A.L. 179 tal-2021

ATT DWAR IS-SERVIZZI VETERINARJI
(KAP. 437)

Regolamenti tal-2021 li jemendaw ir-Regolamenti dwar Prodotti Mediċinali Veterinarji

BIS-SAĦĦA tas-setgħat mogħtija bl-artikoli 30, 38 u 53 tal-Att dwar is-Servizzi Veterinarji, il-Ministru għall-Agrikoltura, is-Sajd, l-Ikel u d-Drittijiet tal-Annimali, wara konsultazzjoni mal-Kap tal-Laboratorju Veterinarju Nazzjonali, għamel dawn ir-regolamenti li ġejjin:-

Titolu u għan.

1. (1) It-titolu ta' dawn ir-regolamenti hu r-Regolamenti tal-2021 li jemendaw ir-Regolamenti dwar Prodotti Mediċinali Veterinarji u dawn ir-regolamenti għandhom jinqraw u jinftiehmu ħaġa waħda mar-Regolamenti dwar il-Prodotti Mediċinali Veterinarji, hawn iżjed 'il quddiem imsejħa "r-regolamenti prinċipali". L.S. 437. 47.

(2) L-għan ta' dawn ir-regolamenti hu li jiżdiedu numru ta' dispożizzjonijiet essenzjali mar-regolamenti prinċipali sabiex jipprovdu qafas legali aktar modern u adegwat għar-regolament u l-kontroll tal-prodotti mediċinali veterinarji.

Jemenda r-regolament 2 tar-regolamenti prinċipali.

2. Ir-regolament 2 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) it-tifsira "Aġenzija" għandha tiġi sostituta bit-tifsira ġdida li ġejja:

" "Aġenzija" tfisser l-Aġenzija Ewropea tal-Mediċini stabbilita permezz tar-Regolament (KE) Nru 726/2004;" u minufih warajha għandu jiżdied it-tifsir ġdid li ġej:

" "Akkwist" tfisser l-att ta' akkwist, għal fini ta' profitt jew le, prodott mediċinali veterinarju, jew parti minnu, minn Stat Membru tal-Unjoni Ewropea;

"Amministrazzjoni profilattika ta' antimikrobiċi" tfisser l-amministrazzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali lil annimal jew grupp ta' annimali qabel ma jkun hemm sinjali kliniċi ta' mard, sabiex tiġi evitata l-okkorrenza ta' mard jew infezzjoni;

"Bejjiegħ bl-ingrossa ta' prodotti veterinarji" tfisser

dik il-persuna awtorizzata li twettaq distribuzzjonijiet bl-ingrossa ta' prodotti mediċinali veterinarji;";

(b) minnufih wara t-tifsira "Bilanċ ta' riskju/benfiċċju" għandu jiżdied it-tifsir ġdid li ġej:

" "Direttur għas-Servizzi Veterinarji" tfisser id-Direttur għas-Servizzi Veterinarji hekk kif definit fl-Att għas-Servizzi Veterinarji, u tinkludi, sakemm tippermetti l-awtorità mogħtija, lil kwalunkwe uffiċjal awtorizzat minnu, bil-miktub, biex jaġixxi f'ismu għal kwalunkwe skop imsemmi fl-Att għas-Servizzi Veterinarji. Kull fejn fit-test jintużaw il-kliem "Servizzi Veterinarji" dawn għandhom jittieħdu li qed jirreferu għad-"Direttur għas-Servizzi Veterinarji;

Kap. 437.

"drogi narkotiċi" tfisser dawk is-sustanzi preżenti fil-Lista s-Safra maħruġa mill-Bord ta' Kontroll Internazzjonali tan-Narkotiċi skont il-Konvenzjoni Unika dwar id-Drogi Narkotiċi, 1961, Protokoll tal-25 ta' Marzu 1972 li jemenda l-Konvenzjoni Unika dwar id-Drogi Narkotiċi, 1961;";

(ċ) minnufih wara t-tifsira "Fuljett tal-pakkett" għandu jiżdied it-tifsir ġdid li ġej:

" "iddispensar" tfisser il-bejgħ jew il-forniment ta' prodotti mediċinali veterinarji. Il-prodotti jinbiegħu jew jiġu fornuti minn spiżerija veterinarja jew minn kirurgu veterinarju fi stabbilimenti veterinarji liċenzjali jew matul visti fuq barra;

"ikel" għandu jkollha l-istess tifsira kif mogħtija lilha fl-Att dwar is-Sigurtà fl-Ikel;";

Kap. 449.

(d) minnufih wara t-tifsira "Isem tal-prodott mediċinali" għandu jiżdied it-tifsir ġdid li ġej:

"jitpoġġa taħt kontroll uffiċjali" tfisser iż-żamma ta' kwalunkwe artiklu mid-Direttur għas-Servizzi Veterinarji

biex ikun permess it-twettiq tal-funzjonijiet kollha tiegħu;

"kirurgu veterinarju" tfisser persuna hekk deskritta u regolata bl-artikolu 43 tal-Att u li ismu huwa inkluż fir-Reġistru tal-Kirurgi Veterinarji, jew dik il-persuna, ġejja minn wieħed mill-Istati Membri tal-Unjoni Ewropea, li isimha huwa inkluż fir-reġistru rilevanti miżmum mill-qafas rilevanti ta' dak l-Istat Membru li jirregola l-professjoni tal-kirurgi veterinarji. Fl-aħħar każ, għandhom japplikaw id-dispożizzjonijiet tal-Att dwar ir-Rikonoxximent Reċiproku ta' Kwalifiki u l-Att dwar Servizzi li jingħataw fis-Suq Intern;";

Kap. 451.
Kap. 500.

(e) it-tifsira "Kummissjoni" għandha tiġi sostitwita bit-tifsira ġdida li ġejja:

" "Kummissjoni" tfisser il-Kummissjoni skont id-Deċiżjoni tal-Kunsill 1999/468/KE tat-28 ta' Ġunju 1999;" u minnufih warajha għandu jiżdied it-tifsir ġdid li ġej:

" "metafilassi" tfisser is-somministrazzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali lil grupp ta' annimali wara dijanjożi li tistabbilixxi marda klinika f'parti mill-grupp, bil-għan li jiġu trattati l-annimali klinikament morda u jiġi kkontrollat it-tixrid ta' din il-marda f'annimali f'kuntatt mill-qrib u li jinsabu f'riskju u li jistgħu jkunu diġà subklinikament infettati;

"pajjiż sors" tfisser Stat Membru tal-UE jew pajjiż fiż-Żona Ekonomika Ewropea minn fejn jistgħu jiġu akkwistati l-prodotti mediċinali veterinarji msemmija fir-regolament 7;";

(f) minnufih wara t-tifsira "Perjodu ta' tiżmim" għandu jiżdied it-tifsir ġdid li ġej:

" "persuna kwalifikata kif xieraq" tfisser dik il-persuna li għandha kwalifika fix-xjenza veterinarja u inkluża f'waħda mill-professjonijiet para-veterinarji msemmija fl-Att;

"preskrizzjoni" tfisser l-att ta' preparazzjoni ta' preskrizzjoni veterinarja minn kirurgu veterinarju kemm jekk fuq il-karta jew b'mezz elettroniku;

"preskrizzjoni veterinarja" tfisser dokument maħruġ minn kirurgu veterinarju għal prodott mediċinali veterinarju jew prodott mediċinali għall-użu mill-bniedem biex jintuża fuq l-annimali;

"prodotti mediċinali" għandu jkollha l-istess tifsira kif mogħtija lilha fl-Att dwar il-Mediċini;"; Kap. 458.

(g) minnufih wara t-tifsira "Prodott medicinali veterinarju immunoloġiku" għandha tiżdied it-tifsira ġdida li ġejja:

" "prodotti mediċinali veterinarji impurtati" tfisser prodotti mediċinali veterinarji miksuba minn sors barra l-UE;";

(h) minnufih wara t-tifsira "Reazzjoni kuntrarja umana" għandha tiżdied it-tifsira ġdida li ġejja:

" "reklamar ta' prodotti mediċinali veterinarji" tfisserkwalunkwe forma ta' rappreżentazzjoni b'konnessjoni ma' prodotti mediċinali veterinarji sabiex tippromwovi l-forniment, id-distribuzzjoni, il-bejgħ, l-għoti ta' riċetta jew l-użu tal-prodotti mediċinali veterinarji u li jinkludu wkoll il-forniment ta' kampjuni u sponsorizzazzjonijiet;

(i) it-tifsira "Spizjar" għandha tiġi sostitwita bit-tifsira ġdida li ġejja:

" "spiżjar tfisser persuna li hija mniżżla fir-Reġistru tal-Ispiżjara miżmum mill-Kunsill tal-Ispiżjara skont l-artikolu 17 tal-Att dwar il-Professjonijiet tas-Saħħa;"; u minnufih warajha għandu jiżdied it-tifsir ġdid li ġej: Kap. 464.

" "spiżerija veterinarja" tfisser il-post minn fejn prodotti mediċinali veterinarji huma, mogħtija direttament lill-pubbliku bl-eċċezzjoni ta' stabbilimenti veterinarji liċenzjati;

"stabbiliment veterinarju liċenzjat" għandha jkollha l-istess tifsira kif mogħtija lilha fir-Regolamenti dwar il-Liċenzjar ta' Stabbilimenti Veterinarji Privati;"; L.S. 437. 106.

(j) it-tifsira "Stat Membru" għandha tiġi sostitwita bit-

tifsira ġdida li ġejja:

" "Stat Membru" tfisser Stat li huwa membru tal-Unjoni Ewropea;";

(k) minnufih wara t-tifsira "Sustanza" għandu jiżdied it-tifsir ġdid li ġej:

" "sustanza attiva" tfisser kull sustanza jew taħlita ta' sustanzi maħsuba biex tintuża fil-manifattura ta' prodott mediċinali veterinarju li, meta tintuża fil-produzzjoni tiegħu, issir ingredjent attiv ta' dak il-prodott;

"sustanzi psikotropiċi" tfisser is-sustanzi inklużi fit-Tielet Skeda li tinsab mal-Ordinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x'jaqsmu magħha u dawk is-sustanzi inklużi fil-Lista l-Ħadra maħruġa mill-Bord ta' Kontroll Internazzjonali tan-Narkotiċi skont il-Konvenzjoni fuq is-Sustanzi Psikotropiċi tal-1971;";

Kap. 31.

(l) minnufih wara t-tifsira"Tikkettar" għandu jiżdied it-tifsir ġdid li ġej:

" "Trattat" għandu jkollha l-istess tifsira kif mogħtija lilha fl-Att dwar l-Unjoni Ewropea;

"Unjoni Ewropea" tfisser l-Unjoni Ewropea kif imsemmi fit-Trattat;" u

Kap. 460.

(m) minnufih wara t-tifsira "Użu mhux skont ma jkun hemm fuq it-tiketta" għandha tiżdied it-tifsira ġdida li ġejja:

" "użu preventiv ta' aġenti antimikrobiċi" tfisser l-amministrazzzjoni ta' aġenti antimikrobiċi lil annimali f'saħħithom bħala prevenzjoni mill-infezzjonijiet biex tikkumpensa għal prattiċi agrikoli mhux adegwati.".

3. Il-paragrafu (e) tas-subregolament (1) tar-regolament 3 tar-regolamenti prinċipali għandu jiġi mħassar.

Jemenda r-regolament 3 tar-regolamenti prinċipali.

4. Minnufih wara s-subregolament (2) tar-regolament 4 tar-regolamenti prinċipali għandhom jiżdiedu s-subregolamenti ġodda li

Jemenda r-regolament 4 tar-regolamenti prinċipali.

ġejjin:

"(3) Sabiex tingħata eżenzjoni għall-prodott mediċinali veterinarju msemmi f'dan is-subregolament, l-applikanti għandhom jissottomettu applikazzjoni mas-Servizzi Veterinarji.

(4) Sabiex jikkwalifika għall-eżenzjoni deskritta fis-subregolament (2) il-prodott għandu jkun immanifatturat mid-:

(a) detentur ta' awtorizzazzjoni ta' manifattura jekk manifatturat f'Malta jew fi Stat Membru ieħor tal-Unjoni Ewropea;

(b) detentur ta' liċenzja relevanti li tawtorizzah jimmanifattura prodotti mediċinali veterinarji jekk il-prodott jiġi manifatturat f'pajjiż Terz.

(5) Il-prodott ma għandux ikun klassifikat bħala prodott li jeħtieġ preskrizzjoni veterinarja.

(6) Il-manifattur, l-importatur, il-bejjiegħ bl-ingrossa jew bejjiegħ bl-imnut ta' prodott mediċinali veterinarju għandu jiddikjara li ser jinnotifika lis-Servizzi Veterinarji fi żmien ħmistax (15)-il jum minn meta jsir jaf b'xi reazzjonijiet avversi serji skont is-subregolamenti (2) u (3) tar-regolament 68. Għandu jinżamm rendikont ta' kull reazzjoni avversa u reazzjonijiet avversi serji malli wieħed isir jaf bihom. Dawn ir-rendikonti għandhom jinżammu għal ħames (5) snin.

(7) Is-Servizz Veterinarju għandu jipprepara u jippubblika lista ta' sustanzi attivi li jistgħu jintużaw fi prodotti mediċinali veterinarji awtorizzati skont is-subregolament (2), fejn jiġi speċifikat l-ispeċi tal-annimali li ma jipproduċux ikel li għalihom huma approvati u jista' jiġi speċifikat ukoll kif is-sustanza attiva jew il-prodott li fih is-sustanzi attivi jiġu amministrati.

(8) Is-Servizz Veterinajru jista' jiddeċiedi li ma japplikax id-dispożizzjonijiet ta' dan ir-Regolament fuq prodott li jkun diġà eżentat f'każ ta' preżenza ta' waħda jew aktar minn dawn li ġejjin:

(a) jiġu rrappurtati reazzjonijiet avversi serji;

(b) jirriżulta, fi kwalunkwe ħin wara l-awtorizzazzjoni, li s-sustanza hija karċinoġenika, ġenotossika jew li turi żviluppi tossiċi (inkluż teratoġeniċità);

(ċ) il-prodott fih sustanzi attivi li huma klassifikati mill-ġdid bħala narkotiċi jew sustanzi psikotropiċi;

(d) l-ingredjent jew l-ingredjenti fil-prodott huwa jew mhux inklużi aktar fil-lista msemmija fis-subregolament (3);

(e) huwa rrappurtat u vverifikat mis-Servizz Veterinarju li l-prodott mhux qed jintuża fuq l-annimali msemmija fis-subregolament (2);

(9) Il-prodott awtorizzat skont is-subregolament (2) għandu jkun ittikkettat u jindika b'mod ċar li huwa eżenti mir-rekwiżiti tar-regolamenti 5, 6, 7 u 8 b'rabta mal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni. L-informazzjoni li għandha tinkiseb mill-pakkett sħiħ għandha turi minn tal-anqas dawn id-dettalji:

(a) l-isem tal-prodott mediċinali veterinarju;

(b) il-forma tad-doża farmaċewtika;

(ċ) l-isem u l-qawwa ta' kull sustanza attiva;

(d) ll-mod ta' amministrazzjoni;

(e) in-numru tal-lott;

(f) id-data ta' skadenza;

(g) sentenza li tispeċifika "Għall-amministrazzjoni biss fuq annimali li ma jipproduċux ikel" hekk kif awtorizzat skont ir-regolament 4(2);

(h) għal liema speċi hu magħmul;

(i) istruzzjonijiet għall-ħażna;

(j) kemm idum tajjeb immedjatament wara li jinfetaħ il-pakkett għall-ewwel darba;

(k) indikazzjonijiet terapewtiċi;

(l) kontra-indikazzjonijiet;

(m) interazzjoni ma' mediċini oħra u forom oħra ta' interazzjoni;

(n) istruzzjonijiet dwar id-doża.

(10) Jekk ikun hemm biżżejjed spazju fuq it-tikketta, l-informazzjoni tista' tiġi ppreżentata fuqha biss mingħajr il-bżonn ta' fuljett fil-pakkett. L-informazzjoni għandha titwassal b'mod ċar u b'mod li jinqara faċilment.

(11) Id-dispożizzjonijiet tas-subregolament (5) għandhom jidħlu fis-seħħ fl-1 ta' Novembru 2021.".

Iżid regolamenti ġodda mar-regolamenti prinċipali.

5. Minnufih wara r-regolament 4 tar-regolamenti prinċipali għandu jkun hemm iż-żieda tas-segwenti regolamenti:

"Prodotti mediċinali veterinarji għal skop ta' riċerka. Kap. 437.

4A. (1)Prodott mediċinali veterinarju jista' jinkiseb minn kwalunkwe pajjiż u jiġi amministrat lill-annimali għal skopijiet ta' riċerka skont l-artikolu 53(3) tal-Att dwar is-Servizzi Veterinarji.

(2) Il-prodotti mediċinali veterinarji awtorizzati skont dan ir-regolament jistgħu jiġu eżentati mid-dispożizzjonijiet tar-regolamenti 5, 6, 7 u 8.

(3) Il-prodotti mediċinali veterinarji għandhom jintużaw biss f'faċilitajiet ta' riċerka awtorizzati li huma konformi mal-Att dwar it-Trattament Xieraq tal-Annimali u r-Regolamenti dwar il-Protezzjoni ta'Annimali li jintużaw għal Skopijiet Xjentifiċi. Kap. 439. L.S. 439. 13.

(4) (a) Sabiex persuna tingħata permess biex twettaq l-attività msemmija fis-subregolament (1), din il-persuna, hawnhekk irreferuta bħala l-applikant għall-prodott mediċinali veterinarju li ser jintuża għal skopijiet ta' riċerka, għandha tissottometti applikazzjoni mas-Servizzi Veterinarji.

(b) Jekk l-applikazzjoni timtela' b'suċċess, tinħareġ liċenzja għal Skopijiet ta' Riċerka. Is-Servizz Veterinarju għandu jagħmel, jimmodifika, iżid jew ineħħi kwalunkwe termini u kundizzjonijiet li jirrigwardaw il-liċenzja hekk kif iħoss li huwa utli fid-dawl tal-avvanzi xjentifiċi jew informazzjoni ġdida li tista' toħroġ fuq sustanzi partikolari jew ingredjenti li jkunu fil-prodotti mediċinali veterinarji użati għal skopijiet ta' riċerka.

(ċ) Id-detentur tal-liċenzja għal prodott mediċinali veterinarju li ser jintuża għal skopijiet ta' riċerka għandu juża l-prodott jew jamministrah biss bħala test fuq l-annimali skont it-termini u l-kundizzjonijiet imsemmija fl-Att dwar it-Trattament Xieraq tal-Annimali. Kap. 439.

(d) Id-detentur tal-liċenzja għal prodott mediċinali veterinarju li se jintuża għal skopijiet ta' riċerka u li jsir konxju ta' kwalunkwe reazzjonijiet avversi serji fuq l-annimal jew fuq il-persuna li jkun qed jamministrah għandu jirrapporta r-reazzjoni lis-Servizzi Veterinarji fi żmien ħmistax (15)-il jum mill-ġurnata li jiskopri r-reazzjoni avversa serja.

(e) Ikel għall-konsum uman jista' jittieħed biss mill-annimali li jkunu qed jiġu ttestjati, skont ir-regolament 86 u b'approvazzjoni minn qabel tas-Servizzi Veterinarji.

(f) L-applikazzjoni sottomessa mill-applikant għandha tingħata mingħajr preġudizzju lil kwalunkwe liċenzja jew permess li l-applikant ikun jeħtieġlu jikseb minn dipartimenti jew direttorati oħra sabiex ikun jista' jieħu sehem fl-attività ta' riċerka msemmija.

(g) L-applikant għal prodott mediċinali veterinarju jew detentur ta' liċenzja huwa soġġett għal spezzjonijiet uffiċjali mis-Servizzi Veterinarji fuq il-post u l-attivitajiet li jsiru fuq il-post.

(h) Is-Servizzi Veterinarji għandu jelenka l-kriterji għall-prodott mediċinali veterinarju skont is-subregolament (1) u jagħmilhom pubbliċi.

Kampjuni u pakketti dimostrattivi ta' prodotti mediċinali veterinarji.

4B. (1) Prodotti mediċinali veterinarji jistgħu jiġu eżentati mid-dispożizzjonijiet fir-regolamenti 5 sa 8 jekk ikun jista' jintwera li l-prodotti huma kampjuni veterinarji jew pakketti dimostrattivi mqassma lill-kirurgi veterinarji jew spiżjara minn distributuri ta' prodotti veterinarji bl-ingrossa.

(2) Il-prodotti li hemm referenza għalihom fis-subregolament (1) jistgħu jintużaw skont dawn il-kundizzjonijiet:

(a) jiġu mqassma b'xejn lil persuni awtorizzati li jirċevuhom jew esebiti waqt konferenzi jew attivitajiet simili li jittellgħu u li jkunu maħsuba għall-kirurgi veterinarji u/jew spiżjara;

(b) fuqhom ikollhom tikketta stampata "Kampjun b'xejn/Pakkett dimostrattiv – Mhux għall-bejgħ";

(ċ) il-pakkett sħiħ ma jridx ikun fih aktar minn:

(i) 50 unità ta' kapsuli/pilloli;

(ii) 10 unitajiet għall-injezzjonijiet u *spot-ons;*

(iii) 300g għat-trab;

(iv) 3L għal-likwidi;

(v) 5 unitajiet għal tubi għal użu intramammarju;

(vi) kwalunkwe qies ieħor kif stabbilit mis-Servizzi Veterinarji għall-forom l-oħra kollha farmaċewtiċi;

(d) l-informazzjoni mogħtija mal-kampjuni ma tridx tkun promozzjonali fin-natura tagħha;

(e) il-perjodu massimu ta' żmien li fih il-bejjiegħ bl-ingrossa ta' prodotti veterinarji li huwa awtorizzat jista' jakkwista prodott minn Stat Membru tal-Unjoni Ewropea bħala kampjun mingħajr ħlas huwa ta' sena (1) mill-ewwel kunsinna tal-prodott;

(f) jekk kwalunkwe prodott awtorizzat skont id-dispożizzjonijiet tas-subregolament (1) jiġi amministrat lil annimal li jipproduċi l-ikel, dak l-annimal huwa eskluż b'mod permanenti mill-katina alimentari.

Obligazzjoniji et relatati ma' prodotti mediċinali veterinarji. Kap. 437.

4Ċ. Kwalunkwe awtorizzazzjoni maħruġa skont ir-regolamenti 4(2), 4A u 4B, għandhom jiġu meqjusa bħala Awtorizzazzjoni ta' Kummerċjalizzazzjoni għal skopijiet tal-artikoli 38, 53 u 57 tal-Att dwar is-Servizzi Veterinarji.

Prodotti mediċinali veterinarji li ġejjin minn pajjiżi oħra għall-użu personali.

4D. (1) Prodotti mediċinali veterinarji jistgħu jiġu eżentati mid-dispożizzjonijiet tar-regolamenti 5 sa 8 meta l-prodotti jiġu minn Stat Membru tal-Unjoni Ewropea jew importati minn pajjiż Terz skont it-termini u l-kundizzjonijiet imsemmija fis-subregolament (2).

