ABBOZZ TA' LIĠI
msejjaħ

ATT biex jemenda 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 u bidu fis-seħħ.

1. (1) It-titolu fil-qosor ta' dan l-Att hu Att tal-2013 li jemenda l-Att dwar il-Mediċini, u dan l-Att għandu jinqara' u jiftiehem ħaġa waħda mal-Att dwar il-Mediċini, hawn iżjed 'il quddiem imsejjaħ "l-Att prinċipali".

(2) Dan l-Att għandu jidħol fis-seħħ f'dik id-data li l-Ministru responsabbli għas-saħħa jista' jistabbilixxi b'avviż fil-Gazzetta, u jistgħu jiġu stabbiliti dati differenti għal dispożizzjonijiet differenti u għal għanijiet differenti ta' dan l-Att.

Emenda tal-artikolu 2 tal-Att prinċipali.

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

(a) minflok it-tifsira "dispensa" għandu jidħol dan li ġej:

" "dispensa" tfisser il-bejgħ jew forniment ta' prodotti mediċinali minn spiżerija;";

(b) minflok it-tifsira "distribuzzjoni bl-ingrossa" għandu jidħol dan li ġej:

" "distribuzzjoni bl-ingrossa", li jkollha x'taqsam ma' prodott mediċinali u ma' sustanzi attivi, tinkludi lil xi attività jew kull attività li tikkonsisti fl-akkwist, tiżmim, forniment jew esportazzjoni ta' prodotti mediċinali u sustanzi attivi, minbarra l-forniment ta' prodotti mediċinali lill-pubbliku.";

(ċ) minnufih wara t-tifsira "distribuzzjoni bl-ingrossa" għandha tiżdied din it-tifsira ġdida li ġejja:

" "eċċipjent" tfisser kull kostitwent ta' prodott mediċinali li ma jkunx is-sustanza attiva u materjal ta' ippakkettjar;";

(d) minnufih wara t-tifsira "fuljett ta' tagħrif" għandha tiżdied din it-tifsira ġdida li ġejja:

" "importazzjoni" tfisser xi waħda jew aktar minn dawn l-attivitajiet li ġejjin: l-akkwist, it-tiżmim, il-bejgħ u r-rilaxx ta' prodotti mediċinali importati f'xi parti minn Malta minkejja kull dispożizzjoni f'xi Att ieħor, imma ma tinkludix prodotti mediċinali importati li jkunu għaddejin fi transit meta l-kunsinna sħiħa ta' dawk il-prodotti tibqa' intatta għalkollox u l-istatus tagħha ma jinbidilx għal wieħed ta' ċirkolazzjoni libera;";

(e) minnufih wara t-tifsira "prodott mediċinali erbali" għandha tiżdied din it-tifsira ġdida li ġejja:

" "prodott mediċinali falsifikat" tfisser kull prodott mediċinali li jkollu rappreżentazzjoni falza:

(a) tal-identità tiegħu, inklużi l-ippakkettjar u ttikkettjar tiegħu, ismu jew il-kompożizzjoni tiegħu dwar xi wieħed mill-ingredjenti tiegħu inklużi eċċipjenti u l-qawwa ta' dawk l-ingredjenti;

(b) is-sors tiegħu, inkluż il-manufattur tiegħu, il-pajjiż fejn jiġi manufatturat, il-pajjiż ta' oriġni tiegħu jew id-detentur tiegħu ta' awtorizzazzjoni għat-tqegħid fis-suq; jew

(ċ) l-istorja tiegħu, inklużi records u dokumenti li għandhom x'jaqsmu mal-kanali ta' distribuzzjoni li jintużaw,

imma jeskludi difetti fil-kwalità mhux intiżi u dan mingħajr preġudizzju għal kull kisur ta' drittijiet dwar il-proprjetà intellettwali;";

(f) minnufih wara t-tifsira "radjonuklidi ġeneratur" għandha tiżdied din it-tifsira ġdida li ġejja:

" "reazzjoni avversa" tfisser rispons għal prodott mediċinali li jkun noċiv u mhux intiż;";

(g) minnufih wara t-tifsira "riskji li għandhom x'jaqsmu mal-użu tal-prodott mediċinali" għandha tiżdied din it-tifsira ġdida li ġejja:

" "senserija ta' prodotti mediċinali" tfisser kull attività li jkollha x'taqsam mal-bejgħ jew xiri ta' prodotti mediċinali, ħlief għad-distribuzzjoni bl-ingrossa, li ma tkunx tinkludi l-maniġġar fiżiku u li jkunu jikkonsistu f'negozjati indipendenti u f'isem xi persuna ġuridika jew fiżika oħra;";

(h) minnufih wara t-tifsira "spiżjar" għandha tiżdied din it-tifsira ġdida li ġejja:

" "studju dwar is-sigurtà wara l-awtorizzazzjoni" tfisser kull studju li jkollu x'jaqsam ma' prodott mediċinali awtorizzat u li jsir bil-għan li jidentifika, jikkaratterizza jew jikkwantifika periklu fis-sigurtà, li jiġi konfermat il-profil tas-sigurtà tal-prodott mediċinali, jew li titkejjel l-effettività ta' miżuri ta' maniġġar tar-riskju;"; u

(i) minnufih wara t-tifsira "sustanza" għandha tiżdied din it-tifsira ġdida li ġejja:

" "sustanza attiva" tfisser kull sustanza jew taħlita ta' sustanzi maħsuba li jintużaw fil-manufattura ta' prodott mediċinali u li, meta dan jintuża fil-produzzjoni tiegħu, dan isir ingredjent attiv ta' dak il-prodott maħsuba biex jeżerċitaw azzjoni farmakoloġika, immunoloġika jew metabolika bil-għan li jiġu restawrati, korretti jew modifikati funzjonijiet fiżjoloġiċi jew li ssir djanjosi medika:".

Emenda tal-artikolu 6 tal-Att prinċipali.

3. Minnufih wara l-paragrafu (i) tas-subartikolu (1) tal-artikolu 6 tal-Att prinċipali, għandu jiżdied dan il-paragrafu (j) ġdid li ġej:

"(j) li tavża lill-Kummissjoni tal-UE dwar prodotti mediċinali li ma jingħatawx b'riċetta li kif tqisha hi jinsabu f'riskju ta' falsifikazzjoni u tista' tgħarraf lill-Kummissjoni tal-UE dwar prodotti mediċinali li jistgħu jitqiesu li ma jkunux ta' riskju kif jidher fil-kriterji stipulati fl-artikolu 54a (2b) tad-Direttiva 2001/83/KE kif emendata.".

Emenda tal-artikolu 16 tal-Att prinċipali.

