



MALTA

MEDICINES  
AUTHORITY

**CAN002-06 Appendix 13 Version 2**

**APPLICATION FOR A VARIATION TO LICENCE ISSUED  
IN ACCORDANCE WITH THE  
PRODUCTION OF CANNABIS FOR MEDICINAL AND RESEARCH  
PURPOSES ACT (Chapter 578 of the Laws of Malta)**

Variation application reference number *(for office use only)*: <Company reference number-VAPP XXX>

Licence holder name:

Licence holder address:

Site Name / Number:

Street:

Locality:

Postcode:

Number of Licence being varied:

Contact name:

Telephone number:

Mobile number:

E-mail address:

**LICENSE IN ACCORDANCE WITH THE PRODUCTION OF CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES ACT (Chapter 578 of the Laws of Malta)**

PLEASE TICK ONE VARIATION TYPE ACCORDINGLY

*A number of changes may be eligible for grouping under the same variation type subject to approval by the Regulatory Authority.*

**A1** Change(s) in company details which includes one or more of the following:  
 Change(s) in address of manufacturing site;  
 Change(s) in details of the licence holder;  
 Change(s) in Declaration of Source of Funds Form (Annex 3 of Application for Licence);  
 Change(s) in the Memorandum and Articles of Association.

**A2** Change(s) in product details

**A3** Change(s) in currently authorised operations

**A4** Change(s) related to persons who fall within the scope of due diligence as per Section 3.3 of GL-CAN001, other than key technical personnel<sup>1</sup>

**A5** Change(s) related to the Qualified Person(s)

**A6** Change(s) related to the Responsible Person(s) – Production Manager

**A7** Change(s) related to the Responsible Person(s) – Quality Control Manager

<sup>1</sup> Key technical personnel shall refer to the Qualified Person(s) and Responsible Person(s) (Production Manager and Quality Control Manager)

**A8** Change(s) in supplier(s) details, cultivation site(s) and/or irradiation site(s) for starting/intermediate material

**A9** Change(s) in contracted-out activities

**A10** Change(s) in destination market(s) and/or client(s) details therein

**A11** Other: (please specify)

*Specify the currently licenced operations/details and proposed changes (variation applications should be limited to one variation type per application).*

CURRENT	PROPOSED

*Please give a brief explanation for the proposed changes to your licence.*

**RATIONALE**

I hereby apply for the licence issued in accordance with the Production of Cannabis for Medicinal and Research Purposes Act (Chapter 578 of the Laws of Malta) to be varied in line with the proposal(s) given above and certify that the changes will not adversely affect any cannabis product(s) produced on the premises. I declare that the supporting information supplied is correct and shall submit to the Malta Medicines Authority any additional information/documents as requested.

**\*Licence Holder Signature:** \_\_\_\_\_

Date: \_\_\_\_\_

Name & Surname: \_\_\_\_\_

\* In case of a company, the legal & judicial representative of the company. Please submit copy of a recent Memorandum & Articles of Association issued by MFSA in support of this.