Suppliment tal-Gazzetta tal-Gvern ta' Malta, Nru. 20,871, 3 ta' Ġunju, 2022
Taqsima C

Nru 6

03. 06. 2022

MALTA

KAMRA TAD-DEPUTATI

ABBOZZ ta' Liġi mressaq mill-Onorevoli Anton Refalo, M.P., Ministru għall-Agrikoltura, is-Sajd u d-Drittijiet tal-Annimali, u moqri għall-Ewwel darba fis-Seduta tal-31 ta' Mejju 2022.

ATT li jemenda l-Att dwar is-Servizzi Veterinarji, Kap. 437.

RAYMOND SCICLUNA
Skrivan tal-Kamra tad-Deputati

HOUSE OF REPRESENTATIVES

A BILL introduced by the Honourable Anton Refalo, M.P., Minister for Agriculture, Fisheries and Animal Rights, and read the First time at the Sitting of the 31st May 2022.

AN ACT to amend the Veterinary Services Act, Cap. 437.

RAYMOND SCICLUNA
Clerk of the House of Representatives

VERŻJONI ELETTRONIKA

ABBOZZ TA' LIĠI
msejjaħ

ATT li jemenda l-Att dwar is-Servizzi Veterinarji, Kap. 437.

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 l-Att tal-2022 li jemenda l-Att dwar is-Servizzi Veterinarji u dan l-Att għandu jinqara u jinftiehem ħaġa waħda mal-Att dwar is-Servizzi Veterinarji, hawn iżjed 'il quddiem imsejjaħ "l-Att prinċipali".

Kap. 437.

(2) Dan l-Att għandu jidħol fi żmien xahrejn mill-pubblikazzjoni tiegħu fil-Gazzetta.

Emenda tal-artikolu 2 tal-Att prinċipali.

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

(a) minnufih wara t-tifsira "attività veterinarja tal-Istat" għandha tiżdied it-tifsira ġdida li ġejja:

" "Awtorità dwar il-Mediċini" tfisser l-Awtorità dwar il-Mediċini mwaqqfa taħt l-Att dwar il-Mediċini;";

Kap. 458.

(b) it-tifsira "Direttur" għandha tiġi sostitwita bit-tifsira ġdida li ġejja:

" "Direttur" tfisser Direttur tas-Servizzi Veterinarji li għandu jkun Kirurgu Veterinarju bil-*warrant* jew uffiċjal nominat minnu;";

(ċ) it-tifsira "għalf" għandha tiġi sostitwita bit-tifsira ġdida li ġejja:

" "għalf" tfisser kull sustanza jew prodott, inklużi addittivi, sew jekk ipproċessati, parzjalment ipproċessati jew mhux ipproċessati maħsuba biex jintużaw għat-tmigħ orali lill-annimali;";

(d) fit-tifsira "importazzjoni", minnufih wara l-kliem "ta' annimali ħajjin" għandhom jiżdiedu l-kliem "prodotti mediċinali veterinarji" u minnufih warajha għandha tiżdied it-tifsira ġdida li ġejja:

" "informazzjoni fuq bejgħ" tfisser informazzjoni fuq il-volum tal-bejgħ;";

(e) it-tifsira "perjodu ta' distakk" għandha tiġi sostitwita bit-tifsira ġdida li ġejja:

" "perjodu ta' rtirar" tfisser il-perjodu minimu bejn l-aħħar somministrazzjoni ta' prodott mediċinali veterinarju lil xi annimal u l-produzzjoni ta' prodotti tal-ikel minn dak l-annimal li skont kondizzjonijiet normali ta' użu huwa meħtieġ sabiex ikun żgurat li dawn il-prodotti tal-ikel ma fihomx residwi fi kwantitajiet li jagħmlu ħsara lis-saħħa pubblika;";

(f) it-tifsira "prodott mediċinali immunoloġiku veterinarju" għandha tiġi mħassra;

(g) it-tifsira "prodott mediċinali veterinarju" għandha tiġi sostitwita bit-tifsira ġdida li ġejja:

" "prodott mediċinali veterinarju" tfisser kwalunkwe sustanza jew taħlita ta' sustanzi li tissodisfa mill-inqas waħda mill-kondizzjonijiet li ġejjin:

(a) hija ppreżentata bħala li għandha l-proprjetajiet għat-trattament jew għall-prevenzjoni ta' mard fl-annimali;

(b) l-iskop tagħha huwa li tintuża fi, jew tiġi amministrata lill-annimali bil-għan li tirkupra, tikkoreġi jew timmodifika funzjonijiet fiżjoloġiċi billi twettaq azzjoni farmakoloġika, immunoloġika jew metabolika;

(ċ) l-iskop tagħha huwa li tintuża f'annimali bil-ħsieb li ssir djanjosi medika;

(d) l-iskop tagħha huwa li tintuża għall-ewtanasja tal-annimali;";

(h) minnufih wara t-tifsira "sieħeb fil-kummerċ" għandha tiżdied it-tifsira ġdida li ġejja:

" "sustanza attiva" tfisser kwalunkwe sustanza jew taħlita ta' sustanzi maħsuba biex tintuża fil-manifattura ta' prodott mediċinali veterinarju li, meta wżat skont il-produzzjoni, isir ingredjent attiv ta' dak l-istess prodott;";u

(i) minnufih wara t-tifsira "tagħlim tul il-ħajja" għandha tiżdied it-tifsira ġdida li ġejja:

" "tagħmir mediku veterinarju" tfisser strument, apparat, għodda, makkinarju, mekkaniżmu, impjant, reaġent in-vitro, jew oġġett ieħor simili jew relatat, inkluż kull komponent, parti, jew aċċessorju, li hu maħsub biex jintuża fid-djanjosi ta' mard jew kondizzjonijiet oħra, jew fil-kura, mitigazzjoni, trattament jew prevenzjoni tal-mard fl-annimali, jew li hu maħsub biex jaffettwa l-istruttura jew kwalunkwe funzjoni tal-ġisem ta' annimali;".

3. Fil-paragrafu (b) tas-subartikolu (1) tal-artikolu 3 tal-Att prinċipali, minnufih wara l-kliem "fi prodotti" għandhom jiżdiedu l-kliem ", sustanzi attivi u tagħmir mediku veterinarju;". Emenda tal-artikolu 3 tal-Att prinċipali.

4. L-artikolu 6 tal-Att prinċipali għandu jiġi emendat kif ġej: Emenda tal-artikolu 6 tal-Att prinċipali.

(a) fil-paragrafu (a) tas-subartikolu (1) tiegħu, il-kliem "elenkata fit-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "msemmija fil-lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali"; u

(b) fis-subartikolu (2) tiegħu, il-kliem "elenkata fit-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "msemmija fil-lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali".

5. Fis-subartikolu (4) tal-artikolu 15 tal-Att prinċipali, il-kliem "fit-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "fil-lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali". Emenda tal-artikolu 15 tal-Att prinċipali.

6. Fil-paragrafu (a) tas-subartikolu (3) tal-artikolu 16 tal-Att prinċipali, il-kliem "elenkata fit-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "msemmija fil-lista ta' mard notifikabbli tal-annimali Emenda tal-artikolu 16 tal-Att prinċipali.

terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali".

Emenda tal-artikolu 24 tal-Att prinċipali.

7. Fl-artikolu 24 tal-Att prinċipali, il-kliem "mal-Kap tal-Laboratorju Veterinarju Nazzjonali" għandhom jiġu sostitwiti bil-kliem "mad-Direttur".

Sostituzzjoni tal-artikolu 29 tal-Att prinċipali.

8. L-artikolu 29 tal-Att prinċipali għandu jiġi sostitwit bl-artikolu ġdid li ġej:

"29. Sakemm jintlaħaq l-iskop ta' dan l-Att, ir-rekwiżiti b'rabta mal-ispezzjoni, is-superviżjoni, l-awtorizzazzjoni, il-manifattura, ir-riċerka, id-distribuzzjoni bl-ingrossa, is-senserija, il-kummerċjalizzazzjoni, il-preskrizzjoni, l-iddispensar, il-provvista, il-bejgħ bl-imnut, ir-reklamar, il-provvista ta' informazzjoni fuq il-bejgħ u l-użu ta' prodotti mediċinali veterinarji, sustanzi attivi u tagħmir mediku veterinarju għandhom jinkludu:

(a) proċeduri li jridu jiġu osservati; u

(b) drittijiet li għandhom jiġu imposti.".

Sostituzzjoni tal-artikolu 30 tal-Att prinċipali.

9. L-artikolu 30 tal-Att prinċipali għandu jiġi sostitwit bl-artikolu ġdid li ġej:

"Setgħat mogħtija lill-Ministru biex jagħmel ir-regolamenti fuq rekwiżiti marbuta mal-prodotti mediċinali veterinarji u t-tagħmir.

30. Il-Ministru jista', wara konsultazzjoni mad-Direttur, jippreskrivi regolamenti li jistabbilixxu r-rekwiżiti b'rabta mal-manifattura, l-importazzjoni, l-introduzzjoni, ir-riċerka, id-distribuzzjoni bl-ingrossa, is-senserija, il-kummerċjalizzazzjoni, il-preskrizzjoni, l-iddispensar, il-provvista, il-bejgħ bl-imnut, ir-reklamar, il-provvista ta' informazzjoni fuq il-bejgħ u l-użu ta' prodotti mediċinali veterinarji, sustanzi attivi u tagħmir mediku veterinarju.".

Sostituzzjoni tal-artikolu 32 tal-Att prinċipali.

10. L-artikolu 32 tal-Att prinċipali għandu jiġi sostitwit bl-artikolu ġdid li ġej:

"Setgħat mogħtija lill-Ministru biex jagħmel ir-regolamenti fuq awtorizzazzjoni għal u superviżjoni ta' prodotti mediċinali veterinarji.

32. Il-Ministru jista', wara konsultazzjoni mad-Direttur, jippreskrivi regolamenti b'rabta mal-awtorizzazzjoni għal u superviżjoni tal-manifattura, l-importazzjoni, l-introduzzjoni, id-distribuzzjoni bl-ingrossa, ir-riċerka, is-senserija, il-kummerċjalizzazzjoni, il-preskrizzjoni, l-iddispensar, il-provvista, il-bejgħ bl-imnut, ir-reklamar, il-provvista ta' informazzjoni fuq il-bejgħ u l-użu ta' prodotti mediċinali veterinarji, sustanzi attivi u tagħmir mediku veterinarju.".

