

MALTA

MEDICINES AUTHORITY

CAN002-09 Appendix 13 Version 1

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):*

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)

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

Variations that are considered eligible for grouping shall be issued collectively, unless the company requests prioritised review for any of the grouped variations falling within the scope of the same variation application. In such cases, the pending variations shall be considered void under the initial variation application and transferred by the licensee to a new variation application.

Changes to the scope of a variation application shall be accepted until proof of payment is received. Variation applications shall not be processed until a valid proof of payment is provided.

Please specify whether this is a fast-tracked variation application [10 days][1]:

- ☐ Yes
- ☐ No

If "Yes", please indicate a justification from the below as appropriate:

- ☐ Patient population: incidence, prevalence and/or orphan designation
- ☐ Disease severity: severity/ burden of the disease and/or end-of-life criteria
- ☐ Alternative treatments: availability, accessibility and/or benefit over alternatives
- ☐ Other: _____

[1] The timeline commences upon acceptance of the application for assessment and excludes any clock-stops. The Medicines Authority may extend the timeline in exceptional circumstances.

Please select <u>one</u> variation type accordingly

☐ **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[2]
☐ **A5** Change(s) related to the Qualified Person(s)
☐ **A6** Change(s) related to the Responsible Person – Production Manager
☐ **A7** Change(s) related to the Responsible Person– Quality Control Manager
☐ **A8** Change(s) in supplier(s) details, cultivation site(s) and/or bioburden reduction site(s) for starting/intermediate material and/or finished product
☐ **A9** Change(s) in contracted-out activities
☐ **A10** Change(s) in destination market(s) and/or client(s) details therein
☐ **A11** Change(s) related to the Responsible Person(s) – Research and Development
☐ **A12** Other: (please specify)

Specify the currently licenced operations/details and proposed changes (only one variation type shall be considered per application).

CURRENT	**PROPOSED**

[2] Key technical personnel shall refer to the Qualified Person(s) and Responsible Person(s) (Production Manager and Quality Control Manager)

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

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.