STATUTORY INSTRUMENTS.

S.I. No. 262 of 2012

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (AMENDMENT) REGULATIONS 2012

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I, SIMON COVENEY, Minister for Agriculture, Food and the Marine, 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 2001/82 of the European Parliament and of the Council of 6 November 2001[1] and Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009[2], hereby make the following regulations:

1. These Regulations may be cited as the European Communities (Animal Remedies) (Amendment) Regulations 2012.

2. In these Regulations "Animal Remedies Regulations" means European Communities (Animal Remedies)(No. 2) Regulations 2007 (S.I. No. 786 of 2007) as amended by the European Communities (Animal Remedies) (Amendment) Regulations 2009 (S.I. No. 182 of 2009).

3. The Animal Remedies Regulations are amended in Regulation 2(1) by—

(*a*) inserting after the definition of "Board" the following-

" 'Commission Regulation (EU) No 37/2010' means Commission Regulation (EU) No. 37/2010 of 22 December 2009[3], as amended by Commission Regulation (EU) No 758/2010 of 24 August 2010[4], Commission Regulation (EU) No 759/2010 of 24 August 2010[5], Commission Regulation (EU) No 761/2010 of 25 August 2010[6], Commission Regulation (EU) No 890/2010 of 8 October 2010[7], Commission Regulation (EU) No 914/2010 of 12 October 2010[8], Commission Regulation (EU) No 362/2011 of 13 April 2011[9], Commission Regulation (EU) No 363/2011 of 13 April 2011[10], Commission Implementing Regulation (EU) No 84/2012 of 1 February 2012[11], Commission Implementing Regulation

[1]O.J. L 311, 28.11.2001, p.1
[2]O.J. L 152, 16.6.2009, p.11
[3]O.J. L15, 20.1.2010, p.1
[4]O.J. L 223, 25.8.2010, p.37
[5]O.J. L 223, 25.8.2010, p.39
[6]O.J. L 224, 26.8.2010, p.1
[7]O.J. L 266, 9.10.2010, p.1
[8]O.J. L 269, 13.10.2010, p.5
[9]O.J. L 100, 14.4.2011, p.26
[10]O.J. L 100, 14.4.2011, p.28
[11]O.J. L 30, 2.2.2012, p.1

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 27*th July*, 2012.

(EU) No 85/2012 of 1 February 2012[12], Commission Implementing Regulation (EU) No 86/2012 of 1 February 2012[13], Commission Implementing Regulation (EU) No 107/2012 of 8 February 2012[14], Commission Implementing Regulation (EU) No 122/2012 of 13 February 2012[15] and Commission Implementing Regulation (EU) No 123/2012 of 13 February 2012[16], Commission Implementing Regulation (EU) No 201/2012 of 8 March 2012[17], Commission Implementing Regulation (EU) No 202/2012 of 8 March 2012[18], Commission Implementing Regulation (EU) No 221/2012 of 14 March 2012[19] and Commission Implementing Regulation (EU) No 222/2012 of 14 March 2012[20]",

(*b*) substituting for the definition of "companion animal" the following-

" 'companion animal' means an animal which is not a food producing animal;",

(*c*) deleting the definition of "Council Regulation (EEC) No. 2377/90",

(*d*) substituting for the definition of "food producing animal", the following-

" 'food producing animal' means an animal of the bovine, caprine, ovine or porcine species, poultry, rabbits, deer, fish or honey bees, if such rabbits, deer or fish are intended for use as food for human consumption, or equidae which have not been permanently excluded from the food chain by completion of Part II of Section IX of the identification document provided for in the European Communities (Equine) Regulations 2011 (S.I. No 357 of 2011);"

(*e*) substituting for the definition of "pharmacist", the following-

" 'pharmacist' means a person registered as a pharmacist under Part 4 of the Pharmacy Act 2007(No 20 of 2007);",

(*f*) substituting for the definition of "pharmacy", the following-

" 'pharmacy' means a business registered under section 17 of the Pharmacy Act 2007;", and

(*g*) inserting after the definition of "record" the following-

[12]O.J. L 30, 2.2.2012, p.4
[13]O.J. L 30, 2.2.2012, p.6
[14]O.J. L 36, 9.2.2012, p.25
[15]O.J. L 40, 14.2.2012, p.2
[16]O.J. L 40, 14.2.2012, p.4
[17]O.J. L 71, 9.3.2012, p.37
[18]O.J. L 71, 9.3.2012, p.40
[19]O.J. L 75, 15.3.2012, p.7
[20]O.J. L 75, 15.3.2012, p.10

" 'Regulation (EC) No. 470/2009' means Regulation (EC) No. 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82 of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council;".

