STATUTORY INSTRUMENTS.

S.I. No. 558 of 2017

ANIMAL HEALTH AND WELFARE (ANIMAL REMEDIES VETERINARY PRACTICE AND VETERINARY MEDICINE) REGULATIONS 2017

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I, MICHAEL CREED, Minister for Agriculture, Food and the Marine, in exercise of the powers conferred on me by section 3 of the European Communities Act (No. 27 of 1972) for the purpose of Regulation 2 and section 36 of the Animal Health and Welfare Act 2013 (No. 15 of 2013), hereby make the following regulations:

Citation and Construction

1. (1) These Regulations may be cited as the Animal Health and Welfare (Animal Remedies Veterinary Practice and Veterinary Medicine) Regulations 2017.

(2) The Animal Remedies Regulations and these Regulations may be cited together as the Animal Remedies Regulations 2007 to 2017 and shall be construed together as one.

Revocation and saver

2. (1) Regulations 43, 44 and Schedule 8 of the Animal Remedies Regulations are revoked.

(2) Any reference to Regulation 43 or 44 of the Animal Remedies Regulation revoked by paragraph (1) shall be construed as a reference to Regulation 4 or 5 of these Regulations respectively.

Interpretation

3. (1) In these Regulations "Animal Remedies Regulations" means the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S.I. No. 786 of 2007).

(2) A word or expression used in these Regulations and also used in the Animal Remedies Regulations has, unless the contrary intention appears, the meaning in these Regulations that it has in the Animal Remedies Regulations.

Prescribing and dispensing animal remedies

4. (1) A person shall not prescribe an animal remedy unless he or she is a registered veterinary practitioner, the animal to which the veterinary prescription relates is under his or her care and he or she is satisfied that—

(*a*) the veterinary prescription will be used to treat the animal to which the prescription relates,

(*b*) use of the animal remedy is justified for the animal,

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(*c*) administration of the animal remedy is, to the best of his or her knowledge and belief, not incompatible with a current or previous treatment, (where appropriate, by consulting with any other veterinary practitioner who has responsibility for the care of the animals), and

(*d*) there is no contra-indication and there will not be an adverse reaction if other animal remedies have been, or are to be, administered or prescribed.

(2) A registered veterinary practitioner shall only prescribe an animal remedy in a quantity necessary for the treatment of the condition in respect of which the animal remedy is prescribed subject, in the case of a food producing animal, to a maximum quantity of 12 months supply from the date the veterinary prescription is issued.

(3) Without prejudice to Regulation 28(6) of the Animal Remedies Regulations, a registered veterinary practitioner who prescribes or administers an animal remedy designated veterinary practitioner only (VPO-1), veterinary practitioner only (VPO), or prescription only for or to an animal shall, at that time, issue a veterinary prescription to the owner or person in charge of the animal.

(4) Without prejudice to Regulation 28(6) of the Animal Remedies Regulations, only a registered veterinary practitioner may issue a veterinary prescription which shall contain at least the particulars listed in Schedule 3 to the Animal Remedies Regulations and-

(*a*) in the case of a paper prescription, be issued in triplicate with the original and one copy given to the owner or person in charge of the animal to be treated and a copy retained by the registered veterinary practitioner, or

(*b*) subject to paragraph (5), in the case where the veterinary practitioner transmits the veterinary prescription by electronic means to the owner or person in charge of the animal, such person shall retain the prescription for the purposes of Regulation 42(3) of the Animal Remedies Regulations.

(5) A registered veterinary practitioner may only issue a veterinary prescription by electronic means where he or she—

(i) supplies an animal remedy at the same time as he or she prescribes an animal remedy,

(ii) has obtained the agreement of the owner or person in charge of the animal to be treated,

(iii) endorses the veterinary prescription with the word “dispensed”, and

(iv) signs the prescription electronically at the time of prescribing.

(6) A registered veterinary practitioner shall retain, at his or her premises, a copy of a veterinary prescription for 5 years and make the copy available for inspection on request by an authorised officer.

(7) If a registered veterinary practitioner issues a veterinary prescription, he or she shall (if there is more than one authorised animal remedy suitable for treatment of the condition to which it applies) specify at least two animal remedies on the veterinary prescription.

(8) 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 record 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.

(9) For the purposes of this Regulation, an animal is considered to be under the care of a registered veterinary practitioner if—

(*a*) the registered veterinary practitioner (or another member of the group veterinary practice of which he or she is a member) has been consulted and has been given responsibility for the professional veterinary care of the animal, herd or flock by the owner or person in charge,

(*b*) the registered veterinary practitioner (or other member of the group veterinary practice of which he or she is a member) has sufficient knowledge of the animal, herd or flock to form an opinion of the condition of the animal and for this purpose he or she (or another

member of the group veterinary practice), shall have visited the farm or other premises on which the animal, herd or flock is kept (or otherwise examined the animal), sufficiently often and recently enough to have acquired an accurate picture of the health, welfare and disease status of the animals on that farm or premises,

(*c*) the registered veterinary practitioner (or other member of the group veterinary practice) is available to respond to requests to provide services of veterinary medicine and surgery and clinical procedures on the animal (or in the herd or flock) in accordance with ethical veterinary practice, and

(*d*) the registered veterinary practitioner is readily available for follow up consultation or monitoring of the condition and evaluation of the therapy.