4. Fl-artikolu 16 tal-Att prinċipali, minflok is-subartikolu (1) għandu jidħol dan li ġej:

"(1) Tkun il-funzjoni tal-Bord ta' Reviżjoni dwar il-Mediċini li jittratta appell magħmul minn applikant ta' awtorizzazzjoni għat-tqegħid fis-suq fuq xi rakkomandazzjoni tal-Awtorità dwar il-Mediċini li jkollha x'taqsam mas-sigurtà, il-kwalità u l-effikaċja ta' prodott mediċinali u li jagħti kull parir u jagħmel ir-rakkomandazzjonijiet tiegħu lill-Awtorità dwar il-Liċenzjar dwar dan kollu.".

Emenda tal-artikolu 28 tal-Att prinċipali.

5. L-artikolu 28 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) fis-subartikolu (1) tiegħu:

(i) minflok il-paragrafu (a) għandu jidħol dan li ġej:

"(a) il-prodott mediċinali jkun ta' ħsara;"; u

(ii) minflok il-paragrafu (ċ) għandu jidħol dan li ġej:

"(ċ) il-bilanċ bejn riskju u benefiċċju ma jkunx wieħed favorevoli;"; u

(b) fis-subartikolu (2) tiegħu, minnufih wara l-kliem "skont dan l-Att jew taħtu." għandhom jiżdiedu l-kliem "Din id-dispożizzjoni tapplika wkoll f'każijiet meta l-manufattura tal-prodott mediċinali ma ssirx b'mod konformi mad-dettalji provduti kif hemm fid-deskrizzjoni tal-metodu ta' manufatturar ippreżentat fl-applikazzjoni għal awtorizzazzjoni għat-tqegħid fis-suq, jew meta l-kontrolli użati mill-

manufattur ma jsirux b'mod konformi mal-metodi ta' kontroll deskritti fl-applikazzjoni għal awtorizzazzjoni għat-tqegħid fis-suq.".

Żieda ta' artikolu 31A ġdid mal-Att prinċipali.

6. Minnufih wara l-artikolu 30 tal-Att prinċipali għandu jiżdied dan l-artikolu 31A li ġej:

"Id-detenturi ta' awtorizzazzjoni għat-tqegħid fis-suq għandhom iżommu *standards* tajbin.

31A. Detenturi ta' awtorizzazzjoni għat-tqegħid fis-suq għandhom iżommu standards tajbin fuq il-farmakoviġilanza, awtorizzazzjonijiet għat-tqegħid fis-suq kif ukoll l-ittikkettjar u l-ippakkettjar hekk kif dawn jistgħu jiġu stabbiliti b'dan l-Att jew taħtu.".

Emenda tal-artikolu 37 tal-Att prinċipali.

7. Fl-artikolu 37 tal-Att prinċipali, minnufih wara l-kliem "ħadd ma għandu" għandhom jiżdiedu l-kliem "jimporta minn pajjiżi li jinsabu barra mill-Unjoni Ewropea jew miż-Żona Ekonomika Ewropea," u fit-test Malti tal-proviso li hemm miegħu minflok il-kliem "għall-fini ta' bejgħ" għandhom jidħlu l-kliem "għall-fini ta' dispensa".

Sostituzzjoni tal-artikolu 43 tal-Att prinċipali.

8. Minflok l-artikolu 43 tal-Att prinċipali għandu jidħol dan li ġej:-

"43. (1) Bla ħsara għad-dispożizzjonijiet ta' dan l-Att, kull liċenza mogħtija taħt din it-Taqsima għandha, kemm-il darba ma tkunx ġiet qabel imġedda jew revokata, tibqa' valida sa dak iż-żmien meta din tiġġedded mill-Awtorità dwar il-Liċenzjar wara spezzjoni.

(2) L-Awtorità dwar il-Liċenzjar għandha tistabbilixxi l-perjodu ta' validità ta' kull liċenza maħruġa taħt din it-Taqsima.

(3) Wara l-ispezzjoni msemmija fis-subartikolu (1), l-Awtorità dwar il-Liċenzjar:

(a) tista' ġġedded il-liċenza, kemm b'modifikazzjonijiet kemm mingħajrhom, għal perjodu itwal kif speċifikat; jew

(b) jekk, wara li tqis id-dispożizzjonijiet ta' dan l-Att, tqis li jkun meħtieġ jew spedjenti li hekk isir, din tista' tirrifjuta li ġġedded il-liċenza.".

Sostituzzjoni tat-Titolu III f'Taqsima III tal-Att prinċipali.

9. Minflok it-Titolu III fit-Taqsima III tal-Att prinċipali għandu jidħol dan it-Titolu ġdid li ġej:

"Titolu III - Distribuzzjoni bl-Ingrossa u Senserija ta' Prodotti Mediċinali għall-Użu tal-Bniedem".

Żieda tal-artikolu 54A ġdid mal-Att prinċipali.

10. Minnufih wara l-artikolu 54 tal-Att prinċipali, għandu jiżdied dan l-artikolu li ġej:

"Senserija.

54A. (1) Persuni jistgħu biss jagħmluha ta' sensara ta' prodotti mediċinali jekk ikunu stabbiliti f'Malta b'indirizz permanenti u jkun jinsabu reġistrati mal-Awtorità dwar il-Liċenzjar. Dawk il-persuni għandhom mill-inqas jagħtu isimhom, isem-il kumpannija u l-indirizz permanenti tagħhom biex ikunu jistgħu jirreġistraw. Għandhom javżaw lill-Awtorità dwar il-Liċenzjar b'kull tibdil relattiv mingħajr ebda dewmien mhux meħtieġ . Persuni li jkunu qegħdin jagħmluha ta' sensara ta' prodotti mediċinali u li jkunu bdew bl-attività tagħhom fid-data meta dan l-Att jidħol fis-seħħ għandhom jirreġistraw mal-Awtorità dwar il-Liċenzjar sat-2 ta' Marzu, 2013.

(2) L-Awtorità dwar il-Liċenzjar għandha ddaħħal l-informazzjoni msemmija fis-subartikolu (1) f'reġistru aċċessibbli għall-pubbliku.".

Sostituzzjoni tal-artikolu 58 tal-Att prinċipali.

11. Minflok l-artikolu 58 tal-Att prinċipali għandu jidħol dan li ġej:-

"58. (1) Bla ħsara għad-dispożizzjonijiet ta' dan l-Att, kull liċenza mogħtija taħt din it-Taqsima għandha, kemm-il darba ma tkunx ġiet qabel imġedda jew revokata, tibqa' valida sa dak iż-żmien meta din tiġġedded mill-Awtorità dwar il-Liċenzjar wara spezzjoni.

(2) L-Awtorità dwar il-Liċenzjar għandha tistabbilixxi l-perjodu ta' validità ta' kull liċenza maħruġa taħt din it-Taqsima.

(3) Wara l-spezzjoni msemmija fis-subartikolu (1), l-Awtorità dwar il-Liċenzjar:

(a) tista' ġġedded il-liċenza, kemm b'modifikazzjonijiet kemm mingħajrhom, għal perjodu itwal kif speċifikat; jew

(b) if, wara li tqis id-dispożizzjonijiet ta' dan l-Att, tqis li jkun meħtieġ jew spedjenti li hekk isir, din tista' tirrifjuta li ġġedded il-liċenza.".

