A.L. 225 ta' l-2005

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

Regoli ta' l-2005 dwar Kondizzjonijiet li Jirregolaw il-Preparazzjoni, t-Tpoġġiegħ fis-Suq u l-Użu ta' Għalf Medikat

BIS-SAĦĦA tas-setgħa mogħtija bl-artikolu 26 ta' l-Att dwar is-Servizzi Veterinarji, il-Ministru ta' l-Affarijiet Rurali u l-Ambjent għamel dawn ir-regoli li ġejjin:-

Titolu u skop.

1. (1) It-titolu ta' dawn ir-regoli huwa Regoli ta' l-2005 dwar Kondizzjonijiet li Jirregolaw il-Preparazzjoni, t-Tpoġġiegħ fis-Suq u l-Użu ta' Għalf Medikat.

(2) Mingħajr preġudizzju għall-adozzjoni tal-lista mniżżla fl-Artikolu 3 punt 1, it-tieni sub-paragrafu tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE, dawn ir-regoli jniżżlu il-kondizzjonijiet barra dawk tas-saħħa ta' l-annimali, li jirregolaw il-preparazzjoni, t-tpoġġiegħ fis-suq u użu ta' għalf medikat fit-territorju ta' Malta.

(3) Dawn ir-regoli ma għandhomx jaffetwaw ir-regoli tal-Komunità ta' l-Unjoni Ewropea applikabbli għall-adittivi wżati fl-għalf, jew regoli nazzjonali adottati skond ir-regoli msemmija, u b'mod partikolari dawk applikabbli għall-adittivi msemmija fl-Artikolu 1 tat-tieni sub-paragrafu tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 90/167/KE.

(4) L-iskop ta' dawn ir-regoli hu l-implimentazzjoni tar-regoli mniżżla taħt id-Direttiva tal-Kunsill ta' l-Unjoni Ewropea tas-26 ta' Marzu, 1990 li tniżżel il-kondizzjonijiet li jirregolaw il-praparazzjoni, t-tpoġġiegħ fis-suq u l-użu ta' għalf medikat fil-Komunità ta' l-Unjoni Ewropea.

Tifsir.

2. (1) Għall-għan ta' dawn ir-regoli d-definizzjonijiet li jidhru fl-Artikolu 1 tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE tal-Parlament ta' l-Unjoni Ewropea u tal-Kunsill tas-6 ta' Novembru, 2001, fuq il-kodiċi tal-Komunità relatati għall-prodotti mediċinali veterinarji u Artikolu 2 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 79/373/KEE tat-2 ta' April, 1979, fuq il-ħruġ fis-suq ta' għalf kompost, kif l-aħħar

emendat bid-Direttiva 2000/16/KE tal-Parlament ta' l-Unjoni Ewropea u tal-Kunsill ta' l-10 ta' April, 2000, għandhom japplikaw kif neċessarjament.

(2) Għall-għan ta' dawn ir-regoli, id-definizzjonijiet li ġejjin għandhom japplikaw ukoll:

"il-Kummissjoni" tfisser il-Kummissjoni ta' l-Unjoni Ewropea;

"il-Komunità" tfisser il-Komunità Ewropea;

"pajjiż tat-tielet dinja" tfisser pajjiż illi mhux membru tal-Komunità Ewropea;

"Servizzi Veterinarji" tfisser l-awtorità kompetenti fit-territorju ta' Malta kif stabbilit taħt l-artikolu 2 ta' l-Att dwar is-Servizzi Veterinarji;

"Stat Membru" tfisser Stat li huwa membru fil-Komunità Ewropea;

"taħlita lesta medikata awtorizzata" tfisser kull taħlita lesta għall-manifattura ta' għalf medikat kif definit fl-Artikolu 1 punt 5 tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE li ġiet mogħtija awtorizazzjoni skond l-Artikoli 5, 6, 7, 8, 9, 10 u 11, ta' dik id-Direttiva;

"tqegħid fis-suq" tfisser l-azjenda fit-territorju tal-Komunità Ewropea għall-bejgħ jew rimi fi kwalunkwe għamla oħra jkun x'ikun lill-partijiet terzi, sew jekk għall-konsiderazzjoni sew jekk le, u l-bejgħ jew rimi attwali.

Għalf medikat li għandu jkun manifatturat minn taħlit lest medikat awtorizzat.

3. (1) Is-Servizzi Veterinarji għandha tippreskrivi illi, fir-rigward ta' komponent mediċinali, għalf medikat jista' jkun manifatturat minn taħlit lest medikat awtorizzat biss.

(2) B'deroga mill-ewwel subparagrafu, is-Servizzi Veterinarji tista', sakemm ikunu konformi mar-rekwiżiti ta' l-Artikolu 6 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2001/82/KE:

(a) bla ħsara għal kwalunkwe kondizzjonijiet speċifiċi mniżżla f'awtorizzazzjonijiet biex jitpoġġew taħlit lesti medikati awtorizzati fis-suq, tawtorizza l-prodotti ntermedjarji li huma preparati minn dawk it-taħlit lesti medikati awtorizzati skond l-Artikoli 6, 7, 8, 9, 10, u 11 tad-Direttiva ta' l-Unjoni Ewropea

2001/82/KE u minn wieħed jew aktar mill-għalf u li huma maħsuba għall-manifattura sussegwenti ta' għalf medikat lest għall-użu.

(b) Is-Servizzi Veterinarji għandha tieħu l-miżuri neċessarji biex tiżgura illi prodotti intermedjarji huma manifatturati minn stabbilimenti awtorizzati biss skond regola 4 u li huma soġġetti għal dikjarazzjoni għas-Servizzi Veterinarji, tawtorizza l-veterinarju li kien immanifattura taħt il-kondizzjonijiet mniżżla fl-Artikolu 4 (3) tad-Direttiva 81/851/KEE, u taħt ir-responsabbilita tiegħu u fuq preskrizzjoni, għalf medikat minn bosta taħlit medikat minn qabel awtorizzat, provvdut illi m'hemmx aġent terapewtiku awtorizzat speċifikament f'forma ta' taħlita lesta biex ikun trattat jew għall-ispeċi konċernata.

(ċ) Sad-data meta s-Servizzi Veterinarji għandha tkun konformi mar-regoli l-ġodda mniżżla fl-Artikolu 9 tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE, regoli nazzjonali li jirregolaw il-kondizzjonijiet mniżżla hawn fuq għandhom jibqgħu applikabbli, bir-rigward ikun magħmul għad-disposizzjonijiet ġenerali tat-Trattat.

(3) Prodotti awtorizzati skond is-sub-regola (1) għandhom ikunu soġġetti għar-regoli mniżżla fl-Artikoli 44 sa 63 tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE.

Kondizzjonijiet għall-manifattura ta' għalf medikat.

