Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 19,979, 17 ta' April, 2018
Taqsima A

MALTA

ATT Nru X tal-2018

ATT maħruġ b'liġi mill-Parlament ta' Malta.

ATT li jirregola l-produzzjoni tal-kannabis għal skopijiet mediċinali u ta' riċerka.

ACT No. X of 2018

AN ACT enacted by the Parliament of Malta.

AN ACT to provide for the production of cannabis for medicinal and research purposes.

Nagħti l-kunsens tiegħi.

(L.S.) **MARIE-LOUISE COLEIRO PRECA**
President

17 ta' April, 2018

ATT Nru X tal-2018

Att li jirregola l-produzzjoni tal-kannabis għal skopijiet mediċinali u ta' riċerka.

Arranġament tal-Att

Taqsima I – Preliminari

1. It-titolu fil-qosor ta' dan l-Att hu l-Att tal-2018 dwar il-Produzzjoni tal-Kannabis għal Skopijiet Mediċinali u ta' Riċerka. Titolu fil-qosor.

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

"awtorità regolatorja" tfisser l-awtorità stabbilita bl-artikolu 4 tal-Att dwar il-Mediċini; Cap. 458.

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

Kap. 465.

"emerġenza fis-saħħa pubblika" għandha l-istess tifsira bħalma hu mogħti lilha bl-artikolu 2 tal-Att dwar is-Saħħa Pubblika;

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

"ittra ta' intenzjoni" tfisser ittra maħruġa 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 suġġetta 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;

(ċ) pjanta jew żerriegħa tal-kannabis;

(d) derivattivi tal-kannabis eskluži derivattivi sintetiċi; u, jew

(e) kull sustanza jew prodott imniżżel fil-linji gwida maħruġa mill-awtorità regolatorja,

ilkoll sabiex jintużaw biss fl-immanifatturar tal-prodotti għal skopijiet mediċinali u, jew ta' riċerka;

"liċenzja" 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 Perikoluži, u l-Att dwar Dipendenza fuq id-Droga (Trattament mhux Priġunerija);

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;

"riċerka" tfisser riċerka għal skopijiet farmaċewtiċi, farmakoloġiċi u, jew kliniċi;

"riskju fis-saħħa pubblika" għandha l-istess tifsira bħalma hu mogħti lilha bl-artikolu 2 tal-Att dwar is-Saħħa Pubblika; Kap. 465.

"saħħa pubblika" għandha l-istess tifsira bħalma hu mogħti lilha bl-artikolu 2 tal-Att dwar is-Saħħa Pubblika; Kap. 465.

"stabbilimenti" tfisser l-istabbilimenti industrijali fejn isseħħ il-produzzjoni ta' prodotti derivanti mill-kannabis għal skopijiet mediċinali u, jew ta' riċerka; u

"suprintendent" tfisser is-Suprintendent tas-Saħħa Pubblika kif stabbilit bl-artikolu 3 tal-Att dwar is-Saħħa Pubblika. Kap. 465.

Taqsima II - Amministrazzjoni

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

B'dan iżda illi s-Suprintendent għandu jkollu l-funzjonijiet u poteri fih vestiti skont:

(a) l-Att dwar is-Saħħa Pubblika f'dak li għandu x'jaqsam ma' saħħa pubblika, emerġenza fis-saħħa pubblika u riskju fis-saħħa pubblika; Kap. 465.

(b) l-Att dwar il-Mediċini. Kap. 458.

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

Taqsima III – Dispożizzjonijiet Ġenerali

4. (1) Ebda kultivazzjoni, importazzjoni jew proċessar ta' kannabis u ebda produzzjoni ta' kwalsiasi prodott derivanti jew riżultanti mill-użu tal-kannabis kif definita f'dan l-Att u intenzjonat għal skopijiet mediċinali u, jew ta' riċerka u ebda attività kummerċjali fil-kannabis u, jew xi preparazzjoni derivanti minnha u intiża għal skopijiet mediċinali u, jew ta' riċerka ma tista' sseħħ f'Malta mingħajr il-pussess ta' kull approvazzjoni, awtorizzazzjoni, liċenzja u, jew permess neċessarji *ai termini* tal-liġijiet applikabbli, inkluż dan l-Att u kwalukwe regolamenti sussidjarji għalih: Projbizzjonijiet.

Iżda kull approvazzjoni, awtorizzazzjoni, liċenzja u, jew permess tista' tingħata biss fejn l-użu intenzjonat tal-kannabis u, jew prodotti derivanti jew riżultanti mill-kannabis, huwa għal finijiet mediċinali u, jew ta' riċerka:

Iżda wkoll il-kultivazzjoni li ma tiffurmax parti integrali minn proċess ta' produzzjoni intenzjonat għall-produzzjoni ta' prodotti għal skopijiet mediċinali u, jew ta' riċerka hija espressament projbita.