(10) (*a*) The requirement to visit the farm or other premises, referred to in paragraph (9)(*b*), does not apply to the prescribing of an intramammary animal remedy, if the animal to be treated belongs to a herd covered by a programme meeting the requirements of the Schedule.

(*b*) The Minister may issue a direction in respect of sampling methods and minimum levels in relation to the programme referred to in paragraph (*a*).

(11) A registered veterinary practitioner shall maintain, at his or her premises, records as follows:

(*a*) in relation to each client, a record, containing at least the following—

(i) the date of each visit to the premises on which the animal, herd or flock is kept or on which the animal was seen,

(ii) the identity or other reference to animals clinically examined,

(iii) the condition identified,

(iv) details of treatment of each condition, and

(v) a cross-reference to any relevant results of laboratory tests undertaken for the purpose of diagnosis, or any other test results, and

(*b*) copies of invoices and statements regarding professional services and supply of medicines in respect of each client.

(12) (*a*) Invoices referred to in paragraph (11)(*b*) shall detail the cost of an animal remedy, administered, sold or supplied separately from a professional veterinary service.

(*b*) Records referred to in paragraph 11 may be maintained in the form of a herd health programme.

Emergency supply of certain animal remedies by a pharmacist

5. (1) A pharmacist may sell or supply an animal remedy which is designated prescription only, if—

(*a*) the pharmacist is requested to sell or supply the animal remedy for the treatment of an animal by a registered veterinary practitioner who, by reason of an emergency, is unable to furnish a veterinary prescription immediately,

(*b*) the registered veterinary practitioner undertakes to furnish a veterinary prescription within 72 hours,

(*c*) the animal remedy is sold or supplied in accordance with the directions of the registered veterinary practitioner requesting it,

(*d*) the animal remedy is not a controlled drug specified in Schedule 1A or 1B (inserted by the Misuse of Drugs (Amendment) Act 2015 (No. 6 of 2015)) to the Misuse of Drugs Act 1977 (No. 12 of 1977),

(*e*) the animal remedy is labelled in accordance with Regulation 28(5) of the Animal Remedies Regulations, and

(*f*) the pharmacist maintains the records prescribed by Regulation 34 of the Animal Remedies Regulations.

(2) A registered veterinary practitioner who makes a request in accordance with paragraph (1) shall immediately issue a veterinary prescription for the animal remedy and shall ensure that the prescription reaches the pharmacist and the owner or person in charge of the animal within the period specified in paragraph 1(*b*).

(3) If a registered veterinary practitioner fails to comply with an undertaking under paragraph (1)(*b*), the pharmacist shall not, at any future date, sell or supply an animal remedy under this Regulation at the request of that registered veterinary practitioner.

6. Regulation 4 and 5 are penal provisions to which section 36(4)(*b*) of the Animal Health and Welfare Act 2013 (No. 15 of 2013) applies.

SCHEDULE

Requirements of the Programme referred to in Regulation 4(10).

1. The Programme shall—

(*a*) be in writing,

(*b*) detail—

(i) the owner or person in charge (referred to in this Schedule as "the farmer") of the animals to which it relates, the relevant herd number and any other relevant identifier,

(ii) the milk purchaser who purchases milk from the farmer and who, along with this person, the veterinary practitioner referred to at (iii) and, where appropriate, the veterinary practitioner referred to at (iv), is responsible for implementing the Programme,

(iii) the veterinary practitioner under whose direction it operates,

(iv) any other person, including any other veterinary practitioner who has responsibility for the care of the animals in accordance with Regulation 4(9), who is assigned formal responsibilities under the Programme relating to its implementation in accordance with subparagraph (*f*),

(*c*) set out that the primary objective of the Programme is the prevention and treatment of clinical and sub-clinical bovine mastitis in a manner designed to minimise use of antibiotic treatments and, where necessary, set targets for a reduction in the number of mastitis cases for that herd,

(*d*) set out the scope of the critical herd disease and husbandry factors essential for effective mastitis control,

(*e*) set out the ongoing measures under the Programme designed to meet the objectives at (*c*) and (*d*) as well as the specific measures to be implemented in cases where particular intervention is required and identifying which of the persons in (*b*)(i) to (iv) is responsible for the implementation of each measure. These measures shall include at least the measures set out in paragraphs (2) to (4),

(*f*) define the respective roles of and the reporting relationship between the persons referred to in (*b*)(iii) and (iv),

(*g*) be signed by each of the persons at (*b*)(i) to (iv), confirming that he or she understands and confirms that he or she will carry out his or her responsibilities, and

(*h*) be updated at least on an annual basis and in any event where a change of any of the personnel referred to in (*b*)(i) to (iv) occurs.