4. (1) Is-Servizzi Veterinarji għandha tieħu l-miżuri neċessarji biex tiżgura illi għalf medikat huwa manifatturat taħt il-kondizzjonijiet mniżżla hawn taħt biss:

(a) il-manifattur għandu jkollu postijiet li jkunu ġew approvati minn qabel mill-awtorità kompetenti nazzjonali, apparat tekniku u adattat u maħżen adekwat u faċilitajiet ta' ispezzjoni;

(b) l-impjant li jimmanifattura l-għalf medikat għandu jkun magħmul minn impjegati li t-tagħrif u kwalifikazzjonijiet tagħhom fit-teknoloġija tat-taħlit huwa adegwat;

(ċ) il-produttur għandu jkun responsabbli biex jiżgura illi:

(i) jkun użat għalf biss jew kombinazzjonijiet mill-għalf li huma konformi mad-disposizzjonijiet tal-Komunità Ewropea fuq l-għalf,

(ii) l-għalf użat jipproduċi taħlita omoġenja u stabbli bit-taħlita lesta medikata awtorizzata,

(iii) it-taħlita lesta medikata awtorizzata hija użata matul il-proċess ta' manifattura skond il-kondizzjonijiet mniżżla meta awtorizazzjoni għat-tqegħid fis-suq tkun ingħatat u, b'mod partikolari, illi:

(1) m'hemmx possibilita ta' interazzjoni mhux mixtieqa bejn prodotti mediċinali veterinarji, adittivi u għalf;

(2) l-għalf medikat jibqa' tajjeb għall-perjodu stipulat;

(3) l-għalf li għandu jintuża biex jipproduċi għalf medikat ma jikkontenix l-istess antibijotiku jew l-istess *coccidiostat* bħal dawk użati bħala sustanza attiva fit-taħlita lesta medikata;

(iv) id-doża ta' kuljum tal-prodott mediċinali hija miżmuma fi kwantità ta' għalf li tikkorrispondi għal ta' lanqas ir-razzjon ta' ikel ta' kuljum ta' l-annimali trattati jew, fil-każ ta' ruminanti, li tikkorrispondi għal ta' lanqas nofs il-ħtieġa ta' kuljum ta' għalf supplimentari mhux minerali;

(d) postijiet, impjegati u apparat użat u li jipparteċipaw fil-proċess kollu ta' manifattura għandhom ikunu konformi mar-regoli ta' iġene ta' manifattura u prinċipji ta' l-Istati Membri fil-kwistjoni; il-proċess ta' manifattura għandu jkun konformi mar-regoli ta' prattiċità tajba ta' manifattura;

(e) l-għalf medikat manifatturat għandu jgħaddi minn kontrolli regolari, inkluż it-testijiet fil-laboratorju approprjati ta' omoġenita mill-istabbilimenti ta' manifattura, taħt is-superviżjoni u kontroll perjodiku tad-dipartiment uffiċjali, biex jiżgura illi l-għalf medikat huwa skond il-ħtiġijiet ta' dawn ir-regoli, speċjalment fir-rispett ta' l-omoġenjita tagħhom, stabilità u ħażna;

(f) manifatturi għandhom ikunu obbligati jżommu reġistri ta' kuljum tat-tipi u kwantitajiet tat-taħlit lest medikat awtorizzat u għalf użat u ta' l-għalf medikat manifatturat, miżmum jew mibgħut, flimkien ma l-ismijiet u l-indirizzi ta' min irabbi jew min iżomm l-annimali, u fil-każ mniżżel f'regola 19(2), l-isem u l-indirizz tad-distributur awtorizzat u, fejn approprjat, l-isem u l-indirizz tal-veterinarju li jippreskrivi. Dawn ir-reġistri, li għandhom jilħqu r-rekwiżiti ta' l-Artikolu 12 u Artikolu 13 (1) tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE, għandhom jinżammu għal ta'

lanqas tlett snin wara d-data ta' l-aħħar entratura u għandhom ikunu disponibbli kull ħin lill-awtoritajiet kompetenti fil-każ ta' kontrolli;

(ġ) taħlit lest u għalf medikat għandu jkun maħżun fi kmamar adatti, separati u siguri jew f'kontenituri ermetiki li huma desinjati speċifikament għall-ħażna ta' dawn il-prodotti.

(2) Is-Servizzi Veterinarji tista', b'deroga minn paragrafu 1, u soġġett għall-garanziji addizzjonali approprjati, tawtorizza l-manifattura ta' għalf medikat fuq irziezet sakemm ikunu konformi ma' l-isetss paragrafu.

Tpoġġiegħ fis-suq ta' għalf medikat.

5. (1) Is-Servizzi Veterinarji għandha tippreskrivi illi għalf medikat jista' jitpoġġa fis-suq f'pakketti jew kontenituri ssiġillati b'tali mod illi, meta l-pakkett jinfetaħ, l-għeluq jew is-siġill jinkiser u ma jkunux jistgħu jerġgħu jintużaw.

(2) Fejn tankijiet tat-triq jew kontenituri simili huma wżati biex jitpoġġa għalf medikat fis-suq, dawn għandhom jitnaddfu qabel kull użu mill-ġdid sabiex tippreveni kull interazzjoni mhux mixtieqa sussegwenti jew kontaminazzjoni.

Tikketjar ta' għalf medikat.

6. (1) Is-Servizzi Veterinarji għandha tieħu l-miżuri neċessarji biex tiżgura illi l-għalf medikat ma jitpoġġiex fiċ-ċirkolazzjoni sakemm it-tikettar ma jkunx konformi mad-disposizzjonijiet fis-seħħ ta' l-Unjoni Ewropea. Barra minn dan, il-pakketti jew kontenituri msemmija f'regola 5(1) għandhom ikunu ċarament immarkati bil-marka "Għalf Medikat".

(2) Fejn it-tankijiet tat-triq jew kontenituri simili huma wżati biex jitqiegħed għalf medikat fis-suq, ikun suffiċenti li l-informazzjoni msemmija f'paragrafu 1 tkun miżmuma fid-dokumenti li jakkompanjawhom.

Rekwiżiti oħra.

7. (1) Is-Servizzi Veterinarji għandha tieħu l-miżuri kollha neċessarji biex tiżgura illi għalf medikat ma jinżammx, jitpoġġa fis-suq jew jiġi wżat sakemm ma kienx immanifatturat skond dawn ir-regoli.

(2) Suġġett għar-rekwiżiti ta' l-Artikolu 6 tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE fir-rigward tat-testijiet li għandhom isiru fuq il-prodotti mediċinali veterinarji, madankollu is-Servizzi Veterinarji tista għal skopijiet xjentifiċi, tipprovdi għall-derogi minn dawn ir-regoli, sakemm hemm kontroll uffiċjali adekwat.

Preskrizzjonijiet ta' għalf medikat.

