

*Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,938, 23 ta' Jannar, 2018*  
*Taqsim C*

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## **Nru. 24**

23. 01. 2018

### **MALTA**

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#### **KAMRA TAD-DEPUTATI**

#### **HOUSE OF REPRESENTATIVES**

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ABBOZZ ta' Liġi mressaq mill-Onorevoli Chris Cardona, M.P., Ministru għall-Ekonomija, l-Investiment u Negozzji ż-Żgħar, u moqri għall-Ewwel darba fis-Seduta tal-15 ta' Jannar 2018.

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A BILL introduced by the Honourable Chris Cardona, M.P., Minister for the Economy, Investment and Small Businesses, and read the First time at the Sitting of the 15 January 2018.

**ATT li jirregola l-produzzjoni tal-kannabis għal użu mediku.**

**AN ACT to provide for the production of cannabis for medicinal use.**

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RAYMOND SCICLUNA  
*Skrivan tal-Kamra tad-Deputati*

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RAYMOND SCICLUNA  
*Clerk of the House of Representatives*



## **Abbozz ta' Liġi msejjah**

*Att li jirregola l-produzzjoni tal-kannabis għal użu mediku.*

### **Arranġament tal-Att**

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### **Taqsimi I – Preliminari**

**1.** It-titolu fil-qosor ta' dan l-Att hu l-Att tal-2018 dwar il- Titolu fil-qosor.  
Produzzjoni tal-Kannabis għall-Użu Medičinali.

**2.** F'dan l-Att, kemm-il darba r-rabta tal-kliem ma teħtieġx Tifsir.  
xort'oħra:

"awtorità regolatorja" tfisser l-awtorità stabbilita bl-artikolu 4 tal-Att  
dwar il-Medičini;

"Bord" tfisser il-Bord tal-Appelli dwar il-Liċenzji kif stabbilit bl-  
artikolu 5;

"formula preskritta" tfisser formula kif minn żmien għal żmien tiġi  
ppublikata mill-Intrapriża ta' Malta;

"ittra ta' intenzjoni" tfisser ittra mahruġa mill-Intrapriża ta' Malta li  
tikkostitwixxi approvazzjoni preliminari u li tista' tinkludi, fost affarijiet  
oħra, ir-regolamentazzjoni tal-assistenza taħt il-liġijiet tal-Intrapriża ta'  
Malta u, ittra ta' intenzjoni li tinkludi assistenza taħt il-liġijiet tal-

Intrapriża ta' Malta tkun dejjem sugġetta għad-dispożizzjonijiet tal-liġijiet tal-Intrapriża ta' Malta, liema dispożizzjonijiet għandhom japplikaw kif ikun il-każ;

"kannabis" tfisser:

- (a) kannabis friska jew niexfa;
- (b) żejt tal-kannabis;
- (c) pjanta jew żerriegħa tal-kannabis;
- (d) derivattivi tal-kannabis; u, jew
- (e) kull sustanza jew prodott imniżżel fil-linji gwida maħruġa mill-awtorità regolatorja sabiex jintuża biss fil-manifattura tal-prodotti għall-użu mediċinali;

"liċenza" tfisser l-approvazzjoni mogħtija mill-awtorità regolatorja jew kull awtorità oħra li tista' minn żmien għal żmien tiġi preskritta;

Kap. 31

Kap. 101.

Kap. 537.

"liġijiet dwar droga" tfisser l-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x'jaqsmu magħha, l-Ordinanza dwar il-Mediċini Perikolużi, u l-Att dwar Dipendenza fuq id-Droga (Trattament mhux Prigunerija).

Kap. 325.

Kap. 463.

"liġijiet tal-Intrapriża ta' Malta" tfisser l-Att dwar il-Promozzjoni ta' Negozji u l-Att dwar l-Intrapriża ta' Malta;

"Ministru" tfisser il-Ministru responsabbli mill-Awtorità tal-Mediċini salv għall-iskopijiet tal-artikolu 3 u tal-artikolu 5(2) fejn għandha tfisser il-Ministru responsabbli għall-industrija;

"preskritti" tfisser preskritti b'regolamenti magħmulin skont is-setgħat mogħtija b'dan l-Att;

"stabbilimenti" tfisser l-istabbilimenti industrijali fejn isseħħ il-produzzjoni ta' prodotti mediċi derivanti mill-kannabis.