4. Regulation 4(5)(*b*) of the Animal Remedies Regulations is amended by substituting the following subparagraph-

"(*b*) Subparagraph (*a*) does not apply to an animal remedy containing a pharmacologically active substance, not listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, which is intended for administration to an equid which is a companion animal,".

5. Regulation 6(6)(*c*) of the Animal Remedies Regulations is amended by the substitution for the reference to "Council Regulation (EEC) No. 2377/90" of "Regulation (EC) No. 470/2009".

6. Regulation 7(2) of the Animal Remedies Regulations is amended by the substitution for the reference to "Council Regulation (EEC) No. 2377/90" of "Regulation (EC) No. 470/2009".

7. Regulation 9 of the Animal Remedies Regulations is amended by the substitution—

(*a*) in subparagraph (9)(*d*), for the reference to "Council Regulation (EEC) No. 2377/90" of "Commission Regulation (EU) No. 37/2010", and

(*b*) for subparagraph (12), of the following-

"(12)(*a*) Subject to paragraph (9) and subparagraph (*b*), the Board shall not grant a veterinary product authorisation or a registration in respect of an animal remedy intended for administration to a food producing animal unless each substance capable of pharmacological action contained in the animal remedy is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010.

(*b*) The Board may authorise an animal remedy containing a substance not listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 for administration to an equid which is a companion animal, except where—

(i) the substance is listed in Table 2 of the Annex to Commission Regulation (EU) No 37/2010, or

(ii) there is already in force an animal remedies authorisation for treatment of the same condition in an equid.".

8. Regulation 18 of the Animal Remedies Regulations is amended by the substitution-

(*a*) in subparagraph (3)(*a*), for "listed in Annex I, II or III to the Council Regulation (EEC) No 2377/90", of "listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010",

(*b*) for subparagraph (5), of the following-

"(5) Paragraphs (3)(*c*) and (*d*) do not apply in the case of a homeopathic animal remedy which contains an active substance classified under Article 14.2(*c*) of Regulation (EC) No. 470/2009.", and

(*c*) for subparagraph (7), of the following-

"For the purposes of paragraph 3(*b*), identification document has the same meaning as in the European Communities (Equine) Regulations 2011 (S.I. No 357 of 2011).".

9. Regulation 19(2)(*b*) of the Animal Remedies Regulations is amended by the substitution for the reference to "Council Regulation (EEC) No. 2377/90", of "Regulation (EC) No. 470/2009".

10. Regulation 30 of the Animal Remedies Regulations is amended by substituting for subparagraph (9), the following-

"(9) Subject to Regulation 49, an animal remedies wholesaler's licence remains in force for an unlimited period, unless a period of validity is specified on the licence.".

11. Regulation 31 of the Animal Remedies Regulations is amended by substituting for subparagraph (8), the following-

"(8) Subject to Regulation 49, an animal remedies merchant's licence remains in force for an unlimited period, unless a period of validity is specified on the licence.".

12. Regulation 34 of the Animal Remedies Regulations is amended by substituting the following—

"34. (1) A registered veterinary practitioner or a pharmacist shall—

(*a*) keep, at his or her premises, a record of purchases and sales (including quantities administered) in respect of each incoming and outgoing transaction, detailing at least—

(i) the date of transaction, and in the case of an animal remedy designated 'veterinary practitioner only (VPO-1)', 'veterinary practitioner only (VPO)', or prescription only (POM), the serial number of the veterinary prescription,

(ii) the precise identity of the animal remedy or where Regulation 18 applies, the medicinal product, including name, pharmaceutical form and pack size,

(iii) the manufacturer's batch number,

(iv) the name and address of the supplier or consignee, and

(v) the quantity received or supplied (including the quantity received or returned in accordance with subparagraph (*c*) or otherwise disposed of),

(*b*) keep the records referred to in subparagraph (*a*) for a period of five years from the date of receipt, sale or supply or administration of the animal remedy and these records shall be made available to an authorised officer on request,

(*c*) have in place arrangements to receive from consignees and return to the person from whom he or she purchased it, an animal remedy that is unused or reached its expiry date and shall take steps to ensure that clients are aware of these arrangements, and

(*d*) at least once a year, carry out an audit to reconcile incoming and outgoing supplies with supplies currently in stock and any discrepancies shall be specifically recorded and this record shall be retained and made available at the premises for inspection by an authorised officer for a period of not less than five years.

(2) Paragraphs (*a*), (*b*) and (*d*) do not apply in the case of an animal remedy designated 'companion animal medicine''.

13. Regulation 36(4)(*b*) of the Animal Remedies Regulations is amended by substituting the following-

"(*b*) A licence granted under paragraph (3)(*a*) or (*b*)-

(i) may only relate to an animal remedy referred to in paragraphs 6 or 7 of Part 1 of Schedule 1, and

(ii) subject to Regulation 49, remains in force for an unlimited period unless a period of validity is specified on the licence.".