Copies of the Programme shall be retained by any person who has signed it in accordance with (*g*) and shall be made available to an authorised officer (authorised for the purposes of the Animal Remedies Regulations) on request.

2. The milk purchaser referred to in paragraph 1(*b*)(ii) shall—

(*a*) Implement a structured sampling programme, at a level consistent with the aims of the Programme or as may be directed by the Minister, in respect of the milk supplied by the farmer as follows—

(i) Milk samples shall be taken in accordance with a written protocol which ensures the integrity of the samples and traceability to the farm of origin,

(ii) Milk samples shall be tested using recognised analytical methods, or, where appropriate, in accordance with methods stipulated by the Minister,

(iii) Milk samples shall be tested for—

(A) Antibiotic residues in accordance with Regulation 21 of the European Communities (Control of Animal Remedies and their Residues) Regulations 2009 (S.I. No. 183 of 2009),

(B) Somatic Cell Counts,

(C) Where appropriate, the presence of mastitis causing pathogens and their sensitivity to a range of antimicrobial agents, including any that may be specified by the Minister, and

(D) Total Bacterial Count,

(*b*) Compile results of testing referred to in (*a*) and make these available to the farmer and the registered veterinary practitioner named in the Programme,

(*c*) Report to the Minister, if requested and in the format required by the Minister, data arising from the testing referred to in (*a*)(iii), and

(*d*) Arrange for the compilation of an annual report on the implementation of the Programme and submit the report to the Minister.

3. The farmer named in the Programme shall—

(*a*) Implement a management regime in respect of the herd and milking operations in the context of the programme designed to reduce the incidence of mastitis and use of antibiotic treatments,

(*b*) Participate in testing conducted by the milk purchaser referred to in paragraph 1(*b*)(ii), or in any additional testing programmes, needed to implement the Programme,

(*c*) Arrange for appropriate monitoring and testing of milking equipment on the farm and for reports arising from such testing to be made available to the milk purchaser and to the registered veterinary practitioner named in the Programme, and

(*d*) Maintain (in addition to the record stipulated in Regulation 42 of the Animal Remedies Regulations) a record in a structured manner and supply the registered veterinary practitioner named in the Programme at the end of each lactation year details of—

(i) Total number of cows in herd during lactation,

(ii) Total number of cows infected with mastitis during lactation,

(iii) Total number of mastitis cases treated during lactation, and

(iv) Total number of intramammary animal remedies used, with a breakdown by type.

4. The registered veterinary practitioner under whose direction the Programme operates may prescribe intramammary animal remedies for animals in the herd referred to at paragraph 1(*b*)(i) provided that he or she complies with the following—

(*a*) He or she takes full consideration of the data and recommendations of the Programme and his or her knowledge of the animals,

(*b*) He or she maintains an up to date knowledge of current developments in relation to mastitis control, in particular, by participation in continuing professional development programmes on this subject,

(*c*) He or she maintains an up to date knowledge of the general herd health situation on the farm and of the milking operations thereon, by reference to relevant data and reports and visits as necessary,

(*d*) He or she provides, as necessary, advice and training, either directly or through the person referred to in paragraph 1(*b*)(iv), to the farmer designed to reduce the incidence of mastitis and use of antibiotic treatments,

(*e*) He or she reviews the results of the effectiveness of the Programme in herds under his or her care with particular reference to antibiotic usage and effectiveness,

(*f*) Where required by reference to the incidence of mastitis on an individual farm, he or she approves a programme of specific remedial

measures, or where appropriate, additional testing required to determine the causal agents and their antibiotic sensitivity, and

(*g*) He or she provides advice on the annual report on the implementation of the Programme with particular reference to achievement of the targets referred to in paragraph 1, together with any recommendations to improve the Programme.

5. Notwithstanding paragraph 4, save in exceptional circumstances, where a registered veterinary practitioner who fulfils the conditions at paragraph 1(*b*)(iv) has signed the Programme as provided for at paragraph 1(*g*), the prescription may only be written by that person. Furthermore, he or she shall, without prejudice to any other requirement of the Animal Remedies Regulations 2007 to 2017, carry out the functions listed at paragraph 4(*a*), (*b*), (*c*), (*d*) and (*f*). The other functions listed at paragraph 4 must be carried out either by the veterinary practitioner under whose direction the programme operates or by the veterinary practitioner mentioned at paragraph 1(*b*)(iii).

L.S.

GIVEN under my Official Seal,
7 December 2017.

MICHAEL CREED,
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 prescribing and dispensing of animal remedies and replace Regulation 43, Regulation 44 and Schedule 8 of the European Communities (Animal Remedies) (No.2) Regulations 2007.

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