

Nru. 18

1. 12. 2017

MALTA

KAMRA TAD-DEPUTATI

HOUSE OF REPRESENTATIVES

ABBOZZ ta' Liġi mressaq mill-Onorevoli Chris Cardona, M.P., Ministru għall-Ekonomija, Investiment u Negozji Żgħar, f'isem id-Deputat Prim Ministru u Ministru għas-Saħħa, u moqri għall-Ewwel darba fis-Seduta tas-27 ta' Novembru, 2017.

ABILL introduced by the Honourable Chris Cardona, M.P., Minister for the Economy, Investment and Small Businesses, on behalf of the Deputy Prime Minister and Minister for Health, and read the First time at the Sitting of the 27 November, 2017.

ATT biex jemenda l-Att dwar Dipendenza fuq id-Droga (Trattament mhux Prigunerija), Kap 537.

AN ACT to amend the Drug Dependence (Treatment not Imprisonment) Act, Cap. 537.

RAYMOND SCICLUNA
Skrivan tal-Kamra tad-Deputati

RAYMOND SCICLUNA
Clerk of the House of Representatives

ABBOZZ TA' LIĠI
msejjah

ATT biex jemenda l-Att dwar Dipendenza fuq id-Droga (Trattament mhux Prigunerija), Kap 537.

IL-PRESIDENT, bil-parir u l-kunsens tal-Kamra tad-Deputati, imlaqqgħa f'dan il-Parlament, u bl-awtorità tal-istess, ħareġ b'liġi dan li ġej:-

1. (1) It-titolu fil-qosor ta' dan l-Att hu l-Att tal-2017 li jemenda l-Att dwar Dipendenza fuq id-Droga (Trattament mhux Prigunerija), u dan l-Att għandu jinqara u jinftiehem haġa waħda mal-Att dwar Dipendenza fuq id-Droga (Trattament mhux Prigunerija), hawn iżjed 'il quddiem imsejjah "l-Att prinċipali".

Titolu fil-qosor u bidu fis-seħh.

Kap. 537.

(2) Dan l-Att għandu jidhol fis-seħh fid-data li l-Ministru jistabbilixxi b'avviż fil-Gazzetta.

2. L-artikolu 2 tal-Att prinċipali għandu jigi emendat kif ġej:

Emenda tal-artikolu 2 tal-Att prinċipali.

(a) minnufih qabel it-tifsira "drogi projbiti", għandhom jiżdiedu t-tifsiriet godda li ġejjin:

" *Cannabinoid*" tfisser waħda minn grupp ta' komponenti li tinstab biss fil-pjanta tal-Cannabis";

" *Cannabinoid* sintetiċi" tfisser sustanzi li għandhom elementi strutturali li jistgħu jingħaqdu mar-riċettaturi tal-cannabinoid, jiġifieri CB1 jew CB2, li huma fiċ-ċelloli umani, kif ukoll elementi oħra li għandhom kompożizzjoni kimika simili";

(b) fit-tifsira "Ministru" minnufih wara l-kliem "responsabbli għall-gustizzja" għandhom jidhlu l-kliem

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"sakemm ma jkunx speċifikat mod ieħor";

(ċ) minnufih wara t-tifsira "Ministru", għandha tiżdied it-tifsira ġdida li ġejja:

" "Prattika Tajba ta' Manifattura" tfisser dik il-parti ta' assigurazzjoni ta' kwalità li taċċerta li l-prodotti jkunu kostantament manufatturati u kkontrollati skont il-livelli ta' kwalità relattivi għall-użu maħsub u skont il-linji gwidi ta' prattiċi tajba ta' manifattura kurrenti u dettaljati kif ippublikati mill-Kummissjoni tal-Unjoni Ewropea".

Emenda tal-
artikolu 10 tal-
Att prinċipali.

3. L-artikolu 10 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) l-artikolu preżenti għandu jiġi enumerat mill-ġdid bħala l-artikolu 10(1) u għandu jiġi sostitwit b'dan li ġej:

Kap. 464 "(1) Tabib liċenzjat registrat skont Att dwar il-Professjonijiet tas-Saħħa għandu l-jedd li jippreskrivi lill-pazjenti preparazzjonijiet mediċinali tal-pjanta kannabis u prodotti *Cannabinoid* sintetiċi li jkunu
Kap. 458 liċenzjati taħt l-Att dwar il-Mediċini jew manufatturati taħt Prattika Tajba ta' Manifattura, jekk jiġi meqjus illi ma jkunx hemm alternattiva vijabbli għal dik il-preskrizzjoni wara li jkun ha kont kif jixraq ta' xi protokoll li jistgħu jkunu fis-seħħ minn żmien għal żmien dwar il-preskrizzjoni ta' mediċini, tal-interessi tal-pazjent u tal-ispejjeż."; u

(b) minnufih wara s-subartikolu (1) kif enumerat mill-ġdid għandhom jizdiedu s-subartikoli godda li ġejja:

"(2) L-ebda waħda mill-preparazzjonijiet imsemmija fis-subartikolu (1) ma tista' tkun indikata għat-tipjip u lanqas f'xi forma għat-tipjip.

