VERŻJONI ELETTRONIKA

Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 20,428, 26 ta' Ġunju, 2020
Taqsima C

Nru. 137

26. 6. 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 tat-22 ta' Ġunju 2020.

ATT sabiex ikompli 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 22nd June 2020.

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

RAYMOND SCICLUNA
Clerk of the House of Representatives

VERŻJONI ELETTRONIKA

ABBOZZ TA' LIĠI
msejjaħ

ATT sabiex ikompli 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. Kap. 458.

1. It-titolu fil-qosor ta' dan l-Att hu l-Att tal-2020 li jemenda l-Att dwar il-Mediċini (Emenda Nru 2) u dan l-Att għandu jinqara u jinftiehem ħaġa waħda mal-Att dwar il-Mediċini, hawn iżjed 'il quddiem imsejjaħ "l-Att prinċipali".

Żieda ta' artikoli ġodda mal-Att prinċipali.

2. Minnufih wara l-artikolu 110 tal-Att prinċipali għandhom jiżdiedu l-artikoli l-ġodda li ġejjin:

"Tagħmir mediku dijanjostiku in vitro Kap. 427.

111. Kwalunkwe regolamenti maħruġa taħt l-Att dwar is-Sigurezza tal-Prodotti li jittrattaw dwar tagħmir mediku dijanjostiku in vitro għandhom jitqiesu li ġew maħruġa taħt dan l-Att.

Lingwa.

112. Regolamenti magħmula taħt kwalunkwe dispożizzjoni ta' dan l-Att tista' ssir bil-lingwa Ingliża biss.".

Għanijiet u Raġunijiet

L-għanijiet u r-raġunijiet ta' dan l-Abbozz ta' Liġi huma sabiex jipprovdu li kull leġiżlazzjoni sussidjarja maħruġa taħt leġiżlazzjonijiet oħrajn, li għandhom x'jaqsmu mar-regolamentazzjoni dwar tagħmir mediku u tagħmir mediku dijanjostiku in vitro għandhom jitqiesu bħala maħruġa taħt l-Att dwar il-Mediċini u fl-aħħar ikunu soġġetti għar-regolatur stabbilit bl-Att dwar il-Medićni.

VERŻJONI ELETTRONIKA

A BILL
entitled

AN ACT to further 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. Cap. 458.

1. The short title of this Act is the Medicines (Amendment No. 2) Act, 2020 and this Act shall be read and construed as one with the Medicines Act hereinafter referred to as "the principal Act".

Addition of new articles to the principal Act.

2. Immediately after article 110 of the principal Act there shall be added the following new articles:

"Medical devices and in vitro diagnostic medical devices Cap. 427.

111. Any regulations issued under the Product Safety Act dealing with medical devices and in vitro diagnostic medical devices shall be deemed to have been issued under this Act.

Language.

112. Regulations made under any provision of this Act may be made in the English language only.".

Objects and Reasons

The objects and reasons of this Bill are to provide that all subsidiary legislation, issued under other legislation, relating to the regulation of medical devices and in vitro diagnostic medical devices shall be considered as issued under the Medicines Act and ultimately be subject to the regulator established by the Medicines Act.

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugħ fl-Istamperija tal-Gvern fuq karta FSC — *Printed at the Government Printing Press on FSC certified paper*

Prezz/*Price*
€0.18