11. Is-subartikolu (1) tal-artikolu 35 tal-Att prinċipali għandu jiġi emendat kif ġej: Emenda tal-artikolu 35 tal-Att prinċipali.

(a) minnufih wara l-kliem "il-bejjiegħ bl-imnut jew" għandhom jiżdiedu l-kliem", kif applikabbli" u minnufih wara l-kliem "taħt id-dispożizzjonijiet ta' dan l-Att biex" għandhom jiżdiedu l-kliem "iżżomm, timmanifattura, timporta, tippreskrivi, tiddistribwixxi bl-ingrossa, tagħmel senserija, tikkummerċjalizza, tinnegozja, tiddispensja, tirreklama, tagħti provvista ta' informazzjoni fuq bejgħ u użu ta' prodotti mediċinali veterinarji, jew biex tforni, tbigħ jew" u l-kliem "jew prodotti mediċinali veterinarji" għandhom jiġu sostitwiti bil-kliem "prodotti mediċinali veterinarji, sustanzi attivi jew tagħmir mediċinali veterinarju";

(b) il-paragrafu (b) tiegħu għandu jiġi emendat kif ġej:

(i) minnufih wara l-kelma "għandu" għandhom jiżdiedu l-kliem "jippermetti dħul fil-binja tagħhom f'ħin raġonevoli u" u l-kliem "lill-uffiċjali tas-servizzi veterinarji, lill-veterinarju uffiċjali jew lill-persunal tiegħu awtorizzati" għandhom jiġu sostitwiti bil-kliem "lid-Direttur jew kwalunkwe uffiċjal ieħor innominat minnu";

(ii) fis-subparagrafu (i) tiegħu, minnufih wara l-kliem "għalf tal-annimali" għandhom jiżdiedu l-kliem ", sustanzi attivi, tagħmir mediku veterinarju";

(iii) is-subparagrafu (iii) tiegħu għandu jiġi sostitwit bis-subparagrafu ġdid li ġej:

"jimmanifatturaw, jiġbru, jittrasportaw u juru fl-aħjar kondizzjonijiet li jilħqu r-rekwiżiti kollha tal-liġijiet applikabbli prodotti ta' oriġini mill-annimali, prodotti elenkati fl-Ewwel Skeda, għalf, sustanzi attivi, tagħmir mediku veterinarju u prodotti mediċinali veterinarji skont id-dispożizzjonijiet ta' dan l-Att dwar il-kontrolli jew spezzjonijiet ta' dawk il-prodotti, għalf tal-annimali, sustanzi attivi, tagħmir mediku veterinarju u prodotti mediċinali veterinarji;";

(iv) fil-paragrafu (iv) tiegħu, minnufih wara l-kliem "għalf tal-annimali" għandhom jiżdiedu l-kliem ", sustanzi attivi, tagħmir mediku veterinarju"; u

(v) fil-paragrafu (v) tiegħu, minnufih wara l-kliem "għalf tal-annimali" għandhom jiżdiedu l-kliem ", sustanzi

attivi, tagħmir mediku veterinarju";

(ċ) il-paragrafu (ċ) tiegħu għandu jiġi emendat kif ġej:

(i) fis-subparagrafu (i) tiegħu, il-kliem "elenkat fit-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "imsemmi fil-lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali";

(ii) fis-subparagrafu (ii) tiegħu, il-kliem "elenkat fit-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "imsemmi fil-lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali" u minnufih wara l-kelma "prodotti" għandhom jiżdiedu l-kliem ", sustanzi attivi, tagħmir mediku veterinarju, prodotti mediċi veterinarji"; u

(iii) fis-subparagrafu (viii) tiegħu, minnufih wara l-kelma "prodotti" għandhom jiżdiedu l-kliem ", sustanzi attivi, tagħmir mediku veterinarju, prodotti mediċi veterinarji";

(d) fil-paragrafu (j) tiegħu, il-kelma "distakk" għandha tiġi sostitwita bil-kelma "rtirar";

(e) fil-paragrafu (l) tiegħu, il-kliem "hawn aktar 'il quddiem; u" għandhom jiġu sotitwiti bil-kliem "hawn aktar 'il quddiem;"; u

(f) fil-paragrafu (m) tiegħu, il-kliem "jew għall-kontroll relattiv." għandhom jiġu sostitwiti bil-kliem "jew għall-kontroll relattiv; u" u minnufih wara għandu jiżdied il-paragrafu ġdid li ġej:

"(n) għandu jrodd lis-servizzi veterinarji kwalunkwe strument, annimal, prodotti li ġejjin mill-annimali, sustanzi attivi, tagħmir mediku veterinarju prodott mediċinali veterinarju, għalf, apparat, prodott jew kwalunkwe sustanza suspetta li tista' tintuża fit-twettiq ta' reat kontra dan l-artikolu.".

Emenda tal-artikolu 36 tal-Att prinċipali.

12. Is-subartikolu (1) tal-artikolu 36 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) minnufih wara l-kliem "il-bejjiegħ bl-imnut jew" għandhom jiżdiedu l-kliem ", kif applikabbli"; u minnufih wara l-kliem "taħt id-dispożizzjonijiet ta' dan l-Att biex" għandhom

jiżdiedu l-kliem "iżżomm, timmanifattura, timporta, tippreskrivi, tiddistribwixxi bl-ingrossa, tagħmel senserija, tikkummerċjalizza, tinnegozja, tiddispensa, tirreklama, tagħti informazzjoni fuq bejgħ u użu ta' prodotti mediċinali veterinarji, jew biex tforni, tbigħ jew" u l-kliem "jew prodotti mediċinali veterinarji" għandhom jiġu sostitwiti bil-kliem "prodotti mediċinali veterinarji jew sustanzi attivi";

(b) fil-paragrafu (ċ) tiegħu, il-kelma "distakk" għandha tiġi sostitwita bil-kelma "rtirar";

(ċ) fil-paragrafu (d) tiegħu, il-kelma "distakk" għandha tiġi sostitwita bil-kelma "rtirar";

(d) fil-paragrafu (h) tiegħu, il-kliem "kif jista' jiġi preskritt; u" għandhom jiġu sostitwiti bil-kliem "kif jista' jiġi preskritt;"; u

(e) fil-paragrafu (i) tiegħu, il-kliem "għall-kontroll relattiv." għandhom jiġu sostitwiti bil-kliem "għall-kontroll relattiv; u" u minnufih warajh għandhom jiżdiedu il-paragrafi ġodda li ġejjin:

"(j) għandu jikseb kwalunkwe awtorizzazzjoni rilevanti mingħand is-servizzi veterinarji qabel it-tbiċċir tal-annimali għall-konsum mill-bniedem jew mill-annimali, sakemm mhux eżenti milli jagħmel dan skont dan l-Att jew kull tip ta' liġi oħra nazzjonali jew tal-UE; u

(k) għandu jrodd lis-servizzi veterinarji kwalunkwe strument, annimal, prodotti li ġejjin mill-annimali, sustanzi attivi, tagħmir mediku veterinarju, prodott mediċinali veterinarju, għalf, apparat, prodotti, jew sustanzi suspettata li jista' tintużaw fit-twettiq ta' offiża kontra dan l-artikolu.".

13. Is-subartikolu (1) tal-artikolu 37 tal-Att prinċipali għandu jiġi emendat kif ġej: Emenda tal-artikolu 37 tal-Att prinċipali.

(a) fil-paragrafu (a) tiegħu, il-kliem "it-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali";

(b) fil-paragrafu (ċ) tiegħu, il-kliem "it-Tieni Skeda" għandhom jiġu sostitwiti bil-kliem "lista ta' mard notifikabbli tal-annimali terrestri kif ukoll akwatiċi maħruġa mill-Organizzazzjoni Dinjija tas-Saħħa tal-Annimali";

(ċ) fil-paragrafu (r) tiegħu, il-kliem "hemm taħtu preskritt; u" għandhom jiġu sostitwiti bil-kliem "hemm taħtu preskritt;" u

(d) fil-paragrafu (s) tiegħu, il-kliem "spezzjon fil-konfini." għandhom jiġu sostitwiti bil-kliem "spezzjon fil-konfini; u" uminnufih warajh għandu jiżdied il-paragrafu ġdid li ġej:

"(t) għandu jirrinunzja d-dritt għas-servizzi veterinarji kwalunkwe strument, annimal, prodotti li ġejjin mill-annimali, sustanzi attivi, tagħmir mediku veterinarju, prodotti mediċinali veterinarji, għalf, apparat, prodotti, jew sustanzi suspettati li jistgħu jintużaw fit-twettiq ta' reat kontra dan l-artikolu.".

Emenda tal-artikolu 38 tal-Att prinċipali.