8. (1) Is-Servizzi Veterinarji għandha tiżgura illi għalf medikat ma jkunx issuplixxit lill-irziezet li jistukkjaw jew lil min iżomm l-

annimali bl-eċċezzjoni fuq preżentazzjoni ta' preskrizzjoni tal-veterinarju reġistrat fuq it-termini li ġejjin:

(a) il-preskrizzjoni tal-veterinarju għandha ssir fuq forma murija fuq il-kampjun fi Skeda I; il-forma oriġinali għandha tkun għall-manifattur jew, fejn approprjat, distributur approvat mill-awtorità kompetenti ta' l-Istat Membru tad-destinazzjoni ta' l-għalf medikat;

(b) il-veterinarju għandu jimla Parti A tal-preskrizzjoni li ġejja u kopji tal-preskrizzjoni murija fi Skeda I:

(i) L-oriġinal tal-manifattur jew tad-distributur awtorizzati, li għandhom jinżammu mill-manifattur jew distributur awtorizzat għall-perjodu ta' mhux inqas minn tlett snin mid-data meta l-preskrizzjoni hija mimlija mill-veterinarju. Il-veterinarju għandu jħalli barra d-dettalji tal-marda għal liema t-trattament huwa preskritt f'Parti A ta' dan l-oriġinal. Il-manifattur jew distributur awtorizzat għandu jimla Parti B ta' dan l-oriġinal. Din il-preskrizzjoni għandha tinżamm disponibbli kull mument lis-Servizzi Veterinarji matul l-ispezzjonijiet uffiċjali;

(ii) Kopja tad-Divisjoni tar-Regolament ta' l-Ikel u l-Veterinarji għandha tintbagħat mill-manifattur jew distributur awtorizzat lis-Servizzi Veterinarji fi żmien ħamest ijiem mill-preżentazzjoni tal-preskrizzjoni. Il-veterinarju għandu jħalli barra d-dettalji tal-marda għal liema t-trattament huwa preskritt f'Parti A ta' din il-kopja. Il-manifattur jew distributur awtorizzat għandu jimla Parti B ta' din il-kopja;

(iii) Il-kopja tal-veterinarju li għandha tinżamm mill-veterinarju għall-perjodu ta' mhux anqas minn tlett snin mid-data meta l-preskrizzjoni tkun saret minnu. Il-marda li għandha tkun trattata għandha tkun indikata biss f'Parti A ta' din il-kopja. Il-kopja tal-preskrizzjoni għandha tinżamm disponibbli kull mument lis-Servizzi Veterinarji matul l-ispezzjonijiet uffiċjali.

(ċ) għalf medikat ma jistax jintuża għal aktar minn trattament wieħed taħt l-istess preskrizzjoni;

(d) il-preskrizzjoni veterinarja għandha tkun valida biss għal perjodu determinat mis-Servizzi Veterinarji li ma tistax tkun iktar minn tlett xhur mid-data meta ssir il-preskrizzjoni mill-veterinarju;

(e) il-preskrizzjoni tal-veterinarju tista' tintuża biss għall-annimali trattati minnu. Il-veterinarju għandu l-ewwel ikun sodisfatt illi:

(i) l-użu ta' din il-medikazzjoni hija ġustifikata għall-ispeċi konċernata fuq raġunijiet veterinarji;

(ii) amministrazzjoni tal-prodott mediċinali ma jkunx inkompatibbli ma trattament preċedenti jew użu u illi ma jkollux kontra-indikazzjoni jew interazzjoni bejn bosta taħlit lesti li huma wżati;

(f) il-veterinarju għandu:

(i) jippreskrivi l-għalf medikat f'dawk il-kwantitajiet biss kif, fil-limiti massimi mniżżla mill-awtorizzazzjoni nazzjonali għat-tpoġġiegħ fis-suq ta' taħlit medikat minn qabel, huma neċessarji għall-iskop tat-trattament;

(ii) jkun sodisfatt illi l-għalf medikat u l-għalf li jkun qiegħed jiġi wżat biex annimali trattati jiġu mitmugħa ma jkunx fih l-istess antibijotiku jew l-istess *coccidiostat* bħala sustanzi attivi.

(2) B'danakollu, fil-każ ta' prodotti mediċinali *anthelmintic (vermifuges)*, is-Servizzi Veterinarji tista', sakemm issir reviżjoni li għandha ssir taħt id-Direttiva ta' l-Unjoni Ewropea 2001/82/KE tar-riskji assoċjati ma' l-użu ta' dawn il-gruppi ta' sustanzi, tagħmel deroga għall-ħames snin wara l-addozzjoni ta' dawn ir-regoli mill-obbligazzjoni mniżżla f'sub-regola (1) sabiex ma jkun suplixxit għalf medikat miġjub minn taħlit lest medikat awtorizzat bl-eċċezzjoni fuq il-preżentazzjoni tal-preskrizzjoni veterinarja, provdut illi:

(a) it-taħlit lest medikat użat ma fihx sustanzi li huma fil-gruppi kemikali użati, fit-territorju ta' Malta, fuq preskrizzjoni medikali għall-mediċina tal-bnedmin,

(b) l-għalf medikat li jkun akkordat dik l-awtorizzazzjoni huma wżati fit-territorju tagħhom huma biss *prophylactically* u fid-dożi neċessarji għall-iskop fil-kwistjoni.

(3) Is-Servizzi Veterinarji għandha tinforma lill-Kummissjoni ta' l-Unjoni Ewropea u lill-Istati Membri fl-i*Standing Veterinary Committee* bl-applikazzjoni ta' din id-deroga, u tispeċifika partikolarment in-natura tal-prodotti mediċinali u l-ispeċi ta' l-annimali li tkopri.

(4) Fejn għalf medikat huwa amministrat lill-annimali li l-laħam, ġilda, offal jew prodotti tagħhom huma maħsuba għall-konsum tal-bniedem, ir-raħħal jew dak li jżomm l-annimali konċernati għandu jiżgura illi l-annimali trattati ma jkunux maqtula biex ikunu offruti għall-konsum qabel ma jispiċċa l-perjodu tat-tneħħija mhumiex mormija bl-iskop li jkunu offruti għall-konsum tal-bniedem.

Ħruġ ta' għalf medikat għall-bdiewa u min iżomm l-annimali.

9. (1) Is-Servizzi Veterinarji għandha tieħu l-miżuri kollha neċessarji biex tiżgura illi l-għalf medikat huwa mogħti dirett lir-raħħal jew lil min iżomm l-annimali biss mill-manifattur jew distributor approvati speċjali mill-awtorità kompetenti ta' l-Istat Membru tad-destinazzjoni.

(2) Barra minn hekk, għalf medikat għat-trattament ta' l-annimali li l-laħam, ġilda, offal jew prodotti tagħhom huma maħsuba għall-konsum tal-bniedem ma jistawx jinħarġu, sakemm:

(a) huma ma jeċċedux il-kwantitajiet preskritti għat-trattament, skond il-preskrizzjoni veterinarja fejn dan huwa provdut għalih,

(b) huma m'humiex maħruġa fi kwantitajiet ikbar mir-rekwiżiti ta' xhar wieħed kif stabbilit skond l-istipulazzjonijiet ta' l-ewwel inċiż.

(3) B'danakollu, minkejja sub-regola (1), is-Servizzi Veterinarji tista' f'każijiet speċjali tawtorizza distributuri speċifikament approvati għal dak l-iskop biex joħorġu, a bażi tal-preskrizzjoni veterinarja, għalf medikat fi kwantitajiet żgħar, pakkettati minn qabel u lesti għall-użu, u preparati, mingħajr preġudizzju għall-regola 8(2) skond ir-rekwiżiti ta' dawn ir-regoli, provdut illi dawn id-distributuri:

(a) iħarsu l-istess kondizzjonijiet bħall-manifattur fir-rigward li jżommu reġistri u l-ħażna, transport u l-ħruġ tal-prodotti konċernati,

(b) huma soġġetti għall-kontrolli speċjali għall-iskop, taħt is-superviżjoni ta' l-awtorità veterinarja kompetenti,

(ċ) jistgħu jissuplixxu biss għalf medikat li jkun pakketat jew pakkeġjat minn qabel lesti għall-użu minn min iżomm jew mill-bidwi li għandhom fuq il-pakketti jew kontenituri istruzzjonijiet għall-użu ta' l-istess għalf medikat u, b'mod partikolari, indikazzjoni tal-perjodu ta' tneħħija.