(2) It-termini u l-kundizzjonijiet li jsegwu għandhom japplikaw:

(a) il-prodotti ma għandhomx jerġgħu jinbigħu għal profitt monetarju;

(b) il-prodotti ma għandhomx jiġu trasferiti lil partijiet terzi sakemm it-tali trasferiment mhux awtorizzat mis-Servizzi Veterinarji;

(ċ) din id-dispożizzjoni mhux applikabbli għal mediċini psikotropiċi, narkotiċi għall-annimali kollha u fil-każ ta' annimali li jipproduċu l-ikel kif ukoll is-sustanzi mniżżla fi Grupp A tal-Skeda I tar-Regoli dwar Miżuri għall-Monitoraġġ ta' Ċerti Sustanzi u Residwi tagħhom f'Annimali Ħajjin u Prodotti ta' l-Annimali u t-Tabella II tar-Regolament (UE) 37/2010

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(d) il-kwantità ta' prodotti miksuba għandha tkun proporzjonali għad-doża skont il-kundizzjoni li tkun ser tintuża għaliha;

(e) il-kwantità ta' prodotti li huma permessi jidħlu fit-territorju ta' Malta għandha tkopri l-perjodu indikat bħala t-tul tat-trattament fl-ispeċifikazzjonijiet tal-prodott jew il-preskrizzjoni veterinarja tal-kirurgu veterinarju. Madankollu, prodotti maħsuba biex jintużaw għall-kundizzjonijiet rikurrenti jew kroniċi jistgħu jitħallew jidħlu f'Malta għadd ta' drabi matul is-sena, sakemm ikun hemm evidenza konvinċenti li turi l-benefiċċji miksuba mill-użu regolari tal-prodotti provduti:

(f) l-individwi jkollhom xorta waħda jipprovdu preskrizzjoni veterinarja għall-prodotti klassifikati bħala prodotti li jeħtieġu preskrizzjoni fil-pajjiż minn fejn dawn ikunu ġew jew għall-prodotti mediċinali veterinarji simili ġewwa Malta;

Iżda s-Servizzi Veterinarji jista' xorta wahda jitlob il-preskrizzjoni veterinarja anke jekk il-prodott huwa klassifikat bħala wieħed li ma jeħtieġx preskrizzjoni veterinarja fil-pajjiż minn fejn ikun ġej;

(g) jistgħu jinkisbu biss prodotti li ma jkunx fihom prodotti sekondarji mill-annimali jekk dawn ikunu ġejjin minn żoni fejn ikun hemm, jew ikun hemm suspett li hemm, preżenza jew prevalenza ta' riskju għoli ta' mard;

(h) jistgħu jinkisbu biss prodotti li ma fihomx ingredjenti li huma klassifikati f'Malta bħala illegali u li ma jkollhomx indikazzjonijiet ta' projbizzjoni f'Malta;

(i) jistgħu jinkisbu biss prodotti li jkollhom tikketti xierqa u li jagħtu indikazzjoni ċara tan-natura tal-ingredjent/i li jkun fihom;

(j) annimali li jipproduċu l-ikel u li jiġu amministrati prodotti mediċinali veterinarji awtorizzati skont dan ir-regolament, jistgħu jiġu kkunsmati biss mill-persuna li tkun qed tieħu l-prodotti mediċinali veterinarji, jew bil-kunsens ta' membri tal-istess dar. Għandu jiġi applikat il-perjodu xieraq ta' irtirar;

(k) qabel tittieħed deċiżjoni fuq prodotti mediċinali veterinarji antimikrobiċi u prodotti li jaffetwaw l-attività ormonali, għandha ssir valutazzjoni f'waqtha tar-riskji mis-Servizzi Veterinarji;

(l) id-deċiżjoni tas-Servizzi Veterinarji hija mingħajr preġudizzju għal kwalunkwe liċenzja jew permess li l-persuna li tkun qed iġġib il-prodotti mediċinali veterinarji jista' jkollha bżonn tikseb skont regolamenti oħra tal-istess dipartiment jew dipartimenti differenti;

(3) Is-servizzi veterinarji għandu jiddeċiedi fuq ir-rilaxx, it-tpoġġija taħt kontroll uffiċjali jew il-qerda ta' prodotti mediċinali veterinarji, jew il-prodotti mediċinali veterinarji preżunti, jekk u meta dawn jiġu interċettati f'punti ta' kontroll varji qabel id-dħul fit-territorju ta' Malta.

(4) Skont is-subregolament (3) is-Servizzi Veterinarji għandu jżomm rendikont tal-opinjonijiet jew id-deċiżjonijiet kollha li jittieħdu. Dan ir-rendikont għandu jinżamm mis-Servizzi Veterinarji għal perjodu ta' mhux anqas minn għaxar (10) snin.

(5) Is-Servizzi Veterinajri għandu jistabbilixxi l-kriterji għall-prodott mediċinali veterinarju li jista' jinkiseb skont is-subregolament (1) u jagħmilhom pubbliċi:

Iżda d-dispożizzjonijiet ta' dawn ir-regolamenti għandhom japplikaw ukoll għall-prodotti mediċinali veterinarji li jiddaħħlu fit-territorju ta' Malta bħala donazzjoni *bona fide* għall-użu fuq l-annimali miżmuma fis-santwarji approvati, dawn huma soġġetti għad-donazzjoni bil-kundizzjoni li s-servizzi veterinarji jiġi nnotifikat minn qabel bit-tali talba bl-isem, il-kwantità u n-natura tal-prodotti, kif ukoll l-ismijiet u l-indirizzi tad-donatur, ir-reċipjent u s-santwarju tal-annimali involut.".

Jemenda r-regolament 7 tar-regolamenti prinċipali.

6. Fir-regolament 7 tar-regolamenti prinċipali, minnufih wara l-kliem "Stat Membru ieħor" għandhom jiżdiedu l-kliem "hawn riferut bħala "l-pajjiż sors".

Iżid regolament ġdid mar-regolamenti prinċipali.

7. Minnufih wara r-regolament 7 tar-regolamenti prinċipali

għandu jiżdied ir-regolament ġdid li ġej:

"Reġistrazzjoni ta' prodotti mediċinali veterinarji skont regolament 7.

7A. (1) Sabiex jinħareġ permess ta' kummerċjalizzazzjoni tal-prodotti skont ir-regolament 7, persuna, hawnhekk irreferuta bħala l-applikant għar-reġistrazzjoni ta' prodott mediċinali veterinarju skont ir-regolament 7, għandha tissottometti applikazzjoni lis-Servizzi Veterinarji.

(2) Fuq talba raġjonevoli, is-Servizzi Veterinarji jista' jiddeċiedi li r-regolamenti 60(10) u 60(11) fuq il-kategorija legali tal-prodotti mediċinali veterinarji u r-regolament 51(4), ma japplikawx għar-reġistrazzjonijiet mogħtija skont ir-regolament 7.

(3) Qabel tingħata tali reġistrazzjoni, is-Servizzi Veterinarji jista':

(a) jitlob lill-awtorità kompetenti fil-'pajjiż sors' jipprovdi kopja tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni li hemm applikabbli;

(b) jassigura li l-entità li qed tapplika għar-reġistrazzjoni skont ir-regolament 7 hija kumpanija stabbilita legalment fl-Unjoni Ewropea jew fiż-Żona Ekonomika Ewropea;

(ċ) jinnotifika lid-detentur tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni bl-intenzjoni tiegħu sabiex jiggarantixxi r-reġistrazzjoni skont ir-regolament 7 meta d-detentur tar-Reġistrazzjoni ma jkunx l-istess entità bħad-detentur tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni fil-pajjiż sors;

(d) jitlob lill-applikant għar-reġistrazzjoni skont ir-regolament 7, jipprovdi kopja awtentika tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni li hemm applikabbli:

Iżda jekk dan ma jkunx possibli għall-applikant li jipprovdi kopja awtentika tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni, huwa għandu jintalab jipprovdi prova oħra ta' Awtorizzazzjoni ta' Kummerċjalizzazzjoni eżistenti fil-pajjiż sors.

(e) jitlob lill-applikant għal dejta fuq l-impatt tal-prodott fuq l-ambjent f'Malta.

(4) Id-detentur tar-reġistrazzjoni mogħtija skont ir-regolament 7 għandu jassigura li:

(a) il-prodott mediċinali veterinajru huwa skont l-Awtorizzazzjoni ta' Kummerċjalizzazzjoni applikabbli attwalment maħruġa mill-pajjiż sors;

(b) jinnotifika lis-servizzi veterinarji b'xi varjazzjonijiet fit-termini tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni approvata fil-pajjiż sors;

(ċ) jimplimenta mingħajr dewmien l-azzjonijiet marbuta ma' suġġetti li jikkonċernaw il-prodott mediċinali veterinarju li rriżulataw f'reazzjoni avversa għall-mediċina u/jew prodott jew irtirar mis-suq tal-lott;

(d) persuna tiġi appuntata jew ikun hu nnifsu responsabbli mir-rekwiżiti fil-paragrafu (ċ)

(e) meta l-applikant ma jkunx id-detentur tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni tal-prodott fil-pajjiż sors, dan għandu jipprovdi lis-Servizzi Veterinarji ittra ta' aċċess maħruġa mid-detentur tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni li tiggarantixxilu l-użu tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni għall-iskop tar-regolament 7:

Iżda jekk dan ma jkunx possibli għall-applikant li jirċievi 'ittra ta' aċċess' mid-detentur tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni fil-pajjiż sors, l-applikant għandu jintalab jipprovdi prova tal-ftehim bejnu nnifsu u distributur bl-ingrossa ta' prodotti veterinarji approvat fil-pajjiż sors;

(f) jkollu sistema stabbilita għall-irrekordjar u l-investigazzjoni ta' reazzjonijiet għall-mediċina u l-lott jew id-difetti tal-prodott.".

Jemenda r-regolament 10 tar-regolamenti prinċipali.

8. Ir-regolament 10 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) fil-paragrafu (ċ) tas-subregolament (1), il-kliem "persuna li tkun awtorizzata skont il-liġi nazzjonali" għandhom jiġu sostitwiti bil-kliem "spiżjar jew kirurgu veterinarju"; u

(b) minnufih wara s-subregolament (2) għandhom jiżdiedu s-subregolamenti ġodda li ġejjin:

"(3) Fil-każ ta' prodott mediċinali veterinarju awtorizzat fi Stat Membru ieħor, il-kirurgi veterinarji għandhom jiksbu awtorizzazzjoni mingħand is-Servizzi

Veterinarji qabel ma jakkwistaw il-prodott għall-amministrazzjoni fuq l-annimal.

(4) Fil-każ li l-prodotti mediċinali veterinarji fihom sustanzi ristretti li jirriżultaw mill-implimentazzjoni tal-konvenzjonijiet relevanti tan-Nazzjonijiet Uniti fuq sustanzi narkotiċi u psikotropiċi, għandha tingħata kunsiderazzjoni lil kull rekwiżit speċjali li jeħtieġ ikun sodisfatt qabel ma l-prodotti jkunu jistgħu jintużaw.

(5) Prodott mediċinali veterinarju jew prodott mediċinali provdut għall-amministrazzjoni skont il-paragrafi(a), (b) u (ċ) tas-subregolament (1), jista' jiġi pprovdut biss skont preskrizzjoni veterinarja minn kirurgu veterinarju, irrispettivament mill-kategorija legali assenjata lill-prodott mediċinali veterinarju matul il-proċedura ta' Awtorizzazzjoni ta' Kummerċjalizzazzjoni.

(6) Il-preskrizzjoni veterinarja maħruġa skont il-kundizzjoni msemmija fis-subregolament (5) għandha tiġi mmarkata bħala tali. Dikjarazzjoni simili għal, jew li tagħti l-istess tifsira lid-dikjarazzjoni li ssegwi: "Dan il-prodott ġie preskritt skont il-Cascade Principle", għandha tiġi inkluża fuq il-preskrizzjoni veterinarja.

(7) Sakemm il-kirurgu veterinarju li ppreskriva l-prodott mediċinali veterinarju jew il-prodott mediċinali ma jissupplixxix kif ukoll jamministrax il-prodott lill-annimal hu stess, il-persuna li tissupplixxih għandha timmarkah (jew tassigura li hu mmarkat) b'minn tal-anqas l-informazzjoni li ssegwi:

(a) l-isem tal-kirurgu veterinarju li ppreskriva l-prodott;

(b) l-identifikazzjoni (iklużż l-ispeċi) tal-annimal jew grupp ta' annimali;

(ċ) id-doża u l-istruzzjonijiet ta' amministrazzjoni.

(8) Meta kirurgu veterinarju jirrikorri għad-dispożizzjonijiet tar-regolament 10, il-kirurgu veterinarju għandu jżomm rendikont adegwat tat-trattament mogħti. Ir-rendikonti għandu minn tal-anqas jinkludu l-partikolaritajiet imsemmija fis-subregolament (7) u għandu jkun aċċessibbli għall-spezzjoni mis-Servizzi Veterinarji

għal perjodu ta' mhux anqas minn tliet (3) snin.

(9) Meta kirurgu veterinarju jirrikorri għad-dispożizzjonijiet tal-paragrafi (a), (b) u (ċ) tas-subregolament (1) l-attività li ssir mill-kirurgu veterinarju tkun eskluża mill-iskop ta' definizzjoni ta' distributur bl-ingrossa skont id-deċiżjoni li tittieħed mis-Servizzi Veterinarji.".

Iżid regolament ġdid mar-regolamenti prinċipali.

9. Minnufih wara r-regolament 10 tar-regolamenti prinċipali għandu jiżdied ir-regolament ġdid li ġej:

"Importazzjoni ta' prodotti mediċinali veterinarji minn kirurgi veterinarji għall-annimali li ma jipproduċux ikel.

10A. (1) Permezz ta' deroga mir-regolament 10(1), fejn m'hemmx prodott mediċinali veterinarju addattat aċċessibbli kemm bħala prodott awtorizzat f'Malta jew skont id-dispożizzjonijiet tar-regolament 10(1), il-kirurgi veterinarji jistgħu, fir-responsabbiltà diretta u personali tagħhom, jibnu każ u jsostnuh quddiem is-Servizzi Veterinarji. Il-kirurgu veterinarju għandu jipprovdi ġustifikazzjonijiet dettaljati għat-talba tiegħu. Is-Servizzi Veterinarji jista', fejn il-marda jew il-kundizzjoni tkun tali li jkun meħtieġ b'urġenza l-prodott mediċinali veterinarju għat-trattament tal-annimal, jippermetti l-importazzjoni tal-prodott mediċinali veterinarju awtorizzat għal kwalunkwe speċi li ma tipproduċix ikel minn kwalunkwe pajjiż terz skont il-kundizzjonijiet li jħoss li huma xierqa. Is-Servizzi Veterinajri għandu jibbaża d-deċiżjonijiet tiegħu purament fuq bażi xjentifika u għandu jieħu l-prekawzjonijiet kollha, b'mod partikolari għas-sigurtà u r-riskji ambjentali li jistgħu jkunu assoċjati mal-użu tal-prodott mediċinali veterinarju, qabel jiggarantixxi l-approvazzjoni għall-importazzjoni, liema importazzjoni għandha tiġi kkonsidrata bħala permess ta' darba bil-possibilità għal talbiet repetuti, b'kull talba meqjusa bħala *sui generis*.

(2) Id-dispożizzjonijiet tas-subregolamenti (3), (4), (5), (7), u (8) tar-regolament 10 għandhom japplikaw.".

Jemenda r-regolament 11 tar-regolamenti prinċipali.

10. Ir-regolament 11 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) fil-paragrafu (ċ) tas subregolament (1) tiegħu, il-kliem "persuna li tkun awtorizzata skont il-liġi nazzjonali"

għandhom jiġi sostitwiti bil-kliem "spiżjar jew kirurgu veterinarju"; u

(b) minnufih wara s-subregolament (5) tiegħu għandhom jiżdiedu s-subregolamenti ġodda li ġejjin:

"(6) Fil-każ ta' prodott mediċinali veterinarju awtorizzat fi Stat Membru ieħor, il-kirurgi veterinarji għandhom jiksbu awtorizzazzjoni mis-Servizzi Veterinarji qabel jakkwistaw il-prodott għall-amministrazzjoni fuq annimal li jipproduċi l-ikel.

(7) Fil-każ li l-prodotti mediċinali veterinarji fihom sustanzi ristretti li jirriżultaw mill-implimentazzjoni tal-konvenzjonijiet relevanti tan-Nazzjonijiet Uniti fuq is-sustanzi -narkotiċi u psikotropiċi, għandha tingħata kunsiderazzjoni lil kull rekwiżit speċjali li jeħtieġ ikun sodisfatt qabel ma l-prodotti jkunu jistgħu jintużaw.

(8) Prodott mediċinali veterinarju jew prodott mediċinali provdut għall-amministrazzjoni skont il-paragrafi (a), (b) u (ċ) tas-subregolament (1), jista' jiġi pprovdut biss skont preskrizzjoni veterinarja minn kirurgu veterinarju, irrispettivament mill-kategorija legali assenjata lill-prodott mediċinali veterinarju skont ir-regolament 60.

(9) Il-preskrizzjoni veterinarja maħruġa skont il-kundizzjoni msemmija fis-subregolament (8) għandha tiġi mmarkata bħala tali. Dikjarazzjoni simili għal, jew li tagħti l-istess tifsira lid-dikjarazzjoni li ssegwi: "Dan il-prodott ġie preskritt skont il-Cascade Principle", għandha tiġi inkluża fuq il-preskrizzjoni veterinarja.

(10) Sakemm il-kirurgu veterinarju li ppreskriva l-prodott mediċinali veterinarju jew il-prodott mediċinali ma jissupplixxix kif ukoll jamministrax il-prodott lill-annimal hu stess, il-persuna li tissupplixxih għandha timmarkah (jew tassigura li hu mmarkat) b'minn tal-anqas l-informazzjoni li ssegwi:

(a) l-isem tal-kirurgu veterinarju li ppreskriva l-prodott;

(b) l-isem u l-indirizz ta' sid l-annimal;

(ċ) l-identifikazzjoni (inkluż l-ispeċi) tal-annimal jew grupp ta' annimali;

(d) id-data tal-forniment;

(e) id-doża u l-istruzzjonijiet ta' amministrazzjoni;

(f) il-perjodu ta' irtirar, jekk applikabbli;

(11) Meta kirurgu veterinarju jirrikorri għad-dispożizzjonijiet tas-subregolament (1), l-attività li ssir mill-kirurgu veterinarju tkun eskluża mill-iskop ta' definizzjoni ta' distributuzzjoni bl-ingrossa.".

Iżid regolament ġdid mar-regolamenti prinċipali.

11. Minnufih wara r-regolament 11 tar-regolamenti principali għandu jiżdied ir-regolament ġdid li ġej:

"Importazzjoni ta' prodotti mediċinali veterinarji minn kirurgi veterinarji għall-annimali li jipproduċu l-ikel.

11A. (1) Permezz ta' deroga mir-regolament 11(1) u tal-Artikolu 16(1) tar-Regolament (KE) Nru 470/2009, fejn m'hemmx prodott mediċinali veterinarju addattat aċċessibbli kemm bħala prodott awtorizzat f'Malta jew skont id-dispożizzjonijiet tas-subregolament (1) tar-regolament 11, il-kirurgu veterinarju jista', fir-responsabbiltà diretta u personali tiegħu, jibni każ u jsostnih quddiem is-Servizzi Veterinarji. Il-kirurgu veterinarju għandu jipprovdi ġustifikazzjonijiet dettaljati għat-talba tiegħu. Is-Servizzi Veterinarji jista', fejn il-marda jew il-kundizzjoni tkun tali li jkun meħtieġ b'urġenza l-prodott mediċinali veterinarju għat-trattament tal-annimal, jippermetti l-importazzjoni tal-prodott mediċinali veterinarju awtorizzat għal kwalunkwe speċi li tipproduċi l-ikel minn kwalunkwe pajjiż terz skont il-kundizzjonijiet li jħoss li huma xierqa. Is-Servizzi Veterinajri għandu jibbaża d-deċiżjonijiet tiegħu purament fuq bażi xjentifika u għandu jieħu l-prekawzjonijiet kollha, b'mod partikolari għas-sigurtà u r-riskji ambjentali li jistgħu jkunu assoċċjati mal-użu tal-prodott mediċinali veterinarju, qabel jiggarantixxi l-approvazzjoni għall-importazzjoni, liema importazzjoni għandha tiġi kkonsidrata bħala permess ta' darba bil-possibilità għal talbiet repetuti, b'kull talba meqjusa bħala *sui generis*.

(2) Id-dispożizzjonijiet tas-subregolamenti (6), (7), (8) u (10) għandhom japplikaw.".

Jemenda r-regolament 30 tar-regolamenti prinċipali.

12. Fir-regolament 30 tar-regolamenti prinċipali, il-kelma "Komunita`" għandha tiġi mħassra kull fejn din tokkorri.

Jissostitwixxi r-regolamenti 38 sa 50 tar-regolamenti prinċipali.

13. Ir-regolamenti 38 sa 50 tar-regolamenti prinċipali għandhom jiġu sostitwiti bir-regolamenti ġodda li ġejjin:

"Regolamenti dwar il-manifattura u l-importazzjoni.

38. (1) Id-dispożizzjonijiet ta' dan it-Titolu ma għandhomx japplikaw għall-:

(a) *magistral formula*;

(b) *officinal formula*;

(ċ) prodotti mediċinali veterinarji maħsuba għar-riċerka u provi ta' żvilupp;

(d) prodotti intermedji maħsuba għal aktar proċessar minn manifattur awtorizzat;

(e) kull tip ta' radjonuklidi fil-forma ta' sorsi ssiġillati;

(f) demm, plasma jew ċelloli tad-demm ta' oriġini mill-annimali, bl-eċċezzjoni ta' plasma li hija ppreparata permezz ta' metodu li jinvolvi proċess industrijali;

(g) prodotti mediċinali veterinarji pprovduti bħala risposta għal ordni *in bona fide* mhux mitluba, ifformulata skont l-ispeċifikazzjonijiet ta' kirurgu veterinarju u għall-użu ta' annimal individwali li jaqa' fir-responsabbiltà diretta u personali tiegħu.

(2) Id-dispożizzjonijiet ta' dawn ir-regolamenti għandhom japplikaw ukoll għall-manifattura tal-prodotti mediċinali veterinarji omeopatiċi, prodotti mediċinali veterinarji li ġejjin mid-demm jew mill-plasma ta' annimali, radjufarmaċewtiċi, prodotti mediċinali veterinarji immunoloġiċi u prodotti mediċinali veterinarji magħmula mill-ħxejjex.

Awtorizzazzjoni ta' Manifattura għall-prodotti mediċinali veterinarji u sustanzi attivi.

39. (1) (a)L-ebda prodott mediċinali veterinarju, sustanza attiva bijoloġika, jew sustanza attiva ma tista' tintuża direttament bħala prodott mediċinali veterinarju għall- investigazzjoni, ma jista' jkun manifatturat f'Malta sakemm ma jkunx hemm, fir-rigward tat-tali prodott jew sustanza, Awtorizzazzjoni ta' Manifattura.

Din il-liċenzja għall-Awtorizzazzjoni ta' Manifattura għandha tkun meħtieġa wkoll għall-proċessi ta' sterilizzazzjoni ta' sustanzi attivi.

(b) L-Awtorizzazzjoni ta' Manifattura għandha tintalab ukoll għall-manifattura ta' prodotti mediċinali veterinarji maħsuba għall-esportazzjoni.

(2) (a) L-Awtorizzazzjoni ta' Manifattura, li għandha tibqa' fis-seħħ għal perjodu li jiġi determinat mis-Servizzi Veterinarji, għandha tkun meħtieġa kemm għal manifattura totali kif ukoll parzjali, u għall-proċessi varji ta' tqassim, ippakkjar u preżentazzjoni.

(b) Awtorizzazzjoni ta' Manifattura m'għandhiex tkun meħtieġa għall-preparazzjoni, it-tqassim, il-bidliet fl-ippakkjar jew fil-preżentazzjoni fejn it-tali proċessi jitwettqu biss għal forniment bl-imnut mill-ispiżjara fi spiżeriji veterinarji, jew minn persuni oħra li huma legalment awtorizzati jwettqu t-tali proċessi.

(3) L-awtorizzazzjoni msemmija fis-subregolament (1) għandha tkun meħtieġa wkoll għal importazzjonijiet fit-territorju ta' Malta minn pajjiżi terzi.

It-territorju ta' Malta għandu jieħu l-miżuri xierqa sabiex jassigura li prodotti mediċinali veterinarji li jiddaħħlu fit-territorju minn pajjiż terz u li jkunu maħsuba għall-Istati Membri jkunu akkumpanjati minn kopja tal-awtorizzazzjoni msemmija fis-subregolament (1).

(4) Kull applikazzjoni għall-għoti ta' liċenzja sabiex ikun hemm manifattura, assemblaġġ jew modifika fuq prodott mediċinali veterinarju għandha ssir mas-Servizzi Veterinarji u għandha tinkludi t-tali informazzjoni, dokumenti, kampjuni u materjal ieħor hekk kif imniżżel fid-dispożizzjonijiet ta' dawn ir-regolamenti.

(5) Awtorizzazzjoni ta' Manifattura għandha tinkludi liċenzja għad-distribuzzjoni bl-ingrossa ta' prodotti mediċinali veterinarji li għalihom tkun inħarġet l-Awtorizzazzjoni ta' Manifattura.

(6) Is-Servizzi Veterinarji għandu jgħaddi kopja tal-Awtorizzazzjoni msemmija fis-subregolament (1) lill-Aġenzija.

(7) Is-Servizzi Veterinarji għandu jdaħħal l-informazzjoni b'rabta mal-Awtorizzazzjoni msemmija fis-subregolament (1) fid-database tal-Unjoni Ewropea msemmi fir-regolament 72(6).

Tiġdid tal-Awtorizzazzjoni ta' Manifattura u Importazzjoni.

40. Is-Servizzi Veterinarji, għandu jagħti biss, jew iġedded Awtorizzazzjoni, jekk l-applikant:

(a) jispeċifika l-prodotti mediċinali veterinarji jew il-forom farmaċewtiċi li jkunu ser jiġu manifatturati jew importati u l-post fejn ser jiġu manifatturati u, jew ikkontrollati;

(b) ikollu għad-dispożizzjoni tiegħu, għall-manifattura jew l-importazzjoni ta' prodotti mediċinali veterinarji, post addattat u suffiċjenti, tagħmir tekniku u faċilitajiet ta' kontroll li jkunu konformi mar-rekwiżiti maħruġa mis-Servizzi Veterinarji;

(ċ) ikollu għad-dispożizzjoni tiegħu s-servizzi ta' minn tal-anqas persuna kwalifikata skont it-tifsira ta' regolament 46; u

(d) jipprovdi d-dokumentazzjoni kollha meħtieġa bħala sapport għall-applikazzjoni tiegħu.

