MALTA
MEDICINES AUTHORITY

CAN002-09 Appendix 1 Version 1

APPLICATION FOR THE GRANT OR RENEWAL OF A LICENCE
IN ACCORDANCE WITH THE
PRODUCTION OF CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES ACT
(Cap. 578 of the Laws of Malta)

For office use only:

Licence number for new applications: CMRU _ _ _/_ _ _ _

Licence number for renewal applications: CMRU _ _ _/(R)_ _ _ _

New/Renewal Application form received on: ___ / ___ / ____

APPLICATION TYPE (select accordingly)

☐ Production Licence for activities related to cannabis for medicinal and research purposes (covers all activities that may be authorised under article 4 of the Act)
To complete sections 1,2,3,4,5 and 6.

☐ Licence for testing activities related to cannabis for medicinal and research purposes
To complete sections 1,2,3,5 and 7.

☐ Licence for activities related to cannabis for research purposes (not commercial)
To complete sections 1,2,3,5 and 8.

1 DETAILS OF PROPOSED LICENCE HOLDER

1.1 If individual:

Name: _____
Surname: _____
ID or passport number: _____

1.2 If company:

Name: _____
Company registration number: _____
Legal and judicial representative of company:
Name: _____
Surname: _____
ID or passport number: _____

2 LEGAL ADDRESS OF PROPOSED LICENCE HOLDER

Building Name/No.: _____
Street: _____
Locality: _____
Postcode: _____

If individual – address on ID card

If company – address registered with MBR

3 DETAILS OF PROPOSED LICENCE HOLDER CONTACT

3.1 Name: _____

Surname: _____

3.2 Address of Licence Holder Contact if different from Section 2

Building Name/No.: _____

Street: _____

Locality: _____

Postcode: _____

3.3 Telephone number: _____

Mobile number: _____

E-mail address: _____

4 DETAILS RELATED TO DUE DILIGENCE

Required for all company shareholders, ultimate beneficial owners (UBOs) (direct or indirect), directors, management, responsible officers, qualified person(s) and any other persons with a financial interest and persons with decision making powers of influence.

Name:_____

Surname:_____

Date of Birth: _____

ID number:_____

Passport number:_____

Position held in the company:_____

Residential Address:

Building Name/No: _____

Street: _____

Locality: _____

Postcode:_____

Country:_____

Contact number:_____

Email:_____

Print and fill in additional copies of this section as necessary. Attach a copy of identity card or passport and MMA Declaration Form for Due Diligence Procedures (Annex 2). The applicant/licence holder commits to provide updated documentation for consideration by the regulatory authority should any changes related to the above come into effect or changes/additions with respect to parties (persons/companies) related to the operations being licensed are proposed. Failure to comply with this shall be considered a significant breach and may lead to withdrawal of licence.

Number of copies attached:____

5 SITE DETAILS

5.1 Address of proposed site

Building Name/No.: _____

Street:_____

Locality: _____

Postcode: _____

5.2 Site contact (if different from section 3)

6 PRODUCTION LICENCE FOR ACTIVITIES RELATED TO CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES

KEY PERSONNEL

QUALIFIED PERSON

Name: _____

Surname: _____

Pharmacy Council QP Registration Number: _____

Pharmacy Council Pharmacist Registration Number: _____

Contact details:

Office telephone number: _____

Mobile number: _____

E-mail address: _____

Position held with the company other than Qualified Person (QP), if any:

_____

QP dosage form eligibility:

_____

I accept to take up the responsibility of QP as described in the Medicines Act (Cap. 458) where applicable. I confirm that the above particulars are to the best of my knowledge and belief, accurate and true.