14. Regulation 43(7) of the Animal Remedies Regulations is amended by substituting the following—

"(7) A person—

(*a*) who dispenses a veterinary prescription in part, shall immediately record on the prescription and on the copy, in a conspicuous, legible and indelible manner, the quantity of an animal remedy

sold or supplied by him or her on foot of the veterinary prescription and the date of each such sale or supply and shall attest to this by means of his or her signature and shall retain a copy (which could be a photocopy) of the prescription,

(*b*) who has completed dispensing a veterinary prescription shall—

(i) at that time write on the prescription and on the copy thereof in a conspicuous, legible and indelible manner, the word "dispensed" and shall attest to this by means of his or her signature and the date,

(ii) return a copy of the veterinary prescription to the person who presented it, and

(iii) retain, at his or her premises, the original veterinary prescription for five years and shall make this available on request to an authorised officer,

(*c*) shall not complete dispensing an animal remedy on foot of a veterinary prescription later than 12 months after the date the veterinary prescription is issued, and

(*d*) shall not alter, deface or destroy a veterinary prescription.".

15. Regulation 49(1) of the Animal Remedies Regulations is amended by substituting the following-

"(1) The Minister may grant a licence, registration or approval under a specified Regulation or refuse an application or may attach a condition to a licence, registration or approval, revoke or vary a condition or vary, suspend or revoke a licence, registration or approval.",

16. Regulation 63(5) of the Animal Remedies Regulations is amended by substituting the following-

"(5) In proceedings for an offence, evidence of the Directive, Regulation (EC) No. 726/2004, Regulation (EC) No 470/2009 or Commission Regulation (EU) No 37/2010 may be given by production of a copy of the Directive or Regulation certified by an officer of the Minister to be a copy of the Directive or Regulation, and it is not necessary to prove the signature of the officer or that he or she is an officer of the Minister.".

17. Regulation 68(1) of the Animal Remedies Regulations is amended by substituting the following-

"(1) The Minister may prosecute an offence under these Regulations in a summary manner.".

18. Regulation 69 of the Animal Remedies Regulations is amended by substituting the following-

"69. (1) A person who contravenes Regulation 18(3)(*d*) or (10), 20(3)(*b*), 28(5) or (6)(*b*), 30(5) or (7), 31(5) or (9), 33, 34, 36(3), 37, 43(4),(5) or (7), or 44(2) commits an offence and is liable on conviction to a Class A fine.

(2) (1) A person who by act or omission—

(*a*) contravenes Regulation 3(1), 7(2)(*d*), 11, 12(3), (4), (7) or (8), 13(4) or (5), 14(4) or (6), 15(4), (5) or (6), 18(1) or (8), 19(1) or (2), 20(1) or (3)(*a*), 23(1) or (3), 25(3) or (5), 27(2), 28(1), (2), (4), (6)(*a*), (7), (8) or (10), 29, 30(1) or (6), 31(1) or (7), 35, 36(1), 38(1), (4) or (5), 39, 40(1) or (2), 42, 43(1), (2), (3), (6), (10) or (11), 48(1), (2), (3), (4) or (5), 57, 58, or 65(2),

(*b*) fails to give assistance to an authorised officer,

(*c*) fails to comply with a requirement of an authorised officer under Regulation 52,

(*d*) (i) contravenes Article 38(4), 41(1), (2), (3), (4), the third paragraph of Article 47, Article 49(1), (2), (3) or (5) of, or

(ii) places a veterinary medicinal product to which it applies on the market in contravention of, Regulation (EC) No. 726/2004,

(*e*) contravenes a term or condition of an animal remedies authorisation, a licence, registration or approval within the meaning of these Regulations, or

(*f*) aids or abets a contravention to which this paragraph relates,

commits an offence and is liable—

(i) on summary conviction to a Class A fine or to a term of imprisonment not exceeding 6 months, or to both, or

(ii) on conviction on indictment to a fine not exceeding €500,000 or to a term of imprisonment not exceeding 3 years, or to both.

19. Regulations 10, 11 and 13 apply to licences in force on the date of coming into force of these Regulations.

L.S.

GIVEN under my Official Seal,
19 July 2012.

SIMON COVENEY,
Minister for Agriculture Food and the Marine.

EXPLANATORY NOTE

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

These Regulations update the regime governing the approval, distribution and administration of animal remedies in further implementation of Directive 2001/82 of the European Parliament and of the Council of 6 November 2001 by providing for certain licences to be of unlimited duration and by amending aspects of associated control and enforcement provisions and also to take account of Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 relating to Maximum Residue Limits.

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