14. Is-subartikolu (1) tal-artikolu 38 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) minnufih wara l-kliem "taħt id-dispożizzjonijiet ta' dan l-Att biex" għandhom jiżdiedu l-kliem "iżżomm, timmanifattura, timporta, tippreskrivi, tiddistribwixxi bl-ingrossa, tagħmel senserija, tikkummerċjalizza, tinnegozja, tiddispensa, tirreklama, tagħti informazzjoni fuq bejgħ u użu ta' prodotti mediċinali veterinarji, jew biex tforni, tbigħ jew" u l-kliem "jew prodotti mediċinali veterinarji" għandhom jiġu sostitwiti bil-kliem "prodotti mediċinali veterinarji, sustanzi attivi jew tagħmir mediku veterinarju";

(b) fil-paragrafu (b) tiegħu, minnufih wara l-kliem "prodotti mediċinali veterinarji" għandhom jiżdiedu l-kliem ", sustanzi attivi jew tagħmir mediċinali veterinarju";

(ċ) fil-paragrafu (ċ) tiegħu, minnufih wara l-kelma "sospensjoni" għandha tiżdied il-kelma ", revoka";

(d) fil-paragrafu (d) tiegħu, il-kliem "jordna l-qirda" għandhom jiżdiedu l-kliem "u jħares kull ordni relatata mal-qirda" u minnufih wara l-kliem "prodotti mediċinali veterinarji" għandhom jiżdiedu l-kliem ", sustanzi attivi jew tagħmir mediċinali veterinarju" u minnufih wara l-kliem "theddida serja għas-saħħa tal-annimali jew għas-saħħa pubblika" għandhom jiżdiedul-kliem " jew għall-ambjent;";

(e) fil-paragrafu (e) tiegħu, il-kliem "hemm fih preskritt; u" għandhom jiġu sostitwiti bil-kliem "hemm fih preskritt;"; u

(f) fil-paragrafu (f) tiegħu, minnufih wara l-kelma

"jgħin" għandhom jiżdiedu l-kliem "jippermetti dħul fil-binja tagħhom f'ħin raġonevoli," u minnufih wara għandhom jiżdiedu l-paragrafi ġodda li ġejjin:

"(g) għandu jieħu kampjuni mill-annimali, prodotti ġejjin mill-annimali, prodotti elenkati fl-Ewwel Skeda, għalf, prodotti mediċinali veterinarji, sustanzi attivi jew tagħmir mediċinali veterinarju, kif jista' jkun mitlub mis-servizzi veterinarji għal skopijiet ta' kontroll. L-ispiża għal dawn il-kampjuni tista' tkun rimborsabbli mid-Direttur, fid-diskrezzjoni tiegħu; u

(h) għandu jrodd lis-servizzi veterinarji kwalunkwe strument, annimal, prodott li ġej mill-annimali, sustanzi attivi, tagħmir mediċinali veterinarju prodott mediċinali veterinarju, għalf, apparat, prodotti, jew sustanzi suspettati li jistgħu jintużaw fit-twettiq ta' reat kontra dan l-artikolu.".

Emenda tal-artikolu 49 tal-Att prinċipali.

15. L-artikolu 49 tal-Att prinċipali għandu jiġi enumerat mill-ġdid bħala l-artikolu 49(1) u għandu jiġi emendat kif ġej:

(a) fil-paragrafu (e) tiegħu, il-kliem "ikun responsabbli; u" għandhom jiġu sostitwiti bil-kliem "ikun responsabbli;"; u

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

"(g) jiddeċiedi dwar kwalunkwe talba li ssir mill-manifattur, jew minn rappreżentant debitament awtorizzat, ta' prodotti mediċinali veterinarji, għall-iskop ta' kisba ta' awtorizzazzjoni għall-kummerċjalizzazzjoni ta' tali prodotti skont id-dispożizzjonijiet ta' dan l-Att;

(h) fejn talba skont il-paragrafu (g) tkun ġiet deċiża b'mod favorevoli, joħroġ awtorizzazzjoni għall-kummerċjalizzazzjoni tal-prodotti mediċinali veterinarji u jinkludi tali prodotti li hemm fil-lista ta' Prodotti Mediċinali Veterinarji approvati, li, minn żmien għal żmien, għandha tiġi ppubblikata mis-Servizzi Veterinarji;

(i) jiddeċiedi dwar il-kontinwazzjoni jew it-twaqqif tal-manifattura, importazzjoni jew il-kummerċjalizzazzjoni ta' prodott mediċinali veterinarju, sustanza attiva jew tagħmir mediċinali veterinarju u, jew il-ġbir lura ta' dak il-prodott, f'każijiet fejn ġie skopert jew suspettat effett mhux mixtieq;

(j) fuq referenza magħmula lilu għal dak il-għan, jiddetermina jekk is-sustanzi partikolari jew is-sustanzi attivi ntużawx fil-manifattura ta' prodott mediċinali veterinarju;

(k) jissorvelja u jwettaq spezzjonijiet fuq il-manifattura, l-importazzjoni, l-introduzzjoni, id-distribuzzjoni bl-ingrossa, is-senserija, il-kummerċjalizzazzjoni, il-bejgħ u l-użu ta' prodotti mediċinali veterinarji u sustanzi attivi;

(l) jiddeċiedi dwar il-kontinwazzjoni jew it-twaqqif tal-manifattura, importazzjoni jew kummerċjalizzazzjoni ta' prodott mediċinali veterinarju, sustanza attiva jew tagħmir mediċinali veterinarju f'każijiet fejn prodott jew difett tal-lott ikun ġie skopert jew suspettat; u

(m) jiddeċiedi dwar il-konfiska, issiġillar, iżolazzjoni jew mod ieħor ta' prodotti mediċinali veterinarji, sustanzi attivi jew tagħmir mediċinali veterinarju li jinsabu li jkunu qed jiksru xi waħda mid-dispożizzjonijiet ta' dan l-Att jew kwalunkwe regolamenti magħmulin taħtu."; u

(ċ) minnufih wara l-paragrafu (m) tiegħu għandhom jiżdiedu s-subartikoli ġodda li ġejjin:

"(2) Mingħajr preġudizzju għas-subartikolu ta' qabel, id-Direttur jista' wkoll:

(a) ifassal u jaġġorna rapporti ta' valutazzjoni fuq ir-riżultati ta' testijiet analitiċi u dawk farma-tossikoloġiċi, u fuq ir-riżultati ta' provi kliniċi ta' prodotti mediċinali veterinarji u valutazzjoni ta' dossiers tagħhom; u

(b) jittestja prodotti mediċinali veterinarji jew kwalunkwe ingredjent tagħhom u, fejn meħtieġ, prodotti intermedji jew materjali oħra konstitwenti, jew jgħaddi t-tali prodotti għall-ittestjar minn laboratorju msieħeb fil-kummerċ jew minn laboratorju apposta għal dan il-għan, bil-għan li jkun assigurat li l-metodi ta' manifattura u ttestjar li ntużaw mill-manifattur u dawk deskritti fl-applikazzjoni huma skont id-dispożizzjonijiet ta' dan l-Att jew kwalunkwe regolamenti magħmula taħtu.

(3) Id-Direttur jista' jeżerċita xi waħda jew aktar mill-funzjonijiet tiegħu sew direttament sew permezz ta' xi wieħed mill-uffiċjali jew impjegati tas-Servizzi Veterinarji jew permezz tal-Awtorità dwar il-Mediċini jew ta' xi aġenzija li tkun awtorizzata għal dak il-għan, jew permezz ta' kuntrattur jew persuna oħra li magħhom ikun sar ftehim għat-twettiq ta' xi waħda jew aktar minn dawk il-funzjonijiet:

Iżda ebda ħaġa f'dan is-subartikolu ma għandha tawtorizza lid-Direttur li jikkuntratta jew jiddelega xi ħaġa mill-:

(a) funzjonijiet regolatorji tiegħu; jew

(b) funzjonijiet ta' awtorizzazzjoni tiegħu, kemm-il darba dawk iż-żewġ tipi ta' funzjonijiet ma jiġux espressament delegati lill-Awtorità dwar il-Mediċini jew xi awtorità pubblika mwaqqfa bil-liġi, b'mod partikolari awtorità nazzjonali kompetenti oħra kif imfissra f'dan l-Att.

(4) Id-Direttur jista' japprova li jsiru kuntratti jew memoranda ta' ftehim bejn is -Servizzi Veterinarji u l-Awtorità dwar il-Mediċini għal kwalunkwe skop ta' kooperazzjoni li jkun meqjus ta' benefiċċju għal kwalunkwe mill-partijiet tal-kuntratt jew memorandum ta' ftehim fil-qadi ta' kwalunkwe mill-funzjonijijiet tagħhom.

(5) Għall-finijiet tat-twettiq tal-funzjonijiet taħt dan l-Att, id-Direttur jew kull uffiċjal jew persuna oħra kif tista' tkun awtorizzata mid-Direttur, tista' titlob l-assistenza tal-Korp tal-Pulizija ta' Malta, kull kunsill lokali, kull dipartiment tal-Gvern, kull aġenzija tal-Gvern, kull organizzazzjoni volontarja jew entità mis-settur privat.

(6) Għall-finijiet tas-subartikoli (3), (4) u (5) fejn applikabbli għall-Awtorità tal-Mediċini, dawn huma soġġetti għal ftehim bejn l-Awtorità tal-Mediċini u d-Direttur Servizzi Veterinarji, permezz ta' kuntratt jew memorandum ta' ftehim.".

16. Il-paragrafi (a) u (b) tas-subartikolu (2) tal-artikolu 50 tal-Att prinċipali għandhom jiġu sostitwiti bil-paragrafi ġodda li ġejjin: Emenda tal-artikolu 50 tal-Att prinċipali.

"(a) jipprepara rapporti fuq prodotti mediċinali veterinarji fuq talba tad-Direttur; u

(b) jgħin lis-servizzi veterinarji fil-kontroll tas-sigurtà fl-ikel u l-għalf fil-produzzjoni primarja ta' ikel ġej mill-annimali,

għalf, prodotti sekondarji mill-annimali, u fil-kontroll ta' mard fuq l-annimali inkluż iż-*zoonosis*.".

Sostituzzjoni tal-artikolu 51 tal-Att prinċipali.

17. L-artikolu 51 tal-Att prinċipali għandu jiġi sostitwit bl-artikolu ġdid li ġej:

"51. Il-Laboratorju Veterinarju Nazzjonali għandu:

(a) jipprovdi analiżi u testijiet laboratorji u jipparteċipa fid-djanjosi u l-kontroll ta' mard fuq l-annimali;

(b) jgħin lis-Servizzi Veterinarji, fuq talba;

(ċ) iwettaq attivitajiet ta' ttestjar fil-kuntest ta' programm b'rabta mas-sorveljanza ta' mard fuq l-annimali, sorveljanza ta' sigurtà fl-ikel, sorveljanza ta' mard żoonotiku, sorveljanza ta' residwi mediċinali veterinarji, u reżistenza antimikrobika; u

(d) jilħaq l-irwol ta' Laboratorju ta' Referenza Nazzjonali.".

Tħassir tal-artikolu 53 tal-Att prinċipali.

18. L-artikolu 53 tal-Att prinċipali għandu jiġi mħassar.

Emenda tal-artikolu 54 tal-Att prinċipali.