Signed (proposed QP):

Date:

Signed (proposed Licence Holder or company representative if Licence Holder is a company):

Date:

Print and fill in additional copies of this section, as necessary, if more than 1 QP is nominated by licence holder. Number of copies attached: ___

PERSON WITH OVERALL RESPONSIBILITY FOR PRODUCTION

Name: _____

Surname: _____

Contact details:

Office telephone number: _____

Mobile number: _____

E-mail address: _____

Qualifications:

_____

_____

_____

Experience in GMP related areas:

_____

_____

Details of the person(s) to whom he/she reports:

_____

PERSON WITH OVERALL RESPONSIBILITY FOR QUALITY CONTROL

Name: _____

Surname: _____

Contact details:

Office telephone number: _____

Mobile number: _____

E-mail address: _____

Qualifications:

_____

_____

_____

Experience in GMP related areas:

_____

_____

Details of the person(s) to whom he/she reports:

_____

A. Cultivation of cannabis

Tick the activities to be held at the site

6.1 ☐ No cultivation will take place

6.2 ☐ Cultivation will take place

6.2.1 Area for growing: _____

B. Importation[1]/sourcing of cannabis

Tick activities to be held at the site

6.3 Importation/sourcing activities

Importation/sourcing of cannabis in a form which shall undergo further processing (*specify form and the processing subsequently required)*:

_____

6.3.1 ☐ Quality control testing of imported/sourced cannabis for medicinal use:

_____

6.3.1.1 ☐ Microbiological: sterility

6.3.1.2 ☐ Microbiological: non-sterility

6.3.1.3 ☐ Chemical/ physical

6.3.1.4 ☐ Biological

6.3.2 ☐ Batch certification of imported/sourced cannabis for medicinal use.

6.3.3 ☐ Other importation activities (please specify):

_____

[1] 'Importation' shall be construed as obtained from a source outside the European Union or the European Economic Area in line with S.L. 458.36.

C. Manufacturing activities

Tick activities to be held at the site

6.4 Production

6.4.1 Dosage forms:

6.4.1.1 ☐ Capsules, hard shell

6.4.1.2 ☐ Capsules, soft shell

6.4.1.3 ☐ Liquids for external use

6.4.1.4 ☐ Liquids for internal use

6.4.1.5 ☐ Pressurised preparations

6.4.1.6 ☐ Semi-solids

6.4.1.7 ☐ Suppositories

6.4.1.8 ☐ Tablets

6.4.1.9 ☐ Transdermal patches

6.4.1.10 ☐ Thin film

6.4.1.11 ☐ Other (please specify): _____

6.5 Quality control testing

6.5.1 ☐ Microbiological: sterility

6.5.2 ☐ Microbiological: non-sterility

6.5.3 ☐ Chemical/Physical

6.5.4 ☐ Biological

6.5.5 ☐ Other (please specify): _____

6.6 Other operations

Bioburden reduction activities:

6.6.1 □ No bioburden reduction activities will take place

6.6.2 □ Bioburden reduction activities will take place

6.6.2.1 □ Filtration

6.6.2.2 □ Dry heat

6.6.2.3 □ Moist heat

6.6.2.4 □ Chemical

6.6.2.5 □ Gamma irradiation

6.6.2.6 □ Electron beam

6.6.2.7 □ Other (please specify): _____

6.6.3 Material which will undergo bioburden reduction

6.6.3.1 □ Active substances

6.6.3.2 □ Excipients

6.6.3.3 □ Finished products

6.6.3.4 □ Other (please specify): _____

6.6.4 Other (please specify): _____

6.7 Packaging

6.7.1 Primary packing of:

6.7.1.1 ☐ Capsules, hard shell

6.7.1.2 ☐ Capsules, soft shell

6.7.1.3 ☐ Liquids for external use

6.7.1.4 ☐ Liquids for internal use

6.7.1.5 ☐ Pressurised preparations

6.7.1.6 ☐ Semi-solids

6.7.1.7 ☐ Suppositories

6.7.1.8 ☐ Tablets

6.7.1.9 ☐ Transdermal patches

6.7.1.10 ☐ Thin film

6.7.1.11 ☐ Other (please specify): _____

6.7.2 Secondary packing of:

6.7.2.1 ☐ Please specify: _____

6.7.3 Child resistance closure of:

6.7.3.1 ☐ Please specify: _____

6.7.4 Over-printing and over-labelling:

6.7.4.1 ☐ Overprinting of primary packaging

6.7.4.2 ☐ Overprinting of secondary packaging

6.7.4.3 ☐ Over-labelling of primary packaging

6.7.4.4 ☐ Over-labelling of secondary packaging

6.7.5 Assembly activities:

6.7.5.1 □ Replacement of secondary packaging

6.7.5.2 □ Replacement of secondary packaging with change in quantity in each pack

