

A.L. 82 ta' l-2006

**ATT DWAR IS-SERVIZZI VETERINARJI
(KAP. 437)**

**Regolamenti ta' l-2006 li jemendaw ir-Regolamenti dwar
Prodotti Mediċinali Veterinarji**

BIS-SAHHA tas-setgħa mogħtija bl-artikoli 30 u 31 ta' l-Att dwar is-Servizzi Veterinarji, il-Ministru ta' l-Affarijiet Rurali u l-Ambjent għamel dawn ir-regoli li ġejjin:-

1. (1) It-titolu ta' dawn ir-regolamenti huwa **Regolamenti ta' l-2006 li jemendaw ir-Regolamenti dwar Prodotti Mediċinali Veterinarji**, u għandhom jinqraw u jiftieħmu haġa waħda mar-Regolamenti ta' l-2004 dwar Prodotti Mediċinali Veterinarji, hawn iżjed 'il quddiem f'dawn ir-regolamenti msejhin "ir-regolamenti prinċipali".

Titolu u skop.

A.L. 469 ta' l-2004.

(2) L-iskop ta' dawn ir-regolamenti huwa l-implimentazzjoni tar-regoli mnizzla taħt id-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28 KE li jemendaw id-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/82/KE fuq il-kodiċi tal-Komunità dwar il-prodotti mediċinali veterinarji.

2. Minflok is-subregolament (3) tar-regolament 1 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jemenda r-regolament 1 tar-regolamenti prinċipali.

“(3) (a) Dawn ir-regolamenti għandhom japplikaw għall-prodotti mediċinali veterinarji, li jinkludu prodotti mħallta minn qabel għal għalf medikat, maħsubin biex jinbiegħu f'Malta u preparati industrijalment jew b'metodu li jinvolvi proċess industrijali.

(b) Fil-każ ta' dubju, meta tqies il-karatteristiċi kollha, prodott jista' jaqa' taħt id-definizzjoni ta' "prodott veterinarju mediċinali" u fid-definizzjoni ta' prodott kopert minn leġislazzjonijiet Komunitarji ohra, għandhom japplikaw id-disposizzjonijiet ta' dawn ir-regolamenti.

(ċ) Minkejja paragrafu (a) hawn qabel, dawn ir-regolamenti għandhom japplikaw ukoll għal sustanzi attivi użati bħala *starting materials* sal-punt imnizzla fir-regolamenti 44, 44A,

45 u 72 u addizzjonali għal ċerti sustanzi li jistgħu jiġu użati bhala prodotti mediċinali veterinarji li għandhom proprjetajiet anabolici, anti-infettivi, anti-parassitiċi, anti-inflammatorji, ormonali jew psikotropiċi sal-punt imniżżla fir-regolament 61. “.

Jemenda r-regolament 2 tar-regolamenti prinċipali.

3. Regolament 2 għandu jiġi emendat kif ġej:

(a) punt (1) għandu jithassar;

(b) minflok punt (2) għandu jidhol dan li ġej:

(2) “Prodott mediċinali veterinarju” tfisser:

(a) kull sustanza jew kombinazzjoni ta’ sustanzi ppreżentati bhala li għandhom proprjetajiet għall-kura jew biex jipprevjenu mard fl-annimali; jew

(b) kull sustanza jew kombinazzjoni ta’ sustanzi li jistgħu jintużaw jew jiġu amministrati lill-annimali bil-hsieb jew li jgħibu f’tagħhom, jikkoreġu jew ibiddu funzjonijiet fiżjoloġiċi billi jeżerċitaw azzjoni farmakoloġika, immunoloġika jew matabolika, jew biex issir djanjosi medika.”;

(ċ) punt (3) għandu jithassar;

(d) minflok punti (8), (9) u (10) għandu jidhol dan li ġej:

“(8) “Prodott mediċinali veterinarju omeopatu” tfisser kull prodott mediċinali veterinarju mhejji minn sustanzi msejha *homeopathic stocks* skond proċedura ta’ manifattura omeopatika deskritta mill-Farmakopea Ewropea jew, fl-assenza tagħha, minn Farmakopej uffiċjalment użati f’xi żmien partikolari fl-Istati Membri. Prodott mediċinali veterinarju omeopatu jista’ jkun fih għadd ta’ prinċipji.

(9) “Perjodu ta’ tiżmim” tfisser il-perjodu mehtieġ bejn l-ahhar amministrazzjoni tal-prodott mediċinali veterinarju lill-annimali, taht ċirkostanzi normali ta’ użu u skond id-disposizzjonijiet ta’ dawn ir-regolamenti, u l-produzzjoni ta’ ikel minn dawk l-annimali, sabiex tkun protetta is-sahha pubblika billi jkun żgurat illi dak l-ikel ma jkunx

fi h fdalijiet fi kwantitajiet li jeċċedu l-limiti massimi ta' residwi għal sustanzi attivi stabbiliti fir-Regolament ta' l-Unjoni Ewropea Nru 2377/90 KEE.

(10) “Reazzjoni kuntrarja” tfisser reazzjoni għal prodott mediċinali veterinarju li tkun ta' hsara u mhux maħsuba u li ssehh f' dozi normalment użati f' animali għal profilassi, dijanjosi jew trattament ta' mard biex tregġa' lura, tikkoreġi jew timmodifika l-funzjoni fiżjoloġika.”;

(e) minnufih wara l-punt 17 għandu jizdied dan il-punt li ġej:

(17A) “Rappreżentant ta' min għandu l-awtorizzazzjoni għall-bejgħ” tfisser il-persuna, ġeneralment magħrufa bhala rappreżentant lokali, appuntat minn min għandu l-awtorizzazzjoni għall-bejgħ biex jirrapreżentah f' Malta.”;

(f) minflok il-punt 18 għandu jidhol dan li ġej:

“(18) “Aġenzija” tfisser l-Aġenzija Ewropea għall-Mediċina stabbilita bir-Regolament ta' l-Unjoni Ewropea Nru 726/2004 KE.”;

(g) minflok punt 19 għandu jidhol dan li ġej:

“(19) “Riskji relatati ma' l-użu tal-prodott” tfisser:

– kull riskju relatat mal-kwalità, harsien tas-saħħa u l-effikaċja tal-prodotti mediċinali veterinarji fir-rigward tas-saħħa ta' l-animali jew tal-bniedem;

– kull riskju li jhalli effetti mhux mixtieqa fuq l-ambjent.”;

(h) minnufih wara l-punt (26) għandu jizdied dan il-punti li ġej:

“(27) “Bilanċ ta' riskju/benefiċċju” tfisser evalwazzjoni ta' l-effetti terapewtiċi possittivi tal-

prodott mediċinali veterinarju fir-rigward tar-riskji mnizzla hawn qabel.

(28) “Riċetta veterinarja” tfisser kull riċetta għall-prodott mediċinali veterinarju mahruġa minn persuna professjonali kwalifikata li tagħmel dan skond il-liġijiet nazzjonali li japplikaw.

(29) “Isem tal-prodott mediċinali veterinarju” tfisser l-isem, li jitsa’ jkun jew isem ivvintat li ma jkunx soġġett għal konfużjoni ma’ l-isem komuni, jew isem komuni jew xjentifiku akkumpanjat minn *trademark* jew l-isem ta’ min ikollu l-awtorizzazzjoni għall-bejgħ.

(30) “Isem komuni” tfisser l-isem internazzjonali mhux proprjetarju rakkomandat mill-Organizzazzjoni Dinjija tas-Sahha (WHO), jew, jekk ma jkunx jeżisti, l-isem komuni tas-soltu.

(31) “Sahha” tfisser il-kontenut tas-sustanzi attivi, espressi b’mod kwantitattiv għal kull *unit* ta’ doża, għal kull *unit* ta’ volum jew piz skond il-forma tad-doża.

(32) “Pakkettar ta’ ġewwa” tfisser il-kontenitur jew kull forma oħra ta’ pakkettar illi hija direttament fil-kuntatt mal-prodott mediċinali.

(33) “Pakkettar ta’ barra” tfisser il-pakkettar li fih jitqiegħed l-ippakkettar ta’ ġewwa.

(34) “Tikkettar” tfisser l-informazzjoni fuq il-pakkett ta’ ġewwa jew ta’ barra.

(35) “Fuljett tal-pakkett” tfisser il-fuljett li fih l-informazzjoni għal min jużah li jakkompanja l-prodott mediċinali.”;

Jissostitwixxi r-regolament 3 tar-regolament 3 tar-regolamenti prinċipali.

4. Minflok ir-regolament 3 tar-regolamenti prinċipali għandu jidhol dan li ġej:

“3. (1) Dawn ir-regolamenti ma għandhomx japplikaw għal:

(a) prodotti ta' l-ikel medikat skond kif imnizzel fid-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 90/167/KEE li tniżżel il-kundizzjonijiet li jirregolaw il-preparazzjoni, it-tqeghid fis-suq u l-użu ta' prodotti medikati fil-Komunità Ewropea;

(b) prodotti mediċinali veterinarji immunoloġikament inattivati li jkunu manifatturati minn patoġeni u antiġeni miksubin minn annimal jew annimali minn xi fond u li jiġu użati għall-kura ta' dak l-annimal jew l-annimali ta' dak ir-razzett fl-istess lokalità;

(ċ) prodotti mediċinali veterinarji bbażati fuq isotopi radjuattivi;

(d) additivi koperti bid-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 70/524/KEE dwar additivi fl-ġhalf, fejn dawn ikunu inkorporati f' ġhalf għall-annimali u ġhalf għall-annimali supplimentari skond dik id-Direttiva; u

(e) mingħajr preġudizzju għar-regolament 86, prodotti mediċinali għall-użu veterinarju mahsuba għal provi ta' riċerka u żvilupp.

Madankollu, prodotti ta' l-ikel medikat imnizzla f' paragrafu (a) hawn qabel, jistgħu jkunu preparati biss minn tahlitiet minn qabel li jkunu ġew awtorizzati skond dawn ir-regolamenti.

(2) Hlief għad-disposizzjonijiet fuq il-pussess, il-preskrizzjoni, ir-rilaxx u l-amministrazzjoni tal-prodotti mediċinali veterinarji, dawn ir-regolamenti ma għandhomx japplikaw għal:

(a) xi prodott mediċinali ippreparat fi spizerija skond riċetta veterinarja għal annimal individwali jew għal grupp żgħir ta' annimali, ġeneralment magħrufa bhala l-formula magistrali; u

(b) xi prodott mediċinali ippreparat fi spizerija skond ir-riċetti ta' Farmakopea u mahsub biex jissupplixxi direttament lill-persuna li tkun ser tużah l-aħhar, ġeneralment magħruf bhala l-formula uffċinali.”.

5. Minflok is-subregolament (2) tar-regolament 4 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jemenda r-regolament 4 tar-regolamenti prinċipali.

“(2) Fil-każ ta’ prodotti mediċinali veterinarji mahsuba unikament għall-hut ta’ l-akkwarju, għasafar domestiċi, hamiem tat-tigrija, annimali f’ terrarju, rodenti żgħar, u nemmiesa u fniek miżmuma esklużivament bhala annimali domestiċi, Malta tista’ tippermetti eżenzjonijiet mid-disposizzjonijiet ta’ regolamenti 5 sa 8, sakemm daww il-prodotti ma jkunx fihom sustanzi li l-użu tagħhom ikun jehtieġ kontroll veterinarju u sakemm ikunu ttiehdu l-miżuri kollha possibli biex jiġi evitat l-użu mhux awtorizzat tal-prodotti għal animalo oħra.”.

Jissostitwixxi r-regolamenti 5 u 6 tar-regolamenti prinċipali.

6. Minflok ir-regolamenti 5 u 6 tar-regolamenti prinċipali għandu jidhol dan li ġej:

“5. (1) L-ebda prodott veterinarju ma jista’ jitqiegħed fis-suq ta’ Malta sakemm ma tkunx inharġet awtorizzazzjoni ta’ bejgħ mis-Servizzi Veterinarji skond dawn ir-regolamenti jew ma tkunx ingħatat awtorizzazzjoni għall-bejgħ fis-suq skond ir-Regolament ta’ l-Unjoni Ewropea (KE) Nru 726/2004.

Meta prodott mediċinali veterinarju jkun ġie mogħti awtorizzazzjoni inizjali skond l-ewwel paragrafu, kull speċi addizzjonali, sahha, formuli ta’ farmaċewtika, il-metodu u l-mod ta’ amministrazzjoni, preżentazzjoni, kif ukoll kull varjazzjoni u estensjoni, għandhom jingħataw ukoll awtorizzazzjoni skond l-ewwel paragrafu jew ikunu inklużi fl-awtorizzazzjoni ta’ bejgħ inizjali. Dawn l-awtorizzazzjonijiet ta’ bejgħ kollha għandhom ikunu kkunsidrati bhala li jappartjenu lill-istess awtorizzazzjoni ta’ bejgħ globali, b’mod partikolari għall-iskop ta’ l-applikazzjoni tar-regolament 13(1).

(2) Id-detentur ta’ l-awtorizzazzjoni ta’ bejgħ għandu jkun responsabbli għall-bejgħ tal-prodott mediċinali. Meta jkun innominat rappreżentant, dan ma għandux jehles lid-detentur ta’ l-awtorizzazzjoni għall-bejgħ, mir-responsabilitajiet legali tiegħu.

6. (1) Prodott mediċinali veterinarju ma jista’ jkun soġġett għal ebda awtorizzazzjoni ta’ bejgħ bl-iskop li jkun amministrat lil xi speċi wahda jew aktar li jipproduċu l-ikel sakemm is-sustanzi attivi farmakoloġiċi li jkun fihom, ikunu jidhru fl-Annessi I, II jew III tar-Regolament ta’ l-Unjoni Ewropea (KEE) Nru 2377/90.

(2) Jekk emenda fl-Annessi mar-Regolament (KEE) Nru 2377/90 tkun hekk tehtieġ, id-detentur ta’ l-awtorizzazzjoni ta’ bejgħ jew, meta jkun hekk adatt, is-Servizzi Veterinarji għandhom jieħdu l-miżuri kollha neċessarji biex jemendaw jew iħassru l-awtorizzazzjoni għall-bejgħ fi żmien 60 ġurnata minn

meta tkun ippublikata l-emenda fl-Annessi ta' dak ir-Regolament fil-Hurnal Uffiċjali ta' l-Unjoni Ewropea.

(3) B'deroga mis-subregolament (1) ta' dan ir-regolament, prodott mediċinali veterinarju li jkun fih sustanzi attivi farmakoloġiċi mhux imniżżla fl-Annessi I, II jew III tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90 jista' jkun awtorizzat għal annimali partikolari tal-familja ta' l-*equidae* li jkunu ġew dikjarati, skond id-Deciżjoni tal-Kummissjoni ta' l-Unjoni Ewropea 93/623/KEE li tistabilixxi d-dokument ta' identifikazzjoni (passaport) li jakkumpanja *equidae* reġistrati u d-Deciżjoni tal-Kummissjoni ta' l-Unjoni Ewropea 2000/68/KE li temenda Deciżjoni 93/623/KEE u tistabilixxi l-identifikazzjoni ta' *equidae* għat-trobbija u produzzjoni, li m'humiex maħsubin għall-qatla għall-konsum mill-bniedem. Dawk il-prodotti veterinarji mediċinali ma għandhom la jinkludu sustanzi attivi li jidhru fl-Anness IV tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90 u lanqas inkunu maħsuba għall-użu ta' trattament ta' kundizzjonijiet, kif imniżżla fis-Sunt ta' Karatteristiċi tal-Prodott awtorizzat, li għalih huwa awtorizzat prodott mediċinali veterinarju għall-annimali tal-familja ta' l-*equidae*.”.

7. Minflok ir-regolament 8 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jissostitwixxi r-regolament 8 tar-regolamenti prinċipali.

“8. (1) Fil-każ ta' mard epizootiku serju, is-Servizzi Veterinarji jistgħu priviżorjament jippermettu l-użu ta' prodott mediċinali veterinarji immunoloġiċi mingħajr l-awtorizzazzjoni għall-bejgħ, fin-nuqqas ta' prodott mediċinali adatt u wara li tkun ġiet informata l-Kummissjoni Ewropea dwar il-kundizzjonijiet dettaljati ta' l-użu.

(2) Meta animal ikun qed jiġi mpurtat, jew esportat lejn pajjiż terz u jkun għalhekk soġġett għal regoli ta' saħha speċifiċi li jkunu jobbligaw, is-Servizzi Veterinarji jistgħu iħallu l-użu, għall-annimal in kwistjoni, ta' prodott mediċinali veterinarju immunoloġiku li ma jkunx kopert minn awtorizzazzjoni għall-bejgħ f'Malta imma li jkun awtorizzat taħt il-legislazzjoni tal-pajjiż terz. Is-Servizzi Veterinarji għandhom jieħdu l-miżuri adatti kollha li jikkonċernaw is-superviżjoni ta' l-importazzjoni u l-użu ta' dawk il-prodotti immunoloġiċi.”.

8. Minflok ir-regolamenti 10 sa 13 tar-regolamenti prinċipali għandhom jidhlu dawn li ġejjin:

Jissostitwixxi r-regolamenti 10 sa 13 tar-regolamenti prinċipali.

“10. (1) Is-Servizzi Veterinarji għandhom jiehdu l-miżuri neċessarji biex jiżguraw illi, jekk ma jkunx hemm prodott mediċinali veterinarju awtorizzat f'Malta għal kondizzjoni li taffettwa xi speċi li ma tipproduċix l-ikel, bhala eċċezzjoni l-veterinarju responsabbli jista', taht ir-responsabilità diretta tiegħu u partikolarment sabiex ikun evitat li tiġi kaġunata tbatija inaċċettabbli, jitratta l-annimal konċernat bi:

(a) prodott mediċinali veterinarju awtorizzat f'Malta taht dawn ir-regolamenti jew taht ir-Regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004 għall-użu fi speċi ta' annimali ohra, jew għal xi kondizzjoni ohra fl-istess speċi, jew

(b) jekk ma jkun hemm ebda prodott kif imsemmi fil-paragrafu (a) -

(i) jew prodott mediċinali awtorizzat għall-użu tal-bniedem f'Malta skond id-Direttiva 2001/83/KE tal-Parlament u tal-Kunsill ta' l-Unjoni Ewropea jew taht ir-Regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004,

(ii) jew skond il-miżuri nazzjonali speċifiċi, prodott mediċinali veterinarju awtorizzat fi Stat Membru iehor skond dawn ir-regolamenti għall-użu ta' l-istess speċi jew fi speċi ohra għall-kondizzjoni in kwistjoni jew għal kondizzjoni ohra; jew

(ċ) jekk ma jkun hemm ebda prodott kif imsemmi fil-paragrafu (b), u fil-parametri tal-liġi ta' Malta, prodott mediċinali veterinarju ippreparat estemporanjament minn persuna li tkun awtorizzata skond il-liġi nazzjonali skond ma jkun hemm miktub fir-riċetta veterinarja.

Il-veterinarju jista' jamministra l-prodott mediċinali personalment jew ihalli persuna ohra biex jagħmel dan taht ir-responsabilità iegħu.

(2) B'deroga minn regolament 11, id-disposizzjonijiet ta' subregolament (1) ta' dan ir-regolament għandhom japplikaw ukoll għat-trattament minn veterinarju ta' annimal li jappartjeni lill-familja ta' l-*equidae* sakemm dan ikun dikjarat li mhux mahsub għall-qtil jew għall-konsum tal-bniedem skond id-Deċiżjonijiet tal-Kummissjoni ta' l-Unjoni Ewropea 93/623/KEE u 2000/68/KE.

11. (1) Is-Servizzi Veterinarji għandhom jiehdu l-miżuri neċessarji biex jiżguraw illi, jekk ma jkunx hemm prodott

medicinali veterinarju awtorizzat f'Malta ghal kondizzjoni li taffettwa xi speċi li tipproduċi l-ikel, bhala eċċezzjoni l-veterinarju responsabbli jista', taht ir-responsabilità diretta tiegħu u partikolarment sabiex ikun evitat li tiġi kaġunata tbatija inaċċettabbli, jittratta l-annimal konċernat bi:

(a) prodott medicinali veterinarju awtorizzat f'Malta taht dawn ir-regolamenti jew taht ir-Regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004 għall-użu fi speċi ta' annimali ohra, jew għal xi kondizzjoni ohra fl-istess speċi; jew

(b) jekk ma jkun hemm ebda prodott kif imsemmi fil-paragrafu (a), jew

(i) prodott medicinali awtorizzat għall-użu tal-bniedem f'Malta skond id-Direttiva 2001/83/KE tal-Parlament u tal-Kunsill ta' l-Unjoni Ewropea jew taht ir-Regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004, jew

(ii) prodott medicinali veterinarju awtorizzat fi Stat Membru iehor skond dawn ir-regolamenti għall-użu ta' l-istess speċi jew fi speċi ohra għall-kondizzjoni in kwistjoni jew għal kondizzjoni ohra; jew

(ċ) jekk ma jkun hemm ebda prodott kif imsemmi fil-paragrafu (b), u fil-parametri tal-liġi ta' Malta, prodott medicinali veterinarju ippreparat estemporanjament minn persuna li tkun awtorizzata skond il-liġi nazzjonali skond ma jkun hemm miktub fir-riċetta veterinarja.

Il-veterinarju jista' jamministra l-prodott medicinali personalment jew iħalli lil xi persuna ohra biex tagħmel dan taht ir-responsabilità tiegħu.

(2) Subregolament (1) ta' dawn ir-regolamenti għandu japplika sakemm is-sustanzi attivi farmakoloġiċi inklużi fil-prodott medicinali jkunu mnizzla fl-Anness I, II jew III tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90, u li l-veterinarju jispeċifika perjodu ta' tiżmim xieraq.

Kemm-il darba l-prodott medicinali ma jkunx jindika perjodu ta' tiżmim għall-ispeċi involuta, il-perjodu ta' tiżmim speċifiku ma għandux ikun ta' inqas minn:

- 7 ijiem għall-bajd,
- 7 ijiem għall-halib,
- 28 jum għal-laham ta' tjur u mammiferi inkluż ix-xaham u l-interjuri,
- 500 granet-gradi għal-laham tal-hut.

(3) Dwar prodotti mediċinali veterinarji omejopatiċi fejn prinċipji attivi jidhru fl-Anness II tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90, il-perjodu ta' tiżmim msemmi fit-tieni paragrafu tas-subregolament (2) għandu jkun imnaqqas għal xejn.

(4) Meta veterinarju jirrikorri għad-disposizzjonijiet tas-subregolamenti (1) u (2) ta' dan ir-regolament, huwa għandu jzomm *records* adegwati tad-data ta' l-eżami ta' l-annimali, id-dettalji tas-sid, l-ghadd ta' annimali eżaminati, id-djanjosi, il-prodotti mediċinali preskritti, id-dożi amministrati, għal kemm żmien iddum il-kura u l-perjodu ta' tiżmim rakkomandat, u jqiegħed dawn ir-*records* disponibbli għal ispezzjoni mis-Servizzi Veterinarji għal perjodu ta' mill-inqas hames snin.

(5) Minghajr preġudizzju għad-disposizzjonijiet l-oħra ta' dawn ir-regolamenti, Malta għandha tiehu l-miżuri kollha neċessarji li jikkonċernaw l-importazzjoni, id-distribuzzjoni, ir-rimi u l-informazzjoni fuq il-prodotti mediċinali li huma jippermettu li jiġu mogħtija lil annimali li jipproduċu l-ikel skond subregolament (1)(b)(ii).

12. (1) Sabiex tinkiseb awtorizzazzjoni ta' bejgħ għal prodott mediċinali veterinarju, li ma jaqax taht il-proċedura mnizzla fir-Regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004, għandha tiġi ppreżentata applikazzjoni lis-Servizzi Veterinarji.

Fil-każ ta' prodotti mediċinali veterinarji li huma maħsuba għal speċi waħda jew aktar li jipproduċu l-ikel iżda li jkollhom sustanzi farmakoloġiċi attivi ma jkunux għadhom ġew miżjuda, għall-ispeċi in kwistjoni, f'Annessi I, II jew III tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90, ma tistax issir applikazzjoni għal awtorizzazzjoni għall-bejgħ sakemm issir applikazzjoni valida sabiex jiġu stabbiliti ta' limiti massimi ta' fdalijiet skond dak ir-Regolament. Ta' lanqas sitt xhur għandhom jgħaddu bejn applikazzjoni valida biex jiġu stabbiliti limiti massimi ta' fdalijiet u applikazzjoni għall-awtorizzazzjoni għall-bejgħ.

