STATUTORY INSTRUMENTS.

S.I. No. 462 of 2024

VETERINARY MEDICINAL PRODUCTS REGULATIONS 2024

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Schedule

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I, CHARLIE MCCONALOGUE, Minister for Agriculture, Food and the Marine, in exercise of the powers conferred on me by sections 5(4), 6(1), 7(6), 12(2), 15(a), 21(3), 24(5), 25(3), 28(3), 29(1), 30, 32 and 34(2)(b) of the Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Act 2023 (No. 21 of 2023), hereby make the following regulations:

Citation and commencement (Regulation 21)

1. (1) These Regulations may be cited as the Veterinary Medicinal Products Regulations 2024.

(2) Regulation 21 comes into operation on the commencement of section 7 of the Act.

Definitions

2. In these Regulations—

"Act" means Veterinary Medicinal Products, Medicated Feed and Fertilisers Regulation Act 2023 (No. 21 of 2023);

"HPRA" means Health Products Regulatory Authority;

"keeper" means a natural person who is registered as the keeper of a herd and who is, irrespective of ownership, responsible for the day-to-day care and welfare of the herd;

"Regulations of 2012" means European Union (Protection of Animals used for Scientific Purposes) Regulations 2012 (S. I. No. 543 of 2012);

"veterinary premises" has the meaning assigned to it by section 105 of the Veterinary Practice Act 2005 (No. 22 of 2005);

"veterinary prescription" has the meaning assigned to it by Article 4(33) of the VMP Regulation;

"veterinary prescription for medicated feed" has the meaning assigned to it by Article 3(2)(h) of the Medicated Feed Regulation.

Veterinary prescriptions

3. (1) The maximum validity period for a veterinary prescription for non-antimicrobial veterinary medicinal products is 6 months, from the date of its issuance.

(2) In addition to the requirements of Article 105(5) of the VMP Regulation, a veterinary prescription shall contain the following elements—

(a) a prescription identifier,

Notice of the making of this Statutory Instrument was published in "Iris Oifigiúil" of 17*th September,* 2024.

(b) the Veterinary Council of Ireland Registration Number of the prescribing veterinarian, and

(c) where applicable, the marketing authorisation number relating to the product being prescribed.

(3) A person who is in receipt of a prescription issued by a veterinarian, other than a prescription issued on the national database, in respect of an animal, other than a companion animal, and who administers the product prescribed or permits the product to be administered shall keep a copy of the prescription and records of administration for a period of at least 5 years.

(4) A veterinarian shall issue a veterinary prescription—

(a) for any medicinal product subject to a prescription he or she administers to a food producing animal,

(b) subject to section 6(3) of the Act, for any antimicrobial medicinal product subject to a prescription he or she administers to a non-food producing animal, or

(c) for any medicinal product subject to a prescription he or she administers to an equine that would have the effect of excluding that equine for slaughter `for human consumption.

(5) A veterinarian shall keep records of any medicine subject to a prescription he or she administers to an animal for a period of at least 5 years.

(6) Paragraph (4) does not apply to a veterinarian who—

(a) administers a medicinal product other than an antimicrobial, in the course of a statutory scheme or programme authorised and operated by, or on behalf of, the Minister for the treatment, control, eradication, monitoring, or surveillance of disease (within the meaning of the Animal Health and Welfare Act 2013 (No. 15 of 2013)) in an animal or for the determination of the health or disease status of an animal, or

(b) is employed by the State and administers a medicinal product in the course of their official duties.

(7) A veterinarian shall supply, upon request by a keeper, in relation to a non-dispensed prescription, details of the product prescribed in the format issued by the national database.

Requirements where a veterinary prescription may be issued and dispensed other than using the national database

4. (1) A veterinary prescription may be issued and dispensed other than using the national database only –

(a) in respect of a medicinal product or a medicated feed prescribed for a non-food producing animal species,

(b) in respect of a medicinal product prescribed for an animal to which the Regulations of 2012 apply,

(c) where the veterinarian prescribing has been granted an exemption by the Minister, from using the national database,

(d) where provided for in guidelines issued by the Minister on the operation of the national database, or

(e) before the commencement of section 7 of the Act.

(2) Issuing other than using the national database as set out in paragraph (1) may only be completed on paper or, subject to paragraph (4), transmitted using electronic means.

(3) If a veterinary prescription is issued on paper, it shall be issued in triplicate with the original and one copy given to the owner or keeper of the animal to be treated and a copy retained by the veterinarian.

(4) A veterinary prescription issued outside of the national database, that is fully dispensed at the time of issuing may be transmitted to a keeper by electronic means if it is endorsed with the word "dispensed".