(4) Id-disposizzjonijiet ta' sub-regola (2) ma għandhomx jaffetwaw ir-regoli nazzjonali fuq il-proprjetarju legali ta' l-għalf medikali.

Kummerċ Intra-komunitarju ta' l-għalf medikat.

10. (1) Is-Servizzi Veterinarji għandha tiżgura li, mingħajr preġudizzju għar-regoli dwar is-saħħa ta' l-annimali, ma jkunx hemm projbizzjonijiet, limitazzjonijiet jew ostakoli fir-rispett ta' kummerċ intra-komunitarju:

(a) Fl-għalf medikat li kien immanifatturat skond ir-rekwiżiti ta' dawn ir-regolamenti, u b'mod partikolari regola 4, b'taħlit lest awtorizzat li għandhom l-istess sustanzi attivi bħal dawk ta' taħlit lest awtorizzat mill-Istat Membru tad-destinazzjoni, skond il-kriteja tad-Direttiva ta' l-Unjoni Ewropea 2001/82/KE, u komposizzjoni kwantitattiva u kwalittativa simili għalihom,

(b) soġġett għad-disposizzjonijiet speċifiċi tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 96/23/KE tad-29 ta' April, 1996 fuq miżuri ta' moniteraġġ ta' ċertu sustanzi u residwi tagħhom f'annimali ħajjin u prodotti ta' l-animali u li tħassar id-Direttivi 85/358/KEE u 86/469/KEE u Deċiżjonijiet 89/187/KEE u 91/664/KEE u Direttiva tal-Kunsill 96/22/KE tad-29 ta' April, 1996 li jikkonċernaw il-projbizzjoni ta' l-użu f'biedja bl-istokk ta' ċerti sustanzi li għandhom azzjoni ormonali jew tirostatika u ta' *ß-agonists,* u li tħassar Direttivi 81/602/KEE, 88/146/KEE kif imsemmi f'Artikolu 7(1) tad-Direttiva tal-Kunsill 96/22/KE, f'annimali li għalihom dawk l-għalf medikat bl-eċċezzjoni ta' dawk prodotti skond regola 3(2), kienu ġew amministrati, jew fil-laħam, ġilda, offal jew prodotti tagħhom minn dawk l-annimali.

(2) Fejn l-applikazzjoni f'sub-regola (1) tagħti lok għal kwistjoni, b'mod partikolari li jikkonċernaw ir-rikonoxximent in-natura simila tat-taħlita lesta, l-Istat Membru konċernat jew il-Kummissjoni tista' tpoġġi l-kwistjoni biex tkun assessjata minn espert li jidher fuq il-lista ta' l-esperti tal-Komunità Ewropea li għandha ssir mill-Kummissjoni fuq proponiment ta' l-Istati Membri. Jekk iż-żewġ Stati Membri hekk jiftehmu minn qabel, il-partijiet għandhom jintrabtu ma' l-opinjoni ta' l-espert, skond il-legislazzjoni tal-Komunità Ewropea.

(3) L-Istat Membru ta' destinazzjoni jista' jeħtieġ illi kull konsinja ta' għalf medikat tkun akkompanjatha b'ċertifikat maħruġ mill-awtorità kompetenti, li jikkorrispondi mal-kampjun fi Skeda II.

Miżuri ta' Salvagwardja.

11. (1) Il-miżuri ta' salvagwardja mniżżla mid-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 89/662/KEE għandhom japplikaw għall-kummerċ ta' taħlit medikat lest u awtorizzat jew għalf medikat.

(2) Ir-regoli mniżżla li jikkonċernaw il-kontroll veterinarju u, b'mod partikolari, il-ħtiġijiet mniżżla fl-Artikolu 5 (2) u Artikolu 20 tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 89/662/KEE għandhom japplikaw għall-kummerċ ta' taħlit medikat lest u awtorizzat jew għalf medikat sakemm huma soġġetti għall-kontroll veterinarju.

Kontroll b'iċċekkjar ta' kampjuni.

12. Is-Servizzi Veterinarji għandha tieħu dawk il-miżuri kollha neċessarji biex tiżgura konformita ma dawn ir-regoli:

(a) billi tagħmel kontrolli ta' kampjuni f'kull stadji ta' produzzjoni u *marketing* tal-prodotti msemmija f'dawn ir-regoli, biex tiżgura illi d-disposizzjonijiet ta' dawn ir-regoli ikunu mħarsa;

(b) partikolarment, billi tagħmel kontrolli tal-kampjuni fuq irziezet u biċċeriji, biex tiżgura illi għalf medikat huwa użat skond il-kondizzjonijiet ta' l-użu, u li l-perjofi ta' tneħħija ġew imħarsa.

Għalf medikat minn Pajjiżi Terzi.

13. Sakemm ikunu mplimentati l-miżuri tal-Komunità Ewropea relatati ma'l-importazzjoni ta' għalf medikat minn pajjiżi terzi, is-Servizzi Veterinarji għandha tapplika dawk il-miżuri ta' importazzjoni li huma ta' lanqas ekwivalenti ma dawk ta' dawn ir-regoli.

Skeda I

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT *Taqsima ta' l-Ikel u Attivita' Veterinarja*	MALTA	**No:** **MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT** *Food and Veterinary Regulation Division*

PARTI A: TRID TINTELA MILL-VETERINARJU LI QED JGĦAMEL IL-PRESKRIZZJONI			
Kunjom u isem tal-veterinarju			
Isem tad-dar jew klinika		**Triq**	
Raħal		**Kodiċi Postali**	
Isem tan-negozju u indirizz tal-produttur jew distributur awtoriżżat ta' l-għalf medikat			
Triq		**Raħal**	
Kodiċi Postali			
Isem tar-raħħal jew pussessur tal-annimali / nru tal-ġarra /timbru/ nru ta' l-stalla.			
Triq		**Raħal**	
Kodiċi Postali			

Numru u identifikazzjoni tal-annimal					
Numru	**Speċi**	**Timbru / Tag/ Tattoo / Microchip**	**Razza**	**Sess**	**Kategorija**
1.					
2.					
3.					

Mard li jrid jiġi ttratat [4]	
Designazzjoni tal*pre-mix* medikat awtorizzat	
Kwantita f'kilogrammi ta' feedingstuff medikat	
Istruzzjonijiet speċjali għar-raħħal jew il-pussesur ta' l-annimali	

Perċentaġġ tal-feedingstuff f'razzjon ta' kuljum	**Frekwenza tat-trattament**	**Dewmien tat-trattament f'ġranet**	**Perjodu ta' diastakk**		
			Bajd	**Laħam**	**Ħalib**
1.					
2.					
3.					