Kap. 458 (3) Id-dispożizzjonijiet tal-Att dwar il-Mediċini, għandhom, *mutatis mutandis*, japplikaw, kif ukoll
L.S. 31.18 għandhom, *mutatis mutandis*, japplikaw id-dispożizzjonijiet tar-Regolamenti dwar il-Kontroll tal-Mediċini, fir-rigward tad-Dokument ta' kontroll:

Iżda l-ebda preskrizzjonijiet urġenti ma għandhom jithallew isiru fir-rigward ta' dawn il-preparazzjonijiet.

(4) It-tabib għandu japplika għall-preparazzjonijiet imsemmija fis-subartikolu (1) fuq bażi tal-isem tal-pazjent kif ordnat mis-Suprintendent tas-Saħħa Pubblika."

4. L-artikolu 12 tal-Att prinċipali għandu jiġi enumerat bħala l-artikolu 12 (1) u minnufih wara għandu jiġi miżjud is-subartikolu (2) għdid li ġej:

Emenda tal-artikolu 12 tal-Att prinċipali.

"(2) Il-Ministru responsabbli għas-Saħħa jista' jagħmel regolamenti għall-implimentazzjoni aħjar tad-dispożizzjonijiet tal-artikolu 10 ta' dan l-Att."

Għanijiet u raġunijiet

L-għanijiet u raġunijiet ta' dan l-Abbozz huma sabiex iwessgħu l-iskop tal-artikolu 10 tal-Att dwar Dipendenza fuq id-Droga (Trattament mhux Prigunerija) sabiex tiġi permessa l-preskrizzjoni ta' *Cannabinoid* sintetiċi, prodotti tal-kannabis manifatturati skont Prattika Tajba ta' Manifattura u sabiex tiġi permessa l-preskrizzjoni mit-tobba liċenzjati kollha li huma reġistrati taħt l-Att dwar il-Professjonijiet tas-Saħħa

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**A BILL
entitled**

AN ACT to amend the Drug Dependence (Treatment not Imprisonment) Act, Cap. 537.

BE IT ENACTED by the President, by and with the advice and consent of the House of Representatives in this present Parliament assembled, and by the authority of the same as follows:-

Short title and commencement.

Cap. 537.

1. (1) The short title of this Act is the Drug Dependence (Treatment not Imprisonment) (Amendment) Act, 2017, and this Act shall be read and construed as one with the Drug Dependence (Treatment not Imprisonment) Act, hereinafter referred to as "the principal Act".

(2) The provisions of this Act shall come into force on such date as the Minister may establish by notice in the Gazette.

Amendment of article 2 of the principal Act.

2. Article 2 of the principal Act shall be amended as follows:

(a) immediately before the definition "conviction", there shall be added the following new definition:

" "Cannabinoid" means one of a group of compounds found only in any plant of the genus Cannabis";

(b) immediately after the definition "drug laws", there shall be added the following new definition:

" "Good Manufacturing Practice" means the part of quality assurance which ensures that products are

consistently produced and controlled in accordance with the quality standards appropriate to their intended use and in line with the current detailed good manufacturing practice guidelines published by the European Union Commission";

(c) in the definition "Minister" immediately after the words "responsible for Justice" there shall be added the words "unless otherwise specified."; and

(d) immediately after the definition "prohibited drug", there shall be added the following new definition:

" "Synthetic cannabinoids" means substances with structural features which allow binding to one of the known cannabinoid receptors, i.e. CB1 or CB2, present in human cells and compounds with similar chemical structures".

3. Article 10 of the principal Act shall be amended as follows:

Amendment of article 10 of the principal Act.

(a) the present article shall be renumbered as article 10(1) and substituted by the following;

Cap. 464 "(1) A licenced medical practitioner who is duly registered in accordance with the Health Care Professions Act, shall be entitled to prescribe to patients medicinal preparations of the plant cannabis and synthetic cannabinoid products licensed under the Cap. 458 Medicines Act or manufactured under Good Manufacturing Practice, if it is considered that there is no viable alternative to such prescription due account being taken of any protocols which may be in force from time to time in respect of the prescription of medicines, of the interests of the patient and of the costs."; and

(b) immediately after sub-article (1) as renumbered there shall be added the following new sub-articles:

"(2) None of the preparations referred to in sub-article (1) may be indicated for smoking or in any form meant for smoking.

Cap. 458 (3) The provisions of the Medicines Act, shall, S.L. 31.18 *mutatis mutandis*, apply, as well as the provisions of the Drugs (Control) Regulations, pertaining to the Control Card, shall, *mutatis mutandis*, apply pertaining to the Control Card:

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Provided that no urgent prescriptions shall be allowed in relation to these preparations.

(4) The medical practitioner shall apply for the preparations referred to in sub-article (1) only on a named patient basis as directed by the Superintendent of Public Health."

Amendment of article 12 of the principal Act.

4. Article 12 of the principal Act shall be renumbered as article 12(1) and immediately thereafter there shall be added the following new sub-article (2):

"(2) The Minister responsible for Health may make regulations for the better implementation of the provisions of article 10 of this Act."

Objects and reasons

The object and reasons of this Bill are to widen the scope of article 10 of the Drug Dependence (Treatment not Imprisonment) Act so as to allow prescription of Synthetic cannabinoids, cannabis products produced under Good Manufacturing Practice and to allow prescribing by all licenced medical practitioners who are duly registered in accordance with the Health Care Professions Act.