Żieda tal-artikolu 60A ġdid mal-Att prinċipali.

12. Minnufih wara l-artikolu 60 tal-Att prinċipali, għandu jiżdied dan l-artikolu 60A li ġej:

"Sospensjoni tal-persuna responsabbli.

60A. L-Awtorità dwar il-Liċenzjar tista', jekk ikollha suspett raġonevoli li taħseb li xi persuna responsabbli tkun qegħda taġixxi bi ksur ta' xi dispożizzjoni ta' dan l-Att, tissospendi l-attività ta' dik il-persuna responsabbli b'avviż bil-miktub li jkun jispeċifika r-raġunijiet għal dik is-sospensjoni sakemm dik il-persuna tkun ikkonformat ruħha ma' kull ħtieġa tal-Awtorità dwar il-Liċenzjar biex tirrimedja n-nuqqas ta' konformità tagħha.".

Żieda tal-artikolu 66A ġdid mal-Att prinċipali.

13. Minnufih wara l-artikolu 66 tal-Att prinċipali, għandu jiżdied dan l-artikolu 66A li ġej:

"Spiżerija minn fuq l-internet jew li tieħu ordnijiet bil-posta.

66A. Ħadd ma jista' jiftaħ jew iżomm spiżerija minn fuq l-internet jew li tieħu ordnijiet bil-posta kemm-il darba ma jkollux liċenza maħruġa kif hemm fil-kondizzjonijiet u kriterji stabbiliti b'dan l-Att jew taħtu.".

Emenda tal-artikolu 67 tal-Att prinċipali.

14. Il-paragrafu (d) tas-subartikolu (1) tal-artikolu 67 tal-Att prinċipali għandu jitħassar.

Emenda tal-artikolu 68 tal-Att prinċipali.

15. Is-subartikolu (1) tal-artikolu 68 tal-Att prinċipali għandu jiġi sostitwit kif ġej :

"(1) L-Awtorità dwar il-Liċenzjar għandha, qabel ma tiddeċiedi dwar applikazzjoni, tispezzjona l-fond indikat fl-applikazzjoni u m'għandhiex toħroġ liċenza sakemm ma tkunx sodisfatta li dak il-fond ikun adatt u adegwat, u li jkun hemm faċilitajiet, stallazzjonijiet u tagħmir adatti biex jiżguraw il-konservazzjoni u d-dispensa kif imiss ta' prodotti mediċinali:

Iżda liċenza tista' tiġi kondizzjonata mat-twettiq ta' dawk l-obbligili li jistgħu jiġu imposti fiha.".

Sostituzzjoni tal-artikolu 70 tal-Att prinċipali.

16. L-artikolu 70 tal-Att prinċipali għandu jiġi sostitwit kif ġej:

"70. (1) Bla ħsara għad-dispożizzjonijiet ta' dan l-Att, kull liċenza mogħtija taħt din it-Taqsima għandha, kemm-il darba ma tkunx ġiet qabel imġedda jew revokata, tibqa' valida sa dak iż-żmien meta tiġġedded mill-Awtorità dwar il-Liċenzjar wara spezzjoni.

(2) L-Awtorità dwar il-Liċenzjar għandha tistabbilixxi l-perjodu ta' validità ta' kull liċenza maħruġa taħt din it-Taqsima.

(3) Wara l-spezzjoni msemmija fis-subartikolu (1), l-Awtorità dwar il-Liċenzjar:

(a) tista' ġġedded l-liċenza, kemm b'modifikazzjonijiet kemm mingħajrhom, għal perjodu itwal kif speċifikat; jew

(b) jekk, wara li tqis id-dispożizzjonijiet ta' dan l-Att, tqis li jkun meħtieġ jew spedjenti li hekk isir, din tista' tirrifjuta li ġġedded il-liċenza.".

Emenda tal-artikolu 74 tal-Att prinċipali.

17. Il-paragrafu (g) tal-artikolu 74 tal-Att prinċipali għandu jiġi enumerat mill-ġdid bħala l-paragrafu (h) tiegħu, u minnufih wara l-paragrafu (f) għandu jiżdied dan il-paragrafu li ġej:

"(g) jiżgura li jkun hemm spiżjar preżenti f'kull waqt li matulu tkun miftuħa l-spiżerija;".

Emenda tal-artikolu 75 tal-Att prinċipali.

18. Il-paragrafu (b) tas-subartikolu (2) tal-artikolu 75 tal-Att prinċipali għandu jiġi sostitwit kif ġej:

"(b) jiżgura li hu jew spiżjar ieħor ikun preżenti fl-ispiżerija f'kull waqt biex ibiegħ jew jissorvelja l-bejgħ ta' prodotti mediċinali u jżomm records tal-ispiżjar li kien preżenti meta l-ispiżerija kienet miftuħa;".

Żieda tal-artikolu 75A ġdid mal-Att prinċipali.

19. Minnufih wara l-artikolu 75 tal-Att prinċipali, għandu jiżdied dan l-artikolu 75A li ġej:

"Sospensjoni tal-ispiżjar responsabbli.

75A. L-Awtorità dwar il-Liċenzjar tista', jekk din ikollha tassew għax tissuspetta li xi spiżjar responsabbli jkun qiegħed jaġixxi bi ksur ta' xi dispożizzjoni ta' dan

l-Att, tissospendi l-attività ta' dak l-ispiżjar responsabbli b'avviż bil-miktub li jkun jispeċifika r-raġunijiet għal dik is-sospensjoni sakemm dik il-persuna tkun ħarset kull ħtieġa tal-Awtorità dwar il-Liċenzjar biex jiġi rimedjat dan in-nuqqas ta' konformità.".

Emenda tal-artikolu 81 tal-Att prinċipali.

20. Minnufih wara s-subartikolu (2) tal-artikolu 81 tal-Att prinċipali, għandu jiżdied dan is-subartikolu li ġej:

"(3) Spiżjar jista' jiddispensa kull prodott mediċinali maħruġa b'riċetta ta' tabib, dentist jew kirurgu veterinarju minn Stat Membru tal-UE iżda l-spiżjar jista' jaċċerta li dak it-tabib, dentist jew kirurgu veterinarju jkollhom liċenza li jeżerċitaw il-professjoni tagħhom fl-Istat Membru ta' oriġni.".

Emenda tal-artikolu 98 tal-Att prinċipali.