Madankollu, fil-każ ta' prodotti mediċinali veterinarji msemmija f'regolament 6(3), tista' ssir applikazzjoni għal awtorizzazzjoni għall-bejgħ mingħajr applikazzjoni valida skond ir-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90. Id-dokumentazzjoni xjentifika kollha neċessarja biex turi l-kwalità, sigurtà u effikaċja tal-prodott mediċinali veterinarju, kif imnizzel f'subregolament (3) ta' dan ir-regolament, għandha tiġi pprezentata.

(2) Awtorizzazzjoni għall-bejgħ tista' tinghata biss lil applikant stabbilit fil-Komunità Ewropea.

(3) L-applikazzjoni għal awtorizzazzjoni għall-bejgħ għandha tinkludi l-informazzjoni amministrattiva kollha u dokumentazzjoni xjentifika neċessarja biex turi l-kwalità, sigurtà u effikaċja tal-prodott mediċinali veterinarju in kwistjoni. Il-*file* għandu jiġi pprezentat skond Skeda I u għandu jkun fih, b'mod partikolari, l-informazzjoni li ġejja:

(a) l-isem jew l-isem tan-negozju u indirizz permanenti jew post reġistrat tan-negozju tal-persuna responsabbli għall-bejgħ tal-prodott u, jekk dan ikun differenti, tal-manifattur jew manifatturi involuti u tas-siti tal-manifattura;

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

(ċ) partikolaritajiet kwalitattivi u kwantitattivi tal-kostitwenti kollha tal-prodott mediċinali veterinarju, inkluż l-isem internazzjonali mhux proprjetarju (INN) rakkomandat mill-Organizzazzjoni Dinjija tas-Saħha (WHO), meta jkun jeżisti INN, jew l-isem kimiku tiegħu;

(d) deskrizzjoni tal-metodu ta' manifattura;

(e) indikazzjonijiet terapewtiċi, kontra-indikazzjonijiet u reazzjonijiet kuntrarji;

(f) doża għall-ispeċi varji ta' animali li għalih il-prodott mediċinali veterinarju jkun maħsub, il-forma farmaċewtika tiegħu, metodu u rotta ta' kif ikun amministrat u t-tul ta' żmien għal kemm jista' jinhażen;

(g) raġunijiet tal-miżuri ta' prekawzjoni u ta' harsien tas-saħha li għandhom jittiehdu meta l-prodott mediċinali veterinarju jkun maħżun, amministrat lill-animali u meta l-fdal tiegħu jintrema, flimkien ma indikazzjoni ta' kull riskju

potenzjali li l-prodott mediċinali jista' joffri lill-ambjent u lis-saħħa tal-bniedem, ta' l-annimali jew tal-pjanti;

(h) indikazzjoni tal-perjodu ta' tiżmim fil-każ ta' prodotti mediċinali maħsuba għal speċi li jipproduċu l-ikel;

(i) deskrizzjonijiet tal-metodi ta' testjar użati mill-manifattur;

(j) riżultati ta':

— testijiet farmaċewtiċi (fiżjokimiċi, bijoloġiċi jew mikrobijoloġiċi),

— testijiet ta' sigurtà u testijiet ta' fdalijiet,

— provi pre-kliniċi u provi kliniċi;

— testijiet li jistudjaw ir-riskji potenzjali lill-ambjent maħluqa mill-prodott mediċinali. Dan l-impatt għandu jkun studjat u għandha tingħata konsiderazzjoni fuq bażi ta' każ b'każ lil disposizzjonijiet speċifiċi li jippruvaw jillimitaw l-impatt.

(k) deskrizzjoni dettaljata tas-sistema farmakoviġilanti u, jekk ikun adatt, tas-sistema ta' immaniġġjar ta' riskju li l-applikant ikun bi hsiebu li jadotta;

(l) tagħrif fil-qosor skond ir-regolament 14 tal-karatteristiċi tal-prodott, *mock-up* tal-ippakkettar ta' ġewwa u ta' barra tal-prodott mediċinali veterinarju, flimkien mal-fuljett tal-pakkett, skond ir-regolamenti 53 sa 55;

(m) dokument li juri li l-manifattur ikun awtorizzat f'pajjiżu biex jipproduċi prodotti veterinarji mediċinali f'pajjiżu;

(n) kopji ta' kull awtorizzazzjoni għall-bejgh miksuba fi Stat Membru jew f'pajjiż terz għall-prodott mediċinali veterinarju rilevanti, flimkien ma' lista ta' dawk l-Istati Membri li jkunu qeghdin jeżaminaw applikazzjoni għal awtorizzazzjoni ppreżentata skond dawn ir-regolamenti. Kopji tat-tagħrif fil-qosor tal-karatteristiċi tal-prodott proposti mill-applikant skond ir-regolament 14 jew approvat mis-Servizzi Veterinarji skond ir-regolament 25 u kopji tal-fuljett tal-pakkett propost, dettalji ta' kull deċiżjoni li tirrifjuta

awtorizzazzjoni, kemm fil-Komunità Ewropea kemm f'pajjiż terz u r-ragunijiet għal dik id-deċiżjoni. Din l-informazzjoni għandha tiġi aġġornata fuq bażi regolari;

(o) prova li l-applikant għandu s-servizzi ta' persuna kwalifikata li jkun responsabbli għall-farmakoviġilanza u jkollu l-mezzi neċessarji biex jinnotifika b'kull reazzjoni kuntrarja suspettata li qed issehh fil-Komunità Ewropea jew f'pajjiż terz;

(p) fil-każ ta' prodotti mediċinali veterinarji maħsuba għal speċi waħda jew iktar li tipproduċi l-ikel u li għandha sustanza attiva farmakoloġika waħda jew aktar li mhumiex inkluzi, għall-ispeċi in kwistjoni, fl-Annessi I, II jew III tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90, dokument li jiċċertifika li applikazzjoni valida sabiex jiġu stabbiliti ta' limiti massimi ta' fdalijiet, ikun ġie mressaq lill-Aġenzija skond l-istess Regolament.

Id-dokumenti u l-partikolaritajiet relatati għar-riżultati msemmija f'punt (j) ta' l-ewwel paragrafu għandhom ikunu akkompanjati b'sommarji dettaljati u kritiċi magħmulin skond kif speċifikat fir-regolament 15.

13. (1) B'deroga minn punt (j) ta' l-ewwel subparagrafu tar-regolament 12(3), u minghajr preġudizzju għall-liġi dwar il-protezzjoni tal-proprjetà industrijali u kummerċjali, l-applikant ma għandux ikun mehtieġ jipprovdi r-riżultati tat-testijiet ta' sigurtà jew tal-provi pre-kliniċi u provi kliniċi jekk huwa jista' juri li l-prodott mediċinali huwa wiehed ġeneriku ta' prodott mediċinali ta' riferenza li hu jew li kien awtorizzat skond ir-regolament 5 għal mhux inqas minn tmien snin fi Stat Membru jew fil-Komunità Ewropea.

Prodott mediċinali veterinarju ġeneriku awtorizzat skond din id-disposizzjoni ma għandux jitpoġġa fis-suq sakemm ma jgħaddux għaxar snin mill-awtorizzazzjoni inizjali tal-prodott ta' riferenza.

L-ewwel subregolament għandu japplika wkoll meta l-prodott mediċinali veterinarju ma jkunx awtorizzat fl-Istat Membru fejn tkun ġiet prezentata l-applikazzjoni għall-prodott mediċinali ġeneriku. F'dan il-każ, l-applikant għandu jindika fl-applikazzjoni l-Istat Membru fejn il-prodott mediċinali ta' riferenza ikun ġie jew kien awtorizzat. Fuq rikjesta tas-Servizzi Veterinarji, l-awtorità kompetenti ta' l-Istat Membru l-iehor għandha, fi żmien xahar, tagħti konferma li l-prodott mediċinali ta' riferenza ikun ġie jew

kien awtorizzat flimkien ma komposizzjoni shiha tal-prodott ta' riferenza u, jekk ikun neċessarju, kull dokumentazzjoni rilevanti ohra. Madankollu, il-perjodu ta' għaxar snin msemmi fit-tieni paragrafu għandu jiġi estiż għal 13-il sena fil-każ ta' prodotti mediċinali veterinarji għal hut jew naħal jew speċi oħrajn msemmija skond il-proċedura mnizzla fl-Artikolu 89(2) tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28 KE.

(2) Għall-iskopijiet ta' dan ir-regolament:

(a) “prodott mediċinali ta' riferenza” tfisser prodott awtorizzat skond it-tifsira ta' regolament 5 skond id-disposizzjonijiet tar-regolament 12;

(b) “prodott mediċinali ġeneriku” tfisser prodott mediċinali li għandu l-istess komposizzjoni kwalitattiva u kwantitattiva f'sustanzi attivi u l-istess forma farmaċewtika bħal tal-prodott mediċinali ta' riferenza, u li għandu bioekwivalenza mal-prodott mediċinali ta' riferenza li tkun ġiet murija bi studji xierqa ta' biodisponibilità. Il-melħ, esteri, eteri, isomeri, tahlit ta' isomeri, kumplessi jew derivattivi ta' sustanza attiva differenti għandhom ikunu kkunsidrati li jkunu l-istess sustanza attiva, sakemm ma jkunux sinifikament differenti fil-proprietajiet fir-rigward ta' sigurtà u/jew effikaċja. F'dawk il-każijiet l-applikant għandu jagħti informazzjoni addizzjonali biex jagħti prova tas-sigurtà u/jew effikaċja tal-melħ, esteri u derivattivi varji ta' sustanza attiva awtorizzata. Il-forom farmaċewtiċi varji ta' rilaxx immedjat li jittiehdu mill-halq għandhom ikunu kkunsiderati bhala forma farmaċetika wahda u l-istess. Ma jkunux mehtieġa mill-applikant studji ta' biodisponibilità jekk dan jista' juri li l-prodott mediċinali ġeneriku jkun jilhaq il-kriterji rilevanti kif definiti fil-gwidi ta' Prattika dettaljati u adatti.

(3) Fil-każijiet fejn il-prodott mediċinali veterinarju ma jaqax taht id-definizzjoni ta' prodott mediċinali ġeneriku kif imnizzel f'subregolament 2(b) jew fejn il-bioekwivalenza ma tistax tiġi murija minn studji ta' biodisponibilità jew fil-każ ta' bdil lis-sustanza jew sustanzi attivi, indikazzjonijiet terapewtiċi, saħħa, formula ta' farmaċewtika u l-mod ta' amministrazzjoni rigward il-prodott mediċinali ta' riferenza, għandhom jingħataw ir-riżultati tat-testijiet adatti tas-sigurtà u ta' fdalijiet u testijiet pre-kliniċi u provi kliniċi.

(4) Fejn il-prodott mediċinali veterinarju bijoloġiku li huwa simili għal prodott mediċinali veterinarju bijoloġiku ta' riferenza

ma jilhaqx il-kundizzjonijiet mnizzla fid-definizzjoni ta' prodotti mediċinali ġeneriċi, partikolarment minhabba differenzi relatati ma' materjal mhux maħdum jew fil-proċess ta' manifattura tal-prodott mediċinali veterinarju bijoloġiku u tal-prodott mediċinali veterinarju bijoloġiku ta' riferenza, għandhom jinghataw ir-rizultati ta' testijiet pre-kliniċi jew provi kliniċi adatti relatati ma' dawn il-kundizzjonijiet. It-tip u l-kwantità ta' informazzjoni supplimentari li għandha tinghata għandha tkun konformi mal-kriterji rilevanti mnizzla fi Skeda I u mal-gwidi dettaljati rilevanti. Ir-rizultati ta' testijiet u ta' provi ohra mid-*dossier* tal-prodott mediċinali ta' riferenza ma għandhomx jinghataw.

(5) Fil-każ ta' prodotti mediċinali veterinarji maħsuba għal speċi waħda jew iktar li tipproduċi l-ikel u li għandha sustanza attiva ġdida li ma ġietx awtorizzata fil-Komunità Ewropea sat-30 t'April, 2004, il-perjodu ta' għaxar snin msemmi fit-tieni paragrafu ta' subregolament (1) għandu jkun estiż b'sena waħda għal kull estenzjoni ta' l-awtorizzazzjoni għall-bejgħ għal speċi ohra li tipproduċi l-ikel, jekk hija tkun awtorizzata fi żmien hames snin wara li tkun inghatat l-awtorizzazzjoni ta' bejgħ inizjali.

Madankollu, dan il-perjodu ma għandux jeċċedi total ta' 13-il sena għal awtorizzazzjoni ta' bejgħ ta' erba' speċi jew aktar li jipproduċu l-ikel.

L-estenzjoni tal-perjodu ta' għaxar snin għal 11, 12, jew 13-il sena għall-prodott mediċinali veterinarju maħsub għall-ispeċi li jipproduċu l-ikel għandu jinghata biss jekk id-detentur ta' l-awtorizzazzjoni għall-bejgħ kien oriġinarjament applika għad-determinazzjoni ta' livelli massimi ta' fdalijiet stabbiliti għall-ispeċi koperti mill-awtorizzazzjoni.

(6) Meta jsiru l-istudji neċessarji, testijiet u provi bil-hsieb li jkunu applikati s-subregolamenti (1) sa (5) u l-htigijiet prattiċi konsegwenzjali, ma għandhomx ikunu meqjusa bhala kuntrarji għad-drittijiet relatati mal-privattivi jew ċertifikati ta' protezzjoni supplimentari għall-prodotti mediċinali.”.

9. Minnufih wara r-regolament 13 tar-regolamenti prinċipali għandhom jidhlu dawn ir-regolamenti ġodda li ġejjin:

Iżid ir-regolamenti 13A sa 13D ġodda mar-regolamenti prinċipali.

“Deroga.

13A. (1) B'deroga minn punt (j) ta' l-ewwel paragrafu tar-regolament 12(3), u minghajr preġudizzju għall-igi fuq il-protezzjoni ta' proprjetà industrijali u kummerċjali, l-applikant ma għandux ikun meħtieġ jagħti r-rizultati ta' testijiet ta' sigurtà u tal-fdalijiet jew ta' testijiet pre-kliniċi

jew provi kliniċi jekk huwa jista' juri li s-sustanzi attivi tal-prodott mediċinali veterinarju kienu f'użu veterinarju stabbilit sewwa fil-Komunità Ewropea għal ta' lanqas għaxar snin, b'effikaċja rikonoxxuta u b'livell ta' sigurtà rikonoxxut ai termini tal-kondizzjonijiet mnizzla fi Skeda I. F'dak il-każ, l-applikant għandu jipprovdi letteratura xjentifika adatta.

(2) Ir-rapport ta' l-istima ippublikat mill-Aġenzija wara li tkun saret evalwazzjoni ta' applikazzjoni għall-istabbiliment ta' limiti massimi ta' fdalijiet skond ir-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90 jista' jintuża f'manjiera adatta bhala letteratura, partikolarment għat-testijiet ta' sigurtà.

(3) Jekk applikant jagħmel użu minn letteratura xjentifika sabiex iġib awtorizzazzjoni għall-speċi li jipproduċu l-ikel, u jipprezenta, fir-rigward ta' l-istess prodott mediċinali u bil-hsieb li jġib awtorizzazzjoni għall-speċi oħrajn li jipproduċu l-ikel, studji godda dwar il-fdalijiet skond ir-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90, flimkien ma iktar provi kliniċi, mhux permess li parti terza jagħmel użu minn dawk l-istudji jew minn dawk il-provi skond regolament 13, għal perjodu ta' tliet snin minn meta tinghata l-awtorizzazzjoni li kienu saru dwarha.

Sustanzi.

13B. Fil-każ ta' prodotti mediċinali veterinarji li fihom sustanzi attivi wżati fil-komposizzjoni ta' prodotti mediċinali veterinarji awtorizzati imma li mhux użati wkoll f'kombinazzjonijiet għal skopijiet terapewtiċi, ir-riżultati ta' testijiet ta' sigurtà u ta' fdalijiet, jekk neċessarji u ta' testijiet pre-kliniċi jew provi kliniċi godda relatati ma' dik il-kombinazzjoni għandhom jingħataw skond punt (j) ta' l-ewwel paragrafu tar-regolament 12(3), imma ma għandux ikun neċessarju li jingħataw riferenzi xjentifiċi relatati għal kull sustanza attiva individwali.

Użu mid-dokumentazzjoni.

13C. Wara li l-awtorizzazzjoni ta' bejgħ tkun inghatat, id-detentur ta' l-awtorizzazzjoni ta' bejgħ jista' jhalli li jsir użu mid-dokumentazzjoni dwar il-farmaċewtika, sigurtà u fdalijiet, pre-kliniċi u kliniċi kontenuti fil-*file* għall-prodott mediċinali veterinarju bil-hsieb li tkun eżaminata applikazzjoni sussegwenti għal prodott mediċinali veterinarju li għandu l-istess komposizzjoni kwalitattiva u kwantitattiva f'sustanzi attivi u ta' l-istess forma farmaċewtika.

Deroga.

13D. B' deroga minn punt (j) ta' l-ewwel paragrafu tar-regolament 12(3), u f' ċirkostanzi eċċezjonali fir-rigward ta' prodotti mediċinali veterinarji immunoloġiċi, l-applikant ma ghandux ikun mehtieġ jipprovdi r-riżultati ta' ċertu *field trials* fuq l-ispeċi li għalihom ikun indikat il-prodott jekk dawn il-provi ma jkunux jistgħu jsiru għal raġunijiet ta' sostenn ta' kuljum, partikolarment akkont ta' disposizzjonijiet ohra tal-Komunità Ewropea.”.

10. Minflok ir-regolamenti 14 sa 16 tar-regolamenti prinċipali għandhom jidhlu dawn li ġejjin:

Jissostitwixxi r-regolamenti 14 sa 16 tar-regolamenti prinċipali.

“14. Ir-riassunt tal-karatteristiċi tal-prodott għandu jkun fih, skond l-ordni indikata hawn taht, l-informazzjoni li ġejja:

(1) l-isem tal-prodott mediċinali veterinarju segwit bis-sahha u l-forma farmaċewtika;

(2) kompożizzjoni kwalitattiva u kwantitattiva skond is-sustanzi attivi u tal-komponenti ta' l-eċċipjent li t-tagħrif dwarhom ikunu essenzjali għall-amministrazzjoni kif imiss tal-prodott mediċinali. Għandu jintuża l-isem komuni tas-soltu jew deskrizzjoni kimika;

(3) il-forma farmaċewtika;

(4) partikolaritajiet kliniċi:

(i) speċi li għalihom ikun indikat il-prodott,

(ii) indikazzjonijiet għall-użu, li jispeċifikaw l-ispeċi li għaliha jkun indikat il-prodott,

(iii) kontra-indikazzjonijiet,

(iv) twissijiet speċjali għal kull speċi li għaliha jkun indikat il-prodott,

(v) prekawzjonijiet speċjali għall-użu, flimkien ma prekawzjonijiet speċjali li għandhom jittiehdu mill-persuna lit kun qed tamministra l-prodott mediċinali lill-animali,

(vi) reazzjonijiet kuntrarji (frekwenza u gravità),

(vii) l-użu waqt tqala, fi żmien it-treddigh u t-tqeghid,

(viii) interazzjoni ma' prodotti mediċinali oħra u forom oħra ta' interazzjoni,

(ix) ammonti ta' amministrazzjoni u r-rotta ta' amministrazzjoni,

(x) doża eċċessiva (sintomi, proċeduri ta' emerġenza, antidoti), jekk ikun meħtieġ,

(xi) perjodi ta' tiżmim għal għalf varju, inkluż għalf li għalih il-perjodu ta' tiżmim huwa xejn;

(5) partikularitajiet farmakoloġiċi:

(i) proprjetajiet farmakodinamiċi,

(ii) partikularitajiet farmakokinetiċi;

(6) partikularitajiet farmatewtiċi:

(i) lista ta' *excipients*,

(ii) inkompatibilitajiet maġġuri,

(iii) it-tul ta' żmien ta' hżin li fih il-prodott jibqa' tajjeb, wara rikompożizzjoni tal-prodott mediċinali jew meta l-pakket ta' barra jinfetaħ għall-ewwel darba,

(iv) prekawzjonijiet speċjali għall-hżin,

(v) ix-xorta u komposizzjoni tal-pakett ta' ġewwa,

(vi) prekawzjonijiet speċjali kif tid-disponi minn prodott mediċinali veterinarju li ma jkunx jintuża jew minn materjal hażin li ġej mill-użu ta' dawg il-prodotti, jekk dan ikun adatt;

(7) id-detentur ta' l-awtorizzazzjoni għall-bejgħ;

(8) in-numru(i) ta' l-awtorizzazzjoni għall-bejgħ;

(9) id-data ta' l-ewwel awtorizzazzjoni jew data ta' tiġdid ta' l-awtorizzazzjoni;

(10) data ta' reviżjoni tat-test.

Għal awtorizzazzjoni skond regolament 13, dawk il-partijiet tar-riassunt tal-karatteristiċi tal-prodott mediċinali ta' riferenza li jirreferu għal indikazzjonijiet jew forum ta' dożi li kienu għadhom koperti minn liġi fuq il-privattivi meta l-mediċina ġenerika kienet għall-bejgħ ma għandhomx għalfejn ikunu inkluzi.

15. (1) L-applikanti għandhom jiżguraw li riassunti dettaljati u kritiċi msemmija fit-tieni paragrafu tar-regolament 12(3) ikunu mfassla u ffirmati minn persuni li għandhom il-kwalifiki tekniċi u professjonali mitluba kif imniżżla fil-*curriculum vitae* qasir, qabel ma jiġu ppreżentati lis-Servizzi Veterinarji.

(2) Persuni bi kwalifiki tekniċi u professjonali msemmija f'subregolament (1) ta' dan ir-regolament għandhom jiġġustifikaw l-użu ta' letteratura xjentifika msemmija f'regolament 13A(1) skond il-kondizzjonijiet mniżżla fi Skeda I.

(3) *Curriculum vitae* qasir tal-persuni msemmija f'subregolament (1) għandu jiġi meħmuż mar-riassunti kritiċi dettaljati.

16. (1) Is-Servizzi Veterinarji għandha tiżgura li l-prodotti mediċinali veterinarji omeopatiċi manifatturati u mqegħda fis-suq tal-Komunità Ewropea għandhom ikunu reġistrati jew awtorizzati skond ir-regolamenti 17, 18 u 19, bl-eċċezzjoni meta dawk il-prodotti mediċinali veterinarji jkunu koperti minn reġistrazzjoni jew awtorizzazzjoni mogħtija skond il-legislazzjoni nazzjonali fil-31 Dicembru 1993 jew qabel. Fil-każ ta' prodotti mediċinali veterinarji omeopatiċi reġistrati skond ir-regolament 17, għandhom japplikaw ir-regolament 32 u r-regolament 33(1) sa (3).

(2) Is-Servizzi Veterinarji għandha tistabilixxi proċedura ta' reġistrazzjoni simplifikata għall-prodotti mediċinali veterinarji omeopatiċi msemmija f'regolament 17.

(3) B'deroga minn regolament 10, prodotti mediċinali veterinarji omeopatiċi jistgħu jkunu amministrati lill-annimali li ma jipproċudux ikel taħt ir-responsabilità ta' veterinarju.

(4) B'deroga minn regolament 11(1) u (2), Malta tista' thalli l-amministrazzjoni ta' prodotti mediċinali veterinarji omeopatiċi maħsuba għall-ispeċi li jipproduċu l-ikel u li għandhom komponenti attivi li jidhru fl-Anness II tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90 taht ir-responsabilità ta' veterinarju. Is-Servizzi Veterinarji għandha tiegħu l-miżuri approprijati biex tikkontrolla l-użu ta' prodotti mediċinali veterinarji omeopatiċi reġistrati jew awtorizzati fi Stat Membru iehor skond dawn ir-regolamenti għall-użu fl-istess speċi.”.

Jemenda r-regolament 17 tar-regolamenti prinċipali.

11. Ir-regolament 17 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) minflok is-subregolament (1) għandu jidhol dan li ġej:

“(1) Mingħajr preġudizzju għad-disposizzjonijiet tar-Regolament ta' l-Unjoni Ewropea (KEE) Nru 2377/90 fuq kif jiġu stabbiliti limiti massimi ta' fdalijiet ta' sustanzi attivi farmakoloġiċi maħsuba għal annimali li jipproduċu l-ikel, dawk il-prodotti mediċinali veterinarji omeopatiċi biss li jissodisfaw il-kundizzjonijiet kollha li ġejjin jistghu jkunu soġġetti għal proċedura ta' reġistrazzjoni speċjali u simplifikata:

(a) ikunu amministrati permezz ta' rotta deskritta fil-Farmakopea Ewropea jew, fin-nuqqas tagħha, mill-Farmakopej uffiċjalment użati f'dak iż-żmien f'Malta;

(b) ma tkun tidher l-ebda indikazzjoni terapewtika speċifika fuq it-tabella tal-prodott mediċinali veterinarju jew f'xi informazzjoni li jkollha x'taqsam miegħu;

(ċ) ikun hemm livell suffiċjenti ta' sustanza dilwita li tiggarantixxi s-sigurtà tal-prodott mediċinali. B'mod partikulari, il-prodott mediċinali ma jistax ikun fih aktar minn parti wahda għal kull 10,000 tat-tintura prinċipali.”; u

(b) is-subregolament (3) għandu jiġi mħassar.