19. L-artikolu 54 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) minnufih wara l-kelma "Att", kull fejn tidher, għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu.";

(b) il-paragrafu (a) tiegħu għandu jiġi sostitwit bil-paragrafu ġdid li ġej:

"(a) fejn veterinarji uffiċjali u, jew uffiċjali ikollhom is-setgħa, bid-dispożizzjonijiet ta' dan l-Att, jew kwalunkwe regolamenti magħulin taħtu, li jwettqu spezzjonijiet u sorveljanza b'rabta mar-restrizzjoni ta' kummerċ ta' annimali jew prodotti tal-annimali, jew il-projbizzjoni ta' moviment ta' persuni, annimali jew prodotti tal-annimali f'żona kontaminata;"; u

(ċ) fil-paragrafu (ċ) tiegħu, il-kliem "uffiċjali veterinarji" għandhom jiġu sostitwiti bil-kliem "veterinarji uffiċjali u, jew uffiċjali".

Emenda tal-artikolu 56 tal-Att prinċipali.

20. L-artikolu 56 tal-Att prinċiplai għandu jiġi emendat kif ġej:

(a) fil-paragrafu (a) tiegħu, minnufih wara l-kliem "veterinarju uffiċjali" għandhom jiżdiedu l-kliem "u, jew

uffiċjal";

(b) fis-subparagrafu (i) tal-paragrafu (ċ) tiegħu, minnufih wara l-kliem "veterinarju uffiċjali" għandhom jiżdiedu l-kliem "u, jew uffiċjal"; u

(ċ) fil-paragrafi (a), (b), (ċ), (d) u (f) tiegħu, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu".

Emenda tal-artikolu 57 tal-Att prinċipali.

21. L-artikolu 57 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) fis-subartikolu (1) tiegħu, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu"; u

(b) fis-subartikolu (2) tiegħu, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu" u minnufih wara l-kliem "l-istrumenti," għandhom jiżdiedu l-kliem "annimali, prodotti ġejjin mill-annimali, sustanzi attivi, tagħmir mediċinali veterinarju, prodotti mediċinali veterinarji, għalf," u fil-verżjoni bl-Ingliż, il-kliem "forfeited to" għandhom jiġu sostitwiti bil-kliem "confiscated by" u fil-verżjoni bl-Ingliż, il-kelma "forfeited" għandha tiġi sostitwita bil-kelma "confiscated".

Emenda tal-artikolu 58 tal-Att prinċipali.

22. Fis-subartikoli (1) u (2) tal-artikolu 58 tal-Att prinċipali, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu".

Emenda tal-artikolu 60 tal-Att prinċipali.

23. L-artikolu 60 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) fis-subartikoli (1) u (2) tiegħu, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew regolamenti magħmulin taħtu"; u

(b) fis-subartikoli (1) u (2) tiegħu, kull fejn tidher il-kelma "liċenzja" minnufih warajha għandha tiżdied il-kelma "awtorizzazjoni".

Emenda tal-artikolu 61 tal-Att prinċipali.

24. L-artikolu 61 tal-Att prinċipali għandu jiġi emendat kif ġej:

(a) fil-paragrafu (a) tas-subartikolu (1) tiegħu, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu";

(b) is-subartikolu (2) tiegħu għandu jiġi emendat kif ġej:

(i) fil-paragrafu (ċ) tiegħu, il-kliem "tingħata

piena; u" għandhom jiġu sostitwiti bil-kliem "tingħata piena;";

(ii) fil-paragrafu (d) tiegħu, il-kliem "is-sejbien ta' ħtija," għandhom jiġu sostitwiti bil-kliem "is-sejbien ta' ħtija, u" u minnufih wara għandu jiżdied il-paragrafu ġdid li ġej:

"(e) kwalunkwe passi rimedjali li għandhom jittieħdu mill-persuna indirizzata fl-avviż sabiex tkun konformi mar-rekwiżiti ta' dan l-Att jew kwalunkwe regolamenti magħmulin taħtu.";

(ċ) fil-paragrafu (b) tas-subartikolu (3) tiegħu, minnufih wara l-kelma "Att" għandhom jiżdiedu l-kliem "jew kwalunkwe regolamenti magħmulin taħtu";

(d) il-paragrafi (a), (b) u (ċ) tas-subartikolu (4) tiegħu għandhom jiġu sostitwiti bil-paragrafi ġodda li ġejjin:

"(a) jammetti r-reat;

(b) jieħu dawk il-passi rimedjali kollha li jistgħu jkunu indikati fl-avviż notifikat skont is-subartikolu (1); u

(ċ) iħallas l-ammont tal-piena lid-Direttur fi żmien tletin (30) ġurnata wara li jkun ġie notifikat lilu avviż tal-piena jew wara kull perjodu sussegwenti hekk kif id-Direttur jista' jispeċifika.";

(e) is-subartikolu (5) tiegħu għandu jiġi sostitwit bis-subartikolu ġdid li ġej:

"(5) Fejn taħt dan l-artikolu persuna tammetti reat u tieħu dawk il-passi rimedjali kollha mitluba fl-avviż skont is-subartikolu (2), id-Direttur għandu jimponi piena monetarja fuq dik il-persuna fir-rigward tar-reat li tkun tammonta għal terz tal-piena massima li għaliha l-persuna teħel li kieku insabet ħatja tar-reat mill-Qorti."; u

(f) is-subartikoli (7) u (8) tiegħu għandhom jiġu sostitwiti bis-subartikoli ġodda li ġejjin:

"(7) Minkejja kull dispożizzjoni oħra ta' dan l-Att jew ta' kull liġi oħra, meta reat ikun ġie ammess taħt dan l-artikolu u l-passi rimedjali neċessarji kollha mitluba jkunu ttieħdu mill-persuna li tkun qiegħda tammetti r-reat sabiex

tkun konformi mar-rekwiżiti ta' dan l-Att jew kwalunkwe regolamenti magħmulin taħtu, ebda akkuża ma tista' titqiegħed fir-rigward tar-reat kontra kwalunkwe persuna li minnha ġiet ammessa.

(8) Fejn persuna li lilha jiġi nnotifikat avviż taħt is-subartikolu (1), fi żmien tletin (30) ġurnata wara li tkun ġiet innotifikat bl-avviż, ma tammettix ir-reat u ma tiħux il-passi rimedjali neċessarji kollha mitluba sabiex tkun konformi mar-rekwiżiti ta' dan l-Att jew kwalunkwe regolamenti magħmulin taħtu, id-Direttur għandu jibda proċedimenti jew iġiegħel li jinbdew proċedimenti quddiem il-Qorti fir-rigward tal-allegat reat.".

Żieda ta' Taqsima ġdida mal-Att prinċipali.

25. Minnufih wara l-artikolu 61 tal-Att prinċipali għandha tiżdied it-Taqsima ġdida li ġejja:

"TAQSIMA X

Spiżeriji Veterinarji u liċenzji għall-manifatturi, importaturi, distributuri bl-ingrossa u sensara ta' prodotti mediċinali veterinarji

Liċenzja għall-ftuħ ta' spiżerija veterinarja.

62. (1) Ma għandux ikun legali għal kwalunkwe persuna li tiftaħ jew tieħu ħsieb spiżerija veterinarja sakemm din ma tkunx fil-pussess ta' liċenzja għal spiżerija veterinarja maħruġa skont id-dispożizzjonijiet ta' dan l-Att jew kwalunkwe regolamenti magħmulin taħtu.

(2) Mingħajr preġudizzju għal kwalunkwe eċċezzjoni li tista' tingħata b'dan jew skont dan l-Att,ebda persuna ma tista' tbigħ xi prodott mediċinali veterinarju sakemm mhux skont il-liċenzja tal-ispiżerija veterinarja maħruġa skont id-dispożizzjonijiet ta' dan l-Att jew kwalunkwe regolamenti jew regoli magħmulin taħtu.

(3) Min ikollu l-liċenzja għandu jkun responsabbli li jikkonforma mal-kondizzjonijiet tal-liċenzja kif jista' jiġi stabbilit mid-Direttur.

Applikazzjoni għal-liċenzja ta' spiżerija veterinarja.

63. (1) Kwalunkwe applikazzjoni għall-għoti ta' liċenzja ta' spiżerija veterinarja għandha tkun magħmula lid-Direttur u għandu jkun fiha dik l-informazzjoni, dokumenti, kampjuni u materjal ieħor hekk kif mitluba minn jew taħt dan l-Att, u b'mod partikolari għandha tinkludi dan li ġej:

(a) l-isem u l-indirizz tal-applikant;

(b) l-indirizz tal-post li ser ikun qiegħed jintuża għall-iskop ta' bejgħ ta' prodotti mediċinali veterinarji;

(ċ) it-tagħmir u l-faċilitajiet ta' kontroll skont kif jista' jkun meħtieġ minn jew taħt dan l-Att;

(d) l-isem tal-ispiżjar li ser ikun qiegħed imexxi l-ispiżerija li għandu jkun professjonalment responsabbli għall-attivitajiet kollha;

(e) kwalunkwe informazzjoni, dokumentazzjoni jew evidenza kif tista' tintalab mid-Direttur skont jew taħt dan l-Att.

(2) Id-Direttur għandu jiddetermina l-applikazzjoni fi żmien li l-Ministru jista' jistabbilixxi permezz ta' regolamenti taħt dan l-Att:

Iżda tali żmien jista' jiġi sospiż sakemm l-informazzjoni meħtieġa tingħata mill-applikant.

Għoti ta' liċenzja ta' spiżerija veterinarja.

64. (1) Id-Direttur għandu, qabel jiddetermina l-applikazzjoni għal-liċenzja għal spiżerija veterinarja, jispezzjona l-post indikat fl-applikazzjoni u ma għandux joħroġ liċenzja sakemm ikun sodisfatt li tali post hu addattat u adegwat, u li jinkludi faċilitajiet, installazzjonijiet u tagħmir adatti biex tkun żgurata l-konservazzjoni u d-dispensar xieraq ta' prodotti mediċinali veterinarji:

Iżda liċenzja tista' ssir kondizzjonali mat-twettiq tal-obbligi imposti fiha, liema kondizzjonijiet jistgħu jiġi revokati jew varjati mid-Direttur fi kwalunkwe ħin, kif jidhirlu xieraq.

(2) Liċenzja għal spiżerija veterinarja għandha tispeċifika l-post u l-attivitajiet li għalihom tapplika:

Iżda d-Direttur jista', fuq applikazzjoni, jagħti liċenzja addizzjonali għall-użu ta' post identifikat bħala maħżen għall-iskop ta' spiżerija veterinarja, wara li jkun sodisfatt li tali post jikkonforma mar-rekwiżiti stabbiliti minn jew taħt dan l-Att.