Ħruġ ta' Awtorizzazzjoni Manifattura u Importazzjoni.

41. (1) (a)Is-Servizzi Veterinarji għandu joħroġ l-Awtorizzazzjoni wara li jivverifika l-kontenut tal-applikazzjoni iżda fi kwalunkwe każ sa mhux aktar tard minn disgħin (90) jum minn meta jirċievi l-applikazzjoni.

(b) Dan il-perjodu ta' żmien għandu jiġi sospiż meta s-Servizzi Veterinarji jitlob informazzjoni addizzjonali mingħand l-applikant.

(ċ) Is-Servizzi Veterinarji għandu, qabel jiddetermina applikazzjoni, jispezzjona l-post indikat fl-applikazzjoni u m'għandux joħroġ Awtorizzazzjoni sakemm ikun sodisfaċenti biżżejjed li l-post huwa konformi mar-rekwiżiti stabbiliti fid-dispożizzjonijiet ta' dawn ir-regolamenti;

(d) Is-Servizzi Veterinajri jista' jiggarantixxi liċenzja kundizzjonali soġġetta għat-twettiq ta' ċertu obbligi imposti fuq l-applikant.

(2) L-Awtorizzazzjoni għandha tapplika biss għall-post, il-prodotti mediċinali veterinarji u l-forom farmaċewtiċi speċifikati fl-applikazzjoni.

(3) Fejn is-Servizzi Veterinarji jikkonsidra li jista' jkun hemm ċirkostanzi li jrendu l-ħtieġa fejn jiġi kkunsidrat il-fatt jekk l-Awtorizzazzjoni għandhiex tkun varjata, sospiża jew revokata, is-Servizzi Veterinarji jista' jimponi avviż lid-detentur ta' Awtorizzazzjoni ta' manifattura u li fih jitolbu, biex fit-tali żmien speċifikat fl-avviż, jipprovdih bl-informazzjoni speċifikata fl-avviż.

Varjazzjoni tal-Awtorizzazzjoni ta' Manifattura u Importazzjoni.

42. (1) Meta d-detentur tal-Awtorizzazzjoni jitlob bidla fid-dettalji speċifikati fir-regolament 4(a) u 4(b), dan għandu japplika bil-miktub mas-Servizzi Veterinarji.

Il-proċess ta' verifika tat-tali informazzjoni m'għandux jaqbeż it-tletin (30) jum. Madanakollu, f'każijiet eċċezzjonali, il-perjodu ta' żmien jista' jiġi estiż għal disgħin (90) jum.

(2) Is-servizzi veterinarji jista', għat-talba ta' applikazzjoni mid-detentur tal-Awtorizzazzjoni, ivarja l-kundizzjonijiet tal-liċenzja jekk ikun sodisfatt li t-tali varjazzjoni ma taffettwax b'mod avvers l-istandard ta' prattika tajba fil-manifattura hekk kif hemm preskritt.

(3) Fejn is-Servizzi Veterinarji jħoss li jista' jkun hemm ċirkostanzi li jġagħluh jikkonsidra jekk l-Awtorizzazzjoni tiġix varjata, sospiża jew revokata, is-Servizzi Veterinarji jista' joħroġ avviż lid-detentur tal-Awtorizzazzjoni ta' manifattura li jitolbu, sabiex fit-tali żmien skont kif speċifikat fl-avviż, jissottometti kull tip ta' informazzjoni speċifika inkluża fl-avviż.

Sospensjoni tal-Awtorizzazzjoni ta' Manifattura u Importazzjoni.

43. (1) Is-Servizzi Veterinarji jista' jissospendi Awtorizzazzjoni ta' manifattura għal perjodu determinat minnu, jew jista' jirrifjuta, jirrevoka, jew ivarja d-dispożizzjonijiet tat-tali Awtorizzazzjoni.

(2) Is-setgħat mogħtija fis-subregolament (1) għandhom jiġu eżerċitati biss fis-segwenti ċirkostanzi, fejn:

(a) l-informazzjoni mogħtija fl-applikazzjoni li fuqha tinħareġ l-Awtorizzazzjoni tkun falza jew mhux kompluta kif meħtieġ;

(b) ikun hemm bidla materjali fiċ-ċirkostanzi b'rabta ma' xi wieħed minn dawk is-suġġetti;

(ċ) ikun hemm ksur ta' xi waħda mill-kundizzjonijiet tal-Awtorizzazzjoni;

(d) ir-rekwiżiti b'rabta mal-liċenzji hekk kif stabbilit fir-regolamenti ma kinux sodisfatti;

(e) il-proċessi ta' manifattura jew assemblaġġ ta' prodott mediċinali veterinarju jsiru b'tali mod li mhumiex konformi mad-dispożizzjonijiet tal-awtorizzazzjoni ta' kummerċjalizzazzjoni ta' dak il-prodott mediċinali veterinarju;

(f) il-kondizzjonijiet għall-prattika ta' manifattura tajba mhumiex sodisfatti;

(g) hemm il-bejgħ u l-ipproċessar ta' sustanzi attivi u prodotti mediċinali veterinarji f'kundizzjonijiet mhux sanitarji jew li jwasslu għal adulterazzjoni; u

(h) fi kwalunkwe ċirkostanza oħra hekk kif stabbilit f'dawn ir-regolamenti.

(3) Is-Servizzi Veterjinarji għandu jwettaq spezzjonijiet regolari sabiex jassigura li r-rekwiżiti stabbiliti permezz ta' dawn ir-regolamenti b'rabta mal-manifattura, l-assemblaġġ jew il-modifika ta' prodott mediċinali veterinarju jew sustanza attiva huma sodisfatti.

(4) Fir-rigward ta' manifattura ta' prodotti mediċinali veterinarji jew sustanzi attivi, is-Servizzi Veterinarji jew kull persuna oħra awtorizzata li twettaq spezzjoni għandha:

(a) tispezzjona l-istabbiliment ta' manifattura u kull post ieħor u fi kwalunkwe ħin reġjonevoli li d-Direttur iħoss li hu xieraq;

(b) teżamina kull dokument relevanti;

(ċ) tieħu kull tip ta' kampjun li d-Direttur iħoss li hu xieraq u jekk meħtieġ tissottomettihom lil-laboratorji magħżula għall-ittestjar;

(d) tiftaħ jew/u teżamina jew/u tikkonfiska kull tip ta' artiklu li temmen li jkun qed jikser dawn ir-regolamenti jew biex tikseb evidenza;

(e) tifformola rapporti bir-riżultati u tikkomunika l-kontenut tagħhom lid-detentur tal-Awtorizzazzjoni tal-Manifattura jew lill-applikant għall-Awtorizzazzjoni tal-Manifattura u lill-persuna kwalifikata b'rabta mat-tali spezzjoni;

(f) twettaq kwalunkwe tip ta' attività oħra li d-Direttur iħoss li hi xierqa għall-eżekuzzjoni proprja tad-dmirijiet u r-responsabbilitajiet tagħha skont dawn ir-regolamenti;

(g) tipproduċi, fuq talba tal-parti li qed tiġi spezzjonata, id-dokument partikolari li fih l-informazzjoni fuq il-bażi u l-iskop legali tal-ispezzjoni u l-identifikazzjoni tal-ispezzjonist;

(h) fil-ħin tal-ispezzjoni tagħmel lista tan-nuqqasijiet li jistgħu jiġu identifikati u għandha tiffirma din il-lista, u t-tali lista għandha tiġi ffirmata wkoll mid-detentur tal-Awtorizzazzjoni u r-rappreżentant legali tiegħu;

(i) tfassal rapport fuq l-ispezzjoni fi żmien tletin (30) jum tax-xogħol mill-ispezzjoni u għandha tgħaddi kopja tat-tali rapport lid-detentur tal-Awtorizzazzjoni.

(5) B'eċċezzjoni għall- każijiet urġenti, l-ispezzjoni għandha ssir fil-preżenza ta' persuna kwalifikata jew rappreżentant tagħha.

(6) Bla ħsara għad-dispożizzjonijiet ta' dawn ir-regolamenti, kull liċenzja għandha, sakemm ma tkunx ġiet imġedda qabel jew revokata, tkompli tibqa' valida sakemm ma tiġix imġedda mis-Servizzi Veterinarji wara l-ispezzjoni.

(7) Is-Servizzi Veterinarji għandu jistabbilixxi l-validità ta' kull liċenzja.

(8) Wara l-ispezzjoni msemmija fis-subregolament (1), is-Servizzi Veterinarji:

(a) jista' jġedded il-liċenzja, bil-modifikazzjonijiet jew mingħajrhom, għal perjodu iehor kif speċifikat; jew

(b) jekk, wara li jikkonsidra d-dispożizzjonijiet ta' dawn ir-regolamenti, jikkonsidra li hu meħtieġ jew utli li jagħmel hekk, jista' jirrifjuta li jġedded il-liċenzja.

Obbligazzjonijiet tad-detentur ta' awtorizzazzjoni ta' manifattura u manifattura ta' sustanzi attivi.

44. (1) Id-detentur tal-Awtorizzazzjoni tal-manifattur tas-sustanza attiva għandu:

(a) jkun konformi mal-prinċipji u l-linji gwida tal-UE fuq prattika tajba ta' manifattura u l-annessi kollha tagħhom għal prodotti mediċinali veterinarji u juża biss sustanzi attivi li jkunu ġew manifatturati skont il-linjigwida tal-UE fuq prattika tajba ta' manifattura għal sustanzi attivi u mqassma skont il-prattiċi ta' distribuzzjoni tajba għas-sustanzi attivi. Għal dan il-għan, it-titular tal-awtorizzazzjoni ta' manifattura għandu jivverifika l-konformità mill-manifattur u d-distributuri tas-sustanzi attivi ma' prattika tajba ta' manifattura billi jagħmel awditjar fis-siti ta' manifattura u ta' distribuzzjoni tal-manifattur u d-distributuri ta' sustanzi attivi. Id-detentur tal-awtorizzazzjoni ta' manifattura għandu jivverifika t-tali kompjaċenza kemm hu nnifsu, jew mingħajr preġudizzju tar-responsabbiltà tiegħu hekk kif provdut f'dawn ir-regolamenti u fl-Att, permezz ta' entità li taġixxi f'ismu b'kuntratt;

(b) jinforma immedjatament lill-awtorità kompetenti u lid-detentur tal-awtorizzazzjoni ta' kummerċjalizzazzjoni jekk jikseb informazzjoni li l-prodotti mediċinali veterinarji li jaqgħu taħt l-ambitu ta' awtorizzazzjoni tal-manifattura tiegħu jew is-sustanza attiva huma, jew għandu suspett li huma, iffalsifikati irrispettivament jekk dawk il-prodotti mediċinali veterinarji ġewx imqassma bħala parti mill-katina tal-provvista legali jew b'mezzi illegali, inkluż bejgħ illegali mill-bogħod permezz ta' servizzi ta' soċjetajiet ta' informazzjoni;

(ċ) jivverifika li l-manifatturi, l-importaturi jew id-distributuri minn fejn hu jikseb is-sustanzi attivi huma rreġistrati mal-awtorità kompetenti tal-Istat Membru fejn huma stabbiliti;

(d) jivverifika l-awtentiċità u l-kwalità tas-sustanzi attivi u l-eċċipjenti;

(e) għandu għad-disponibbiltà tiegħu s-servizzi ta' ħaddiema li huma konformi mar-rekwiżiti legali stabbiliti mis-Servizzi Veterinarji kemm mil-lat ta' manifattura kif ukoll kontrolli;

(f) jiddisponi mill-prodotti mediċinali veterinarji biss skont il-liġi tat-territorju ta' Malta;

(g) jinnotifika minn qabel lis-Servizzi Veterinarji b'kull bidla li jkun jixtieq jagħmel lil kull dettall mogħti skont ir-regolament 40 jew bidliet sinifikanti oħra jew il-kundizzjonijiet li jistgħu jaffettwaw il-kwalità, is-sigurtà jew l-effiċjenza tal-prodott mediċinali veterinarju.

Is-Servizzi Veterinarji għandu, f'kull każ, ikun informat immedjatament jekk il-persuna kwalifikata msemmija fir-regolament 46(1) ġiet mibdula;

(h) jippermetti lill-persuna kwalifikata msemmija f'regolament 46(1) sabiex twettaq id-doveri tagħha, b'mod partikolari billi jpoġġi għad-dispożizzjoni tagħha l-faċilitajiet kollha meħtieġa;

(i) data;

(ii) isem tal-prodott mediċinali veterinarju;

(iii) kwantità fornuta;

(iv) isem u indirizz tar-reċipjent;

(v) numru tal-lott.

Dawn ir-reġistri għandhom ikunu aċċessibli għall-ispezzjoni mis-Servizzi Veterinarji għal perjodu ta' minn tal-anqas tliet (3) snin.

(j) minn tal-anqas, l-informazzjoni li ssegwi għandha tkun irreġistrata għal kull tranżazzjoni, kemm jekk issir bi ħlas jew u anke jekk ma ssirx bil-ħlas;

(k) jirreġistra kull suspett ta' reazzjoni avversa serja u reazzjonijiet avversi umani marbuta mal-użu tal-prodotti mediċinali veterinarji li jsir jaf bihom u jirrapportahom immedjatament lis-Servizzi Veterinarji mhux aktar tard minn ħmistax (15)-il jum wara li jkun irċieva t-tali informazzjoni;

(l) jimplimenta sistema għar-reġistrazzjoni u reviżjoni ta' ilmenti flimkien ma' sistema effettiva għall-ġbir lura b'mod immedjat fi kwalunkwe ħin ta' prodotti mediċinali veterinarji jew ta' sustanzi attivi li jagħmlu parti min-netwerk ta' distribuzzjoni;

(m) jirreġistra u jinvestiga kull ilment li jikkonċerna difetti fil-kwalità;

(n) responsabbiltajiet oħra li jistgħu jiġu stabbiliti minn żmien għal żmien mis-Servizzi Veterinarji.

(2) Għall-finijiet ta' dan ir-regolament, il-manifattura ta' sustanzi attivi li jintużaw bħala materjali tal-bidu għandha tinkludi kemm il-manifattura totali kif ukoll dik parzjali jew importazzjoni ta' sustanza attiva li tintuża bħala materjal tal-bidu kif definit fl-Iskeda Parti 2. Taqsima Ċ ta' dawn ir-regolamenti, u l-proċessi varji ta' tqassim, ippakkjar jew preżentazzjoni qabel l-inkorporazzjoni tagħhom fi prodott mediċinali veterinarju, inkluż l-ippakkjar mill-ġdid jew l-ittikkettar mill-ġdid, jitwettqu minn distributur ta' materjali tal-bidu.

(3) Detenturi ta' Awtorizzazzjoni ta' Manifattura għandhom jitqiesu bħala produtturi u għaldaqstant responsabbli għall-ħsarat fil-kaxxi u skont il-kundizzjonijiet stipulati fl-Att dwar l-Affarijiet tal-Konsumatur.

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(4) Għandu jkun id-dover tal-importatur biex jiżgura illi:

(a) fil-każ ta' prodotti mediċinali veterinarji u prodotti mediċinali veterinarji investigattivi impurtati minn pajjiżi terzi, dawn ikunu ġew manifatturati skont l-istandards li tal-anqas huma ekwivalenti għall-istandards ta' prattika ta' manifattura tajba kif stipulati fir-Regoli dwar il-Prattika ta' Manifattura Tajba għall-Prodotti Mediċinali Veterinarji;

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(b) fil-każ ta' prodotti mediċinali veterinarji, it-tali prodotti jkunu ġew manifatturati minn manifatturi awtorizzati kif xieraq għal dak il-għan; u

(ċ) fil-każ ta' prodotti mediċinali veterinarji investigattivi, it-tali prodotti jkunu ġew manifatturati minn manifattur li jkun innotifika lill-awtoritajiet kompetenti u ġie aċċettat minnhom għal dak il-għan.

Informazzjoni addizzjonali skond l-applikazzjoni ta' awtorizzazzjoni ta' manifattura u importazzjoni.

45. Is-Servizzi Veterinarji jista' jitlob lill-applikant għal aktar informazzjoni kemm fir-rigward tad-dettalji mogħtija skont ir-regolament 40 u l-persuna kwalifikata msemmija fir-regolament 46(1). Meta s-Servizzi Veterinarji jeżerċita dan id-dritt, l-applikazzjoni tal-limitazzjonijiet taż-żmien imsemmija fir-regolamenti 41 u 42(1) għandha tiġi sospiża sakemm tiġi provduta l-informazzjoni addizzjonali mitluba.

Persuna kwalifikata.

46. (1) Id-detentur tal-Awtorizzazzjoni għandu jkollu fid-dispożizzjoni tiegħu kemm b'mod permanenti kif ukoll b'mod kontinwu, is-servizzi ta' minn tal-anqas persuna kwalifikata, skont il-kondizzjonijiet imsemmija fir-regolament 47, responsabbli b'mod partikolari għat-twettiq tad-dmirijiet speċifikati fir-regolament 49:

Iżda ma jkunx hemm aktar minn persuna waħda nominata, l-applikazzjoni għandha telenka b'mod ċar ir-responsabbiltajiet speċifiċi ta' kull persuna:

Iżda wkoll il-persuna kwalifikata ma tinnominax persuna oħra bi kwalifiki simili biex taġixxi bħala rappreżentanta tagħha.

(2) Meta l-persuna kwalifikata tinnomina rappreżentant kif imsemmi qabel, dan għandu jinforma immedjatament lis-Servizzi Veterinarji bit-tali nomina.

(3) Jekk id-detentur ta' Awtorizzazzjoni ta' manifattura personalment għandu l-kwalifiki msemmija fir-regolament 47, ikun jista' hu nnifsu jieħu r-responsabbiltà tal-persuna kwalifikata.

Kwalifiki tal-persuna kwalifikata.

47. Sabiex persuna tkunu meqjusa bħala persuna kwalifikata, minn tal-anqas għandu jkollha is-segwenti kwalifiki:

(a) diploma;

(b) ċertifikat jew evidenza oħra ta' kwalifika formali mogħtija mat-tkomplija ta' kors ta' studju universitarju; jew

(ċ) kors rikonoxxut bħala ekwivalenti mit-territorju ta' Malta, li jestendi fuq perjodu ta' minn tal-anqas erba' snin ta' studju teoretiku u prattiku f'waħda mid-dixxiplini fl-oqsma xjentifiċi li jsegwu – farmaċija, mediċina, xjenza veterinarja, kimika, kimika farmaċewtika u teknoloġika, bijoloġija.

(2) Madanakollu, it-tul minimu tal-kors universitarju jista' jkun ta' tliet snin u nofs (3.5) meta l-kors ikun segwit minn perjodu ta' taħriġ teoretiku u prattiku ta' minn tal-anqas sena u jinkludi perjodu ta' taħriġ ta' minn tal-anqas sitt xhur fi spiżerija miftuħa għall-pubbliku, korraborat permezz ta' eżami fil-livell universitarju.

(3) Il-kors għandu jinkludi tagħlim teoretiku u prattiku relatat tal-anqas ma' dawn is-suġġetti bażiċi:

(a) fiżika sperimentali;

(b) kimika ġenerali u inorganika;

(ċ) kimika organika;

(d) kimika analitika;

(e) kimika farmaċewtika, inkluż analiżi ta' prodotti mediċinali;

(f) bijokimika ġenerali u applikata (medika);

(g) fiżjoloġija;

(h) mikrobijoloġija;

(i) farmakoloġija;

(j) teknoloġija farmaċewtika;

(k) tossikoloġija;

(l) *pharmacognosy* (l-istudju tal-kompożizzjoni u l-effetti tal-prinċipji attivi ta' sustanzi naturali ta' oriġini minn pjanti u annimali).

(4) It-tagħlim f'dawn is-suġġetti għandu jkun ibbilanċjat biżżejjed li jippermetti lill-persuna kkonċernata tissodisfa l-obbligazzjonijiet imsemmija fir-regolament 49.

(5) Fejn ċertu diplomi, ċertifikati jew evidenzi oħra ta' kwalifiki formali msemmija f'dan is-subregolament ma jissodisfawx il-kriterji msemmija hawn fuq, is-Servizzi Veterinarji għandu jassigura li l-persuna kkonċernata tipprovdi evidenza li hi għandha, fis-suġġetti involuti, l-għarfien meħtieġ dwar il-manifattura u l-kontroll ta' prodotti mediċinali veterinarji.

(6) Il-persuna kwalifikata għandha tkun kisbet esperjenza prattika fuq minn tal-anqas sentejn (2), f'waħda jew aktar mill-kumpaniji li huma manifatturi awtorizzati, fl-attivitajiet ta' analiżi kwalitattiva ta' prodotti mediċinali, f'analiżi kwantitattiva ta' sustanzi attivi u fl-ittestjar u l-iċċekkjar neċessarju biex tkun assigurata l-kwalità tal-prodotti mediċinali veterinarji.

(7) It-tul tal-esperjenza prattika tista' titnaqqas b'sena meta l-kors universitarju jdum għal minn tal-anqas ħames (5) snin u b'sena u nofs fejn il-kors idum għal minn tal-anqas sitt (6) snin.

Persuni kwalifikati f'impjieg kurrenti.

48. (1) Persuna involuta, f'Malta, fl-attivitajiet tal-persuna msemmija fir-regolament 46(1) dakinhar li jidħlu fis-seħħ dawn ir-regolamenti, mingħajr ma tkun konformi mad-dispożizzjonijiet tar-regolament 47, għandha tkun eleġibbli li tkompli tkun involuta f'dawk l-attivitajiet fi ħdan l-UE.

(2) Id-detentur ta' diploma, ċertifikat jew evidenza oħra ta' kwalifiki formali mogħtija mat-tkomplija ta' kors universitarju jew kors rikonoxxut bħala ekwivalenti mit-territorju ta' Malta f'dixxiplina xejntifika li tippermettilu jinvolvi ruħu fl-attivitajiet tal-persuna msemmija fir-regolament 46(1) skont il-liġijiet tat-territorju ta' Malta, jista', jekk ikun beda l-kors tiegħu qabel id-data meta jiddaħħlu fis-seħħ dawn ir-regolamenti, ikun meqjus bħala kwalifikat biex iwettaq fit-territorju ta' Malta id-dmirijiet tal-persuna msemmija fir-regolament 46(1), ladarba jkun diġà ħa sehem qabel f'dawn l-attivitajiet għal minn tal-anqas sentejn (2) qabel id-data meta jiddaħħlu fis-seħħ dawn ir-regolamenti f'waħda jew aktar mill-kumpaniji b'awtorizzazzjoni ta' manifattura, superviżjoni tal-produzzjoni u, jew analiżi kwalitattiva u kwantitattiva ta' sustanzi attivi, u t-testijiet u l-iċċekkjar meħtieġ taħt l-awtorità diretta ta' persuna kif imsemmi fir-regolament 46(1) sabiex tkun assigurata l-kwalità tal-prodotti mediċinali veterinarji.

Jekk il-persuna kkonċernata tkun kisbet l-esperjenza prattika msemmija fis-subregolament (1) qabel id-data minn meta jiddaħħlu fis-seħħ dawn ir-regolamenti, għandha titkompla sena oħra ta' esperjenza prattika skont il-kondizzjonijiet imsemmija fis-subregolament (1) immedjatament qabel ma l-persuna tinvolvi ruħha fit-tali attivitajiet.

Responsabbiltajiet tal-persuna kwalifikata.

49. (1) Il-persuna kwalifikata, mingħajr l-ebda preġudizzju għar-relazzjoni tagħha mad-detentur tal-Awtorizzazzjoni, għandha tkun responsabbli biex tiżgura li:

(a) kull lott ta' prodotti mediċinali veterinarji manifatturati f'Malta jiġi manifatturat u ċċekkjat skont it-termini tal-liġijiet li hemm fis-seħħ u jkun skont ir-rekwiżiti tal-awtorizzazzjoni tal-kummerċjalizzazzjoni;

(b) fil-każ ta' prodotti mediċinali veterinarji ġejjin minn pajjiż terzi, irrispettivament jekk il-prodott hux manifatturat fl-UE jew le, kull lott ta' produzzjoni f'kull Stat Membru għandu jkun għadda u ssodisfa analiżi kwalitattiva, analiżi kwantitattiva ta' minn tal-anqas tas-sustanzi attivi kollha u t-testijiet u l-iċċekkjar l-oħra kollha meħtieġa biex tkun assigurata l-kwalità tal-prodott mediċinali veterinajru skont ir-rekwiżiti tal-awtorizzazzjoni ta' kummerċjalizzazzjoni:

Iżda meta l-lottijiet tal-prodotti mediċinali jkunu diġà ġew ikkontrollati kif imsemmi hawn fuq fi Stat Membru, għandhom ikunu eżenti minn aktar kontrolli jekk ikollhom ir-rapporti ta' kontroll iffirmati mill-persuna kwalifikata, u huma kummerċjalizzati fi ħdan l-UE;

(ċ) l-istandards ta' prattika tajba fil-manifattura huma mħarsa f'kull ħin.