## Taqsim II - Amministrazzjoni

Amministrazzjoni.

**3.** (1) L-amministrazzjoni ta' dan l-Att għandha tkun vestita fil-Ministru jew f'xi persuna oħra, aġenzija jew awtorità imsemmija mill-Ministru għal xi wieħed mill-għanijiet ta' dan l-Att.

(2) Kemm-il darba ma jiġix xort'oħra provdut minn jew taħt dan l-Att, id-dispożizzjonijiet ta' dan l-Att għandhom japplikaw biss għall-produzzjoni tal-kannabis għall-użu mediċinali.

### Taqsimha III – Dispożizzjonijiet Ġenerali

4. (1) L-ebda kultivazzjoni, importazzjoni jew proċessar ta' <sup>Projbizzjonijiet.</sup> kannabis u ebda produzzjoni ta' kwalsiasi prodott derivanti jew riżultanti mill-użu tal-kannabis kif imfissra f'dan l-Att u intenzjonat għall-użu mediċinali u ebda attività kummerċjali fil-kannabis u, jew xi preparazzjoni derivanti minnha u intiża għall-użu mediku ma tista ssejtni f'Malta mingħajr il-pussess ta' kull approvazzjoni, awtorizzazzjoni, liċenza u, jew permess neċessarji skont il-liġijiet applikabbli, inkluż dan l-Att u kwalukwe regolamenti magħmula tahtu.

(2) Kull persuna li għandha l-intenzjoni li twettaq xi attività identifikata fis-subartikolu (1) għandha:-

(a) tikkonforma mad-dispożizzjonijiet ta' dan l-Att;

(b) tikseb ittra ta' intenzjoni mill-Intrapriża ta' Malta wara li tagħmel applikazzjoni fuq il-formula preskritta. L-Intrapriża ta' Malta għandha taċċerta ruħha illi l-attività proposta hija waħda esklussivament ta' proċess ta' produzzjoni;

(ċ) tikkonforma mar-regolamenti kollha applikabbli, inkluż obbligi internazzjonali li jirriżultaw min trattat li għalih Malta tista' minn żmien għal żmien tkun firmatarja, applikabbli skont il-każ;

(d) tikkonforma mar-regolamenti konċernanti l-produzzjoni u l-kwalità ta' prodotti għal użu mediċinali kif applikabbli skont l-Att dwar il-Mediċini u ma' kull regolamenti <sup>Kap. 458.</sup> oħra applikabbli;

(e) tikseb liċenzja mill-awtorità regolatorja;

(f) tikkonforma ma' kull regolament rilevanti ieħor li jkun relevanti kif jista' minn żmien għal żmien jiġi promulgat taht dan l-Att jew kull liġi oħra applikabbli.

### Taqsimha IV – Liċenza u Ittra ta' Intenzjoni

5. (1) Il-ħruġ ta' liċenza mill-awtorità regolatorja għandha tkun <sup>Htiġiet operattivi.</sup> sugġetta:

(a) għas-sottomissjoni mill-applikant u l-evalwazzjoni ta' dokumenti u informazzjoni oħra preskritta, inkluż dawk relattivi għad-diligenza dovuta, skont ma jista' jitqies li jkun meħtieġ sabiex jiġi żgurat l-adempiment tal-htigiet tal-liċenzja;

(b) il-kisba mill-applikant ta' awtorizzazzjonijiet,

permessi, approvazzjonijiet u kunsensi oħra skont ma jista' jiġi preskritt u skont ma jkun japplika b'leġislazzjoni oħra relevanti u kurrenti f'dak iż-żmien;

Kap. 451.

