The Regulations to the Act require that changes be notified promptly to the South African Health Products Regulatory Authority.

Relevant Qualifications for Manufacturing

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.

~~11 THE RESPONSIBLE PERSON~~

~~Please give the following details of the pharmacist who is to control the manufacture or import of medicinal Cannabis in terms of the provisions of Regulation 23 of the Act. Please submit a certified copy of the candidate's Registration Certificate from the SA Pharmacy Council with this application.~~

~~11.1 PERSONAL INFORMATION~~

~~Surname~~	
~~First Name~~	
~~Position in company~~	
~~Qualification~~	
~~SAPC Registration number~~	

~~11.2 RELEVANT QUALIFICATIONS~~

~~Degree/ Diploma~~	~~Field of study~~	~~Institution~~	~~Year graduated~~

~~11.3 RELEVANT EXPERIENCE (last job first)~~

~~Employer~~	~~No. of years~~	~~Position held~~

11.4 BUSINESS ADDRESS AND PHONE NUMBER	
~~Line 1~~	
~~Town/ City~~	
~~Province~~	
~~Postal code~~	
~~Telephone number~~	

~~11.5 NOMINATION OF RESPONSIBLE PHARMACIST~~	
~~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 or import of medicinal Cannabis substances as detailed in this licence application.~~	
~~Name (Responsible pharmacist):~~	
~~Signed~~	~~Date:~~
~~Name (designee)~~	
~~Signed (designee)~~	~~Date:~~

12 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF PRODUCTION	
12.1 PERSONAL INFORMATION	
Surname	Not yet known
~~First Name~~	
~~Position in company~~	

~~12.2 RELEVANT QUALIFICATIONS~~			
Degree/ Diploma	~~Field of study~~	~~Institution~~	~~Year graduated~~

~~12.3 RELEVANT EXPERIENCE (last job first)~~		
~~Employer~~	~~No. of years~~	~~Position held~~

13 NOMINATION OF PERSON WHO WILL HAVE CONTROL OF QUALITY CONTROL/ASSURANCE	
13.1 PERSONAL INFORMATION	
Surname	Not yet known
~~First Name~~	
~~Position in company~~	

~~13.2 RELEVANT QUALIFICATIONS~~			
~~Degree/ Diploma~~	~~Field of study~~	~~Institution~~	~~Year graduated~~

~~13.3 RELEVANT EXPERIENCE (last job first)~~		
~~Employer~~	~~No. of years~~	~~Position held~~

~~14 PERSON(S) RESPONSIBLE FOR SECURITY~~	
~~14.1 PERSONAL INFORMATION~~	
Surname	Not yet known
~~First Name~~	
~~Position in company~~	

~~14.2 RELEVANT QUALIFICATIONS~~			
~~Degree/ Diploma~~	~~Field of study~~	~~Institution~~	~~Year graduated~~

~~14.3 RELEVANT EXPERIENCE (last job first)~~		
~~Employer~~	~~No. of years~~	~~Position held~~

~~14.4 NAME AND FUNCTION TO WHOM HE/SHE REPORTS~~

15 PROPOSED DATE OF AUDIT

PART E: DECLARATION

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

A.	**I declare that:** (Tick one box only in each case)	**YES**	**NO**
(i)	The applicant had a licence revoked after being granted such a licence.		X
(ii)	The applicant has been convicted of an offence against the Medicines and Related Substances Act, 1965 or a law of a state or territory relating to medicines and related substances.		X
(iii)	The applicant has been convicted of an offence against use or dealings in illicit drugs.		X
(iv)	The information provided in this application is current and correct.	X	

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

B. **I/ We** apply for the **new/ renewal** (indicate by crossing out the non-applicable section) of a Manufacturer's Licence to the proposed holder name 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 Cultivator / Manufacturer's Licences under regulations for the time being in force under Section 22C of the Medicines and Related Substance Act, 1965.
2. The cultivation, manufacturing or import 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 cultivators or importers or manufacturers and / or packaging relating to the Cannabis products we wish to cultivate or import or 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 as follows:

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

Full Name	Black Widow
Signature	
Position within organisation	Owner
Date	30 October 2019

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 authorised person above.*