(2) Il-persuna kwalifikata m'hemmx bżonn li twettaq il-kontrolli msemmija hawn fuq f'każ ta' prodotti mediċinali veterinarji impurtati, fejn ikunu saru arranġamenti mill-UE mal-pajjiż li jkun qed jesporta biex ikun assigurat li l-manifattur tal-prodotti mediċinali veterinarji japplika l-istandards ta' prattika ta' manifattura tajba minn tal-anqas ekwivalenti għal dawk imposti mill-UE, u biex ikun assigurat li l-kontrolli msemmija hawn fuq ikunu saru fil-pajjiż li jkun qed jesporta.

(3) Is-Servizzi Veterinarji, jista', jekk ikollu suspett raġonevoli fuq il-fatt li xi persuna kwalifikata tkun qed taġixxi b'mod li jmur kontra xi waħda mid-dispożizzjonijiet ta' dawn ir-regolamenti, jissospendi l-attività tat-tali persuna kwalifikata billi jinnotifikaha bil-miktub filwaqt li jispeċifika r-raġunijiet għat-tali sospensjoni sakemm it-tali persuna ma tkunx konformi mar-rekwiżit tas-Servizzi Veterinarji biex tirrimedja n-nuqqas ta' konformità.

Id-doveri tal-persuna kwalifikata.

50. (1) Għandu jkun id-dover tal-persuna kwalifikata li żżomm reġistru biex fih jiġi dokumentat u ċċertifikat li kull lott ta' produzzjoni jissodisfa d-dispożizzjonijiet ta' dawn ir-regolamenti.

(2) L-imsemmi reġistru għandu jinżamm aġġornat skont kif isiru l-operazzjonijiet u għandu jkun aċċessibbli għall-ispezzjoni mis-Servizzi Veterinarji għal minn tal-anqas ħames (5) snin.

Konferma ta' persuna kwalifikata mill-awtorita` kompetenti.

50A. L-obbligazzjonijiet tal-persuni kwalifikati msemmija fir-regolament 46(1) għandhom ikunu sodisfatti jew permezz ta' mezzi xierqa ta' miżuri amministrattivi jew billi t-tali persuni jkunu soġġetti għall-kodiċi ta' mġieba professjonali.

(2) Is-Servizzi Veterinarji jista' jikkonsidra s-sospensjoni temporanja tat-tali persuna mal-bidu ta' proċessi amministrattivi jew dixxiplinarji kontriha għal falliment li twettaq l-obbligi tagħha.

Reġistrazzjoni ta' sustanzi attivi impurtaturi, esportaturi, distributuri u manifatturi.

50B. (1) Importaturi, esportaturi, distributuri u manifatturi ta' sustanzi attivi li huma stabbiliti f'Malta għandhom jirreġistraw l-attività tagħhom mas-Servizzi Veterinarji.

(2) Il-formola ta' reġistrazzjoni għandha tinkludi, minn tal-anqas, l-informazzjoni segwenti:

(a) isem jew l-isem tal-kumpanija u l-indirizz permanenti;

(b) is-sustanzi attivi li ser jiġu impurtati, esportati, imqassma jew manifatturati

(ċ) dettalji rigward il-binja u t-tagħmir tekniku għall-attività tagħhom:

Iżda l-persuni msemmija fis-subregolament (1) għandhom jissottomettu l-formola ta' reġistrazzjoni lis-Servizzi Veterinarji minn tal-anqas sittin (60) jum qabel il-bidu intenzjonat tal-attività tagħhom.

(3) Is-Servizzi Veterinarji jista', abbażi ta' assessjar tar-riskji, jiddeċiedi li jwettaq spezzjoni. Jekk is-Servizzi Veterinarji jinnotifika lill-applikant fi żmien sittin (60) jum minn meta jirċievi l-formola ta' reġistrazzjoni li ser issir spezzjoni, l-attività ma tkunx tista' tibda qabel ma s-Servizzi Veterinarji jinnotifika lill-applikant li jista' jibda bl-attività tiegħu. Jekk f'temp ta' sittin (60) jum mid-data ta' meta tkun irċeviet il-formola ta' reġistrazzjoni l-Awtorità għal-Liċenzji ma tkunx innotifikat lill-applikant li tkun ser issir spezzjoni, l-applikant jista' jibda bl-attività tiegħu.

(4) Il-persuni msemmija fis-subregolament (1) għandhom jgħaddu kull sena lis-Servizzi Veterinarji inventarju tal-bidliet li jkunu saru fir-rigward tal-informazzjoni mogħtija fil-formola ta' reġistrazzjoni. Kull bidla li jista' jkollha impatt fuq il-kwalità jew is-sigurtà tas-sustanzi attivi li jkunu qed jiġu manifatturati, esportati, mqassma jew impurtati għandha tiġi nnotifikata immedjatament.

(5) Is-Servizzi Veterinarji, jista' jiggarantixxi jew iġedded Approvazzjoni, biss jekk l-applikant:

(a) jispeċifika l-prodotti mediċinali veterinarji u l-forom farmaċewtiċi li jkunu ser jiġu manifatturati jew impurtati u l-post fejn ser ikunu qed jiġu manifatturati u, jew ikkontrollati;

(b) għandu għad-dispożizzjoni tiegħu, għall-manifattura jew importazzjoni ta' prodotti mediċinali veterinarji, binja addattata u suffiċjenti, tagħmir tekniku u faċilitajiet ta' kontroll kompjaċenti mar-rekwiżiti stabbiliti mis-Servizzi Veterinarji;

(ċ) għadu għad-dispożizzjoni tiegħu s-servizzi ta' minn tal-anqas persuna kwalifikata skont it-tifsira tar-regolament 46(1); u

(d) jipprovdi d-dokumentazzjoni kollha meħtieġa bħala sapport għall-applikazzjoni tiegħu.

(6) Is-Servizzi Veterinarji għandu joħroġ l-Awtorizzazzjoni wara li jivverifika l-kontenut tal-applikazzjoni iżda f'kull każ sa mhux aktar tard minn disgħin (90) jum minn meta jirċievi l-applikazzjoni.

(7) Il-perjodu ta' żmien imsemmi fis-subregolament 6 għandu jiġi sospiż meta s-Servizzi Veterinarji jitlob informazzjoni addizzjonali mingħand l-applikant.

Importazzjoni ta' esportazzjoni mill-ġdid.

50Ċ. (1) Meta l-prodotti mediċinali veterinarji jinġiebu f'Malta minn pajjiż terz għall-iskop waħdieni ta' esportazzjoni mill-ġdid, u mingħajr ma jitpoġġew fis-suq f'Malta, id-dispożizzjonijiet tar-regolament 38 japplika xorta waħda anke jekk il-prodott jibqa' intatt u ma jkun hemm l-ebda attività ta' manifattura.

(2) L-unika esklużjoni fid-dawl tar-rekwiżiti fir-regolament 38, hija meta l-operazzjonijiet ta' importazzjoni għall-għan waħdieni ta' esportazzjoni mill-ġdid tkun affetwata ġewwa l-port ħieles, f'żona ta' negozju liberu jew f'maħżen tad-dwana. Madanakollu, fit-tali ċirkostanzi xorta waħda tkun tenħtieġ awtorizzazzjoni għad-distribuzzjoni bl-ingrossa ta' prodotti veterinarji mill-kumpanija involuta fil-proċess.

(3) F'dawk il-każijiet li jinvolvu attività ta' manifattura b'rabta ma' prodotti impurtati li huma maħsuba biss għall-esportazzjoni mill-ġdid, hija meħtieġa awtorizzazzjoni ta' manifattura, anke jekk l-operazzjonijiet jiġu affettwati ġewwa l-port ħieles, f'żona ta' negozju liberu jew fid-dwana (maħżen ikkontrollat). L-operazzjonijiet ta' tikkettar mill-ġdid u/jew twaħħil ta' tabelli fuq il-pakkett minn barra jaqgħu wkoll f'din il-kategorija.

(4) Is-Servizzi Veterinarji għandu jistabbilixxi proċeduri sabiex jassigura li jkun hemm konformità mar-rekwiżiti tas-subregolamenti (2) u (3).

(5) Il-prodotti mediċinali veterinarji impurtati għall-għan waħdieni ta' esportazzjoni mill-ġdid jistgħu jkunu eżentati milli jiksbu Awtorizzazzjoni ta' Kummerċjalizzazzjoni mis-Servizzi Veterinarji.

(6) L-awtorizzazzjoni biex wieħed jieħu sehem f'attività simili tingħata biss lil persuni li jkollhom fil-pussess tagħhom awtorizzazzjoni għal bejgħ bl-ingrossa ta' prodotti veterinarji u mingħajr preġudizzju lejn awtorizzazzjonijiet oħra li l-persuni jista' jkollhom, b'mod partikolari fir-rigward tar-rekwiżiti tar-Regolamenti dwar il-Kontroll ta' l-Importazzjoni.

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Liċenzji oħra li jistgħu jkunu meħtieġa minflok awtorizzazzjoni ta' manifattura u importazzjoni.

50D. Awtorizzazzjoni ta' manifattura mogħtija skont dawn ir-regolamenti ma teżenta lill-ebda persuna mill-ħtieġa li tikseb permess, liċenzja jew awtorizzazzjoni skont kif mitlub minn kwalunkwe liġi oħra.".

Jemenda r-regolament 58 tar-regolamenti prinċipali.

14. Minnufih wara t-tieni paragrafu tas-subregolament (1) tar-regolament 58 tar-regolamenti prinċipali għandu jiżdied il-paragrafu ġdid li ġej:

"Meta s-sitwazzjoni tas-suq f'Malta tkun tali li twassal għal problemi temporanji tal-forniment għal prodott mediċinali veterinarju awtorizzat, l-akkwist ta' kwantitajiet żgħar tal-istess prodott mediċinali veterinarju awtorizzat, jew prodott mediċinali veterinarju essenzjalment simili, minn kirurgu veterinarju huwa permess u eskluż mill-iskop ta' definizzjoni ta' distribuzzjoni bl-ingrossa:

Iżda meta kirurgu veterinarju jirrikorri għal dan ir-regolament, irid ikollu l-mezzi xierqa biex iżomm ruħu infurmat mill-fornitur tiegħu dwar kull tip ta' lott li jiġi msejjaħ lura mis-

suq jew prodott u reazzjonijiet avversi għall-mediċina.".

Jenumera mill-ġdid it-Titolu VII u t-Titolu VIII tar-regolamenti prinċipali.

15. It-Titolu VII u t-Titolu VIII tar-regolamenti prinċipali għandhom jigu enumerati mill-ġdid bħala t-Titolu X u t-Titolu XI rispettivament.

Iżid Titolu u regolament ġdid mar-regolamenti prinċipali.

16. Minnufih wara r-regolament 58 tar-regolamenti prinċipali għandu jiżdied it-Titolu u r-regolament ġdid li ġej:

"TITOLU VII
PROVVISTA BL-IMNUT TA' PRODOTTI MEDIĊINALI VETERINARJI

Forniment bl-imnut ta' prodotti mediċinali veterinarji.

58A. Fit-territorju ta' Malta, il-forniment bl-imnut ta' prodotti mediċinali veterinarji għandha sseħħ biss minn spiżeriji veterinarji, stabbilimenti veterinarji liċenzjati, stabbilimenti oħra msemmija fir-regolament 60(4)(d) u minn kirurgi veterinarji meta jagħmlu viżti fuq il-post.".

Jissostitwixxi r-regolament 59 tar-regolamenti prinċipali.

17. Minnufih wara r-regolament 58A tar-regolamenti prinċipali għandu jiżdied it-Titolu ġdid li ġej:

"TITOLU VIII
REGOLAMENTI DWAR L-IDDISPENSAR".

18. Ir-regolament 59 tar-regolamenti prinċipali għandu jiġi sostitwit bir-regolament ġdid li ġej:

"Id-dispensar minn spiżjara, kirurgi veterinarji, u persuni kompetenti kwalifikati.

59. (1) Fit-territorju ta' Malta, id-dispensar tal-prodotti mediċinali veterinarji għandu jsir biss skont id-dispożizzjonijiet ta' dan ir-regolament.

(2) Kirurgi veterinarji jistgħu jiddispensaw prodotti mediċinali veterinarji meta jissejħu fuq il-post mis-sid/mill-indokratur/minn min iżomm l-annimali fl-istabbiliment veterinarju liċenzjat u matul viżti fuq il-post għall-kura tal-annimali fil-kustodja tagħhom.

(3) Kirurgi veterinarji għandhom jiddispensaw prodott mediċinali veterinarju fit-tali kwantitajiet li jkunu meħtieġa għat-trattament tal-kundizzjoni, fejn id-dewmien fl-amministrazzjoni tal-prodott tista' taffettwa b'mod avvers is-saħħa tal-annimal:

Iżda l-kirurgu veterinarju ghandu jissupplixxi l-kwantitajiet tal-prodott mediċinali veterinarju għat-trattamenti jew il-kundizzjonijiet ta' annimali li jaqgħu taħt il-kura tiegħu biss. Jekk it-tip ta' ppakkjar ikun tali li l-kirurgu veterinarju ma jkunx jista' jissupplixxi kwantità iżgħar minnu, il-kirurgu veterinarju jista' jissupplixxi lil sid l-annimal/l-indokratur/min jieħu ħsieb l-annimal il-kwantitajiet meħtieġa għat-trattament sħiħ tal-kundizzjoni:

Iżda wkoll li dak imsemmi hawn fuq jista' ma japplikax għal prodott mediċinali veterinajru li huwa rregolat bi strumenti speċifiċi.

(4) Prodott mediċinali veterinarju jista' jiġi ddispensat biss minn postijiet imsemmija fir-regolament 60.

(5) Id-distributuri għandhom jintalbu jżommu rendikont aġġornat tal-prodotti mediċinali veterinarji jew it-trattamenti li jistgħu jiġu pprovduti biss permezz tar-riċetta, bl-informazzjoni li ssegwi tiġi rrekordjata għal kull tranżazzjoni li tidħol jew li toħroġ:

(a) data tat-tranżazzjoni;

(b) isem tal-prodott mediċinali veterinarju inkluż, skont il-każ, il-forma farmaċewtika u l-qawwa tiegħu;

(ċ) in-numru tal-lott;

(d) il-kwantità li jirċievu jew li jissupplixxu;

(e) isem jew isem il-kumpanija u l-indirizz permanenti jew il-post tan-negozju rreġistrat tal-fornitur f'każ ta' xiri, jew tar-reċipjent f'każ ta' bejgħ;

(f) isem u dettalji ta' kuntatt tal-kirurgu veterinajru li jagħmel ir-riċetta u, skont il-każ, kopja tar-riċetta veterinarja;

(g) in-numru tal-awtorizzazzjoni ta' kummerċjalizzazzjoni.

Minn tal-anqas darba fis-sena għandu jsir awditjar dettaljat, u prodotti mediċinali veterinarji li jidħlu kif ukoll li joħorġu u prodotti oħra li jingħataw bir-riċetta għandhom jiġu rrikonċiljati mal-prodotti li jkun hemm attwalment fl-istokk, kull diskrepanza għandha tiġi mniżżla fir-reġistru appożitu. Dan ir-rendikont għandu jkun aċċessibbli għal spezzjoni mis-Servizzi Veterinarji għal perjodu ta' mhux anqas minn ħames (5) snin.

(6) Meta ssir distribuzzjoni ta' prodott mediċinali veterinarju, id-distributur għandu jkun sodisfatt li l-persuna li tkun ser tuża l-prodott hija kompetenti biex tagħmel dan b'mod sigur, u għandha l-intenzjoni li tużah għall-iskop li huwa awtorizzat għalih jew kif indikat mill-kirurgu veterinarju.

(7) Meta ssir distribuzzjoni ta' prodott mediċinali veterinajru, id-distributur għandu jinforma lil min jirċievi l-prodott bid-doża, l-amministrazzjoni sigura tal-prodott jew xi avviżi jew kontro-indikazzjonijiet fuq it-tabella jew fuq il-fuljett fil-pakkett, inkluż informazzjoni fuq kwalunkwe perjodu/i ta' irtirar applikabbli.

(8) Jekk id-distributur jissupplixxi ammont ta' prodott mediċinali veterinarju li huwa anqas mid-doża indikata fuq il-pakkett, il-kirurgu veterinarju jista' jiftaħ pakkett li jkun fih prodott għal skopijiet ta' forniment, għajr l-ippakkjar immedjat ta' prodott mediċinali injettabbli.

(9) Meta ssir distribuzzjoni ta' aġent antimikrobiku, id-distributur għandu jkun sodisfatt li jkunu ttieħdu l-prekawzjonijiet meħtieġa biex ikunu imnaqqsa r-riskji ta' reżistenza antimikrobika u li jkun ġie kkunsidrat l-użu prudenti tal-aġent antimikrobiku, b'mod partikolari fl-użu ta' antimikrobiċi kritikalment importanti.

(10) Jekk id-distributur ikollu xi dubji fuq il-kontenut ta' riċetta veterinarja għandu jsolvihom mal-kirurgu veterinajru li jkun ħareġ ir-riċetta qabel jissupplixxi l-prodott.

(11) Jekk prodott mediċinali veterinarju huwa pprovdut f'kontenitur ieħor li mhux dak speċifikat fl-awtorizzazzjoni tal-kummerċjalizzazzjoni, il-kirurgu veterinarju li jissupplixxi l-prodott għandu jassigura li l-kontenitur huwa mmarkat kif xieraq u għandu jipprovdi biżżejjed informazzjoni bil-miktub bil-għan li l-prodott ikun jista' jintuża b'mod sigur.

(12) Il-kirurgu veterinarju msemmi fir-regolament 79(2) għandu jkun responsabbli għall-armarju fejn jinżammu l-prodotti mediċinali veterinarji. B'mod partikolari, għandhom jiġu mħarsa l-kundizzjonijiet tal-ħażna, tat-traċċabilità u r-rekwiżiti ta' żamma ta' informazzjoni.

(13) Kirurgu veterinarju li jissupplixxi prodott mediċinali veterinarju għandu jkun preżenti meta l-prodott jiġi mogħti lill-klijent, sakemm il-kirurgu veterinajru:

(a) jawtorizza kull tranżazzjoni b'mod individwali qabel ma jiġi pprovdut il-prodott;

(b) huwa sodisfatt li l-persuna li qed tagħtih lill-klijent hija kompetenti li tagħmel dan.

(14) Għandhom jingħataw biss prodotti mediċinali veterinarji li ma skadewx.

(15) Id-dispożizzjonijiet tal-paragrafu (e) tas-subregolament (5) paragrafu għandhom jidħlu fis-seħħ mill-1 ta' Novembru 2021.".

Iżid Titolu u regolament ġdid mar-regolamenti prinċipali.

19. Minnufih wara r-regolament 59 tar-regolamenti prinċipali għandu jiżdied it-Titolu u r-regolament ġdid li ġej:

"TITOLU IX
REGOLAMENTI DWAR PRESKRIZZJONIJIET

Preskrizzjoni maħruga minn kirurgi veterinarji.

59A. (1) Fit-territorju ta' Malta kirurgi veterinarji jistgħu jippreskrivu biss prodotti mediċinali veterinarji skont id-dispożizzjonijiet ta' dan ir-regolament.

(2) Fir-territorju ta' Malta, il-preskrizzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali għall-annimali għandha ssir biss minn kirurgi veterinarji.

(3) Il-preskrizzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali għall-annimali għandha ssir biss fuq il-preskrizzjonijiet veterinarji.

(4) Kirurgi veterinarji jistgħu jippreskrivu biss prodott mediċinali veterinarju jew prodott mediċinali għall-annimali li jkunu eżaminaw huma nfushom u għandhom jerfgħu responsabbiltà klinika għat-trattament tal-annimali fil-kura tagħhom.

(5) Prodott mediċinali veterinajru jew prodott mediċinali jista' ma jintużax għal trattament wieħed biss skont l-istess preskrizzjoni.

(6) Qabel il-preskrizzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali li jeħtieġ preskrizzjoni, il-kirurgi veterinarji għandhom jagħmlu viżta klinika tal-annimal fil-kura tagħhom.

(7) Il-viżta klinika mill-kirurgi veterinarji għandu jsir riċentament biżżejjed għall-kirurgi veterinajri biex ikollhom għarfien personali dwar il-kundizzjoni tal-annimal jew l-istat ta' saħħa preżenti tal-bhejjem jew merħla biex tkun tista' ssir djanjosi ta' min joqgħod fuqha jew jibda t-trattament empiriku.

(8) Qabel il-preskrizzjoni ta' prodott mediċinali veterjinarju jew prodott mediċinali, il-kirurgi veterinarji għandhom qabel xejn jissodisfaw lilhom infushom li:

(a) l-użu tal-prodott mediċinali veterinarju jew il-prodtt mediċinali huwa ġustifikat għall-ispeċi kkonċernati fuq bażi veterinarja;

(b) l-amministrazzjoni tal-prodott mediċinali veterinjarju jew il-prodott mediċinali mhix inkompatibbli ma' trattament jew użu preċedenti u li mhemm l-ebda kontro-indikazzjoni jew interazzjoni meta jintużaw għadd ta' ikel imħallat mal-mediċina għal-lest;

(ċ) il-prodott mediċinali veterinarju jew il-prodott mediċinali huma preskritti biss f'tali kwantitajiet kif meħtieġ għall-iskop ta' trattament;

(d) ikunu ttieħdu l-prekawzjonijiet kollha meħtieġa biex jiġu mnaqqsa r-riskji ta' reżistenza antimikrobika u li jkun ġie kkunsidrat l-użu prudenti tal-aġent antimikrobiku, b'mod partikolari fl-użu ta' antimikrobiċi kritikalment importanti.

(9) Meta ssir preskrizzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali, il-kirurgi veterinarji għandhom ikunu sodisfatti li l-persuna li ser tuża l-prodott hija kompetenti biex tagħmel dan b'mod sigur u għandha l-intenzjoni li tużah għall-iskop li huwa awtorizzat għalih.

(10) Meta ssir preskrizzjoni ta' aġenti antimikrobiċi, il-kirurgi veterinarji għandhom jikkonsidraw l-aktar linjigwida riċenti maħruġa mis-Servizzi Veterinajri, u organizzazzjonijiet oħra nazzjonali, Ewropej jew Internazzjonali relevanti fir-rigward ta' antimikrobiċi kritikalment importanti.

(11) Waqt il-preparazzjoni ta' preskrizzjoni veterinarja, il-kirurgu veterinarju għandu jinforma lil min se jirċievi l-preskrizzjoni fuq l-amministrazzjoni sigura tal-prodott preskritt u fuq kwalunkwe avviżi jew kontra-indikazzjonijiet assoċċjati mal-prodott.

(12) Prodott mediċinali veterinarju klassifikat bħala soġġett għal preskrizzjoni veterinarja jista' jiġi amministrat mingħajr preskrizzjoni veterinarja personalment mill-kirurgu veterinarju. Dan ma jipprekludix kirurgi mill-obbligazzjonijiet ta' żamma ta' informazzjoni msemmija fir-regolament 59(6).

(13) Il-preskrizzjonijiet veterinarji għandhom ikunu konformi mal-linjigwida li jkunu ħarġu mis-Servizzi Veterinarji.".

Jemenda r-regolament 60 tar-regolamenti prinċipali.

