L.N. 391 of 2018

PRODUCTION OF CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES ACT (CAP. 578)

Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations, 2018

IN EXERCISE of the powers conferred by article 11(i) of the Production of Cannabis for Medicinal and Research Purposes Act, the Minister for Justice, Culture and Local Government, in consultation with the Minister for Finance, has made the following regulations:

Citation.

1. The title of these regulations is the Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations, 2018.

Interpretation.

2. In these regulations, unless the context otherwise requires –

Cap. 578.

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

"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;

S.L. 458.46.

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

Cap. 458.

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

Cap. 458.

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

"Unit product" means the product pack authorised for dispensing to the patient.

Fees.

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.

(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*.

SCHEDULE
(Regulation 3)
Fees and Contributions
PART I

Activity	Fee	
	Application/Renewal Fee	Annual Fee
Manufacturing site licence related to cannabis for medicinal purposes (involving an inspection in Malta)	€35,000 For manufacturing that includes local cultivation, the following additional contribution per footprint allocated for cultivation applies* *€5 per m^2 up to 2000m^2. €20 per m^2 for part of footprint exceeding 2000m^2 up to 4000m^2; €40 per m^2 for part of footprint exceeding 4000m^2 up to 6000m^2; €100 per m^2 for part of footprint exceeding 6000m^2	€35,000
Licence for activities related to cannabis for research purposes only (not commercial)	€10,000	€8,000
GMP certificate related to cannabis for medicinal purposes (involving an inspection in Malta or within the European Union/European Economic Area) **	€15,000	€5,000
GMP certificate related to cannabis for medicinal purposes (involving an inspection in a third country outside the European Union/ European Economic Area)** **The applicant must additionally cover all travel expenses, including flights and accommodation of the inspectors.	€25,000 plus €600 per day per inspector including days for inspections and for travel, exclusive of travel and accommodation expenses	€15,000
Additional data integrity, research, and security inspections/audits	€5,000 per inspection/audit	
Consultation on scientific matters	€200 per man/hour	
Research and education contribution to the regulatory authority	€1.00 per unit product transacted	

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

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