Data meta intliet il-preskrizzjoni			**Firma personal tal-Veterinarju**	**Numru ta' reġistrazzjoni**	**Timbru**
Jum	**Xhar**	**Sena**			

PARTI B: TRID TINTELA MILL-PRODUTTUR JEW MID-DISTRIBUTUR TA' L-GĦALF AWTORIŻŻAT	
Jum tal-kunsinna (jum-xhar-sena)	
Trid tiġi wżata (jum-xhar-sena)	

Jum meta il-preskrizzjoni ġiet ippreżentata			**Firma tal-produttur jew distributur awtoriżżat**	**Timbru tal-produttur jew distributur awtoriżżat**
Jum	**Xhar**	**Sena**		

[1] Trid tintela skond ir-regola 8 (1) (b).
[2] Din il-preskrizzjoni hi valida għal perjodu li ma jeċċedix tlett xhur u għanda tintlea darba biss.
[3] Din il-preskrizzjoni għanda tinżamm għal perjodu ta' mhux anqas min tlett snin mid-data min liema l-preskrizzjoni intliet mill-veterinarju .
[4] Il-mard li qed jiġi ittratat għandu jinkiteb biss fil-kopja tal-veterinarju.

Oriġinal tal-produttur jew distributur awtoriżżat

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PARTI A: TRID TINTELA MILL-VETERINARJU LI QED JGĦAMEL IL-PRESKRIZZJONI			
Kunjom u l-isem tal-veterinarju			
Isem tad-dar jew klinika		**Triq**	
Raħal		**Kodiċi Postali**	
Isem tan-negozju u indirizz tal-produttur jew distributur awtoriżżat ta' l-għalf medikat			
Triq		**Raħal**	
Kodiċi Postali			
Isem u indirizz tar-raħħal jew pussesur tal-annimali / nru tal ġarra/timbru / nru ta' l-istalla.			
Triq		**Raħal**	
Kodiċi Postali			

Identifikazzjoni u numru tal-annimali					
Numru	**Speċi**	**Timbru/ Misluta Tattoo / Microchip**	**Razza**	**Sess**	**Kategorija**
1.					
2.					
3.					

Mard ittrattat [3]	
Designjazzjoni ta' l-*pre-mix* awtorizzat	
Kwantita' ta' l-għalf medikat f'kilogrammi	
Istruzzjonijiet speċjali għar-raħħal jew pussesur tal-annimali	

Perċentaġġ ta' għalf medikat fir-razzjon ta' kuljum	Frekwenza tat-trattament	Dewmien tat-trattament fi ġranet	Perjodu ta' distakk fi ġranet		
			Bajd	**Laħam**	**Ħalib**
1.					
2.					
3.					

Jum meta l-preskrizzjoni ntliet			Firma personal ital-veterinarju	Numru ta' Reġistrazzjoni	Timbru
Jum	**Xhar**	**Sena**			

PARTI B: TRID TIĠI TINTELA MILL-PRODUTTUR JEW MID-DISTRIBUTUR TA' L-GĦALF AWTORIŻŻAT	
Jum tal-kunsinna (jum-xhar-sena)	
Trid tiġi wżata (jum-xhar-sena)	

Jum meta il-preskrizzjoni ġiet ippreżentata			Firma tal-produttur jew distributur awtoriżżat	Timbru tal-produttur jew distributur awtoriżżat
Jum	**Xhar**	**Sena**		

[1] **Trid tintela skond ir-regola 8 (1) (b).**
[2] **Din il-preskrizzjoni għanda tintbgħat mill-produttur jew distributur awtoriżżat lit Taqsima ta' l-Ikel u Attivita' Veterinarja fi żmien ħamest ijiem mid-data meta tiġi ppreżentata din il-preskrizzjoni**
[3] **Il-mard li qed jiġi ittratat għandu jinkiteb biss fil-kopja tal-veterinarju.**

Kopja tat-Taqsima ta' l-Ikel u Attivita' Veterinarja

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PARTI A: TRID TINTELA MILL-VETERINARJU LI QED JGĦAMEL IL-PRESKRIZZJONI			
Kunjom u l-isem tal-veterinarju			
Isem tad-dar jew klinika		**Triq**	
Raħal		**Kodiċi Postali**	
Isem tan-negozju u indirizz tal-produttur jew distributur awtoriżżat ta' l-għalf medikat			
Triq		**Raħal**	
Kodiċi Postali			
Isem u indirizz tar-raħħal jew pussesur tal-annimali / churn no. /timbru / nru ta' l-istalla.			
Triq		**Raħal**	
Kodiċi Postali			

Identifikazzjoni u numru tal-annimali					
Numru	**Speċi**	**Timbru/ Tag/ Tattoo / Microchip**	**Razza**	**Sess**	**Kategorija**
1.					
2.					
3.					

Mardli jrid jiġi ttrattat [3]	
Designjazzjoni tal-pre-mix awtorizzat	
Kwantita' ta' l-għalf medikat f'kilogrammi	
Istruzzjonijiet speċjali għar-raħħal jew pussesur tal-annimali	

Perċentaġġ ta' għalf medikat fir-razzjon ta' kuljum	**Frekwenza tat-trattament**	**Dewmien tat-trattament fi ġranet**	**Perjodu ta' distakk fi ġranet**		
			Bajd	**Laħam**	**Ħalib**
1.					
2.					
3.					

Jum meta l-preskrizzjoni ntliet			**Firma personal ital-veterinarju**	**Numru ta' Reġistrazzjoni**	**Timbru**
Jum	**Xhar**	**Sena**			

PARTI B: TRID TIĠI TINTELA MILL-PRODUTTUR TA' L-GĦALF JEW MID-DISTRIBUTUR AWTORIŻŻAT	
Jum tal-kunsinna (jum-xhar-sena)	
Trid tiġi wżata (jum-xhar-sena)	

Jum meta il-preskrizzjoni ġiet ippreżentata			**Firma tal-produttur jew distributur awtoriżżat**	**Timbru tal-produttur jew distributur awtoriżżat**
Jum	**Xhar**	**Sena**		

[1] Trid tintela skond ir-regola 8 (1) (b).
[2]) Din il-preskrizzjoni għanda tinżamm għal perjodu ta' mhux anqas min tlett snin mid-data min liema l-preskrizzjoni intliet mill-veterinarju .
[3] Il-mard li qed jiġi ittratat għandu jinkiteb biss fil-kopja tal-veterinarju.

Kopja tal-Veterinarju

Skeda II

ĊERTIFIKAT T' AKKOMPANJAZZJONI FIR-RISPETT TA'
GĦALF MEDIKAT GĦALL-ANNIMALI MAĦSUBA GĦALL-KUMMERĊ

Isem u indirizz tal-manifattur jew distributur approvat: …….....
…….
…….
…….
Isem ta' l-għalf medikat: …….....
…….
Tip ta' animal għal liema l-għalf medikat hu maħsub: ……..
Isem u kompożizzjoni tat-taħlita lesta medikata awtorizzata: …….....
…….
Doża tat-taħlita lesta medikata awtorizzata fl-għalf medikat: …….....
…….
Kwantità ta' għalf medikat: …….....
Isem u indirizz tar-reċipjent: ……..
…….
…….

