A.L. 96 ta' l-2005

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

Regoli tal-2005 dwar Projbizzjoni ta' l-Użu ta' Sustanzi li Għandhom Azzjoni Ormonali jew Tirostatika u ta' Betaagnosti fit-Trobbija ta' l-Annimali

BIS-SAĦĦA tas-setgħa mogħtija bl-artikolu 13(a) ta' l-Att dwar is-Servizzi Veterinarji, il-Ministru għall-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-2004 dwar il-Projbizzjoni ta' l-Użu ta' Sustanzi li Għandhom Azzjoni Ormonali jew Tirostatika u ta' Betaagnosti fit-Trobbija ta' l-Annimali.

(2) L-iskop ta' dawn ir-regoli hu l-implimetazzjoni tar-regoli mniżżla taħt id-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 96/22/KEE dwar il-Projbizzjoni ta' l-Użu ta' Sustanzi li Għandhom Azzjoni Ormonali jew Tirostatika u ta' Betaagnosti fit-Trobbija ta' l-Annimali.

Tifsir.

2. Għall-finijiet ta' dawn ir-regoli, u kemm-il darba r-rabta tal-kliem ma tkunx teħtieġ mod ieħor –

"annimali ta' l-irziezet" tfisser annimali domestiċi ta' l-ispeċi bovina, porċina, ovina u kaprina, annimali domestiċi li għandhom difrejhom sodi (*solipeds*), tjur u fniek, kif ukoll annimali selvaġġi ta' dawk l-ispeċi u ruminanti selvaġġi li jkunu ġew imrobbija f'razzett;

"l-awtorità kompetenti" tfisser is-Servizzi Veterinarji kif provdut taħt artikolu 2 ta' l-Att dwar is-Servizzi Veterinarji;

"il-Komunità" tfisser il-Komunità Ewropea kif stabbilita mit-Trattat li jistabilixxi l-Komunità Ewropea;

"il-Kummissjoni" tfisser il-Kummissjoni Ewropea;

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

"trattament illegali" tfisser l-użu ta' sustanzi jew prodotti mhux awtorizzati jew l-użu ta' sustanzi jew prodotti awtorizzati minn kull liġi oħra għal raġunijet jew taħt kundizzjonijet differenti minn dawk stipulati f'kull liġi oħra;

"trattament terapewtiku" tfisser l-amministrazzjoni, stipulata fir-regola 4 ta' dawn ir-regoli, lil annimal ta' razzett individwali, ta' sustanza awtorizzata sabiex tikkura, wara eżami minn veterinarju, problema ta' fertilità inkluża t-terminazzjoni ta' ġestazzjoni mhux mixtieqa u, fil-każ ta' betaagonisti, sabiex tikkaġuna tokolosi f'baqar tqal u sabiex tikkura problemi respiratorji u sabiex jikkaġunaw tokolosi f'*equidae* mrobbija għal raġunijiet oħra barra minn dawk ta' produzzjoni tal-laħam;

"trattament zootekniku" tfisser l-amministrazzjoni:

(a) lill-annimal tar-razzett individwali ta' kull sustanza awtorizza kif stipulat fir-regola 6 ta' dawn ir-regoli għas-sinkronizzar taċ-ċiklu sesswali u l-preparazzjoni ta' donaturi u reċipjenti għall-implantazzjoni tal-embrijoni, wara eżami ta' l-annimal minn veterinarju jew, skond it-tieni paragrafu tar-regola 6, taħt ir-responsabbiltà tiegħu;

(b) fil-każ ta' annimali akwatici, lil grupp ta' annimali mrobbija għat-tnissil għall-inverżjoni tas-sess, fuq preskrizzjoni tal-veterinarju u taħt ir-responsabbilità tiegħu.

Projbizzjonijiet f'Malta.

3. F'Malta, dan li ġej ikun projbit -

(i) it-tqegħid fis-suq ta' *stilbenes*, derivattivi ta' l-*istilbene*, il-melħ u *esters* tagħhom u sustanzi tirostatiċi biex jiġu amministrati lill-annimali ta' kull speċi;

(ii) it-tqegħid fis-suq ta' betaagonisti biex jiġu amministrati lill-annimali, meta dak il-laħam u prodotti huma intiżi għall-konsum mill-bniedem, għal raġunijiet oħra barra minn dawk stipulati fis-sub-paragrafu (ii) tar-regola 5.