20. Ir-regolament 60 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) minnufih wara s-subparagrafu (ii) tal-paragrafu (a) tas-subregolament (1) tiegħu għandu jiżdied is-subparagrafu ġdid li ġej:

"(iii) prodotti mediċinali veterinarji li ma jaqgħux fi ħdan il-klassifikazzjoni tar-regolament 60(1)(a)(i), (b) u (ċ) iżda madanakollu huma meqjusa li jeħtieġu preskrizzjoni veterinarja għal perjodu temporanju.";

(b) minnufih wara l-paragrafu (h) tas-subregolament (2) tiegħu għandu jiżdied is-subparagrafu ġdid li ġej:

"(i) prodott mediċinali veterinarju klassifikat bħala mediċina mogħtija biss bi preskrizzjoni jista' jiġi eżentat milli jkun preskritt u ddispensat bi preskrizzjoni jekk ikun amministrat kollu kemm hu mill-kirurgu veterinarju responsabbli mill-annimal li ma jipproduċix ikel, li hu nnifsu jipprovdi l-prodott mediċinali veterinarju, u jekk sid l-annimal ma jitlobx espliċitament preskrizzjoni."u minnufih wara għandhom jiżdiedu s-subregolamenti ġodda li ġejjin:

"(3) Skont is-subregolament (1) għandu jkun hemm l- erba' (4) kategoriji ta' distribuzzjoni ta' prodotti mediċinali veterinarji li ġejjin:

(a) mediċina soġġetta għal Preskrizzjoni Medika, Kirurgu Veterinarju u Spiżjar- imqassra għal **POM-VP;**

(b) mediċina soġġetta għal Preskrizzjoni Medika, Kirurgu Veterinajru- mqassra għal **POM-V;**

(ċ) prodott Mediċinali mhux bi Preskrizzjoni, mqassra għal **OTC;**

(d) bejgħ Ġenerali, mqassra għal **GS.**

(4) Il-forniment ta' prodotti mediċinali veterinarji għal kull kategorija ta' distribuzzjoni għandha ssir bil-mod segwenti:

(a) POM-VP, għandha tiġi preskritta biss u/jew iddispensata minn kirurgu veterinajru jew iddispensata minn spiżjar skont it-termini tal-preskrizzjoni veterinarja. Postijiet minn fejn dawn il-prodotti jistgħu jiġu pprovduti huma spiżeriji veterinarji, stabbilimenti veterinarji liċenzjati, u minn kirurgu veterinarju waqt viżti fuq il-post;

(b) POM-V għandha tiġi preskritta biss, iddispensata u amministrata minn kirurgu veterinarju. Postijiet minn fejn dawn il-prodotti jistgħu jiġu pprovduti huma stabbilimenti veterinarji liċenzjati, u minn kirurgu veterinarju waqt viżti fuq il-post;

(ċ) OTC, tista' tiġi ddispensata mingħajr preskrizzjoni veterinarja. Il-persuni li jistgħu jiddispensaw din il-kategorija ta' prodotti mediċinali veterinarji huma kirurgi veterinarji, spiżjara u persuni kwalifikati kif meħtieġ skont l-ordni ta' spiżjar jew kirurgu veterinarju. Postijiet minn fejn dawn il-prodotti jistgħu jiġu pprovduti huma spiżeriji veterinarji, stabbilimenti veterinajri liċenzjati, u minn kirurgu veterinajru waqt viżti fuq il-post;

(d) GS, tista' tiġi ddispensata mingħajr preskrizzjoni veterinarja. Il-persuni li jistgħu jiddispensaw din il-kategorija ta' prodotti mediċinali veterinarji huma kirurgi veterinarji, spiżjara jew persuni kwalifikati kif meħtieġ. Prodotti li jaqgħu f'din il-kategorija jistgħu jiġu pprovduti minn spiżeriji veterinarji, stabbilimenti veterinarji, pet shops irreġistrati, bejjiegħa bl-imnut irreġistrati ta' ħut tal-akwarju u kummerċjanti approvati fejn jiġi prodott, mibjugħ jew innegozjat għalf immedikat għall-annimali:

Iżda s-Servizzi Veterinarji jista' jagħmel rekwiżiti biex jippermetti li prodotti klassifikati f'din

il-kategorija jiġu provduti minn postijiet oħra minbarra dawk imniżżla hawn fuq biex jagħmel tajjeb għal nuqqasijiet fil-forniment u jiffaċilita l-aċċess għat-trattament biex ma jkunx ta' detriment għall-kura tal-annimal. It-tali postijiet ma jistgħux ikunu ħwienet ġeneriċi u għandhom jaqgħu fir-responsabbiltà ta' persuna bl-esperjenza ta' mhux anqas minn sentejn (2) fl-immaniġġjar ta' prodotti mediċinali veterinarji ta' din il-kategorija.

(5) Is-Servizzi Veterinarji għandu jikkategorizza l-kategoriji ta' distribuzzjoni ta' prodotti mediċinali veterinarji meta jawtorizza prodotti mediċinali veterinarji.

(6) Meta jiddeċiedi fuq il-kategorija ta' distribuzzjoni ta' prodott mediċinali veterinarju, is-Servizzi Veterinajri jista' jitlob parir mingħand kumitati ta' esperti fil-qasam u jista' jikkonsidra l-linjigwida ta' korpi oħra relevanti kemm mil-lat Nazzjonali, Ewropew jew Internazzjonali, skont kif jiġi deċiż mis-Servizzi Veterinarji.

(7) Minkejja dak li jiġi deċiż waqt il-proċedura inizzjali ta' Awtorizzazzjoni ta' Kummerċjalizzazzjoni, is-Servizzi Veterinarji jista' jibdel il-kategorija ta' distribuzzjoni ta' prodott mediċinali veterinarju kemm fuq talba mad-detentur tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni jew minħabba varjazzjoni obbligatorja.

(8) Is-Servizzi Veterinajri għandu jistabbilixxi l-kriterji għall-ikkategorizzar ta' prodott mediċinali veterinarju u jagħmilhom pubbliċi.

(9) Qisien differenti ta' pakketti tal-istess Awtorizzazzjoni ta' Kummerċjalizzazzjoni jistgħu jingħataw kategoriji ta' distribuzzjoni differenti.

(10) Meta l-kategorija ta' distribuzzjoni tal-prodott mediċinali veterinarju hija POM-V jew POM-VP din għandha tkun indikata fuq il-pakkett immedjat u/jew fuq barra tal-prodott b'mod leġibbli, u mingħajr karattri mħassra.

(11) Il-kliem li jispeċifika l-kategorija ta' distribuzzjoni tal-prodott mediċinali veterinarju u li

għandu jkun jinqara u ma jitħassarx, jistgħu jkunu stampati fuq il-pakkett immedjat u/jew fuq barra tal-prodott jew fuq tabella addattata li tidher sew.

(12) Kemm il-forma mqassra kif ukoll id-deskrizzjoni sħiħa tal-kategorija ta' distribuzzjoni tal-prodott mediċinali veterinarju preżenti fuq il-pakkett immedjat u/jew fuq barra tal-prodott għandhom ikunu aċċettabbli.

(13) Id-detentur tal-awtorizzazzjoni għad-distribuzzjoni bl-ingrossa għandu jqassam biss il-prodotti mediċinali veterinarji f'postijiet awtorizzati għall-bejgħ ta' prodotti mediċinali veterinarji skont dawn ir-regolamenti.

(14) Id-detentur tal-awtorizzazzjoni għad-distribuzzjoni bl-ingrossa għandhom iqassmu biss f'postijiet awtorizzati li jbigħu biss prodotti mediċinali veterinarji tal-kategorija/i ta' prodotti mediċinali veterinajri li huma awtorizzati li jinbigħu minn kull tip ta' post skont dawn ir-regolamenti.".

Jemenda r-regolament 62 tar-regolamenti prinċipali.

21. Ir-regolament 62 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) l-ewwel paragrafu tiegħu għandu jiġi sostitwit bil-paragrafu ġdid li ġej:

"Malta għandha tassigura illi s-sidien jew persuni li jieħdu ħsieb l-annimali li jipproduċu l-ikel jew persuni li jieħdu ħsieb annimali li huma magħluqa ġewwa postijiet, murija lin-nies jew miżmuma għat-trobbija, jistgħu jipprovdu evidenza ta' xiri, pussess u amministrazzjoni ta' prodotti mediċinali veterinarji ta' dawn l-annimali għall-ħames (5) snin wara l-amministrazzjoni tagħhom, inklużi wkoll meta l-annimal jiġi maqtul matul il-perjodu ta' ħames (5) snin.";

(b) minnufih wara l-kliem "It-territorju ta' Malta jista' jestendi l-iskop ta' dan l-obbligu lil prodotti mediċinali veterinarji" għandhom jiżdiedu l-paragrafi ġodda li ġejjin:

"Ir-rendikont għandu jinżamu b'mod elettroniku jew stampat. Kopji stampati għandhom jinżammu llegati jew fil-forma ta' *paper binders*. Kopji uffiċjali stampati jew mudelli elettroniċi jistgħu jingħataw mis-Servizzi Veterinarji. Ir-rendikont għandu jinżamm f'post addattat

fir-razzett u immedjatament aċċessibbli għal spezzjoni mis-Servizzi Veterinarji.

Prova tax-xiri tirreferi b'mod partikolari għall-fatturi u/jew l-irċevuti jew kull tip ta' dokument ieħor li jeżisti fil-forma stampata jew fil-forma elettronika li jipprovdi evidenza dokumentata ta' kif, meta u mingħand min ġew miġjuba l-prodotti mediċinali veterinarji jew il-prodotti mediċinali.";

(ċ) minnufih wara l-paragrafu (e) tiegħu għandhom jiżdiedu l-paragrafi ġodda li ġejjin:

"(f) f'xenarju fejn il-prodott mediċinali veterinarju ġie preskritt, jista' jkun wieħed minn dawn it-tliet xenarji possibli, trattament, profilattiku jew użu metafilattiku;

(g) Xjentifikament ġustifikat għaliex aġenti antimikrobiċi ġew rakkomandati mill-kirurgu veterinarju fil-każ ta' użu metafilattiku u/jew profilattiku.".

Jemenda r-regolament 64 tar-regolamenti prinċipali.

22. Fis-subregolament (1) tar-regolament 64, il-kliem "skont il-leġislazzjoni nazzjonali" għandhom jiġu mħassra.

Jemenda r-regolament 72 tar-regolamenti prinċipali.

23. Regolament 72 tar-regolamenti prinċpali għandu jiġi emendat kif isegwi:

(a) fis-subregolament (1) tiegħu, minnufih wara l-kliem "mal-prodotti mediċinali veterinarji" għandhom jiżdiedu l-kliem "u ta' kwalunkwe post fejn is-sustanzi attivi u l-prodotti mediċinali veterinarji huma manifatturati, imqassma, impurtati, esportati jew użati.";

(b) fl-ewwel paragrafu tas-subregolament (1) tiegħu, minnufih wara l-kelma "jistgħu jagħmlu wkoll" għandhom jiżdiedu l-kliem "fi kwalunkwe ħin raġonevoli" u minnufih wara l-kliem "Direttiva tal-Kusnill 2004/28/KE" għandhom jiżdiedu l-kliem "jew kwalunkwe dispożizzjoni oħra ta' dawn ir-regolamenti."; u

(ċ) minnufih wara s-subregolament (7) tiegħu għandu jiżdied is-subregolament ġdid li ġej:

"(8) Il-persuni responsabbli mill-postijiet imsemmija f'dan ir-regolament għandhom jippermettu d-dħul tar-rappreżentanti awtorizzati tas-servizzi veterinarji biex iwettqu d-dmirijiet tagħhom.".

24. Minnufih wara r-regolament 77 tar-regolamenti prinċipali għandu jiżdied ir-regolament ġdid li ġej: Iżid regolament ġdid mar-regolamenti prinċipali.

"Regolamenti fuq reklamar ta' prodotti mediċinali veterinarji.

77A. (1) Is-Servizzi Veterinarji għandu jippermetti r-reklamar ta' prodotti mediċinali veterinarji li skont ir-regolament 60, huma aċċessibbli permezz ta' preskrizzjoni veterinarja għal:

(a) kirurgi veterinarji u spiżjara;

(b) indokraturi professjonali tal-annimali, sakemm il-prodotti mediċinali veterinarji huma prodotti immunoloġiċi preventivi jew terapiji anti-helmintic.

(2) Is-Servizzi Veterinarji għandu jippermetti r-reklamar ta' prodotti mediċinali veterinarji għall-pubbliku inġenerali li, permezz tal-kompożizzjoni u l-iskop tagħhom, huma maħsuba u ddisinjati għall-użu bil-parir tal-ispiżjar, jekk meħtieġ, iżda mingħajr l-intervent ta' kirurgu veterinarju għal skopijiet ta' djanjosi jew għall-preskirzzjoni jew monitoraġġ tat-trattament.

(3) L-ebda persuna ma tista' tirreklama prodott mediċinali veterinarju għall-amministrazzjoni fuq l-annimali. Jista' jintbagħat materjal xjentifiku informattiv fuq talba tal-kirurgu veterinarju meta jiġu applikati d-dispożizzjonijiet tar-regolamenti 10 u 11. L-informazzjoni m'għandhiex tkun promozzjonali fin-natura tagħha u m'għandhiex tinkludi lista ta' prezzijiet.

(4) (a) Mhux permissibli li persuni jkunu jistgħu jissupplixxu prodotti mediċinali veterinarji lil kirurgi veterinarji jew sidien ta' spiżeriji f'tentattiv biex jippreskrivu jew jissupplixxu prodotti mediċinali veterinarji bħala rigal, offerta jew wegħda ta' kull tip ta' benefiċċju jew bonus, kemm fi flus jew in natura.

(b) Mhux permissibli li persuni jkunu jistgħu jissupplixxu prodotti mediċinali veterinarji biex jagħmlu kwalunkwe forma ta' ftehim kuntrattwali ma' indoktraturi tal-annimali li jibbenefikaw mill-bejgħ tal-prodotti tagħhom.

(ċ) Mhux permissibli li persuni jkunu jistgħu jissupplixxu prodotti mediċinali veterinarji biex jissolleċitaw jew jaċċettaw kull tip ta' premjijiet projbiti mis-subregolamenti 4(a) u 4(b). Madanakollu, il-miżuri eżistenti jew il-prattiċi tan-negozju marbuta mal-prezzijiet, marġini ta' profitti u skontijiet m'għandhomx jiġu affettwati.

(5) Ir-reklamar ta' prodott mediċinali veterinarju għandu:

(a) iħeġġeġ l-użu razzjonali ta' prodott mediċinali veterinarju, billi jippreżenta b'mod oġġettiv u mingħajr eseġerazzjonijiet il-proprjetajiet tiegħu;

(b) ikun konformi mal-partikolaritajiet imniżżla fis-sommarju tal-karatteristiċi tal-prodott;

(ċ) ma jkunx qarrieqi;

(d) ikun magħmul b'tali manjiera li juri biċ-ċar li l-messaġġ huwa wieħed ta' reklamar u li l-prodott huwa identifikat bħala prodott mediċinali veterinarju b'mod ċar;

(e) ma jagħtix l-impressjoni li mhemmx bżonn ta' kirurgu veterinarju, b'mod partikolari billi joffri djanjosi jew billi jissuġġerixxi trattament permezz tal-posta, l-internet jew kwalunkwe mezz ieħor;

(f) ma għandux jissuġġerixxi li l-effetti ta' amministrazzjoni tal-prodott mediċinali veterinarju huma garantiti, mhux akkumpanjati minn reazzjonijiet avversi jew huma aħjar, jew ekwivalenti għal, dawk ta' trattament ieħor jew prodott mediċinali veterinarju;

(g) ma jissuġġerix li s-saħħa tal-annimal tista' tissaħħaħ billi jingħata l-prodott mediċinali veterinarju;

(h) ma jissuġġerix li s-saħħa tal-annimal tista' tkun affettwata jekk ma jittiħedx il-prodott mediċinali veterinarju sakemm dan ma jkunx japplika għall-kampanji ta' vaċċinazzjoni;

(i) ma jissuġġerix li l-prodott mediċinali veterinarju huwa ikel, prodott kożmetiku jew prodott ieħor għall-konsum;

(j) ma jissuġġerix li s-sigurtà u l-effiċjenza tal-prodott mediċinali veterinarju hija riżultat tal-fatt li hu naturali;

(6) (a) Kull reklamar ta' prodott mediċinali veterinarju lil persuni kwalifikati biex jippreskrivu jew jissupplixxu t-tali prodotti għandu jinkludi:

(i) l-isem tad-ditta;

(ii) lista tal-ingredjenti attivi;

(iii) il-forma farmaċewtika;

(iv) indikazzjonijiet maġġuri għall-użu;

(v) id-doża u l-mod ta' użu;

(vi) effetti kollaterali, avvertenzi, prekawzjonijiet u kontro-indikazzjonijiet;

(vii) l-isem u l-indirizz mad-detentur tal-awtorizzazzjoni tal-kummerċjalizzazzjoni;

(viii) kwalunkwe riċerka u/jew pubblikazzjoni fuq l-użu tas-sustanzi attivi.

(b) L-informazzjoni kollha li jkun fiha d-dokumentazzjoni msemmija fis-subregolament (6) (a) għandha tkun preċiża, aġġornata, verifikabbli u xjentifikament kompluta biex tippermetti lir-reċipjent jifformola opinjoni personali fuq il-valur terapewtiku tal-prodott mediċinali veterinarju kkonċernat.

(ċ) Kwotazzjonijiet kif ukoll tabelli u kull tip ta' informazzjoni illustrativa meħudin minn xogħlijiet xjentifiċi għall-użu fid-dokumentazzjoni msemmija fis-subregolament (9)(a) għandha tkun lealment riprodotta.

(7) (a) Kampjuni bla ħlas għandhom jiġu provduti biss fuq bażi eċċezzjonali lil persuni kwalifikati biex jippreskrivuhom skont il-kondizzjonijiet li jsegwu:

(i) kull kampjun ma għandux ikun akbar mill-iżgħar preżentazzjoni fis-suq;

(ii) kull kampjun għandu jkun immarkat "kampjun bla ħlas – mhux għall-bejgħ";

(iii) kull kampjun għandu jkun akkumpanjat minn kopja tas-sommarju tal-karatteristiċi tal-prodott;

(iv) prodotti mediċinali veterinarji li jkun fihom sustanzi psikotropiċi jew narkotiċi skont kif definiti fl-Ewwel Skeda li tinsab mal-Ordinanza dwar il-Mediċini Perikoluż u t-Tielet Skeda li tinsab mal-Oridinanza dwar il-Professjoni Medika u l-Professjonijiet li għandhom x'jaqsmu magħha ma jistgħux jiġu mqassma bħala kampjuni;

Kap. 101.

Kap. 31.

(b) *Starter packs* m'għandhomx jitqiesu bħala kampjuni u m'għandhomx jiġu ttikkettati bħala tali.

(ċ) Waqt viżti li jsiru għand persuni minn rappreżentanti tal-bejgħ, dawn għandhom jingħataw l-informazzjoni dwar l-użu tal-prodotti mediċinali veterinarji, b'referenza partikolari għal kull tip ta' reazzjoni avversa.

(8) Il-persuna li tirreklama l-prodotti mediċiniali veterinajri għandha:

(a) żżomm aċċessibbli għal, jew tikkomuika mas-Servizzi Veterinarji, kampjun tar-reklami kollha maħruġa mill-kumpanija tagħha flimkien ma' stqarrija li tindika lill-persuni li tkun inidirizzata għalihom, il-metodu ta' disseminazzjoni u d-data tal-ewwel disseminazzjoni;

(b) tipprovdi lis-Servizzi Veterinarji l-informazzjoni u l-assistenza meħtieġa biex twettaq ir-responsabbiltajiet tagħha;

(ċ) tassigura li tkun konformi immedjatament u b'mod sħiħ mad-deċiżjonijiet li ttieħdu u l-kundizzjonijiet imposti mis-Servizzi Veterinarji.

(9) Mhux permissibli li jiġu rreklamati prodotti mediċinali veterinarji li mhux irreġistrati mas-Servizzi Veterinarji.".

Jemenda r-regolament 79 tar-regolamenti prinċipali.

25. Ir-regolament 79 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) is-subregolament (2) tiegħu għandu jiġi sostitwit bis-subregolament ġdid li ġej:

"(2) Għall-iskopijiet ta' dawn ir-regolamenti, kull stabbiliment irreġistrat jew illiċenzjat fejn jinżammu annimali li jipproduċu l-ikel u mhux esklużi mid-dispożizzjonijiet tar-Regolament fuq il-Kontrolli Uffiċjali (UE) 2017/625 mis-servizzi veterinarji, u l-istabbilimenti fejn jinżammu l-annimali għall-wiri lill-pubbliku jew għal skopijiet ta' tnissil fit-territorju ta' Malta għandu jkollhom programm xieraq ta' kontroll tas-saħħa tal-annimali iddisinjat u implimentat taħt ir-responsabbiltà ta' professjonist reġistrat mal-Kunsill tal-Kirurgi Veterinarji:

Iżda għandu jinżamm reġistru tal-professjonisti responsabbli għal kull programm ta' kontroll tas-saħħa tal-annimali mis-Servizzi Veterinarji.

Iżda wkoll minn żmien għal żmien, is-Servizzi Veterinarji jista' jippubblika r-rekwiżiti relatati mal-programmi ta' kontroll tas-saħħa tal-annimali fuq il-Gazzetta.";

(b) is-subregolament (3) tiegħu għandu jiġi sostitwit bis-subregolament ġdid li ġej:

"(3) Id-dispożizzjonijiet tas-subregolament (2) għandhom jidħlu fis-seħħ sentejn (2) mid-data meta jidħlu fis-seħħ dawn ir-regolamenti.".

Jenumera mill-ġdid it-Titolu IX u t-Titolu X tar-regolamenti prinċipali.

26. It-titolu IX u t-Titolu X tar-regolamenti prinċipali għandhom jiġu enumerati mill-ġdid bħala t-Titolu XIII u t-Titolu XIV rispettivament.

Iżid Titolu u regolament ġdid mar-regolamenti prinċipali.

27. Minnufih wara r-regolament 79 tar-regolamenti prinċipali għandhom jiżdiedu t-Titolu u r-regolament ġdid li ġej:

"TITOLU XII
AMMINISTRAZZJONI TA' PRODOTTI MEDIĊINALI VETERINARJI U PRODOTTI MEDIĊINALI GĦALL-ANNIMALI

Amministrazzjoni ta' prodotti mediċinali veterinarji u prodotti mediċinali għall-annimali.

79A. (1) F'sitwazzjoni estrema u/jew urġenti biex tnaqqas it-tbatija tal-annimali jew twaqqaf it-tixrid tal-mard kwalunkwe persuna tista' tamministra prodott mediċinali veterinarju jew prodott mediċinali li jeħtieġ preskrizzjoni veterinarja mingħaJr il-preskrizzjoni veterinarja jew l-istruzzjonijiet ta' amministrazzjoni tal-prodott minn kirurgu veterinarju.

(2) L-ebda persuna ma tista' tamministra, tissupplixxi għall-amministrazzjoni, prodott mediċinali veterinarju lill-annimali sakemm il-prodott ma jiksibx awtorizzazzjoni mis-Servizzi Veterinarji.

(3) Prodotti li l-effetti terapewtiċi tagħhom huma sempliċiment aneddotali għandhom jintużaw b'kawtela fuq l-annimali kollha. L-amministrazzjoni ta' dawn il-prodotti lil speċi li jipproduċu l-ikel hija soġġetta għal approvazzjoni mis-servizzi veterinarji. Is-servizzi veterinarji jista' jitlob lill-indokratur tal-annimali jipprovdi dejta kimika, dokumentazzjoni klinika u studji dwar il-possibiltà ta' impatt ambjentali qabel jiggarantixxi l-approvazzjoni.

(4) L-indokratur/is-sid/min jieħu ħsieb l-annimali għandu jżomm prova tax-xiri tal-prodotti kollha amministrati jew li huma maħsuba biex jiġu amministrati lill-annimali għat-trattament jew il-prevenzjoni ta' mard jew, jekk ma jkunux xtrawhom huma, evidenza dokumentata kif ġew miġjuba.

(5) Trattament antimikrobiku metafilattiku jew profilattiku jista' jkun permess skont ċerta kundizzjonijiet. L-użu preventiv ta' antimkrobiċi mhux permess.

(6) Ħlief f'sitwazzjonijiet ta' emerġenza, qabel issir preskrizzjoni ta' prodott mediċinali veterinarju jew prodott mediċinali li fihom aġent antimikrobiku li huwa kritikalment importanti għas-saħħa umana jew li hu wżat għat-trattament ta' infezzjonijiet fuq l-annimali li għalihom ma jeżisti l-ebda trattament effettiv alternattiv, il-kirurgu veterinajru li jippreskrivi l-prodott għandu jikkonsidra r-riżultati tal-informazzjoni djanjostika tal-laboratorju (iżolament patoġeniku, identifikazzjoni u l-antibijogrammi).

(7) L-ebda persuna ma tista' tamministra prodott mediċinali veterinarju jew prodott mediċinali lil speċi li tipproduċi l-ikel u jpoġġi lill-annimal għat-tbiċċir biex jiġi kkunsmat sakemm ma jkun osservat il-perjodu relevanti ta' distakk.

(8) Kumulazzjoni ta' prodotti antimikrobiċi, prodotti mediċinali veterinarji jew prodotti mediċinali fir-razzett biex jiġu amministrati aktar 'il quddiem, mhux permessa.

(9) L-użu ta' kombinazzjoni ta' antimikrobiċi għandu jkun imsaħħaħ b'mod xjentifiku.".

Jemenda r-regolament 82 tar-regolamenti prinċipali.

28. Is-subregolament (2) tar-regolament 82 għandu jiġi enumerat mill-ġdid bħala s-subregolament (2)(a) u minnufih wara għandhom jiżdiedu s-subregolamenti ġodda li ġejjin:

(b) Id-detentur tal-awtorizzazzjoni ta' kummerċjalizzazzjoni għandu jimplimenta sistema għall-irrekordjar u r-reviżjoni ta' lmenti flimkien ma' sistema effettiva għall-ġbir immedjat lura u fi kwalunkwe ħin il-prodotti mediċinali veterinarji li jagħmlu parti min-netwerk ta' distribuzzjoni.