Jemenda r-regolament 18 tar-regolamenti prinċipali.

12. Ir-regolament 18 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) minflok il-paragrafu (ċ) għandu jidhol dan li ġej:

“(c) *file* ta’ manifattura u ta’ kontroll għal kull forma farmaċewtika u deskrizzjoni tal-metodu ta’ dilwizzjoni u potenzjali tagħha,”;

(b) minflok il-paragrafu (f) tiegħu, għandu jidhol dan li ġej:

“(f) *mock-up* wiehed jew aktar tal-pakkett minn barra u tal-pakkett ta’ ġewwa tal-prodotti mediċinali li għandhom jiġu reġistrati,”; u

(c) minnufih wara l-paragrafu (g) għandu jiġi miżdud dan il-paragrafu gdid li ġej:

“(h) perjodu ta’ tiżmim propost flimkien mal-gustifikazzjoni kollha meħtieġa.”.

13. Minflok ir-regolament 19 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jissostitwixxi r-regolament 19 tar-regolamenti prinċipali.

“19. (1) Prodotti mediċinali veterinarji omeopatiċi barra minn dawk imsemmija f’regolament 17(1) għandhom ikunu awtorizzati skond ir-regolamenti 12, 13A, 13B, 13C, 13D u 14.

(2) Malta tista’ tintroduċi jew thalli fis-seħh fit-territorju tagħha regoli speċifiċi għat-testijiet ta’ sigurtà u għall-provi pre-kliniċi u provi kliniċi ta’ prodotti mediċinali veterinarji omeopatiċi maħsuba għal annimali domestiċi u għal speċi eżotiċi li ma jipproduċux ikel, barra minn dawk imsemmija fir-regolament 17(1), skond il-prinċipji u l-karatteristiċi ta’ l-omeopatija kif Prattikata f’Malta. F’dan il-każ, is-Servizzi Veterinarji għandha tinnotifika lill-Kummissjoni Ewropea dwar ir-regoli speċifiċi li jkunu fis-seħh.”.

14. Minflok ir-regolamenti 21, 22 u 23 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jissostitwixxi r-regolamenti 21 sa 23 tar-regolamenti prinċipali.

“21. (1) Is-Servizzi Veterinarji għandha tiehu l-miżuri kollha adatti biex tiżgura li l-proċedura biex tagħti awtorizzazzjoni għall-bejgħ għall-prodott mediċinali veterinarju tkun lesta fi żmien massimu ta’ 210 ġurnata minn meta tiġi ppreżentata applikazzjoni valida.

Applikazzjonijiet għall-awtorizzazzjonijiet għall-bejgħ ta’ l-istess prodott mediċinali veterinarju f’żewġ Stati Membri jew aktar, għandhom jiġu ppreżentati skond ir-regolamenti 31 sa 43.

(2) Meta Malta tinnota li applikazzjoni ghal awtorizzazzjoni ta' bejgh ohra ghall-istess prodott mediċinali tkun qieghdha diġa tiġi eżaminata f'xi Stat Membru ieħor, is-Servizzi Veterinarji ghandha tieqaf milli tistima l-applikazzjoni u ghandha tavża lill-applikant li jkunu japplikaw ir-regolamenti 31 sa 43.

22. Meta s-Servizzi Veterinarji tkun infurmata skond paragrafu (n) tar-regolament 12(3), li Stat Membru ieħor jkun awtorizza prodott mediċinali veterinarju li jkun is-suġġett ta' applikazzjoni ghal awtorizzazzjoni f'Malta, is-Servizzi Veterinarji ghandhom iwarrbu l-applikazzjoni sakemm din ma tkunx giet ipprezentata skond ir-regolamenti 31 sa 43.

23. Sabiex teżamina l-applikazzjoni pprezentata skond ir-regolamenti 12 sa 13D, is-Servizzi Veterinarji:

(1) ghandhom jivverifikaw li d-dokumentazzjoni pprezentata in sostenn ta' l-applikazzjoni tkun konformi mar-regolamenti 12 sa 13D u jaċċertaw jekk il-kundizzjonijiet biex tinhareġ l-awtorizzazzjoni għall-bejgh jkunux ġew segwiti;

(2) jistghu jipprezentaw il-prodott mediċinali, il-materja prima tiegħu u, jekk ikun meħtieġ, prodotti intermedji jew materjali komponenti ohra ghal ittestjar minn Laboratorju Uffiċjali għall-Kontroll tal-Mediċini jew laboratorju appuntat ghal dak l-iskop mis-Servizzi Veterinarji, sabiex jiżguraw li l-metodi ta' ttestjar magħżula mill-manifattur u deskritti fid-dokumenti ta' l-applikazzjoni, skond punt (i) ta' l-ewwel paragrafu tar-regolament 12(3), huma sodisfaċenti;

(3) l-istess jistghu jivverifikaw, partikolarment b'konsultazzjoni ma' laboratorju ta' riferenza nazzjonali jew tal-Komunità Ewropea, li l-metodu analitiku użat biex tkun skoperta l-preżenza ta' fdalijiet kif pprezentata mill-applikant għall-iskopijiet tar-regolament 12(3)(j), it-tieni inċiż tkun sodisfaċenti;

(4) jistghu, fejn approprjat, jitolbu lill-applikant jipprovdi aktar informazzjoni dwar il-prodotti elenkati fir-regolamenti 12, 13A, 13B, 13C u 13D. Meta s-Servizzi Veterinarji jimxu skond din l-azzjoni, it-termini taż-żmien speċifikati fir-regolament 21 ghandhom ikunu sospizi sakemm tkun giet provduta dik l-informazzjoni ulterjuri li tkun meħtieġa. Bl-istess mod, dawk it-termini ta' żmien ghandhom jiġu sospizi għal kull perjodu li l-applikant jista' jingħata biex jipprovdi spjegazzjonijiet bil-fomm jew bil-miktub.”.

15. Minflok ir-regolament 25 tar-regolamenti prinċipali ghandu jidhol dan li ġej:

Jissostitwixxi r-regolament 25 tar-regolamenti prinċipali.

“25. (1) Meta tinhareġ l-awtorizzazzjoni għall-bejgħ, is-Servizzi Veterinarji għandhom jinfurmaw lid-detentur bir-riassunt tal-karatteristiċi tal-prodott kif approvat minnha.

(2) Is-Servizzi Veterinarji għandhom jiehdu l-miżuri kollha neċessarji biex jiżguraw li l-informazzjoni li tikkonċerna l-prodott mediċinali veterinarju, u b’mod partikulari it-tabelli u tal-fuljett tal-pakkett, huma konformi mar-riassunt tal-karatteristiċi tal-prodott approvati meta l-awtorizzazzjoni għall-bejgħ tkun inharġet jew sussegwentament.

(3) Is-Servizzi Veterinarji għandhom jagħmlu l-awtorizzazzjoni ta’ bejgħ disponibbli għall-pubbliku minghajr dewmien, flimkien ma riassunt tal-karatteristiċi tal-prodott għal kull prodott mediċinali veterinarju li jkun ġie approvat minnha.

(4) Is-Servizzi Veterinarji għandhom ifasslu rapport ta’ l-istima u kummenti fuq il-*file* fuq ir-riżultati tat-testijiet farmatewtiċi, ta’ sigurtà u tal-fdalijiet, u tal-provi pre-kliniċi u kliniċi, tal-prodott mediċinali veterinarju konċernat. Ir-rapport ta’ valutazzjoni għandu jkun aġġornat kull meta tkun disponibbli xi informazzjoni ġdida, liema informazzjoni tkun ta’ importanza għall-evalwazzjoni tal-kwalità, il-harsien tas-saħħa jew l-effikaċja tal-prodott mediċinali veterinarju konċernat.

Is-Servizzi Veterinarji għandhom jagħmlu r-rapport ta’ valutazzjoni u r-raġunijiet tagħha għall-opinjoni pubblika disponibbli minghajr dewmien, wara li jhassru kull informazzjoni ta’ natura kunfidenzjali u kummerċjali.”.

16. Ir-regolament 26 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

Jemenda r-regolament 26 tar-regolamenti prinċipali.

(a) minflok is-subregolament (1) għandu jidhol dan li ġej:

“(1) L-awtorizzazzjoni għall-bejgħ tista’ titlob lid-detentur biex jindika fuq il-pakkett ta’ barra u, jew fuq il-pakkett ta’ barra u l-fuljett tal-pakkett, meta dan ikun meħtieġ, partikolaritajiet essenzjali ohra għall-protezzjoni tas-saħħa u s-sigurtà, inkluża kull prekawzjoni speċjali dwar l-użu u kull twissija ohra li tirriżulta mill-provi kliniċi u farmakoloġiċi stabbiliti fir-regolament 12(3)(j) u fir-regolamenti 13 sa 13D

jew mill-esperjenza miksuba mill-użu tal-prodott mediċinali veterinarju, għadarba dan ikun qieghed jinbiegh.”;

(b) subregolament (2) għandu jiġi mħassar; u

(ċ) subregolament (3) għandu jiġi enumerat mill-ġdid bhala s-subregolament (2) u minfloku għandu jidhol dan li ġej:

“(2) F’ċirkostanzi eċċezzjonali, u wara konsultazzjoni ma’ l-applikant, tista’ tinghata awtorizzazzjoni bla hsara għall-htieġa ta’ l-applikant li jintroduċi proċeduri speċifiċi, b’mod partikolari dawk li jikkonċernaw is-sigurtà tal-prodott mediċinali veterinarju, in-notifika lill-awtoritajiet kompetenti ta’ kull incident relatat ma’ l-użu tiegħu, u l-azzjoni li għandha tittiehed. Dawn l-awtorizzazzjonijiet jistgħu jinghataw biss għal raġunijiet oġġettivi u li jistgħu jkunu verifikati. Il-kontinwazzjoni ta’ l-awtorizzazzjoni għandha tkun kollegata mal-valutazzjoni annwali mill-ġdid ta’ dawk il-kondizzjonijiet.”.

Jemenda r-regolament 27 tar-regolamenti prinċipali.

17. Ir-regolament 27 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

(a) minflok is-subregolamenti (2) u (3) għandhom jidhlu dawn li ġejjin:

(2) Is-Servizzi Veterinarji jistgħu jehtieġu lill-applikant jew lid-detentur ta’ l-awtorizzazzjoni biex jipprovdi kwantitajiet suffiċjenti tas-sustanzi biex ikunu jistgħu jsiru kontrolli fuq l-identifikazzjoni tal-preżenza ta’ fdalijiet tal-prodotti mediċinali veterinarji in kwistjoni.

Fuq talba tas-Servizzi Veterinarji, id-detentur ta’ l-awtorizzazzjoni tal-bejgħ għandu jipprovdi l-hila teknika tiegħu biex iħaffef l-implimentazzjoni tal-metodu analitiku biex jiskopri fdalijiet tal-prodotti mediċinali veterinarji fil-laboratorju ta’ riferenza nazzjonali nominat skond id-Direttiva tal-Kunsill ta’ l-Unjoni Ewropea 96/23/KE fuq mizuri għall-kontroll ta’ ċerti sustanzi u fdalijiet tagħhom f’annimali hajjin u prodotti ta’ l-annimali.

(3) Id-detentur ta’ l-awtorizzazzjoni għall-bejgħ għandu minnufih jinforma lis-Servizzi Veterinarji dwar kull informazzjoni ġdida li tista’ twassal għall-emendi tal-partikolaritajiet u tad-dokumenti msemmija fir-regolamenti 12(3), 13, 13A, 13B u 14 jew fi Skeda I.

B'mod partikolari, huwa ghandu minnufih jinforma lis-Servizzi Veterinarji dwar kull projbizzjoni jew restrizzjoni imposta mill-awtoritajiet kompetenti ta' xi pajjiż fejn il-prodott mediċinali veterinarju jkun qed jinbiegh u b'kull informazzjoni ohra ġdida li tista' tinfluwenza l-valutazzjoni tal-benefiċċji u r-riskji tal-prodott mediċinali veterinarju konċernat.

Sabiex tithalla valutazzjoni kontinwa tal-bilanċ bejn ir-riskju u l-benefiċċju, is-Servizzi Veterinarji jistgħu f'kull waqt jitolbu lid-detentur ta' l-awtorizzazzjoni għall-bejgħ biex jagħti informazzjoni li tkun turi li l-bilanċ bejn ir-riskju u l-benefiċċju tibqa' favorevoli.”;

(b) is-subregolament (4) ghandu jiġi mhassar;

(ċ) minflok is-subregolament (5) ghandu jidhold an li ġejj:

(5) Id-detentur ta' l-awtorizzazzjoni għall-bejgħ ghandu minnufih jinforma lis-Servizzi Veterinarji, sabiex dawn ikunu awtorizzati, b'kull tibdil li jkun qed jipproponi li jagħmel fil-partikolaritajiet jew fid-dokumenti msemmija fir-regolamenti 12 sa 13D.”;

18. Minnufih wara r-regolament 27 tar-regolamenti prinċipali, ghandu jiżdied dan ir-regolament ġdid li ġejj:

Iżid ir-regolament 27A ġdid mar-regolamenti prinċipali.

“Detentur ghandu jinforma lis-Servizzi Veterinarji.

27A. Wara li jinghata awtorizzazzjoni għall-bejgħ, id-detentur ta' l-awtorizzazzjoni ghandu jinforma lis-Servizzi Veterinarji bid-data ta' meta huwa attwalment iqieghed fis-suq il-prodott mediċinali veterinarju f'Malta, billi jqis id-diversi preżentazzjonijiet awtorizzati.

Id-detentur ghandu wkoll jinnotifika lis-Servizzi Veterinarji jekk il-prodott jieqaf milli jinbiegh f'Malta, kemm jekk temporanjament jew permanentement. Din innotifikazzjoni ghandha, jekk mhux f'ċirkostanzi eċċezjonali, issir mhux inqas minn xaharejn qabel ma l-prodott jtemm milli jibqa' jinbiegh aktar fis-suq.

Fuq talba minghand is-Servizzi Veterinarji, partikolarment fil-kuntest ta' farmakoviġilanza, id-detentur ta' l-awtorizzazzjoni ta' bejgħ ghandu jagħti lis-Servizzi Veterinarji l-informazzjoni kollha relatata għall-volum ta' bejgħ tal-prodott mediċinali veterinarju, u kull informazzjoni relatata mal-volum ta' riċetti.”.

19. Minflok ir-regolament 28 tar-regolamenti prinċipali ghandu jidhol dan li ġej:

“28. (1) Minghajr preġudizzju ghas-subregolamenti (4) u (5), l-awtorizzazzjoni għall-bejgħ ghandha tkun valida għal hames snin.

(2) L-awtorizzazzjoni tista' tiġi mġedda wara hames snin fuq il-bażi ta' valutazzjoni mill-ġdid tal-bilanċ bejn ir-riskju u l-benefiċċju.

Għal dan il-ghan, id-detentur ghandu jipprezenta lista konsolidata tad-dokumenti kollha dwar il-kwalità, sigurtà u effikaċja, inklużi l-varjazzjonijiet kollha introdotti minn meta tkun ingħatat l-awtorizzazzjoni għall-bejgħ, ta' l-anqas sitt xhur qabel ma l-awtorizzazzjoni għall-bejgħ tieqaf milli tibqa' valida skond is-subregolament (1) ta' dan ir-regolament. Is-Servizzi Veterinarji jistgħu jehtieġu lill-applikant jipprezenta id-dokumenti elenkati f'kull waqt.

(3) Meta l-awtorizzazzjoni għall-bejgħ tiġi mġedda, hija ghandha tibqa valida għal perjodu mhux limitat, sakemm is-Servizzi Veterinarji jiddeċiedu, għal raġunijiet ġustifikati relatati mal-farmakovigilanza, biex jipproċedu b'tiġdid wiehed addizzjonali ta' hames snin skond is-subregolament (2).

(4) Kull awtorizzazzjoni li ma tkunx ġiet segwita fi żmien tlett snin minn meta tinhareġ, billi l-prodott mediċinali veterinarju awtorizzat jitqiegħed fis-suq, ghandha tieqaf milli tibqa' valida.

(5) Meta prodott mediċinali veterinarju awtorizzat li kien għall-bejgħ fis-suq f'Malta ma jkunx għadu aktar attwalment preżenti f'Malta għal perjodu ta' tlett snin konsekuttivi, l-awtorizzazzjoni mogħtija għall-prodott mediċinali veterinarju ma ghandhiex tibqa' valida.

(6) F'ċirkostanzi eċċezjonali u fuq raġunijiet tas-saħħa tal-bniedem jew ta' l-annimali, is-Servizzi Veterinarji jistgħu jagħtu eżenzjonijiet minn subregolamenti (4) u (5). Dawn l-eżenzjonijiet ghandhom ikunu ġustifikati.”.

20. Minflok ir-regolament 30 tar-regolamenti prinċipali, ghandu jidhol dan li ġej:

“30. L-awtorizzazzjoni tal-bejgh ghandha tkun irrifjutata jekk il-*file* pprezentat lis-Servizzi Veterinarji ma jkunx konformi mar-regolamenti 12 sa 13D u r-regolament 15.

L-awtorizzazzjoni ghandha wkoll tigi rifjutata jekk, wara eżami tad-dokumenti u tal-partikolaritajiet mnizzla f’regolamenti 12 u 13(1), ikun ċar li:

(a) il-bilanċ bejn ir-riskju u l-benefiċċju tal-prodott mediċinali veterinarju jkun, taht il-kondizzjonijiet awtorizzati ta’ l-użu, mhux favorevoli; meta l-applikazzjoni tikkonċerna prodott mediċinali veterinarju għal użu zootekniku, għandu jittqies sew il-benefiċċju għas-saħħa u l-benesseri ta’ l-annimali u għas-sigurtà tal-konsumatur; jew

(b) il-prodott ma jkollu ebda effett terapewtiku jew l-applikant ma jkunx ta provi biżżejjed ta’ dan l-effett fir-rigward ta’ l-ispeċi ta’ annimal li għandu jiġi ikkurat; jew

(ċ) il-kompożizzjoni kwalitattiva jew kwantitattiva tal-prodott ma tkunx skond dik dikjarata; jew

(d) il-perjodu ta’ tiżmim rakkomandat mill-applikant ma jkunx biżżejjed biex jiżgura li l-prodotti ta’ l-ikel miksuba mill-annimal ikkurat ma fihomx fdalijiet li jistgħu jikkostitwixxu xi periklu għas-saħħa tal-konsumatur, jew ma jkunx sostanzjat b’mod suffiċjenti; jew

(e) it-tikkettar jew il-fuljett mal-pakkett kif propost mill-applikant ma jkunx konformi ma dawn ir-regolamenti; jew

(f) il-prodott mediċinali veterinarju jkun offrut għall-bejgh għal użu projbit taht disposizzjonijiet ohra tal-Komunità Ewropea.

Madankollu, meta qafas leġislattiv tal-Komunità Ewropea jkun qiegħed fil-fażi li jiġi adottat, is-Servizzi Veterinarji jistgħu jirrifjutaw l-awtorizzazzjoni għal prodott mediċinali veterinarju meta dik l-azzjoni tkun neċessarja għall-protezzjoni tas-saħħa pubblika, dik tal-konsumatur jew ta’ l-annimal.

L-applikant jew id-detentur ta’ l-awtorizzazzjoni għall-bejgh ikun responsabbli għall-eżattezza tad-dokumenti u ta’ l-informazzjoni li tigi pprezentata.”.

Jissostitwixxi l-intestatura tal-Kapitolu 4 tar-regolamenti prinċipali.

21. Minflok l-intestatura tal-Kapitolu 4 tar-regolamenti prinċipali ghandu jidhol dan li ġej:

“KAPITOLU 4

Proċedura ta’ gharfien reċiproku u proċedura diċentralizzata”.

Jissostitwixxi r-regolamenti 31 sa 34 tar-regolamenti prinċipali.

22. Regolamenti 31 sa 34 tar-regolamenti prinċipali ghandu jidhol dan li ġej:

“31. (1) Bil-ghan li tinghata awtorizzazzjoni għall-bejgh għal prodott mediċinali veterinarju f’iktar minn Stat Membru wiehed, l-applikant ghandu jippreżenta applikazzjoni ibbażata fuq *dossier* identiku f’dawk l-Istati Membri. Id-*dossier* ghandu jkollu l-informazzjoni kull amministrattiva u dokumentazzjoni xjentifika u teknika kif deskritti f’regolamenti 12 sa 14. Id-dokumenti ppreżentati għandhom jinkludu lista ta’ l-Istati Membri konċernati bl-applikazzjoni.

L-applikant ghandu jitlob lil xi Stat Membru biex jagħmilha ta’ Stat Membru ta’ riferenza u biex jipprepara r-rapport tal-valutazzjoni fir-rigward tal-prodott mediċinali veterinarju skond is-subregolament (2) jew (3).

Meta jkun hekk adatt, ir-rapport ta’ l-istima għandu jkun fih valutazzjoni għall-iskopijiet tar-regolament 13(5) jew tar-regolament 13A(3).

(2) Jekk il-prodott mediċinali veterinarju jkun diġà rċieva awtorizzazzjoni għall-bejgh fil-waqt ta’ l-applikazzjoni, l-Istati Membri konċernati għandhom jirrikonoxxu l-awtorizzazzjoni għall-bejgh mogħtija mill-Istat Membru ta’ riferenza. Għal dan il-ghan, id-detentur ta’ l-awtorizzazzjoni għall-bejgh ghandu jitlob lill-Istat Membru ta’ riferenza jew biex jipprepara rapport ta’ valutazzjoni dwar il-prodott mediċinali veterinarju, jew, jekk ikun meħtieġ, biex jaġġorna r-rapport ta’ valutazzjoni eżistenti. L-Istat Membru ta’ riferenza għandu jipprepara jew jaġġorna r-rapport ta’ valutazzjoni fi żmien 90 jum minn meta jkun irċieva l-applikazzjoni. Ir-rapport ta’ valutazzjoni flimkien mar-riassunt approvat tal-karatteristiċi tal-prodott, tikketta u l-fuljett tal-pakkett għandhom ikunu mġoddija lill-Istati Membri konċernati u lill-applikant.

(3) Jekk il-prodott mediċinali veterinarju ma jkunx irċieva awtorizzazzjoni fil-hin ta’ l-applikazzjoni, l-applikant

ghandu jitlob lill-Istat Membru ta' riferenza biex jipprepara abbozz ta' rapport ta' valutazzjoni u abbozzi tar-riassunt tal-karatteristiċi tal-prodott, tikketta u l-fuljett tal-pakkett. L-Istat Membru ta' riferenza ghandu jipprepara dawn l-abbozzi fi żmien 120 jum minn meta jkun irċieva applikazzjoni valida u ghandu jibgħathom lill-Istati Membri konċernati u lill-applikant.

(4) Fi żmien 90 jum wara li jkun irċieva d-dokumenti msemmija f'subregolamenti (2) u (3), l-Istati Membri konċernati għandhom japprovaw ir-rapport ta' stima, ir-riassunt tal-karatteristiċi tal-prodott, it-tikketta u l-fuljett tal-pakkett, u jinfurmaw lill-Istat Membru ta' riferenza b'dan. L-Istat Membru ta' riferenza ghandu jirreġistra l-ftehim tal-partijiet kollha, jagħlaq il-proċedura u jinforma lill-applikant b'dan.

(5) Kull Stat Membru fejn tkun sottomessa applikazzjoni skond subregolament (1) ghandu jadotta deċiżjoni f'konformità mar-rapport ta' valutazzjoni approvat, riassunt tal-karatteristiċi tal-prodott, tikketta u l-fuljett tal-pakkett fi żmien 30 jum wara r-rikonoxximent tal-ftehim.

32. (1) Jekk matul il-perjodu permess fir-regolament 31(4), Malta ma tistax taqbel mar-rapport ta' valutazzjoni, riassunt tal-karatteristiċi tal-prodott, tikketta u l-fuljett tal-pakkett minhabba raġunijiet ta' potenzjal ta' riskju għas-saħħa tan-nies jew għas-saħħa ta' l-annimali jew għall-ambjent, għandha tingħata dikjarazzjoni dettaljata tar-raġunijiet lill-Istat Membru ta' riferenza, lill-Istati Membri l-oħra konċernati u lill-applikant. Il-punti ta' nuqqas ta' ftehim għandhom jiġu riferiti mingħajr dewmien lill-grupp ta' koordinazzjoni.