6.7.5.3 □ Removal/insertion of other items

(please specify):_____

6.7.6 Dosage form assembly:

6.7.6.1 □ Liquid dosage forms

6.7.6.2 □ Semi-solid dosage forms (including creams and ointments)

6.7.6.3 □ Solid dosage forms (including tablets, capsules and powders)

6.7.6.4 □ Other dosage forms

(please specify):_____

6.8 Batch Certification

6.8.1 □ Products to be batch released specified in Section 6.9

6.9 Unit Product

The following must be completed per unit product manufactured:

Product name:

_____

Dosage form:

_____

Weight/volume of the manufactured unit product (pack size):

_____

% CBD and %THC of the manufactured unit product[2]:

_____

Batch specific labelling (tick box if applicable) ☐

Mode(s) of use: _____

Proposed retail price (specify for multiple markets, if applicable):

_____

Source(s) of starting and/or intermediate material:

_____

Starting and/or intermediate material description:

_____

Strain(s) of starting and/or intermediate material:

_____

% CBD and %THC of the starting and/or intermediate material[2]:

_____

[2] Percentage/content of cannabinoid(s) expressed in % w/w for cannabis inflorescence and % w/w and % w/v for cannabis oils and extracts.

Proposed shelf-life of the manufactured unit product:

_____

Estimated annual weight/volume of starting and/or intermediate material required for further processing: _____

Estimated annual number of unit products to be manufactured:

_____

Estimated annual weight/volume of unit products to be manufactured:

_____

Intended client(s) and market(s) for manufactured unit product:

- ☐ Local market
- ☐ Export

Please specify client(s) and country(ies): _____

Print and fill in additional copies of this section as necessary. Number of copies attached:

D. Contracted-out activities

Fill in as applicable.

6.10 Quality control testing

Applicant is contract giver (i.e. uses external testing facilities for some/all testing)

Name of proposed laboratory:

_____

Site Address of proposed laboratory:

Building Name/No.: _____

Street: _____

Locality: _____

Postcode: _____

Country: _____

Testing activities at this site:

- ☐ Chemical/physical
- ☐ Microbiological
- ☐ Stability studies
- ☐ Other (please specify): _____

Print and fill in additional copies of this section as necessary and attach copy of valid EU-GMP certificate of proposed contractor, as applicable. Number of copies attached: __

6.11 Bioburden reduction site

Name of proposed bioburden reduction site:

_____

Site address of bioburden reduction site:

Building Name/No.: _____

Street: _____

Locality: _____

Postcode: _____

Country: _____

Description of bioburden reduction activities on site:

_____

_____

Bioburden reduction activities performed on:

- ☐ Raw material
- ☐ Intermediate material
- ☐ Finished product
- ☐ Other (please specify)

  _____

Print and fill in additional copies of this section as necessary and attach copy of valid EU-GMP certificate of proposed contractor, as applicable. Number of copies attached: __

6.12 Other manufacturing activities

Type of manufacturing activity/ies:

_____

Name of proposed manufacturing site:

_____

Site address of manufacturing site:

Building Name/No. _____

Street _____

Locality _____

Postcode _____

Country _____

Print and fill in additional copies of this section as necessary and attach copy of valid EU-GMP certificate of proposed contractor, as applicable. Number of copies attached: __

6.13 Transportation

Name of proposed transportation contractor:

_____

Site Address of transportation site:

Building Name/No.: _____

Street: _____

Locality: _____

Postcode: _____

Country: _____

Print and fill in additional copies of this section as necessary. Number of copies attached:__

6.14 Cannabis waste management

Please specify the proposed method for destruction/disposal:

_____

Destruction and/or disposal of cannabis:

- ☐ In-house
- ☐ Third-party contractor

Name of proposed third-party waste contractor, if applicable:

_____

Site address of third-party waste contractor:

Building Name/No. _____

Street _____

Locality _____

Postcode _____

Country _____

Print and fill in additional copies of this section as necessary. Number of copies attached: __

Any clarifying remarks related to the scope of these contracted-out manufacturing operations:

6.15 Research activities

Refer to section 8.

