MALTA MEDICINES AUTHORITY

CAN001-03 Appendix 2 Version 2

Application for wholesale distributors to place cannabis-based products or synthetic cannabinoid products on the market in accordance with the Medicines Act and the Drug Dependence (Treatment not Imprisonment) Act

For RENEWAL, please indicate authorisation number: MC _ _ _/_ _ _ _

For office use only:

Application Form/Renewal Form received on: ___ / ___ / ____

Application number:

To be submitted by CESP / by email to:
cannabis.medicinesauthority@gov.mt

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Application (new/renewal) [90 working days] ☐
Fast track application (new/renewal) [15 working days] * ☐

*The Medicines Authority may extend the timeline in exceptional circumstances.
*Timeline applies from the validation of the application and excludes clock-stops.

1. PRODUCT DETAILS

1.1 (a) Product (invented) Name

1.1 (b) Strain Name(s)

1.1 (c) Form

1.1 (d) Strength(s) of the active substance(s)

1.1 (e) Mode(s) of use

1.2 Active Substances and Excipients

Active Substance(s)	Amount of active substance(s) per unit dose	Reference / Monograph / Standard (if applicable)

Name of the excipient(s):	Quantity per unit dose	Reference / Monograph / Standard (if applicable)

1.3 Container, closure (including details on child-resistant features, as applicable) and administration device(s), of product to be placed on the market in Malta (including description and specifications of material(s) from which the component(s) are composed of).

1.4 For each type of pack, provide package size(s) to be placed on the market in Malta.

2. Applicant and Contact Person(s)

2.1 Applicant* for placing product on the market in Malta:

Company Name
Address

Telephone

Contact person
E-mail

2.2 Designated person for safety monitoring:

Name
Address

Telephone
E-mail

* Applicant must be authorised to act on behalf of the company which should be in possession of a wholesale dealer's license.

2.3 Designated person for quality monitoring:

Name

Address

24-hour contact telephone number

E-mail

3. DETAILS OF THE PRODUCT AS IN THE COUNTRY OF SOURCE

3.1 Specify the Member State(s) from which the product is being sourced

3.2 Manufacturer(s)†, including any contracted-out labs for final product release testing and manufacturers of any intermediate products, if applicable.

Company Name

Address

Telephone

E-mail

Contact person

3.3 Wholesale dealer/exporter† in source country:

Company Name

Address

Telephone

E-mail

Contact person

† Valid certificate should be provided

3.4 EU batch release site (if imported from outside the EU):

4. PROPOSED RETAIL PRICE

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Estimated number of sourced products annually per product pack.

5. DECLARATION

I, hereby confirm that to the best of my knowledge, all the particulars I have given in this application form, its annexes and all documentation submitted, are correct and complete. I declare that I am fully aware:

- of my obligations as per the Medicines Act, 2003 and the Drug Dependence (Treatment not Imprisonment) Act, and will fully abide by them and by the conditions of the approval;
- that the pack of the product to be placed on the market in Malta shall be in the English or Maltese language;
- that the product cannot be advertised;
- that the product(s) has not been assessed for quality, safety and efficacy as intended for a Marketing Authorisation in accordance with the Medicines Act (Marketing Authorisation Regulations);
- that I have the means for receiving and reporting adverse events for the product and of notifying the Malta Medicines Authority of any quality defects;
- that I have the means to carry out batch/product recalls in line with the legislation and requirements on wholesale dealing;
- that the product is only to be used for medicinal purposes and will be sold only to pharmacies and wholesale dealers licensed for narcotics and psychotropics in line with the Medicines Act.

I confirm that I am in agreement with the following fees and contributions, which may be amended by the Malta Medicines Authority:

- €450 at new/renewal application (attach proof of payment with application)
- €275 annual maintenance fee
- € 1.00 per unit product transacted, as research and education contribution to the Malta Medicines Authority (collected with the request for tamper-evident labels made to the Malta Medicines Authority, which are required to be affixed on each pack, as authorised for dispensing to the patient, within ten (10) days of receipt of the products, and prior to any further transactions related to the product, or as requested by the Authority).

Name of the applicant (use block letters):

Signature/s:

Position:

Place and Date:

Annex 1

Documents to be included with the application form (certified translations are required, where applicable)

1. Proof of payment.	☐
2. Copy of a valid wholesale dealer's licence covering narcotics and psychotropics issued by the Malta Medicines Authority (MMA).	☐
3. Copy of a Good Agricultural and Collection Practices declaration for the cultivation site(s) and declaration of pesticides used.	☐
4. Copy of a valid EU Good Manufacturing Practice (GMP) certificate issued by an EU/EEA country for the company manufacturing the product including any contracted-out labs for final product release testing, manufacturers of any intermediate products and irradiation site(s), if applicable. A copy of certificate for processing for irradiated products, if applicable.	☐
5. Copy of a valid wholesale dealer's licence or export licence from source country competent authority, as applicable.	☐
6. Copy of certificate/authorisation/permit issued by a competent authority to place the product on the market in an EU/EEA country.	☐
7. Labelling of product details in the English and/or Maltese language, including information on the product package components.	☐
8. Specifications of the finished product, stability studies, certificate of analysis, including compendia, methods and ranges or limits, in accordance with the applicable MMA guidelines.	☐
9. Details of the manufacturing process, from cultivation to EU batch release of finished products, including radioactivity analysis and/or other contracted-out activities, as applicable.	☐
10. Procedures in place for reporting, including adverse reaction reports and recalls.	☐