

SUBSIDIARY LEGISLATION 578.01

**PRODUCTION OF CANNABIS FOR MEDICINAL AND
RESEARCH PURPOSES (FEES) REGULATIONS**

23rd November, 2018

LEGAL NOTICE 391 of 2018, as amended by Legal Notices 100 of 2023 and 189 of 2025.

1. The title of these regulations is the Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations. Citation.

2. In these regulations, unless the context otherwise requires – Interpretation.
Amended by:
L.N. 100 of 2023;
L.N. 189 of 2025.

"the Act" means the Production of Cannabis for Medicinal and Research Purposes Act; Cap. 578.

"Contribution" means a payment per unit product marketed, made to the Regulatory Authority for corresponding research and education activities;

"clock-stop" means any period during which the Regulatory Authority is awaiting the applicant's submission of documents or information it has formally requested

"distribution" includes activities consisting of procuring, holding or supplying, apart from distributing to the public, medicinal preparations of cannabis in the authorised product pack size;

"GMP certificate" has the same meaning as "GMP certificate" in article 2 of the Medicines Authority (Fees) Regulations; S.L. 458.46.

"Licensing Authority" means the authority established by article 3 of the Medicines Act; Cap. 458.

"preceding year" means the period of twelve (12) consecutive months commencing on the date an annual fee becomes due and ends on the day immediately preceding the next annual fee due date:

Provided that for the purpose of calculating the first annual fee, the twelve (12) month period shall be deemed to commence on the date on which the license is officially granted in accordance with the Act and these regulations;

"Regulatory Authority" means the authority established by article 4 of the Medicines Act; and Cap. 458.

"Unit product" means the final product pack as authorised for release, which pack shall in any case not exceed one (100) hundred grams in weight or four (400) hundred millilitres in volume, or as otherwise approved by the Regulatory Authority taking into consideration composition and intended market.

Fees.

Amended by:
L.N. 100 of 2023;
L.N. 189 of 2025.

3. (1) The Regulatory Authority shall receive the fees specified in the Schedule of these regulations from persons intending to carry out importation, wholesale distribution, cultivation and processing, and/or production of cannabis, and any other activity related to cannabis for medicinal use and/or research purposes as determined by the Regulatory Authority.

(2) The validation and processing of applications submitted for the approval, renewal, authorisation, licence, and/or permit, shall only start once the relevant fees have been paid in full by the applicant to the Regulatory Authority, unless otherwise decided by the Regulatory Authority:

Provided that the application and renewal fee must be paid on first application and upon the renewal of the licence three (3) years after the granting of the licence or as determined by the Regulatory Authority from time to time. The annual fee shall be payable upon the licence being granted and is due every twelve (12) months thereafter.

(3) The fees are exclusive of any additional fees that may be charged by other competent authorities for ancillary and supporting documentation, reports, or other services that may be required by the regulatory authority to process the application and issue the requisite licences, certificates, or permits.

(4) Any additional expenses incurred by the Regulatory Authority shall be charged to the applicant separately.

(5) The Regulatory Authority shall be exempt from any liability for the payment of any tax on income or duty on documents in force in Malta.

(6) The Licensing Authority may suspend or revoke licences, certificates, or permits granted or issued if the fees stipulated in these regulations are not paid in full and on time:

Provided that the Regulatory Authority may charge interest for late payment at a rate of six percent (6%) *per annum*.

Research and
education
contributions.
Added by:
L.N. 100 of 2023.
Amended by:
L.N. 189 of 2025.

4. (1) Contributions as specified in the Schedule shall be made by any licence holder to the Regulatory Authority in connection with research and education and shall be capped at three hundred thousand Euro (€300,000) *per annum*.

(2) The contribution shall not apply to products intended for export for the first two (2) years, commencing from the date of the first commercial export.

(3) Whilst the contributions by licence holders shall be capped or are exempt from these contributions in accordance with sub-regulations (1) and (2), all other provisions as may be prescribed and applicable under all relevant legislation and, or set out in guidelines as issued or as may be issued by the Regulatory Authority in force at the time, shall still apply.

(4) These contributions shall be directed towards the funding of innovative projects, the provision of resources that enhance scientific research endeavours, educational development, exposures and programmes that mitigate skills mismatch, the creation of awareness, promoting responsibility and alignment with the regulations, and other initiatives ancillary thereto.

5. (1) The administration and management of the contributions shall be entrusted to a board appointed by the Minister called the Contributions Management Board (hereinafter referred to as "the Board"). The Board, in the exercise of its functions, shall regulate its own procedures and meetings as it deems appropriate, and act within a reasonable time with impartiality in accordance with the principles of fair hearing. In its deliberations, the Board shall have the right of access to all relevant information and may request appropriate expertise from, or collaboration with third parties, as it may consider necessary.