21. Il-paragrafu (b) tal-artikolu 98 tal-Att prinċipali għandu jiġi sostitwit kif ġej:

"(b) xjentement jew mhux xjentement ibiegħ jew iforni, jew joffri jew jesponi għall-bejgħ jew biex iforni, jew ikollu fil-pussess tiegħu għall-fini ta' bejgħ jew biex jiġi fornut:

(i) xi prodott mediċinali li l-kompożizzjoni tiegħu tkun intlaqtet ħażin biż-żieda jew astrazzjoni ta' xi sustanza;

(ii) xi prodott mediċinali li jkun ġie b'mod deliberat u frawdolenti ittikkettjat ħażin f'dak li għandu x'jaqsam mal-identità u, jew sors inklużi prodotti li jkollhom ingredjenti tajba, ma' ingredjenti ħżiena, mingħajr ingredjenti attivi, fi kwantità mhux sufiċjenti jew eċċessiva ta' ingredjenti attivi jew li jkollu ippakkettjar finta.".

Emenda tal-artikolu 99 tal-Att prinċipali.

22. L-artikolu 99 tal-Att prinċipali għandu jiġi sostitwit kif ġej:

99. (1) Mingħajr preġudizzju għal kull responsabbiltà oħra taħt kull liġi oħra, kull min jonqos milli jħares xi dispożizzjonijiet ta' dan l-Att jew ta' xi regolamenti jew regoli magħmulin taħtu jkunu ħatja ta' reat u jista', meta jinsab ħati, jeħel, fil-każ ta' reat kontra:

(a) id-dispożizzjonijiet tal-artikoli 20(1), 37, 54, 54A, 98 u 104A, multa ta' mhux anqas minn ħdax-il elf u sitt mija u sitta u erbgħin euro u sebgħa u tmenin ċenteżmu (11,646.87) u mhux iżjed minn mija u sittax-il elf u erba' mija u tmienja u sittin euro u sebgħa u sittin ċenteżmu (116,468.67) jew priġunerija għal żmien mhux iżjed minn sentejn, jew dik il-multa u priġunerija flimkien;

(b) id-dispożizzjonijiet tal-artikoli 31A, 44 u 56(3), multa ta' mhux anqas minn ħamest elef tmien mija u tlieta u għoxrin euro u ħamsa u sebgħin ċenteżmu (5,823.75) u mhux iżjed minn disgħa u sittin elf u tmien mija u wieħed u tmenin euro u għoxrin ċenteżmu (69,881.20) jew priġunerija għal żmien mhux iżjed minn sitt xhur, jew dik il-multa u priġunerija flimkien;

(ċ) id-dispożizzjonijiet tal-artikoli 32(4), 45, 66(1), 66(5), 66(6), 66A, 71, 75(3), 75(4), 76(1), 81(1) u 91, multa ta' mhux anqas minn elfejn u tliet mija u disgħa u għoxrin euro u tmienja u tletin ċenteżmu (2,329.38) u mhux iżjed minn sitta u erbgħin elf u ħames mija u sebgħa u tmenin euro u sebgħa u erbgħin ċenteżmu (46,587.47) jew priġunerija għal żmien mhux iżjed minn tliet xhur, jew dik il-multa u priġunerija flimkien;

(d) id-dispożizzjonijiet tal-artikoli 59, 60, 74, 75(1), 75(2), 84, 93, 94(1) u 96, multa ta' mhux anqas minn elf u mija u erbgħa u sittin euro u disgħa u sittin ċenteżmu (1,164.69) u mhux iżjed minn tlieta u għoxrin elf u mitejn u tlieta u disgħin euro u tlieta u sebgħin ċenteżmu (23,293.73);

(e) id-dispożizzjonijiet tal-artikoli 78, 83, 85(1), 85(2), 86, 87 u 94(2), multa ta' mhux anqas minn erba' mija u ħamsa u sittin euro u sebgħa u tmenin ċenteżmu (465.87) u mhux iżjed minn ħdax-il elf u sitt mija u sitta u erbgħin euro u sebgħa u tmenin ċenteżmu (11,646.87);

(f) id-dispożizzjonijiet tal-artikoli 31, 73(1), 79(1), 79(2), 80(1), 80(2) u 94(3), multa ta' mhux anqas minn mitejn u tnejn u tletin euro u erbgħa u disgħin ċenteżmu (232.94) u mhux iżjed minn elfejn u tliet mija u disgħa u għoxrin euro u sebgħa u tletin ċenteżmu (2,329.37).

(2) Mingħajr preġudizzju għas-setgħat tal-Awtorità dwar il-Liċenzjar taħt dan l-Att, meta xi ħadd jagħmel reat u jkun id-detentur ta' liċenza jew ta' xi awtorizzazzjoni taħt dan l-Att, il-Qorti għandha, fuq talba tal-prosekuzzjoni, tordna r-revoka jew is-sospensjoni tal-liċenza jew awtorizzazzjoni hawn qabel imsemmija.".

Emenda tal-artikolu 100 tal-Att prinċipali.

23. Is-subartikoli (2), (3) u (4) tal-artikolu 100 tal-Att prinċipali għandhom jiġu enumerati mill-ġdid bħala s-subartikoli (3), (4) u (5) tiegħu rispettivament, u minnufih wara s-subartikolu (1) tiegħu, għandu jiżdied dan is-subartikolu li ġej:

"(2) Id-dispożizzjonijiet tas-subartikolu (1) m'għandhomx japplikaw għal reati meta jkun hemm ksur tal-artikoli 20(1), 37, 44, 54, 56(3), 98 u 104A.".

Żieda tal-artikolu 101A ġdid mal-Att prinċipali.

24. Minnufih wara l-artikolu 101 tal-Att prinċipali, għandu jiżdied artikolu 101A ġdid kif ġej:

"Ħtiġiet għall-ittestjar u spezzjonijiet ta' manufatturi, importaturi, sensara u distributuri ta' prodotti mediċinali, inkluż APIs, eċċipjenti u materjal tal-bidu ieħor.

101A. (1) L-Awtorità dwar il-Liċenzjar għandha, b'koperazzjoni mal-Aġenzija tal-Mediċini Ewropea, tiżgura li jitħarsu l-ħtiġiet legali li jirregolaw prodotti mediċinali, permezz ta' spezzjonijiet, jekk ikun hekk meħtieġ li ma jitħabbrux minn qabel, u, fejn ikun adatt, billi jintalab xi Laboratorju ta' Kontroll tal-Mediċini Uffiċjali jew laboratorju li jagħmel dak ix-xogħol biex jagħmel testijiet fuq kampjuni. Din il-koperazzjoni tkun tikkonsisti fil-qsim ta' informazzjoni mal-Aġenzija tal-Mediċini Ewropea kemm dwar spezzjonijiet li jkunu ġew ippjanati u li jkun saru kemm fil-kordinazzjoni ta' spezzjonijiet f'pajjiżi terzi.