Projbizzjonijiet oħra f'Malta.

4. F'Malta, dawn li ġejjin għandhom jiġu wkoll projbiti -

(i) l-amministrazzjoni lill-annimali tar-razzett jew akwatiku, permezz ta' kull metodu, ta' sustanzi li għandhom azzjoni tirostatika, ostroġenika, androġenika jew ġestaġenika u ta' betaagonisti;

(ii) iż-żamma, minbarra taħt kontroll uffiċjali, ta' annimali msemmija f'paragrafu (i) fir-razzett, it-tqegħid fis-suq jew qatla għal konsum mill-bniedem ta' annimali tar-razzett jew annimali akwatici li jkollhom sustanzi msemmija f'paragrafu (i) jew fejn il-preżenza ta' sustanzi bħal dawn tkun ġiet stabbilita, sakemm ma tingħatax prova illi l-annimali in kwistjoni ġew ikkurati skond ir-regoli 5 jew 6;

(iii) it-tqegħid fis-suq għal konsum mill-bniedem ta' annimali akwatici li ġew amministrati b'sustanzi msemmija f'paragrafu (i) u ta' prodotti proċessati derivanti minn annimali bħal dawn;

(iv) it-tqegħid fis-suq ta' laħam ta' annimali msemmija f'paragrafu (b) ;

(v) l-ipproċessar ta' laħam imsemmi f'paragrafu (iv).

Eżenzjonijiet minn projbizzjonijiet.

5. Minkejja d-dispożizzjonijiet f'regoli 3 u 4, għandu jkun awtorizzat dan li ġej:

(i) l-amministrazzjoni lill-annimali tar-razzett, għal raġunijiet terapewtici, ta' *ßoestradiol* 17, *testosterone* u *progesterone* u derivattivi li jirrilaxxaw f'ħin qasir il-kompost prinċipali ma' l-idrolisi wara li jiġi assorbit fil-lok ta' applikazzjoni:

Iżda prodotti mediċinali veterinarji wżati għat-trattament terapewtiku għandhom jaqblu mar-rekwiżiti għat-tqegħid fis-suq stabbiliti fid-direttiva tal-Unjoni Ewropea 81/851/EEC u jiġu amministratti minn veterinarju biss, permezz ta' injezzjoni jew għat-trattament ta' malfunzjoni ta' l-ovarji permezz ta' spirali vaġinali, iżda mhux permezz ta' *implant*, lill-annimali tar-razzett li jkunu ġew identifikati b'mod ċar. Trattament ta' annimali identifikati għandu jiġi reġistrat mill-veterinarju responsabbli. Dan ta' l-aħħar għandu jniżżel għall-inqas dawn id-dettalji li ġejjin f'reġistru, li jista' jkun dak stabbilit fid-direttiva tal-Unjoni Ewropea 81/851/EEC –

(a) it-tip ta' trattament;

(b) it-tip ta' prodotti awtorizzati;

(ċ) id-data tat-trattament;

(d) l-identità ta' l-annimali kkurati.

Iżda wkoll ir-reġistru għandu jkun disponnibli għas-Servizzi Veterinarji meta dawn jitolbuh;

(ii) l-amministrazzjoni għal raġunijiet terapewtiċi ta' prodotti mediċinali veterinarji awtorizzati li għandu jkun fihom:

(a) *allyl trenbolone*, amministrat oralment, jew betaagonisti għal *equidae* u annimali domestiċi mansi, sakemm dawn huma wżati skond l-istruzzjonijiet pprovduti mill-manifattur;

(b) betaagonisti, fl-għamla ta' injezzjoni sabiex jikkaġunaw tokolosi fil-baqar tqal.

Sustanzi bħal dawn għandhom jiġu amministrati minn veterinarju jew, fil-każ tal-prodotti mediċinali veterinarji msemmija f'paragrafu (a) hawn qabel, taħt ir-responsabbiltà diretta tiegħu; trattament għandu jiġi reġistrat mill-veterinarju responsabbli, li għandu jniżżel għall-inqas id-dettalji msemmija f'paragrafu (i).

