STATUTORY INSTRUMENTS.

S.I. No. 361 of 2014

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (AMENDMENT) (NO. 2) REGULATIONS 2014

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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/EC of the European Parliament and of the Council of 6 November 2001[1], hereby make the following Regulations:

1. These Regulations may be cited as the European Communities (Animal Remedies) (Amendment) (No. 2) Regulations 2014.

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

(*a*) in Regulation 2(1) by the substitution, for the definition (inserted by the European Communities (Animal Remedies) (Amendment) Regulations 2009 (S.I. No. 182 of 2009)) 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 Health Products Regulatory Authority in accordance with Regulation 9,

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

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

(*d*) a licence granted by the Health Products Regulatory Authority under Regulation 19, or

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

(*b*) in Regulation 17, by the substitution for paragraph (2) of—

[1]O.J. L311,.28.11.2001

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 1*st August*, 2014.

"(2) Without prejudice to the generality of paragraph (1), the Minister shall not grant a licence unless the applicant establishes to the satisfaction of the Minister that all of the animal remedy will be—

(a) supplied to the Health Products Regulatory Authority or the Minister for the purpose of an application for an animal remedies authorisation,

(b) supplied to a University or other institution concerned with higher education or scientific research or analysis for the purposes of such education or research or analysis,

(c) used for in vitro or other studies or analysis not involving administration to animals, or

(d) exported from the State.".

(*c*) by the substitution, for Regulation 19 (as amended by the European Communities (Animal Remedies) (Amendment) Regulations 2012 (S.I. No. 262 of 2012)), of—

"19. (1) Notwithstanding Regulation 20, a person shall not import or administer an animal remedy to an animal—

(*a*) for the purpose of tests and trials of an animal remedy referred to in Article 12(3)(*j*) of the Directive, or

(*b*) for the purpose of scientific research or analysis not covered by subparagraph (*a*),

except in accordance with a licence, granted by the Health Products Regulatory Authority following consultation with the Minister (referred to in this Regulation as "a research licence").

(2) A person shall not cause produce derived from an animal which has been administered in the course of a test, trial or research to which this Regulation applies to be used for human consumption unless the Health Products Regulatory Authority determines a withdrawal period which shall—

(*a*) be at least as laid down in Article 11(2) of the Directive, including as appropriate a safety factor reflecting the nature of the substance being tested, or

(*b*) ensure that the maximum residue limit will not be exceeded in foodstuffs if this limit has been established for the substance concerned in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.

(3) Notwithstanding Regulation 40, a person, where this Regulation is complied with, may have in his or her possession or under his or her

control and may slaughter, sell, supply or export an animal to which a research licence relates.

(4) A research licence in force immediately before the making of the European Communities (Animal Remedies) (Amendment) (No. 2) Regulations 2014 remains in force, and may be amended or revoked, as if granted after such commencement.",

(*d*) in Regulation 49 (9) by—

(i) the deletion of "19" and

(ii) the insertion, after paragraph (9), of-

"10. This Regulation operates, in relation to Regulation 19, as if each reference to the Minister is a reference to the Health Products Regulatory Authority.",

(*e*) in Regulation 63 by the deletion in paragraph (2)(*c*), of "19",

and

(*f*) in Regulation 63 (amended by the European Communities (Animal Remedies) (Amendment) Regulations 2009 (S.I. No. 182 of 2009)), by the substitution for paragraph (3)(*b*), of—

"(*b*) a person was or was not the holder of a research licence granted under Regulation 19 or the holder of a manufacturer's licence granted under Regulation 22, or".

L.S.

GIVEN under my Official Seal,
17 July 2014.

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 transferring competency for the granting of research licences to the Health Products Regulatory Authority.

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