(ċ) Jirrekordja u jinvestiga kwalunkwe lment li jikkonċerna difett fil-kwalità.

(d) Is-Servizzi Veterinarji għandu jiġi informat mit-tenut tal-Awtorizzazzjoni ta' Kummerċjalizzazzjoni bi kwalunkwe difett fil-kwalità li tista' tirriżulta fi ġbir lura jew restrizzjoni anormali fuq il-forniment. Fejn huwa possibli, għandhom jiġu indikati wkoll il-pajjiżi fejn il-prodotti jiġu kummerċjalizzati.".

Jissostitwixxi r-regolament 87 tar-regolamenti prinċipali.

29. Ir-regolament 87 tar-regolamenti prinċipali għandu jiġi

sostitwit bir-regolament ġdid li ġej:

"Rimi tal-iskart ta' prodotti mediċinali veterinarji użati.

87. (1) Kull persuna li fil-perkors tal-attività tagħha tiġġenera skart ta' prodotti mediċinali veterinarji, għandha tinforma lilha nnifisha bil-proċeduri preżenti b'rabta mar-rimi sigur ta' prodotti mediċinali mhux użati, mhux addattati jew skaduti mill-entità responsabbli għall-immaniġjar tal-iskart f'Malta u għandha ssegwi l-linjigwida maħruġa mis-servizzi veterinarji.

(2) Kumpaniji, stabbilimenti kbar u korpi professjonali għandhom jiddeskrivu l-proċedura li jsegwu għar-rimi sigur ta' prodotti mediċinali veterinarji mhux użati, mhux addattati jew skaduti, bil-miktub, u jżommuha aġġornata skont ir-rekwiżiti li jistgħu jinbidlu minn żmien għal żmien.

(3) Is-Servizzi Veterinajri għandu jassigura li produtturi tal-iskart ta' prodotti mediċinali veterinarji għandhom il-proċeduri xierqa stabbiliti għar-rimi ta' prodotti mediċinali veterinarji mhux użati, mhux addattati jew skaduti skont il-liġijiet ta' Malta u kwalunkwe istruzzjoni partikolari deskritta fis-sommarju tal-karatteristiċi tal-prodott.".

Iżid regolament ġdid mar-regolamenti prinċipali.

30. Minnufih wara r-regolament 87 tar-regolamenti prinċipali għandhom jiżdiedu r-regolamenti ġodda li ġejjin:

"Reati u pieni.

88. Kull persuna li tikser ir-regolamenti 5(1), 39(1)(a)(b), 39(2)(a), 39(3), 46(1), 50B, 50C, 58(1), 58A, 59(1), 59A(2), 59A(3), 60(13), 60(14), 62 u 77A(4) għandha tkun ħatja ta' reat kontra l-artikolu 38 tal-Att u teħel, meta tinstab ħatja, multa ta' mhux inqas minn ħamest elef euro (€5,000) u mhux aktar minn għaxart elef euro (€10,000).

89. Kull persuna li tikser ir-regolamenti 39(3), 59A(2) u 59A(3), għandha tkun ħatja ta' reat kontra l-artikolu 38 tal-Att u teħel, meta tinstab ħatja, multa ta' mhux inqas minn tlett elef euro (€3,000) u mhux aktar minn sebat elef euro (€7,000).

90. Kull persuna li tikser ir-regolament 72(8) għandha tkun ħatja ta' reat kontra l-artikolu 35 tal-Att u teħel, meta tinstab ħatja, multa ta' mhux inqas minn tlett elef euro (€3,000) u mhux aktar minn sebat elef euro (€7,000).

91. Kull persuna li tikser ir-regolamenti 27A, 46(1), 50B, 50Ċ, 59(1), 60(13), 60(14), 62 u 77A(4) għandha tkun ħatja ta' reat kontra l-artikolu 38 tal-Att u teħel, meta tinstab ħatja, multa ta' mhux inqas minn ħames mitt euro (€500) u mhux aktar minn elf euro (€1,000).

Reati oħra.

92. Kull persuna li tikser kwalunkwe regolament minbarra dawk imsemmija fir-regolament 88, 89, 90 u 91 għandha tkun ħatja ta' reat u teħel, meta tinstab ħatja, multa ta' mhux anqas minn mitejn euro (€200) u mhux aktar minn erba' mitt euro (€400).

93. Meta d-Direttur ikollu raġuni biex jemmen li reat kontra dawn ir-regolamenti jkun ġie mwettaq u li jkun xieraq li jimponi piena amministrattiva taħt l-artikolu 61 tal-Att, id-Direttur għandu jipproċedi skont id-dispożizzjonijiet tal-imsemmi artikolu 61 tal-Att.".

Emendi għar-regolamenti prinċipali.

31. Ir-regolamenti prinċipali għandhom jiġu emendati kif ġej:

(a) il-kelma "veterinarju", kull fejn tokkorri, għandha tiġi sostitwitabil-kliem "kirurgu veterinarju";

(b) il-kelma "veterinarji", kull fejn tokkorri, għandha tiġi sostitwita bil-kliem "kirurgi veterinarji";

(ċ) il-kliem "territorju ta' Malta", kull fejn jokkorru bl-eċċezzjoni tal-istess kliem użati fit-tifsira tat-terminu "Servizzi Veterinarji" fir-regolament 2 u fir-regolament 51, għandhom jiġu sostitwiti bil-kelma "Direttur"; u

(d) il-kelma "Komunità", kull fejn tokkorri bl-eċċezzjoni tal-istess kelma użata fir-fis-subregolament (2) tar-regolament 1 u fir-regolament 30 għandhom jiġu sostitwiti bil-kelma "Unjoni".

L.N. 179 of 2021

VETERINARY SERVICES ACT
(CAP. 437)

Veterinary Medicinal Products (Amendment) Regulations, 2021

IN EXERCISE of the powers conferred by articles 30, 38 and 53 of the Veterinary Services Act, the Minister for Agriculture, Fisheries, Food and Animal Rights after consultation with the Head of the National Veterinary Laboratory, has made the following regulations:-

Citation and scope.

S.L. 437. 47.

1. (1) The title of these regulations is Veterinary Medicinal Products (Amendment) Regulations, 2021 and these regulations shall be read and construed as one with the Veterinary Medicinal Products Regulations, hereinafter referred to as "the principal regulations".

(2) The scope of these regulations is to add a number of essential provisions in the "principal regulations" in order to provide a more adequate and modern legal framework for the regulation and control of veterinary medicinal products.

Amends regulation 2 of the principal regulations.

2. Regulation 2 of the principal regulations shall be amended as follows:

(a) immediately before the definition "animal" there shall be added the following new definitions:

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

"advertising of veterinary medicinal products" means the making of a representation in any form in connection with veterinary medicinal products in order to promote the supply, distribution, sale, prescription or use of veterinary medicinal products and comprising also the supply of samples and sponsorships;

"Agency" means the European Medicines Agency established by Regulation (EC) No 726/2004;";

(b) the definition "the Commission" shall be substituted by the following new definition:

" "Commission" means the Commission in accordance with Council Decision 1999/468/EC of 28th June, 1999;";

(c) immediately after the definition "Commission" there shall be added the following new definition:

" "Director for Veterinary Services" means the Director for Veterinary Services as defined in the Veterinary Services Act, and includes, to the extent of the authority given, to any officer authorised by him, in writing, to act on his behalf for any of the purposes mentioned in the Veterinary Services Act. Whenever in the text the words "Veterinary Services" are used these should be construed as referring to the "Director for Veterinary Services";"; and immediately thereafter there shall be added the following new definitions:

Cap. 437.

" "dispensing" means the sale or supply of veterinary medicinal products. The products are sold or supplied from a veterinary pharmacy or by a veterinary surgeon in licensed veterinary establishments or during out calls;

"European Union" means the European Union as referred to in the Treaty;";

(d) immediately after the definition "feeding stuffs" there shall be added the following new definition:

" "food" shall have the same meaning as assigned to it in the Food Safety Act;";

Cap. 449.

(e) immediately after the definition "importation" there shall be added the following new definitions:

" "imported veterinary medicinal products" means veterinary medicinal products obtained from a source outside the EU;

"licensed veterinary establishment" has the same meaning as assigned to it in the Private Veterinary Establishments (Licensing) Regulations;";

S.L. 437. 106.

(f) immediately after the definition "lifelong learning"

there shall be added the following new definitions:

" "Medicinal products" shall have the same meaning as is assigned to in the Medicines Act;

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"Member State" means a State which is a member of the European Union;

"Metaphylactic" means the administration of a veterinary medicinal product or a medicinal product to a group of animals after a diagnosis of clinical disease in part of the group has been established, with the aim of treating the clinically sick and controlling the spread of the disease to animals in close contact and at risk and which may already be sub clinically infected;";

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

" "Narcotic drugs" means the substances present on the Yellow List prepared by the International Narcotics Control Board in accordance with the Single Convention on Narcotic Drugs, 1961, Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs, 1961;";

(h) the definition "pharmacist" shall be substituted by the following new definition:

" "Pharmacist" means a person who is enlisted in the Register of Pharmacists kept by the Pharmacy Council in terms of article 17 of the Health Care Professions Act;";

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(i) immediately after the definition "placing on the market" there shall be added the following new definitions:

" "placing under official control" means the detaining of any article by the Director for Veterinary Services in order to permit the accomplishment of any of its functions;

"prescribing" means the act of preparing a veterinary prescription by a veterinary surgeon being it on paper or electronic media;

"preventive use of an antimicrobial agents" means the

administration of antimicrobial agents to healthy animals to prevent infections to compensate for inadequate good farming practice;";

(j) immediately after the definition "private veterinary activity" there shall be added the following new definitions:

" "procurement" means the act of acquiring, for profit or not, a veterinary medicinal product, or part thereof, from a Member State of the European Union;

"prophylactic administration of antimicrobials" means the administration of a veterinary medicinal product or a medicinal product to an animal or group of animal before clinical signs of a disease, in order to prevent the occurrence of disease or infection:

"psychotropic drugs" means the substances listed in the Third schedule to the Medical and Kindred Professions Ordinance and those substances listed on the Green List prepared by International Narcotics Control Board in accordance with the Convention on Psychotropic Substances of 1971;

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"source country" means a Member State of the EU or a country in the European Economical Area from where the veterinary medicinal products referred to in regulation 7 can be procured;";

(k) immediately after the definition "State veterinary activities" there shall be added the following new definition:

" "Suitably Qualified Persons" means that person who has a qualification in a veterinary science and included in one of the para-veterinary professions mentioned in the Act;";

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

" "Treaty" shall have the same meaning as is assigned to it in the European Union Act;

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"veterinary pharmacy" means the premises from where veterinary medicinal products are, dispensed directly to the public except for licensed veterinary establishments;

"veterinary prescription" means a document issued by a veterinary surgeon for a veterinary medicinal product or a medicinal product for human use for its use in animals;";

(m) immediately after the definition "veterinary services" there shall be added the following new definition:

" "veterinary surgeon" means a person as described and regulated by article 43 of the Act and whose name is entered in the Register of Veterinary Surgeons' Register, or that person, coming from any other Member State of the European Union, whose name is entered in the relevant register kept by the relevant body of that Member State which regulates the profession of Veterinary surgeons. In the latter case the provisions of the Mutual Recognition of Qualifications Act and the Services (Internal Market) Act shall apply;"; and

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Cap. 500.

(n) immediately after the definition veterinary medicinal product" there shall be added the following new definition:

" "veterinary wholesale dealer" means that person authorised to carry out wholesale distribution of veterinary medicinal products;".

3. Paragraph (e) of sub-regulation (1) of regulation 3 of the principal regulations shall be deleted.

Amends regulation 3 of the principal regulations.

4. Immediately after sub-regulation (2) of regulation 4 of the principal regulations, there shall be added the following new sub-regulations:

Amends regulation 4 of the principal regulations.

"(3) In order to be granted the exemption for the veterinary medicinal product referred to in this sub-regulation applicants shall submit an application with the Veterinary Services.

(4) In order to qualify under the exemption described in this sub-regulation (2) the product must be manufactured by:

(a) the holder of a manufacturing authorisation if manufactured in Malta or in another Member State of the European Union;

(b) the holder of a relevant licence conferring authorisation to manufacture veterinary medicinal products if the product is manufactured in a Third country.

(5) The product must not be classified as requiring a veterinary prescription.

(6) The manufacturer, importer, wholesale dealer or retailer of a veterinary medicinal product shall declare that he will notify the Veterinary Services within fifteen (15) days of learning of any serious adverse reactions in accordance with sub-regulations (2) and (3) of regulation 68. A record of each adverse reaction and serious adverse reaction must be maintained on becoming aware of it. The records shall be kept for five (5) years.

(7) The Veterinary Services shall prepare and publish a list of active substances that can be used in veterinary medicinal products authorised under sub-regulation (2), specifying the species of non-food producing animals for which it is approved and may specify how the active substance or a product containing the active substances to be administered.

(8) The Veterinary Services may decide not to apply the provisions of this Regulation to a previously exempted product if any one or more of the following occur:

(a) serious adverse reactions are reported;

(b) it is demonstrated, at any time after authorisation, that the substance is carcinogenic, genotoxic or that it shows developmental toxicity (including teratogenicity);

(c) the product contain active substances that are re-classified as narcotic or psychotropic substances;

(d) any one of the ingredient/s in the product is/are not included anymore in the list mentioned in paragraph (d) of sub-regulation (3);

(e) it is reported and is verified by the Veterinary Services that the product is not being used on the animals mentioned in sub-regulation (2);

(9) The product authorised under sub-regulation (2) shall be clearly labelled as being exempt from the requirements of regulations 5, 6, 7 and 8 in relation to a Marketing Authorisation. The information obtainable from the whole pack must at least show the following details:

(a) the name of the veterinary medicinal product;

(b) the pharmaceutical dosage form;

(c) the name and strength of each active substance;

(d) the route of administration;

(e) the batch number;

(f) the expiry date;

(g) a sentence to the effect of "For administration on non-food producing animals only" authorised in accordance to regulation 4(2) of these regulations;

(h) the target species;

(i) storage instructions;

(j) the shelf-life after the immediate packaging has been opened for the first time;

(k) therapeutic indications;

(l) contra-indications;

(m) interaction with other medicines and other forms of interaction;

(n) dosage instructions.

(10) If there is sufficient room on the label, the information may be present only on it without the need of a package leaflet. The information must be conveyed in a clear and legible manner.

(11) The provisions of sub-regulation 5 shall come into force on the 1st November 2021.".

Adds new regulation to the principal regulations.

5. Immediately after regulation 4 of the principal regulations, there shall be added the following new regulations:

Veterinary medicinal products for research purposes.

"4A. (1)A veterinary medicinal product may be obtained from any country and administered to animals for research purposes in accordance with article 53(3) of the Veterinary Services Act.

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(2) The veterinary medicinal products authorised according this regulation may be exempt from the provisions of regulations 5, 6, 7 and 8.

(3) The veterinary medicinal products shall only be used in authorised research facilities which are in conformity with the Animal Welfare Act and the Protection of Animals for Scientific Purposes Regulations.

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(4) (a) In order to be allowed to carry out the activity mentioned in sub-regulation (1) a person, herein referred to as the "applicant for a veterinary medicinal product to be used for research purposes", shall submit an application with the Veterinary Services.

(b) If the application is positively completed a licence for Research Purposes shall be issued. The Veterinary Services shall make, modify, add or remove any terms and conditions pertaining to the licence that it may deem fit in light of scientific advancements or new information that may emerge on particular substances or ingredients contained in the veterinary medicinal products used for research purposes.

(c) The holder of the licence for a veterinary medicinal product to be used for research purposes shall utilise a product or administer it to a test animal only under the terms and conditions set out under the Animal Welfare Act.

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(d) The holder of the licence for a veterinary medicinal product to be used for research purposes who becomes aware of any serious adverse reactions on the animal or on the person administering it shall report the reaction to the Veterinary Services within fifteen (15) days from the day the serious adverse reaction was discovered.

(e) Food for human consumption can be taken from test animals only in accordance with regulation 86 and with the prior approval of the Veterinary Services.

(f) The application submitted by the applicant shall be granted without prejudice to any licence or permit that the applicant may need to obtain from other departments and directorates in order to engage in the indicated research activity.

(g) The applicant for a veterinary medicinal product or holder of the licence is subject to official inspections by the Veterinary Services on the premises and the activities undertaken within the premises.

(h) The Veterinary Services shall set out the criteria for veterinary medicinal product which are obtained in accordance with sub-regulation (1) and make them public.

Samples and demonstration packs of veterinary medicinal products.

4B. (1) Veterinary medicinal products may be exempted from the provisions in regulations 5 to 8 if it can be demonstrated that the products are veterinary samples or demonstration packs distributed to veterinary surgeons or pharmacists by veterinary wholesale distributors.

(2) The products referred to in sub-regulation (1) may be used under the following conditions:

(a) they are distributed for free to persons authorised to receive them or are exhibited during conferences or similar activities which are held for intended for veterinary surgeons and/or pharmacists;

(b) they bear a label printed "Free sample/ Demonstration pack – Not for sale";

(c) the unit pack should not contain more than:

(i) 50 units for capsules/tablets;

(ii) 10 units for injections and spot-ons

(iii) 300g for powders

(iv) 3L for liquids

(v) 5 units for intra-mammary tubes

(vi) any other measurement as established by the Veterinary Services for all other Pharmaceutical forms

(d) the information provided with the samples shall not be promotional in nature;

(e) the maximum period of time the authorised veterinary wholesale dealer can procure a product from a Member State of the European Union as a free sample is one (1) year from the first consignment thereof;

(f) if any product authorised in accordance with the provisions of sub-regulation (1) is administered to a food producing animals, that animal is excluded permanently from the food chain.

Obligations relating to veterinary medicinal products. Cap. 437.

4C. Any authorisation issued under regulations 4(2), 4A and 4B, shall be deemed to be a Marketing Authorisation for the purposes of articles 38, 53 and 57 of the Veterinary Services Act.

Veterinary medicinal products obtained from other countries for personal use.

4D. (1) Veterinary medicinal products may be exempted from the provisions in regulations 5 to 8 when the products are procured from a Member State of the European Union or imported from a Third country under the terms and conditions mentioned in sub-regulation (2).

(2) The following terms and conditions shall apply:

(a) the products shall not be re-sold for monetary gain;

(b) the products shall not be transferred to other third parties unless such transfer is authorised by the Veterinary Services;

(c) this provision is not applicable to psychotropic drugs, narcotic drugs for all animals and in the case of food producing animals also the substances listed in Group A in Schedule I of Measures to monitor certain Substances and Residues thereof in Live Animals and Animal Products Rules and Table II of Regulation (EU) 37/ 2010;

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(d) the quantity of products obtained shall be proportional to the dosage regime of the condition it will be used for;

(e) the quantity of products which is allowed entry in Maltese territory shall cover the period indicated as the duration of treatment in the product's specifications or on the veterinary surgeons 's veterinary prescription. However, products intended to be used for recurrent or chronic conditions can be allowed entry in Malta several times a year, provided that cogent evidence that demonstrate the benefits obtained by the regular use of the products can be provided;

(f) the individuals shall be required to provide a veterinary prescription for products classified as requiring such a prescription in the country from where they are obtained or for similar veterinary medicinal products in Malta:

Provided that the Veterinary Services may still ask for such a veterinary prescription even if the products are classified as not requiring a veterinary prescription in the country from where they are obtained;

(g) only products that do not contain animal by-products which are derived from high risk areas where certain diseases may be, or suspected to be, present or prevalent, can be obtained;

(h) only products that do not contain ingredients that are classified as illegal in Malta and do not have banned indications in Malta can be obtained;

(i) only appropriately labelled products which give clear indication of the nature of the ingredient/s within can be obtained;

(j) food producing animals administered with the veterinary medicinal products authorised in accordance with this regulation can only be consumed by the person getting the veterinary medicinal products, or by consenting members of the same household. The appropriate withdrawal period shall apply;

(k) before a decision on antimicrobial veterinary medicinal products and products that have a hormonal activity is taken, a risk assessment shall be prepared by the Veterinary Services in a timely manner;

(l) the decision by the Veterinary Service is without prejudice to any license or permit that the person getting the veterinary medicinal products may need to obtain under other regulations of the same or of different department.

(3) The veterinary services shall decide on the release, placing under official control or destruction of veterinary medicinal products, or the products presumed to be veterinary medicinal products, if and when these are intercepted at the various entry control points throughout the territory of Malta.

(4) Pursuant to sub-regulation (3), the Veterinary Services shall keep a record of all the opinions or decisions taken. These records shall be kept by the Veterinary Services for a period of not less than ten (10) years.

(5) The Veterinary Services shall set out the criteria for veterinary medicinal product which can be obtained in accordance with sub-regulation (1) and make them public:

Provided that the provisions of this regulations shall also apply to veterinary medicinal products that are brought in the territory of Malta as a *bona fide* donation for use on animals kept in the approved sanctuary subject to the donation on condition that the veterinary services is pre-notified of such a request with the name, quantity and nature of the products, and the names and addresses of the donator, the recipient and the animal sanctuary involved.".

Amends regulation 7 of the principal regulations.

6. In regulation 7 of the principal regulations, immediately after the words "Member State", there shall be added the words "referred to as the "source country".

Adds new regulation to the principal regulations.

7. Immediately after regulation 7 of the principal regulations there shall be added the following new regulation:

Registration of veterinary medicinal products according to regulation 7.

7A. (1) In order to be allowed to market the products under regulation 7, a person, herein referred to as the "applicant for the registration of veterinary medicinal product" under regulation 7, shall submit an application to the Veterinary Services.

(2) Upon a reasoned request the Veterinary Services may decide that regulations 60(10) and 60(11) on the legal category of Veterinary medicinal products and regulation 51(4) do not apply to registrations granted under regulation 7.

(3) Before granting such a registration the Veterinary Services may:

(a) request the competent authority in the source country to furnish a copy of the Marketing Authorisation in force;

(b) ensure that the entity applying for a registration in accordance with regulation 7 is a legally established company in the European Union or European Economic Area;

(c) notify the Marketing Authorisation Holder of its intention to grant a registration according to regulation 7 when the Registration Holder is not the same entity as the Marketing Authorisation Holder in the country of source;

(d) request the applicant for a registration in accordance with regulation 7 to furnish an authenticated copy of the Marketing Authorisation in force:

Provided that it is not possible for the applicant to provide an authenticated copy of the Marketing Authorisation he shall be requested to provide other proof of an existing Marketing Authorisation in the country of source.

(e) request from the applicant data on the impact of the product on the environment in Malta.

(4) The holder of the registration granted in accordance with regulation 7 shall ensure that:

(a) the veterinary medicinal product is in accordance with the current Marketing Authorisation issued in the source country;

(b) notify the veterinary services of any variations to the terms of the Marketing Authorisation approved in the country of source;

(c) there are implemented without any delay actions relating to issues concerning the veterinary medicinal product which have resulted in adverse drug reaction and/or a product or batch recall;

(d) a person is appointed or be himself responsible for the requirements in paragraph (c);

(e) when the applicant is not the Market Authorisation Holder of the product in the source country he shall furnish to the Veterinary Services a letter of access issued by the Market Authorisation Holder granting him the use of the Marketing Authorisation for the purpose of regulation 7:

Provided that it is not possible for the applicant to receive a ‘letter of access’ from the Market Authorisation Holder in the country of source the applicant shall be requested to provide proof of the agreement between himself and a duly authorised veterinary wholesale distributor in the country of source;

(f) have a system in place for recording and investigation adverse drug reactions and batch or product defects.".

Amends regulation 10 of the principal regulations.

8. Regulation 10 of the principal regulations shall be amended as follows:

(a) in paragraph (c) of sub-regulation (1) thereof, the words "a person authorized to do so under national legislation" shall be substituted by the words "a pharmacist or a veterinary surgeon"; and

(b) immediately after sub-regulation (2) thereof there shall be added the following new sub-regulations:

"(3) In the case of a veterinary medicinal product authorised in another member State, veterinary surgeons shall obtain an authorisation from the Veterinary Services before getting the product for the administration to the animal.

(4) In case the veterinary medicinal products contain restricted substances resulting from the implementation of the relevant United Nations conventions on narcotic and psychotropic substances, consideration should be given to any special requirement that need to be satisfied before the products could be used.

(5) A veterinary medicinal product or a medicinal product supplied for administration under paragraphs (a), (b) and (c) of sub-regulation (1) may only be supplied in accordance with a veterinary prescription from a veterinary surgeon, irrespective of the legal category assigned to the veterinary medicinal product during the Marketing Authorisation procedure.

(6) The veterinary prescription issued under the condition referred to in sub-regulation (5) shall be marked as such. A statement similar to, or stating the equivalent meaning of, the following statement: "This Product has been prescribed in accordance with the Cascade Principle", shall be included on the veterinary prescription.