(ċ) il-konformità mill-applikant ma' dawk il-pattijiet u kundizzjonijiet li jistgħu jiġu preskritti, inklużi l-pussess ta' kwalifiki rilevanti li jkunu konformi mal-Att dwar ir-Rikonoxximent Reċiproku ta' Kwalifiki, u ma kull regolament magħmul tahtu:

Iżda l-awtorità regolatorja tista' wkoll, fid-diskrezzjoni tagħha, titlob informazzjoni addizzjonali li hija tqis neċessarja għall-evalwazzjoni tal-applikazzjoni.

(2) Il-ħruġ ta' ittra ta' intenzjoni mill-Intrapriża ta' Malta tkun suġġetta għall-applikazzjoni tal-applikant magħmula fuq il-formula preskritta:

Iżda l-Intrapriża ta' Malta tista', fid-diskrezzjoni tagħha, titlob informazzjoni addizzjonali li hija tqis neċessarja għall-evalwazzjoni tal-applikazzjoni tiegħu.

(3) Minkejja il-ħruġ ta' xi liċenza, permess jew awtorizzazzjoni, il-Kummissarju tal-Pulizija jista', f'każ li jseħh, jew hemm is-suspett li ser iseħh jew hemm stennija li ser iseħh, xi reat fi stabbiliment fejn tkun qed titwettagħ xi attività awtorizzata skont dan l-Att, jieħu kull azzjoni li tkun raġonevolment meħtieġa.

(4) It-tneħħija, r-revokazzjoni, il-kancellament, jew l-iskandenza tal-liċenza jew tal-ittra ta' intenzjoni, jew tat-tnejn, maħruġa taht dan l-Att tipprekludi lill minn kien jipposjedihom milli jkompli b'xi attività regolata b'dan l-Att.

### Taqsim V – Appelli

Bord tal-Appelli  
dwar il-Liċenzi.

6. (1) Il-Ministru għandu jappunta Bord tal-Appelli dwar il-Liċenzi li jkun magħmul minn President u tliet membri li wieħed minnhom ikun persuna li tkun eżerċitat bħala xjentist kwalifikat għal mhux inqas minn seba' snin.

(2) Il-membri tal-Bord għandhom jiġu mahtura mill-Ministru għal perjodu ta' hames snin u jistgħu jiġu biss imneħħija mill-kariga mill-Prim Ministru meta jkun hemm provi ta' inkapaċità li jwettqu l-funzjonijiet tal-kariga tagħhom (sew minhabba f'debulizza fil-ġisem jew tal-moħħ jew xi raġuni oħra) jew imġieba hażina bil-provi.

(3) Membru tal-Bord jista' jiġi rikuzat jew jastjeni għal kull waħda mir-raġunijiet li dwarhom imħallef jista' jiġi rikuzat jew inkella jastjeni skont l-artikolu 734 tal-Kodiċi ta' Organizzazzjoni u Proċedura Ċivili. F'kull każ bhal dak il-Ministru għandu jahtar persuna, li jkollha l-kwalifiki tal-membru li jkun rikuzat jew qed jastjeni, biex toqgħod bhala membru tal-Bord minflok dak il-membru. Kap. 12

(4) Membru tal-Kamra jew ta' kunsill lokali, imħallef jew maġistrat ikun skwalifikat milli jiġi mahtur jew milli jkompli jkun membru tal-Bord għal daqskemm huwa jkun għadu detentur ta' dik il-kariga.

(5) Il-Ministru għandu wkoll jahtar persuna biex tagħmilha ta' segretarju tal-Bord:

Izda l-Ministru jista' jahtar segretarju sostitut f'dawn il-każijiet li ġejjin:

(a) f'każijiet ta' urġenza meta s-segretarju mahtur għal xi raġuni ma jkunx disponibbli biex iwettaq dmirijietu; u

(b) f'każijiet meta s-segretarju mahtur jastjeni għal dawk l-istess raġunijiet li għalihom membru tal-Bord ikun jista' jastjeni kif hawn qabel imsemmi.