Avviż għal aktar informazzjoni.

65. Fejn id-Direttur jikkonsidra li jistgħu jeżistu ċirkostanzi li jagħmluha neċessarja li l-konsiderazzjoni ta' jekk il-liċenzja għandhiex tkun varjata, sospiża jew revokata, id-Direttur jista' joħroġ avviż lid-detentur ta' liċenzja ta' spiżerija veterinarja li fih jitolbu, li fi żmien speċifikat fl-avviż, jipprovdilu kwalunkwe informazzjoni speċifikata fl-avviż.

Durata u tiġdid tal-liċenzja ta' spiżerija veterinarja.

66. (1) Bla ħsara għad-dispożizzjonijiet ta' dan l-Att, kull liċenzja mogħtija taħt din it-Taqsima għandha, sakemm ma tkunx ġiet revokata qabel skont id-dispożizzjonijiet tal-artikolu 68, tibqa' valida sa dak iż-żmien li jista' jkun speċifikat fil-liċenzja jew fir-regolamenti adottati mill-Ministru taħt dan l-Att:

Iżda d-Direttur għandu, qabel it-tiġdid tal-perjodu ta' validità tal-liċenzja, jwettaq spezzjoni tal-post speċifikat fil-liċenzja.

(2) Wara spezzjoni kif imsemmi fis-subartikolu ta' qabel, id-Direttur jista' jew:

(a) iġedded il-liċenzja, bi kwalunkwe modifika meqjusa meħtieġa, għal perjodu ieħor kif jista' jiġi speċifikat fil-liċenzja jew fir-regolamenti adottati mill-Ministru taħt dan l-Att; jew

(b) jekk, wara li jikkunsidra d-dispożizzjonijiet ta' dan l-Att, huwa jqis li huwa neċessarju jew spedjenti li jagħmel hekk, jirrifjuta li jġedded il-liċenzja.

Trasferiment tal-liċenzja ta' spiżerija veterinarja.

67. Ebda persuna ma tista' tittrasferixxi liċenzja sakemm mhux awtorizzata li tagħmel dan mid-Direttur, liema awtorizzazzjoni ma għandhiex tinħareġ sakemm id-Direttur ma jkunx sodisfatt li d-detentur il-ġdid tal-liċenzja jikkonforma mar-rekwiżiti stabbiliti minn jew taħt dan l-Att, u mal-ħlas tad-dritt preskritt.

Sospensjoni jew revoka ta' liċenzja għal spiżerija veterinarja.

68. Id-Direttur jista' jissospendi liċenzja għal spiżerija veterinarja mogħtija skont dan l-Att qabel jiskadi l-perjodu msemmi fl-artikolu 66, għal dak il-perjodu ta' żmien li huwa jista' jiddetermina, jew jista' jirrevoka jew ivarja d-dispożizzjonijiet ta' tali liċenjza fi kwalunkwe ċirkostanza li ġejja:

(a) fejn kwalunkwe informazzjoni indikata fl-applikazzjoni li abbażi tagħha inħarġet il-liċenzja sussegwentement tinstab li tkun falza jew mhux kompluta;

(b) fejn tkun seħħet bidla materjali fiċ-ċirkostanzi b'rabta ma' kwalunkwe kwistjoni indikata fl-applikazzjoni;

(ċ) fejn il-kondizzjonijiet tal-liċenzja jkunu ġew miksura mid-detentur tal-liċenzja; jew

(d) fi kwalunkwe ċirkostanza oħra li tista' tiġi stabbilita minn jew taħt dan l-Att:

Iżda d-Direttur għandu jinnotifika lid-detentur tal-liċenzja bi kwalunkwe deċiżjoni maħruġa taħt dan l-artikolu, filwaqt li jagħti raġunijiet dettaljati għal tali deċiżjoni.

Għeluq temporanju ta' spiżerija veterinarja.

69. (1) Id-detentur ta' liċenzja ta' spiżerija veterinarja ma għandux jagħlaq tali spiżerija veterinarja, temporanjament jew mod ieħor, sakemm ma jkunx avża minn tal-anqas erbgħa u għoxrin (24) siegħa qabel, u tali għeluq ikun ġie awtorizzat, mid-Direttur:

Iżda għall-finijiet ta' dan l-artikolu, għeluq temporanju ma għandux jinkludi l-għeluq ta' spiżerija veterinarja li jirriżulta minn assenza mhux pjanata jew mhux prevista tal-ispiżjar li jmexxiha, *force majeure* li tirriżulta fin-nuqqas ta' abbiltà li jiftaħ il-post, jew għeluq barra s-sigħat tan-negozju għal spiżeriji veterinarji kif jista' jiġi stabbilit mir-regolamenti adottati mill-Ministru.

(2) Bla ħsara għad-dispożizzjonijjiet tas-subartikolu (1), il-liċenzja fir-rigward ta' spiżerija veterinarja li nżammet magħluqa għal perjodu ta' ħamest (5) ijiem tax-xogħol konsekuttivi mingħajr l-awtorizzazzjoni tad-Direttur għandha titqies li tkun ġiet revokata b'mod awtomatiku.

(3) Id-Direttur jista', malli jirċievi avviż kif imsemmi fis-subartikolu (1), jew meta jsir jaf li spiżerija veterinarja kienet magħluqa għal perjodu ta' għaxart (10) ijiem tax-xogħol konsekuttivi, jissiġilla l-prodotti mediċinali veterinarji kollha, kull fejn jinżammu mid-detentur tal-liċenzja skont id-dispożizzjonijiet ta' dan l-Att, u jieħu fl-inkarigu tiegħu kull tip ta' reġistru meħtieġ biex jinżamm mid-detentur tal-liċenzja skont ir-regolamenti li jistgħu jiġu adottati mill-Ministru.

Setgħat mogħtija lill-Ministru biex jagħmel xi regolamenti b'rabta mal-illiċenzjar u l-operat ta' spiżeriji veterinarji.

70. Il-Ministru jista', wara konsultazzjoni mad-Direttur, jadotta regolamenti biex jagħmel dispożizzjonijiet relatati mal-ħruġ, sospensjoni u revoka ta' liċenzji ta' spiżeriji veterinarji, il-perjodu ta' validità ta' tali liċenzji, l-obbligi tad-detenturi ta' liċenzja ta' spiżerija veterinarja, l-obbligi tal-ispiżjar li jmexxiha, il-prodotti mediċinali veterinarji li jistgħu jiġu mibjugħa b'mod esklussiv mill-ispiżerija veterinarja, l-istandards għall-preskrizzjoni, dispensar, ħażna u rimi ta' prodotti mediċinali veterinjari, id-drittjiet li għandhom jitħallsu għall-ħruġ ta' liċenzji u l-ħinijiet tax-xogħol ta' spiżeriji veterinarji.

Liċenzji għall-manifattura, importazzjoni u distribuzzjoni ta' prodotti mediċinali veterinajri.

71. (1) Ma għandux ikun legali għal xi persuna li taġixxi bħala manifattur, importatur, bejjiegħ bl-ingrossa jew sensar ta' prodotti mediċinali veterinarji sakemm ma jkollhiex fil-pussess tagħha liċenzja maħruġa skont id-dispożizzjonijiet ta' dan l-Att jew kwalunkwe regolamenti li maħruġa taħtu.

(2) Detentur ta' liċenzja skont dan l-artikolu għandu jkun responsabbli li jikkonforma mal-kondizzjonijiet tal-liċenzja hekk kif jistgħu jiġu stabbiliti mid-Direttur.

Applikazzjoni għal-liċenzja ta' manifattura, importazzjoni u distribuzzjoni.

72. (1) Kwalunkwe applikazzjoni għall-għoti ta' liċenzja biex wieħed jaġixxi bħala manifattur, importatur, bejjiegħ bl-ingrossa jew sensar ta' prodotti mediċinali veterinarji għandha ssir lid-Direttur u għandha tinkludi tali informazzjoni, dokumenti, kampjuni u materjal ieħor kif provdut minn jew taħt dan l-Att, u għandha tinkludi b'mod partikolari l-informazzjoni li ġejja:

(a) l-isem u l-indirizz tal-applikant;

(b) l-indirizz tal-post li ser jintuża għall-iskop ta' manifattura, importazzjoni, distribuzzjoni, ħażna jew senserija ta' prodotti mediċinali veterinarji;

(ċ) it-tagħmir u l-faċilitajiet ta' kontroll kif jista' jkunmeħtieġ minn jew taħt dan l-Att;

(d) kwalunkwe informazzjoni, dokumentazzjoni jew evidenza oħra kif tista' tintalab mid-Direttur skont jew taħt dan l-Att.

(2) Id-Direttur għandu jiddetermina l-applikazzjoni f'dak iż-żmien li l-Ministru jista' jistabbilixxi permezz ta' regolamenti taħt dan l-Att:

Iżda tali żmien jista' jiġi sospiż sakemm l-informazzjoni meħtieġa tingħata mill-applikant.

(3) Id-Direttur għandu, qabel jiddetermina l-applikazzjoni għal-liċenzja skont dan l-artikolu, jispezzjona l-post indikat fl-applikazzjoni u ma għandux joħroġ liċenzja sakemm ma jkunx sodisfatt li tali post huwa addattat u adegwat, u li jinkludi l-faċilitajiet addattati, installazzjonijiet u tagħmir sabiex ikunu assigurati l-manifattura proprja, il-kontroll u l-konservazzjoni ta' prodotti mediċinali veterinarji:

Iżda liċenzja tista' ssir kondizzjonali mat-twettiq tal-obbligi imposti fiha, liema kondizzjonijiet jistgħu jiġu revokati jew varjati mid-Direttur fi kwalunkwe ħin, kif jidhirlu xieraq.

Setgħat mogħtija lill-Ministru biex jagħmel xi regolamenti b'rabta mal-illiċenzjar u l-operat ta' manifatturi, importaturi u distributuri ta' prodotti mediċinali veterinarji.