Il-bdiewa għandhom ikunu pprojbiti milli jżommu prodotti medeċinali veterinarji li jkollhom betaagonisti li jistgħu jiġu wżati għal raġunijiet ta' induzzjoni fit-trattament tat-tokolosi.

Madankollu, mingħajr preġudizzju għall-ewwel subparagrafu tal-punt (b) ta' dan il-paragrafu, it-trattament terapewtiku ta' annimali għall-produzzjoni, inkluż annimali għat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom, huwa projbit.

Ċertu trattamenti permessi.

6. (1) Minkejja regola 4(i) u mingħajr preġudizzju għar-regola 3, l-amministrazzjoni lill-annimali tar-razzett hija awtorizzata, għal raġunijiet ta' trattament zootekniku, ta' prodotti mediċinali veterinarji li għandhom azzjoni estroġenika, androġenika jew ġestaġenika li huma awtorizzata skond id-direttiva ta' l-Unjoni Ewropea 81/851/EEC u 81/852/EEC. Prodotti mediċinali veterinarji bħal dawn għandhom jiġu amministrati minn veterinarju lill-annimali identifikati b'mod ċar; it-trattament għandu jigi mniżżel mill-veterinarju responsabbli skond ir-regola 5 (i):

Iżda s-Servizzi Veterinarji jistgħu jippermettu s-sinkronizazzjoni taċ-ċiklu sesswali u preparazzjoni ta' donaturi u reċipjenti biex isir impjant ta' embrijuni li ma jkunux se jsiru mill-veterinarju direttament, iżda taħt ir-responsabbilita tiegħu.

(2) Fir-rigward ta' l-annimali fl-akwakultura, ħut li għadu żgħir jista' jiġi kkurat għall-ewwel tlett xhur għar-raġuni ta' inversjoni

ta' sess permezz ta' prodotti mediċinali veterinarji li għandhom azzjoni androġena u li huma awtorizzati skond id-direttiva tal-Unjoni Ewropea 81/851/EEC u 81/852/EEC.

(3) Fil-każijiet stipulati f'din ir-regola, il-veterinarju għandu jagħmel riċetta li ma tistax tiġi mġedda, u jispeċifika l-kura in kwistjoni u l-kwantita' tal-prodott neċessarju u għandu jniżżel il-prodotti preskritti:

Iżda trattament zootekniku ta' annimali tal-produzzjoni, inkluż matul il-perjodu ta' tħaxxin għall-annimali tat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom, huwa projbit.

Awtorizazzjoni ta' amministrazzjoni ta' prodotti ormonali u Betaagonisti.

7. (1) Prodotti ormonali u Betaagonisti li huma awtorizzati skond ir-regoli 5 u 6 sabiex jiġu amministrati lill-annimali f'razzett, għandhom ikunu skond il-ħtiġijiet stabbiliti fid-direttivi tal-Unjoni Ewropea 81/851/EEC u 81/852/EEC.

(2) Madankollu is-segwenti mhumiex awtorizzati skond is-subregola (1) -

(a) dawn il-prodotti ormonali:

(i) prodotti li jaġixxu ta' depositi;

(ii) prodotti b'*withdrawal period* ta' iktar minn 15-il ġurnata wara t-tmiem tat-trattament;

(iii) prodotti:

(1) li huma awtorizzati taħt regoli li jippreċedu xi liġi nazzjonali li tistabbilixxi proċeduri in konformita' ma' ftehim internazzjonali għall-awtorizazzjoni u s-superviżjoni ta' prodotti mediċinali għall-użu mill-bniedem u dak veterinarju,

(2) li l-kundizzjonijiet ta' użu tagħhom mhumiex magħrufa,

(3) jew fejn ma jeżistux reaġenti jew apparat għall-użu fit-tekniċi analitiċi sabiex tinstab il-preżenza ta' residwi li jeċċedu l-limiti permessi,

(b) prodotti mediċinali veterinarji li fihom betaagonisti li għandhom *withdrawal period* ta' iktar minn 28 ġurnata wara t-tmiem tat-trattament.

Kummerċ, tnissil u marki ta' saħħa relattivi.

