

CHAPTER 578

PRODUCTION OF CANNABIS FOR MEDICINAL
AND RESEARCH PURPOSES ACT

*An Act to provide for the production of cannabis for medicinal and
research purposes.*

17th April, 2018

[ACT X of 2018](#)

Arrangement of Act

	Article
Part I Preliminary	1-2
Part II Administration	3
Part III General Provisions	4
Part IV Operational Requirements	5
Part V Appeals	6-10
Part VI Miscellaneous Provisions	11-14

PART I
PRELIMINARY

1. The short title of this Act is the Production of Cannabis for Medicinal and Research Purposes Act. Short title.

2. In this Act, unless the context otherwise requires: Interpretation.

"Board" means the Licensing Appeals Board established by article 5;

"cannabis" means:

- (a) fresh or dried cannabis;
- (b) cannabis oil;
- (c) cannabis plant or seeds;
- (d) derivatives of cannabis excluding synthetic derivatives; and, or
- (e) any substance and, or product set out in guidelines issued by the regulatory authority,

all of the foregoing to be used exclusively for manufacturing of products for medicinal and, or research purposes;

Cap. 31
Cap. 101.
Cap. 537.

"drugs laws" means the [Medical and Kindred Professions Ordinance](#), the [Dangerous Drugs Ordinance](#) and the [Drug Dependence \(Treatment not Imprisonment\) Act](#);

"letter of intent" means a letter issued by Malta Enterprise which shall constitute a preliminary approval and may include *inter alia* the regulating of assistance under the Malta Enterprise laws, and a letter of intent that includes assistance under the Malta Enterprise laws shall be subject to the provisions of the Malta Enterprise laws, which shall, *mutatis mutandis*, apply;

"licence" means the approval given by the regulatory authority or any other authority as may from time to time be prescribed;

Cap. 325.
Cap. 463.

"Malta Enterprise laws" means the [Business Promotion Act](#) and the [Malta Enterprise Act](#);

"Minister" means the Minister responsible for the Medicines Authority save for the purposes of article 3 and article 5(2) where it shall mean the Minister responsible for industry;

"premises" means the industrial premises where the production of products derived from cannabis, for medicinal and, or research purposes, is to be carried out;

"prescribed" means prescribed by regulations made under the powers conferred by this Act;

"prescribed form" means a form as from time to time published by Malta Enterprise;

Cap. 465.

"public health" has the same meaning as is assigned to it by article 2 of the [Public Health Act](#);

Cap. 465.

"public health emergency" has the same meaning as is assigned to it by article 2 of the [Public Health Act](#);

Cap. 465.

"public health risk" has the same meaning as is assigned to it by article 2 of the [Public Health Act](#);

Cap. 458.

"regulatory authority" means the authority as established by article 4 of the [Medicines Act](#);

"research" means research for pharmaceutical, pharmacological and, or clinical purposes; and

Cap. 465.

"superintendent" means the Superintendent of Public Health as established by article 3 of the [Public Health Act](#).

**PART II
ADMINISTRATION**

3. (1) The administration of this Act shall be vested in the Minister or such other person, agency or authority designated by the Minister for any of the purposes of this Act: Administration.

Provided that the Superintendent shall have the functions and powers vested in him by virtue of:

(a) the [Public Health Act](#), in relation to matters of public health, public health emergency and public health risk; Cap. 465.

(b) the [Medicines Act](#). Cap. 458.

(2) Unless otherwise explicitly provided by or under this Act, the provisions of this Act shall apply only to the production of cannabis for medicinal and, or research purposes.

**PART III
GENERAL PROVISIONS**

4. (1) No cultivation, importation or processing of cannabis and no production of any products intended for medicinal and, or research purposes deriving from or resulting from the use of cannabis as defined in this Act and no trade in cannabis and, or any preparations intended for medicinal and, or research purposes as deriving from cannabis shall be carried out in Malta prior to obtaining all necessary approvals, authorisations, licences and, or permits as required by or under all applicable laws including this Act and any regulations subsidiary to it: Prohibitions.

Provided that an approval, authorisation, licence and, or permit may only be granted where the intended use of cannabis and, or products deriving therefrom is for medicinal and, or research purposes:

Provided further that cultivation that does not form an integral part of a production process intended for production of products for medicinal and, or research purposes is expressly prohibited.