(2) L-ispezzjonijiet għandhom jinkludu imma ma jkunux limitati għal dawk imsemmija fis-subparagrafi (a) sa (b) kif ġejjin:

(a) manufatturi, li jkunu jinsabu fl-Unjoni Ewropea jew f'pajjiżi terzi, u distributuri bl-ingrossa ta' prodotti mediċinali jkunu soġġetti għal spezzjonijiet ripetuti;

(b) l-Awtorità dwar il-Liċenzjar għandu jkollha sistema ta' superviżjoni inkluż permezz ta' spezzjonijiet li

jsiru bi frekwenza adatta ibbażata fuq ir-riskju, fil-fond tal-manufatturi, importaturi, jew distributuri ta' sustanzi attivi, li jkunu jinsabu f'territorju Malti, u l-prosegwiment effettiv tagħhom.

(3) Kull meta tqis li jkun hemm għaliex jiġi suspettat li jkun hemm nuqqas ta' konformità mal-ħtiġiet legali stipulati f'dan l-Att u l-leġislazzjoni sussidjarja relattiva, inklużi prinċipji u linji gwida tal-Unjoni Ewropea dwar il-prattiċi tajba ta' manifattura u distribuzzjoni, l-Awtorità dwar il-Liċenzjar tista' twettaq dawk l-ispezzjonijiet fil-fond:

(a) ta' manufatturi jew distributuri ta' sustanzi attivi li jkunu jinsabu f'pajjiżi terzi;

(b) ta' manufatturi jew importaturi ta' eċċipjenti.

(4) Jistgħu jsiru wkoll spezzjonijiet imsemmija fis-subartikoli (2) u (3) hawn qabel fl-Unjoni Ewropea u f'pajjiżi terzi fuq talba ta' Stat Membru tal-Unjoni Ewropea, tal-Kummissjoni tal-Unjoni Ewropea jew tal-Aġenzija tal-Mediċini Ewropea.

(5) L-ispezzjonijiet jistgħu jsiru wkoll fil-fond ta' detenturi ta' awtorizzazzjoni għat-tqegħid fis-suq u ta' sensara ta' prodotti mediċinali.

(6) L-ispezzjonijiet għandhom isiru minn uffiċjali li jirrappreżentaw lill-Awtorità dwar il-Liċenzjar li jkollhom is-setgħa li jispezzjonaw kull fond, records, dokumenti u master file tas-sistema ta' farmakoviġilanza tad-detentur ta' awtorizzazzjoni għat-tqegħid fis-suq jew ta' ditti mqabbda mid-detentur ta' awtorizzazzjoni għat-tqegħid fis-suq biex iwettqu attivitajiet ta' farmakoviġilanza.

(7) L-ispezzjonijiet għandhom isiru kif hemm fil-linji gwida u fid-dispożizzjonijiet imsemmija fl-artikoli 101 sa 104 ta' dan l-Att.

(8) Wara kull spezzjoni, l-Awtorità dwar il-Liċenzjar għandha tirrapporta dwar jekk entità spezzjonata tkunx tikkonforma mal-prinċipji tal-Unjoni Ewropea u mal-linji gwida tal-prattiċi tajba ta' manifattura u distribuzzjoni li jkunu japplikaw, jew dwar jekk id-detentur ta' awtorizzazzjoni għat-tqegħid fis-suq ikunx konformi mal-ħtiġiet ta' farmakoviġilanza stipulati f'dan l-Att u fil-leġislazzjoni sussidjarja relattiva.

(9) L-Awtorità dwar il-Liċenzjar għandha twassal il-kontenut ta' dawk ir-rapporti lill-entit¬à spezzjonata. Qabel ma tadotta r-rapport, l-Awtorità dwar il-Liċenzjar għandha tagħti lill-entità spezzjonata involuta l-opportunità li tippreżenta l-kummenti tagħha.

(10) Mingħajr preġudizzju għal kull arranġament li seta' sar bejn l-Unjoni Ewropea u pajjiżi terzi, Stat Membru, il-Kummissjoni tal-Unjoni Ewropea jew l-Aġenzija tal-Mediċini Ewropea tista' titlob lil manufattur stabbilit f'pajjiż terz jippreżenta spezzjoni kif imsemmija f'dan l-artikolu.

(11) Fi żmien 90 jum minn spezzjoni kif imsemmija fis-subartikolu (1), ċertifikat dwar prattiċi tajba ta' manifattura jew distribuzzjoni għandhom, meta dawn ikunu japplikaw, jinħarġu lill-entità spezzjonata jekk l-eżitu tal-ispezzjoni jkun juri li jikkonforma mal-prinċipji u l-linji gwida ta' prattiċi tajba ta' manifattura jew distribuzzjoni kif provdut dwarhom mill-liġijiet tal-Unjoni Ewropea.

(12) Jekk isiru spezzjonijiet bħala parti mill-proċedura ta' ċertifikazzjoni għall-monografi tal-farmakopoeia Ewropea, għandu jintgħamel ċertifikat.

(13) Iċ-ċertifikati ta' prattiċi tajba ta' manifattura u distribuzzjoni li jinħarġu għandhom jiddaħħlu fid-*database* tal-Unjoni Ewropea kif maniġġata mill-Aġenzija tal-Mediċini Ewropea f'isem l-Unjoni Ewropea. L-informazzjoni dwar ir-reġistrazzjoni ta' importaturi, manufatturi u distributuri ta' sustanzi attivi għandha wkoll tiddaħħal f'dik id-database.".

Emenda tal-artikolu 102 tal-Att prinċipali.

25. L-artikolu 102 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) minnufih wara s-subartikolu (1)(ċ), għandu jiżdied dan is-subartikolu li ġej:

"(d) kull fond, records, dokumenti u *master file* tas-sistema ta' farmakoviġilanza tad-detentur ta' awtorizzazzjoni għat-tqegħid fis-suq jew ta' ditti mqabbda mid-detentur ta' awtorizzazzjoni għat-tqegħid fis-suq biex iwettqu attivitajiet ta' farmakoviġilanza kif stabbiliti taħt l-artikolu 31A ta' dan l-Att:"; u

(b) fis-subartikolu (2) tal-artikolu 102 tal-Att prinċipali, minnufih wara l-kliem "Uffiċjal awtorizzat jista', għal kull fini speċifikata fis-subartikolu preċedenti, jieħu kampjun" għandhom jiżdiedu l-kliem, ", inkluż bil-għan li jsiru provi indipendenti f'Laboratorju ta' Kontroll tal-Mediċini Uffiċjali jew f'laboratorju li jagħmel dak ix-xogħol għal xi Stat Membru tal-Unjoni Ewropea,".

Enumerazzjoni mill-ġdid tal-artikolu 104A tal-Att prinċipali.

26. L-artikolu 104A tal-Att prinċipali għandu jiġi enumerat mill-ġdid bħala l-artikolu 104B tiegħu.

Żieda tal-artikolu 104A ġdid mal-Att prinċipali.

27. Minnufih wara l-artikolu 104 tal-Att prinċipali, għandu jiżdied dan l-artikolu li ġej:

"Ostakoli eċċ. għall-Awtorità dwar il-Liċenzjar.