8. (1) Għall-fini ta' kummerċ, huwa permess, it-tqegħid fis-suq ta' annimali għat-tnissil u annimali għat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom illi, matul dak il-perjodu ta' l-aħħar, ikunu ħadu trattament msemmi fir-regoli 5 u 6 biex jista' jiġi awtorizzat l-affissjoni ta' marki ta' saħħa ta' Skeda I, Kapitolu XI, (50) tad-direttivi ta' l-Unjoni Ewropea 64/433/EEC fuq laħam minn annimali bħal dawn fejn il-kundizzjonijiet stipulati fir-regoli 5 u 6 u l-*withdrawal periods* minimi stipulati f'regola 7(2), taħt l-paragrafu (a) (ii) jew (b) rispettivament jew il-*withdrawal periods* stipulati fl-awtorizazzjoni għat-tqegħid fis-suq, jiġu mħarsa:

Iżda l-kummerċ fi żwiemel ta' valur għoli, u b'mod partikolari żwiemel tal-ġiri, żwiemel tal-kompetizzjonijiet, żwiemel taċ-ċirku u żwiemel intenzjonati għat-tnissil jew għall-esibizzjonijiet, inklużi *equidae* reġistrati li ġew amministrati bi prodotti mediċinali veterinarji li fihom *allyl trenbolone* jew betaagonisti għar-raġunijiet imsemmija f'regola 5, jista' jsir qabel it-tmiem tal-*withdrawal period*, sakemm il-kundizzjonijiet marbuta ma' l-amministrazzjoni jkunu mħarsa u t-tip u d-data tal-kura huma mniżżla fiċ-ċertifikat jew fil-passaport li jakkumpanja dawn l-annimali.

(2) Laħam jew prodotti minn annimali li ġew amministrati b'sustanzi li għandhom azzjoni estroġenika, androġenika jew ġestaġenika jew betaagonisti skond il-provvedimenti ta' dispensa ta' dawn ir-regoli ma jistgħux jitqegħdu fis-suq għall-konsum mill-bniedem, ħlief meta l-annimali in kwistjoni ġew ikkurati minn prodotti mediċinali veterinarji li jħarsu l-ħtiġijiet f'regola 7 u sakemm il-*withdrawal period* stipulat ikun ġie osservat qabel ma l-annimali jkunu ġew maqtula.

Pusses u użu ta' sustanzi minn persuni awtorizzati.

9. F'Malta -

(i) fil-perjodu ta' l-importazzjoni, manifattura, ħażna, distribuzzjoni, bejgħ u użu tas-sustanzi msemmija f'regoli 3 u 4 (i), il-pussess tagħhom huwa ristrett għall-persuni awtorizzati minn kull liġi oħra skond l-Artiklu 1 (5) tad-direttiva tal-Unjoni Ewropea 81/851/EEC;

(ii) flimkien mal-kontrolli stipulati fl-Ordnijiet li jirregolaw it-tqegħid fis-suq tad-diversi prodotti in kwistjoni, il-kontrolli uffiċjali stipulati fl-Artiklu 11 tad-direttiva ta' l-Unjoni Ewropea 96/23/EEC isiru mill-awtoritajiet kompetenti nazzjonali mingħajr preavviz, bil-ħsieb li jiġi zgurat:

(a) il-pusses jew preżenza ta' sustanzi jew prodotti projbiti taħt ir-regola 3, intiżi biex jiġu amministrati lill-annimali sabiex jitħaxxnu;

(b) it-trattament illegali ta' l-annimali;

(c) in-nuqqas ta' osservazzjoni tal-*withdrawal periods* stipulati f'regola 7;

(d) in-nuqqas ta' osservazzjoni tar-restrizzjonijiet fuq l-użu ta' ċertu sustanzi jew prodotti stipulati f'regoli 5 u 6;

(iii) l-eżamijiet għall-preżenza ta' -

(a) sustanzi msemmija f'punt (i) fl-annimali, fl-ilma tax-xorb ta' l-annimali u fil-postijiet kollha fejn jitrabbew jew jinżammu l-annimali;

(b) residwi tas-sustanzi msemmija hawn qabel f'annimali ħajjin, fil-ħmieġ u fil-fluwidi tagħhom u fit-tessuti u fil-prodotti ta' l-annimali isiru skond l-Iskedi III u IV tad-direttiva 96/23/EEC;