(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 minn trattat li għalih Malta tista' minn żmien għal żmien tkun firmatarja, applikabbli skont il-każ;

(d) tikkonforma mar-regolamenti li jikkonċernaw il-produzzjoni u l-kwalità ta' prodotti għal użu mediċinali u, jew ta' riċerka, skont il-każ, kif applikabbli skont l-Att dwar il-Mediċini u ma' kull regolamenti oħra applikabbli;

Kap. 458.

(e) tikseb liċenzja mill-awtorità regolatorja;

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

Taqsima IV – Ħtiġijiet Operattivi

Ħtiġijiet operattivi.

5. (1) Il-ħruġ ta' liċenzja mill-awtorità regolatorja għandha tkun suġġetta:

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

(b) għall-kisba mill-applikant ta' awtorizzazzjonijiet, permessi, approvazzjonijiet u kunsensi oħra skont ma jista' jiġi preskritt u skont ma jkun japplika b'leġiżlazzjoni oħra rilevanti u

kurrenti f'dak iż-żmien;

(ċ) għall-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 taħtu: Kap. 451.

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 l-ħruġ ta' xi liċenzja, permess jew awtorizzazzjoni, il-Kummissarju tal-Pulizija jista', f'każ li jseħħ, jew hemm is-suspett li ser iseħħ jew hemm stennija li ser iseħħ, xi reat fi stabbiliment fejn tkun qed titwettaq xi attività awtorizzata skont dan l-Att, jieħu kull azzjoni li tkun raġonevolment meħtieġa.

(4) It-tneħħija, ir-revokazzjoni, il-kanċellament, jew l-iskandenza tal-liċenzja jew tal-ittra ta' intenzjoni, jew tat-tnejn, maħruġa taħt dan l-Att tipprekludi lil min kien jipposjedihom milli jkompli b'xi attività regolata b'dan l-Att.

Taqsima V – Appelli

Bord tal-Appelli dwar il-Liċenzji.

6. (1) Il-Ministru għandu jappunta Bord tal-Appelli dwar il-Liċenzji 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 maħtura mill-Ministru għal perjodu ta' ħames 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 minħabba f'debulizza fil-ġisem jew tal-moħħ jew xi raġuni oħra) jew imġiba ħażina bil-provi.

(3) Membru tal-Bord jista' jiġi rikużat jew jastjeni għal kull waħda mir-raġunijiet li dwarhom imħallef jista' jiġi rikużat jew inkella jastjeni skont l-artikolu 734 tal-Kodiċi ta' Organizzazzjoni u Proċedura Ċivili. F'kull każ bħal dak il-Ministru għandu jaħtar persuna, li jkollha l- Kap. 12

kwalifiki tal-membru li jkun rikużat jew qed jastjeni, biex toqgħod bħala membru tal-Bord minflok dak il-membru.

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

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

Iżda l-Ministru jista' jaħtar segretarju sostitut f'dawn il-każijiet li ġejjin:

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

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

Dritt ta' appell.

7. (1) Jista' jsir appell lill-Bord fuq kull deċiżjoni meħuda skont id-dispożizzjonijiet ta' dan l-Att u kull regolamenti magħmulin taħtu. 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-liċenzja.

(2) Jista' jiġi ppreżentat 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 r-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 taħt dan l-artikolu l-Bord jista':

(a) jiċħad 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' regolamenti magħmula taħtu.

(2) Biex ikun jista' jwettaq il-funzjonijiet tiegħu, il-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 jaħtar esperti biex jagħtu pariri lill-Bord dwar kull kwistjoni teknika li tista' tkun rilevanti għad-deċiżjonijiet li jkollu jagħmel.

(3) Għall-finijiet hawn qabel imsemmija, il-Bord għandu jkollu l-istess setgħat bħalma 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 dawk 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.

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 ppreżentat fir-reġistru ta' dik il-qorti, fi żmien għoxrin ġurnata mid-data tad-deċiżjoni tal-Bord.

Kap. 12.

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

Kap. 12.

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

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 minħabba li jkun qed isir dak l-appell.

Taqsima VI – Dispożizzjonijiet Mixxellanji

Poteri li jsiru regolamenti.