7 LICENCE FOR TESTING ACTIVITIES RELATED TO CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES

KEY PERSONNEL

PERSON WITH OVERALL RESPONSIBILITY FOR TESTING

Name: _____

Surname: _____

Contact details:

Office telephone number: _____

Mobile number: _____

E-mail address: _____

Qualifications:

_____

_____

Experience in the concerned testing activity(ies):

_____

_____

Details of the person(s) to whom he/she reports:

_____

PERSON WITH OVERALL RESPONSIBILITY FOR QUALITY CONTROL

Name: _____

Surname: _____

Contact details:

Office telephone number: _____

Mobile number: _____

E-mail address: _____

Qualifications:

_____

_____

_____

Experience in GMP related areas:

_____

_____

Details of the person(s) to whom he/she reports:

_____

7.1 Testing activities at this site:

- ☐ Chemical/physical
- ☐ Microbiological
- ☐ Stability studies
- ☐ Other (please specify): _____

8 LICENCE FOR ACTIVITIES RELATED TO CANNABIS FOR RESEARCH PURPOSES (NOT COMMERCIAL)

KEY PERSONNEL

Please note that products intended for use in clinical trials also require EU-GMP certification (refer to previous sections)

PERSON WITH OVERALL RESPONSIBILITY FOR RESEARCH

Name: _____

Surname: _____

Contact details:

Office telephone number: _____

Mobile number: _____

E-mail address: _____

Qualifications:

_____

_____

Experience in the concerned research area(s) (pharmaceutical, pharmacological and/or clinical):

_____

_____

Details of the person(s) to whom he/she reports:

_____

A. Cultivation of cannabis

Tick the activities to be held at the site

8.1 ☐ No cultivation will take place

8.2 ☐ Cultivation will take place

7.2.1 Area for growing:

_____

B. Source and supply of cannabis

8.3 Company/sponsor/individual responsible for purchasing/sourcing cannabis for research purposes, as applicable:

_____

8.4 Company/sponsor/individual responsible for supplying cannabis for research purposes:

_____

Specify form, strain and cannabinoid concentration:

8.4.1 ☐ Bulk products _____

8.4.2 ☐ Intermediate products _____

8.4.3 ☐ Finished products _____

8.4.4 ☐ Other (please specify): _____

C. Manufacturing activities

Tick activities to be held at the site

8.5 Production

8.5.1 Dosage forms

8.5.1.1 ☐ Capsules, hard shell

8.5.1.2 ☐ Capsules, soft shell

8.5.1.3 ☐ Liquids for external use

8.5.1.4 ☐ Liquids for internal use

8.5.1.5 ☐ Pressurised preparations

8.5.1.6 ☐ Semi-solids

8.5.1.7 ☐ Suppositories

8.5.1.8 ☐ Tablets

8.5.1.9 ☐ Transdermal patches

8.5.1.10 ☐ Thin film

8.5.1.11 ☐ Other cannabis products (please specify): _____

8.6 Other manufacturing activity

8.6.1 Bioburden reduction of active substances/excipients/finished preparation:

8.6.1.1 ☐ Filtration

8.6.1.2 ☐ Dry heat

8.6.1.3 ☐ Moist heat

8.6.1.4 ☐ Chemical

8.6.1.5 ☐ Gamma irradiation

8.6.1.6 ☐ Electron beam

8.6.1.7 ☐ Others (please specify): _____

8.6.2 Other (please specify): _____

8.7 Packaging

8.7.1 □ Primary packing
Please specify: _____

8.7.2 □ Secondary packing
Please specify: _____

8.8 Laboratory Analysis

8.8.1 □ Microbiological: sterility

8.8.2 □ Microbiological: non-sterility

8.8.3 □ Chemical/Physical

8.8.4 □ Biological

8.8.5 □ Other (please specify): _____

8.9 Contracted-out activities

Please specify: _____

8.10 Destruction and/or disposal of cannabis

Please specify the proposed method for destruction/disposal:

_____

PROPOSED LICENSE HOLDER'S DECLARATION

This application is intended for the granting or renewal of a Licence, in accordance with the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta) to the proposed holder named in this application form in respect of the activities to which the application refers, in relation to cannabis for medicinal and/or research purposes only.