Huwa hawn hekk ċertifikat illi l-għalf medikat kif deskritt hawn fuq ġie manifatturat minn persuna awtorizzata skond id-Direttiva 90/167/KEE.

Magħmul ……., fil-……

(post) (data)

Timbru ta' l-awtorità veterinarja
jew awtorità kompetenti oħra

(Firma)

(isem u posizzjoni)

L.N. 225 of 2005

VETERINARY SERVICES ACT, 2001
(ACT NO. XXIII OF 2001)

Conditions governing the preparation, placing on the market and use of medicated feedingstuffs Rules, 2005

IN exercise of the powers conferred by article 26 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope.

1. (1) The title of these rules is Conditions governing the preparation, placing on the market and use of medicated feedingstuffs Rules, 2005.

(2) These rules lay down, without prejudice to the adoption of the list laid down in Article 3 point 1, second sub-paragraph to European Union Directive 2001/82/EC, the conditions other than those of animal health, governing the preparation, placing on the market and use of medicated feedingstuffs within the territory of Malta.

(3) These rules shall not affect European Community rules applicable to additives used in feedingstuffs, or national rules adopted pursuant to the said rules, and in particular those applicable to the additives referred to in Article 1 second sub-paragraph to European Union Council Directive 90/167/EC

(4) The scope of these rules is to implement the rules found under the European Union Council Directive of the 26th March, 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community

Definitions.

2. (1) For the purposes of these rules the definitions appearing in Article 1 of European Union Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products and Article 2 of Council Directive 79/373/EEC of 2 April 1979 on the marketing of compound feedingstuffs, as last amended by Directive 2000/16/EC of the European Parliament and the Council of 10 April 2000 shall apply as necessary.

(2) For the purposes of these rules, the following definitions shall also apply:

"authorized medicated pre-mix" means any pre-mix for the manufacture of medicated feedingstuffs as defined in Article 1

point 5 of European Union Directive 2001/82/EC which has been granted an authorization in accordance with Articles 5,6,7,8,9,10,and 11, of that Directive;

"Member State" means a State which is a Member within the European Community;

"placing on the market" means the holding in the territory of the Community for sale or disposal in any other form whatever to third parties, whether or not for consideration, and actual sale or disposal;

"the Commission" means the European Union Commission;

"the Community" means the European Community;

"Third Country" means a State which is not a Member within the European Community;

"Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

Medicated feedingstuffs to be manufactured from authorised medicated pre-mixes.

3. (1) The Veterinary Services shall prescribe that, as regards the medicinal component, medicated feedingstuffs may be manufactured from authorized medicated pre-mixes only.

(2) By way of derogation from the first subparagraph, the Veterinary Services may, provided they comply with the requirements of Article 6 of European Union Directive 2001/82/EC:

(a) subject to any specific conditions laid down in authorizations to place authorized medicated pre-mixes on the market, authorize intermediate products which are prepared from such medicated pre-mixes authorized in accordance with Article 6, 7, 8, 9,10, and 11 of Directive European Union Directive 2001/82/EC and from one or more feedingstuffs and which are intended for the subsequent manufacture of medicated feedingstuffs ready for use.

(b) The Veterinary Services shall take all necessary steps to ensure that intermediate products are manufactured only by establishments authorized in accordance with rule 4 and that they are the subject of a declaration to the Veterinary Services, authorize the veterinarian to have manufactured under the conditions laid down in Article 4 (3) of Directive 81/851/EEC, and under his

responsibility and on prescription, medicated feedingstuffs from several authorized medicated pre-mixes, provided that there is no specific authorized therapeutic agent in pre-mix form for the disease to be treated or for the species concerned.

(c) Until the date on which the Veterinary Services has to comply with the new rules laid down in Article 9 of European Union Directive 2001/82/EC, national rules governing the above conditions shall remain applicable, with due regard for the general provisions of the Treaty.

(3) Products authorized pursuant to sub-rule (1) shall be subject to the rules laid down in Articles 44 to 63 of European Union Directive 2001/82/EC.

Conditions for the manufacture of medicated feedingstuffs.

4. (1) The Veterinary Services shall take all necessary measures to ensure that medicated feedingstuffs are manufactured only under the conditions set out below:

(a) the manufacturer shall have premises which have been previously approved by the competent national authority, technical equipment and suitable and adequate storage and inspection facilities;

(b) the medicated feedingstuffs manufacturing plant shall be manned by staff whose knowledge of and qualifications in mixing technology are adequate;

(c) the producer shall be responsible for ensuring that:

(i) only feedingstuffs or combinations thereof which comply with Community provisions on feedingstuffs are used,

(ii) the feedingstuff used produces a homogeneous and stable mix with the authorized medicated pre-mix,

(iii) the authorized medicated pre-mix is used during the manufacturing process in accordance with the conditions laid down when authorization for placing on the market was given and, in particular, that:

(1) there is no possibility of any undesirable interaction between veterinary medicinal products, additives and feedingstuffs;

(2) the medicated feedingstuff will keep for the stipulated period;

(3) the feedingstuff to be used for producing the medicated feedingstuff does not contain the same antibiotic or the same coccidiostat as those used as an active substance in the medicated pre-mix;

(iv) the daily dose of medicinal product is contained in a quantity of feedingstuff corresponding to at least half the daily feed ration of the animals treated or, in the case of ruminants, corresponding to at least half the daily requirement of nonmineral supplementary feedingstuffs;

(d) premises, staff and equipment used and participating in the entire manufacturing process must comply with the manufacturing hygiene rules and principles of the Member State in question; the manufacturing process must conform to the rules of good manufacturing practice;

(e) the medicated feedingstuffs manufactured shall undergo regular checks, including appropriate laboratory tests of homogeneity by the manufacturing establishments, under the supervision and periodic control of the official department, to ensure that the medicated feedingstuff complies with the requirements of these rules, especially in respect of its homogeneity, stability and storability;

(f) manufacturers shall be obliged to keep daily records of the types and quantities of the authorized medicated pre-mixes and feedingstuffs used and of the medicated feedingstuffs manufactured, held or dispatched, together with the names and addresses of the breeders or holders of the animals, and in the case provided for in rule 10 (2), the name and address of the authorized distributor and, where appropriate, the name and address of the prescribing veterinarian. The records, which must meet the requirements of Article 12 and Article 13 (1) of European Union Directive 2001/82/EC, must be kept for at least three years after the date of the last entry and must be made available at any time to the competent authorities in case of checking;

(g) pre-mixes and medicated feedingstuffs shall be stored in suitable separate and secured rooms or hermetic containers which are specially designed for the storage of such products.

(2) The Veterinary Services may, by way of derogation from paragraph 1, subject to any additional guarantees appropriate, authorize the manufacture of medicated feedingstuffs on farms provided that the said paragraph is complied with.

Placing on the market of medicated feedingstuffs.

5. (1) The Veterinary Services shall prescribe that medicated feedingstuffs may be placed on the market only in packages or containers sealed in such a way that, when the package is opened, the closure or seal is damaged and they cannot be re-used.