73. Il-Ministru jista', wara konsultazzjoni mad-Direttur, jadotta regolamenti biex jagħmel dispożizzjonijiet relatati mal-ħruġ, sospensjoni u revoka ta' liċenzji ta' manifattura, importazzjoni, riċerka, bejgħ bl-ingrossa u ta' sensarija, il-perjodu ta' validità ta' tali liċenzji, l-obbligi u r-responsabbiltajiet tad-detenturi ta' tali liċenzji u tal-impjegati tagħhom, standards fil-manifattura, importazzjoni, distribuzzjoni, sensarija u rimi ta' prodotti mediċinali veterinjari, id-drittijiet li jistgħu jiġu imposti mid-Direttur għall-ħruġ ta' tali liċenzji.".

Tħassir tat-Tieni Skeda li tinsab mal-Att prinċipali.

26. It-Tieni Skeda li tinsab mal-Att prinċipali għandha tiġi mħassra.

Tħassir tas-Sitt Skeda li tinsab mal-Att prinċipali.

27. Is-Sitt Skeda li tinsab mal-Att prinċipali għandha tiġi mħassra.

Għanijiet u Raġunijiet

L-għanijiet u r-raġunijiet ta' dan l-Abbozz ta' Liġi huma sabiex jipprovdi regolamenti u kontroll fl-użu, il-bejgħ, id-distribuzzjoni bl-ingrossa, il-manifattura, l-importazzjoni, il-kummerċjalizzazzjoni, ir-reklamar u s-sensarija ta' prodotti mediċinali veterinarji, jipprovdi aktar fuq l-illiċenzjar ta' spiżeriji veterinarji, importaturi, manifatturi, sensara u distributri bl-ingrossa ta' prodotti mediċinali veterinarji u jistabbilixxi wkoll dispożizzjonijiet għall-kontroll effettiv tal-moviment, l-użu u rimi ta' annimali ħajjin u prodotti ġejjin minnhom, u fuq il-konteniment ta' ċertu mard tal-annimali.

A BILL
entitled

AN ACT to amend the Veterinary Services Act, Cap. 437.

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 Veterinary Services (Amendment) Act, 2022 and this Act shall be read and construed as one with the Veterinary Services Act, hereinafter referred to as "the principal Act".

Cap. 437.

(2) This Act shall come into force within two months from its publication 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 "animal" there shall be added the following new definition:

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

(b) immediately after the definition "Council" there shall be added the following new definition:

" "data on sales" means data on the volume of sales;";

(c) the definition "Director" shall be substituted by the following new definition:

" "Director" means the Director Veterinary Services who shall be a warranted Veterinary Surgeon or an officer

nominated by him;";

(d) the definition "feeding stuffs" shall be substituted by the following new definition:

" "feedingstuffs" means any substance or product including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;";

(e) the definition "immunological veterinary medicinal product" shall be deleted;

(f) in the definition "importation", immediately after the words "of live animals," there shall be added the words "veterinary medicinal products,";

(g) immediately after the definition "lifelong learning" there shall be added the following new definition:

" "Medicines Authority" means the Medicines Authority established under the Medicines Act;";

Cap. 458.

(h) immediately after the definition "trading partner" there shall be added the following new definition:

" "veterinary medical device" means an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease in animals, or which is intended to affect the structure or any function of the body of animals;";

(i) the definition "veterinary medicinal product" shall be substituted by the following new definition:

" "veterinary medicinal product" means any substance or combination of substances which fulfils at least one of the following conditions:

(a) it is presented as having properties for treating or preventing disease in animals;

(b) its purpose is to be used in, or administered to, animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action;

(c) its purpose is to be used in animals with a view to making a medical diagnosis;

(d) its purpose is to be used for euthanasia of animals;"; and

(j) the definition "withdrawal period" shall be substituted by the following new definition:

" "withdrawal period" means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health;".

Amendment of article 3 of the principal Act.

3. In paragraph (b) of sub-article (1) of article 3 of the principal Act, immediately after the word "products" there shall be added the words ", active substances and veterinary medical devices;".

Amendment of article 6 of the principal Act.

4. Article 6 of the principal Act shall be amended as follows:

(a) in paragraph (a) of sub-article (1) thereof, the words "listed in the Second Schedule" shall be substituted by the words "referred to in the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health"; and

(b) in sub-article (2) thereof, the words "listed in the Second Schedule" shall be substituted by the words "referred to in the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health".

Amendment of article 15 of the principal Act.

5. In sub-article (4) of article 15 of the principal Act, the words "Second Schedule" shall be substituted by the words "list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health".

Amendment of article 16 of the principal Act.

6. In paragraph (a) of sub-article (3) of article 16 of the principal Act, the words "listed in the Second Schedule" shall be substituted by the words "referred to in the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health".

Amendment of article 24 of the principal Act.

7. In article 24 of the principal Act, the words "Head of the National Veterinary Laboratory" shall be substituted by the word "Director".

Substitution of article 29 of the principal Act.

8. Article 29 of the principal Act shall be substituted by the following new article:

"29. Within the scope of this Act, the requirements in connection with the inspection, supervision, authorisation, manufacture, research, wholesale distribution, brokering, marketing, prescribing, dispensing, supply, retail, advertising, provision of data on sales and use of veterinary medicinal products, active substances and veterinary medical devices shall include:

(a) procedures to be observed; and

(b) fees to be levied.".

Substitution of article 30 of the principal Act.

9. Article 30 of the principal Act shall be substituted by the following new article:

"Power of the Minister to make regulations on requirements relating to veterinary medicinal products and devices.

30. The Minister may, after consulting the Director, prescribe regulations establishing requirements relating to the manufacture, importation, introduction, research, wholesale distribution, brokering, marketing, prescribing, dispensing, supply, retail, advertising, provision of data on sales and use of veterinary medicinal products, active substances, and veterinary medical devices.".

Substitution of article 32 of the principal Act.

10. Article 32 of the principal Act shall be substituted by the following new article:

"Power of the Minister to make regulations on authorisation for and supervision of veterinary medicinal products.

32. The Minister may, after consulting the Director, prescribe regulations regarding the authorisation for, and the inspections and supervision of, the manufacture, importation, wholesale distribution, research, brokering, marketing, prescribing, dispensing, supply, retail, advertising, provision of data on sales and use of veterinary medicinal products, active substances and veterinary medical devices.".

Amendment of article 35 of the principal Act.

11. (1) Sub-article (1) of article 35 of the principal Act shall be amended as follows:

(a) immediately after the words "retailer or" there shall be added the words ",where applicable" and immediately after the words "under the provisions of this Act to" there shall be added the words "keep, manufacture, import, prescribe, wholesale distribute, broker, market, trade, dispense, advertise, provide data on sales and use of veterinary medicinal products,

or to supply, retail or" and the words "or veterinary medicinal products" shall substituted by the words "veterinary medicinal products, active substances or veterinary medical devices";

(b) paragraph (b) thereof shall be amended as follows:

(i) immediately after the word "shall" there shall be added the words "allow entry into their premises at any reasonable time and" and the words "officers of the veterinary services, the official veterinarian or his authorised staff" shall be substituted by the words "Director or any other officer nominated by him";

(ii) in sub-paragraph (i) thereof, immediately after the words "stuffs" there shall be added the words ", active substances, veterinary medical devices";

(iii) sub-paragraph (iii) thereof shall be substituted by the following new sub-paragraph:

"manufacture, collect, transport and show in the best conditions that meet all the requirements of the applicable laws products of animal origin, products listed in the First Schedule, feedingstuffs, active substances, veterinary medical devices and veterinary medicinal products in accordance with the provisions of this Act relating to controls or inspections of such products, feeding stuffs, active substances, veterinary medical devices and veterinary medicinal products;";

(iv) in sub-paragraph (iv) thereof, immediately after the word "stuffs" there shall be added the words ", active substances, veterinary medical devices"; and

(v) in sub-paragraph (v) thereof, immediately after the word "stuffs" there shall be added the words ", active substances, veterinary medical devices";

(c) paragraph (c) thereof shall be amended as follows:

(i) in sub-paragraph (i) thereof, the words "listed in the Second Schedule" shall be substituted by the words "referred to in the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health";

(ii) in sub-paragraph (ii) thereof, the words "listed

in the Second Schedule" shall be substituted by the words "referred to in the list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health" and immediately after the word "stuffs" there shall be added the words ", active substances, veterinary medical devices, veterinary medicinal products"; and

(iii) in sub-paragraph (viii) thereof, immediately after the word "stuffs" there shall be added the words ", active substances, veterinary medical devices, veterinary medicinal products";

(d) in the Maltese version, in paragraph (j) thereof, the word "distakk" shall be substituted by the word "rtirar";

(e) in paragraph (l) thereof, the words "be prescribed thereunder; and" shall be substituted by the words "be prescribed thereunder;"; and

(f) in paragraph (m) thereof, the words "for the control thereof." shall be substituted by the words "for the control thereof; and" and immediately thereafter there shall be added the following new paragraph:

"(n) shall forfeit to the veterinary services any instruments, animals, products of animal origin, active substances, veterinary medical devices, veterinary medicinal product, feedingstuffs, appliances, products, or substances suspected to be used in the commission of the offence against this article.".

Amendment of article 36 of the principal Act.

12. Sub-article (1) of article 36 of the principal Act shall be amended as follows:

(a) immediately after the words "retailer or" there shall be added the words ", where applicable," and immediately after the words "under the provisions of this Act to" there shall be added the words "keep, manufacture, import, prescribe, wholesale distribute, broker, market, trade, dispense, advertise, provide data on sales and use of veterinary medicinal products or to supply, retail or" and the words "or veterinary medicinal products" shall be substituted by the words "veterinary medicinal products or active substances";

(b) in the Maltese version, in paragraph (c) thereof, the word "distakk" shall be substituted by the word "rtirar";

(c) in the Maltese version, in paragraph (d) thereof, the word "distakk" shall be substituted by the word "rtirar";

(d) in paragraph (h) thereof, the words "may be prescribed; and" shall be substituted by the words "may be prescribed;"; and

(e) in paragraph (i) thereof, the words "for the control thereof." shall be substituted by the words "for the control thereof; and" and immediately thereafter there shall be added the following new paragraphs:

"(j) shall obtain any relevant authorisations from the veterinary services prior to the slaughtering of animals for human or animal consumption, unless exempted from doing so by or under this Act or any other national or EU law; and

(k) shall forfeit to the veterinary services any instruments, animals, products of animal origin, active substances, veterinary medical devices, veterinary medicinal products, feeding stuffs, appliances and other products or substances which are suspected to have been used in the commission of an offence against this article.".