7. (1) Jista' jsir appell lill-Bord fuq kull deċiżjoni meħuda skont id-dispożizzjonijiet ta' dan l-Att u kull regolamenti magħmulin tahtu. Id-dritt ta' appell jappartjeni lill-applikant u lil kull min juri dak l-interess kif jiġi preskritt li jkun ressaq oġġezzjoni kif dovut jew ilmenta kontra l-għoti tal-liċenza. Dritt ta' appell.

(2) Jista' jiġi pprezentat appell lill-Bord għal kull waħda mir-raġunijiet li ġejjin:

(a) li jkun sar żball materjali dwar il-fatti;

(b) li kien hemm żball materjali proċedurali;

(ċ) li jkun sar żball tal-liġi;

(d) li kien hemm xi illegalità materjali, inkluża ir-raġonevolezza jew nuqqas ta' proporzjonalità.

(3) Il-Bord għandu, wara li jisma' lill-appellant, lill-awtorità regolatorja u lill-applikant, jekk dan ma jkunx l-appellant, jiddeċiedi l-appell u jagħti raġunijiet għad-deċiżjonijiet tiegħu waqt seduta pubblika.

(4) Meta jkun qed jiddeċiedi appell taht dan l-artikolu il-Bord jista':

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(a) jiċċhad l-appell;

(b) jannulla d-deċiżjoni, u jirreferi l-kwistjoni lill-awtorità regolatorja.

Kompetenza tal-Bord.

**8.** (1) Il-Bord ikun kompetenti li jittratta u jiddeċiedi kull appell li jsir quddiemu skont id-dispożizzjonijiet ta' dan l-Att u ta' egolamenti magħmula tahtu.

(2) Biex ikun jista' jwettaq il-funzjonijiet tiegħu, l-Bord jista' jħarrek lil kull persuna biex tidher quddiemu, biex tixhed u ġġib magħha dokumenti; u l-president għandu s-setgħa jamministra l-ġurament. Il-Bord jista' wkoll jahtar esperti biex jagħtu pariri lill-Bord dwar kull kwistjoni teknika li tista' tkun rilevanti għad-deċiżjonijiet li jkollu jagħmel.

(3) Għall-finijiet ta' hawn qabel imsemmija, il-Bord għandu jkollu l-istess setgħat bħal ma għandha l-Prim'Awla tal-Qorti Ċivili skont il-liġi.

(4) Il-proċedura li għandha tiġi segwita quddiem il-Bord, it-terminu li fih u l-mod kif appell lill-Bord għandu jsir ikunu daww kif jistgħu jiġu preskritti; u bla ħsara għal dan, u għal kull dispożizzjoni oħra li tapplika ta' dan l-Att, il-Bord jista' jistabbilixxi l-proċedura tiegħu stess.

Appell lill-Qorti tal-Appell.

Kap. 12.

Kap. 12.

Sospensjoni ta' effett ta' deċiżjoni li dwarha jkun hemm appell.

**9.** (1) Kull parti f'appell lill-Bord li tħoss ruħha aggravata b'deċiżjoni tal-Bord, jew tal-awtorità regolatorja, li tħoss ruħha mhux sodisfatta b'xi deċiżjoni bħal dik, tista' dwar punt ta' liġi tappella lill-Qorti tal-Appell kif magħmul skont l-artikolu 41(6) tal-Kodiċi ta' Organizzazzjoni u Proċedura Ċivili b'rikors li jiġi pprezentat fir-reġistru ta' dik il-qorti, fi żmien għoxrin ġurnata mid-data tad-deċiżjoni tal-Bord.

(2) Il-dispożizzjonijiet tal-Kodiċi ta' Organizzazzjoni u Proċedura Ċivili li jirregolaw is-smiegħ u d-determinazzjoni tal-appelli għandhom japplikaw għall-appelli mid-deċiżjonijiet tal-Bord.

**10.** L-effett ta' deċiżjoni li dwarha jkun hemm appell m'għandux, ħlief meta l-Bord jew il-Qorti tal-Appell, skont il-każ, hekk jordnaw, ikun sospiż minhabba li jkun qed isir dak l-appell.

### Taqsim VI – Dispożizzjonijiet Mixxellanji

Poteri li jsiru regolamenti.

