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L.N. 100 of 2023

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

Production of Cannabis for Medicinal and Research Purposes (Fees) (Amendment) Regulations, 2023

IN EXERCISE of the powers conferred by article 11 of the Production of Cannabis for Medicinal and Research Purposes Act, the Minister responsible for the Medicines Authority, has made the following regulations:-

Citation.

1. The title of these regulations is the Production of Cannabis for Medicinal and Research Purposes (Fees) (Amendment) Regulations, 2023 and these regulations shall be read and construed as one with the Production of Cannabis for Medicinal and Research Purposes (Fees) Regulations, hereinafter referred to as "the principal regulations".

S.L. 578.01.

Amends regulation 2 of the principal regulations.

2. Regulation 2 of the principal regulations shall be amended as follows:

(a) immediately after the definition "the Act" thereof, there shall be added the following new definition:

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

(b) the definition "Unit product" thereof shall be substituted by the following new definition:

" "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.".

Amends regulation 3 of the principal regulations.

3. In sub-regulation (2) of regulation 3 of the principal regulations, the words "regulatory authority, unless otherwise decided by the regulatory authority.", shall be substituted by the words "Regulatory Authority, unless otherwise decided by the Regulatory

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Authority:" and immediately thereafter there shall be added the following new proviso:

"Provided that the application and renewal fee must be paid on first application and upon the renewal of the licence every three (3) years 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.".

Adds new regulations 4, 5 and 6 to the principal regulations.

4. Immediately after regulation 3 of the principal regulations there shall be added the following new regulations:

"Research and education contributions.

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:

(a) products intended for export for the first two (2) years, starting from the date the licence is granted;

(b) start-up and small companies that meet the applicable criteria for exclusion.

(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.

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Contributions Management Board.

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 reasonbable 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.

(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.

Exemptions for research activities.

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:

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.".

Substitutes Part I of the Schedule to the principal regulations.

5. Part I of the Schedule to the principal regulations shall be substituted by the following new Schedule:

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SCHEDULE

(REGULATIONS 3 and 4)

FEES AND CONTRIBUTIONS

PART I

Activity	Fee or Contribution	
	Application or Renewal Fee	Annual Fee
Manufacturing site licence related to cannabis for medicinal purposes (involving an inspection in Malta)	€25,000† For manufacturing that includes local cultivation, the following additional fee 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 † With effect from the 1 January 2023; Should the licence holder fail to prove that any of the product listed on the licence has been placed on the local market during the preceding year, subsequent annual fees shall be charged at €35,000	€25,000† † With effect from the 1 January 2023; Should the licence holder fail to prove that any of the product listed on the licence has been placed on the local market during the preceding year, subsequent annual fees shall be charged at €35,000
Variation to a manufacturing site licence related to cannabis for medicinal and research purposes	€500 per variation application†	
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 or European Economic Area)**	€15,000	€5,000

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GMP certificate related to cannabis for medicinal purposes (involving an inspection in a third country outside the European Union or 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, security and EU-GMP inspections or audits	€5,000 per inspection or audit	
Consultation on scientific matters	€200 per person per hour	
Research and educational contribution to the Regulatory Authority	€1 per unit product transacted (as per sub-regulations (1), (2) and (3) of regulation 4).	

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