

Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 20,366, 13 ta' Marzu, 2020

Taqsim A

MALTA

ATT Nru VII tal-2020

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

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

ACT No. VII of 2020

AN ACT enacted by the Parliament of Malta.

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

Nagħti l-kunsens tiegħi.

(L.S.)

GEORGE VELLA
President

13 ta' Marzu, 2020

ATT Nru VII tal-2020

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, hareġ b'liġi dan li ġej:-

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 haġa waħda mal-Att dwar il-Mediċini, hawn iżjed 'il quddiem imsejjaħ "l-Att prinċipali".

Titolu fil-qosor.

Kap. 458.

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

Emenda tal-artikolu 106 tal-Att prinċipali.

(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 godda li ġejjin:

"(r) ir-regolamenti tal-użu ta' tagħmir mediku għal skop medicinali jew ta' riċerka iżda mingħajr ħsara għall-generalità 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 thassir 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 u 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 u approvazzjoni jista' jagħmel oġġezzjoni jew ilment;

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

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

(ix) biex jistabilixxi d-drittijiet li għandhom jiġihallu għal awtorizzazzjonijiet, approvazzjonijiet u

għal xi servizzi oħra hekk kif mogħtija mill-Awtorità dwar il-Mediċini bħal pariri xjentifiċi jew xogħol ieħor, skont ma jista' jitqies li jkun meħtieġ sabiex l-Awtorità dwar il-Mediċini twettaq il-funzjonijiet tagħha:

Iżda regolamenti magħmula taħt dan is-subparagrafu jistgħu jstabbilixxu l-inqas u l-ogħla ammont ta' kull dritt li jithallas dwar l-awtorizzazzjonijiet, approvazzjonijiet jew għal xi servizzi oħra hekk kif mogħtija mill-Awtorità dwar il-Mediċini bħal pariri xjentifiċi jew xogħol ieħor, skont ma jista' jitqies li jkun meħtieġ sabiex l-Awtorità dwar il-Mediċini twettaq il-funzjonijiet tagħha; u

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

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

Mgħoddi mill-Kamra tad-Deputati fis-Seduta Nru 308 tal-11 ta' Marzu, 2020.

ANĠLU FARRUGIA

Speaker

RAYMOND SCICLUNA

Skrivan tal-Kamra tad-Deputati

A 200

I assent.

(L.S.)

GEORGE VELLA
President

13th March, 2020

ACT No. VII of 2020

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 renumbered 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 and 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 already established under this 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 Act 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 this 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;".

Passed by the House of Representatives at Sitting No. 308 of the 11th March, 2020.

ANĠLU FARRUGIA
Speaker

RAYMOND SCICLUNA
Clerk of the House of Representatives