1. The applicant commits to comply with Maltese legislation, and the Courts of Malta shall have exclusive jurisdiction to settle any claim, difference, or dispute which may arise out of or in connection with the applicant's/licence holder's operations. The applicant/license holder irrevocably waives any claim that such action or proceeding has been brought in an inconvenient forum or that the Courts of Malta do not have jurisdiction.

2. The applicant is familiar with and will comply with the provisions of the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta), and the relevant regulations and guidelines, that may be amended from time to time, as applicable to the license.

3. In the interest of protecting public health and the prevention of the illicit diversion of cannabis, the applicant authorises the regulatory authority to carry out due diligence, know-your-client (KYC), and any other procedures or evaluation permitted under Maltese law, on company shareholders, ultimate beneficial owners (UBOs), directors, officers, and employees, including the company's history, source of funds, business operations, commercial associations and affiliations, medical screening and ethical conduct.

4. The applicant is informed and understands that notwithstanding the granting or renewal of any licence, permit, or authorisation granted by the Licensing Authority, the Commissioner of Police may, in line with Article 5(3) of The Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta), take any necessary reasonable action necessary to investigate, prevent and prosecute any crime carried out or is expected/suspected to be carried out on the premises where any activity authorized under the mentioned Act is taking place.

5. The applicant attests that the suspension, withdrawal, revocation, cancellation or expiry of the licence and/or the letter of intent for any reason, shall preclude the applicant from carrying out any activity related to cannabis.

6. The applicant hereby authorises the Regulatory Authority to furnish the Malta Police Force, Customs Officials, International Narcotics Control Board and any other local or foreign law enforcement entity with any information and documentation if requested.

7. All operations are to be carried out only in accordance with the information set out in the application or furnished in connection therewith. The applicant commits to provide updated documentation, which may include details of specifications, methods of analysis, import/export estimates and comprehensive reports, as may be periodically requested by the regulatory authority.

8. The applicant declares that he holds the relevant product licences, or equivalent, relating to any products the applicant intends to manufacture and/or assemble pursuant to this application, as applicable.

9. The applicant undertakes to notify the Regulatory Authority without undue delay of any material change in circumstances that may affect the validity of the information provided in this application, including but not limited to changes in ownership, corporate structure, key personnel or intended operations.

10. The applicant acknowledges and undertakes to comply with the applicable data protection legislation, including Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR) and the Data Protection Act (Chapter 586 of the Laws of Malta), in relation to any personal data processed in connection with this application and subsequent licensed operations. The applicant also understands and accepts that any personal data and confidential information submitted may be processed by the Regulatory Authority and shared with competent authorities, in accordance with applicable law, for the purposes of assessing this application, conducting ongoing supervision, and fulfilling legal and regulatory obligations.

11. The applicant acknowledges that the granting of a licence does not absolve the licensee from any other legal obligations.

12. The applicant attests that all the information and documents submitted in support of the application are, to the best of his knowledge, correct and complete.
(*If other than applicant, a power of attorney from proposed licence holder nominating and authorising signatory to apply on his behalf is required)*

Signed: _____

Surname: _____

Name: _____

ID/Passport No: _____

Date: _____

ANNEX 1: DOCUMENTS TO BE ATTACHED TO APPLICATION

A. Production Licence for activities related to cannabis for medicinal and research purposes (covers all activities that may be authorised under article 4 of the Act):