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

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

(b) biex jipprovdi l-mod li bih isiru applikazzjonijiet

għall-għoti, tiġdid, sospensjoni, trasferiment jew tħassir ta' liċenzji u awtorizzazzjonijiet jew ta' xi kategorija jew klassi waħda jew iktar tagħhom;

(ċ) 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-istabbilimenti;

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

(g) biex jippreskrivi kontrolli fuq l-inventarji, reġistri, dokumenti, u *databases* li għandhom jinżammu mid-detentur ta' liċenzja fl-istabbiliment kif ukoll il-garanziji finanzjarji li d-detentur tal-liċenzja għandu jagħti;

Kap. 458.

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

(i) biex jistabbilixxi d-drittijiet li għandhom jitħallsu 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 jitħallsu għal perjodi mhux sħaħ:

Iżda regolamenti magħmulin taħt dan il-paragrafu jistgħu jistabbilixxu l-inqas u l-ogħla ammont ta' kull dritt li jitħallas dwar l-ittra ta' intenzjoni, il-liċenzji, awtorizzazzjonijiet jew approvazzjonijiet jew xi kategorija jew klassi waħda jew iktar tagħhom;

(j) biex jiġu stabbiliti l-pieni jew sanzjonijiet amministrattivi li jista' jeħel kull min jikser xi dispożizzjoni ta' dan l-Att jew regolamenti magħmulin taħtu, minbarra jekk tali

ksur jikkostitwixxi reat taħt il-liġijiet dwar id-droga, liema sanzjonijiet amministrattivi m'għandhomx jeċċedu l-mitt elf euro (€100,000) u l-elf euro (€1,000) għal kull ġurnata 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.

Monitoraġġ.

13. (1) L-awtorità regolatorja għandha twettaq monitoraġġ u tirrevedi l-operazzjoni rilevanti ta' stabbilimenti sabiex taċċerta ruħha li kull operat li jkun qed iseħħ taħt dan l-Att ikun qed jitwettaq skont id-dispożizzjonijiet ta' dan l-Att u b'konformità ma' kull deċiżjoni legalment meħuda taħt dan l-Att u kull liġi oħra rilevanti u kurrenti.

(2) Għall-iskopijiet ta' monitoraġġ u reviżjoni bħal dawn, l-awtorità regolatorja, jew kwalunkwe persuna awtorizzata minnha għal dak il-għan, ikollha d-dritt, f'kull ħin raġonevoli, li tidħol u tispezzjona kull stabbiliment.

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

14. (1) Kull persuna li taġixxi skont id-dispożizzjonijiet ta' dan l-Att jew ta' kwalunkwe regolament magħmul taħtu jew liċenzja maħruġa, tkun, għall-iskop tal-implimentazzjoni tad-dispożizzjonijiet ta' dan l-Att, eżenti mid-dispożizzjonijiet tal-liġijiet dwar id-droga limitatament 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 taħtu jew mal-kundizzjonijiet ta' liċenzja maħruġa skont dan l-Att, u l-att imwettaq minn dik il-persuna jikkostitwixxi ksur tal-liġijiet dwar id-droga, tkun soġġetta għad-dispożizzjonijiet tal-liġijiet dwar id-droga.

Mgħoddi mill-Kamra tad-Deputati fis-Seduta Nru 100 tas-16 ta' April, 2018.

CLAUDETTE BUTTIGIEG
Deputy Speaker

RAYMOND SCICLUNA
Skrivan tal-Kamra tad-Deputati

I assent.

(L.S.) **MARIE-LOUISE COLEIRO PRECA**
President

17th April, 2018

ACT No. X of 2018

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

Arrangement of Act

Part I – Preliminary

Short title.

1. The short title of this Act is the Production of Cannabis for Medicinal and Research Purposes Act, 2018.

Interpretation.

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

"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;

"drugs laws" means the Medical and Kindred Professions Ordinance, the Dangerous Drugs Ordinance and the Drug Dependence (Treatment not Imprisonment) Act; Cap. 31 Cap. 101. Cap. 537.

"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;

"Malta Enterprise laws" means the Business Promotion Act and the Malta Enterprise Act; Cap. 325. Cap. 463.

"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;

"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 Cap. 465.

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

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:

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

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

Cap. 458. (b) the Medicines 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 and, or research purposes.

Part III – General Provisions

Prohibitions. **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:

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;

(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; Cap. 458.

(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

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 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: Cap. 451.

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.

(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.

Appeal to the Court of Appeal.

Cap. 12.

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.

(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 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:

(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 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; 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.

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.

Passed by the House of Representatives at Sitting No. 100 of the 16th April 2018.

CLAUDETTE BUTTIGIEG
Deputy Speaker

RAYMOND SCICLUNA
Clerk of the House of Representatives

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