

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:-

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”. Title and scope.

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.

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

“(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”.