I. MANUFACTURE

1. Intended manufacturing process and supply chain model describing the stages involved from cultivation to unit product(s) commercialisation, clearly indicating the responsibilities, details and site addresses of all parties involved including supplier(s), contractor(s) for outsourced activities, client(s) and other operator(s), as applicable.
2. Copy of EU-Good Manufacturing Practice (GMP) covering the authorised activities in the local site.
3. Copy of Good Agricultural and Collection Practices (GACP) declaration/certification and QP signed declaration for pesticides used in the cultivation site(s).
4. Copy of EU-GMP certificate and/or QP audit report for source(s), as applicable.
5. Copy of EU-GMP certificate for contractor(s), as applicable.
6. Labelling and any product information (in English) available for the unit product. For products intended for export, a QP declaration that labels and artworks are in line with any applicable legislative and regulatory provisions as set out in the receiving territory and in line with the product specifications, as applicable.
7. Specifications, technical drawings and certificate(s) of compliance from supplier(s) for packaging of products to be released from the local facility. Electronic mock-up which shall consist of photographic evidence of all components of the unit product pack, inclusive of child-resistant closure, as applicable.
8. Specifications, hold time studies, certificate of analysis, including compendia, methods and ranges or limits, of the starting/intermediate material, as applicable.
9. Specifications, stability studies, certificate of analysis, including compendia, methods and ranges or limits of the unit products.
10. Copy of EU-GMP certificate(s) for the bioburden reduction site(s) and certificate(s) of processing for bioburden reduction, as applicable.
11. Procedures in place for reporting, including adverse reaction reports and recalls.
12. Details of client(s) in destination country, including wholesale dealer's licence and narcotic licence, as applicable.

II. MANUFACTURING FACILITY

1. Site Master File in line with EU-GMP guidelines requirements.
2. ERA Permits for unlicensed sites listed on application, as applicable.
3. Floor plan of the site and building, building site plans and location survey, as applicable
4. Architect's report, as applicable.
5. Name and contact information of the project's supervisor (if the building is under construction).
6. Proposed operational hours of the facility.

7. Environmental, waste management and sanitation plan/procedures and signed copy(ies) of waste disposal agreement(s), as applicable.
8. Facility security documentation in fulfilment of obtaining the Facility Security Clearance Certificate (FSCC); site plan indicating: entrances and exits (including emergency exits); and locations of - access control system, CCTV, CCTV control room, security personnel, physical security policy, physical security risk assessment, policies and procedures related to physical entry controls, policies and procedures related to delivery and loading areas controls, policies and procedures for stock-taking, process flow chart showing the incoming, processing and outgoing of products, SOP/policies for unauthorised access, theft and emergency procedures as applicable to transportation including responsibility, record keeping and reconciliation, audit report of outsourced transport activities and signed copy of agreement(s) (as applicable).

III. COMPANY/PERSONNEL

1. Curriculum vitae of Production Manager. For academic qualifications obtained overseas, a recognition statement issued by the MFHEA Malta Qualifications Recognition Information Centre (MQRIC).
2. Curriculum vitae of Quality Control Manager. For academic qualifications obtained overseas, a recognition statement issued by the MFHEA Malta Qualifications Recognition Information Centre (MQRIC).
3. Curriculum vitae of Qualified Person. For academic qualifications obtained overseas, a recognition statement issued by the MFHEA Malta Qualifications Recognition Information Centre (MQRIC).
4. Copy of Pharmacy Council QP certificate, copy of Pharmacy Council Pharmacist warrant of Qualified Person(s) and QP approval letter(s) indicating dosage form(s) eligibility.
5. Company organisational chart.
6. Certificate of Registration issued by MBR (for private & public companies).
7. Memorandum and articles of association.
8. Letter of Intent as issued by Malta Enterprise to reflect the proposed activities.
9. Identity card/passport copies (as per Section 4) and MMA Declaration Form for Due Diligence Procedures (Annex 2).
10. Declaration of Source of Funds Form (Annex 3).
11. Power of attorney to sign on behalf of the licence holder (as applicable).
12. Proof of Payment.

