e-form

Application for the Importation and/or Wholesale Distribution of Cannabis Based Products or Synthetic Cannabinoid Products 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 hand (CD/DVD)/ by email to: innovation.medicinesauthority@gov.mt

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1. PRODUCT DETAILS:

1.1 (a) Product (invented) Name:	
1.1 (b) Dosage Form:	
1.1 (c) Strength(s) of the active substance(s):	
1.1 (d) Route(s) of administration:	

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 and administration device(s), of product to be placed on the market in Malta (including description of material from which it is constructed):

1.4 For each type of pack, give package size/s to be placed on the market in Malta:

2. APPLICANT / CONTACT PERSONS

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

Company Name:	
Address:	
Telephone:	
Contact person:	
E-mail:	

2.2 Person in the company responsible for receiving and reporting adverse events:

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 and/or importer license (as applicable).**

2.3 Contact person in the company for product defects and recalls:

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/source country of the product. Only one country may be listed as the country of source per application:

3.2 Manufacturer/s, including any contracted out labs for final product release testing and manufacturers of any intermediate products, if applicable, of the product in the source country:**

Company Name:	
Address:	
Telephone:	
E-mail:	
Contact person:	

****Valid certificate should be provided.**

3.3 Wholesale dealer/ exporter in source country:**

Company name:	
Address:	
Telephone:	
E-mail:	
Contact person:	

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

4. PROPOSED RETAIL PRICE

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Estimated number of imported products annually including amount and % of cannabis and THC:

**Valid certificate should be provided.

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 is not assessed for quality, safety and efficacy and the approval is not intended to be a Marketing Authorisation in accordance with the Medicines (Marketing Authorisation Regulations);

- that I have the means for receiving and reporting adverse events for the product and of notifying the 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 contribution, which may be amended by the Medicines Authority:

• €450 at submission/ renewal of application (attach proof with application),
• €275 annual maintenance fee/ contribution,
• €1 per unit product transacted, as research and education contribution to the Malta Medicines Authority (collected upon the supply of tamper-evident labels by 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:	Kindly fill in the Declaration form at the following link http://www.medicinesauthority.gov.mt/onlineapplications A Declaration form should be submitted for each signatory.
Position:	
Place and Date:	

Annex 1
Documents to be included with the application form (certified translations are required, when applicable).

- [ ] 1. Proof of payment.
- [ ] 2. Copy of a valid wholesale dealer's/ importer's licence covering narcotics and psychotropics issued by the Medicines Authority.
- [ ] 3. Copy of a valid GMP certificate issued by a EU/EEA or MRA country for the company manufacturing the product including any contracted out labs for final product release testing and manufacturers of any intermediate products, if applicable.
- [ ] 4. Copy of a valid wholesale dealer's licence or export licence from source country competent authority, as applicable.
- [ ] 5. Copy of certificate/ authorisation/ permit issued by a competent authority to place the product on the market in the source country or to export it, as applicable.
- [ ] 6. Labelling and any product information (in English) available for the product, including information on the pack of the product to be marketed.
- [ ] 7. Specifications of the finished product, stability studies, certificate of analysis, including compendia, methods and ranges or limits, details of manufacturing process, including radioactivity analysis, as applicable.