(2) All persons intending to carry out any of the activities identified in sub-article (1) shall:-

(a) comply with the provisions of this Act;

(b) obtain a letter of intent from Malta Enterprise after making an application on the prescribed form. Malta Enterprise shall ensure that the proposed activity is solely a production process;

Cap. 458.

- (c) comply with all regulations, including international obligations resulting from a treaty to which Malta may from time to time be a party, as may be applicable;
- (d) comply with all regulations relating to the production and quality standards of products for medicinal and, or research purposes, as the case may be, as applicable under the [Medicines Act](#) and with any other relevant regulations;
- (e) obtain a licence from the regulatory authority;
- (f) comply with any other relevant regulations as shall, from time to time, be promulgated under this Act or any other applicable law.

PART IV
OPERATIONAL REQUIREMENTS

Operational requirements.

5. (1) The issuing of a licence by the regulatory authority shall be subject to:

Cap. 451.

- (a) the submission by the applicant and the evaluation of documents, including due diligence documentation, and other prescribed information as may be deemed necessary in order to ensure fulfilment of licence requirements;
- (b) the attainment by the applicant of authorizations, permits, approvals and clearances from other entities as may be prescribed and applicable under this Act and under any other relevant legislation current at the time;
- (c) compliance by the applicant with terms and conditions as may be prescribed, including the possession of relevant qualifications in line with the [Mutual Recognition of Qualifications Act](#) and of any regulations made there under:

Provided that the regulatory authority may at its own discretion request additional information as may be necessary for the evaluation of the application.

(2) The issuing of a letter of intent by Malta Enterprise shall be subject to the applicant submitting an application on the prescribed form:

Provided that Malta Enterprise may at its own discretion request additional information as may be necessary for the evaluation of the application.

(3) Notwithstanding any licence, permit or authorisation issued, the Commissioner of Police may, if a crime is carried out on the premises where any activity authorised under this Act is taking place, or is suspected to be carried out or is expected to happen take any action as reasonably necessary.

(4) The withdrawal, revocation, cancellation or expiry of either the license or the letter of intent, or both the license and the letter of intent, issued under this Act shall preclude the holder thereof from carrying out any activity under this Act.

PART V APPEALS

6. (1) The Minister shall appoint a Licensing Appeals Board, consisting of a Chairperson and three members of whom one of the members shall be a person who has practiced as a qualified scientist for not less than seven years.

Licensing Appeals
Board.

(2) The members of the Board shall be appointed by the Minister for a period of five years, and may only be removed from office by the Prime Minister on grounds of proved inability to perform the functions of their office (whether arising from infirmity of body or mind or any other cause) or proved misbehaviour.

(3) A member of the Board may be challenged or abstain for any of the reasons for which a judge may be challenged or abstain in accordance with article 734 of the [Code of Organization and Civil Procedure](#). In any such case, the Minister shall appoint a person, having the qualifications of the member challenged or abstaining, to sit as a member of the Board in substitution of the said member.

Cap. 12.

(4) A member of the House of Representatives or of a local council, a judge or a magistrate shall be disqualified from being appointed or continuing to be a member of the Board for so long as he holds that office.

(5) The Minister shall also designate a person to serve as secretary to the Board:

Provided that the Minister may appoint a substitute secretary in the following cases:

- (a) in cases of urgency if the designated secretary is in any way not available to perform his duties; and

- (b) in cases where the designated secretary abstains himself for the same reasons that a member of the Board may abstain himself as mentioned above.

Right of appeal.

7. (1) An appeal shall lie to the Board on any decision taken according to the provisions of this Act and any regulations made thereunder. The right of appeal shall be competent to the applicant and to any person showing such interest as may be prescribed, who has duly filed an objection or made representations against the grant of the licence.

(2) An appeal to the Board may be filed on any of the following grounds:

- (a) that a material error as to the facts has been made;
- (b) that there was a material procedural error;
- (c) that an error of law has been made;
- (d) that there was some material illegality, including unreasonableness or lack of proportionality.

(3) The Board shall, after hearing the appellant, the regulatory authority and the applicant, if he is not the appellant, decide the appeal giving reasons for its decisions in open session.

(4) In determining an appeal under this article the Board may:

- (a) dismiss the appeal;
- (b) annul the decision, and refer the matter to the regulatory authority.

Competence of the Board.

8. (1) The Board shall be competent to hear and decide any appeal made to it in accordance with the provisions of this Act and any regulations made thereunder.

(2) For the exercise of its functions, the Board may summon any person to appear before it and give evidence and produce documents and the chairperson shall have the power to administer the oath. The Board may also appoint experts to advise it on any technical issue that may be relevant to its decision.