B. TESTING PURPOSES

1. Copy of EU-Good Manufacturing Practice (GMP) covering the authorised activities in the local site.
2. Copy of EU-GMP certificate for contractor(s), as applicable.
3. Facility security review process documents as prescribed by the Regulatory Authority.
4. Letter of Intent issued by Malta Enterprise to reflect the testing activities.

5. Environmental, waste management and sanitation plan/procedures and signed copy(ies) of waste disposal agreement(s), as applicable.
6. Curriculum vitae of Quality Control Manager. For academic qualifications obtained overseas, a recognition statement issued by the MFHEA Malta Qualifications Recognition Information Centre (MQRIC).
7. Certificate of Registration issued by MBR (for private & public companies).
8. Memorandum and articles of association.
9. Declaration of Source of Funds Form (Annex 3).
10. Power of attorney to sign on behalf of the licence holder (as applicable).
11. Proof of payment.

C. RESEARCH PURPOSES

1. Quality third party agreement(s) (analytical testing, waste management, transportation etc).
2. Details of contracted-out activities and related certification documents as applicable.
3. Facility security clearance certificate.
4. Detailed research protocol including:

    i. Ethics committee approval (as applicable)
    ii. Supplier of cannabis-based material
    iii. Scope of research
    iv. Quantity and form of cannabis used in the course of research (inclusive of prospective timelines)
    v. Research process flow

5. Any internal procedures governing the research activities, as applicable.
6. Letter of Intent issued by Malta Enterprise to reflect the research activities.
7. Certificate of Registration issued by MBR (for private & public companies).
8. Memorandum and articles of association.
9. Facility security review process documents as prescribed by the Regulatory Authority.

ANNEX 2: MALTA MEDICINES AUTHORITY DECLARATION FORM FOR DUE DILIGENCE PROCEDURES

Please complete the table below for all the Shareholders, Ultimate Beneficial Owners (direct or indirect), Directors, Managers, Qualified Person(s), Responsible Officers and any other persons with a financial interest and persons with decision-making powers of influence of the proposed Licence Holder.

Name and Surname	Position	ID Card Number/Passport Number	Address	Nationality

Print and fill in additional copies of this section as necessary

I, the applicant/licensee for a Licence in accordance with the Production of Cannabis for Medicinal and Research Purposes Act (Cap. 578 of the Laws of Malta), hereby declare on oath that I have included all the persons falling within the scope of due diligence and that all the information given in the Due Diligence Declaration Form is true, complete and correct. I also

hereby bind myself to inform Malta Medicines Authority immediately as soon as there are any changes to the information provided in the Due Diligence Declaration Form but in any case by no later than five (5) working days from such an occurrence. Furthermore, I acknowledge that the personnel engaged in this capacity are deemed fit and appropriately compliant with the necessary security safeguards and control measures to assume such roles in the interim until official clearance has been issued.

Company Name: _____

Company Registration Number:_____

Name & Surname*: _____

Position: _____

Signature*_____

Date:_____

*Name, surname and signature have to be those of the company representative.

I, the appointed due diligence specialist of (Company Name), hereby certify that the information provided in this declaration form is true, complete and correct.

Name & Surname: _____

Warrant Number (as applicable):
_____

Signature:_____

Date: _____

ANNEX 3: DECLARATION OF SOURCE OF FUNDS FORM

Malta Financial Services Authority (MFSA), Malta Business Registry (MBR) and Financial Intelligence Analysis Unit (FIAU) guidelines require the Malta Medicines Authority to obtain information on the source of funds of individual transactions. Information is therefore being collated in this form on the activity, event, business, occupation or employment from which the funds used in order to settle the fees for the application of a licence for the production of Cannabis for Medicinal and Research Purposes are generated.

In fulfilling its regulatory obligations, the Malta Medicines Authority may require the applicant to support the information provided herein.

Ultimate Beneficial Owner's Name: _____

Personal Identification Number: _____

Full details of the activity, event, business, occupation or employment which generated the funds used for this transaction:

_____

_____

_____

_____

_____

I hereby declare on oath that the above information is accurate and complete.

_____ _____

Ultimate Beneficial Owner's Signature **Date**