(iv) fejn il-kontrolli stipulati f'punti (ii) u (iii) juru:

(a) il-preżenza ta' sustanzi jew prodotti li l-użu jew pussess tagħhom huwa projbit, jew il-preżenza ta' residwi ta' sustanzi li l-amministrazzjoni tagħhom taqa' taħt il-kap ta' trattament illegali, dawn is-sustanzi jew prodotti huma konfiskati, filwaqt illi kull annimal ikkurat jew il-laħam tagħhom jitqiegħed taħt superviżjoni uffiċjali sakemm jiġu applikati l-penali neċessarji;

(b) nuqqas ta' ħarsien mar-rekwiżiti ta paragrafi (ii) (b) u

(c) is-Servizzi Veterinarji għandhom jieħdu l-miżuri adatti konsistenti mal-gravita' tal-ksur ta' liġi.

Żamma ta' reġistri ta' sustanzi.

10. (1) Mingħajr preġudizzju għad-direttiva 81/851/KEE, persuni fi sħab li jixtru jew jipproduċu sustanzi li għandhom azzjoni tirostatika, estroġenika, androġenika jew ġestaġenika u betaagonisti, persuni bi sħab awtorizzati fi kwalunkwe kapaċità li jqegħdu fis-suq sustanzi bħal dawk u persuni fi sħab li jixtru jew jipproduċu prodotti mediċinali veterinarji u farmaċewtiċi minn sustanzi bħal dawn, għandhom iżommu reġistri li jkollhom dettalji, f'ordni kronoloġiku, tal-kwantitajiet prodotti jew akwistati u dawk mibjugħin jew użati għall-produzzjoni ta' prodotti mediċinali veterinarji u farmaċewtiċi u l-ismijiet tal-persuni li lilhom ikunu ġew mibjugħa dawn il-kwantitajiet jew mingħand min inxtraw.

(2) L-informazzjoni f'sub-regola (1) hawn fuq għandha tkun disponnibli għall-awtorita' kompetenti meta din titlobhom u, fil-każ ta' informazzjoni li tinżamm f'kompjuter, fil-forma ta' karta stampata.

Nuqqas ta' ħarsien tar-rekwiziti ta' dawn ir-regoli.

11. Meta r-riżultati ta' kontrolli li saru f'Malta juru nuqqas ta' ħarsien tar-rekwiżiti ta' dawn ir-regoli fil-pajjiż ta' oriġini ta' l-annimali jew prodotti, l-awtorita' kompetenti għandha tirrikorri għall-provvedimenti meħuda skond il-proċedura stipulata f'Artiklu RE1 ta' l-Att dwar is-Servizzi Veterinarji dwar l-assistenza reċiproka bejn awtoritajiet amministrattivi ta' Malta u ta' l-Istati Membri sabiex tiġi żgurata l-applikazzjoni korretta tal-leġislazzjoni f'materji veterinarji u zooteknici.

Limitazzjoni ta' importazzjoni.

12. (1) Pajjiżi terzi li għandhom leġislazzjoni li tawtorizza it-tpoġġija fis-suq u l-amministrazzjoni ta' *stilbenes*, derivattivi ta' *stilbene*, il-melħ u *esters* tagħhom, jew ta' sustanzi tirostatiċi biex jiġu amministrati lill-annimali ta' kull speċje jista' ma jidher fuq l-ebda waħda mil-listi ta' pajjiżi stabbiliti bil-leġislazzjoni veterinarja li minnhom Malta tawtorizza l-importazzjoni ta' annimali tar-razzett jew ta' l-akwakultura jew laħam jew prodotti ġejjin minn dawn l-annimali.

(2) Hija projbita l-importazzjoni ġewwa Malta minn terzi pajjiżi fuq xi lista minn dawk imsemmija f'sub-regola (1):

(a) fil-każ ta' annimali tar-razzett jew ta' l-akwakultura

(i) li jkunu ġew lilhom amministrati b'kull mezz prodotti jew sustanzi msemmija f'punt (i) ta' regola 3;

(ii) li jkunu ġew lilhom amministrati sustanzi jew prodotti msemmija f'punt (i) tar-regola 4, ħlief jekk dawk is-sustanzi jew prodotti ġew amministrati konformement mad-dispożizzjonijiet u mar-rekwiżiti stipulati f'regoli 5, 6 u 8 u l-*withdrawal periods* aċċettati skond rakkomandazzjonijiet internazzjonali jkunu ġew imħarsa;

(b) laħam jew prodotti li ġejjin minn annimali li l-importazzjoni tagħhom hija projbita taħt il-paragrafu (a).