Contributions
Management
Board.
Added by:
L.N. 100 of 2023.

(2) The Minister shall designate a competent person to act as secretary for the Board.

(3) The members of the Board shall be appointed by the Minister for a term of three (3) years under such terms and conditions as may be specified in their appointment. Members so appointed may be re-appointed on the expiration of their term of office.

(4) Where any member of the Board is unable to act, the substitute member having the same qualifications shall act in his stead.

(5) A person shall cease to be a member of the Board at the expiration of his term of office.

(6) A member of the Board may be removed from office by the Minister if, in his opinion, such member is no longer fit to continue in office or has become incapable of properly performing his duties as a member.

6. The Regulatory Authority shall have the discretion to exempt research activities carried out solely for academic purposes, from any or all licence requirements, fees and, or contributions:

Exemptions for
research activities.
Added by:
L.N. 100 of 2023.

Provided that the Regulatory Authority may, where and to the extent it deems fit, establish regulatory conditions and measures, in relation to exempt academic cannabis research practices, and require the enforcement of such regulatory conditions and compliance thereto.

Amended by:
L.N. 100 of 2023;
L.N. 189 of 2025.

SCHEDULE
(REGULATIONS 3 and 4)
FEES AND CONTRIBUTIONS

PART I

Activity	Fee/Contribution	
	Application Renewal Fee	or Annual Fee

Production Licence for activities related to cannabis for medicinal and research purposes (covers all activities that may be authorised under article 4 of the Act)	€25,000[†] For manufacturing that includes local cultivation, the following additional fee per footprint allocated for cultivation applies* *€5 per m² up to 2,000m²; €20 per m² for part of footprint exceeding 2,000m² up to 4,000m²; €40 per m² for part of footprint exceeding 4,000m² up to 6,000m²; €100 per m² for part of footprint exceeding 6,000m² [†]With effect from 1 January 2023.	€25,000[†] The annual fee shall be waived when renewal fee is due[†] If the licence holder fails to prove that any of the products listed on the licence have been placed on the local market during the preceding year, subsequent annual fees shall be charged at €35,000 [†]With effect from 1 January 2023.
Licence for testing activities related to cannabis for medicinal and research purposes	€5,000	€5,000
Licence for activities related to cannabis for research purposes (not commercial)	€10,000	€8,000
Variation to a licence related to cannabis for medicinal and, or research purposes	€500 per variation application	

Fast-track application variation [10 days]* to a licence related to cannabis for medicinal and, or research purposes (not requiring an inspection and, or third-party involvement)	€1000 per variation application	
GMP certificate related to a Production Licence for activities related to cannabis for medicinal purposes (involving an inspection in Malta) **	€15,000	€5,000
GMP certificate for testing activities related to cannabis for medicinal purposes (involving an inspection in Malta) **	€5,000	€1,000
GMP certificate related to cannabis for medicinal purposes (involving an inspection, remotely or on-site, in a third country outside the European Union or European Economic Area)***	€25,000 in addition to €600 per day, per inspector and per person deemed relevant by the Regulatory Authority, including days for inspections and for travel, exclusive of travel and accommodation expenses	€15,000
Additional inspections or audits related to data integrity, research, security and EU-GMP	€5,000 per inspection or audit	
Consultation on scientific matters	€200 per person per hour	
Research and educational contribution to the Regulatory Authority	€1.00 per unit product distributed (in accordance with regulation 4(1), (2) and (3))	

* 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.

** Should the applicant engage in GMP activities falling within the scope of the Medicines Act (Cap. 458), and where the fees under these regulations differ from those applicable under the Medicines Authority (Fees) Regulations (S.L. 458.46), the applicant shall pay the fee applicable under these regulations in addition to the difference between that fee and the fee under the Medicines Authority (Fees) Regulations (S.L. 458.46). This is to ensure that the total amount paid corresponds to the higher applicable fee. Administrative GMP variations not requiring an inspection shall be subject to the fees established in the Medicines Authority (Fees) Regulations (S.L. 458.46).

*** The applicant shall additionally cover all travel expenses, including flights and accommodation of the inspectors and personnel deemed relevant by Regulatory Authority.

All fees and contributions payable in accordance with these regulations shall be non-refundable.

PART II

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	
Application / renewal [#] (for each form and strength) [#] Renewal must be submitted 3 months before expiry.	€450
Fast track application [15 working days] [*] (for each form and strength) [*] Timeline applies from the validation of the application and excludes clock-stops. The Medicines Authority may extend the timeline in exceptional circumstances.	€3,000
Annual maintenance fee (for each form and strength)	€275
Research and education contribution to the regulatory authority	€1.00 per unit product transacted