(2) Where road tankers or similar containers are used to place medicated feedingstuffs on the market, these must be cleaned before any re-use in order to prevent any subsequent undesirable interaction or contamination.

Labelling of medicated feedingstuffs.

6. (1) The Veterinary Services shall take all necessary measures to ensure that medicated feedingstuffs are not put into circulation unless the labelling complies with the European Community provisions in force. Furthermore, the packages or containers referred to in rule 5 (1) shall be clearly marked "Medicated Feedingstuffs".

(2) Where road tankers or similar containers are used to place medicated feedingstuffs on the market, it shall be sufficient for the information referred to in paragraph 1 to be contained in the accompanying documents.

Further requirements.

7. (1) The Veterinary Services shall take all necessary measures to ensure that a medicated feedingstuff cannot be held, placed on the market or used unless it has been manufactured in accordance with these rules.

(2) Subject to the requirements of Article 6 of European Union Directive 2001/82/EC with regard to the tests to be carried out on veterinary medicinal products, the Veterinary Services may, however, for scientific purposes, provide for derogations from these rules, provided there is adequate official control.

Medicated feedingstuff prescriptions.

8. (1) The Veterinary Services shall ensure that medicated feedingstuffs are not supplied to stockfarmers or holders of animals except on presentation of a prescription from a registered veterinarian on the following terms:

(a) the veterinarian's prescription shall be made out on a form shown on the specimen in Schedule I; the original form shall be for the manufacturer or, where appropriate, a distributor

approved by the competent authority of the Member State of destination of the medicated feedingstuffs;

(b) the veterinarian shall fill Part A of the following prescription and copies of prescription shown in Schedule I:

(i) Manufacturer's or authorised distributors original, which shall be retained by the manufacturer or authorised distributor for a period which is not less than three years from date when the prescription was filled by the veterinarian. The veterinarian shall omit the details of the disease for which the treatment is prescribed in Part A of this original. The manufacturer or authorised distributor shall fill Part B of this original. This prescription shall be made available at all times to the Veterinary Services during official inspections;

(ii) Food and Veterinary Regulation Division copy which shall be sent by the manufacturer or authorised distributor to the Veterinary Services within five days of the presentation of the prescription. The veterinarian shall omit the disease for which the treatment is prescribed in Part A of this copy. The manufacturer or authorised distributor shall fill Part B of this copy;

(iii) The veterinarian's copy which shall be retained by the veterinarian for a period of not less than three years from the date the prescription was made by him. The disease to be treated shall only be indicated in Part A of this copy. This prescription copy shall be made available at all times to the Veterinary Services during official inspections.

(c) medicated feedingstuffs may not be used for more than one treatment under the same prescription;

(d) the veterinary prescription shall be valid only for a period determined by the Veterinary Services which shall not exceed three months from the date on which the prescription is made by the veterinarian;

(e) the veterinarian's prescription may be used only for animals treated by him. The veterinarian must first satisfy himself that:

(i) the use of this medication is justified for the species concerned on veterinary grounds;

(ii) administration of the medicinal product is not incompatible with a previous treatment or use and that there is no contra-indication or interaction where several pre-mixes are used;

(f) the veterinarian must:

(i) prescribe the medicated feedingstuffs only in such quantities as, within the maximum limits laid down by the national authorization for placing medicated pre-mixes on the market, are necessary for the purpose of the treatment;

(ii) satisfy himself that the medicated feedingstuff and the feedingstuff currently used to feed treated animals do not contain the same antibiotic or the same coccidiostat as active substances.

(2) However, in the case of anthelmintic medicinal products (vermifuges), the Veterinary Services may, pending the review to be carried out under European Union Directive 2001/82/EC of the risks associated with the use of these groups of substances, derogate for five years after the adoption of these rules from the obligation laid down in sub-rule (1) not to supply medicated feedingstuffs obtained from authorized medicated pre-mixes except on presentation of a veterinary prescription, provided that:

(a) the medicated pre-mixes used do not contain active substances which belong to the chemical groups used, in the territory of Malta, on medical prescription for human medicine,

(b) the medicated feedingstuffs accorded such authorization are used in their territory only prophylactically and in the dosages necessary for the purpose in question.

(3) The Veterinary Services shall inform the European Union Commission and the other Member States within the Standing Veterinary Committee of the application of such a derogation, specifying in particular the nature of the medicinal products and animal species that it covers.

(4) Where medicated feedingstuffs are administered to animals whose meat, flesh, offal or products are intended for human consumption, the stockfarmer or holder of the animals concerned must ensure that treated animals are not slaughtered in order to be offered for consumption before the end of the withdrawal period and that products obtained from a treated animal before the end of such a withdrawal

period are not disposed of with a view to their being offered for human consumption.

Issuing of medicated feedingstuffs to stockfarmers or holder of the animals.

9. (1) The Veterinary Services shall take all necessary measures to ensure that medicated feedingstuffs are issued directly to the stockfarmer or holder of the animals only by the manufacturer or distributor specially approved by the competent authority of the Member State of destination.

(2) Furthermore, medicated feedingstuffs for the treatment of animals whose meat, flesh, offal or products are intended for human consumption may not be issued unless:

(a) they do not exceed the quantities prescribed for the treatment, in accordance with the veterinary prescription where this is provided for,

(b) they are not issued in quantities greater than one month's requirements as established in accordance with the stipulations of the first indent.

(3) However, notwithstanding sub-rule (1), the Veterinary Services may in special cases authorize distributors specifically approved for that purpose to issue, on the basis of a veterinary prescription, medicated feedingstuffs in small quantities, prepacked and ready for use, and prepared, without prejudice to rule 8 (2) in accordance with the requirements of these rules, provided that these distributors:

(a) comply with the same conditions as the manufacturer regarding the keeping of registers and the storage, transport and issue of the products concerned,

(b) are subject to special checking for the purpose, under the supervision of the competent veterinary authority,

(c) may supply only prepacked or prepackaged medicated feedingstuffs ready for use by the holder or stockfarmer that have on the packaging or containers instructions for the use of the said medicated feedingstuffs and, in particular, an indication of the withdrawal period.

(4) The provisions of sub-rule (2) shall not affect national rules on the legal ownership of the medicated feedingstuffs.

Intra-Community Trade of medicated feedingstuffs.

10. (1) The Veterinary Services shall ensure that, without prejudice to animal-health rules, there are no prohibitions, limitations or obstacles in respect of intra-Community trade:

(a) in medicated feedingstuffs which have been manufactured in accordance with the requirements of these regulations, and in particular rule 4 thereof, with authorized pre-mixes which have the same active substances as pre-mixes authorized by the Member State of destination, in accordance with the criteria of European Union Directive 2001/82/EC, and a quantitative and qualitative composition similar thereto,

(b) subject to the specific provisions of European Union Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC and Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of b-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC as referred to in Article 7 (1) of Council Directive 96/22/EC, in animals to which those medicated feedingstuffs except those produced pursuant to rule 3 (2), have been administered, or in meat, flesh, offal or their products from such animals.