Jekk Stat Membru li jkun ġie ppreżentat b'applikazzjoni jinvoka r-raġunijiet msemmija fir-regolament 64(1), dak l-Istat ma jibqax jiġi meqjus bħala Stat Membru konċernat minn dan il-Kapitolu.

(2) Fil-grupp ta' koordinazzjoni, l-Istati Membri kollha msemmija f'subregolament (1) għandhom jużaw l-aħjar mezz tagħhom biex jintlaħaq ftehim dwar l-azzjoni li għandha tittiehed. Huma għandhom jipprovdu lill-applikant bl-opportunità li jsemmi l-pożizzjoni tiegħu, kemm bil-fomm kemm bil-miktub. Jekk, fi żmien 60 jum mill-komunikazzjoni tar-raġunijiet għal nuqqas ta' ftehim lill-grupp ta' koordinazzjoni, l-Istati Membri fil-fatt jilhqu ftehim, l-Istat Membru ta' riferenza ghandu jirreġistra l-ftehim, jagħlaq il-proċedura u jinforma lill-applikant b'dan. Ir-regolament 31(5) ghandu japplika f'dak il-każ.

(3) Jekk matul il-perjodu ta' 60 jum l-Istati Membri ma jilhqx ftehim, l-Aġenzija għandha tkun infurmata minnufih bil-ghan li tkun applikata l-proċedura mnizzla fl-Artikoli 36, 37 u 38 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE. L-Aġenzija għandha tkun provduta b'deskrizzjoni dettaljata tal-materji li fuqhom ma jkunx intlaħaq ftehim u r-raġunijiet għal dak in-nuqqas ta' ftehim. L-applikant għandu jinghata kopja ta' dik l-informazzjoni.

(4) Hekk kif ikun infurmat li l-materja tkun giet riferita lill-Aġenzija, l-applikant għandu minnufih jgħaddi lill-Aġenzija kopja ta' l-informazzjoni u l-partikolaritajiet msemmija fir-regolament 31(1).

(5) Fil-każ imsemmi fis-subregolament (3), l-Istati Membri li jkunu approvaw ir-rapport ta' valutazzjoni, riassunt tal-karatterisistiċi tal-prodott, tikketta u l-fuljett tal-pakkett ta' l-Istat Membru ta' riferenza jistgħu, fuq talba minghand l-applikant, jagħtu awtorizzazzjoni għall-bejgħ għall-prodott mediċinali veterinarju minghajr ma jistennew ir-rizultat tal-proċedura mnizzla fl-Artikolu 36 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE. F'dak il-każ, l-awtorizzazzjoni mogħtija għandha tkun minghajr preġudizzju għar-rizultat tal-proċedura.

33. (1) Jekk ikunu ġew ipprezentati żewġ applikazzjonijiet jew aktar skond ir-regolamenti 12 sa 14 biex tinhareg awtorizzazzjoni għall-bejgħ għal xi prodott mediċinali veterinarju u l-Istati Membri jkunu adottaw deċiżjonijiet differenti li jikkonċernaw l-awtorizzazzjoni għal dak il-prodott mediċinali veterinarju, jew sospensjoni jew irtirar ta' dik l-awtorizzazzjoni, Stat Membru, jew il-Kummissjoni Ewropea, jew id-detentur ta' l-awtorizzazzjoni għall-bejgħ, jistgħu jirreferu l-fatt lill-Kumitat għall-Prodotti Mediċinali għall-Użu Veterinarju, hawnhekk iżjed 'il quddiem imsejjah "il-Kumitat", għall-applikazzjoni tal-proċedura mnizzla fl-Artikoli 36, 37 u 38 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE.

34. (1) Malta jew il-Kummissjoni Ewropea jew l-applikant jew id-detentur ta' l-awtorizzazzjoni għall-bejgħ jistgħu, f'każijiet speċifiċi fejn ikunu involuti l-interessi tal-Komunità Ewropea, jirreferu l-każ lill-Kumitat għall-applikazzjoni tal-proċedura mnizzla fl-artikoli 36, 37 u 38 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE qabel ma tittiehed deċiżjoni fuq talba għal awtorizzazzjoni għall-bejgħ jew dwar is-sospensjoni jew l-irtirar ta' xi awtorizzazzjoni, jew dwar xi varjazzjoni oħra tal-pattijiet ta' awtorizzazzjoni għall-bejgħ li tidher meħtieġa, b'mod

partikulari biex jittiehed kont ta' l-informazzjoni miġbura skond it-Titolu VII.

Malta jew il-Kummissjoni Ewropea ghandhom jidentifikaw b'mod ċar il-kwistjoni li tkun riferita lill-Kumitat għall-kunsiderazzjoni tiegħu u ghandhom jinfurmaw lill-applikant jew lid-detentur ta' l-awtorizzazzjoni għall-bejgħ.

Malta u l-applikant jew id-detentur ta' l-awtorizzazzjoni għall-bejgħ ghandhom jgħaddu lill-Kumitat l-informazzjoni disponibbli kollha relatata mas-sugġett in kwistjoni.”.

23. Minflok ir-regolament 37 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jissostitwixxi r-regolament 37 tar-regolamenti prinċipali.

“37. Regolamenti 32(3), (4) u (5) u 33 sa 34 ma ghandhomx japplikaw għal prodotti mediċinali veterinarji omeopatiċi msemmija fir-regolament 17.

Regolamenti 31 sa 34 ma ghandhomx japplikaw għal prodotti mediċinali veterinarji omeopatiċi msemmija fir-regolament 19(2).”.

24. Minnufih wara s-subregolament (3) tar-regolament 38 tar-regolamenti prinċipali għandu jżied dan is-subregolament ġdid li ġej:

Jemenda r-regolament 38 tar-regolamenti prinċipali.

“(4) Malta għandha tibghat lill-Aġenzija kopja ta' l-awtorizzazzjonijiet għall-manifattura msemmija f'subregolament (1). L-Aġenzija għandha ddahhal dik l-informazzjoni fid-*database* tal-Komunità msemmija fl-Artikolu 80(6) tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE.”.

25. Il-paragrafu (f) tar-regolament 44 tar-regolamenti prinċipali, għandu jiġi sostitwit b'dan li ġej:

Jemenda r-regolament 44 tar-regolamenti prinċipali.

“(f) issegwi l-prinċipji u l-gwidi ta' prattika ta' manifattura tajba għal prodotti mediċinali u tuża bhala *starting materials* sustanzi attivi biss li ġew manifatturati skond il-gwidi dettaljati fuq prattika ta' manifattura tajba għal *starting materials*.”.

26. Minnufih wara r-regolament 44 tar-regolamenti prinċipali għandu jidhol dan ir-regolament ġdid li ġej:

Iżid ir-regolament 44A ġdid mar-regolamenti prinċipali.

“*Starting materials*.

44A. (1) Għall-iskopijiet ta' dawn ir-regolamenti, sustanzi attivi ta' manifattura għal użu bhala *starting materials* ghandhom jinkludu sustanza attiva kompluta jew manifattura parzjali, jew l-importazzjoni ta' dik is-sustanza użata bhala

starting material, kif definit f'Parti 2, Sezzjoni C ta' l-Iskeda I, u l-proċessi varji ta' tqassim, ippakkjar jew preżentazzjoni qabel ma tkun inkorporata fi prodott mediċinali veterinarju, inkluż ippakkjar mill-ġdid jew tabellar mill-ġdid, bhal ma jwettaq distributtur ta' *starting material*.”.

Jemenda r-regolament 46 tar-regolamenti prinċipali.

27. Is-subregolament (1) tar-regolament 46 tar-regolamenti prinċipali għandu jiġi sostitwit b'dan li ġejj:

“(1) Malta għandha tiżgura li l-persuna kwalifikata msemmija fir-regolament 45 isegwi l-kondizzjonijiet ta' kwalifika msemmija fis-subregolamenti (2) u (3).”.

Jemenda r-regolament 47 tar-regolamenti prinċipali.

28. Is-subregolament (1) tar-regolament 47 tar-regolamenti prinċipali għandu jiġi sostitwit b'dan li ġejj:

“(1) Jekk f'Malta, il-persuna li twettaq l-attivitajiet tal-persuna imsemmija fir-regolament 45(1) fid-data li fiha dawn ir-regolamenti jkunu bdew japplikaw, ma tkunx tikkonforma mad-disposizzjonijiet tar-regolament 46, hija għandha tkun eligibbli li tkompli twettaq dawk l-attivitajiet fil-Komunità.”.

Jemenda r-regolament 48 tar-regolamenti prinċipali.

29. Fir-regolament 48 tar-regolamenti prinċipali, minflok il-paragrafu (b) tas-subregolament (1), għandu jidhol dan li ġejj:

“(b) fil-każ ta' prodotti mediċinali veterinarji ġejjin minn pajjiżi terzi, anki jekk manifatturati fil-Komunità, kull lott ta' produzzjoni importat jkun għadda f'Malta minn analiżi kwalitattiva kompluta, analiżi kwantitattiva ta' mill-anqas is-sustanzi kollha attivi u t-testijiet jew kontrolli l-oħra kollha mehieġa biex tkun żgurata l-kwalità tal-prodotti mediċinali veterinarji skond il-htigijiet ta' l-awtorizzazzjoni għall-bejgħ.”.

Jemenda r-regolament 51 tar-regolamenti prinċipali.

30. Ir-regolament 51 tar-regolamenti prinċipali għandu jiġi emendat kif ġejj:

(a) subregolament (1) għandu jiġi emendat kif ġejj:

(i) Minflok il-kliem “(1) L-informazzjoni” sal-kliem “mediċinali -” għandhom jidhlu l-kliem:

“Hlief fil-każ tal-prodotti mediċinali msemmija fir-regolament 17(1), is-Servizzi Veterinarji għandhom japprovaw il-pakkettar immedjat u l-pakkett ta' barra tal-prodotti mediċinali veterinarji. Il-pakkettar għandu jkollu l-informazzjoni li ġejja, li għandha tkun konformi

mal-partikolaritajiet u d-dokumenti provduti skond ir-regolamenti 12 sa 13D u r-riassunt tal-karatteristiċi tal-prodott, u ghandha tidher b'ittri legibbli.”;

(ii) Minflok il-paragrafi (a) u (b) ghandu jidhol dan li ġej:

“(a) l-isem tal-prodott mediċinali, segwit bil-formula tas-saħħa u farmaċewtika tiegħu. L-isem komuni ghandu jidher jekk il-prodott mediċinali ikun fih sustanza attiva wahda biss u l-isem tiegħu ikun isem ivvintat;

(b) dikjarazzjoni tas-sustanzi attivi espressi b'mod kwalitattiv u kwantitattiv għal kull *unit* jew skond il-forma ta' amministrazzjoni għal volum jew piż partikolari, bl-użu ta' ismijiet komuni;”;

(iii) Minflok il-paragrafu (e) ghandu jidhol dan li ġej:

“(e) l-isem u l-isem tal-kumpanija u l-indirizz permanenti jew post reġistrat tan-negozju tad-detentur ta' l-awtorizzazzjoni għall-bejgħ u, skond ma jkun adatt, tar-rappreżentant nominat mid-detentur ta' l-awtorizzazzjoni għall-bejgħ;”;

(iv) Minflok il-paragrafu (f) ghandu jidhol dan li ġej:

“(f) l-ispeċi ta' l-animali li għalih ikun indikat il-prodott mediċinali veterinarju; il-metodu u, jekk ikun meħtieġ, il-mod ta' amministrazzjoni. Ghandu jithalla post biex tkun indikata id-doża preskritta;”;

(v) Minflok il-paragrafu (g) ghandu jidhol dan li ġej:

“(g) il-perjodu ta' tiżmim għal prodotti mediċinali veterinarji biex jiġu amministrati li speċi li jipproduċu l-ikel, għall-ispeċi kollha konċernati u għall-għalf varju konċernat (laħam u interjuri, bajd, halib, għasel), inklużi dawk li l-perjodu ta' tiżmin għalihom ikun xejn;”;

(vi) Minflok il-paragrafu (j) ghandu jidhol dan li ġej:

“(j) prekawzjonijiet speċifiċi relatati mar-rimi ta' prodotti mediċinali mhux użati jew materjal hażin li ġej minn prodotti mediċinali veterinarji, skond ma jkun adatt,

kif ukoll riferenza ghal kull sistema ta' kollezzjoni adatta fil-post;";

(vii) Minflok il-paragrafu (l) ghandu jidhol dan li ġej:

“(l) il-kliem “*Għall-kura ta' l-animali biss*” jew, fil-każ ta' prodotti mediċinali msemmija fir-regolament 60, il-kliem “*Għall-kura ta' l-animali biss – għandu jingħata biss bil-preskrizzjoni tal-veterinarju.*”; u

(b) Minnufih wara s-subregolament (4) ghandu jizzied dan is-subregolament ġdid li ġej:

“(5) Fil-każ ta' prodotti mediċinali li jkunu ġew mogħtija awtorizzazzjoni għall-bejgħ skond ir-Regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004, Malta tista' thalli jew teħtieġ li l-pakkettar ta' barra ikollha informazzjoni addizzjonali li tikkonċerna d-distribuzzjoni, il-pussess, il-bejgħ jew xi prekawzjonijiet neċessarji, sakemm dik l-informazzjoni ma tmurx kontra l-liġi Komunitarja jew il-pattijiet ta' l-awtorizzazzjoni għall-bejgħ, u ma tkunx ta' xorta promozzjonali.

Din l-informazzjoni addizzjonali għandha tidher f'kaxxa li jkollha bordura kahlanija sabiex tkun separata biċ-ċar mill-informazzjoni msemmija fis-subregolament (1).”.

Jemenda r-regolament 52 tar-regolamenti prinċipali.

31. Ir-regolament 52 tar-regolamenti prinċipali ghandu jiġi emendat kif ġej:

(a) minflok il-kliem minn “(1) Rigward” sa “li ġejjin -” fis-subregolament (1), għandhom jidhlu l-kliem li ġejjin:

“(1) Rigward kunjetti, il-partikolaritajiet elenkati fl-ewwel paragrafu tar-regolament 51(1) għandhom jingħataw fuq il-pakkett ta' barra. Madankollu, fuq il-pakkettar immedjat, huma meħtieġa biss dawn il-partikolaritajiet li ġejjin:”;

(b) minflok is-subregolamenti (2) u (3) ghandu jidhol dan li ġej:

“(2) Rigward pakkettar immedjat zghir li jkun fih doża wahda, barra minn kunjetti, li fuqhom ikun impossibli li tagħti l-partikolaritajiet imsemmija fis-subregolament (1), il-ħtiġiet tar-regolamenti 51(1), (2) u (3) għandhom japplikaw biss għall-pakkett ta' barra.

(3) Il-partikolaritajiet imsemmija fil-paragrafi (ċ) u (f) tas-subregolament (1) għandhom jidhru fuq il-pakkett ta' barra u l-pakkettar immedjat tal-prodotti mediċinali fil-lingwa jew lingwi tal-pajjiż fejn il-prodotti jitqeghdu fis-suq.”.

32. Minflok ir-regolament 53 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jissostitwixxi r-regolament 53 tar-regolamenti prinċipali.

“53. Meta ma jkunx hemm pakkett ta' barra, il-partikolaritajiet kollha li għandhom jidhru fuq dan il-pakkett skond ir-regolamenti 51 u 52 għandhom jintwerew fuq il-pakkettar immedjat.”.

33. Ir-regolament 54 tar-regolamenti prinċipali għandu jiġi emendat kif ġej:

Jemenda r-regolament 54 tar-regolamenti prinċipali.

(a) minflok is-subregolament (1) għandu jidhol dan li ġej:

“(1) L-inklużjoni tal-fuljett tal-pakkett fl-ippakkjar ta' prodotti mediċinali veterinarji għandu jkun obligatorju hlief jekk l-informazzjoni kollha meħtieġa b'dan ir-regolament tkun tista' tingieb fuq il-pakkettar immedjat u fuq il-pakkett ta' barra. Malta għandha tiegħu l-miżuri kollha xierqa biex tiżgura li l-fuljett tal-pakkett ikun biss dwar il-prodott mediċinali veterinarju li jkun inkluż miegħu. Il-fuljett tal-pakkett għandu jkun miktub f'termini li jkunu jiftexmu mill-pubbliku ġenerali u fil-lingwa jew lingwi uffiċjali ta' Malta.

Subregolament (1) m'għandux jipprevjeni l-fuljett tal-pakkett milli jkun miktub b'diversi lingwi, sakemm l-informazzjoni mogħtija tkun identika fil-lingwi kollha.

Is-Servizzi Veterinarji jistgħu jeżentaw tabelli u l-fuljett tal-pakkett għal prodotti mediċinali veterinarji mill-obbligazzjoni għal ċerti partikolaritajiet milli jidhru u għall-fuljett milli jkun fil-lingwa jew lingwi uffiċjali ta' Malta, meta l-prodott ikun maħsub li jkun amministrat biss minn veterinarju.”;

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

(i) Minflok il-kliem minn “(2) Il-fuljett” sal-kliem “mis-Servizzi Veterinarji -” għandhom jidhru dawn il-kliem li ġejjin:

“(2) Is-Servizzi Veterinarji ghandhom japprovaw il-fuljetti tal-pakkett. Il-fuljett għandu jkun fih ta’ l-anqas l-informazzjoni li ġejja, fl-ordni indikata, li għandha tkun konformi mal-partikolaritajiet u d-dokumenti provduti konformement mar-regolamenti 12 sa 13D u mar-riassunt approvat tal-karatteristiċi tal-prodott.”; u

(ii) il-paragrafi (a) u (b) ghandhom jiġu sostitwiti b’dan li ġejj:

“(a) l-isem jew l-isem tal-kumpannija u l-indirizz permanenti jew post reġistrat tad-detentur ta’ l-awtorizzazzjoni għall-bejgħ u tal-manifattur u, meta jkun adatt, tar-rappreżentant tad-detentur ta’ l-awtorizzazzjoni għall-bejgħ;

(b) l-isem tal-prodott mediċinali veterinarju segwit bil-formula ta’ saħħa u dik farmaċewtika tiegħu. L-isem komuni għandu jidher jekk il-prodott ikun fih sustanza attiva waħda biss u l-isem tal-prodott ikun isem ivvintat. Meta il-prodott mediċinali ikun awtorizzat skond il-proċedura li hemm provdut dwarha fl-Artikoli 31 sa 43 tad-Direttiva tal-Kunsill ta’ l-Unjoni Ewropea 2004/28/KE taht l-ismijiet differenti f’Malta, lista ta’ l-ismijiet awtorizzati f’Malta;”; u

(ċ) is-subregolament (3) għandu jiġi mħassar.

Jissostitwixxi r-regolament 55 tar-regolamenti prinċipali.

34. Minflok ir-regolament 55 tar-regolamenti prinċipali għandu jidhol dan li ġejj:

“55. Meta d-disposizzjonijiet ta’ dan it-Titolu ma jkunux osservati u l-ghoti avviz formali indirizzat lill-persuna konċernata ma jkun halla ebda effett, is-Servizzi Veterinarji jistgħu jissospendu jew jirrevokaw l-awtorizzazzjoni għall-bejgħ.”.

Jemenda r-regolament 57 tar-regolamenti prinċipali.

35. Is-subregolament (2) tar-regolament 57(2) tar-regolamenti prinċipali għandu jiġi emendat kif ġejj:

(a) Minflok il-kliem minn “(2) B’ zieda” sal-kliem “l-ebda informazzjoni ohra - “ għandhom jidhlu l-kliem li ġejjin:

“(2) B’zieda mal-kliem imsemmi b’mod ċar “prodott mediċinali veterinarju omeopatu minghajr indikazzjonijiet terapwtiċi approvati”, it-tikketta u, fejn ikun adatt, il-fuljett tal-pakkett għall-prodotti mediċinali veterinarji omeopatiċi

msemija fir-regolament 17(1) ghandu jkollhom din l-informazzjoni li ġejja u l-ebda informazzjoni oħra:”; u

(b) minflok il-paragrafu (a) ghandu jidhol dan li ġej:

(a) l-isem xjentifiku ta’ l-oġġett jew oġġetti segwit bil-grad ta’ tahlit, bl-użu tas-simboli tal-Farmakopea użata skond il-paragrafu (8) tar-regolament 2. Jekk il-prodott mediċinali veterinarju omeopatu huwa magħmul minn iktar minn oġġett wiehed, it-tikketta tista’ ssemmi isem ivvintat b’żieda ma’ dawk l-ismijiet xjentifiċi ta’ l-oġġetti.”.

36. Minflok it-titolu tat-**Titolu VI** tar-regolamenti prinċipali ghandu jidhol dan li ġej:

Jissostitwixxi it-**Titolu VI** tar-regolamenti prinċipali.

“TITOLU VI

PUSSESS, DISTRIBUZZJONI U GHOTI B’ RIĊETTA TA’ PRODOTTI MEDIĊINALI VETERINARJI”.

37. Ir-regolament 58 tar-regolamenti prinċipali ghandu jiġi emendat kif ġej:

Jemenda r-regolament 58 tar-regolamenti prinċipali.

(a) minnufih wara s-subregolament (3) ghandu jizdied dan is-subregolament ġdid li ġej:

“3A. Id-detentur ta’ awtorizzazzjoni ta’ distribuzzjoni ghandu jkollu pjan ta’ emergenza li tiggarantixxi l-implimentazzjoni effettiva ta’ xi operazzjoni li tregġa’ lura oġġetti ordnata mill-awtoritajiet kompetenti jew magħmula b’kooperazzjoni mal-manifattur tal-prodott mediċinali inkwistjoni jew mad-detentur ta’ l-awtorizzazzjoni għall-bejgħ.”;

(b) minnufih wara s-subregolament (4) ghandu jizdied dan is-subregolament ġdid li ġej:

“(5) Kull distributtur, li ma jkunx id-detentur ta’ l-awtorizzazzjoni għall-bejgħ, li jimporta prodott minn Stat Membru iehor ghandu jinnotifika lid-detentur ta’ l-awtorizzazzjoni għall-bejgħ u lis-Servizzi Veterinarji għal li l-prodott ikun se jiġi impurtat għandhom bl-intenzjoni tiegħu li jimporta l-prodott. Fil-każ ta’ prodotti li ma jkunux ingħataw awtorizzazzjoni konformement mar-Regolament ta’ l-Unjoni Ewropea (KE) Nru 726/2004, in-notifika lis-Servizzi Veterinarji għandha tkun mingħajr preġudizzju għal proċeduri

addizzjonali li hemm provdut dwarhom fil-legislazzjoni ta' Malta.”.

Jemenda r-regolament 59 tar-regolamenti prinċipali.

38. Ir-regolament 59 tar-regolamenti prinċipali ghandu jiġi emendat kif ġej:

(a) subregolament (2) ghandu jiġi emendat kif ġej:

(i) minflok il-kliem minn “(2) Kull persuna” sal-kliem “u ta' hruġ -” ghandu jidhol dan li ġej:

“(2) Kull persuna li ghandha permess taht is-subregolament (1) biex tbiegh prodotti mediċinali veterinarji ghandha tkun mehtieġa li żżomm *records* ghall-prodotti mediċinali veterinarji li jistgħu jingħataw biss bir-riċetta, din l-informazzjoni li ġejja li ghandha tkun reġistrata dwar kull transazzjoni ta' dhul jew ta' hruġ:”; u

(ii) it-tielet paragrafu minflok il-kliem “għal perjodu ta' tliet snin” ghandhom jidhlu l-kliem:

“għal perjodu ta' hames snin”;

(b) minflok is-subregolament (3) ghandu jidhol dan li ġej:

“(3) Is-Servizzi Veterinarji jistgħu jippermettu l-provvista f'Malta tal-prodotti mediċinali veterinarji għall-annimali li jintużaw għall-ikel li dwarha tkun mehtieġa riċetta veterinarja bi jew taht is-supervizjoni ta' persuna reġistrata għal dan il-ghan li jipprovdi garanziji fir-rigward ta' kwalifiki, żamma ta' reġistri u rappurtar skond il-liġi nazzjonali. Is-Servizzi Veterinarji ghandhom javżaw lill-Kummissjoni Ewropea bid-disposizzjonijiet rilevanti tal-liġi nazzjonali. Din id-disposizzjoni ma ghandiex tapplika għall-provvista ta' prodotti mediċinali veterinarji għat-trattament orali jew parenterali ta' infezzjonijiet bakterjali.”; u

(ċ) is-subregolament (4) ghandu jithassar.

Jemenda r-regolament 60 tar-regolamenti prinċipali.