(3) For the purposes aforesaid, the Board shall have the same powers as are competent to the First Hall, Civil Court according to law.

(4) The procedure to be followed before the Board, the time within which and the manner in which an appeal to the Board is to be made, shall be such as may be prescribed and subject thereto, and to

any other applicable provision of this Act, the Board may regulate its own procedure.

9. (1) Any party to an appeal before the Board who feels aggrieved by a decision of the Board, or the regulatory authority if it feels dissatisfied with any such decision, may on a question of law, appeal to the Court of Appeal as constituted in accordance with article 41(9) of the [Code of Organization and Civil Procedure](#) by means of an application filed in the registry of that court within twenty days from the date of the Board's decision.

Appeal to the
Court of Appeal.

Cap. 12.

(2) The provisions of the [Code of Organization and Civil Procedure](#) regulating the hearing and determination of appeals shall apply to appeals from decisions of the Board.

Cap. 12.

10. The effect of a decision to which an appeal relates shall not, except where the Board or the Court of Appeal, as the case may be, so orders, be suspended in consequence of the filing of the appeal.

Suspension of
effects of a
decision pending
appeal.

PART VI MISCELLANEOUS PROVISIONS

11. The Minister may make regulations for the purpose of regulating the use of cannabis for the production of products for medicinal and, or research purposes, but without prejudice to the generality of this provision, he may make regulations for all or any of the following purposes:

Power to make
regulations.

- (a) for prescribing the conditions under which the licence and authorisations may be granted, renewed, suspended, transferred or cancelled;
- (b) for providing the manner in which applications for the grant, renewal, suspension, transfer or cancellation of the license and authorisation, or of any one or more categories or classes thereof are to be made;
- (c) for providing the manner in which applications for such licence, authorisations and approvals as may be prescribed are to be publicised and for providing the manner in which any person, who may be prejudiced by such licence, authorisations and approvals may make an objection or representation thereon;
- (d) for establishing the duration of the validity of the licence and authorisations or of any one or more categories or classes thereof;

Cap. 458.

- (e) for establishing the qualifications that certain key personnel involved in or with the premises may be required to possess;
- (f) for regulating inspections to be carried out at the premises;
- (g) for prescribing the inventory controls, registers, records or databases that have to be kept by the licence holder at the premises and any financial guarantees which the licence holder shall have to give;
- (h) for the establishment of quality controls and quality assurances other than those under the [Medicines Act](#) and any matter in relation to any activity carried on or any premises or by any person licensed under this Act;
- (i) for establishing the fees leviable in respect of the letter of intent, licence, authorisations and approvals or of any one or more categories or classes thereof, either by direct determination or by reference to the manner in which such fees are to be reckoned; and to make provision for fees leviable in respect of broken periods:

Provided that regulations made under this paragraph may establish the minimum and the maximum of any fee leviable in respect of the letter of intent, licence, authorisations and approvals or of any one or more categories or classes thereof;

- (j) for establishing the penalties or administrative sanctions to which any offender against the provisions of this Act or any regulations made thereunder shall be liable, except where anything done constitutes an offence under the drugs laws, which administrative penalties shall not exceed one hundred thousand euro (€100,000) and one thousand euro (€1,000) for every day during which an offence or a default subsists.

Power to issue guidelines.

12. Malta Enterprise and the regulatory authority may issue guidelines and, or directives for prescribing any matter, including high level of security considered necessary or expedient for the better carrying out of any of the provisions of this Act.

Monitoring.

13. (1) The regulatory authority shall monitor and review relevant operations within premises to ensure that any operation within

the ambit of this Act is carried out only in accordance with the provisions of this Act and in compliance with the decisions lawfully taken under this Act as well as other relevant and applicable legislation.

(2) For the purposes of such monitoring and review the regulatory authority or any person authorised thereby to that effect shall have the right at all reasonable times to enter and inspect any premises.

14. (1) Any person acting in accordance with the provisions of this Act or of any regulations or licence issued thereunder shall, for the purposes of the implementation of the provisions of this Act, be exempt from the provisions of the drugs laws insofar as those laws relate to cannabis.

Terms of
exemption from
drugs laws.

(2) Where a person fails to abide by the provisions of this Act or by any regulations issued thereunder or by the conditions of a licence issued under this Act and the act done by such person constitutes an offence under the drugs laws, the provisions of the drugs laws shall apply.