(7) Unless the veterinary surgeon who prescribed the veterinary medicinal product or medicinal product both supplies the product and administers it to the animal in

person, the person supplying it must label it (or ensure that it is labelled) with at least the following information:

(a) the name of the veterinary surgeon who has prescribed the product;

(b) the identification (including the species) of the animal or group of animals;

(c) dosage and administration instructions.

(8) When a veterinary surgeon has recourse to the provisions of regulation 10, the veterinary surgeon shall keep adequate records of the treatment given. The records shall at least contain the particulars mentioned in sub-regulation (7) and shall be available for inspection by the Veterinary Services for a period of not less than three (3) years.

(9) When a veterinary surgeon has recourse to the provisions in paragraphs (a), (b) and (c) of sub-regulation (1), the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution under a decision to be laid down by the Veterinary Services.".

9. Immediately after regulation 10 of the principal regulations

Adds new regulation to the principal regulations.

there shall be added the following new regulation:

Importation of veterinary medicinal products for non-food animals by veterinary surgeons.

"10A.(1)(By way of derogation from regulation 10(1), where there is no suitable veterinary medicinal product available either as an authorised product in Malta or under the provisions of regulation 10(1), veterinary surgeons may, under their direct and only personal responsibility, build up a case and expound it to the Veterinary Services. Veterinary surgeon shall provide detailed justifications to their request. The Veterinary Services may where the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal, allow the importation of a veterinary medicinal product authorised for any non-food producing species from any third country under any conditions it may deem fit. The Veterinary Services shall base its decision on purely scientific grounds and shall take all precautions, in particular for the safety and environmental risks which may be associated with the use of the veterinary medicinal product, before granting the approval for the importation, which importation shall be considered as a once only grant with the possibility for repeated requests, with each request considered as *sui generis*.

(2) The provisions in regulations 10 (3), (4), (5), (7), and (8) shall apply.".

Amends regulation 11 of the principal regulations.

10. Regulation 11 of the principal regulations shall be amended as follows:

(a) in paragraph (c) of sub-regulation (1) of regulation 11, the words "a person authorized to do so under national legislation" shall be substituted by the words "a pharmacist or a veterinary surgeon"; and

(b) immediately after sub-regulation (5) thereof, there shall be added the following new sub-regulations:

"(6) In the case of a veterinary medicinal product authorised in another member State, the veterinary surgeons shall obtain an authorisation from the Veterinary Services before procuring the product for the administration to the food producing animal.

(7) In case the veterinary medicinal products contain restricted substances resulting from the

implementation of the relevant United Nations conventions on narcotic and psychotropic substances, consideration shall be given to any special requirement that need to be satisfied before the products could be used.

(8) A veterinary medicinal product or a medicinal product supplied for administration under paragraphs (a), (b) and (c) of sub-regulation (1), may only be supplied in accordance with a prescription from a veterinary surgeon, irrespective of the legal category assigned to the veterinary medicinal product in accordance with regulation 60.

(9) The prescription issued under the condition referred to in sub-regulation (8) shall be marked as such. A statement similar to, or stating the equivalent meaning of, the following statement: "This Product has been prescribed in accordance with Cascade Principle", shall be included on the veterinary prescription.

(10) Unless the veterinary surgeon who prescribed the veterinary medicinal product or the medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information:

(a) the name of the veterinary surgeon who has prescribed the product;

(b) the name and address of the animal owner;

(c) the identification (including the species) of the animal or group of animals;

(d) the date of supply;

(e) dosage and administration instructions;

(f) the withdrawal period, if relevant.

(11) When a veterinary surgeon has recourse to the provisions in sub-regulation (1) the activity undertaken by the veterinary surgeon is excluded from the scope of the definition of wholesale distribution.".

11. Immediately after regulation 11 of the principal regulations

Adds new regulation to the principal regulations.

there shall be added the following new regulation:

Importation of veterinary medicinal products for food producing animals by veterinary surgeons.

11A. (1) By way of derogation from regulation 11 (1) and from Article 16(1) of Regulation (EC) No 470/ 2009, where there is no suitable veterinary medicinal product available either as an authorised product in the Malta or under the provisions of regulation 11(1), veterinary surgeon may, under their direct and only personal responsibility, build up a case and expound it to the Veterinary Services. Veterinary surgeons shall provide detailed justifications to their request. The Veterinary Services shall and where the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal, allow the importation of a veterinary medicinal product authorised for any food producing species from any Third country under any conditions it may deem fit, including the assignment of an appropriate withdrawal period, if applicable. The Veterinary Services shall base its decision on purely scientific grounds and shall take all precautions, in particular for the safety and environmental risks which may be associated with the use of the veterinary medicinal product, before granting the approval for the importation, which importation shall be considered as a once only grant with the possibility for repeated requests, with each request considered as a once only grant with the possibility for repeated requests, with each request considered as *sui generis*.

(2) The provisions of sub-regulations (6), (7), (8) and (10)of regulations 11 shall apply.".

12. In regulation 30 of the principal regulations, the word "Community" shall be deleted wherever it occurs.

Substitutes regulations 38 to 50 of the principal regulations.

13. Regulations 38 to 50 of the principal regulations shall be substituted by the following new regulations:

Manufacturing and importation regulations.

38. (1) The provisions of this Title shall not apply to:

(a) *magistral formula*;

(b) *officinal formula*;

(c) veterinary medicinal products intended for research and development trials;

(d) intermediate products intended for further processing by an authorised manufacturer;

(e) any radionuclides in the form of sealed sources;

(f) whole blood, plasma or blood cells of animal origin, except for plasma which is prepared by a method involving an industrial process;

(g) veterinary medicinal products supplied in response to a *bona fide* unsolicited order, formulated in accordance with the specifications of a veterinary surgeon and for use by an individual animal under his direct personal responsibility.

(2) The provisions of these regulations shall apply also to the manufacture and assembly of homeopathic veterinary medicinal products, veterinary medicinal products derived from animal blood or plasma, radiopharmaceuticals, immunological veterinary medicinal products and herbal veterinary medicinal products.

Manufacturing authorisation for veterinary medicinal products and active substances.

39. (1) (a)No veterinary medicinal product, biological active substance, or active substance to be used directly as an investigational veterinary medicinal product, may be manufactured in Malta unless there is, in respect of such product or substance, a Manufacturing Authorisation.

This Manufacturing Authorisation shall also be required for the processes of sterilisation of active substances.

(b) The Manufacturing Authorisation shall also be required for the manufacture of veterinary medicinal products intended for export.

2. (a) The Manufacturing Authorisation, which shall remain in force for a period to be determined by the Veterinary Services, shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.

(b) A Manufacturing Authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where such processes are carried out solely for retail supply by pharmacists in veterinary pharmacies, or by other persons legally authorised to carry out such processes.

(3) The authorisation referred to in sub-regulation (1) shall also be required for imports from third countries into the territory of Malta;

The territory of Malta shall take all appropriate measures to ensure that veterinary medicinal products brought into the territory from a third country and destined for Member States are accompanied by a copy of the authorisation referred to in sub-regulation (1).

(4) Any application for the grant of a licence to manufacture, assemble or modify a veterinary medicinal product shall be made to the Veterinary Services and shall contain such information, documents, samples and other material as provided by the provisions of these regulations.

(5) A Manufacturing Authorisation shall include a licence to distribute by wholesale the veterinary medicinal products in respect of which the Manufacturing Authorisation has been issued.

(6) The Veterinary Services shall forward to the Agency a copy of the Authorisation referred to in sub-regulation (1).

(7) The Veterinary Services shall enter the information relating to the Authorisation referred to in sub-regulation (1) in the European Union database referred to in regulation 72(6).

Renewal of a manufacturing and import Authorisation.

40. The Veterinary Services, shall only grant or renew an Authorisation, if the applicant:

(a) specifies the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and the place where they are to be manufactured and, or controlled;

(b) has at his disposal, for the manufacture or import of veterinary medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with requirements set by the Veterinary Services;

(c) has at his disposal the services of at least one qualified person within the meaning of regulation 46; and

(d) provides all necessary documentation in support of his application.

Issuing of manufacturing and import Authorisation.

41. (1) (a)The Veterinary Services shall issue the Authorisation after verifying the contents of the application but in any case not later than ninety (90) days from receipt of the application.

(b) This time period shall be suspended when the Veterinary Services requests additional information from the applicant.

(c) The Veterinary Services shall, before determining an application, inspect the premises indicated in the application and shall not issue an Authorisation until it is satisfied that such premises conform with the requirements established by the provisions of these regulations;

(d) The Veterinary Services may grant a conditional licence subject to the carrying out of certain obligations imposed on the applicant.

(2) The Authorisation shall apply only to the premises, veterinary medicinal products and pharmaceutical forms specified in the application.

(3) Where the Veterinary Services considers that circumstances may exist which would render necessary the consideration of whether the Authorisation should be varied, suspended or revoked, the Veterinary Services may serve on the holder of a manufacturer's Authorisation a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Variation of a manufacturing and import Authorisation.

42. (1) When the holder of the Authorisation requests a change in the particulars specified in regulation 4(a) and 4(b), he shall apply in writing to the Veterinary Services.

The process of verification of such information shall not exceed thirty (30) days. However, in exceptional cases, this period of time may be extended to ninety (90) days.

(2) The veterinary services may upon such an application made by the holder of Authorisation in request thereof, vary the condition of the licence if it is satisfied that such variation will not adversely affect standard of good practice in manufacture as may be prescribed.

(3) Where the Veterinary Services considers that circumstances may exist which would render necessary the consideration of whether the Authorisation should be varied, suspended or revoked, the Veterinary Services may serve on the holder of a manufacturing Authorisation a notice requiring him, within such time as may be specified in the notice, to furnish it with any information specified in the notice.

Suspension of a manufacturing and import Authorisation.

43. (1) The Veterinary Services may suspend a manufacturing Authorisation for such period as it may determine, or may refuse, revoke, or vary the provisions of, any such Authorisation.

(2) The powers vested in sub-regulation (1) shall only be exercisable in any of the following circumstances, where:

(a) the matters stated in the application on which the Authorisation was granted were false or incomplete in an essential manner;

(b) a material change of circumstances has occurred in relation to any of those matters;

(c) any of the conditions of the Authorisation has been contravened;

(d) the requirements in relation to the licences as established by these regulations have not been complied with;

(e) the processes of manufacture or assembly of a veterinary medicinal product are carried out in a manner that is not in compliance with the provisions of the marketing authorisation of that veterinary medicinal product;

(f) the conditions for good manufacturing practice are not being complied with;

(g) there is sale and processing of active substance and veterinary medicinal products under unsanitary conditions or leading to adulteration; and

(h) in any other circumstance as is established under these regulations.

(3) The Veterinary Services shall carry out regular inspections to ensure that the requirements established by these regulations in relation to the manufacture, assembly or modification of a veterinary medicinal product or active substance are complied with.

(4) With respect to the manufacture of veterinary medicinal products or active substance the Veterinary Services or any authorised person carrying out an inspection shall:

(a) inspect the manufacturing establishment and any other location and at any reasonable time the Director may deem necessary;

(b) examine any relevant documents;

(c) take any samples the Director may deem necessary and if necessary submit them to designated laboratories for testing;

(d) open or/and examine or/and seize any article believed to be in violation of these regulations or for obtaining evidence;

(e) draw up a report of the findings and communicate the contents of such report to the Manufacturing Authorisation holder or the applicant for a Manufacturing Authorisation and to the qualified person in relation to such inspection;

(f) carry out any other activity the Director may deem appropriate for the proper execution of his duties and responsibilities as provided by these regulations;

(g) produce, upon request by the inspected part, the designated document containing information on the legal basis and scope of the inspection and the identification of the inspector/s;

(h) at the time of the inspection draw up a list of deficiencies that may have been identified and shall sign this list, and such list shall be countersigned by the holder of the Authorisation or his legal representative;

(i) shall draw up a report of the inspection within thirty (30) working days of the inspection and shall forward a copy of such report to the holder of the Authorisation.

(5) Except in urgent cases an inspection shall be carried out in the presence of a qualified person or his representative.

(6) Subject to the provisions of these regulations, every licence shall, unless previously renewed or revoked, continue to be valid until such time as it is renewed by the Veterinary Services following an inspection.

(7) The Veterinary Services shall establish the period of validity of any licence.

(8) Following the inspection mentioned in sub-regulation (1), the Veterinary Services:

(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 these regulations, it considers it necessary or expedient to do so, may refuse to renew the licence.

Obligations of the holder of manufacturing authorisation and manufacturer of active substance.

44. (1) The holder of the Authorisation or the manufacturer of active substance shall:

(a) comply with the EU principles and guidelines of good manufacturing practice and any annexes thereof for veterinary medicinal products and use only active substances which have been manufactured in accordance with the EU guidelines on good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances. To this end, the holder of the manufacturing authorisation shall verify compliance by the manufacturer and distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. The holder of the manufacturing authorisation shall verify such compliance either by himself or, without prejudice to his responsibility as provided for in these regulations and in the Act, through an entity acting on his behalf under a contract;

(b) inform the competent authority and the marketing authorisation holder immediately if he obtains information that veterinary medicinal products which come under the scope of his manufacturing authorisation or the active substance are, or are suspected of being, falsified irrespective of whether those veterinary medicinal products were distributed within the legal supply chain or by illegal means, including illegal sale at a distance by means of information society services;

(c) verify that the manufacturers, importers or distributors from whom he obtains active substances are registered with the competent authority of the Member State in which they are established;

(d) verify the authenticity and quality of the active substances and the excipients.

(e) have at his disposal the services of staff complying with the legal requirements set by the Veterinary Services as regards both manufacture and controls

(f) dispose of the veterinary medicinal products only in accordance with the legislation of the territory of Malta;

(g) give prior notice to the Veterinary Services of any changes which he may wish to make to any of the particulars supplied pursuant to regulation 40 or other significant changes or of conditions which may affect the quality, safety or efficacy of the veterinary medicinal product.

The Veterinary Services shall, in any event, be immediately informed if the qualified person referred to in regulation 46(1) is replaced;

(h) enable the qualified person referred to in regulation 46(1) to carry out his duties, particularly by placing at his disposal all the necessary facilities;

(i) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with the laws of the countries of destination:

(i) date;

(ii) name of the veterinary medicinal product;

(iii) quantity supplied ;

(iv) name and address of the recipient;

(v) batch number;

These records shall be available for inspection by the Veterinary Services for a period of at least three (3) years.

(j) the following information at least shall be recorded in respect of each transaction, whether or not it is made for payment;

(k) record all suspected serious adverse reactions and human adverse reactions relating to the use of veterinary medicinal products that are brought to his attention and report them promptly to the Veterinary Services in no later than fifteen days following receipt of the information;

(l) implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medicinal products or the active substance in the distribution network;

(m) record and investigate any complaint concerning quality defects;

(n) other responsibilities as may be established by the Veterinary Services from time to time;

(2) For the purposes of this regulation, manufacture of active substances used as starting materials shall include both total and partial manufacture or import of an active substance used as a starting material as defined in the Schedule Part 2. Section C of these regulations, and the various processes of dividing up, packaging or presentation prior to its incorporation into a veterinary medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of starting materials.

(3) Manufacturing Authorisation holders shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in the Consumer Affairs Act.

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(4) It shall be the duty of the importer to ensure that:

(a) in the case of veterinary medicinal products and investigational veterinary medicinal products imported from third countries, these have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down in the Good Manufacturing Practice for Veterinary Medicinal Products Rules; S.L. 437. 108.

(b) in the case of veterinary medicinal products, such products have been manufactured by manufacturers duly authorised for the purpose; and

(c) in the case of investigational veterinary medicinal products, such products have been manufactured by a manufacturer notified to the competent authorities and accepted by them for that purpose.

Additional information pursuant to the application of a manufacturing and import Authorisation.

45. The Veterinary Services may require from the applicant further information concerning both the particulars supplied pursuant to regulation 40 and the qualified person referred to in regulation 46(1). Where the Veterinary Services exercise this right, application of the time limits referred to in regulations 41 and 42(1) shall be suspended until the additional data required have been supplied.

Qualified person.

46. (1) The holder of the Authorisation shall have permanently and continuously at his disposal the services of at least one qualified person, in accordance with the conditions laid down in regulation 47, responsible in particular for carrying out the duties specified in regulation 49:

Provided that when more than one qualified person is nominated, the application will clearly delineate the specific responsibilities of each person:

Provided further that the qualified persons may nominate another person similarly qualified to act as his representative.

(2) When the qualified person has nominated a representative as aforesaid he shall immediately inform the Veterinary Services of such nomination.

(3) If the manufacturing Authorisation holder personally has the qualifications laid down in regulation 47, then he may himself assume the responsibility of a qualified person.

Qualifications of the qualified person.

47. (1) For a person to be designated as qualified person, he must possess the following qualifications:

(a) a diploma;

(b) certificate or other evidence of formal qualifications awarded on completion of a university course of study; or

(c) a course recognised as equivalent by the territory of Malta, extending over a period of at least four (4) years of theoretical and practical study in one of the following scientific disciplines - pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology.

(2) However, the minimum duration of the university course may be three and a half (3.5) years where the course is followed by a period of theoretical and practical training of at least one (1) year and includes a training period of at least six (6) months in a pharmacy open to the public, corroborated by an examination at university level.

(3) The course shall include theoretical and practical tuition bearing upon at least the following basic subjects:

(a) experimental physics;

(b) general and inorganic chemistry;

(c) organic chemistry;

(d) analytical chemistry;

(e) pharmaceutical chemistry, including analysis of medicinal products;

(f) general and applied biochemistry (medical);

(g) physiology;

(h) microbiology;

(i) pharmacology,

(j) pharmaceutical technology;

(k) toxicology;

(l) pharmacognosy (study of the composition and effects of the active principles of natural substances of plant and animal origin).

(4) Tuition in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in regulation 49.

(5) Where certain diplomas, certificates or other evidence of formal qualifications mentioned in this sub-regulation do not fulfil the criteria laid down above, the Veterinary Services shall ensure that the person concerned provides evidence that he has, in the subjects involved, the knowledge required for the manufacture and control of veterinary medicinal products.

(6) The qualified person shall have acquired practical experience over at least two (2) years, in one or more undertakings which are authorised manufacturers, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of veterinary medicinal products.

(7) The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six (6) years.

Qualified persons in current employment.

48. (1) A person engaging, in Malta, in the activities of the person referred to in regulation 46(1) on the date on which these regulations become applicable, without complying with the provisions of regulation 47, shall be eligible to continue to engage in those activities within the EU.

(2) The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or a course recognised as equivalent by the territory of Malta in a scientific discipline allowing him to engage in the activities of the person referred to in regulation 46(1) in accordance with the laws of the territory of Malta, may, if he began his course prior to the date on which these regulations became applicable, be considered as qualified to carry out in the territory of Malta the duties of the person referred to in regulation 46(1), provided that he has previously engaged in the following activities for at least two (2) years before the date on which these regulations became applicable in one or more undertakings with a manufacturing authorisation, production supervision and, or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of a person as referred to in regulation 46(1) to ensure the quality of veterinary medicinal products.

If the person concerned has acquired the practical experience referred to in sub-regulation (1) before the date on which these regulations became applicable, a further one year's practical experience in accordance with the conditions referred to in sub-regulation (1) shall be completed by him immediately before he engages in such activities.

Responsibilities of the qualified person.

49. (1) The qualified person, without prejudice to his relationship with the holder of the Authorisation, shall be responsible to ensure that:

(a) each batch of veterinary medicinal products manufactured in Malta has been manufactured and checked in terms of the laws in force and is in accordance with the requirements of the marketing authorisation;

(b) in the case of veterinary medicinal products coming from third countries, irrespective of whether the product has been manufactured in the EU, each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the veterinary medicinal product in accordance with the requirements of the marketing authorisation:

Provided that when the batches of medicinal products have already undergone the controls above mentioned in a Member State, they shall be exempt from further controls if they are accompanied by the control reports signed by the qualified person, and are marketed within the EU;

(c) standards of good practice in manufacturing are complied with at all times.

(2) The qualified person need not carry out the controls above mentioned in the case of imported veterinary medicinal products, where arrangements have been made by the EU with the exporting country to ensure that the manufacturer of the veterinary medicinal products applies standards of good manufacturing practice at least equivalent to those laid down by the EU, and to ensure that the controls referred to above have been carried out in the exporting country.

(3) The Veterinary Services, may if it has reasonable suspicion to believe that any qualified person is acting in contravention of any of the provisions of these regulations, suspend the activity of such qualified person by notice in writing specifying the reasons for such suspension until such person has complied with any requirement of the Veterinary Services to remedy the non-compliance.

Duties of the qualified person.

50. (1) It shall be the duty of the qualified person to keep a register to document and certify that each production batch satisfies provisions of these regulations.

(2) The said register shall be kept up to date as operations are carried out and must be made available for inspection by the Veterinary Services for at least five (5) years.

Confirmation of a qualified person by the competent authority.

50A.(1) The obligations of qualified persons referred to in regulation 46(1) shall be fulfilled either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.

(2) The Veterinary Services may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary proceedings against him for failure to fulfil his obligations.

Registration of active substances importers, exporters, distributors and manufacturers.

50B. (1) Importers, exporters, distributors and manufacturers of active substances who are established in Malta shall register their activity with the Veterinary Services.

(2) The registration form shall include, at least, the following information

(a) name or corporate name and permanent address;

(b) the active substances which are to be imported, exported, distributed or manufactured;

(c) particulars regarding the premises and the technical equipment for their activity:

Provided that the persons referred to in sub-regulation (1) shall submit the registration form to the Veterinary Services at least sixty (60) days prior to the intended commencement of their activity.

(3) The Veterinary Services may, based on a risk assessment, decide to carry out an inspection. If the Veterinary Services notifies the applicant within sixty (60) days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the Veterinary Services has notified the applicant that he may commence the activity. If within sixty (60) days of the receipt of the registration form the Licensing Authority has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.

(4) The persons referred to in sub-regulation (1) shall communicate annually to the Veterinary Services an inventory of the changes which have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, exported, distributed or imported shall be notified immediately.

(5) The Veterinary Services, shall only grant or renew an Authorisation, if the applicant:

(a) specifies the veterinary medicinal products and pharmaceutical forms which are to be manufactured or imported and the place where they are to be manufactured and, or controlled;

(b) has at his disposal, for the manufacture or import of veterinary medicinal products, suitable and sufficient premises, technical equipment and control facilities complying with requirements set by the Veterinary Services;

(c) has at his disposal the services of at least one qualified person within the meaning of regulation 46(1); and

(d) provides all necessary documentation in support of his application.

(6) The Veterinary Services shall issue the Authorisation after verifying the contents of the application but in any case not later than ninety (90) days from receipt of the application.

(7) The time period mentioned in sub-regulation 6 shall be suspended when the Veterinary Services requests additional information from the applicant.

Importation for re-export.

50C. (1) When veterinary medicinal products are brought from a third country into Malta for the sole purpose of re-export, and without placing them on the market in Malta, the provisions of regulation 38 still apply even though the product remains intact and no manufacturing activities are carried out.

(2) The only exclusion in respect of the requirement in regulation 38, is when the operations of import for the sole purpose of re-export are effected within a freeport, free trade zone or customs warehouse. However, in such instances a veterinary wholesale dealer's licence is still required by the company engaging in the process.

(3) In those cases involving a manufacturing activity in relation to imported products that are destined for re-export only, a manufacturing authorisation is required, even if the operations are effected within the freeport, free trade zone or customs (e.g. bonded warehouse). Operations of re-labelling and/or affixing of labels to the outer pack also fall within this category.

(4) The Veterinary Services shall establish procedures to ensure that the requirements of sub-regulations (2) and (3) are complied with.

(5) The Veterinary medicinal products imported for the sole purpose of re-export may be exempted from obtaining a Marketing Authorisation from the Veterinary Services.

(6) The authorisation to engage in such an activity is only given to persons in possession of a veterinary wholesale dealer licence and without prejudice to other authorisations that the persons may have to obtain, particularly with respect to the requirements of the Importation Control Regulations.

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Other licences that may be required apart from a manufacturing and import Authorisation.

50D. A manufacturing authorisation granted under these regulations shall not relieve any person from the need to obtain any permit, license or authorisation as may be required by any other law.".

Amends regulation 58 of the principal regulations.

14. Immediately after the second paragraph of sub-regulation (1) of regulation 58 of the principal regulations there shall be added the following new paragraph:

"When the market situation in Malta is such that it gives rise to a temporary supply issues for an authorised veterinary medicinal product, the procurement of small quantities of the same authorised veterinary medicinal product, or an essentially similar veterinary medicinal product, by a veterinary surgeon is permitted and is excluded from the scope of the definition of wholesale distribution:

Provided that when a veterinary surgeon has recourse to this regulation he has the appropriate means to be kept informed by this supplier of any batch or product recall and adverse drug reactions.".

15. Title VII and Title VIII of the principal regulations shall be renumbered as Title X and Title XI respectively.

Renumbers Title VII and Title VIII of the principal regulations.