39. Ir-regolament 60 tar-regolamenti prinċipali ghandu jiġi emendat kif ġej:

(a) minflok il-kliem minn “(1) Mingħajr preġudizzju” sal-kliem “Veterinarji li ġejjin -” ghandhom jidhlu l-kliem li ġejjin:

“Minghajr preġudizzju għal regoli aktar stretti tal-Komunità Ewropea jew regoli nazzjonali dwar il-bejgħ ta’ prodotti mediċinali veterinarji u sabiex tkun protetta s-saħħa tal-bniedem u dik ta’ l-annimali, għandha tkun meħtieġa riċetta veterinarja biex jinbiegħu lill-pubbliku dawn il-prodotti mediċinali veterinarji li ġejjin:”;

(b) minnufih wara l-paragrafu (a) għandu jizdied dan il-paragrafu ġdid li ġej:

“(aa) prodotti mediċinali veterinarji għall-annimali li jipproduċu l-ikel. Madankollu, Malta tista’ tagħti eżenzjoni minn din il-ħtieġa skond il-kriterji stabbiliti skond il-proċedura msemmija fl-Artikolu 89(2) tad-Direttiva tal-Kunsill ta’ l-Unjoni Ewropea 2004/28/KE;”;

(ċ) is-subparagrafu (iii) tal-paragrafu (b) għandu jiġi mhassar u s-subparagrafu (iv) għandu jiġi enumerat mill-ġdid bhala s-subparagrafu (iii) tiegħu;

(d) minflok il-paragrafu (d) għandu jiġi sostitwit dan li ġej:

“(d) formuli maġisterjali, skond it-tifsir ta’ l-artikolu 3(2)(b) tad-Direttiva tal-Kunsill ta’ l-Unjoni Ewropea 2004/28/KE, maħsuba għall-annimali li jintużaw għall-ikel.”;

u

(e) minflok il-kliem minn “B’zieda, għandha” sal-kliem “ma jkun japplika.” Għandu jidhol dan li ġej:

“Malta għandha tiegħu l-miżuri kollha neċessarji sabiex tiżgura li, fil-każ ta’ prodotti mediċinali pprovduti biss b’riċetta, il-kwantità maħruġa b’riċetta għandha tkun ristretta għall-ammont minimu meħtieġ għat-trattament jew għat-terapija konċernata.

B’zieda, għandha tkun meħtieġa riċetta għal prodotti mediċinali veterinarji godda li jkun fihom sustanza attiva li tkun ġiet awtorizzata għall-użu fi prodott mediċinali veterinarju għal anqas minn hames snin.”.

40. Fir-regolament 62 tar-regolamenti prinċipali, minflok il-kliem minn “(1) Fit-territorju ta’ Malta,” sal-kliem “fir-regolament 61.” għandu jidhol dan li ġej:

Jemenda r-regolament 62 tar-regolamenti prinċipali.

“Malta ghandha tiżgura li s-sidien jew persuni li jżommu l-annimali li jipproduċu l-ikel jistgħu jipprovdu prova ta’ xiri, pussess u amministrazzjoni ta’ prodotti mediċinali veterinarji għal dawk l-annimali għal perjodu ta’ hames snin wara l-amministrazzjoni tagħhom, inkluż meta l-annimal jiġi maqtul matul il-perjodu ta’ hames snin.”.

Jemenda r-regolament 63 tar-regolamenti prinċipali.

41. Fir-regolament 63 tar-regolamenti prinċipali, minflok il-kliem minn “Bla hsara għar-regolamenti 9 u 60,” sal-kliem “li ġejjin -” għandu jidhol dan li ġejj:

“B’deroga minn regolament 9 u minghajr preġudizzju għar-regolament 60, Malta ghandha tiżgura li veterinarji li jipprovdu servizzi fi Stat Membru ieħor jistgħu jieħdu magħhom u jamministraw lill-annimali kwantitajiet żgħar ta’ prodotti mediċinali veterinarji li ma jkunux jeċċedu l-htigijiet ta’ jum wiehed minbarra dawk il-prodotti mediċinali veterinarji immunoloġiċi li ma humiex awtorizzati għall-użu fl-Istat Membru fejn is-servizzi jkunu provduti, kemm-il darba jkunu sodisfatti dawn il-kundizzjonijiet li ġejjin:”.

Jemenda r-regolament 64 tar-regolamenti prinċipali.

42. Minnufih fi tmiem is-subregolament (1) tar-regolament 64 tar-regolamenti prinċipali, għandu jidhol dan il-paragrafu li ġejj:

“Malta tista’ wkoll tinvoka d-disposizzjonijiet ta’ l-ewwel paragrafu sabiex twaqqaf awtorizzazzjoni għall-bejgħ skond proċedura diċentralizzata li hemm provdut dwarha fl-Artikoli 31 sa 43 tad-Direttiva tal-Kunsill ta’ l-Unjoni Ewropea 2004/28/KE.”.

Jemenda r-regolament 65 tar-regolamenti prinċipali.

43. Minflok is-subregolament (2) tar-regolament 65 tar-regolamenti prinċipali, għandu jidhol dan li ġejj:

“(2) Malta tista’ timponi htigijiet speċifiċi għal tobba veterinarji u professjonisti ohra fil-qasam tas-saħħa dwar ir-rapurtagġ ta’ reazzjonijiet suspettati serji jew dawk kuntrarji mhux mistennija u reazzjonijiet kuntrarji fil-bniedem.”.

Jemenda r-regolament 66 tar-regolamenti prinċipali.

44. Ir-regolament 66 tar-regolamenti prinċipali għandu jiġi emendat kif ġejj:

(a) minflok il-kliem minn “Sabiex tiġi żgurata” sal-kliem “din l-informazzjoni xjentifika” għandu jidhol dan li ġejj:

“Sabiex tiġi żgurata l-adozzjoni ta’ deċiżjonijiet regolatorji xierqa u armonizzati rigward il-prodotti mediċinali veterinarji awtorizzati fil-Komunità Ewropea, filwaqt li

jinghata każ ta' l-informazzjoni miksuba dwar ir-reazzjonijiet kuntrarji suspettati għall-prodotti mediċinali veterinarji f'kundizzjonijiet normali ta' użu, Malta għandha tamministra sistema farmakoviġilanti veterinarja. Din is-sistema għandha tintuża biex tingabar informazzjoni utili fis-sorveljanza ta' prodotti mediċinali veterinarji, b'riferenza partikolari għal reazzjonijiet kuntrarji f'annimali u b'nedmin relatati ma' l-użu ta' prodotti mediċinali veterinarji, u biex jevalwaw din l-informazzjoni xjentifikament.”; u

(b) minnufih wara t-tieni paragrafu li jtemm bil-kliem “ta' prodotti mediċinali veterinarji.” għandu jidhol dan il-paragrafu li ġej :

“Malta għandha tiżgura illi informazzjoni adatta miġbura f'din is-sistema hija komunikata lill-Istati Membri l-oħra u lill-Aġenzija. Din l-informazzjoni għandha tkun reġistrata fid-*database* msemmija f'punt (k) tat-tieni subparagrafu ta' l-Artiklu 57(1) tar-regolament ta' l-Unjoni Ewropea (KE) Nru 726/2004 u għandu jkun disponibbli b'mod permanenti lill-Istati Membri kollha u lill-pubbliku mingħajr dewmien.”.

45. Minnufih wara r-regolament 66 tar-regolamenti prinċipali, għandu jiżdied dan ir-regolament ġdid li ġej:

Iżid ir-regolament 66A ġdid mar-regolamenti prinċipali.

“Immaniġġar ta' flus.

66A. L-immaniġġar ta' flus maħsuba għal attivitajiet konnessi ma' farmakoviġilanza, l-operazzjoni ta' *networks* ta' komunikazzjoni u sorveljanza tas-suq għandhom ikunu taħt il-kontroll permanenti tas-Servizzi Veterinarji sabiex tkun garantita l-indipendenza tagħhom.”.

46. Minflok il-kliem “Dik il-persuna kwalifikata għandha tkun responsabbli għal dan li ġej -” fir-regolament 67 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jemenda r-regolament 67 tar-regolamenti prinċipali.

“Dik il-persuna kwalifikata għandha tkun tgħix fil-Komunità Ewropea u tkun responsabbli għal dan li ġej:”.

47. Minflok ir-regolament 68 tar-regolamenti prinċipali għandu jidhol dan li ġej:

Jissostitwixxi r-regolament 68 tar-regolamenti prinċipali.

“68. (1) Id-detentur ta' l-awtorizzazzjoni għall-bejgħ għandu jzomm *records* dettaljati tar-reazzjonijiet suspettati kollha li jseħhu fil-Komunità Ewropea jew f'pajjiż terz.

Salv f'ċirkostanzi eċċezzjonali, dawn ir-reazzjonijiet ghandhom ikunu komunikati b'mod elettroniku fil-forma ta' rapport skond il-gwidi msemmija fir-regolament 70(1).

(2) Id-detentur ta' l-awtorizzazzjoni għall-bejgħ għandu jirreġistra r-reazzjonijiet kuntrarji suspettati kollha u r-reazzjonijiet kuntrarji umani relatati ma' l-użu tal-prodott mediċinali veterinarju li jkunu nġiebu għall-attenzjoni tiegħu, u jirrapportahom immedjatament lis-Servizzi Veterinarji, u dan mhux aktar tard minn 15-il jum wara li jkun irċieva l-informazzjoni.

Id-detentur ta' l-awtorizzazzjoni għall-bejgħ għandu jirreġistra wkoll ir-reazzjonijiet kuntrarji kollha u r-reazzjonijiet kuntrarji umani relatati ma' l-użu ta' prodotti mediċinali veterinarji li huwa mistenni b'mod raġonevoli li jkollu tagħrif dwarhom, u jirrapportahom immedjatament lis-Servizzi Veterinarji, u dan mhux aktar tard minn 15-il jum wara li jkun irċieva dik l-informazzjoni.

(3) Id-detentur ta' l-awtorizzazzjoni għall-bejgħ għandu jiżgura li r-reazzjonijiet kuntrarji u mhux mistennija, ir-reazzjonijiet kuntrarji għall-bniedem u kull trasmissjoni suspettata permezz ta' prodott mediċinali veterinarju ta' xi aġent infettat li tigri fit-territorju ta' pajjiż terz, ikunu rapportati immedjatament skond il-gwidi msemmija fir-regolament 70(1), sabiex ikunu disponibbli għall-Aġenzija u l-awtoritajiet kompetenti ta' l-Istati Membri fejn ikun gie awtorizzat il-prodott mediċinali veterinarju, u f'ebda każ aktar tard minn 15-il jum wara li jkun irċieva l-informazzjoni.

(4) B'deroga minn subregolamenti (2) u (3), fil-każ ta' prodotti mediċinali veterinarji li huma koperti mid-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 87/22/KEE, li jkunu ibbenefikaw mill-proċeduri ta' awtorizzazzjoni skond l-Artikoli 31 u 32 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE jew li jkunu soġġetti għall-proċeduri mniżżla fl-Artikoli 36, 37 u 38 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE, id-detentur ta' l-awtorizzazzjoni għall-bejgħ għandu jiżgura wkoll li r-reazzjonijiet kuntrarji serji suspettati u r-reazzjonijiet kuntrarji għall-bniedem, li jsehhu fil-Komunità jkunu rapportati b'tali mod li jkunu disponibbli għall-Istat Membru ta' riferenza jew għall-awtorità kompetenti nominata bhala Stat Membru ta' riferenza. L-Istat Membru ta' riferenza għandu jassumi r-responsabilità għal kull analiżi u prosegwiment ta' kull reazzjoni kuntrarja.

(5) Sakemm ma jkunux stabbiliti htigijiet ohra bhala kundizzjoni għall-ghoti ta' l-awtorizzazzjoni għall-bejgħ jew sussegwentement kif indikat fil-gwidi msemmija fir-regolament

70(1), rapporti ta' kull reazzjoni kuntrarja ghandhom jiġu pprezentati lis-Servizzi Veterinarji fil-forma ta' rapport perjodikament aġġornat dwar il-harsien tas-sahha, malli jiġi mitlub jew ta' lanqas kull sitt xhur wara l-awtorizzazzjoni sakemm jitqiegħed fis-suq. Rapport perjodikament aġġornat dwar il-harsien tas-sahha ghandhom jiġu pprezentati immedjatement meta mitluba jew ta' lanqas kull sitt xhur matul l-ewwel sentejn wara t-tqegħid fis-suq inizjali u darba fis-sena għas-sentejn ta' wara. Wara dan, ir-rapporti ghandhom ikunu pprezentati f'intervalli ta' tlett snin, jew hekk kif dawn jiġu mitlubin.

Ir-rapporti aġġornati perjodiċi dwar il-harsien tas-sahha ghandhom jinkludu evalwazzjoni xjentifika tal-bilanċ tal-benefiċċji u r-riskji tal-prodott mediċinali veterinarju.

(6) Wara li tinghata l-awtorizzazzjoni għall-bejgh, id-detentur ta' dik l-awtorizzazzjoni jista' jitlob l-emenda fil-perjodi msemmija fis-subregolament (5) ta' dan ir-regolament skond il-proċedura mnizzla fir-Regolament tal-Kummissjoni Ewropea (EK) Nru 1084/2003.

(7) Id-detentur ta' l-awtorizzazzjoni għall-bejgh ma jistax jikkomunika informazzjoni relatata ma' imprizi ta' farmakoviġilanza lill-pubbliku ġenerali fir-rigward tal-prodott mediċinali veterinarju awtorizzat minghajr ma jagħti notifikazzjoni minn qabel jew simultanja lis-Servizzi Veterinarji.

F'kull każ, id-detentur ta' l-awtorizzazzjoni għall-bejgh ghandu jiżgura li dik l-informazzjoni tiġi pprezentata oġġettivament u ma tkunx waħda qarrieqa.

Malta ghandha tiehu l-miżuri neċessarji sabiex tiżgura li detentur ta' awtorizzazzjoni għall-bejgh li jonqos milli jwettaq dawn l-obbligazzjonijiet ikun soġġett għal penalitajiet effettivi, proporzjonati u dissważivi.”.

48. Minflok is-subregolament (2) tar-regolament 71 tar-regolamenti prinċipali ghandu jidhol dan li ġej:

Jemenda r-regolament 71 tar-regolamenti prinċipali.

“(2) Jekk tkun neċessarja azzjoni urġenti għall-protezzjoni tal-bniedem u s-sahha ta' l-annimal, Malta tista' tissospendi l-awtorizzazzjoni għall-bejgh ta' prodott mediċinali veterinarju, kemm-il darba l-Aġenzija, il-Kummissjoni u l-Istati Membri l-oħra jiġu infurmati mhux aktar tard mill-ewwel jum ta' xogħol li jmiss.”.

49. Ir-regolament 72 tar-regolamenti prinċipali ghandu jiġi emendat kif ġej:

(a) minflok is-subregolament (1) ghandu jidhol dan li ġej:

“(1) Is-Servizzi Veterinarju ghandhom jiżguraw, permezz ta’ ispezzjonijiet ripetuti u, jekk ikun neċessarju ta’ ispezzjonijiet mingħajr pre-avviż, u fejn adatt, billi jsaqsu lil-Laboratorju Uffiċjali għall-Kontroll ta’ Mediċini jew laboratorju magħmul għal dak il-ghan biex jagħmlu testijiet fuq kampjuni, li l-htigijiet legali relatati mal-prodotti mediċinali jkunu segwiti.

Is-Servizzi Veterinarji jistghu jagħmlu wkoll spezzjonijiet mingħajr pre-avviż fil-postijiet ta’ manifatturi ta’ sustanzi attivi użati bhala *starting materials* għal prodotti mediċinali veterinarji, u tal-postijiet tad-detentur ta’ l-awtorizzazzjoni għall-bejgħ fejn jikkunsidraw li hemm raġunijiet għas-suspett li hemm nuqqas ta’ konformità mad-disposizzjonijiet ta’ l-Artikolu 51 tad-Direttiva tal-Kunsill ta’ l-Unjoni Ewropea 2004/28/KE. Dawn l-ispezzjonijiet jistghu jsiru wkoll fuq talba ta’ Stat Membru iehor, tal-Kummissjoni Ewropea jew ta’ l-Aġenzija.

Sabiex jivverifika jekk l-informazzjoni pprezentata biex tikseb ċertifikat ta’ konformità li jkun jaqbel mal-monografi tal-Farmakopea Ewropea, il-korp ta’ standardizzazzjoni għal nomenklaturi u normi ta’ kwalità fit-tifsira tal-Konvenzjoni relatata ma’ l-elaborazzjoni tal-Farmakopea Ewropea (Direttorat ta’ l-Unjoni Ewropea għall-Kwalità ta’ Mediċini) jiġta’ jitlob lill-Kummissjoni jew lill-Aġenzija biex titlob dik l-ispezzjoni meta li *starting material* konċernat ikun soġġett għal monografu tal-Farmakopea Ewropea.

Is-Servizzi Veterinarja jistghu jagħmlu spezzjonijiet ta’ manifatturi ta’ *starting material* fuq talba stess tal-manifattur.

Dawk l-ispezzjonijiet ghandhom isiru minn rapreżentanti awtorizzati tas-Servizzi Veterinarji li jkunu jistghu:

(a) jispezzjonaw stabbilimenti ta’ manifattura jew ta’ kummerċ u kull laboratorju li jkun ingħata l-funzjoni li jagħmel testijiet ta’ kontroll skond ir-regolament 24 mid-detentur ta’ l-awtorizzazzjoni għall-bejgħ;

(b) jieħdu kampjuni bil-ghan ta' analiżi indipendenti minn Laboratorju Uffiċjali għall-Kontroll tal-Mediċini jew minn laboratorju nominat għal dak l-iskop minn Malta;

(ċ) jeżaminaw kull dokument relatat ma' l-oġġett ta' l-ispezzjoni, bla ħsara għad-disposizzjonijiet fis-seħħ f' Malta li jagħmlu restrizzjonijiet fuq dawn il-poteri fir-rigward tad-deskrizzjoni tal-metodu ta' manifattura;

(d) jispezzjonaw il-postijiet, reġistri u dokumenti tad-detenturi ta' l-awtorizzazzjoni għall-bejgħ jew ditti li jagħmlu l-attivitajiet elenkati fit-Titolu VII, u b' mod partikolari ir-regolamenti 67 u 68 ta' dak it-Titolu, għan-nom ta' detentur ta' l-awtorizzazzjoni għall-bejgħ.”;

(b) is-subregolament (3) għandu jiġi sostitwit b'dan li ġej:

“(3) Ir-rappreżentanti awtorizzati tas-Servizzi Veterinarji għandhom jirraportaw wara kull waħda mill-ispezzjonijiet msemmija fis-subregolament (1) dwar jekk il-prinċipji u gwidi ta' Prattika Tajba ta' Manifattura msemmija fl-Artikolu 51 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2004/28/KE jew, fejn ikun adatt, il-htigijiet imniżżla fit-Titolu VII, ikunu qegħdin jiġu mharsa. Il-manifattur li tkun saritlu spezzjoni, jew id-detentur ta' l-awtorizzazzjoni għall-bejgħ, għandhom ikunu infurmati bil-kontenut ta' dawk ir-rapporti.”;

u

(ċ) minnufih wara s-subregolament (3), għandu jizdied dan is-subregolament ġdid li ġej:

“(4) Mingħajr preġudizzju għal kull arrangament li seta sar bejn il-Komunità Ewropea u pajjiż terz, Malta, il-Kummissjoni Ewropea jew l-Aġenzija jistgħu jeħtieġu lil manifattur stabbilit f' pajjiż terz biex jgħaddi minn ispezzjoni kif imsemmija fis-subregolament (1).

(5) Fi żmien 90 jum wara spezzjoni kif imsemmija fis-subregolament (1), għandu jinhareġ ċertifikat ta' Prattika Tajba ta' Manifattura lill-manifattur jekk l-ispezzjoni tistabbilixxi li l-manifattur in kwistjoni jkunu konformi mal-prinċipji u gwidi ta' Prattika Tajba ta' Manifattura kif provdut mil-liġi Komunitarja.

Fil-każ ta' spezzjoni maghmula fuq talba tal-Farmakopea Ewropea, ghandu jinhareg ċertifikat ta' konformità mal-monografu, jekk dan ikun adatt.

(6) Malta ghandha ddaħhal iċ-ċertifikati ta' Prattika tajba ta' manifattura li tohrog f'*database* Komunitarja immaniġġata mill-Aġenzija ghan-nom tal-Komunità Ewropea.

(7) Jekk ir-riżultat ta' l-ispezzjoni kif imsemmija fis-subregolament (1) huwa dak li l-manifattur ma jkunx konformi mal-prinċipji u gwidi ta' Prattika tajba ta' manifattura kif provdut mill-leġislazzjoni Komunitarja, l-informazzjoni ghandha tidhol fid-*database* Komunitarja msemmija fis-subregolament (6).”.

Jissostitwixxi r-regolament 74 tar-regolamenti prinċipali.

50. Ir-regolament 74 tar-regolamenti prinċipali ghandu jiġi sostitwit b'dan li ġej:

“74. (1) Meta jqisu li jkun hekk mehtieg ghal raġunijiet ta' saħha tal-bniedem u ta' l-animali, is-Servizzi Veterinarji jistgħu jitolbu lid-detentur ta' l-awtorizzazzjoni għall-bejgħ ta' prodotti immunoloġiċi, li jagħti kampjuni mill-lottijiet ta' l-ingrossa u, jew mill-prodotti mediċinali veterinarji, għall-kontroll mil-Laboratorju Uffiċjali għall-Kontroll tal-Mediċini qabel ma l-prodott jiddaħhal fiċ-ċirkolazzjoni.

(2) Fuq talba tas-Servizzi Veterinarji, id-detentur ta' l-awtorizzazzjoni ta' bejgħ ghandu minnufih jiprovdi l-kampjuni msemmija f'subregolament (1), flimkien mar-rapporti tal-kontroll msemmija f'regolament 73(2).

Is-Servizzi Veterinarji ghandhom jinformaw lill-Istati Membri l-oħra kollha fejn il-prodott mediċinali veterinarju huwa awtorizzar kif ukoll lid-Direttorat ta' l-Unjoni Ewropea dwar il-Kwalità tal-Mediċini bil-hsieb tagħha li tikkontrolla l-lottijiet jew il-lott in kwistjoni.

(3) Wara li jkun studja r-rapporti ta' kontroll imsemmija f'regolament 73(2), il-laboratorju responsabbli mill-kontroll ghandu jirrepeti, fuq il-kampjuni provduti, it-testijiet kollha magħmulin mill-manifattur fuq il-prodott lest, skond id-disposizzjonijiet rilevanti murija fid-*dossier* għal awtorizzazzjoni għall-bejgħ.

Il-lista ta' testijiet li ghandhom ikunu ripetuti mil-laboratorju responsabbli ghall-kontroll ghandha tkun restritta ghal testijiet ġustifikati, sakemm l-Istati Membri kollha konċernati, u jekk ikun adatt id-Direttorat ta' l-Unjoni Ewropea ghal Kwalità tal-Mediċini, jaqblu li jsir dan.

Ghall-prodotti mediċinali veterinarji immunoloġiċi awtorizzati skond ir-Regolament ta' l-Unjoni Ewropea (EK) Nru 726/2004, il-lista ta' testijiet li ghandhom ikunu ripetuti mil-laboratorju ta' kontroll jista' jkun ridott biss wara ftehim ma' l-Aġenzija.

(4) Malta ghandha tirrikonoxxi dawn ir-riżultati tat-testijiet.

(5) Hlief meta l-Kummissjoni Ewropea tkun giet infurmata li jkun mehtieg perjodu itwal biex titwettaq l-analiżi, is-Servizzi Veterinarji ghandhom jiżguraw li kontroll bhal dan jitlesta fi żmien 60 jum minn meta jaslu l-kampjuni.

Is-Servizzi Veterinarji ghandhom jinnotifikaw lill-Istati Membri l-oħra konċernati, lid-Direttorat ta' l-Unjoni Ewropea ghal kwalità tal-Mediċini, lid-detentur ta' l-awtorizzazzjoni ghall-bejgħ u, jekk ikun adatt, lill-manifattur, bir-riżultati tat-testijiet matul l-istess perjodu ta' żmien.

Jekk is-Servizzi Veterinarji jikkonkludu li lott ta' prodott mediċinali veterinarju ma jkunx konformi mar-rapport tal-kontroll tal-manifattur jew l-ispeċifikazzjonijiet mniżżla fl-awtorizzazzjoni ta' bejgħ, dawn ghandhom jieħdu l-miżuri kollha neċessarji fil-konfront tad-detentur ta' l-awtorizzazzjoni ghall-bejgħ u l-manifattur, fejn adatt, u ghandhom jinformaw b'dan lill-Istati Membri kollha fejn il-prodott mediċinali veterinarju jkun awtorizzat.”.