104A. Kull min b'xi mezz li jkun, iżomm jew jostakola lill-Awtorità dwar il-Liċenzjar jew lil xi uffiċjal awtorizzat milli jeżerċita xi setgħa u funzjoni taħt dan l-Att ikun ħati ta' reat kontra dan l-Att.".

Żieda tal-artikolu 104C ġdid mal-Att prinċipali.

28. Minnufih wara l-artikolu 104B tal-Att prinċipali kif enumerat mill-ġdid, għandu jiżdied dan l-artikolu li ġej:

"Sejħiet lura u allarmi ta' malajr.

104C. (1). l-Awtorità dwar il-Liċenzjar għandha tiżgura li jkun hemm taħdem sistema li jkollha l-għan li tipprevjeni prodotti mediċinali li jkunu suspettati li jippreżentaw periklu għas-saħħa milli jaslu għand il-pazjent.

(2) Is-sistema msemmija fis-subartikolu (1) għandha tkun tkopri l-wasla u l-immaniġġar ta' notifikazzjonijiet ta' prodotti mediċinali falsifikati sospettati kif ukoll ta' difetti fil-kwalità sospettati fi prodotti mediċinali. Is-sistema għandha tkun ukoll tkopri sejħiet lura ta' prodotti mediċinali minn detenturi ta' awtorizzazzjoni għat-tqegħid fis-suq jew l-irtirar ta' prodotti mediċinali mis-suq ordnati mill-awtoritajiet kompetenti nazzjonali mingħand l-atturi rilevanti kollha fil-katina ta' forniment kemm matul il-ħinijiet tax-xogħol normali u mhux fihom. Is-sistema tirrendiha wkoll ħaġa possibbli li jissejħu lura, fejn hekk meħtieġ bl-għajnuna ta' professjonisti tas-saħħa, prodotti mediċinali mingħand pazjenti li jkunu rċevew dawk il-prodotti.

(3) Jekk il-prodott mediċinali involut ikun sospettat li jippreżenta riskju serju għas-saħħa pubblika, l-Awtorità dwar il-Liċenzjar għandhom, mingħajr ebda dewmien, jittrażmettu notifikazzjoni ta' allarm ta' malajr lill-iStati Membri kollha tal-Unjoni Ewropea u lill-atturi kollha fil-katina ta' forniment f'Malta. Fil-każ li dawk il-prodotti mediċinali jitqiesu li jkunu waslu għand il-pazjenti, għandhom jinħarġu avviżi pubbliċi urġenti fi żmien 24 siegħa biex isejħu lura lil dawk il-prodotti mediċinali mingħand il-pazjenti. Dawk l-avviżi għandu jkun fihom biżżejjed informazzjoni fuq id-difett fil-kwalità jew falsifikazzjoni sospettati u r-riskji li jkun hemm involuti.".

GĦANIJIET U RAĠUNIJIET

DIRETTIVA 2011/62/UE TAL-PARLAMENT EWROPEW U TAL-KUNSILL tat-8 ta' Ġunju 2011 li temenda d-Direttiva 2001/83/KE dwar il-kodiċi tal-Komunità li għandu x'jaqsam ma' prodotti mediċinali għall-użu mill-bniedem, rigward il-prevenzjoni tad-dħul fil-katina legali tal-provvista ta' prodotti mediċinali falsifikati.

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 and commencement.

1. (1) The short title of this Act is the Medicines (Amendment) Act 2013, and this Act shall be read and construed as one with the Medicines Act, hereinafter referred to as "the principal Act".

(2) This Act shall come into force on such date as the Minster responsible for health may by notice in the Gazette appoint, and different dates may be so appointed for different purposes and for different provisions of this Act.

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 "advertising" there shall be inserted the following new definition:

" "active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological,

immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis:";

(b) immediately after the new definition "active substance" there shall be inserted the following new definition:

" "adverse reaction" means a response to a medicinal product which is noxious and unintended;";

(c) immediately after the definition "authorised officer" there shall be inserted the following new definition:

" "brokering of medicinal products" means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;";

(d) for the definition "dispensing" there shall be substituted the following:

" "dispensing" means the sale or supply of medicinal products from a pharmacy;";

(e) immediately after the definition "dispensing" there shall be inserted the following new definition:

" "excipient" means any constituent of a medicinal product other than the active substance and the packaging material;";

(f) immediately after the new definition "exipient" there shall be inserted the following new definition:

" "falsified medicinal product" means any medicinal product with a false representation of:

(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(c) its history, including the records and documents relating to the distribution channels used, but excludes unintentional quality defects and is without prejudice to infringements of intellectual property rights;";

(g) immediately after the definition "immunological medicinal product" there shall be inserted the following new definition:

" "importation" means any one or more of the following activities: procuring, holding, selling and release of imported medicinal products in any part of Malta notwithstanding any provisions in any other Act, but does not include imported medicinal products that are in transit where the whole consignment of the said products remains fully intact and its status is not changed for free circulation;";

(h) immediately after the definition "pharmacy technician" there shall be inserted the following new definition:

" "post-authorisation safety study" means any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures;"; and

(i) for the definition "wholesale distribution" there shall be substituted the following:

" "wholesale distribution", in relation to a medicinal product and active substances, includes any one or all activities consisting of procuring, holding, supplying or exporting medicinal products and active substances, apart from supplying medicinal products to the public.".

3. Immediately after paragraph (i) of sub-article (1) of article 6 of the principal Act, there shall be inserted a new paragraph (j) as follows: Amendment of article 6 of the principal Act.

"(j) to notify the EU Commission of non-prescription medicinal products which in its judgement are at risk of falsification and may inform the EU Commission of medicinal products which may be deemed not to be at risk according to the criteria set out in article 54a (2b) of Directive 2001/83/EC as amended.".

4. In article 16 of the principal Act, for sub-article (1) there shall be substituted the following: Amendment of article 16 of the principal Act.

"(1) It shall be the function of the Medicines Review Board to hear an appeal submitted by the applicant of a marketing authorisation on any recommendation of the Medicines Authority in relation to the safety, quality and efficacy of a medicinal product and to provide advice and make its recommendations to the Licensing Authority in this regard.".

5. Article 28 of the principal Act shall be amended as follows: Amendment of article 28 of the principal Act.

(a) in sub-article (1) thereof:

(i) for paragraph (a) there shall be substituted the following:

"(a) the medicinal product is harmful;"; and

(ii) for paragraph (c) there shall be substituted the following:

"(c) the risk benefit balance is not favourable;"; and

(b) in sub-article (2) thereof, immediately after the words "under this Act have not been carried out." there shall be added the words "This provision also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to the description of the manufacturing method submitted in the application for a marketing authorisation, or where

controls employed by the manufacturer are not carried out in compliance with the control methods described in the application for a marketing authorisation.".

Addition of new article 31A to the principal Act.