Amendment of article 37 of the principal Act.

13. Sub-article (1) of article 37 of the principal Act shall be amended as follows:

(a) in paragraph (a) thereof, the words "Second Schedule" shall be substituted by the words "list of notifiable terrestrial and aquatic animal diseases issued by the World Organization for Animal Health";

(b) in paragraph (c) thereof, the words "Second Schedule" shall be substituted by the words "list of notifiable terrestrial and aquatic animal diseases issued by World Organization for Animal Health";

(c) in paragraph (r) thereof, the words "prescribed thereunder; and" shall be substituted by the words "prescribed thereunder;"; and

(d) in paragraph (s) thereof, the words "border inspection posts." shall be substituted by the words "border inspection posts; and" and immediately thereafter there shall be added the following new paragraph

"(t) shall forfeit to the veterinary services any

instruments, animals, products of animal origin, veterinary medicinal products, feeding stuffs, appliances and other products or substances which are suspected to have been used in the commission of an offence against this article.".

Amendment of article 38 of the principal Act.

14. Sub-article (1) of article 38 of the principal Act shall be amended as follows:

(a) immediately after the words "under the provisions of this Act to" there shall be added the words "keep, manufacture, import, prescribe, wholesale distribute, broker, market, trade, dispense, advertise, provide data on sales and use of veterinary medicinal products, or to supply, retail or" and the words "or veterinary medicinal products" shall be substituted by the words "veterinary medicinal products, active substances or veterinary medical devices";

(b) in paragraph (b) thereof, immediately after the words "veterinary medicinal products" there shall be added the words ", active substances or veterinary medical devices";

(c) in paragraph (c) thereof, immediately after the word "suspension" there shall be added the word ", revocation";

(d) in paragraph (d) thereof, the word "ordering" shall be substituted by the words "comply with any order relating to" and immediately after the words ‘veterinary medicinal products’ there shall be added the words ‘, active substances or veterinary medical devices’ and immediately after the words "threat to animal or public health" there shall be added the words "or to the environment;";

(e) in paragraph (e) thereof, the words "as may be prescribed thereunder; and" shall be substituted by the words "as may be prescribed thereunder;";

(f) in paragraph (f) thereof, immediately after the word "assist" there shall be added the words "allow entry into their premises at any reasonable time," and immediately thereafter there shall be added the following new paragraphs:

"(g) shall take samples from animals, products of animal origin, products listed in the First Schedule, foodstuffs, veterinary medicinal products, active substances or veterinary medical devices, as may be demanded by the veterinary services for control purposes. The cost of these samples may be reimbursed by the Director at his discretion; and

(h) shall forfeit to the veterinary services any instruments, animals, products of animal origin, active substances, veterinary medical devices, veterinary medicinal products, feedingstuffs, appliances and other products or substances which are suspected to have been used in the commission of an offence against this article.".

Amendment of article 49 of the principal Act.

15. Article 49 of the principal Act shall be renumbered as article 49(1) and it shall be amended as follows:

(a) in paragraph (e) thereof, the words "his responsibility; and" shall be substituted by the words "his responsibility;"; and

(b) in paragraph (f) thereof, the words "of veterinary activities." shall be substituted by the words "of veterinary activities;" and immediately thereafter there shall be added the following new paragraph:

"(g) decide upon any request made by the manufacturer, or by a duly authorized representative, of veterinary medicinal products, for the purpose of obtaining authorisation for the marketing of such products in accordance with the provisions of this Act;

(h) where a request under paragraph (g) has been favourably decided upon, issue the authorisation for the marketing of the veterinary medicinal products and include such products in the list of approved Veterinary Medicinal Products, which shall, from time to time, be published by the Veterinary Services;

(i) decide on the continuation or cessation of the manufacture, importation or marketing of a veterinary medicinal product, active substance or veterinary medical device and, or on the recalling of that product, in cases where an undesirable effect has been detected or suspected;

(j) upon a reference made to him for that purpose, determine whether particular substances or active substances have been used in the manufacture of a veterinary medicinal product;

(k) exercise supervision and conduct inspections on the manufacture, importation, introduction, wholesale distribution, brokering, marketing, retail and use of veterinary medicinal products and active substances;

(l) decide on the continuation or cessation of the manufacture, importation or marketing of a veterinary medicinal product, active substance or veterinary medical device in cases where a product or batch defect has been detected or suspected; and

(m) decide on the confiscation, sealing, isolation or otherwise of veterinary medicinal products, active substances or veterinary medical devices which are found to be in breach of any of the provisions of this Act or any Regulations made thereunder."; and

(c) immediately after paragraph (m) thereof there shall be added the following new sub-articles:

"(2) Without prejudice to the preceding sub-article, the Director may also:

(a) draw up and update assessment reports on the results of analytical and pharmaco-toxicological tests, and on the results of clinical trials of veterinary medicinal products and assessment of dossiers thereof; and

(b) test veterinary medicinal products or any of the ingredients thereof and, where necessary, intermediate products or other constituent materials, or submit such products for testing by a trading partner laboratory or by a laboratory designated for that purpose, with a view to ensuring that the manufacturing and testing methods employed by the manufacturer and described in the application are in accordance with the provisions of this Act or any regulations made thereunder.

(3) The Director may exercise any one or more of his functions either directly or through any of the officers or employees of the Veterinary Services or through the Medicines Authority or any agency authorised for that purpose, or through a contractor or other person with whom an agreement for the performance of any one or more of such functions has been entered into:

Provided that nothing in this sub-article shall authorise the Director to contract out or delegate any of:

(a) his regulatory functions, or

(b) his authorisation functions, unless such functions are expressly delegated to the Medicines Authority or to another public authority established by law, in particular another national competent authority as defined in this Act.

(4) The Director may approve the entering into contracts and memoranda of understanding between the Veterinary Services and the Medicines Authority for any purpose of cooperation which is deemed beneficial to any of the parties to the contract or memorandum of understanding in the carrying out of any of their functions.

(5) For the purpose of performance of any functions under this Act, the Director or any other such officer or person as may be authorised by the Director may request the assistance of the Malta Police Force, any local council, any department of Government, any agency of Government, any voluntary organisation or private sector entity.

(6) For the purposes of sub-articles (3), (4) and (5) where applicable to the Medicines Authority, these are subject to an agreement between the Medicines Authority and the Director Veterinary services, such as in the form of a contract or memorandum of understanding.".

Amendment of article 50 of the principal Act.

16. Paragraphs (a) and (b) of sub-article (2) of article 50 of the principal Act shall be substituted by the following new paragraphs:

"(a) to prepare reports on veterinary medicinal products at the request of the Director; and

(b) to support the veterinary services in the control of food and feed safety in the primary production of food of animal origin, feed, animal by-products, and in the control of animal diseases including zoonosis.".

Substitution of article 51 of the principal Act.

17. Article 51 of the principal Act shall be substituted by the following new article:

"51. The National Veterinary Laboratory shall:

(a) provide laboratory analyses and tests and participate in the diagnosis and control of animal diseases;

(b) support the Veterinary Services, upon request;

(c) conduct testing activities in the context of programmes relating to animal disease surveillance, food health surveillance, zoonotic disease surveillance, veterinary drug residue surveillance, and antimicrobial resistance; and

(d) fulfil the role of National Reference Laboratory.".

Deletion of article 53 of the principal Act.

18. Article 53 of the principal Act shall be deleted.

Amendment of article 54 of the principal Act.

19. Article 54 of the principal Act shall be amended as follows:

(a) immediately after the word "Act", wherever it occurs, there shall be added the words "or any regulations made thereunder";

(b) paragraph (a) thereof shall be substituted by the following new paragraph:

"(a) where official veterinarians and, or officers are empowered, by the provisions of this Act or any regulations made thereunder, to carry out inspections and supervision in connection with the restriction of trading of animals or animal products, or the prohibition of the movement of persons,animals or animal products in a contaminated area;"; and

(c) in paragraph (c) thereof, immediately after the words "official veterinarians" there shall be added the words "and, or officers".

Amendment of article 56 of the principal Act.

20. Article 56 of the principal Act shall be amended as follows:

(a) in paragraph (a) thereof, immediately after the words "official veterinarian" there shall be added the words "and, or officer";

(b) in sub-paragraph (i) of paragraph (c) thereof, immediately after the words "official veterinarian" there shall be added the words "and, or officer"; and

(c) in paragraphs (a), (b), (c), (d) and (f) thereof, immediately after the word "Act" there shall be added the words "or any regulations made thereunder".

Amendment of article 57 of the principal Act.

21. Article 57 of the principal Act shall be amended as follows:

(a) in sub-article (1) thereof, immediately after the word "Act" there shall be added the words "or any regulations made thereunder";

(b) in sub-article (2) thereof, immediately after the word "Act" there shall be added the words "or any regulations made thereunder" and immediately after the word "instruments," there shall be added the words "animals, products of animal origin, active substances, veterinary medical devices, veterinary medicinal products, feedingstuffs," and the words "forfeited to" shall be substituted by the words "confiscated by" and the word "forfeited" shall be substituted by the word "confiscated".

Amendment of article 58 of the principal Act.

22. In both sub-articles (1) and (2) of article 58 of the principal Act, immediately after the word "Act" there shall be added the words "or any regulations made thereunder".

Amendment of article 60 of the principal Act.

23. Article 60 of the principal Act shall be amended as follows:

(a) in sub-articles (1) and (2) thereof, immediately after the word "Act", wherever it occurs, there shall be added the words "or any regulations made thereunder"; and

(b) in sub-articles (1) and (2) thereof, immediately after the word "licence" wherever it occurs, there shall be added the word "authorisation".

Amendment of article 61 of the principal Act.

