*Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,366, 16 ta' Jannar, 2009*
*Taqsima B*

**A.L. 23 ta' l-2009**

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

## Regolamenti ta' l-2009 li jemendaw ir-Regolamenti dwar Prodotti Mediċinali Veterinarji

BIS-SAĦĦA tas-setgħat mogħtija bl-artikoli 30 u 31 ta' l-Att dwar is-Servizzi Veterinarji, il-Ministru għar-Riżorsi u Affarijiet Rurali, wara konsultazzjoni mal-Kap tal-Laboratorju Veterinarju Nazzjonali, għamel dawn ir-regolamenti li ġejjin:-

Titolu u skop.

**1.** (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2009 li jemendaw ir-Regolamenti dwar Prodotti Mediċinali Veterinarji u għandhom jinqraw u jinftehmu ħaġa waħda mar-Regolamenti ta' l-2004 dwar Prodotti Mediċinali Veterinarji, hawn iżjed 'l quddiem jissejjħu "ir-regolamenti prinċipali".

A.L. 469 ta' l-2004.

(2) L-iskop ta' dawn ir-regolamenti hu sabiex jiġu implimentati r-regoli li jinsabu fid-Direttiva tal-Kummissjoni ta' l-Unjoni Ewropea 2006/130/KE li jemendaw id-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 2001/82/KEE dwar is-servizzi mediċinali veterinarji.

Jemenda r-regolament 60 tar-regolamenti prinċipali.

**2.** Minnufih wara s-subartikolu (1) ta' l-artikolu 60 tar-regolamenti prinċipali għandu jidħol is-subartikolu (2) li ġej:

"(2) Prodotti mediċinali veterinarji għall-annimali li jipproduċu l-ikel jistgħu jkunu eżentati mill-ħtiega ta' riċetta veterinarja jekk jiġu sodisfatti l-kriterji li ġejjin:

(a) l-amministrazzjoni tal-prodotti mediċinali veterinarji tkun ristretta għall-prodotti li ma jirrikjedu ebda għarfien jew sengħa partikolari fl-użu tagħhom;

(b) il-prodotti mediċinali veterinarji ma jkunu ta' ebda riskju, dirett jew indirett, anke jekk somministrati b'mod żbaljat, għall-annimal jew annimali li jkunu qedgħdin jiġu ikkurati, għall-persuna li tkun qed tissomministra il-prodott jew għall-ambjent;

(ċ) is-sommarju tal-karatteristiċi tal-prodott mediċinali veterinarju ma fihx avviż ta' xi effetti kollaterali li huma potenzjalment serji u li jistgħu jirriżultaw mill-użu korrett tal-prodott;

(d) la l-prodott mediċinali veterinarju lanqas kull prodott ieħor li jikkontjeni l-istess sustanzi attivi fil-passat qatt ma kien qabel rappurtat li ta lok għal reazjonijiet avversi serji u frekwenti;

(e) is-sommarju tal-karatteristiċi tal-prodott ma jagħmilx riferenza għall-kontroindikazzjonijiet relatati ma' prodotti mediċinali veterinarji oħra li soltu jintużaw mingħajr riċetta;

(f) il-prodott mediċinali veterinarju ma jkunx soġġett għall-kundizzjonijiet specjali ta' kif għandu jinħażen;

(g) ma jkun hemm ebda riskju għas-saħħa tal-konsumatur fir-rigward tar-residwi fl-ikel minn annimali li jiġu trattati bil-prodotti mediċinali veterinarji anke jekk jintużaw b'mod żbaljat;

(h) ma jkun hemm ebda riskju għas-saħħa tal-bnedmin jew tal-annimali fl-iżvilupp għar-resistanza tas-sostanzi antimikrobiċi jew antelmintiċi , ukoll meta l-prodotti mediċinali veterinarji li jkunu jikkontjenu dawk is-sostanżi jintużaw b'mod żbaljat".

**L.N. 23 of 2009**

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

## Veterinary Medicinal Products (Amendment) Regulations, 2009

IN exercise of the powers conferred by article 30 and 31 of the Veterinary Services Act, the Minister for Resources and Rural Affairs, after consulting the Head of the National Veterinary Laboratory, has made the following regulations:-

Title and scope.

**1.** (1) The title of these regulations is the Veterinary Medicinal Products (Amendment) Regulations, 2009 and they shall be read and construed as one with the Veterinary Medicinal Products Regulations, 2004, hereinafter referred to as "the principal regulations".

L.N. 469 of 2004.

(2) The scope of these regulations is to implement the rules found under European Union Commission Directive 2006/130/EC amending European Union Council Directive 2001/82/EEC relating to veterinary medicinal services.

Amends regulation 60 of the principal regulations.

**2.** Immediately after subarticle (1) of article 60 of the principal regulations there shall be added subarticle (2) as follows:

"(2) Veterinary medicinal products for food-producing animals may be exempted from the requirement to be dispensed only against veterinary prescription, if all of the following criteria are satisfied:

(a) the administration of veterinary medicinal products is restricted to formulations requiring no particular knowledge or skill in using the products;

(b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal or animals treated, to the person administering the product or to the environment;

(c) the summary of product characteristics of the veterinary medicinal product does not contain any warnings of potential serious side effects deriving from its correct use;

(d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent serious adverse reaction reporting;

(e) the summary of product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription;

(f) the veterinary medicinal product is not subject to special storage conditions;

(g) there is no risk for consumer safety as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly;

(h) there is no risk to human or animal health as regards the development of resistance to antimicrobials or anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly".

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