
STATUTORY INSTRUMENTS

2005 No. 2745

The Veterinary Medicines Regulations 2005

PART 1

Introduction

Title and commencement

1. These Regulations may be cited as the Veterinary Medicines Regulations 2005 and come into force—

- (a) except for regulation 14 and Schedule 5, on 30th October 2005;
- (b) in the case of regulation 14 and Schedule 5, on 1st January 2006.

Definition of “veterinary medicinal product”, interpretation and scope

2.—(1) In these Regulations “veterinary medicinal product” means—

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or
- (b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

(2) In addition—

“adverse reaction” means a reaction to a veterinary medicinal product that is harmful and unintended and that occurs at doses normally used in animals for the prophylaxis, diagnosis or treatment of disease or to restore, correct or modify a physiological function;

“the Agency” means the European Medicines Agency established by Regulation (EC) No. 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency⁽¹⁾;

“animal” means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees;

“the cascade” has the meaning assigned in paragraph 2 of Schedule 4;

“immunological veterinary medicinal product” means a veterinary medicinal product administered to animals in order to produce active or passive immunity or to diagnose the state of immunity;

“risk-benefit balance” means an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to —

(1) OJ No. L136, 30.4.2004, p. 1.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- (a) any risk relating to the quality, safety and efficacy of the veterinary medicinal product as regards animal or human health; or
- (b) any risk of undesirable effects on the environment;

“strength” means the amount of active substances in a dosage unit or unit of volume or weight.

(3) In these Regulations any reference to a member State is a reference to a member State of the European Union and Norway, Iceland and Liechtenstein.

(4) For the avoidance of doubt, these Regulations apply to all veterinary medicinal products irrespective of whether or not there is other legislation controlling a product.

Products to which these Regulations do not apply

3.—(1) These Regulations do not apply to a veterinary medicinal product based on radio-active isotopes.

(2) They do not apply to a veterinary medicinal product that is the subject of a licence granted under the Animals (Scientific Procedure) Act 1986⁽²⁾, except that, if the animals used under that licence are to be put into the human food chain, the veterinary medicinal product must be administered in accordance with an animal test certificate granted under regulation 8(3).

(2) 1986 c. 14.