(3) Madankollu, annimali intiżi għat-tnissil, annimali tat-tnissil fl-aħħar tal-ħajja riproduttiva tagħhom, jew laħam tagħhom, minn pajjiżi terzi jistgħu jiġu impurtati jekk dawn jagħtu garanzija mill-inqas ekwikalenti għal dawk stipulati f'dawn ir-regoli jew li jew li jkunu ġew stabbiliti għall-implimentazzjoni u l-inforzar tal-Kapitolu V tad-direttiva ta' l-Unjoni Ewropea 96/23/KEE fuq miżuri li għandhom jittieħdu fil-każ ta' ksur ta' liġi.

(4) Kontrolli fuq importazzjoni minn terzi pajjizi ghandhom isiru skond l-Artiklu 17 (2) and (3) ta' l-Att dwar is-Servizzi Veterinarji.

L.N. 96 of 2005

VETERINARY SERVICES ACT, 2001
(CAP. 437)

Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2005

IN exercise of the powers conferred under article 13(a) of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and scope and applicability.

1. (1) The title of these rules is Prohibition on the Use in Stock-Farming of Substances having a Hormonal or Thyrostatic Action and of Betaagonists Rules, 2005.

(2) The scope of these regulations is to implement the rules found under European Union Council Directive 96/22/EEC on the Prohibition on the Use in Stock-Farming of Certain Substances having a Hormonal or Thyrostatic Action and of Betaagonists.

Definitions.

2. For the purpose of these rules, and unless the context otherwise requires –

"the Commission" means the European Commission;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"Competent authority" means the Veterinary Services within the territory of Malta as provided under article 2 of the Veterinary Services Act;

"farm animals" shall mean domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding;

"illegal treatment" shall mean the use of unauthorised substances or products or the use of substances or products authorised under national legislation for purposes or under conditions other than those laid down in national legislation;

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

"therapeutic treatment" shall mean the administering under rule 4 of these rules to an individual farm animal of an authorised substance to treat, after examination by a veterinarian, a fertility problem including the termination of unwanted gestation and, in the case of betaagonists, to induce tocolysis in cows when calving and to treat respiratory problems and to induce tocolysis in equidae raised for purposes other than meat production;

"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.

"zootechnical treatment" shall mean the administering:

(a) to an individual farm animal of any substance authorised under rule 6 of these rules for synchronising oestrus and preparing donors and recipients for the implantation of embryos, after examination of the animal by a veterinarian or, in accordance with the second paragraph of rule 6, under his responsibility;

(b) in the case of aquaculture animals, to a group of breeding animals for sex inversion, on a veterinarian's prescription and under his responsibility.

Prohibitions within Malta.

3. In the territory of Malta, the following shall be prohibited -

(i) the placing on the market of stilbenes, stilbene derivatives, their salts and esters and thyrostatic substances for administering to animals of all species;

(ii) the placing on the market of betaagonists for administering to animals the flesh and products of which are intended for human consumption for purposes other than those provided for in sub-paragraph (ii) of rule 5.

Further prohibitions within Malta.

4. In Malta, the following shall also be prohibited -

(i) the administering to a farm or aquaculture animal, by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of betaagonists;

(ii) the holding, except under official control, of animals referred to in paragraph (i) on a farm, the placing on the market or slaughter for human consumption of farm animals or of aquaculture animals which contain the substances referred to in paragraph (i) or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with rules 5 or 6;

(iii) the placing on the market for human consumption of aquaculture animals to which substances referred to in paragraph (i) have been administered and of processed products derived from such animals;

(iv) the placing on the market of meat of the animals referred to in paragraph (ii) ;

(v) the processing of the meat referred to in paragraph (iv).