51. Ir-regolament 75 tar-regolamenti prinċipali ghandu jiġi emendat kif ġej:

Jemenda r-regolament 75 tar-regolamenti prinċipali.

(a) is-subregolament (1) ghandu jiġi emendat kif ġej:

(i) minflok il-kliem minn “(1) Is-Servizzi Veterinarji” sal-kliem “jkun ċar li -” ghandhom jidhlu l-kliem:

“Is-Servizzi Veterinarji ghandhom jissospendu, jirrevokaw, jirtiraw jew ivarjaw l-awtorizzazzjonijiet ghall-bejgħ meta jkun ċar li:”;

(ii) minflok il-paragrafu (a) ghandu jidhol dan li ġej:

“(a) l-istima bejn ir-riskju u l-benefiċċju tal-prodott mediċinali veterinarju hija, taht il-kondizzjonijiet ta’ l-użu awtorizzati, mhux favorevoli, partikolarment fir-rigward tal-benefiċċji għas-saħha u l-benesseri ta’ l-annimal u għas-sigurtà tal-konsumatur, meta l-awtorizzazzjoni tkun tikkonċerna prodott mediċinali veterinarju għall-użu zootekniku;”;

(iii) il-kliem minn “Madankollu, sakemm” sal-kliem “tas-saħha ta’ l-annimali;” fil-paragrafu (e) ghandu jithassar;

(iv) minflok il-paragrafu (f) ghandu jidhol dan li ġej:

“(f) l-informazzjoni mogħtija fid-dokumenti ta’ l-applikazzjoni skond ir-regolamenti 12 sa 13D u 27 ma tkunx korretta;”;

(v) paragrafu (h) ghandu jiġi mħassar;

(vi) minnufih fi tmiem il-paragrafu (h) ghandu jiżdied dan it-tieni paragrafu li ġej:

“Madankollu, meta qafas leġislattiv Komunitarju ikun qiegħed jiġi adottat, is-Servizzi Veterinarji jistgħu jirrifjutaw awtorizzazzjoni għal prodott mediċinali veterinarju meta dik l-azzjoni tkun neċessarja għall-protezzjoni tas-saħha pubblika, tal-konsumatur u ta’ l-annimali.”; u

(b) is-subregolament (2) ghandu jiġi emendat kif ġej:

(i) minflok il-kliem minn “Awtorizzazzjoni tista’” sal-kliem “stabbilit li-” għandhom jiġu sostitwiti dawn il-kliem li ġejjin:

“Awtorizzazzjonijiet ta’ bejgħ jistgħu jiġu sospizi, revokati, mnehhija jew mibdula meta jiġi stabbilit li:”;
u

(ii) minflok paragrafu (a) ghandu jidhol dan li ġej:

“(a) il-partikolaritajiet b’sostenn ta’ l-applikazzjoni, kif provdut fir-regolamenti 12 sa 13D, ma jkunux ġew emendati skond ir-regolamenti 27(1) u (5);”.

52. Fir-regolament 76 tar-regolamenti prinċipali, minflok il-paragrafu (a) tas-subregolament (1) ghandu jidhol dan li ġej:

Jemenda r-regolament 76 tar-regolamenti prinċipali.

“(a) ikun ċar li l-istima bejn ir-riskju u l-benefiċċji tal-prodott mediċinali veterinarju tkun, taht il-kondizzjonijiet ta’ użu awtorizzati, mhux favorevoli, ghar-rigward partikolari tal-benefiċċji ghas-saħħa u l-benesseri ta’ l-annimali u għall-benefiċċji ta’ sigurtà u tas-saħħa tal-konsumaturi, meta l-awtorizzazzjoni tikkonċerna prodott mediċinali veterinarju għall-użu żootekniku.”.

53. Fir-regolament 77 tar-regolamenti prinċipali, minnufih wara s-subregolament (2) ghandu jżidded dan is-subregolament ġdid li ġej:

Jemenda r-regolament 77 tar-regolamenti prinċipali.

“(3) Is-Servizzi Veterinarji ghandhom jipprojbixxu r-reklamar għall-pubbliku ġenerali ta’ prodotti mediċinali veterinarji li:

(a) skond ir-regolament 60, huma disponibbli fuq riċetta veterinarja biss; jew

(b) ikun fihom mediċinali psikotropiċi jew narkotiċi, bħal dawk koperti mill-Konvenzjonijiet tan-Nazzjonijiet Uniti ta’ 1-1961 u ta’ 1-1971.”.

54. Ir-regolament 81 tar-regolamenti prinċipali, ghandu jiġi sostitwit kif ġej:

Jissostitwixxi r-regolament 81 tar-regolamenti prinċipali.

“81. Is-Servizzi Veterinarji ghandhom jikkomunikaw l-informazzjoni xierqa lill-awtoritajiet kompetenti fi Stati Membri ohra, b’mod partikolari dwar il-konformità mal-htigijiet adottati għall-awtorizzazzjoni msemmija fir-regolament 38, għaċ-ċertifikati msemmija fir-regolament 72(5) jew għall-awtorizzazzjoni biex il-prodotti jitqegħdu fis-suq.

Fuq talba motivata, is-Servizzi Veterinarji ghandhom minnufih jikkomunikaw ir-rapporti riferiti fir-regolament 72(3) lill-awtoritajiet kompetenti fi Stati Membri ohra.

Il-konkluzjonijiet milhuqa wara spezzjoni kif imsemmija fir-regolament 72(1) magħmula minn spetturi tas-Servizzi Veterinarji ghandhom ikunu validi għall-Komunità Ewropea.

Madankollu, bhala eċċezzjoni, jekk Malta ma tkunx kapaċi, għal raġunijiet serji tas-saħħa tal-bniedem jew ta’ l-annimali, li taċċetta il-konkluzjonijiet ta’ spezzjoni kif imsemmija fir-

regolament 72(1), is-Servizzi Veterinarji ghandhom minnufih jinforma lill-Kummissjoni u lill-Aġenzija.

Meta l-Kummissjoni Ewropea tkun infurmata b'dawk ir-raġunijiet serji, hija tista', wara li tikkonsulta mas-Servizzi Veterinarji, ssaqsi lill-ispettur tas-Servizzi Veterinarji biex jagħmel spezzjoni ġdida; l-ispettur jista' jkun akkompanjat minn żewġ spetturi ohra minn Stati Membri li m'humiex parti minn dawk li ma ftehmux.”.

Jemenda r-regolament 85 tar-regolamenti prinċipali.

55. Fir-regolament 85 tar-regolamenti prinċipali, minflok il-kliem minn “Awtorizzazzjonijiet” sal-kliem “fil-Gazzetta tal-Gvern.” ghandu jidhol dan li ġej:

“Deċiżjonijiet biex jinghataw jew jiġu revokati awtorizzazzjonijiet għall-bejgħ ghandhom jitqeghdu għad-disposizzjoni tal-pubbliku.”.

Jissostitwixxi r-regolament 86 tar-regolamenti prinċipali.

56. Minflok ir-regolament 86 tar-regolamenti prinċipali, ghandu jidhol dan li ġej:

“86. Is-Servizzi Veterinarji ma ghandhomx jippermettu li prodotti ta' l-ikel għall-konsum mill-bniedem ikunu magħmulin minn annimali użati f'test, hlief jekk ikun ġie stabbilit perjodu ta' tiżmim xieraq. Il-perjodu ta' tiżmim xieraq ghandu:

(a) ikun ta' lanqas kif imniżzel f'regolament 11(2) inkluż, meta jkun hekk adatt, fattur ta' sigurtà li jirriflettu n-natura tas-sustanza lit kun qed tiġi ttestjata; jew

(b) jekk il-limiti massimi ta' fdalijiet ikunu ġew stabbiliti mill-Komunità skond id-disposizzjonijiet tar-Regolament (KEE) Nru 2377/90, jiġi żgurat li dak il-limitu massimu ma jinqabiżx fil-prodotti ta' l-ikel.”.

Iżid ir-regolament 87 ġdid mar-regolamenti prinċipali.

57. Minnufih wara r-regolament 86 tar-regolamenti prinċipali ghandu jidher dan ir-regolament ġdid li ġej:

“Sistemi ta' kollezzjoni.

87. Is-Servizzi Veterinarji ghandhom jiżguraw illi jkun hemm fis-seħh sistemi ta' kollezzjoni adatti għal prodotti mediċinali veterinarji li ma jkunux qegħdin jiġu użati jew li jkunu skaduti.”.

L.N. 82 of 2006

**VETERINARY SERVICES ACT
(CAP. 437)**

Veterinary Medicinal Products (Amendment) Regulations, 2006

IN exercise of the powers conferred by articles 30 and 31 of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following regulations:-

1. (1) The title to these regulations is the Veterinary Medicinal Products (Amendment) Regulations, 2006 and they shall be read and construed as one with the Veterinary Medicinal Products Regulations, 2004 hereinafter in these regulations referred to as “the principal regulations”. Title and scope.
L.N. 469 of 2004.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 2004/28 EC amending European Council Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

2. For sub-regulation (3) of regulation 1 of the principal regulations, there shall be substituted the following: Amends regulation
1 of the principal
regulations.

“(3) (a) These regulations shall apply to veterinary medicinal products, including pre-mixes for medicated feedingstuffs, intended to be placed on the market in Malta and prepared industrially or by a method involving an industrial process.

(b) In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a “veterinary medicinal product” and within the definition of a product covered by other Community legislation, the provisions of these regulations shall apply.

(c) Notwithstanding paragraph (a) hereof, these regulations shall also apply to active substances used as starting materials to the extent set out in regulations 44, 44A, 45 and 72 and additionally to certain substances that may be used as veterinary medicinal products that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties to the extent set out in regulation 61.”.

Amends regulation
2 of the principal
regulations.

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

(a) point (1) shall be deleted;

(b) for point (2) there shall be substituted the following:

“(2) “Veterinary medicinal product” means:

(a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or

(b) any substance or combination of substances which may be used in or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.”;

(c) point (3) shall be deleted;

(d) for points (8), (9) and (10) there shall be substituted the following:

“(8) “Homeopathic veterinary medicinal product” means any veterinary medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the Pharmacopoeias currently used officially in Member States. A homeopathic veterinary medicinal product may contain a number of principles.

(9) “Withdrawal period” means the period necessary between the last administration of the veterinary medicinal product to animals, under normal conditions of use and in accordance with the provisions of these regulations, and the production of foodstuffs from such animals, in order to protect public health by ensuring that such foodstuffs do not contain residues in quantities in excess of the maximum residue limits for active substances laid down pursuant to European Union Regulation (EEC) No 2377/90.

(10) “Adverse reaction” means a reaction to a veterinary medicinal product which is harmful and unintended

and which occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function.”;

(e) immediately after point 17 there shall be inserted the following new point:

“(17A) “Representative of the marketing authorisation holder” means the person, commonly known as local representative, designated by the marketing authorisation holder to represent him in Malta.”;

(f) for point 18 there shall be substituted the following:

“(18) “Agency” means the European Medicines Agency established by European Regulation (EC) No 726/2004.”;

(g) for point 19 there shall be substituted the following:

“(19) “Risks relating to use of the product” means:

– any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health;

– any risk of undesirable effects on the environment.”;

(h) immediately after point (26) there shall be added the following points:

“(27) “Risk/benefit balance” means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks as defined above.

(28) “Veterinary prescription” means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law.

(29) “Name of veterinary medicinal product” means the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorisation holder.

(30) “Common name” means the international non-proprietary name recommended by the World Health Organisation, or, if one does not exist, the usual common name.

(31) “Strength” means the content of active substances, expressed quantitatively per dosage unit, per unit of volume or weight according to the dosage form.

(32) “Immediate packaging” means the container or any other form of packaging that is in direct contact with the medicinal product.

(33) “Outer packaging” means the packaging into which is placed the immediate packaging.

(34) “Labelling” means information on the immediate or outer packaging.

(35) “Package leaflet” means the leaflet containing information for the user that accompanies the medicinal product.”.

Substitutes regulation 3 of the principal regulations.

4. For regulation 3 of the principal regulations there shall be substituted the following:

“3. (1) These regulations shall not apply to:

(a) medicated feedingstuffs as defined in European Union Council Directive 90/167/EEC laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the European Community;

(b) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or the animals of that holding in the same locality;

(c) veterinary medicinal products based on radio-active isotopes;

(d) any additives covered by European Union Council Directive 70/524/EEC concerning additives in feedingstuffs where they are incorporated in animal feedingstuffs and

supplementary animal feedingstuffs in accordance with that Directive; and

(e) without prejudice to regulation 86, medicinal products for veterinary use intended for research and development trials.

However, medicated feedingstuffs referred to in paragraph (a) hereof may be prepared only from pre-mixes that have been authorised under these regulations.

(2) Except for the provisions on the possession, prescription, dispensing and administration of veterinary medicinal products, these regulations shall not apply to:

(a) any medicinal product prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals, commonly known as the magistral formula; and

(b) any medicinal product prepared in a pharmacy in accordance with the prescriptions of a Pharmacopoeia and intended to be supplied directly to the end-user, commonly known as the officinal formula.”.

5. For sub-regulation (2) of regulation 4 of the principal regulations there shall be substituted the following: Amends regulation 4 of the principal regulations.

“(2) In the case of veterinary medicinal products intended solely for aquarium fish, cage birds, homing pigeons, terrarium animals, small rodents, and ferrets and rabbits kept exclusively as pets, Malta may permit exemptions from the provisions in regulations 5 to 8, provided that such products do not contain substances the use of which requires veterinary control and that all possible measures are taken to prevent unauthorised use of the products for other animals.”.

6. For regulations 5 and 6 of the principal regulations there shall be substituted the following: Substitutes regulations 5 and 6 of the principal regulations.

“5. (1) No veterinary medicinal product may be placed on the market of Malta unless a marketing authorisation has been granted by the Veterinary Services in accordance with these regulations or a marketing authorisation has been granted in accordance with European Union Regulation (EC) No 726/2004.

When a veterinary medicinal product has been granted an initial authorisation in accordance with the first paragraph, any additional species, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions, shall also be granted an authorisation in accordance with the first paragraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of regulation 13(1).

(2) The marketing authorisation holder shall be responsible for the marketing of the medicinal product. The designation of a representative shall not relieve the marketing authorisation holder of his legal responsibility.

6. (1) A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appear in Annexes I, II or III to European Regulation (EEC) No 2377/90.

(2) If an amendment to the Annexes to Regulation (EEC) No 2377/90 so warrants, the marketing authorisation holder or, where appropriate, the Veterinary Services shall take all necessary measures to amend or revoke the marketing authorisation within 60 days of the date on which the amendment to the Annexes to that Regulation was published in the Official Journal of the European Union.

(3) By way of derogation from subregulation (1) hereof, a veterinary medicinal product containing pharmacologically active substances not included in Annexes I, II or III to European Regulation (EEC) No 2377/90 may be authorised for particular animals of the equidae family that have been declared, in accordance with European Commission Decision 93/623/EEC establishing the identification document (passport) accompanying registered equidae and European Commission Decision 2000/68/EC amending Decision 93/623/EEC and establishing the identification of equidae for breeding and production, as not being intended for slaughter for human consumption. Such veterinary medicinal products shall neither include active substances that appear in Annex IV to European Regulation (EEC) No 2377/90 nor be intended for use in the treatment of conditions, as detailed in the authorised Summary of Product Characteristics, for which a veterinary medicinal product is authorized for animals of the equidae family.”.

7. For regulation 8 of the principal regulations there shall be substituted the following:

Substitutes regulation 8 of the principal regulations.

“8. (1) In the event of serious epizootic diseases, the Veterinary Services may provisionally allow the use of immunological veterinary medicinal products without a marketing authorisation, in the absence of a suitable medicinal product and after informing the European Commission of the detailed conditions of use.

(2) If an animal is being imported from, or exported to, a third country and is thereby subject to specific binding health rules, the Veterinary Services may permit the use, for the animal in question, of an immunological veterinary medicinal product that is not covered by a marketing authorisation in Malta but is authorized under the legislation of the third country. The Veterinary Services shall take all appropriate measures concerning the supervision of the importation and the use of such immunological products.”.

8. For regulations 10 to 13 of the principal regulations there shall be substituted the following:

Substitutes regulations 10 to 13 of the principal regulations.

“10. (1) The Veterinary Services shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in Malta for a condition affecting a non food-producing species, by way of exception, the veterinarian responsible may, under his/her direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animal concerned with:

(a) a veterinary medicinal product authorised in Malta under these regulations or under European Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or

(b) if there is no product as referred to in paragraph (a) –

(i) either a medicinal product authorised for human use in Malta in accordance with European Directive 2001/83/EC of the European Parliament and of the European Council or under European Regulation (EC) No 726/2004,

(ii) or, in accordance with specific national measures, a veterinary medicinal product authorised in another Member State in accordance with these regulations for use in the same species or in another species for the condition in question or for another condition; or

(c) if there is no product as referred to in paragraph (b), and within the limits of the law of Malta, a veterinary medicinal product prepared extemporaneously by a person authorized to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

(2) By way of derogation from regulation 11, the provisions of subregulation (1) hereof shall also apply to the treatment by a veterinarian of an animal belonging to the equidae family provided that it has been declared, in accordance with European Commission Decisions 93/623/EEC and 2000/68/EC, as not being intended for slaughter for human consumption.

11. (1) The Veterinary Services shall take the necessary measures to ensure that, if there is no authorised veterinary medicinal product in Malta for a condition affecting a food-producing species, by way of exception, the veterinarian responsible may, under his direct personal responsibility and in particular to avoid causing unacceptable suffering, treat the animals concerned on a particular holding with:

(a) a veterinary medicinal product authorised in Malta under these regulations or under European Regulation (EC) No 726/2004 for use with another animal species, or for another condition in the same species; or

(b) if there is no product as referred to in paragraph (a), either:

(i) a medicinal product for human use authorised in Malta in accordance with European Directive 2001/83/EC or under European Regulation (EC) No 726/2004, or

(ii) a veterinary medicinal product authorised in another Member State in accordance with these regulations for use in the same species or in another food-producing species for the condition in question or for another condition; or

(c) if there is no product as referred to in paragraph (b), and within the limits of the law of Malta, a veterinary medicinal product prepared extemporaneously by a person authorized to do so under national legislation in accordance with the terms of a veterinary prescription.

The veterinarian may administer the medicinal product personally or allow another person to do so under the veterinarian's responsibility.

(2) Subregulation (1) hereof shall apply provided that pharmacologically active substances included in the medicinal product are listed in Annex I, II or III to European Regulation (EEC) No 2377/90, and that the veterinarian specifies an appropriate withdrawal period.

Unless the medicinal product used indicates a withdrawal period for the species concerned, the specified withdrawal period shall not be less than:

- 7 days for eggs,
- 7 days for milk,
- 28 days for meat from poultry and mammals including fat and offal,
- 500 degree-days for fish meat.

(3) With regard to homeopathic veterinary medicinal products in which active principles figure in Annex II to European Regulation (EEC) No 2377/90, the withdrawal period referred to in the second paragraph of subregulation (2) shall be reduced to zero.

(4) When a veterinarian has recourse to the provisions of subregulations (1) and (2) hereof, he shall keep adequate records of the date of examination of the animals, details of the owner, the number of animals treated, the diagnosis, the medicinal products prescribed, the doses administered, the duration of treatment and

the withdrawal periods recommended, and shall make these records available for inspection by the Veterinary Services for a period of at least five years.

(5) Without prejudice to the other provisions of these regulations, Malta shall take all necessary measures concerning the import, distribution, dispensing of and information on the medicinal products which they permit for administration to food-producing animals in accordance with subregulation (1)(b)(ii).

12. (1) For the purposes of obtaining a marketing authorisation in respect of a veterinary medicinal product, otherwise than under the procedure established by European Regulation (EC) No 726/2004, an application shall be lodged with the Veterinary Services.

In the case of veterinary medicinal products which are intended for one or more food-producing species but whose pharmacologically active substances have not yet been included, for the species in question, in Annexes I, II or III to European Regulation (EEC) No 2377/90, a marketing authorisation may not be applied for until after a valid application has been made for the establishment of maximum residue limits in accordance with that Regulation. At least six months shall elapse between a valid application for the establishment of maximum residue limits and an application for a marketing authorisation.

However, in the case of veterinary medicinal products referred to in regulation 6(3), a marketing authorisation may be applied for without a valid application in accordance with European Regulation (EEC) No 2377/90. All the scientific documentation necessary for the demonstration of the quality, safety and efficacy of the veterinary medicinal product, as provided for in subregulation (3) hereof, shall be submitted.

(2) A marketing authorisation may only be granted to an applicant established in the European Community.

(3) The application for marketing authorisation shall include all the administrative information and scientific documentation necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question. The file shall be submitted in accordance with Schedule I and shall contain, in particular, the following information:

(a) name or business name and permanent address or registered place of business of the person responsible for placing the product on the market and, if different, of the manufacturer or manufacturers involved and of the sites of manufacture;

(b) name of veterinary medicinal product;

(c) qualitative and quantitative particulars of all the constituents of the veterinary medicinal product, including its international non-proprietary name (INN) recommended by the WHO, where an INN exists, or its chemical name;

(d) description of the method of manufacture;

(e) therapeutic indications, contra-indications and adverse reactions;

(f) dosage for the various species of animal for which the veterinary medicinal product is intended, its pharmaceutical form, method and route of administration and proposed shelf life;

(g) reasons for any precautionary and safety measures to be taken when storing the veterinary medicinal product, administering it to animals and disposing of waste, together with an indication of potential risks that the veterinary medicinal product might pose to the environment, to human and animal health and to plants;

(h) indication of the withdrawal period in the case of medicinal products intended for food-producing species;

(i) description of the testing methods employed by the manufacturer;

(j) results of:

– pharmaceutical (physico-chemical, biological or microbiological) tests,

– safety tests and residue tests,

– pre-clinical and clinical trials;

– tests assessing the potential risks posed by the medicinal product for the environment. This impact shall be studied and consideration shall be given on a case-by-case basis to specific provisions seeking to limit it.

(k) a detailed description of the pharmacovigilance system and, where appropriate, the risk management system that the applicant will put in place;

(l) a summary in accordance with regulation 14 of the product characteristics, a mock-up of the immediate packaging and the outer packaging of the veterinary medicinal product, together with the package leaflet, in accordance with regulations 53 to 55;

(m) a document showing that the manufacturer is authorized in his own country to produce veterinary medicinal products;

(n) copies of any marketing authorisation obtained in another Member State or in a third country for the relevant veterinary medicinal product, together with a list of those Member States in which an application for authorisation submitted in accordance with these regulations is under examination. Copies of the summary of the product characteristics proposed by the applicant in accordance with regulation 14 or approved by the Veterinary Services in accordance with regulation 25 and copies of the package insert proposed, details of any decision to refuse authorisation, whether in the European Community or a third country and the reasons for that decision. All this information shall be updated on a regular basis;

(o) proof that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the European Community or in a third country;

(p) in the case of veterinary medicinal products intended for one or more food-producing species and containing one or more pharmacologically active substances not yet included, for the species in question, in Annexes I, II or III to European Regulation (EEC) No 2377/90, a document certifying that a valid application for the establishment of

maximum residue limits has been submitted to the Agency in accordance with the aforementioned Regulation.

The documents and particulars relating to the results of the tests referred to in point (j) of the first paragraph shall be accompanied by detailed and critical summaries, drawn up as specified in regulation 15.

13. (1) By way of derogation from point (j) of the first subparagraph of regulation 12(3), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of the safety and residue tests or of the pre-clinical and clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under regulation 5 for not less than eight years in a Member State or the European Community.

A generic veterinary medicinal product authorized pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product.

The first subregulation shall also apply when the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the Member State in which the reference medicinal product is or has been authorised. At the request of the Veterinary Services, the competent authority of the other Member State shall transmit, within a period of one month, confirmation that the reference medicinal product is or has been authorized together with the full composition of the reference product and if necessary other relevant documentation. However, the ten-year period provided for in the second paragraph shall be extended to 13 years in the case of veterinary medicinal products for fish or bees or other species designated in accordance with the procedure referred to in Article 89(2) of European Union Council Directive 2004/28 EC.

(2) For the purposes of this regulation:

(a) “reference medicinal product” shall mean a product authorised within the meaning of regulation 5 in accordance with the provisions of regulation 12;

(b) “generic medicinal product” shall mean a medicinal product which has the same qualitative and quantitative

composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information intended to provide proof of the safety and/or efficacy of the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.

(3) In cases where the veterinary medicinal product does not fall under the definition of a generic medicinal product set out in subregulation 2(b) or where bio-equivalence cannot be demonstrated through bioavailability studies or in the case of changes to the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of the appropriate safety and residue tests and pre-clinical tests or clinical trials shall be provided.

