Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 20,344, 7 ta' Frar, 2020
Taqsima C

Nru. 115

7. 02. 2020

MALTA

KAMRA TAD-DEPUTATI

ABBOZZ ta' Liġi mressaq mill-Onorevoli Chris Fearne, M.P., Deputat Prim Ministru u Ministru għas-Saħħa, u moqri għall-Ewwel darba fis-Seduta tal-5 ta' Frar 2020.

ATT biex jemenda l-Att dwar il-Mediċini, Kap. 458.

RAYMOND SCICLUNA
Skrivan tal-Kamra tad-Deputati

HOUSE OF REPRESENTATIVES

A BILL introduced by the Honourable Chris Fearne, M.P., Deputy Prime Minister and Minister for Health, and read the First time at the Sitting of the 5th February 2020.

AN ACT to amend the Medicines Act, Cap. 458.

RAYMOND SCICLUNA
Clerk of the House of Representatives

ABBOZZ TA' LIĠI
msejjaħ

ATT biex jemenda l-Att dwar il-Mediċini, Kap 458.

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:-

Titolu fil-qosor.

1. It-titolu fil-qosor ta' dan l-Att huwa l-Att tal-2020 li jemenda l-Att dwar il-Mediċini, u dan l-Att għandu jinqara u jinftiehem ħaġa waħda mal-Att dwar il-Mediċini, hawn iżjed 'il quddiem imsejjaħ "l-Att prinċipali". Kap. 458.

Emenda tal-artikolu 106 tal-Att prinċipali.

2. L-artikolu 106 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) il-paragrafu (r) tiegħu, għandu jiġi enumerat mill-ġdid bħala l-paragrafu (t); u

(b) minnufih wara l-paragrafu (q) tiegħu, għandhom jiżdiedu l-paragrafi ġodda li ġejjin:

" "(r) ir-regolamenti tal-użu ta' tagħmir mediku għal skop mediċinali jew ta' riċerka iżda mingħajr ħsara għall-ġeneralità ta' din id-dispożizzjoni, il-Ministru jista' jagħmel regolamenti għal xi wieħed jew kull wieħed mill-għanijiet li ġejjin:

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

(ii) biex jipprovdi l-mod li bih isiru applikazzjonijiet għall-għoti, tiġdid, sospensjoni, trasferiment jew tħassir ta' awtorizzazzjonijiet jew

ta' xi kategorija jew klassi waħda jew iktar tagħhom;

(iii) biex jipprovdi dwar il-mod li bih applikazzjonijiet għal dawk l- 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 l- awtorizzazzjoni jew approvazzjoni jista' jagħmel oġġezzjoni jew ilment;

(iv) biex jistabbilixxi għal kemm żmien l-awtorizzazzjoni jew xi kategorija jew klassi waħda jew iktar tagħhom idumu validi;

(v) biex jistabbilixxi l-kwalifiki li għandhom ikunu miżmuma minn persunal ewlenin involuti fl-istabbilimenti;

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

(vii) 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;

(viii) biex jistabbilixxi proċeduri għall-kontrolli u assigurazzjoni ta' kwalità, minbarra dawk diġà stabbiliti f'dan l-Att, u kull ħaġa li għandha x'taqsam ma' attività jew xi stabbiliment jew xi persuna liċenzjata taħt din il-liġi;

(ix) biex jistabbilixxi d-drittijiet li għandhom jitħallsu għal awtorizzazzjonijiet, approvazzjonijiet jew għal xi servizzi oħra hekk kif mgħotija mill-Awtorità dwar il-Mediċina bħal pariri xjentifiċi jew xogħol ieħor, skont ma jista' jitqies li jkun meħtieġ sabiex l-Awtorità dwar il-Mediċina twettaq il-funzjonijiet tagħha:

Iżda regolamenti magħmula taħt dan is-subparagrafu jistgħu jistabbilixxu l-inqas u l-ogħla ammont ta' kull dritt li jitħallas dwar l-awtorizzazzjonijiet, approvazzjonijiet jew għal xi servizzi oħra hekk kif mogħtija mill-Awtorità dwar il-Mediċina bħal pariri xjentifiċi jew xogħol ieħor,

skont ma jista' jitqies li jkun meħtieġ sabiex l-Awtorità dwar il-Mediċina twettaq il-funzjonijiet tagħha; u

(x) biex jiġu stabbiliti l-pieni jew sanzjonijiet amministrattivi li jista' jeħel kull min jikser xi dispożizzjoni ta' dan l-Att jew regolamenti magħmula taħtu;

(s) biex jiġu stabbiliti r-reati u pieni relattivi b'rabta ma' xi dispożizzjoni ta' dan l-Att jew regolamenti magħmulin taħtu, liema piena ta' mhux inqas minn tnax-il elf euro (€12,000) u mhux iżjed minn mija u għoxrin elf euro (€120,000) jew il-piena ta' priġunerija għal mhux iżjed minn sentejn, jew dik il-multa u priġunerija flimkien;".

Għanijiet u Raġunijiet

L-għanijiet u r-raġunijiet ta' dan l-Abbozz huwa sabiex tingħata s-setgħa lill-Ministru sabiex jippreskrivi regolamenti relatati li għandhom x'jaqsmu ma' tagħmir mediku u s-setgħa sabiex jinħargu regolamenti biex jistabbilixxu r-reati u pieni.

C 3852

A BILL
entitled

An Act to amend the Medicines Act, Cap 458.

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.

1. The short title of this Act is the Medicines (Amendment) Act, 2020, and this Act shall be read and construed as one with the Medicines Act, hereinafter referred to as "the principal Act".

Cap. 458.

Amendment of article 106 of the principal Act.

2. Article 106 of the principal Act shall be amended as follows:

(a) paragraph (r) thereof shall be re-numbered as paragraph (t); and

(b) immediately after paragraph (q) thereof, there shall be added the following new paragraphs:

" "(r) the regulation of the use of Medical Devices for medical and, or research purposes, but without prejudice to the generality of this paragraph, the Minister may make regulations for all or any of the following purposes:

(i) for prescribing the conditions under which the authorisations may be granted, renewed, suspended, transferred or cancelled;

(ii) for providing the manner in which applications for the grant, renewal, suspension, transfer or cancellation of the authorisations, or of any one or more categories or classes thereof are to be made;

(iii) for providing the manner in which applications for such 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 the authorisations and approvals may make an objection or representation thereon;

(iv) for establishing the duration of the validity of the authorisations or of any one or more categories or classes thereof;

(v) for establishing the qualifications that certain key personnel involved in or with the premises may be required to possess;

(vi) for regulating inspections to be carried out at the premises;

(vii) 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;

(viii) 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 any premises or by any person licensed under this legislation;

(ix) for establishing the fees leviable in respect of the authorisations, approvals and for any other service provided by the Medicines Authority such as scientific advice or other work as may be deemed necessary for the Medicines Authority to carry out its function:

Provided that regulations made under this sub-paragraph may establish the minimum and the maximum of any fees leviable in respect of the authorisations, approvals and for any other service provided by the Medicines Authority such as scientific advice or other work as may be deemed necessary for the Medicines Authority to carry out its function; and

(x) for establishing the penalties or administrative sanctions to which any offender against the provisions of this Legislation or any regulations made thereunder shall be liable;

(s) the establishing of offences and the relative penalty in relation to the contravention of any provisions of the Act or regulations issued under this Act which penalty shall not be less than a fine (*multa*) of twelve thousand euro (€12,000) and not exceeding one hundred and twenty thousand euro (€120,000) or to imprisonment for a term not exceeding two years, or to both such fine and imprisonment;".

Objects and Reasons

The objects and reasons of this Bill is to provide for the power of the Minister to prescribe regulations relative to matters relating to medical devices and the power to issue regulations to establish offences and penalties.

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