**11.** (1) Il-Ministru jista' jagħmel regolamenti bil-għan li jirregola l-użu tal-kannabis għall-produzzjoni ta' prodotti għal skop medicinali iżda mingħajr ħsara għall-ġeneralità ta' din id-dispożizzjoni, jista' jagħmel regolamenti għal xi wiehed jew kull wiehed mill-iskopijiet li ġejjin:



(a) biex jippreskrivi l-kondizzjonijiet li taħthom liċenzi u awtorizzazzjonijiet jistgħu jingħataw, jiġu mġedda, sospizi, trasferiti jew imħassra;

(b) biex jipprovdi l-mod li bih isiru applikazzjonijiet għall-ġhoti, tiġdid, sospensjoni, trasferiment jew tħassir ta' liċenzji u awtorizzazzjonijiet jew ta' xi kategorija jew klassi waħda jew iktar tagħhom;

(c) biex jipprovdi dwar il-mod li bih applikazzjonijiet għal dawk il-liċenzji, awtorizzazzjonijiet jew approvazzjonijiet kif jista' jkun preskritt għandhom ikunu mgħarrfa lill-pubbliku u biex jipprovdu l-mod li bih kull min jista' jkun preġudikat b'dik il-liċenzja, awtorizzazzjoni jew approvazzjoni jista' jagħmel oġġezzjoni jew ilment;

(d) biex jistabbilixxi għal kemm żmien il-liċenzji, awtorizzazzjoni jew xi kategorija jew klassi waħda jew iktar tagħhom idumu validi;

(e) biex jistabbilixxi l-kwalifiki li għandhom ikunu miżmuma minn individwi ewlenin involuti fl-istabillimenti;

(f) biex jirregola l-ispezzjonijiet li għandhom jitwettqu fl-istabillimenti;

(g) biex jippreskrivi kontrolli fuq l-inventarji, registri, dokumenti, u databases li għandhom jinżammu mid-detentur ta' liċenza fl-istabilliment kif ukoll il-garanziji finanzjarji li id-detentru tal-liċenza għandu jagħti;

(h) biex jistabbilixxi proċeduri għall-kontrolli u assigurazzjoni ta' kwalità, apparti dawk diġà stabbiliti fl-Att dwar il-Medicini, u kull haġa li għandha x'taqsam ma' attività jew xi stabbiliment jew xi persuna liċenzjata taħt dan l-Att;

Kap. 458.

(i) biex jistabbilixxi d-drittijiet li għandhom jithallsu għal ħruġ ta' ittra ta' intenzjoni, liċenzji, awtorizzazzjonijiet jew approvazzjonijiet jew xi kategorija jew klassi waħda jew iktar tagħhom, sew billi dan jiġi determinat b'mod dirett jew b'riferenza għall-mod li bih għandhom jiġu kalkolati dawk id-drittijiet; u biex jipprovdi dwar id-drittijiet li għandhom jithallsu għal perjodi mhux sħaħ:

Izda regolamenti magħmulin taħt dan il-paragrafu jistgħu jistabbilixxu l-inqas u l-oġhla ammont ta' kull dritt li jithallas dwar l-ittra ta' intenzjoni, il-liċenzi, awtorizzazzjonijiet jew approvazzjonijiet jew xi kategorija jew klassi waħda jew

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iktar tagħhom;

(j) biex jiġu stabbiliti l-pieni jew sanzjonijiet amministrattivi li jista' jehel kull min jikser xi dispożizzjoni ta' dan l-Att jew regolamenti magħmulin tahtu, minbarra jekk tali ksur jikkostitwixxi reat taht il-liġijiet dwar id-droga, liema sanzjonijiet amministrattivi m'għandhomx jeċċedu il-mitt elf euro (€100,000) u l-elf euro (€1,000) għal kull gurnata li fiha jissussisti r-reat jew in-nuqqas.

Setgħat li jsiru linji gwida.