(2) Where the application of sub-rule (1) gives rise to dispute, in particular as concerns recognition of the similar nature of the pre-mix, the Member States concerned or the Commission may submit the dispute to assessment by an expert appearing on a list of Community experts to be drawn up by the Commission on a proposal from the Member States. If the two Member States so agree beforehand, the parties shall abide by the opinion of the expert, in compliance with Community legislation.

(3) The Member State of destination may require that each consignment of a medicated feedingstuff be accompanied by a certificate issued by the competent authority, corresponding to the specimen form in Schedule II.

Safeguard Measures.

11. (1) The safeguard measures laid down by European Union Council Directive 89/662/EEC shall apply to trade in authorized medicated pre-mixes or medicated feedingstuffs.

(2) The rules laid down concerning veterinary control and, in particular, the requirements laid down in Article 5 (2) and Article 20

of European Union Council Directive 89/662/EEC shall apply to trade in authorized pre-mixes or medicated feedingstuffs to the extent that they are subject to veterinary control.

Control by sampling checks.

12. The Veterinary Services shall take all necessary measures to ensure compliance to these rules:

(a) by making sampling checks at all stages of the production and marketing of the products referred to by these rules, to ensure that the provisions of these rules are complied with;

(b) in particular, by making sampling checks on farms and slaughterhouses, to ensure that medicated feedingstuffs are used in compliance with the conditions of use, and that withdrawal periods have been complied with.

Medicated feedingstuffs from Third Countries.

13. Pending the implementation of Community measures relating to imports of medicated feedingstuffs from third countries, the Veterinary Services shall apply to those imports measures which are at least equivalent to those of these rules.

Schedule I

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Surname and forename of veterinarian			
Name of house or clinic		Street	
Village		Postal Code	
Name or business name and address of manufacturer or supplier of the medicated feedingstuff			
Street		Village	
Postal code			
Name and address of stockfarmer or holder of animals / churn no. /stamp / stable no.			
Street		Village	
Postal Code			

Identification and number of animals					
Number	Species	Stamp / Tag Tattoo / Microchip	Breed	Sex	Category
1.					
2.					
3.					

Disease to be treated [4]	
Designation of authorised medicated pre-mixes	
Quantity of medicated feedingstuff in kilograms	
Special instructions for the stockfarmer or holder of the animals	

Percentage of medicated feedingstuff in the daily ration	Frequency of treatment	Duration of treatment in days	Withdrawal time in days		
			Eggs	Meat	Milk
1.					
2.					
3.					

Date when prescription was filled			Personal signature of veterinarian	Registration Number	Stamp
Day	Month	Year			

PART B: TO BE COMPLETED BY THE MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	

Date when prescription was presented			Signature of manufacturer or supplier	Stamp of manufacturer or supplier
Day	Month	Year		

[1] To be filled in accordance with sub-rule 8 (1) (b).
[2] This prescription is valid for a period not exceeding 3 months and shall be used only once.
[3] This prescription shall be kept for a period of not less than three years from the date from which the prescription is filled by the veterinarian.
[4] Disease to be treated shall be entered only on Veterinarian's copy.

Manufacturer's or Authorised Distributor's Original

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Surname and forename of veterinarian			
Name of house or clinic		Street	
Village		Postal Code	
Name or business name and address of manufacturer and supplier of the medicated feedingstuff			
Street		Village	
Postal code			
Name and address of stockfarmer or holder of animals / churn no. /stamp / stable no.			
Street		Village	
Postal Code			

Identification and number of animals					
Number	Species	Stamp / Tag Tattoo / Microchip	Breed	Sex	Category
1.					
2.					
3.					

Disease to be treated (3)	
Designation of authorised medicated pre-mixes	
Quantity of medicated feedingstuff in kilograms	
Special instructions for the stockfarmer or holder of the animals	

Percentage of medicated feedingstuff in the daily ration	Frequency of treatment	Duration of treatment in days	Withdrawal time in days		
			Eggs	Meat	Milk
1.					
2.					
3.					

Date when prescription was filled			Personal signature of veterinarian	Registration Number	Stamp
Day	Month	Year			

PART B: TO BE COMPLETED BY THE MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	

Date when prescription was presented			Signature of manufacturer or supplier	Stamp of manufacturer or supplier
Day	Month	Year		

(1) To be filled in accordance with sub-rule 8 (1) (b).
(2) This prescription shall be sent by manufacturer or authorised distributor to the Food and Veterinary Regulation Division within 5 days of presentation of this prescription.
(3) Disease to be treated shall be entered only on Veterinarian's copy.

Food and Veterinary Regulation Division Copy

No:

MINISTERU GHALL-AFFARIJIET RURALI U L-AMBJENT

Taqsima ta' l-Ikel u Attivita' Veterinarja

MALTA

MINISTRY FOR RURAL AFFAIRS AND THE ENVIRONMENT

Food and Veterinary Regulation Division

PART A: TO BE COMPLETED BY THE PRESCRIBING VETERINARIAN			
Surname and forename of veterinarian			
Name of house or clinic		Street	
Village		Postal Code	
Name or business name and address of manufacturer or supplier of the medicated feedingstuff			
Street		Village	
Postal code			
Name and address of stockfarmer or holder of animals / churn no. / stamp / stable no.			
Street		Village	
Postal Code			

Identification and number of animals					
Number	Species	Stamp / Tag Tattoo / Microchip	Breed	Sex	Category
1.					
2.					
3.					

Disease to be treated [3]	
Designation of authorised medicated pre-mixes	
Quantity of medicated feedingstuff in kilograms	
Special instructions for the stockfarmer or holder of the animals	

Percentage of medicated feedingstuff in the daily ration	Frequency of treatment	Duration of treatment in days	Withdrawal time in days		
			Eggs	Meat	Milk
1.					
2.					
3.					

Date when prescription was filled			Personal signature of veterinarian	Registration Number	Stamp
Day	Month	Year			

PART B: TO BE COMPLETED BY THE MANUFACTURER OR AUTHORISED DISTRIBUTOR						
Date of delivery	Day		Month		Year	
To be used before	Day		Month		Year	

Date when prescription was presented			Signature of manufacturer or supplier	Stamp of manufacturer or supplier
Day	Month	Year		

[1] To be filled in accordance with sub-rule 8 (1) (b).
[2] This prescription shall be kept for a period of not less than three years from the date when the prescription is filled by the veterinarian.
[3] Disease to be treated shall be entered only on Veterinarian's copy.

Veterinarian's Copy

Schedule II

ACCOMPANYING CERTIFICATE IN RESPECT OF MEDICATED FEEDINGSTUFFS FOR ANIMALS INTENDED FOR TRADE

Name and address of the manufacturer or approved distributor: ……..
……
.....
.....

Name of the medicated feedingstuff: .....
.....

Type of animal for which the medicated feedingstuff is intended: .....

Name and composition of the authorised medicated pre-mix: .....
.....

Dosage of the medicated pre-mix authorised in the medicated feedingstuff: .....
.....

Quantity of medicated feedingstuff: .....

Name and address of the recipient: .....
.....
.....

It is hereby certified that the medicated feedingstuff as described above has been manufactured by an authorised person in accordance with Directive 90/167/EEC.

Done at ....., **on** .....
(place) ***(date)***

.....
(Signature)
(Name and position)

Stamp of the veterinary authority or other competent authority

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