16. Immediately after regulation 58 of the principal regulations there shall be added the following new Title and regulation:

Adds new Title and regulation to the principal regulations.

"TITLE VII
RETAIL SUPPLY OF VETERINARY
MEDICINAL PRODUCTS

Retail supply of veterinary medicinal products.

58A. In the territory of Malta, the retail supply of veterinary medicinal products shall be conducted only from veterinary pharmacies, licensed veterinary establishments, other establishments mentioned in regulation 60(4)(d) and by veterinary surgeons during out call visits.".

17. Immediately after regulation 58A of the principal regulations there shall be added the following new Title:

Adds new Title to the principal regulations.

"TITLE VIII
DISPENSING REGULATIONS".

18. Regulation 59 of the principal regulations shall be substituted by the following new regulation:

Substitutes regulation 59 of the principal regulations.

Dispensing by pharmacists, veterinary surgeons and suitably qualified persons.

59. (1) In the territory of Malta the dispensing of veterinary medicinal products shall only be conducted in accordance with the provisions of this regulation.

(2) Veterinary surgeons may dispense veterinary medicinal products during an in-call by the animal owner/carer/keeper in the licensed veterinary establishments and during out-call visits to the animals under their care.

(3) Veterinary surgeons shall dispense a veterinary medicinal product in such quantities as would be required for the treatment of the condition, where delay in the administration of the product may adversely affect the health of the animal:

Provided that the veterinary surgeon shall supply the quantities of veterinary medicinal product for treatments or conditions only to animals under his care. If the type of the packaging is such that the veterinary surgeon cannot supply lesser quantities thereof, the veterinary surgeon may supply the animal owner/keeper/ carer with the quantities needed for the full treatment of the condition.

Provided further that the above may not apply for veterinary medicinal product that are regulated by specific instruments:

(4) Veterinary medicinal products can only be dispensed from the premises referred to in regulation 60.

(5) The dispensers shall be required to keep detailed records for veterinary medicinal products or treatments that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:

(a) date of the transaction;

(b) name of the veterinary medicinal product including, as appropriate, pharmaceutical form and strength;

(c) batch number;

(d) quantity received or supplied;

(e) name or company name and permanent address or registered place of business of the supplier in the event of purchase, or of the recipient in the event of sale;

(f) name and contact details of the prescribing veterinary surgeon and, where appropriate, a copy of the veterinary prescription;

(g) marketing authorisation number.

At least once a year a detailed audit shall be carried out, and incoming and outgoing veterinary medicinal products and other products issued on a veterinary prescription shall be reconciled with products currently held in stock, any discrepancies being recorded in an appropriate register. These records shall be available for inspection by the Veterinary Services for a period of not less than five (5) years.

(6) When dispensing a veterinary medicinal product the dispenser must be satisfied that the person who will use the product is competent to do so safely, and intends to use it for a purpose for which it is authorised or indicated by the veterinary surgeon.

(7) When dispensing veterinary medicinal product, the dispenser shall advise the receiver of the product on the dosing, safe administration of the product and on any warnings or contra-indications on the label or package leaflet, including information on any applicable withdrawal period/s.

(8) If the dispenser dispenses an amount of veterinary medicinal product that is less than the unit dose of a package, the veterinary surgeons may break open any package containing a product for the purposes of supply, other than the immediate packaging of an injectable product.

(9) When dispensing an antimicrobial agent the dispenser must be satisfied that all necessary precautions have been taken to minimise the risks of antimicrobial resistance and that the prudent use of the antimicrobial agent have been taken in consideration, in particular to the use of critically important antimicrobials.

(10) If the dispenser has concerns about the content of a veterinary prescription he shall resolve them with the prescribing veterinary surgeon before dispensing the product.

(11) If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the veterinary surgeon dispensing the product must ensure that the container is suitably labelled and shall supply sufficient written information to enable the product to be used safely.

(12) The veterinary surgeon referred to in regulation 79(2) shall be responsible for the cabinet where veterinary medicinal products are kept. In particular, storage conditions, traceability issues and record keeping requirements shall be strictly adhered to.

(13) A veterinary surgeon dispensing a veterinary medicinal product must be present when the product is handed over unless the veterinary surgeon:

(a) authorises each transaction individually before the product is supplied;

(b) is satisfied that the person handing it over is competent to do so.

(14) Only veterinary medicinal product that have not passed their expiry date shall be dispensed.

(15) The provisions of paragraph (e) of sub-regulation (5) shall come into force on the 1st November 2021.".

Adds new Title and regulation to the principal regulations,

19. Immediately after regulation 59 of the principal regulations there shall be added the following new Title and regulation:

"TITLE IX
PRESCRIBING REGULATIONS

Prescribing by veterinary surgeons.

59A. (1) In the territory of Malta veterinary surgeons can only prescribe veterinary medicinal products in accordance with the provisions of this regulation.

(2) In the territory of Malta, the prescribing of veterinary medicinal product or medicinal product to animals shall be conducted only by Veterinary surgeons.

(3) The prescribing of veterinary medicinal product or medicinal product for animals shall be made only on the veterinary prescriptions.

(4) Veterinary surgeons may only prescribe a veterinary medicinal product or medicinal product for animals which they have examined themselves and shall accept clinical responsibility for the treatment of the animal under their care.

(5) Veterinary medicinal product or medicinal product may not be used for more than one treatment under the same prescription.

(6) Before prescribing a veterinary medicinal product or medicinal product which requires a prescription, veterinary surgeons shall carry out a clinical assessment of the animal under their care.

(7) The clinical assessment by the veterinary surgeons shall be carried out recently enough for the veterinary surgeons to have personal knowledge of the condition of the animal or current health status of the herd or flock to make a reliable diagnosis or start empirical treatment.

(8) Before prescribing a veterinary medicinal product or medicinal product the veterinary surgeons must first satisfy themselves that:

(a) the use of the veterinary medicinal product or medicinal product is justified for the species concerned on veterinary grounds;

(b) the administration of the veterinary medicinal product or medicinal product is not incompatible with a previous treatment or use and that there is no contra-indication or interaction where several pre-mixes are used;

(c) the veterinary medicinal product or medicinal product are prescribed only in such quantities as are necessary for the purpose of the treatment;

(d) all necessary precautions have been taken to minimise the risks of antimicrobial resistance and that the prudent use of the antimicrobial agent have been taken in consideration, in particular to the use of critically important antimicrobials.

(9) When prescribing a veterinary medicinal product or medicinal product veterinary surgeons must be satisfied that the person who will use the product is competent to do so safely and intends to use it for a purpose for which it is authorised.

(10) When prescribing antimicrobial agents veterinary surgeons shall consider the latest guidelines issued by the Veterinary Services, and other relevant national, European and International organisations with regard to critically important antimicrobials.

(11) When preparing a veterinary prescription the prescribing veterinary surgeon shall advise the receiver of the prescription on the safe administration of the product and on any warnings or contra-indications associated with the product.

(12) A veterinary medicinal product classified as subject to veterinary prescription may be administered without a veterinary prescription by a veterinary surgeon personally. This does not preclude veterinary surgeons from the record keeping obligations referred to in regulation 59(5).

(13) The veterinary prescriptions shall be in line with the guidelines that may be issued by the veterinary Services.".

Amends regulation 60 of the principal regulations.

20. Regulation 60 of the principal regulations shall be amended as follows:

(a) immediately after sub-paragraph (ii) of paragraph (a) of sub-regulation (1) thereof there shall be added the following new sub-paragraph:

"(iii) veterinary medicinal products that do not fall within the classification of regulation 6 (1)(a)(i), (b) and (c) but nonetheless are deemed to require a veterinary prescription for a temporary period.";

(b) immediately after paragraph (h) of sub-regulation (2) thereof there shall be added the following new paragraph:

"(i) veterinary medicinal product classified as prescription only medicines may be exempted from being prescribed and dispensed by a prescription if entirely administered by the veterinary surgeon responsible for the non-food producing animal, who himself provides the veterinary medicinal product, and if the animal owner does not explicitly request a prescription." and immediately thereafter there shall be added the following new sub-regulations:

"(3) Pursuant to sub-regulation (1) there shall be the following four (4) distribution categories of veterinary medicinal product:

(a) Prescription-Only-Medicine, Veterinary surgeon and Pharmacist- abbreviated to **POM-VP.**

(b) Prescription-Only-Medicine, Veterinary surgeon- abbreviated to **POM-V.**

(c) Over- the- Counter –Medicine, abbreviated to **OTC**

(d) General Sales, abbreviated to **GS**

(4) The supply of veterinary medicinal products for each distribution category shall be made as follows:

(a) POM-VP, shall only be prescribed and/or dispensed by a veterinary surgeon or dispensed by a pharmacist according the terms of a veterinary prescription. Premises from where the products can be supplied are veterinary pharmacies, licensed

veterinary establishments, and by the veterinary surgeon during an outcall.

(b) POM-V shall only be prescribed, dispensed and administered by a veterinary surgeon. Premises from where the products can be supplied are licensed veterinary establishments, and by the veterinary surgeon during an outcall.

(c) OTC, may be dispensed without a veterinary prescription. The persons who can dispense this category of veterinary medicinal products are veterinary surgeons, pharmacists and suitably qualified persons under the direction of a pharmacist or a veterinary surgeon. Premises from where the products can be supplied are veterinary pharmacies, licensed veterinary establishments, and by the veterinary surgeon during an outcall.

(d) GS, may be dispensed without a veterinary prescription. The persons who can dispense this category of veterinary medicinal products are veterinary surgeons, pharmacists and suitably qualified persons. Products that fall under this category can be supplied from veterinary pharmacies, veterinary establishments, registered pet shops, registered aquarium fish product retailers and approved feed traders where animal medicated feeds are produced, sold or traded:

Provided that the veterinary services may make requirements to allow products classified in this category to be supplied from premises other those listed above to alleviate supply shortages and facilitate accessibility to treatment that otherwise could be detrimental to animal welfare. Such premises shall not be general retail outlets and must be under the responsibility of a person with an experience of not less than two (2) years in the handling of this category of veterinary medicinal products.

(5) The Veterinary Services shall categorise the distribution category of the veterinary medicinal product when authorising veterinary medicinal products.

(6) When deciding the distribution category of a veterinary medicinal product the Veterinary Services may seek the advice from suitable expert committees and may

take in consideration the guidelines of other National, European and International relevant bodies, as may be decided by the Veterinary Services.

(7) Notwithstanding what had been decided during the initial Marketing Authorisation procedure, the Veterinary Services may change the distribution category of a veterinary medicinal product either at the request of the Marketing Authorisation Holder or due to a compulsory variation.

(8) The Veterinary Services shall set out the criteria for the categorisation of a Veterinary Medicinal product and make them public.

(9) Different pack sizes of the same Marketing Authorisation may be assigned a different distribution category.

(10) When the distribution category of the veterinary medicinal product is POM-V or POM-VP this shall be indicated on the immediate and/or outer packaging of the product in legible, undeletable characters.

(11) The legible, undeletable characters citing the distribution category of the veterinary medicinal product may be printed on the immediate and/or outer packaging or made noticeable through an appropriate label.

(12) Both the abbreviated form and the full description of the distribution category of the veterinary medicinal product present on the immediate and/or outer packaging shall be acceptable.

(13) The holders of a wholesale distribution authorisation shall distribute veterinary medicinal products only to the premises authorised to retailed veterinary medical according to these regulations.

(14) The holders of a wholesale distribution authorisation shall distribute to the premises authorised to retailed veterinary medical only the category/categories of veterinary medicinal products that are authorised to be retailed from each type of premises in accordance with these regulations.".

21. Regulation 62 of the principal regulations shall be amended as follows:

Amends regulation 62 of the principal regulations.

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

"Malta shall ensure that the owners or keepers of food-producing animals or keeper of animals that are confined within enclosures, displayed to the public, or kept for breeding can provide proof of purchase, possession and administration of veterinary medicinal products or medicinal products to such animals for five (5) years after their administration, including when the animal is slaughtered or culled during the five (5) year period.";

(b) immediately following the words "The territory of Malta may extend the scope of this obligation to other veterinary medicinal products or medicinal products," there shall be added the following new paragraphs:

"The records shall be kept electronically or printed hard copies. Hard copies shall be kept as hard bound records or in paper binders. Official hard copies or electronic templates may be provided by the Veterinary Services. The records shall be kept in a suitable place in the farm and available immediately for inspection by the Veterinary Services.

Proof of purchase refers in particular to the invoices and/or to the receipts or any document existing as hard copy or in electronic format that provides documentary evidence of how, when and from whom the veterinary medicinal product or medicinal product were acquired."; and

(c) immediately after paragraph (e) thereof there shall be added the following paragraphs:

"(f) scenario under which the veterinary medicinal product or medicinal products were prescribed, which could be one or more of the following scenario: treatment, prophylactic or metaphylactic use.

(g) scientific justification as to why antimicrobial veterinary medicinal products or medicinal products were prescribed by the veterinary surgeon in the case of metaphylactic and/or prophylactic use.".

Amends regulation 64 of the principal regulations.

22. In sub-regulation (1) of regulation 64, the words "in accordance with its national legislation" shall be deleted.

Amends regulation 72 of the principal regulations.

23. Regulation 72 of the principal regulations shall be amended as follows:

(a) in sub-regulation (1) thereof, immediately after the words "veterinary medicinal products" there shall be added the words "in any place where active substances and veterinary medicinal products are manufactured, distributed, imported, exported or used";

(b) in the first paragraph to sub-regulation (1) thereof, immediately after the words "carry out" there shall be added the words "at any reasonable time" and immediately after the words "Council Directive 2004/28/EC" there shall be added the words "or any provisions of these regulations."; and

(c) immediately after sub-regulation (7) thereof there shall be added the following new sub-regulation:

"(8) the persons responsible for the premises mentioned in this regulation shall allow entry to the authorised representatives of the veterinary services to carry out their duties.".

Adds new regulation to the principal regulations.

24. Immediately after regulation 77 of the principal regulations there shall be added the following new regulation:

Advertising of veterinary medicinal products regulations.

77A. (1) The Veterinary Services shall permit the advertising of veterinary medicinal products that in accordance with regulation 60, are available on veterinary prescription to:

(a) veterinary surgeons and pharmacists;

(b) professional keepers of animals, provided that the veterinary medicinal products are preventive immunological products or anti-helmintic therapies.

(2) The Veterinary Services shall permit the advertising of veterinary medicinal products to the general public which, by virtue of their composition and purpose, are intended and designed for use with the advice of the pharmacist, if necessary, but without the intervention of a veterinary surgeon for diagnostic purposes or for the prescription or monitoring of treatment.

(3) No person may advertise medicinal product for administration to animals. Scientific informative material can be sent on request to the veterinary surgeon when the provisions of regulation 10 and 11 are to be applied. The information must not be promotional in nature and must not include a price list.

(4) (a) It shall not be permissible for persons allowed to supply veterinary medicinal products to veterinary surgeons or pharmacy owners to induce them to prescribe or supply veterinary medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind.

(b) It shall not be permissible for persons allowed to supply veterinary medicinal products to make any form of contractual agreement with animal keepers that benefits the sale of their products.

(c) It shall not be permissible for persons allowed to supply veterinary medicinal products to solicit or accept any inducement prohibited under sub-regulations 4(a) and 4(b). Provided that existing measures or trade practices relating to prices, profit margins and discounts shall not be affected.

(5) The advertising of a veterinary medicinal product shall:

(a) encourage the rational use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties;

(b) comply with the particulars listed in the summary of product characteristics;

(c) not be misleading;

(d) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a veterinary medicinal product;

(e) not give the impression that a veterinary surgeon is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail, internet or any other means;

(f) not suggests that the effects of administering the veterinary medicinal product are guaranteed, are not accompanied by adverse reactions or are better than, or equivalent to, those of another treatment or veterinary medicinal product;

(g) not suggests that the health of the animal can be enhanced by taking the veterinary medicinal product;

(h) not suggests that the health of the animal could be affected by not taking the veterinary medicinal product provided that this shall not apply to the vaccination campaigns;

(i) not suggests that the veterinary medicinal product is a foodstuff, cosmetic or other consumer product;

(j) not suggests that the safety or efficacy of the veterinary medicinal product is due to the fact that it is natural.

(6) (a) Any advertising of a veterinary medicinal product to persons qualified to prescribe or supply such products shall include:

(i) the trade name;

(ii) a list of active ingredients;

(iii) the pharmaceutical form;

(iv) major indications for use;

(v) the dosage and method of use;

(vi) side effects, warnings, precautions and contraindications;

(vii) the name and address of the marketing authorisation holder;

(viii) any research and/or publications on the use of the active substance.

(b) All the information contained in the documentation referred to in sub-regulation (6)(a) shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the veterinary medicinal product concerned.

(c) Quotations as well as tables and other illustrative matter taken from scientific works for use in the documentation referred to in sub-regulation (9)(a) shall be faithfully reproduced.

(7) (a) Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:

(i) each sample shall be no larger than the smallest presentation on the market;

(ii) each sample shall be marked "free sample - not for sale";

(iii) each sample shall be accompanied by a copy of the summary of product characteristics;

(iv) veterinary medicinal products containing psychotropic or narcotic substances as defined under the First Schedule to the Dangerous Drugs Ordinance and the Third Schedule to the Medical and Kindred Professions Ordinance cannot be distributed as samples;

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(b) Starter packs shall not be regarded as samples and shall not be labelled as such.

(c) During visits by sales representatives the persons visited should be given information about the use of the veterinary medicinal products, with particular reference to any adverse reactions.

(8) The person who advertises the veterinary medicinal products shall:

(a) keep available for, or communicate to, the Veterinary Services, a sample of all advertisements emanating from his undertaking together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;

(b) supply the Veterinary Services with the information and assistance it requires to carry out its responsibilities;

(c) ensure that the decisions taken and conditions imposed by the Veterinary Services are immediately and fully complied with.

(9) It is not permissible to advertise veterinary medicinal products which are not registered with the Veterinary Services.".

25. Regulation 79 of the principal regulations shall be amended as follows:

Amends regulation 79 of the principal regulations.

(a) sub-regulation (2) thereof shall be substituted by the

following new sub-regulation:

"(2) For the purposes of these regulations every registered or licensed establishment where food producing animals are kept and are not excluded from the provisions of the Official Controls Regulation (EU) 2017/625 by the veterinary services , and the establishments where animals are kept for display to the public or for breeding purposes in the territory of Malta shall have an appropriate animal health control programme designed and implemented under the responsibility of a professional registered with the Veterinary Surgeons Council:

Provided that a register of the professionals responsible for each animal health control programme shall be kept by the Veterinary Services:

Provided further that the Veterinary Services may from time to time publish requirements related to animal health control programmes in the Gazette."; and

(b) sub-regulation (3) thereof shall be substituted by the following new sub-regulation:

"(3) The provisions of sub-regulation (2) shall come into force two (2) years from the date of coming into force of these regulations.".

Renumbers Title IX and Title X of the principal regulations.

26. Title IX and Title X of the principal regulations shall be renumbered as Title XIII and Title XIV respectively.

Adds new Title and regulation to the principal regulations.

27. Immediately after regulation 79 of the principal regulations, there shall be added the following new Title and regulation:

"TITLE XII
ADMINISTRATION OF VETERINARY MEDICINAL PRODUCTS AND MEDICINAL PRODUCT TO ANIMALS

Administration of veterinary medicinal products and medicinal products to animals.

79A. (1) In extreme and/or urgent situation to alleviate suffering of the animal or impending spread of disease any person can administer a veterinary medicinal product or medicinal product which requires a veterinary prescription without the veterinary prescription or the instructions to administer the product by the veterinary surgeon.

(2) No person can administer, or supply for administration, a veterinary medicinal product to animals unless the product obtains an authorisation from the Veterinary Services.

(3) Products whose therapeutic effectiveness is merely anecdotal should be used with caution in all animals. The administration of these products to food producing species is subject to the approval of the veterinary services. The veterinary services may ask the animal keeper to provide chemical data, clinical documentation and studies about the possible environmental impact before granting its approval.

(4) The keeper/owner/carer of animals must keep proof of purchase of all products administered or intended to be administered to the animals for the treatment or prevention of disease or, if he did not buy them, documentary evidence of how he acquired them.

(5) Metaphylactic or prophylactic antimicrobial treatment may be allowed with conditions. Preventive use of antimicrobials veterinary medicinal products or medicinal products is not allowed.

(6) Except in emergency situations, before prescribing a veterinary medicinal product or a medicinal product that contains an antimicrobial agent classified as critically important to human health or that is reserved for treating infections in animals for which no effective alternative treatments exist, the prescribing veterinary surgeon shall take into account the results of the diagnostic laboratory information (pathogen isolation, identification and antibiogram).

(7) No person shall administer a veterinary medicinal product or a medicinal product to a food producing species and place the animal for slaughter to be consumed unless the relevant withdrawal period has been observed.

(8) Stockpiling of antimicrobial veterinary medicinal products or medicinal products in a farm to be administered at a later stage is not permitted.

(9) Use of combination of antimicrobials should be scientifically supported.".

Amends regulation 82 of the principal regulation.

28. Sub-regulation (2) of regulation 82 of the principal regulations shall be renumbered as sub-regulation (2)(a) and immediately thereafter there shall be added the following new sub-

regulations:

"(b) The marketing authorisation holder shall implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time the veterinary medicinal products in the distribution network.

(c) record and investigate any complaint concerning a quality defect.

(d) The Veterinary Services shall be informed by the Marketing Authorisation holder of any quality defect that could result in a recall or abnormal restriction on the supply. In so far as possible, the countries where the products are marketed shall also be indicated.".

Substitutes regulation 87 of the principal regulations.

29. Regulation 87 of the principal regulations shall be substituted by the following new regulation:

Disposal of veterinary medicinal products waste.

87. (1) Any person who in the course of his activity generates veterinary medicinal products waste, shall inform himself of the current procedures regarding the safe disposal of unused, unsuitable or expired medicinal products from the entity responsible for waste management in Malta and shall follow the guidelines issued by the veterinary services.

(2) Companies, large establishments and professional bodies shall describe the procedure they follow for the safe disposal of unused, unsuitable or expired veterinary medicinal products in writing, and keep it updated according to the requirements that may change over-time.

(3) The Veterinary Services shall ensure that veterinary medicinal product waste producers have appropriate procedures set in place for the disposal of unused, unsuitable or expired veterinary medicinal products in accordance with the law of Malta and any particular instructions described in the summary of product characteristics of the product.".

Adds new regulations to the principal regulations.

30. Immediately after regulation 87 of the principal regulations

there shall be added the following new regulations:

"Offences and penalties.

88. Any person who contravenes regulations 5(1), 27(A), 39(1)(a)(b), 39(2)(a), 39(3), 46(1), 50B, 50C, 58(1), 58A, 59(1), 59A(2), 59A(3), 60(13), 60(14), 62 and 77A(4) shall be guilty of an offence against Article 38 of the Act and shall be liable, on conviction, to a fine (*multa*) of not less than five thousand euro (€5,000) and not more than ten thousand euro (€10,000).

89. Any person who contravenes regulations 39(3), 59A(2) and 59A(3), shall be guilty of an offence against article 38 of the Act and shall be liable, on conviction, to a fine *(multa)* of not less than three thousand euro (€3,000) and not more than seven thousand euro (€7,000).

90. Any person who contravenes regulation 72(8) shall be guilty of an offence against article 35 of the Act and shall be liable, on conviction, to a fine (*multa*) of not less than three thousand euro (€3,000) and not more than seven thousand euro (€7,000).

91. Any person who contravenes regulations 27A, 46(1), 50B, 50C, 59(1), 60(13), 60(14), 62 and 77A(4) shall be guilty of an offence against article 38 of the Act and shall be liable, on conviction, to a fine (*multa*) of not less than five hundred euro (€500) and not more than one thousand euro (€1,000).

Other offences.

92. Any person who contravenes any regulation other than those mentioned in regulations 88,89, 90 and 91 shall be guilty of an offence and shall be liable, on conviction, to a fine (*multa*) of not less than two hundred euro (€200) and not more than four hundred euro (€400).

93. Where the Director has reasonable cause to believe that an offence against these regulations has been committed and that it would be appropriate to impose an administrative penalty under article 61 of the Act, the Director shall proceed in accordance with the provisions of the said article 61 of the Act.".

31. The principal regulations shall be amended as follows:

Amendments to the principal regulations.

(a) the word "veterinarian", wherever it occurs, shall be substituted by the words "veterinary surgeon";

(b the word "veterinarians", wherever it occurs, there shall be substituted the words "veterinarian surgeons";

(c) the words "territory of Malta", wherever they occur with the exception of the same words used in the meaning of the term "Veterinary Services" in regulation 2 and in regulation 51, shall be substituted by the word "Director"; and

(d) the word "Community", wherever it occurs with the exception of the same word used in sub-regulation (2) of regulation 1 and regulation 30, shall be substituted by the word "Union".