(4) Where a biological veterinary medicinal product which is similar to a reference biological veterinary medicinal product does not meet the conditions in the definition of generic medicinal products, owing to, in particular, differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product, the results of appropriate pre-clinical tests or clinical trials relating to these conditions must be provided. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Schedule I and the related detailed guidelines. The results of other tests and trials from the reference medicinal product's dossier shall not be provided.

(5) In the case of veterinary medicinal products intended for one or more food-producing species and containing a new active substance that has not been authorised in the European Community by 30 April 2004 the ten-year period provided for in the second paragraph of subregulation (1) shall be extended by

one year for each extension of the marketing authorisation to another food-producing species, if it is authorised within the five years following the granting of the initial marketing authorisation.

This period shall not, however, exceed a total of 13 years, for a marketing authorisation for four or more food-producing species.

The extension of the ten-year period to 11, 12, or 13 years for a veterinary medicinal product intended for food-producing species shall be granted only if the marketing authorisation holder also originally applied for determination of the maximum residue limits established for the species covered by the authorisation.

(6) Conducting the necessary studies, tests and trials with a view to the application of sub-regulations (1) to (5) and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products.”.

9. Immediately after regulation 13 of the principal regulations there shall be added the following new regulations:

Adds new regulations 13A to 13D to the principal regulations.

“Derogation. 13A. (1) By way of derogation from point (j) of the first paragraph of regulation 12(3), and without prejudice to the law on the protection of industrial and commercial property, the applicant shall not be required to provide the results of safety and residue tests or of pre-clinical tests or clinical trials if he can demonstrate that the active substances of the veterinary medicinal product have been in well-established veterinary use within the European Community for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Schedule I. In that event, the applicant shall provide appropriate scientific literature.

(2) The assessment report published by the Agency following the evaluation of an application for the establishment of maximum residue limits in accordance with European Regulation (EEC) No 2377/90 may be used in an appropriate manner as literature, particularly for the safety tests.

(3) If an applicant makes use of scientific literature to obtain authorisation for a food-producing species, and submits, in respect of the same medicinal product and with a view to obtaining authorisation for another

foodproducing species, new residue studies in accordance with European Regulation (EEC) No 2377/90, together with further clinical trials, it shall not be permissible for a third party to use such studies or such trials pursuant to regulation 13, for a period of three years from the grant of the authorization for which they were carried out.

Active substances.

13B. In the case of veterinary medicinal products containing active substances used in the composition of authorized veterinary medicinal products but not hitherto used in combination for therapeutic purposes, the results of safety and residue tests, if necessary, and new pre-clinical tests or new clinical trials relating to that combination shall be provided in accordance with point (j) of the first paragraph of regulation 12(3), but it shall not be necessary to provide scientific references relating to each individual active substance.

Use of Documentation.

13C. After the marketing authorisation has been granted, the marketing authorisation holder may allow use to be made of the pharmaceutical, safety and residues, pre-clinical and clinical documentation contained in the file for the veterinary medicinal product with a view to examining a subsequent application for a veterinary medicinal product having the same qualitative and quantitative composition in active substances and the same pharmaceutical form.

Derogation.

13D. By way of derogation from point (j) of the first paragraph of regulation 12(3), and in exceptional circumstances with respect to immunological veterinary medicinal products, the applicant shall not be required to provide the results of certain field trials on the target species if these trials cannot be carried out for duly substantiated reasons, in particular on account of other European Community provisions.”.

Substitutes regulations 14 to 16 of the principal regulations.

10. For regulations 14 to 16 of the principal regulations there shall be substituted the following:

“14. The summary of the product characteristics shall contain, in the order indicated below, the following information:

(1) name of the veterinary medicinal product followed by the strength and the pharmaceutical form;

(2) qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used;

(3) pharmaceutical form;

(4) clinical particulars:

(i) target species,

(ii) indications for use, specifying the target species,

(iii) contra-indications,

(iv) special warnings for each target species,

(v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals,

(vi) adverse reactions (frequency and seriousness),

(vii) use during pregnancy, lactation or lay,

(viii) interaction with other medicinal products and other forms of interaction,

(ix) amounts to be administered and administration route,

(x) overdose (symptoms, emergency procedures, antidotes), if necessary,

(xi) withdrawal periods for the various foodstuffs, including those for which the withdrawal period is zero;

(5) pharmacological properties:

(i) pharmacodynamic properties,

(ii) pharmacokinetic particulars;

- (6) pharmaceutical particulars:
 - (i) list of excipients,
 - (ii) major incompatibilities,
 - (iii) shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,
 - (iv) special precautions for storage,
 - (v) nature and composition of immediate packaging,
 - (vi) special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products, if appropriate;
- (7) marketing authorisation holder;
- (8) marketing authorisation number(s);
- (9) date of the first authorisation or date of renewal of the authorisation;
- (10) date of revision of the text.

For authorisation under regulation 13, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.

15. (1) Applicants shall ensure that the detailed and critical summaries referred to in the second paragraph of regulation 12(3) are drafted and signed by persons with the requisite technical or professional qualifications, set out in a brief curriculum vitae, before being submitted to the Veterinary Services

(2) Persons with the technical or professional qualifications referred to in subregulation (1) hereof shall justify any use made of the scientific literature referred to in regulation 13A(1) in accordance with the conditions set out in Schedule I.

(3) A brief curriculum vitae of the persons referred to in subregulation (1) shall be appended to the detailed critical summaries.

16. (1) The Veterinary Services shall ensure that homeopathic veterinary medicinal products manufactured and placed on the market within the European Community are registered or authorised in accordance with regulations 17, 18 and 19, except where such veterinary medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In the case of homeopathic medicinal products registered in accordance with regulation 17, regulation 32 and regulation 33(1) to (3) shall apply.

(2) The Veterinary Services shall establish a simplified registration procedure for the homeopathic veterinary medicinal products referred to in regulation 17.

(3) By way of derogation from regulation 10, homeopathic veterinary medicinal products may be administered to non-food producing animals under the responsibility of a veterinarian.

(4) By way of derogation from regulation 11(1) and (2), Malta shall permit the administration of homeopathic veterinary medicinal products intended for food-producing species the active constituents of which appear in Annex II to European Regulation (EEC) No 2377/90 under the responsibility of a veterinarian. The Veterinary Services shall take appropriate measures to control the use of veterinary homeopathic medicinal products registered or authorised in another Member State in accordance with these regulations for use in the same species.”.

11. Regulation 17 of the principal regulations shall be amended as follows:- Amends regulation 17 of the principal regulations.

(a) for subregulation (1) thereof, there shall be substituted the following:

“(1) Without prejudice to the provisions of European Regulation (EEC) No 2377/90 on the establishment of maximum residue limits of pharmacologically active substances intended for food-producing animals, only homeopathic veterinary medicinal products which satisfy all

of the following conditions may be subject to a special, simplified registration procedure:

(a) they are administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the Pharmacopoeias currently used officially in Malta;

(b) no specific therapeutic indication appears on the labelling of the veterinary medicinal product or in any information relating thereto;

(c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product. In particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture.”; and

(b) subregulation (3) thereof shall be deleted.

Amends regulation 18 of the principal regulations.

12. Regulation 18 of the principal regulations shall be amended as follows:

(a) for paragraph (c) thereof, there shall be substituted the following:

“(c) manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentiation,”;

(b) for paragraph (f) thereof, there shall substituted the following:

“(f) one or more mock-ups of the outer packaging and immediate packaging of the medicinal products to be registered,”; and

(c) immediately after paragraph (g) thereof there shall be added the following new paragraph:

“(g) proposed withdrawal period together with all requisite justification.”.

Substitutes regulation 19 of the principal regulation

13. For regulation 19 of the principal regulations there shall be substituted the following:

“19. (1) Homeopathic veterinary medicinal products other than those referred to in regulation 17(1) shall be authorized in accordance with regulations 12, 13A, 13B, 13C, 13D and 14.

(2) Malta may introduce or retain on its territory specific rules for the safety tests and pre-clinical and clinical trials of homeopathic veterinary medicinal products intended for pet species and non-food-producing exotic species other than those referred to in regulation 17(1), in accordance with the principles and characteristics of homeopathy as practised in Malta. In this case, the Veterinary Services shall notify the European Commission of the specific rules in force.”.

14. For regulations 21, 22 and 23 of the principal regulations shall be substituted the following:

Substitutes regulations 21 to 23 of the principal regulations.

“21. (1) The Veterinary Services shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for a veterinary medicinal product is completed within a maximum of 210 days after the submission of a valid application.

Applications for marketing authorisations for the same veterinary medicinal product in two or more Member States, shall be submitted in accordance with regulations 31 to 43.

(2) Where Malta notes that another marketing authorisation application for the same medicinal product is being examined in another Member State, Malta shall decline to assess the application and shall advise the applicant that regulations 31 to 43 apply.

22. Where the Veterinary Services is informed, in accordance with paragraph (n) of regulation 12(3), that another Member State has authorised a veterinary medicinal product which is the subject of an application for authorisation in Malta, the Veterinary Services shall reject the application unless it was submitted in compliance with regulations 31 to 43.

23. In order to examine the application submitted pursuant to regulations 12 to 13D, the Veterinary Services:

(1) shall check that the documentation submitted in support of the application complies with regulations 12 to 13D and ascertain whether the conditions for the issue of the marketing authorisation have been fulfilled;

(2) may submit the medicinal product, its starting materials and if necessary intermediate products or other constituent materials for testing by an Official Medicines Control Laboratory or a laboratory that has designated for that purpose by the Veterinary Services, in order to ensure that the testing methods employed by the manufacturer and described in the application documents, in accordance with point (i) of the first paragraph of regulation 12(3), are satisfactory;

(3) may similarly check, in particular through consultation of a national or European Community reference laboratory, that the analytical method used for detecting residues presented by the applicant for the purposes of regulation 12(3)(j), second indent is satisfactory;

(4) may, where appropriate, require the applicant to provide further information as regards the items listed in regulations 12, 13a, 13b, 13c and 13d. Where the Veterinary Services take this course of action, the time-limits specified in regulation 21 shall be suspended until the further data required have been provided. Similarly, these time-limits shall be suspended for any period which the applicant may be given to provide oral or written explanations.”.

Substitutes regulation 25 of the principal regulations.

15. For regulation 25 of the principal regulations there shall be substituted the following:

“25. (1) When granting a marketing authorisation, the Veterinary Services shall inform the holder of the summary of product characteristics that it has approved.

(2) The Veterinary Services shall take all necessary measures to ensure that information concerning the veterinary medicinal product, and in particular the labelling and package leaflet, is in conformity with the summary of product characteristics approved when the marketing authorisation was granted or subsequently.

(3) The Veterinary Services shall make the marketing authorisation publicly available without delay, together with the summary of product characteristics for each veterinary medicinal product that it has authorised.

(4) The Veterinary Services shall draw up an assessment report and comments on the file as regards the results

of the pharmaceutical, safety and residue tests and the pre-clinical and clinical trials of the veterinary medicinal product concerned. The assessment report shall be updated whenever new information becomes available which is of importance for the evaluation of the quality, safety or efficacy of the veterinary medicinal product concerned.

The Veterinary Services shall make the assessment report and its reasons for the opinion publicly available without delay, after deleting any information of a commercially confidential nature.”.

16. Regulation 26 of the principal regulations shall be amended as follows: Amends regulation 26 of the principal regulations.

(a) for subregulation (1) thereof, there shall be substituted the following:

“(1) The marketing authorisation may require the holder to indicate on the immediate packaging and, or the outer wrapping and the package leaflet, where the latter is required, other particulars essential for safety or health protection, including any special precautions relating to use and any other warnings resulting from the clinical and pharmacological trials prescribed in regulation 12(3)(j) and in regulations 13 to 13D or from experience gained during the use of the veterinary medicinal product once it has been marketed.”;

(b) subregulation (2) thereof shall be deleted; and

(c) subregulation (3) shall be renumbered as subregulation (2) thereof and it shall be substituted as follows:

“(2) In exceptional circumstances, and following consultation with the applicant, the authorization may be granted subject to a requirement for the applicant to introduce specific procedures, in particular concerning the safety of the veterinary medicinal product, notification to the competent authorities of any incident relating to its use, and action to be taken. Such authorisations may be granted only for objective, verifiable reasons. Continuation of the authorization shall be linked to the annual reassessment of such conditions.”.

17. Regulation 27 shall be amended as follows:

Amends regulation 27 of the principal regulations.

(a) for subregulations (2) and (3) thereof, there shall be substituted the following:

“(2) The Veterinary Services may require the applicant or the marketing authorisation holder to provide sufficient quantities of the substances to enable controls to be made on the identification of the presence of residues of the veterinary medicinal products in question.

At the Veterinary Services’ request, the marketing authorisation holder shall provide his technical expertise to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal products in the national reference laboratory designated under European Union Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

(3) The authorisation holder shall immediately supply the Veterinary Services with any new information that might entail the amendment of the particulars or documents referred to in regulations 12(3), 13, 13A, 13B and 14 or Schedule I.

In particular, he shall immediately inform the Veterinary Services of any prohibition or restriction imposed by the competent authorities of any country in which the veterinary medicinal product is placed on the market and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned.

In order to permit continuous assessment of the risk-benefit balance, the Veterinary Services may at any time ask the marketing authorisation holder to forward data demonstrating that the risk-benefit balance remains favourable.”;

(b) subregulation (4) thereof shall be deleted;

(c) for subregulation (5) there shall be substituted the following:

“(5) The marketing authorisation holder shall immediately inform the Veterinary Services, with a view to authorisation, of any alteration which he proposes to make to

the particulars or documents referred to in regulations 12 to 13D.”.

18. Immediately after regulation 27 of the principal regulations, there shall be added the following new regulation:

Adds new regulation 27A to the principal regulations.

“Holder to inform the Veterinary Services.

27A. After a marketing authorisation has been granted, the holder of the authorisation shall inform the Veterinary Services of the date of the actual placing on the market of the veterinary medicinal product in Malta, taking into account the various presentations authorised.

The holder shall also notify the Veterinary Services if the product ceases to be placed on the market of Malta, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than two months before the interruption in the placing on the market of the product.

Upon request by the Veterinary Services, particularly in the context of pharmacovigilance, the marketing authorization holder shall provide the Veterinary Services with all data relating to the volume of sales of the veterinary medicinal product, and any data in his possession relating to the volume of prescriptions.”.

19. For regulation 28 of the principal regulations there shall be substituted the following:

Substitutes regulation 28 of the principal regulations.

“28. (1) Without prejudice to subregulations (4) and (5), a marketing authorisation shall be valid for five years.

(2) The authorisation may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance.

To this end, the marketing authorisation holder shall submit a consolidated list of all documents submitted in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorisation ceases to be valid in accordance with subregulation (1) hereof. The Veterinary Services may require the applicant to submit the listed documents at any time.

(3) Once renewed, the marketing authorisation shall be valid for an unlimited period, unless the Veterinary Services decides, on justified grounds relating to pharmacovigilance, to

proceed with one additional five-year renewal in accordance with subregulation (2).

(4) Any authorisation that is not followed within three years of its granting by the actual placing on the market of the authorised veterinary medicinal product in Malta, shall cease to be valid.

(5) When an authorised veterinary medicinal product previously placed on the market in Malta is no longer actually present on Malta for a period of three consecutive years, the authorisation granted for that veterinary medicinal product shall cease to be valid.

(6) The Veterinary Services may, in exceptional circumstances, and on human or animal health grounds, grant exemptions from subregulations (4) and (5). Such exemptions shall be duly justified.”

Substitutes
regulation 30 of the
principal
regulations.

20. For regulation 30 of the principal regulations, there shall be substituted the following:

“30. The marketing authorisation shall be refused if the file submitted to the Veterinary Services does not comply with regulations 12 to 13D and regulation 15.

The authorisation shall also be refused if, after examination of the documents and particulars listed in regulations 12 and 13(1), it is clear that:

(a) the risk-benefit balance of the veterinary medicinal product is, under the authorised conditions of use, unfavourable; when the application concerns a veterinary medicinal product for zootechnical use, particular regard shall be had to the benefits for animal health and welfare and to consumer safety; or

(b) the product has no therapeutic effect or the applicant has not provided sufficient proof of such effect as regards the species of animal which is to be treated; or

(c) its qualitative or quantitative composition is not as stated; or

(d) the withdrawal period recommended by the applicant is not long enough to ensure that foodstuffs obtained

from the treated animal do not contain residues which might constitute a health hazard to the consumer, or is insufficiently substantiated; or

(e) the labelling or the package leaflet proposed by the applicant does not comply with these regulations; or

(f) the veterinary medicinal product is offered for sale for a use prohibited under other European Union Community provisions.

However, when a European Union Community legislative framework is in the course of being adopted, the Veterinary Services may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer or animal health.

The applicant or marketing authorisation holder shall be responsible for the accuracy of documents and data submitted.”.

21. The heading of Chapter 4 of the principal regulations shall be substituted as follows:

Substitutes heading of Chapter 4 of the principal regulations.

“CHAPTER 4

Mutual recognition procedure and decentralized procedure”.

22. For regulations 31 to 34 of the principal regulations there shall be substituted the following:

Substitutes regulations 31 to 34 of the principal regulations.

“31. (1) With a view to the granting of a marketing authorization for a veterinary medicinal product in more than one Member State, the applicant shall submit an application based on an identical dossier in those Member States. The dossier shall contain all the administrative information and scientific and technical documentation described in regulations 12 to 14. The documents submitted shall include a list of Member States concerned by the application.

The applicant shall request one Member State to act as reference Member State and to prepare an assessment report in respect of the veterinary medicinal product in accordance with subregulation (2) or (3).

Where appropriate, the assessment report shall contain an evaluation for the purposes of regulation 13(5) or regulation 13A(3).

(2) If the veterinary medicinal product has already received a marketing authorisation at the time of application, the concerned Member States shall recognize the marketing authorisation granted by the reference Member State. To this end, the marketing authorization holder shall request the reference Member State either to prepare an assessment report in respect of the veterinary medicinal product or, if necessary, to update any existing assessment report. The reference Member State shall prepare or update the assessment report within 90 days of receipt of a valid application. The assessment report together with the approved summary of product characteristics, labelling and package leaflet shall be forwarded to the concerned Member States and the applicant.

(3) If the veterinary medicinal product has not received authorisation by the time of application, the applicant shall request the reference Member State to prepare a draft assessment report and drafts of the summary of product characteristics, labelling and package leaflet. The reference Member State shall prepare these drafts within 120 days of the receipt of a valid application and shall send them to the concerned Member States and the applicant.

(4) Within 90 days after receipt of the documents referred to in sub-regulations (2) and (3), the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and the package leaflet and inform the reference Member State accordingly. The reference Member State shall record the agreement of all parties, close the procedure and inform the applicant accordingly.

(5) Each Member State in which an application following paragraph 1 has been submitted shall adopt a decision in conformity with the approved assessment report, summary of product characteristics, labelling and package leaflet within 30 days after acknowledgement of the agreement.

32. (1) If Malta cannot, within the period allowed in regulation 31(4), agree with the assessment report, summary of product characteristics, labelling and package leaflet on grounds of a potential serious risk to human or animal health or to the environment, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States concerned

and the applicant. The points of disagreement shall be referred without delay to the coordination group.

If a Member State to which an application has been submitted invokes the reasons referred to in regulation 64(1), it shall no longer be regarded as a Member State concerned by this Chapter.

(2) Within the coordination group, all Member States referred to in subregulation (1) shall use their best endeavours to reach agreement on the action to be taken. They shall provide the applicant with the opportunity to make his point of view known orally or in writing. If, within 60 days of the communication of the reasons for disagreement to the coordination group the Member States reach an agreement, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. Regulation 31(5) shall apply in such cases.

(3) If within the period of 60 days the Member States fail to reach an agreement, the Agency shall be immediately informed with a view to application of the procedure laid down in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC. The Agency shall be provided with a detailed description of the matters on which agreement could not be reached and the reasons for the disagreement. The applicant shall be provided with a copy of such information.

(4) As soon as the applicant has been informed that the matter has been referred to the Agency, he shall forthwith forward to the Agency a copy of the information and documents referred to in the first subparagraph of regulation 31(1).

(5) In the case referred to in subregulation (3), the Member States that have approved the assessment report, summary of product characteristics, labelling and package leaflet of the reference Member State may, on request by the applicant, grant a marketing authorisation for the veterinary medicinal product without waiting for the outcome of the procedure laid down in Article 36 of European Union Council Directive 2004/28/EC. In that case, the authorisation granted shall be without prejudice to the outcome of that procedure.

33. (1) If two or more applications submitted in accordance with regulations 12 to 14 have been made for marketing authorisation for a particular veterinary medicinal product and Member States have adopted divergent decisions concerning the authorisation of that veterinary medicinal product, or suspension

or revocation of authorisation, a Member State, or the European Commission, or the marketing-authorisation holder may refer the matter to the Committee for Medicinal Products for Veterinary Use, hereinafter referred to as “the Committee”, for the application of the procedure laid down in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC.

34. (1) Malta or the European Commission or the applicant or marketing authorisation holder shall, in specific cases where the interests of the European Community are involved, refer the matter to the Committee for the application of the procedure laid down in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC before a decision is reached on a request for a marketing authorization or on the suspension or withdrawal of an authorisation, or on any other variations to the terms of a marketing authorisation which appear necessary, so as to take account in particular of the information collected in accordance with Title VII.

Malta or the European Commission shall clearly identify the question which is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.

Malta and the applicant or the marketing authorisation holder shall forward to the Committee all available information relating to the matter in question.”.

Substitutes regulation 37 of the principal regulations.

23. For regulation 37 of the principal regulations there shall be substituted the following:

“37. Regulations 32(3), (4) and (5) and 33 to 34 shall not apply to the homeopathic veterinary medicinal products referred to in regulation 17.

Regulations 31 to 34 shall not apply to the homeopathic veterinary medicinal products referred to in regulation 19(2).”.

Amends regulation 38 of the principal regulations.

24. Immediately after subregulation (3) of regulation 38 of the principal regulations there shall be added the following subregulation:

“(4) Malta shall forward to the Agency a copy of the manufacturing authorisations referred to in subregulation (1). The Agency shall enter that information in the Community database referred to in Article 80(6) of European Union Council Directive 2004/28/EC.”.

25. Paragraph (f) in regulation 44 of the principal regulations shall be substituted as follows: Amends regulation 44 of the principal regulations.

“(f) comply with the principles and the guidelines on good manufacturing practice for medicinal products and use as starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials;”.

26. Immediately after regulation 44 of the principal regulations there shall be added the following new regulation: Adds new regulation 44A to the principal regulations.

“Starting materials.

44A. (1) For the purposes of these regulations, manufacturing active substances for use as starting materials shall include the complete or partial manufacture or the import of an active substance used as a starting material, as defined in Part 2, Section C of Schedule I, and the various processes of dividing up, packaging or presentation prior to its incorporation in a veterinary medicinal product, including repackaging or re-labelling, such as carried out by a starting material distributor.”.

27. Subregulation (1) of regulation 46 of the principal regulations shall be substituted as follows: Amends regulation 46 of the principal regulations.

“(1) Malta shall ensure that the qualified person referred to in regulation 45 fulfils the conditions of qualification referred to in subregulations (2) and (3).”.

28. Subregulation (1) of regulation 47 of the principal regulations shall be substituted as follows: Amends regulation 47 of the principal regulations.

“(1) A person engaging, in Malta, in the activities of the person referred to in regulation 45(1) on the date on which these regulations became applicable, without complying with the provisions of regulation 46, shall be eligible to continue to engage in those activities within the Community.”.

29. In regulation 48 of the principal regulations, for paragraph (b) of subregulation (1) thereof, there shall be substituted the following: Amends regulation 48 of the principal regulations.

“(b) in the case of veterinary medicinal products coming from third countries, even if manufactured in the Community, each production batch imported has undergone in Malta a full qualitative analysis, a quantitative analysis of at least all the active substances, and all the other tests or controls necessary to ensure the quality of

veterinary medicinal products in accordance with the requirements of the marketing authorisation.”.

Amends regulation 51 of the principal regulations.