6. Immediately after article 30 of the principal Act there shall be inserted the following new article 31A:

"Marketing authorisation holders to abide by standards.

31A. Marketing authorisation holders will have to abide by the standards on pharmacovigilance, marketing authorisations as well as labelling and packaging as may be established by or under this Act.".

Amendment of article 37 of the principal Act.

7. In article 37 of the principal Act, immediately after the words "no person shall" there shall be inserted the words "import from countries which are outside the European Union or European Economic Area," and in the Maltese text of the proviso thereto for the words "għall-fini ta' bejgħ" there shall be substituted the words "għall-fini ta' dispensa".

Substitution of article 43 of the principal Act.

8. For article 43 of the principal Act there shall be substituted the following:-

"43.(1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Licensing Authority following an inspection.

(2) The Licensing Authority shall establish the period of validity of any licence issued under this Part.

(3) Following the inspection mentioned in sub-article (1), the Licensing Authority:

(a) may renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.".

9. For Title III in Part III of the principal Act there shall be substituted the following new Title: Substitution of Title III in Part III of the principal Act.

"Title III - Wholesale Distribution and Brokering of Medicinal Products for Human Use".

10. Immediately after article 54 of the principal Act, there shall be inserted the following new article: Addition of new article 54A to the principal Act.

"Brokering.

54A. (1) Persons may only broker medicinal products if they are established in Malta with a permanent address and are registered with the Licensing Authority. Those persons shall submit, at least, their name, corporate name and permanent address in order to register. They shall notify the Licensing Authority of any changes thereof without unnecessary delay. Persons brokering medicinal products who have commenced their activity on the date of coming into force of this Act shall register with the Licensing Authority by March 2, 2013.

(2) The Licensing Authority shall enter the information referred to in sub-article (1) in a register that shall be publicly accessible.".

11. For article 58 of the principal Act there shall be substituted the following:- Substitution of article 58 of the principal Act.

"58. (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Licensing Authority following an inspection.

(2) The Licensing Authority shall establish the period of validity of any licence issued under this Part.

(3) Following the inspection mentioned in sub-article (1), the Licensing Authority:

(a) may renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.".

Addition of new article 60A to the principal Act.

12. Immediately after article 60 of the principal Act, there shall be inserted the following new article 60A:

"Suspension of responsible person.

60A. The Licensing Authority may, if it has reasonable suspicion to believe that any responsible person is acting in contravention of any of the provisions of this Act, suspend the activity of such responsible person by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Licensing Authority to remedy the non compliance.".

Addition of new article 66A to the principal Act.

13. Immediately after article 66 of the Principal Act, there shall be added the following new article 66A:

"Internet or mail order pharmacy.

66A. It shall not be lawful for any person to open or keep an internet or mail order pharmacy unless he is in possession of a licence issued in accordance with conditions and criteria established by or under this Act.".

Amendment of article 67 of the principal Act.

14. Paragraph (d) of sub-article (1) of article 67 of the principal Act shall be deleted.

Amendment of article 68 of the principal Act.

15. Sub-article (1) of article 68 of the principal Act shall be substituted as follows :

"(1) The Licensing Authority shall, before determining an application, inspect the premises indicated in the application and shall not issue a licence until it is satisfied that such premises are suitable and adequate, and that there are suitable facilities, installations, and equipment so as to ensure proper conservation and dispensing of medicinal products:

Provided that a licence may be made conditional to the carrying out of such obligations as may be imposed therein.".

Substitution of article 70 of the principal Act.

16. Article 70 of the principal Act shall be substituted as follows:

"70. (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Licensing Authority following an inspection.

(2) The Licensing Authority shall establish the period of validity of any licence issued under this Part.

(3) Following the inspection mentioned in sub-article (1), the Licensing Authority:

(a) may renew the licence, with or without modifications, for such a further period as specified; or

(b) if, having regard to the provisions of this Act, it considers it necessary or expedient to do so, may refuse to renew the licence.".

Amendment of article 74 the principal Act.

17. Paragraph (g) of article 74 of the principal Act shall be renumbered as paragraph (h) thereof, and immediately after paragraph (f) there shall be added the following new paragraph:

"(g) ensure that a pharmacist is present at all times during the time when the pharmacy is open;".

Amendment of article 75 of the principal Act.

18. Paragraph (b) of sub-article (2) of article 75 of the principal Act shall be substituted as follows:

"(b) ensure that he or another pharmacist is present in the pharmacy at all times in order to sell or supervise the sale of medicinal products and to keep records of the pharmacist who was present while the pharmacy was open;".

Addition of new article 75A to the principal Act.

19. Immediately after article 75 of the principal Act, there shall be added the following new article 75A:

"Suspension of managing pharmacist.

75A. The Licensing Authority may, if it has reasonable suspicion to believe that any managing pharmacist is acting in contravention of any of the provisions of this Act, suspend the activity of such managing pharmacist by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Licensing Authority to remedy the non compliance.".

Amendment of article 81 of the principal Act.

20. Immediately after subarticle (2) of article 81 of the principal Act, there shall be added the following new sub-article:

"(3) It shall be lawful for a pharmacist to dispense any medicinal product on the prescription of a medical practitioner, dentist or veterinary surgeon from an EU member state provided that the pharmacist can ascertain that such medical practitioner, dentist or veterinary surgeon is licensed to practice his profession in the member state of origin.".

Amendment of article 98 of the principal Act.

21. Paragraph (b) of article 98 of the principal Act shall be substituted as follows:

"(b) knowingly or unknowingly sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply:

(i) any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance;

(ii) any medicinal product which is deliberately and fraudulently mislabeled with respect to identity and, or source including products with the correct ingredients, with the wrong ingredients, without active ingredients, in an insufficient quantity or excessive quantity of active ingredients or with fake packaging.".

Amendment of article 99 of the principal Act.

22. Article 99 of the principal Act shall be substituted as follows:

99. (1) Without prejudice to any other liability under any other law, any person who fails to comply with any of the provisions of this Act or any regulations or rules made thereunder shall be guilty of an offence and shall, on conviction, be liable, in the case of an offence against:

(a) the provisions of articles 20(1), 37, 54, 54A, 98 and 104A, to a fine (multa) of not less than eleven thousand and six hundred and forty six euro and eighty seven cents (11,646.87) and not exceeding one hundred and sixteen thousand and four hundred and sixty-eight euro and sixty-seven cents (116,468.67) or to imprisonment for a term not exceeding two years, or both such fine and imprisonment;

(b) the provisions of articles 31A, 44 and 56(3), to a fine (multa) of not less than five thousand eight hundred and twenty three euro and seventy five cents (5,823.75) and not

exceeding sixty-nine thousand and eight hundred and eighty-one euro and twenty cents (69,881.20) or to imprisonment for a term not exceeding six months, or both such fine and imprisonment;

