



MALTA

MEDICINES
AUTHORITY

CAN002-07 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 (please tick one)

MANUFACTURING FOR MEDICINAL AND RESEARCH PURPOSES
(COMMERCIAL)

RESEARCH PURPOSES ONLY (NOT COMMERCIAL)

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

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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)

Name: _____

Surname: _____

Telephone number: _____

Mobile number: _____

E-mail address: _____

6 MEDICINAL 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

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6.1 **No cultivation will take place**

6.2 **Cultivation will take place**

6.2.1 Area for growing: _____

B. Importation¹/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): _____

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6.6 Other operations

Sterilisation:

6.6.1 No sterilisation will take place

6.6.2 Sterilisation 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 sterilisation

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 Products

6.9.1 Finished Products

The following must be completed per finished product manufactured:

Product name:

Dosage form:

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

% CBD and %THC of the manufactured finished product²:

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 material²:

Proposed shelf-life of the manufactured finished product:

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

Estimated annual number of finished products to be manufactured:

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

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

Intended client(s) and market(s) for manufactured finished 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: _____

6.9.2 Intermediate products

The following must be completed per intermediate product manufactured.

Product name:

Dosage form:

Weight/volume of the manufactured intermediate product (bulk quantity):

% CBD and %THC of the manufactured intermediate product²:

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:

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

% CBD and %THC of starting and/or intermediate material²:

Proposed shelf-life of the manufactured intermediate product:

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

Estimated annual number of intermediate products to be manufactured:

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

Intended client and market for the manufactured intermediate 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 EU-GMP certificate of proposed contractor.

Number of copies attached: _____

6.11 Irradiation site

Name of proposed irradiation site:

Site address of irradiation site:

Building Name/No.: _____

Street: _____

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Locality: _____

Postcode: _____

Country: _____

Description of irradiation activities on site:

Irradiation activities performed on:

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

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

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.

Number of copies attached: _____

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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.

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

7 RESEARCH PURPOSES

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 (as applicable)

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

7.1 **No cultivation will take place**

7.2 **Cultivation will take place**

7.2.1 Area for growing:

B. Source and supply of cannabis

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

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

Specify form, strain and cannabinoid concentration:

7.4.1 Bulk products _____

7.4.2 Intermediate products _____

7.4.3 Finished products _____

7.4.4 Other (please specify): _____

C. Manufacturing activities

Tick activities to be held at the site

7.5 Production

7.5.1 Dosage forms

- 7.5.1.1 Capsules, hard shell
- 7.5.1.2 Capsules, soft shell
- 7.5.1.3 Liquids for external use
- 7.5.1.4 Liquids for internal use
- 7.5.1.5 Pressurised preparations
- 7.5.1.6 Semi-solids
- 7.5.1.7 Suppositories
- 7.5.1.8 Tablets
- 7.5.1.9 Transdermal patches
- 7.5.1.10 Thin film
- 7.5.1.11 Other cannabis products (please specify): _____

7.6 Other manufacturing activity

7.6.1 Sterilisation of active substances/excipients/finished preparation:

- 7.6.1.1 Filtration
- 7.6.1.2 Dry heat
- 7.6.1.3 Moist heat
- 7.6.1.4 Chemical
- 7.6.1.5 Gamma irradiation
- 7.6.1.6 Electron beam
- 7.6.1.7 Others (please specify): _____

7.6.2 Other (please specify): _____

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7.7 Packaging

7.7.1 Primary packing

Please specify: _____

7.7.2 Secondary packing

Please specify: _____

7.8 Laboratory Analysis

7.8.1 Microbiological: sterility

7.8.2 Microbiological: non-sterility

7.8.3 Chemical/Physical

7.8.4 Biological

7.8.5 Other (please specify): _____

7.9 Contracted-out activities

Please specify: _____

7.10 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.
9. 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. MANUFACTURE

1. Intended manufacturing process and supply chain model describing the stages involved from cultivation to final 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. Good Agricultural and Collection Practices (GACP) declaration/certification and QP signed declaration for pesticides used in the cultivation site(s).
3. Copy of EU-Good Manufacturing Practice (GMP) certificate and/or QP audit report for source(s), as applicable.
4. Copy of EU-GMP certificate for contractor(s), as applicable.
5. Labelling and any product information (in English) available for the final 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.
6. Specifications, technical drawings and certificate(s) of compliance from supplier(s) for packaging of products to be released from the local facility. A physical mock-up of the finished product inclusive of child-resistant closure, as applicable.
7. Specifications, hold time studies, certificate of analysis, including compendia, methods and ranges or limits, of the starting/intermediate material, as applicable.
8. Specifications, stability studies, certificate of analysis, including compendia, methods and ranges or limits of the final products.
9. Copy of EU-GMP certificate(s) for the irradiation site(s) and certificate(s) of processing for irradiation, as applicable.
10. Procedures in place for reporting, including adverse reaction reports and recalls.
11. Details of client(s) in destination country, including wholesale dealer's licence and narcotic licence, as applicable.

B. 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 and signed copy(ies) of waste disposal agreement(s), as applicable.
8. Facility security documentation; 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

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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).

9. For renewal applications, Facility Security Clearance (FSC) recertification document(s).

C. 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. Malta Enterprise Letter of Intent.
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 (if applicable).
12. Proof of Payment.

D. RESEARCH PURPOSES

1. Quality third party agreement(s) (analytical testing, waste management, transportation etc).
2. Details of contracted-out activities and related certification documents if 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. Updated Letter of Intent issued by Malta Enterprise to reflect the research activities, as applicable.

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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.

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