30. Regulation 51 of the principal regulations shall be amended as follows:

(a) subregulation (1) shall be amended as follows:

(i) For the words from “(1) The following” to the words “of medicinal products –” there shall be substituted the following:

“Except in the case of the medicinal products referred to in regulation 17(1), the Veterinary Services shall approve the immediate packaging and outer packaging of veterinary medicinal products. Packaging shall bear the following information, which shall conform with the particulars and documents provided pursuant to regulations 12 to 13d and the summary of product characteristics, and shall appear in legible characters.”;

(ii) for paragraphs (a) and (b) there shall be substituted the following:

“(a) the name of the medicinal product, followed by its strength and pharmaceutical form. The common name shall appear if the medicinal product contains only one active substance and its name is an invented name;

(b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using the common names;”;

(iii) for paragraph (e) there shall be substituted the following:

“(e) name or corporate name and permanent address or registered place of business of the marketing authorisation holder and, where appropriate, of the representative designated by the marketing authorization holder;”;

(iv) for paragraph (f) there shall be substituted the following:

“(f) the species of animal for which the veterinary medicinal product is intended; the method and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;”;

(v) for paragraph (g) there shall be substituted the following:

“(g) the withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, eggs, milk, honey), including those for which the withdrawal period is zero;”;

(vi) for paragraph (j) shall be substituted the following:

“(j) specific precautions relating to the disposal of unused medicinal products or waste derived from veterinary medicinal products, where appropriate, as well as a reference to any appropriate collection system in place;”;

(vii) for paragraph (l) shall be substituted the following:

“(l) the words “*For animal treatment only*” or, in the case of the medicinal products referred to in regulation 60, the words “*For animal treatment only – to be supplied only on veterinary prescription.*””; and

(b) immediately after subregulation (4) there shall be added the following subregulation:

“(5) In the case of medicinal products that have been granted a marketing authorisation under European Regulation (EC) No 726/2004, Malta may permit or require that the outer packaging bear additional information concerning distribution, possession, sale or any necessary precautions, provided that such information is not in infringement of Community law or the terms of the marketing authorisation, and is not promotional.

This additional information shall appear in a box with a blue border to separate it clearly from the information referred to in subregulation (1).”.

Amends regulation 52 of the principal regulations.

31. Regulation 52 of the principal regulations shall be amended as follows:

(a) for the words from “(1)As regards” to “be necessary –” in subregulation (1) thereof, there shall be substituted the words:

“(1) As regards ampoules, the particulars listed in the first paragraph of regulation 51(1) shall be given on the outer package. On the immediate packaging, however, only the following particulars shall be necessary:”; and

(b) for subregulations (2) and (3) thereof, there shall be substituted the following:

“(2) As regards small immediate packaging containing a single dose, other than ampoules, on which it is impossible to give the particulars mentioned in subregulation (1), the requirements of regulation 51(1), (2) and (3) shall apply only to the outer package.

(3) The particulars mentioned in paragraphs (c) and (f) of subregulation (1) shall appear on the outer package and on the immediate packaging of the medicinal products in the language or languages of the country in which they are placed on the market.”.

Substitutes regulation 53 of the principal regulations.

32. For regulation 53 of the principal regulations there shall be replaced by the following:

“53. Where there is no outer package, all the particulars which should feature on such a package pursuant to regulations 51 and 52 shall be shown on the immediate packaging.”.

Amends regulation 54 of the principal regulations.

33. Regulation 54 of the principal regulations shall be amended as follows:

(a) for subregulation (1) thereof, there shall be substituted the following:

“(1) The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this regulation can be conveyed on the immediate packaging and the outer packaging. Malta shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included. The package leaflet shall be written in

terms that are comprehensible to the general public and in the official language or languages of Malta.

Subregulation (1) shall not prevent the package leaflet from being written in several languages, provided that the information given is identical in all the languages.

The Veterinary Services may exempt labels and package leaflets for specific veterinary medicinal products from the obligation for certain particulars to appear and for the leaflet to be in the official language or languages of Malta, when the product is intended to be administered only by a veterinarian.”;

(b) subregulation (2) shall be amended as follows:

(i) for the words from “(2) The package insert” to the words “by the Veterinary Services –“ there shall be substituted the following:

“(2) The Veterinary Services shall approve package leaflets. Leaflets shall contain at least the following information, in the order indicated, which shall conform to the particulars and documents provided pursuant to regulations 12 to 13D and the approved summary of product characteristics:”; and

(ii) for paragraphs (a) and (b) there shall be substituted the following:

“(a) name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where appropriate, of the representative of the marketing authorization holder;

(b) name of the veterinary medicinal product followed by its strength and pharmaceutical form. The common name shall appear if the product contains only one active substance and its name is an invented name. Where the medicinal product is authorised according to the procedure provided for in regulations Articles 31 to 43 of European Union Council Directive 2004/28/EC under different names in Malta, a list of the names authorised in Malta;”; and

(c) subregulation (3) thereof shall be deleted.

Substitutes regulation 55 of the principal regulations.

34. For regulation 55 of the principal regulations there shall be substituted the following:

“55. Where the provisions of this Title are not observed and a formal notice addressed to the person concerned has been ineffectual, the Veterinary Services may suspend or revoke the marketing authorisation.”.

Amends regulation 57 of the principal regulations.

35. Subregulation (2) of regulation 57 of the principal regulations shall be amended as follows:

(a) for the words from “(2) In addition to” to the words “no other information –“ there shall be substituted the following:

“(2) In addition to the clear mention of the words “homeopathic veterinary medicinal product without approved therapeutic indications”, the labelling and, where appropriate, package leaflet for the homeopathic veterinary medicinal products referred to in regulation 17(1) shall bear the following information and no other information:”; and

(b) for paragraph (a) thereof, there shall be substituted the following:

“(a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the Pharmacopoeia used in accordance with paragraph (8) of regulation 2. If the homeopathic veterinary medicinal product is composed of more than one stock, the labelling may mention an invented name in addition to the scientific names of the stocks,”.

Substitutes heading of Title VI of the principal regulations.

36. For Title VI of the principal regulations, there shall be substituted the following:

“TITLE VI

POSSESSION, DISTRIBUTION AND DISPENSING OF VETERINARY MEDICINAL PRODUCTS”.

Amends regulation 58 of the principal regulations.

37. Regulation 58 of the principal regulations shall be amended as follows:

(a) immediately after subregulation (3) there shall be inserted the following new subregulation:

“3A. The holder of a distribution authorisation shall have an emergency plan guaranteeing the effective implementation of any recall operation ordered by the competent authorities or undertaken in cooperation with the manufacturer of the medicinal product in question or the holder of the marketing authorisation.”;

(b) immediately after subregulation (4) there shall be inserted the following new subregulation:

“(5) Any distributor, not being the marketing authorization holder, who imports a product from another Member State shall notify the marketing authorization holder and the Veterinary Services to which the product will be imported of his intention to import it. In the case of products which have not been granted an authorisation pursuant to European Regulation (EC) No 726/2004, the notification to the Veterinary Services shall be without prejudice to additional procedures provided for in the legislation of Malta.”.

38. Regulation 59 of the principal regulations shall be amended as follows:

Amends regulation 59 of the principal regulations.

(a) subregulation (2) shall be amended as follows:

(i) for the words from “(2) Any person permitted” to the words “or outgoing transaction –” there shall be substituted the following:

“(2) Any person permitted under subregulation (1) to supply veterinary medicinal products shall be required to keep detailed records for veterinary medicinal products that may be supplied only on prescription, the following information being recorded in respect of each incoming or outgoing transaction:”; and

(ii) in the third paragraph thereof, for the words “for a period of the years” there shall be substituted the words:

“for a period of five years”;

(b) for subregulation (3) there shall be substituted the following:

“(3) The Veterinary Services may permit the supply in Malta of veterinary medicinal products for foodproducing

animals for which a veterinary prescription is required by or under the supervision of a person registered for this purpose who provides guarantees with respect to qualifications, record-keeping and reporting in accordance with national law. The Veterinary Services shall notify the European Commission of relevant provisions of national law. This provision shall not apply to the supply of veterinary medicinal products for the oral or parenteral treatment of bacterial infections.”; and

(c) subregulation (4) thereof shall be deleted.

Amends regulation 60 of the principal regulations.

39. Regulation 60 of the principal regulations shall be amended as follows:

(a) for the words from “Without prejudice” to the words “medicinal products –” there shall be substituted by the following:

“Without prejudice to stricter European Community or national rules relating to dispensing veterinary medicinal products and serving to protect human and animal health, a veterinary prescription shall be required for dispensing to the public the following veterinary medicinal products:”;

(b) immediately after paragraph (a) thereof there shall be inserted the following new paragraph:

“(aa) veterinary medicinal products for foodproducing animals.

However, Malta may grant exemptions from this requirement according to criteria established in accordance with the procedure referred to in Article 89(2) of European Union Council Directive 2004/28/EC;”;

(c) subparagraph (iii) of paragraph (b) shall be deleted and subparagraph (iv) shall be renumbered as subparagraph (iii) thereof;

(d) for subparagraph (d) there shall be substituted the following:

“(d) official formula, within the meaning of Article 3(2)(b) of European Union Council Directive 2004/28/EC, intended for food-producing animals.”; and

(e) for the words from “In addition,” to the words “sub-regulation (1) apply.” there shall be substituted the following:

“Malta shall take all necessary measures to ensure that, in the case of medicinal products supplied only on prescription, the quantity prescribed and supplied shall be restricted to the minimum amount required for the treatment or therapy concerned.

In addition, a prescription shall be required for new veterinary medicinal products containing an active substance that has been authorised for use in a veterinary medicinal product for fewer than five years.”.

40. In regulation 62 of the principal regulations, for the words “In the territory of Malta,” to the words “in regulation 61.” there shall be substituted the following: Amends regulation 62 of the principal regulations.

“Malta shall ensure that the owners or keepers of food-producing animals can provide proof of purchase, possession and administration of veterinary medicinal products to such animals for five years after their administration, including when the animal is slaughtered during the five-year period.”.

41. In regulation 63 of the principal regulations, for the words from “Notwithstanding regulations 9 and 60,” to the words “are satisfied –” there shall be substituted the following: Amends regulation 63 of the principal regulations.

“By way of derogation from regulation 9 and without prejudice to regulation 60, Malta shall ensure that veterinarians providing services in another Member State can take with them and administer to animals small quantities of veterinary medicinal products not exceeding daily requirements other than immunological veterinary medicinal products which are not authorised for use in the Member State in which the services are provided, provided that the following conditions are satisfied:”.

42. Immediately at the end of subregulation (1) of regulation 64 of the principal regulations, there shall be added the following paragraph:- Amends regulation 64 of the principal regulations.

“Malta may also invoke the provisions of the first paragraph in order to withhold marketing authorisation in accordance with a decentralised procedure as provided for in Articles 31 to 43 of European Union Council Directive 2004/28/EC.”.

43. For subregulation (2) of regulation 65 of the principal regulations, there shall be substituted the following: Amends regulation 65 of the principal regulations.

“(2) Malta may impose specific requirements on veterinary practitioners and other health-care professionals in respect of the reporting of suspected serious or unexpected adverse reactions and human adverse reactions.”.

Amends regulation 66 of the principal regulations.

44. Regulation 66 of the principal regulations shall be amended as follows:

(a) for the words from “In order to ensure” to the words “such information scientifically.” there shall be substituted the following:

“In order to ensure the adoption of appropriate and harmonised regulatory decisions concerning the veterinary medicinal products authorised within the European Community, having regard to information obtained about suspected adverse reactions to veterinary medicinal products under normal conditions of use, Malta shall administer a veterinary pharmacovigilance system. This system shall be used to collect information useful in the surveillance of veterinary medicinal products, with particular reference to adverse reactions in animals and in human beings relating to the use of veterinary medicinal products, and to evaluate such information scientifically.”; and

(b) immediately after the second paragraph ending with the words “medicinal products.” there shall be inserted the following new paragraph:

“Malta shall ensure that suitable information collected within this system is communicated to other Member States and the Agency. This information shall be recorded in the database referred to in point (k) of the second subparagraph of Article 57(1) of European Regulation (EC) No 726/2004 and shall be permanently accessible to all Member States and without delay to the public.”.

Adds new regulation 66A to the principal regulations.

45. Immediately after regulation 66 of the principal regulations there shall be added the following new regulation:

“Management of Funds.

66A. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the Veterinary Services in order to guarantee their independence.”.

46. For the words “The qualified person shall be responsible for the following -” in regulation 67 of the principal regulations, there shall be substituted the following: Amends regulation 67 of the principal regulations.

“That qualified person shall reside in the European Community and shall be responsible for the following:”.

47. For regulation 68 of the principal regulations there shall be substituted the following: Substitutes regulation 68 of the principal regulations.

“68. (1) The marketing authorisation holder shall maintain detailed records of all suspected adverse reactions occurring within the European Community or in a third country.

Save in exceptional circumstances, these reactions shall be communicated electronically in the form of a report in accordance with the guidelines referred to in regulation 70(1).

(2) The marketing authorisation holder shall 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, and no later than 15 days following receipt of the information.

The marketing authorisation holder shall also record all suspected serious adverse reactions and human adverse reactions related to the use of veterinary medicinal products of which he can reasonably be expected to have knowledge, and report them promptly to the Veterinary Services, and no later than 15 days following receipt of the information.

(3) The marketing authorisation holder shall ensure that all suspected serious unexpected adverse reactions, human adverse reactions and any suspected transmission via a veterinary medicinal product of any infectious agent occurring on the territory of a third country are reported promptly in accordance with the guidelines referred to in regulation 70(1), so that they are available to the Agency and the competent authorities of the Member States in which the veterinary medicinal product is authorised, and no later than 15 days following the receipt of the information.

(4) By way of derogation from subregulations (2) and (3), in the case of veterinary medicinal products which are covered by European Directive 87/22/EEC, have benefited from the authorisation procedures under Articles 31 and 32 of European

Union Council Directive 2004/28/EC or have been the subject of the procedures provided for in Articles 36, 37 and 38 of European Union Council Directive 2004/28/EC, the marketing authorisation holder shall additionally ensure that all suspected serious adverse reactions and human adverse reactions occurring in the Community are reported in such a way so as to be accessible to the reference Member State or a competent authority designated as reference Member State. The reference Member State shall assume responsibility for the analysis and follow-up of any such adverse reactions.

(5) Unless other requirements have been laid down as a condition for the granting of the marketing authorisation or subsequently as indicated in the guidelines referred to in regulation 70(1), reports of all adverse reactions shall be submitted to the Veterinary Services in the form of a periodic safety update report, immediately upon request or at least every six months after authorisation until the placing on the market. Periodic safety update reports shall also be submitted immediately upon request or at least every six months during the first two years following the initial placing on the market, and once a year for the following two years. Thereafter, the reports shall be submitted at three-yearly intervals, or immediately upon request.

The periodic safety update reports shall include a scientific evaluation of the risk-benefit balance of the veterinary medicinal product.

(6) Following the granting of a marketing authorisation, the holder of such authorisation may request the amendment of the periods referred to in subregulation (5) hereof in accordance with the procedure laid down by European Commission Regulation (EC) No 1084/2003.

(7) The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorized veterinary medicinal product without giving prior or simultaneous notification to the Veterinary Services.

In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading.

Malta shall take the necessary measures to ensure that a marketing authorisation holder who fails to discharge these

obligations is subject to effective, proportionate and dissuasive penalties.”.

48. For subregulation (2) of regulation 71 of the principal regulations there shall be substituted the following: Amends regulation 71 of the principal regulations.

“(2) If urgent action is necessary for protecting human or animal health, Malta may suspend the marketing authorisation of a veterinary medicinal product, provided that the Agency, the Commission and the other Member States are informed on the following working day at the latest.”.

49. Regulation 72 of the principal regulations shall be amended as follows: Amends regulation 72 of the principal regulations.

(a) For subregulation (1) thereof, there shall be substituted the following:

“(1) The Veterinary Services shall ensure, by means of repeated inspections and, if necessary, unannounced inspections, and where appropriate, by asking an Official Medicines Control Laboratory or a laboratory designated for that purpose to conduct tests on samples, that the legal requirements relating to veterinary medicinal products are complied with.

The Veterinary Services may also carry out unannounced inspections at the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and of the premises of the marketing authorisation holder whenever it considers that there are grounds for suspecting non-compliance with the provisions of regulation Article 51 of European Union Council Directive 2004/28/EC. Such inspections may also be carried out at the request of another Member State, the Commission or the Agency.

In order to verify whether the data submitted in order to obtain a conformity certificate comply with the monographs of the European Pharmacopoeia, the standardization body for nomenclatures and quality norms within the meaning of the Convention relating to the elaboration of a European Pharmacopoeia (European Directorate for the Quality of Medicines) may ask the Commission or the Agency to request such an inspection when the starting material concerned is the subject of a European Pharmacopoeia monograph.

The Veterinary Services may carry out inspections of starting material manufacturers at the manufacturer's own request.

Such inspections shall be carried out by authorized representatives of the Veterinary Services who shall be empowered to:

(a) inspect manufacturing or trading establishments and any laboratories entrusted by the holder of the manufacturing authorisation with the task of carrying out control tests pursuant to regulation 24;

(b) take samples including with a view to an independent analysis by an Official Medicines Control Laboratory or by a laboratory designated for that purpose by Malta;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in Malta placing restrictions on these powers with regard to the description of the manufacturing method;

(d) inspect the premises, records and documents of marketing authorisation holders or any firms performing the activities described in Title VII, and in particular regulations 67 and 68 thereof, on behalf of a marketing authorisation holder.”;

(b) subregulation (3) thereof shall be substituted by the following:

“(3) The authorised representatives of the Veterinary Services shall report after each of the inspections mentioned in subregulation (1) on whether the principles and guidelines on good manufacturing practice referred to in Article 51 of European Union Council Directive 2004/28/EC or, where appropriate, the requirements set out in Title VII, are being complied with. The inspected manufacturer or market authorization holder shall be informed of the content of such reports.”; and

(c) immediately at the end of subregulation (3) thereof, there shall be added the following new subregulations:

“(4) Without prejudice to any arrangements which may have been concluded between the European Community and a third country, Malta, the European Commission or the Agency may require a manufacturer established in a third country to undergo an inspection as referred to in subregulation (1).

(5) Within 90 days after an inspection as referred to in subregulation (1), a certificate of good manufacturing practice shall be issued to the manufacturer if the inspection established that the manufacturer in question is complying with the principles and guidelines on good manufacturing practice as provided for by Community law.

In the event of an inspection carried out at the request of the European Pharmacopoeia, a certificate of compliance with the monograph shall be issued, if appropriate.

(6) Malta shall enter the certificates of good manufacturing practice which they issue in a Community database managed by the Agency on behalf of the Community.

(7) If the outcome of the inspection as referred to in subregulation (1) is that the manufacturer does not comply with the principles and guidelines of good manufacturing practice as provided for by Community legislation, the information shall be entered in the Community database as referred to in subregulation (6).”.

50. Regulation 74 of the principal regulations shall be substituted as follows:

Substitutes regulation 74 of the principal regulations.

“74. (1) Where it considers it necessary for reasons of human or animal health, the Veterinary Services may require the marketing authorisation holder for an immunological veterinary medicinal product to submit samples of batches of the bulk product and, or veterinary medicinal product, for control by an Official Medicines Control Laboratory before the product is put into circulation.

(2) On request by the Veterinary Services, the marketing authorisation holder shall promptly supply the samples referred to in subregulation (1), together with the reports of the control referred to in regulation 73(2).

The Veterinary Services shall inform all the other Member States in which the veterinary medicinal product is authorised as well as the European Directorate for the Quality of Medicines of its intention to control batches or the batch in question.

(3) After studying the control reports referred to in regulation 73(2), the laboratory responsible for the control shall repeat, on the samples provided, all the tests carried out by the manufacturer on the finished product, in accordance with the relevant provisions shown in the dossier for marketing authorisation.

The list of tests to be repeated by the laboratory responsible for the control shall be restricted to justified tests, provided that all Member States concerned, and if appropriate the European Directorate for the Quality of Medicines, agree to this.

For immunological veterinary medicinal products authorized under European Regulation (EC) No 726/2004, the list of tests to be repeated by the control laboratory may be reduced only after agreement by the Agency.

(4) Malta shall recognise the results of the tests.

(5) Unless the European Commission is informed that a longer period is necessary to conduct the tests, the Veterinary Services shall ensure that this control is completed within 60 days of receipt of the samples.

The Veterinary Services shall notify the other Member States concerned, the European Directorate for the Quality of Medicines, the marketing authorisation holder and, if appropriate, the manufacturer, of the results of the tests within the same period of time.

If the Veterinary Services concludes that a batch of a veterinary medicinal product is not in conformity with the control report of the manufacturer or the specifications provided for in the marketing authorisation, it shall take all the necessary measures vis-a-vis the marketing authorisation holder and the manufacturer, where appropriate, and shall inform accordingly the other Member States in which the veterinary medicinal product is authorised.”;

Amends regulation 75 of the principal regulations.

51. Regulation 75 of the principal regulations shall be amended as follows:

(a) subregulation (1) shall be amended as follows:

(i) for the words from “(1) The Veterinary Services” to the words “is clear that-” there shall be substituted the words:

“The Veterinary Services shall suspend, revoke, withdraw or vary marketing authorisations when it is clear that:”;

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

“(a) the risk-benefit assessment of the veterinary medicinal product is, under the authorized conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to consumer safety, when the authorisation concerns a veterinary medicinal product for zootechnical use;”;

(iii) the words from “However, pending” to the words “or animal health;” in paragraph (e) shall be deleted;

(iv) for paragraph (f) there shall be substituted the following:

“(f) information given in the application documents pursuant to regulations 12 to 13D and 27 is incorrect;”;

(v) paragraph (h) shall be deleted; and

(vi) immediately at the end of paragraph (h), the following second paragraph shall be added:

“However, when a Community legislative framework is in the course of being adopted, the Veterinary Services may refuse authorisation for a veterinary medicinal product where such action is necessary for the protection of public health, consumer and animal health.”; and

(b) subregulation (2) shall be amended as follows:

(i) for the words from “(2) Authorisation” to the words “established that-” there shall be substituted the following words:

“Marketing authorisations may be suspended, revoked, withdrawn or varied when it is established that:”; and

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

“(a) the particulars supporting the application, as provided for in regulations 12 to 13D, have not been amended in accordance with regulations 27(1) and (5);”.

Amends regulation 76 of the principal regulations.

52. In regulation 76 of the principal regulations, for paragraph (a) of subregulation (1) there shall be substituted the following:

“(a) it is clear that the risk-benefit assessment of the veterinary medicinal product is, under the authorized conditions of use, unfavourable, particular regard being had to the benefits for animal health and welfare and to the safety and health benefits for the consumer, when the authorisation concerns a veterinary medicinal product for zootechnical use.”.

Amends regulation 77 of the principal regulations.

53. In regulation 77 of the principal regulations, immediately after subregulation (2) thereof, there shall be added the following new subregulation:

“(3) The Veterinary Services shall prohibit the advertising to the general public of veterinary medicinal products that:

(a) in accordance with regulation 60, are available on veterinary prescription only; or

(b) contain psychotropic drugs or narcotics, such as those covered by the United Nations Conventions of 1961 and 1971.”.

Substitutes regulation 81 of the principal regulations.

54. Regulation 81 of the principal regulations shall be substituted as follows:

“81. The Veterinary Services shall communicate the appropriate information to competent authorities in other Member States, particularly regarding compliance with the requirements adopted for the authorisations referred to in regulation 38, for the certificates referred to in regulation 72(5) or for authorization to place products on the market.

Upon reasoned request, the Veterinary Services shall forthwith communicate the reports referred to in regulation 72(3) to the competent authorities of another Member State.

The conclusions reached following an inspection as referred to in regulation 72(1) carried out by the inspectors of the Veterinary Services shall be valid for the European Community.

However, by way of exception, if Malta has not been able, for serious reasons of human or animal health, to accept the conclusions of an inspection as referred to in regulation 72(1), the Veterinary Services shall forthwith inform the Commission and the Agency.

When the European Commission is informed of such serious reasons, it may, after consulting the Veterinary Services, ask the inspector of the Veterinary Services to carry out a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.”.

55. In regulation 85 of the principal regulations, for the words from “Marketing authorizations” to the words “Government Gazette” there shall be substituted the following: Amends regulation 85 of the principal regulations.

“Decisions to grant or revoke a marketing authorization shall be made publicly available.”.

56. Regulation 86 of the principal regulations shall be substituted as follows: Substitutes regulation 86 of the principal regulations.

“86. The Veterinary Services shall not permit foodstuffs for human consumption to be taken from test animals unless an appropriate withdrawal period has been established. The withdrawal period shall either:

(a) be at least as laid down in regulation 11(2) including, where appropriate, a safety factor reflecting the nature of the substance being tested; or

(b) if maximum residue limits have been established by the Community in accordance with Regulation (EEC) No 2377/90, ensure that this maximum limit will not be exceeded in foodstuffs.”.

B 1886

Adds new
regulation 87 to the
principal
regulations.

57. Immediately after regulation 86 of the principal regulations there shall be added the following new regulation:

“Collection. 87. The Veterinary Services shall ensure that appropriate Systems collection systems are in place for veterinary medicinal products that are unused or expired.”.