(c) the provisions of articles 32(4), 45, 66(1), 66(5), 66(6), 66A, 71, 75(3), 75(4), 76(1), 81(1) and 91, to a fine (multa) of not less than two thousand and three hundred and twenty nine euro and thirty eight cents (2,329.38) and not exceeding forty-six thousand and five hundred and eighty-seven euro and forty-seven cents (46,587.47) or to imprisonment for a term not exceeding three months, or to both such fine and imprisonment;

(d) the provisions of articles 59, 60, 74, 75(1), 75(2), 84, 93, 94(1) and 96, to a fine (multa) of not less than one thousand and one hundred and sixty-four euro and sixty-nine cents (1,164.69) and not exceeding twenty-three thousand and two hundred and ninetythree euro and seventy-three cents (23,293.73);

(e) the provisions of articles 78, 83, 85(1), 85(2), 86, 87 and 94(2), to a fine (multa) of not less than four hundred and sixty five euro and eighty seven cents (465.87) and not exceeding eleven thousand and six hundred and forty six euro and eighty seven cents (11,646.87);

(f) the provisions of articles 31, 73(1), 79(1), 79(2), 80(1), 80(2) and 94(3), to a fine (multa) of not less than two hundred and thirty two euro and ninety four cents (232.94) and not exceeding two thousand and three hundred and twenty nine euro and thirty seven cents (2,329.37).

(2) Without prejudice to the powers of the Licensing Authority under this Act, where any person who has committed an offence is the holder of a licence or an authorisation under this Act, the Court shall, at the request of the prosecution, order the revocation or suspension of the aforesaid licence or authorisation.".

Amendment of article 100 of the principal Act.

23. Sub-articles (2), (3) and (4) of article 100 of the principal Act shall be renumbered as sub-articles (3), (4) and (5) thereof respectively, and immediately after sub-article (1) thereof, there shall be added the following new sub-article:

"(2) The provisions of sub-article (1) shall not apply in offences where there is a breach of articles 20(1), 37, 44, 54, 56(3), 98 and 104A.".

Addition of new article 101A to the principal Act.

24. Immediately after article 101 of the principal Act, there shall be added a new article 101A as follows:

"Requirements for testing and inspections of manufacturers, importers, brokers and distributors of medicinal products, including APIs, excipients and other starting materials.

101A. (1) The Licensing Authority shall, in cooperation with the European Medicines Agency, ensure that the legal requirements governing medicinal products are complied with, by means of inspections, if necessary unannounced, and, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to carry out tests on samples. This cooperation shall consist in sharing information with the European Medicines Agency on both inspections that are planned and that have been conducted as well as in the coordination of inspections in third countries.

(2) The inspections shall include but not be limited to the ones mentioned in sub-paragraphs (a) to (b) as follows:

(a) manufacturers, located in the European Union or in third countries, and wholesale distributors of medicinal products shall be subject to repeated inspections;

(b) the Licensing Authority shall have a system of supervision including by inspections at an appropriate frequency based on risk, at the premises of the manufacturers, importers, or distributors of active substances, located in Maltese territory, and effective follow-up thereof.

(3) Whenever it considers that there are grounds for suspecting non-compliance with the legal requirements laid down in this Act and its subsidiary legislation, including the European Union principles and guidelines of good manufacturing practice and good distribution practices, the Licensing Authority may carry out inspections at the premises of:

(a) manufacturers or distributors of active substances located in third countries;

(b) manufacturers or importers of excipients.

(4) Inspections referred to in subarticles (2) and (3) above may also be carried out in the European Union and in third countries at the request of a European Union Member State, the European Union Commission or the European Medicines Agency.

(5) Inspections may also take place at the premises of marketing authorisation holders and of brokers of medicinal products.

(6) Inspections shall be carried out by officials representing the Licensing Authority who shall be empowered to inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform any pharmacovigilance activities.

(7) Inspections shall be carried out in accordance with the guidelines and provisions referred to in Articles 101 to 104 of this Act.

(8) After every inspection, the Licensing Authority shall report on whether the inspected entity complies with the European Union principles and guidelines of good manufacturing practice and good distribution as applicable, or on whether the marketing authorisation holder complies with the pharmacovigilance requirements laid down in this Act and its subsidiary legislation.

(9) The Licensing Authority shall communicate the content of those reports to the inspected entity. Before adopting the report, the Licensing Authority shall give the inspected entity concerned the opportunity to submit comments.

(10) Without prejudice to any arrangements which may have been concluded between the European Union and third countries, a Member State, the European Union Commission or the European Medicines Agency may require a manufacturer established in a third country to submit to an inspection as referred to in this article.

(11) Within 90 days of an inspection as referred to in sub-article (1), a certificate of good manufacturing practice or good distribution practices shall, when applicable, be issued to the inspected entity if the outcome of the inspection shows that it complies with the principles and guidelines of good manufacturing

practice or good distribution practices as provided for by European Union legislation.

(12) If inspections are performed as part of the certification procedure for the monographs of the European Pharmacopoeia, a certificate shall be drawn up.

(13) Certificates of good manufacturing practice and good distribution practices issued shall be entered in the European Union database managed by the European Medicines Agency on behalf of the European Union. Information shall also be entered in that database regarding the registration of importers, manufacturers and distributors of active substances.".

Amendment of article 102 of the principal Act.

25. Article 102 of the principal Act shall be amended as follows:

(a) immediately after subarticle (1)(c), there shall be added the following new sub-article:

"(d) any premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any firms employed by the marketing authorisation holder to perform pharmacovigilance activities as established under article 31A of this Act:"; and

(b) in sub-article (2) of article 102 of the principal Act, immediately after the words "An authorised officer may, for the purpose specified in the preceding subarticle, take a sample" there shall be inserted the words, ", including with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory designated for that purpose by an European Union Member State,".

Renumbering of article 104A of the principal Act.

26. Article 104A of the principal Act shall be renumbered as article 104B thereof.

Addition of new article 104A to the principal Act.

27. Immediately after article 104 of the principal Act, there shall be inserted the following new article:

"Hindering etc. the Licensing Authority.

104A. Any person who by any means whatsoever, hinders or obstructs the Licensing Authority or an authorised

officer from exercising any of his powers and functions under this Act shall be guilty of an offence against this Act.".

Addition of new article 104C to the principal Act.

28. Immediately after article 104B of the principal Act as renumbered, there shall be inserted the following new article:

"Recalls and rapid alerts.

104C. (1). The Licensing Authority shall ensure that there is a system in place which aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.

(2) The system referred to in sub-article (1) shall cover the receipt and handling of notifications of suspected falsified medicinal products as well as of suspected quality defects of medicinal products. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by national competent authorities from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.

(3) If the medicinal product in question is suspected of presenting a serious risk to public health, the Licensing Authority shall, without any delay, transmit a rapid alert notification to all European Union Member States and all actors in the supply chain in Malta. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.".

OBJECTS AND REASONS

The object of this Bill is the amendments to the Medicines Act are necessary to effect the transposition of Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

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