5. Notwithstanding rules 3 and 4, in Malta, the following is authorised: Exemptions to prohibitions.

(i) the administering to farm animals, for therapeutic purposes, of floestradiol 17, testosterone and progesterone and derivatives which readily yield the parent compound on hydrolysis after absorption at the site of application.

Veterinary medicinal products used for therapeutic treatment must comply with the requirements for placing on the market laid down in Order (81/851) and be administered only by a veterinarian, by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals, but not by implant, to farm animals which have been clearly identified. Treatment of identified animals must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be the one provided for in Directive 81/851/EEC –

(a) type of treatment;

(b) the type of products authorised;

(c) the date of treatment;

(d) the identity of the animals treated.

The register must be made available to the Veterinary Services at its request;

(ii) the administering for therapeutic purposes of authorised veterinary medicinal products containing:

(a) allyl trenbolone, administered orally, or betaagonists to equidae and pets, provided they are used in accordance with the manufacturer's instructions;

(b) betaagonists, in the form of an injection to induce tocolysis in cows when calving.

Such substances must be administered by a veterinarian or, in the case of the veterinary medicinal products referred to in paragraph (a) hereof, under his direct responsibility; treatment must be registered by the veterinarian responsible, who shall record at least the details referred to in point (i).

Farmers shall be prohibited from holding veterinary medicinal products containing betaagonists which may be used for induction purposes in the treatment of tocolysis.

However, without prejudice to the first subparagraph of point ii (b), therapeutic treatment of production animals, including breeding animals at the end of their reproductive life, shall be prohibited.

Certain treatments permitted within the Maltese territory.

6. (1) Notwithstanding rule 4 (i) and without prejudice to rule 3, in Malta the administering to farm animals is authorised, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic, androgenic or gestagenic action which are authorised in accordance with Orders (81/851) and (81/852). Such veterinary medicinal products must be administered by a veterinarian to clearly identified animals; the treatment must be recorded by the veterinarian responsible in accordance with rule 5 (i):

Provided that Veterinary Services may allow the synchronisation of oestrus and the preparation of donors and recipients for the implantation of embryos to be effected not by the veterinarian direct, but under his responsibility.

(2) With regard to aquaculture animals, young fish may be treated for the first three months for the purpose of sex inversion with veterinary medicinal products that have an androgenous action and are authorised in accordance with Directives 81/851/EEC and 81/852/EEC.

(3) In the cases provided for in this rule, the veterinarian shall make out a non-renewable prescription, specifying the treatment

in question and the quantity of the product required and shall record the products prescribed:

Provided that zootechnical treatment of production animals, including during the fattening period for breeding animals at the end of their reproductive life, shall be prohibited.

Authorisation of administration of hormonal products and Betaagonists.

7. (1) Hormonal products and Betaagonists the administration of which to farm animals is authorised in accordance with rules 5 and 6 must meet the requirements of Directives 81/851/EEC and 81/852/EEC.

(2) The following are not, however, authorised in accordance with sub-rule (1)

(a) the following hormonal products:

(i) products acting as a deposit;

(ii) products with a withdrawal period of more than 15 days after the end of treatment;

(iii) products:

(1) which were authorised under rules that preceded the national legislation laying down procedures in conformity with international agreement for the authorisation and supervision of medicinal products for human and veterinary use,

(2) whose conditions of use are not known,

(3) or which no reagents or equipment exist for use in the analytical techniques for detecting the presence of residues in excess of the permitted limits,

(b) veterinary medicinal products containing betaagonists which have a withdrawal period of more than 28 days after the end of treatment.

Trade, breeding and relative health marks.

8. (1) For the purpose of trade, it is permitted in Malta, the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in rules 5 and 6 and may authorise the affixing of the health mark of Annex I, Chapter XI, (50) of Directive 64/433/EEC to meat from such animals where the conditions laid down in rules 5 and 6 and the minimum withdrawal periods laid down in rule

7 (2), under paragraph (a) (ii) or (b) respectively or the withdrawal periods provided for in the authorisation to place on the market are complied with.

However, trade in highvalue horses, and in particular racehorses, competition horses, circus horses or horses intended for stud purposes or for exhibitions, including registered equidae to which veterinary medicinal products containing allyl trenbolone or betaagonists have been administered for the purposes referred to in rule 5, may take place before the end of the withdrawal period, provided that the conditions governing administration are fulfilled and that the type and date of treatment are entered on the certificate or passport accompanying these animals.