24. Article 61 of the principal Act shall be amended as follows:

(a) in paragraph (a) of sub-article (1) thereof, immediately after the word "Act" there shall be added the words "or any regulations made thereunder";

(b) sub-article (2) thereof shall be amended as follows:

(i) in paragraph (c) thereof, the words "imposition of a penalty; and" shall be substituted by the words "imposition of a penalty;";

(ii) in paragraph (d) thereof, the words "of such conviction," shall be substituted by the words "of such conviction;" and immediately thereafter there shall be added the following new paragraph:

"(e) any necessary remedial steps to be taken by the person to whom the notice is addressed to be in compliance with the requirements of this Act or any regulations made thereunder,";

(c) in paragraph (b) of sub-article (3) thereof, immediately after the word "Act", wherever it occurs, there shall be added the words "or any regulations made thereunder";

(d) paragraphs (a), (b) and (c) of sub-article (4) thereof shall be substituted by the following new paragraphs:

"(a) admit the offence;

(b) carry out all the necessary remedial steps which may be indicated in the notice served in terms of sub-article (1); and

(c) pay the amount of the penalty to the Director within thirty (30) days after the notice of the penalty is served or after such subsequent period as the Director may determine.";

(e) sub-article (5) thereof shall be substituted by the following new sub-article:

"(5) Where under this article a person admits an offence and carries out all the necessary remedial steps requested in the notice in accordance with sub-article (2), the Director shall impose a monetary penalty on that person in respect of the offence amounting to one third of the maximum penalty to which the person would be liable if he were convicted of the offence by the Court."; and

(f) sub-articles (7) and (8) thereof shall be substituted by the following new sub-articles:

"(7) Notwithstanding any other provisions of this Act or of any other enactment, where an offence has been admitted under this article and all requested necessary remedial steps have been taken by the person admitting such offence to be in compliance with the requirements of this Act or any regulations made thereunder no charge may be laid in respect of the offence against any person by whom it has been admitted.

(8) Where a person on whom a notice under sub-article (1) is served does not, within thirty (30) days after the notice is served on him, admit the offence and take all requested necessary remedial steps to be in compliance with the requirements of this Act or any regulations made thereunder, the Director shall institute proceedings or cause

proceedings to be instituted before the Court in respect of the alleged offence.".

Addition of new Part to the principal Act.

25. Immediately after article 61 of the principal Act there shall be added the following new Part:

"PART X

Veterinary Pharmacies and licences for manufacturers, importers, wholesale distributors and brokers of Veterinary Medicinal Products

Licence to open a veterinary pharmacy.

62. (1) It shall not be lawful for any person to open or keep a veterinary pharmacy unless he is in possession of a veterinary pharmacy licence issued in accordance with the provisions of this Act or any regulations made thereunder.

(2) Without prejudice to any exemption that may be granted by or under this Act, no person shall retail any veterinary medicinal product unless in accordance with a veterinary pharmacy licence issued in accordance with the provisions of this Act or any regulations or rules made thereunder.

(3) The licensee shall be responsible for complying with the conditions of the licence as may be established by the Director.

Application for a veterinary pharmacy licence.

63. (1) Any application for the grant of a veterinary pharmacy licence shall be made to the Director and shall contain such information, documents, samples and other material as required by or under this Act, and shall in particular include the following:

(a) the name and address of the applicant;

(b) the address of the premises that is to be used for the purpose of the retail of the veterinary medicinal products;

(c) the equipment and control facilities as may be required by or under this Act;

(d) the name of a managing pharmacist who shall be professionally responsible for all activities;

(e) any other information, documentation or evidence as may be requested by the Director in accordance with or under this Act.

(2) The Director shall determine the application in such time-frame as the Minister may establish by regulations under this Act:

Provided that such time-frame may be suspended until the required information is provided by the applicant.

Granting of a veterinary pharmacy licence.

64. (1) The Director shall, before determining an application for a veterinary pharmacy licence, inspect the premises indicated in the application and shall not issue a licence until he is satisfied that such premises is suitable and adequate, and that it includes suitable facilities, installations and equipment so as to ensure the proper conservation and dispensing of veterinary medicinal products:

Provided that a licence may be made conditional upon the carrying out of such obligations as may be imposed therein, which conditions may be revoked or varied by the Director at any time, as he may deem fit.

(2) A veterinary pharmacy licence shall specify the premises and the activities to which it applies:

Provided that the Director may, upon application, grant an additional licence for the use of identified premises as a store for the purpose of a veterinary pharmacy, after he is satisfied that such premises complies with any requirements established by or under this Act.

Notice for further information.

65. Where the Director considers that circumstances may exist which would render necessary the consideration of whether the licence should be varied, suspended or revoked, the Director may serve on the holder of a veterinary pharmacy licence a notice requiring him, within such time as may be specified in the notice, to furnish him with any information specified in the notice.

Duration and renewal of veterinary pharmacy licence.

66. (1) Subject to the provisions of this Act, every licence granted under this Part shall, unless previously revoked in accordance with the provisions of article 68, continue to be valid until such time as may be specified in the licence or in regulations adopted by the Minister under this Act:

Provided that the Director shall, prior to the renewal of the period of validity of a licence, conduct an inspection of the premises specified in the licence.

(2) Following an inspection as referred to in the preceding sub-article, the Director may either:

(a) renew the licence, with any modifications deemed necessary, for such a further period as may be specified in the licence or in regulations adopted by the Minister under this Act; or

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

Transfer of a veterinary pharmacy licence.

67. No person may transfer a licence unless authorised to do so by the Director which authorisation shall not be issued unless the Director is satisfied that the new licensee complies with any requirements established by or under this Act, and upon payment of the prescribed fee.

Suspension or revocation of veterinary pharmacy licence.

68. The Director may suspend a veterinary pharmacy licence granted under this Act prior to the expiry of the period referred to in article 66, for such period of time as he may determine, or may revoke or vary the provisions of any such licence in any of the following circumstances:

(a) where any information indicated in the application on the basis of which the licence was issued is subsequently found to be false or incomplete;

(b) where a material change of circumstances has occurred in relation to any matter indicated in the application;

(c) where the conditions of the licence have been breached by the licensee; or

(d) in any other circumstance as may be established by or under this Act:

Provided that the Director shall notify the licensee of any decision issued under this Article, giving detailed reasons for such decision.

Temporary closure of veterinary pharmacy.

69. (1) The licensee of a veterinary pharmacy shall not close such veterinary pharmacy, temporarily or otherwise, unless he has given at least twenty-four (24) hours notice to, and such closure has been authorised by, the Director:

Provided that, for the purposes of this article, temporary closure shall not include the closure of a veterinary pharmacy resulting from the unforeseen or unexpected absence of the managing pharmacist, *force majeure* resulting in the inability to open the premises, or closure outside the business hours for veterinary pharmacies as may be established by regulations adopted by the Minister.

(2) Subject to the provisions of sub-article (1), the licence in relation to a veterinary pharmacy which has remained closed for a period of five (5) consecutive working days without the authorisation of the Director shall be deemed to have been automatically revoked.

(3) The Director may, upon receipt of a notice as referred to in sub-article (1), or where it has come to his knowledge that a veterinary pharmacy has been closed for a period of ten (10) consecutive working days, seal all the veterinary medicinal products, wherever kept by the licensee in terms of the provisions of this Act, and take charge of any register required to be kept by the licensee pursuant to regulations as may be adopted by the Minister.

Powers of the Minister to make regulations relating to the licensing and operation of veterinary pharmacies.

70. The Minister may, after consultation with the Director, adopt regulations to make provisions relating to the issuing, suspension and revocation of veterinary pharmacy licenses, the period of validity of such licences, the obligations of the holders of a veterinary pharmacy licence, the obligations of managing pharmacists, the veterinary medicinal products that may exclusively be retailed from a veterinary pharmacy, standards for prescribing, dispensing, storage and disposal of veterinary medicinal products, the fees to be levied for the issuing of licences and the business hours of veterinary pharmacies.

Licences for manufacturing, importation and distribution of veterinary medicinal products.

71. (1) It shall not be lawful for any person to act as a manufacturer, importer, wholesale distributor or broker of veterinary medicinal products unless he is in possession of a licence issued in accordance with the provisions of this Act or any regulations made thereunder.

(2) A licensee pursuant to this article shall be responsible for complying with the conditions of the licence as may be established by the Director.

Application for manufacturing, importation and distribution licenses.

72. (1) Any application for the grant of a licence to act as manufacturer, importer, wholesale distributor or broker of veterinary medicinal products shall be made to the Director and shall contain such information, documents, samples and other material as provided by or under this Act, and shall include in particular the following information:

(a) the name and address of the applicant;

(b) the address of the premises that is to be used for the purpose of the manufacture, importation, distribution, storage or brokering of veterinary medicinal products;

(c) the equipment and control facilities as may be required by or under this Act;

(d) any other information, documentation or evidence as may be requested by the Director in accordance with or under this Act.

(2) The Director shall determine the application within such time-frame as the Minister may establish by regulations under this Act:

Provided that such time-frame may be suspended until the required information is provided by the applicant.

(3) The Director shall, before determining an application for any licence pursuant to this article, inspect the premises indicated in the application and shall not issue a licence until he is satisfied that such premises is suitable and adequate, and that it includes suitable facilities, installations and equipment so as to ensure the proper manufacture, control and conservation of veterinary medicinal products:

Provided that a licence may be made conditional upon the carrying out of such obligations as may be imposed therein, which conditions may be revoked or varied by the Director at any time, as he may deem fit.

Powers of the Minister to make regulations relating to the licensing and operations of manufacturers, importers and distributors of veterinary medicinal products.

73. The Minister may, after consultation with the Director, adopt regulations to make provision relating to the issuing, suspension and revocation of manufacture, import, research, wholesale distributor and broker licenses, the period of validity of such licences, the obligations and responsibilities of the holders of such licences and of their employees, standards in the manufacture, importation, distribution, brokering and disposal of veterinary medicinal products, and the fees that may be levied by the Director for the issuing of such licences.".

26. The Second Schedule to the principal Act shall be deleted.

Deletion of the Second Schedule to the principal Act.

27. The Sixth Schedule to the principal Act shall be deleted.

Deletion of the Sixth Schedule to the principal Act.

Objects and Reasons

The objects and reasons of this Bill are to provide for the regulation of the use, retail, wholesale distribution, manufacture, importation, marketing, advertising and brokering of veterinary medical products, provide further for the licensing of veterinary pharmacies, importers, manufactures, brokers and wholesale distributors of veterinary medicinal products and it also lays down provisions for effective control over the movement, use and disposal of live animals and products derived from them, and over the containment of certain animal diseases.

VERŻJONI ELETTRONIKA

VERŻJONI ELETTRONIKA

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*
€1.98