STATUTORY INSTRUMENTS

2013 No. 2033

The Veterinary Medicines Regulations 2013

PART 1

Introduction

Title and commencement

1. These Regulations may be cited as the Veterinary Medicines Regulations 2013 and come into force on 1st October 2013.

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 these Regulations—

"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 given in paragraph 1 of Schedule 4;

"Commission Regulation (EC) No 1234/2008" means Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products(**2**);

"Commission Regulation (EU) No 37/2010" means Commission Regulation (EU) No 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin(**3**);

(**1**) OJ No L136, 30.4.2004, p. 1.
(**2**) OJ No L334, 12.12.2008, p.7.
(**3**) OJ No L 15, 20.1.2010, p. 1.

"extension variation" has the same meaning as "Extension of a marketing authorisation" in Article 2 of Commission Regulation EC No 1234/2008;

"horse passport" means a passport issued in accordance with the provisions of Commission Regulation (EC) No 504/2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae(**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;

"Regulation (EC) No 470/2009 of the European Parliament and of the Council" means Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin(**5**);

"Regulation (EC) No 767/2009 of the European Parliament and of the Council" means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed in relation to feedingstuffs containing specified feed additives(**6**);

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

(a) any risk to human or animal health relating to the quality, safety or efficacy of the veterinary medicinal product; 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 references to types of variation are to those specified in Commission Regulation (EC) No 1234/2008;

(4) 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.

(5) For the avoidance of doubt, these Regulations apply to 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 in relation to a product intended for administration in the course of a procedure licensed under the Animals (Scientific Procedures) Act 1986(**7**), except that, if the animals are to be put into the human food chain, the only products that may be administered to the animals are—

(a) authorised veterinary medicinal products administered in accordance with their marketing authorisation; or

(b) products administered in accordance with an animal test certificate granted under paragraph 9 of Schedule 4.

(**4**) OJ No L 149, 7.6.2008, p. 3.
(**5**) OJ No L152, 16.6.2009, p. 11.
(**6**) OJ No L229, 1.9.2009, p. 1. Regulation (EC) No 767 2009 was last amended by Regulation (EC) 939/2010 (OJ No L277, 20.10. 2010, p. 4).
(**7**) 1986 c. 14.