**12.** L-Intrapriża ta' Malta u l-awtorità regolatorja jistgħu jippreskrivu linji gwida jew direttivi li jitqiesu meħtieġa jew spedjenti inkluż miżuri ta' sigurtà ta' livell għoli meħtieġ biex ikunu jistgħu jitwettqu aħjar id-dispożizzjonijiet kollha ta' dan l-Att.

Moniteragg.

**13.** (1) L-awtorità regolatorja għandha twettaq moniteragg u tirrevedi l-operazzjoni relevanti ta' stabbilimenti sabiex taċċerta ruħha li kull operat li jkun qed iseħh taht dan l-Att ikun qed jitwettaq skont id-dispożizzjonijiet ta' dan l-Att u b'konformità ma' kull deċiżjoni legalment meħudha taht dan l-Att u kull liġi oħra relevanti u kurrenti.

(2) Għall-iskopijiet ta' moniteragg u reviżjoni bħal dawn, l-awtorità regolatorja, jew kwalunkwe persuna awtorizzata minnha għal dak il-għan, ikollha id-dritt, f'kull hin raġjonevoli, li tidhol u tispezzjona kull stabbiliment.

Termini tal-eżenzjoni mill-liġijiet dwar id-droga.

**14.** (1) Kull persuna li taġixxi skont id-dispożizzjonijiet ta' dan l-Att jew ta' kwalunkwe' regolament magħmul tahtu jew liċenzja maħruġa, tkun, għall-iskop tal-implimentazzjoni tad-dispożizzjonijiet ta' dan l-Att, eżenti mid-dispożizzjonijiet tal-liġijiet dwar id-droga limitament għal fejn dawk il-liġijiet jirreferu għall-kannabis.

(2) Persuna li tonqos milli tikkonforma mad-dispożizzjonijiet ta' dan l-Att jew ta' kwalunkwe regolament magħmul tahtu jew mal-kundizzjonijiet ta' liċenza maħruġa skont dan l-Att, u l-att imwettaq min dik il-persuna jikkostitwixxi ksur tal-liġijiet dwar id-droga, tkun soġġetta għad-dispożizzjonijiet tal-liġijiet dwar id-droga.

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### Għanijiet u raġunijiet

L-għanijiet u r-raġunijiet ta' dan l-Att huma sabiex jippermettu l-produzzjoni industrijali lokali ta' prodotti tal-kannabis għal-użu mediċinali f'ambitu ikkontrollat u taht superviżjoni.

**A BILL  
entitled**

*An Act to provide for the production of cannabis for medicinal use.*

**Arrangement of Act**

		Article
Part I	Preliminary	1-2
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**Part I – Preliminary**

**1.** The short title of this Act is the Production of Cannabis for Medicinal Use Act, 2018. 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; and, or
- (e) any substance and, or product set out in guidelines

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issued by the regulatory authority to be used exclusively for manufacturing of products for medical use;

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 cannabis 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. 458.

"regulatory authority" means the authority as established by article 4 of the Medicines Act.

## **Part II - Administration**

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.

(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 use.

## **Part III – General Provisions**

Prohibitions.

**4.** (1) No cultivation, importation or processing of cannabis

and no production of any products intended for medicinal use 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 use 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 made thereunder.

(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;
- (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 medical use as applicable under the Medicines Act and with any other relevant regulations; Cap. 458.
- (e) obtain a license 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 – License and Letter of Intent**

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

- (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 Cap. 451.

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**

Licensing  
Appeals Board.

**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.

(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.

Cap. 12.

(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.

(4) A member of the House 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 designate secretary abstains himself for the same reasons that a member of the Board may abstain himself as mentioned above.

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. Right of appeal.

(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.

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. Competence of the Board.

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(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.

Appeal to the Court of Appeal.

**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(6) 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.

Cap. 12.

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.

Suspension of effects of a decision pending appeal.

**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.

**Part VI - Miscellaneous Provisions**

Power to make regulations.

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

(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;

(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 license 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; Cap. 458.

(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.

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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.

Terms of exemption from drugs laws.

**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.

(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.

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### Objects and Reasons

The objects and reasons of this Bill are to permit the local industrial production of cannabis products for medical use in the context of a controlled and supervised environment.