(2) Meat or products from animals to which substances having an oestrogenic, androgenic or gestagenic action or betaagonists have been administered in accordance with the dispensatory provisions of these regulations may not be placed on the market for human consumption unless the animals in question have been treated with veterinary medicinal products complying with the requirements of rule 7 and in so far as the withdrawal period laid down was observed before the animals were slaughtered.

Possession and use of substances by authorised persons.

9. Within the territory of Malta -

(i) at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in rules 3 and 4 (i), their possession is restricted to the persons authorised by national legislation in accordance with Article 1 (5) of Order (81/851);

(ii) in addition to the checks provided for in the Orders governing the placing on the market of the various products in question, the official checks provided for in Article 11 of Directive 96/23/EEC are carried out by the competent national authorities without prior notice, with a view to ascertaining:

(a) the possession or presence of substances or products prohibited under rule 3, intended to be administered to animals for the purpose of fattening;

(b) the illegal treatment of animals;

(c) failure to observe the withdrawal periods provided for in regulation 7;

(d) failure to observe the restrictions on the use of certain substances or products laid down in rules 5 and 6;

(iii) the tests for the presence of:

(a) the substances referred to in point (i) in animals, in the drinking water of animals and in all places where animals are bred or kept;

(b) residues of the aforementioned substances in live animals, their excrement and body fluids and in animal tissues and products, are carried out in accordance with Annexes III and IV to Directive 96/23/EEC;

(iv) where the checks provided for in points (ii) and (iii) reveal:

(a) the presence of substances or products the use or possession of which is prohibited, or the presence of residues of substances the administering of which comes under the heading of illegal treatment, such substances or products are confiscated, while any animals treated or the meat therefrom is placed under official supervision until the requisite penalties have been applied;

(b) failure to comply with the requirements of points (ii) (b) and (c), the Veterinary Services takes appropriate measures consistent with the gravity of the infringement.

Keeping of registers of substances.

10. (1) Without prejudice to Directive 81/851/EEC, undertakings buying or producing substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and betaagonists, undertakings authorised in any capacity to market such substances and undertakings buying or producing pharmaceutical and veterinary medicinal products from such substances shall be required to keep registers detailing, in chronological order, quantities produced or acquired and those sold or used for the production of pharmaceutical and veterinary medicinal products and the names of the persons to whom such quantities were sold or from whom they were purchased.

(2) The information in sub-rule (1) hereof shall be made available to the Veterinary Services at its request and, in the case of computerised records, in the form of a print-out.

Failure to comply with the requirements of these rules.

11. Where the results of checks carried out in the territory of Malta show failure to comply with the requirements of these regulations in the country of origin of the animals or products, the Veterinary Services shall have recourse to provisions taken according to the procedure laid down in Article RE1 of the Veterinary Framework Act on mutual assistance between the administrative authorities of Malta and of the Member States to ensure the correct application of legislation on veterinary and zootechnical matters.

Limitation of importation.

12. (1) Third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, their salts and esters, or of thyrostatic substances for administering to animals of all species may not appear on any of the lists of countries provided for under veterinary legislation from which Malta authorizes to import farm or aquaculture animals or meat or products obtained from such animals.

(2) In Malta, it is prohibited to import from third countries on any of the lists referred to in sub-rule (1) of:

(a) farm or aquaculture animals

(i) to which products or substances referred to in point (i) of rule 3 have been administered by any means whatsoever;

(ii) to which substances or products referred to in point (i) of rule 4 have been administered, unless those substances or products were administered in compliance with the provisions and requirements laid down in rules 5, 6 and 8 and the withdrawal periods allowed in international recommendations have been observed;

(b) meat or products obtained from animals the importation of which is prohibited under point (a).

(3) However, animals intended for breeding, breeding animals at the end of their reproductive life, or meat there from, from third countries may be imported subject to their affording guarantees at least equivalent to those laid down in these regulations or which have been established for the implementation and enforcement of Chapter V of Directive 96/23/EEC on measures to be taken in the event of infringement.

(4) Checks on imports from third countries shall be carried out in accordance with Article 17 (2) and (3) of the Veterinary Framework Act.

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