STATUTORY INSTRUMENTS.

S.I. No. 182 of 2009

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (AMENDMENT) REGULATIONS 2009

(Prn. A9/0660)

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I, BRENDAN SMITH, Minister for Agriculture, Fisheries and Food, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972), for the purpose of giving further effect to Directive No. 2001/82/EC of the European Parliament and of the Council of 6 November 2001 as amended by Directive No. 2004/28/EC of the European Parliament and of the Council of 31 March 2004, and giving effect to Commission Directive No. 2009/9/EC of 10 February 2009[1], hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Animal Remedies) (Amendment) Regulations 2009 and come into operation on 7 May 2009.

2. The European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007) are amended—

(*a*) in Regulation 2(1)—

(i) by the substitution for the definition of animal remedies authorisation of—

" 'animal remedies authorisation' means—

(*a*) a veterinary product authorisation, within the meaning of Article 5 of the Directive, or a registration following an application under Regulation 7(2), granted by the Board in accordance with Regulation 9,

(*b*) a licence granted by the Minister under Regulation 16, 17 or 19,

(*c*) a marketing authorisation granted under Regulation (EC) No. 726/2004, or

(*d*) such other document, registration, licence or authorisation deemed by these Regulations to be an animal remedies authorisation;",

(ii) by the substitution for the definition of Directive of—

" 'Directive' means Directive No. 2001/82/EC of the European Parliament and of the Council of 6 November 2001 as amended

[1] O.J. L 44 of 14.2.2009, p. 10.

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 15*th May*, 2009.

by Directive No. 2004/28/EC of the European Parliament and of the Council of 31 March 2004 and Commission Directive No. 2009/9/EC of 10 February 2009;",

(iii) by the insertion after the definition of premix for a medicated feedingstuff of—

" 'prohibited animal remedy' means an animal remedy or ingredient for an animal remedy in respect of which, by virtue of these Regulations, a licence, authorisation, registration or direction is required for the purpose of its administration to an animal or for other purposes and either—

(*a*) such licence, authorisation, registration or direction has not been issued, or

(*b*) where such licence, authorisation, registration or direction has been issued, a condition or other requirement, to which it is subject, has not been complied with or is no longer complied with;",

(*b*) in Regulation 3 by the substitution for paragraph (1) of—

"(1) Without prejudice to Regulations 15, 18 and 20, a person shall not import, possess, sell or supply an animal remedy unless there is in force an animal remedies authorisation in respect of the animal remedy.",

(*c*) in Regulation 9 by the substitution for paragraph (1) of—

"(1) The Board may grant a veterinary product authorisation or registration arising from an application under Regulation 4, 6, 7 or 8, attach conditions to a veterinary product authorisation or registration, revoke or vary a condition, or suspend or revoke a veterinary product authorisation or registration.",

(*d*) in Regulation 28 by the substitution for paragraph (9) of—

"(9) Paragraphs (1), (4), (5), (7) and (8) do not apply to the holder of a manufacturer's licence, or the holder of an animal remedies wholesaler's licence supplying a person who may lawfully sell or supply the animal remedy.",

(*e*) in Regulation 36(4)(*a*) by the substitution for sub-paragraph (i) of—

"(i) the holder of an animal remedies merchant's licence or a person registered in accordance with Regulation 33(1), or",

(*f*) in Regulation 38 by the substitution for paragraph (4) of—

"(4) (*a*) A person, other than the holder of a manufacturer's licence, the holder of an animal remedies wholesaler's licence or a registered veterinary practitioner, shall not have an animal remedy designated veterinary practitioner only (VPO — 1) or veterinary practitioner only (VPO) in his or her possession or under his or her control unless he or she has a veterinary prescription relating to the animal remedy in his or her possession.

(*b*) Notwithstanding subparagraph (*a*), a person, other than a registered veterinary practitioner, shall not have an animal remedy designated veterinary practitioner only (VPO — 1) or veterinary practitioner only (VPO) in his or her possession or under his or her control on a premises where an animal is kept, sold, supplied or slaughtered.",

(*g*) in Regulation 63 by the substitution for paragraph (3) of—

"(3) A certificate purporting to be signed by the Secretary of the Board or other officer of the Board, authorised by the Board in that regard, certifying that on a specific day or days or during the whole of a specified period—

(*a*) an animal remedy was or was not the subject of a veterinary product authorisation or registration granted under Regulation 9,

(*b*) a person was or was not the holder of a manufacturer's licence granted under Regulation 22, or

(*c*) a particular authorisation, licence or registration, referred to in this paragraph, was subject to a particular condition or conditions,

is, without proof of the signature of the person purporting to sign the certificate or that he or she is the Secretary or an officer of the Board, evidence, unless the contrary is shown of the matters stated in the certificate.",

and

(*h*) by the substitution for Schedule 3 of—

"SCHEDULE 3

A VETERINARY PRESCRIPTION

A veterinary prescription shall bear a serial number, contain a declaration that the prescription is granted in respect of an animal under the care of the prescribing veterinary practitioner and contain at least the following—

(*a*) details of the animal remedy (and if Regulation 43(6) applies, an alternative) to be administered, specifying the authorised name and (unless the animal remedy has been supplied at the time of prescribing) the number of the veterinary product authorisation or licence issued in accordance with Regulation 18(11),

(*b*) quantity of the animal remedy prescribed,

(*c*) date of issue,

(*d*) manner and site of administration,

(*e*) dose rate and withdrawal period to be observed,

(*f*) description of the animal or animals to which the prescription relates,

(*g*) name and address of the person to whom the prescription is granted,

(*h*) period during which the prescription is valid,

(*i*) special instructions, precautions or risks, and

(*j*) name, address and signature of the registered veterinary practitioner.".

L.S.

GIVEN under my Official Seal,
7 May 2009

BRENDAN SMITH,
Minister for Agriculture, Fisheries and Food.

EXPLANATORY NOTE

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations transpose Commission Directive 2009/9/EC of 10 February 2009, amending Directive 2001/82 of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary use.

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