(5) A person who dispenses a paper veterinary prescription—

(a) which is dispensed—

(i) in part, shall immediately—

(I) record on the prescription and on a copy of it, in a conspicuous, legible and indelible manner, the quantity of a medicinal product or medicated feed dispensed on foot of the prescription and the date of supply and attest to this by means of his or her signature and the date, and

(II) shall retain a copy (which could be a photocopy) of the prescription, and return the original prescription to the person who presented it,

or

(ii) in full, shall immediately —

(I) record on the prescription and on a copy of it, in a conspicuous, legible and indelible manner, the word "dispensed" and attest to this by means of his or her signature and the date, and

(II) return a copy of the prescription to the person who presented it, and retain, at his or her premises, the original prescription for 5 years and shall make this available on request to an authorised officer,

(b) shall not dispense on foot of the prescription after the validity period of the prescription has elapsed, and

(c) shall not alter, deface, or destroy the veterinary prescription.

Prescribing of antiparasitic veterinary medicinal products for non-therapeutic purposes in food-producing animals

5. (1) In order to prescribe an antiparasitic veterinary medicinal product for non-therapeutic purposes to a food producing animal or group of animals, the prescribing veterinarian shall complete the proper assessment protocol set out in the Schedule.

(2) The information required to complete the proper assessment protocol may be supplied to a veterinarian by the owner or keeper of an animal or a person nominated on their behalf having obtained the relevant information from the owner or keeper of an animal.

(3) Where an owner or keeper has nominated a person to provide the information referred to in paragraph (2), that owner or keeper shall provide a written declaration that the information provided for the proper assessment protocol is accurate.

(4) The prescribing veterinarian concerned shall—

(a) complete the proper assessment protocol prior to prescribing an antiparasitic veterinary medicinal product,

(b) provide a follow up and emergency after hours clinical service relating to any treatment prescribed and any reported adverse reaction to the product prescribed,

(c) retain an electronic or paper record of the proper assessment protocol for a period of at least 5 years which shall be made available to an authorised officer on request, and

(d) provide a copy of the proper assessment protocol to the owner or keeper of an animal.

(5) Completion of the proper assessment protocol set out in the Schedule is not required if the prescribing veterinarian is providing ongoing veterinary services to the owner or keeper of a herd or flock, including clinical contact with the animals in it.

Circumstances where product other than product prescribed may be dispensed

6. (1)(a) Where a veterinary medicinal product is prescribed, and that product appears on the list of comparable products on the national database, a comparable product to the prescribed product from the list may be dispensed in lieu of the prescribed product.

(b) At the point of dispensing a comparable veterinary medicinal product in the circumstances referred to in subparagraph (a) the person dispensing the product must –

(i) ensure any differences in the information contained within the summary of product characteristics of the prescribed product and the comparable product are fully evaluated,

(ii) ensure the owner or keeper of the animal is fully advised of any differences between the comparable product and the prescribed product, particularly those that may affect the

safe and effective use of the product, including any differences in withdrawal periods, and

(iii) obtain the consent of the owner or keeper of the animal to the dispensing of the comparable product from the list.

(2) (a) Where a human medicinal product is prescribed for an animal, for use under Article 112, 113 or 114 of the VMP Regulation, and an interchangeable human medicinal product exists as determined by the HPRA under the Health (Pricing and Supply of Medical Goods) Act 2013 (No. 14 of 2013), the interchangeable human medicinal product may be dispensed in lieu of the prescribed product.

(b) At the point of dispensing a human medicinal product in the circumstances referred to in subparagraph (a) the person dispensing the product must obtain the consent of the owner or keeper of the animal to the dispensing of the interchangeable product, and

(c) Dispensing under this paragraph may only be undertaken by a pharmacist and the pharmacist shall keep a record of the product dispensed for a period of 5 years which shall be made available to an authorised officer on request.

Record keeping for veterinarians

7. (1) A veterinarian shall keep copies of veterinary prescriptions issued by him or her, including those for medicated feed, at his or her premises, that are not held on the national database for a period of at least 5 years. The records shall be made available to an authorised officer on request.

(2) A veterinarian shall maintain, at his or her premises, records which shall be made available to an authorised officer on request, in relation to each client containing at least the following:

(a) the date of each visit to the premises on which the animal or group of animals was seen or the date they were properly assessed,

(b) the identification of the animals clinically examined, or the subject of a proper assessment,

(c) the clinical condition diagnosed or disease to be prevented,

(d) details of treatment, including details of all medicinal products, for each clinical condition diagnosed or disease to be prevented,

(e) details of any medicine administered to an animal,

(f) quantity of medicinal product required for the treatment of each clinical condition diagnosed or disease to be prevented,

(g) a cross-reference to any relevant results of laboratory tests, or any other test results undertaken, or records evaluated for the purpose of diagnosis or proper assessment, and

(h) a statement outlining the justification for a veterinary prescription if prescribing an antimicrobial veterinary medicinal product, in particular for metaphylaxis and for prophylaxis.

(3) This Regulation is in addition to the requirements of Article 103(3) of the VMP Regulation in so far as it applies to the sale or supply of medicinal products subject to a prescription.

Emergency dispensing of certain medicinal products by a pharmacist

8. (1) A pharmacist shall not dispense a medicinal product without being in possession of a veterinary prescription, unless requested by a veterinarian who, by reason of an emergency, is unable to furnish the prescription immediately, and only in the following circumstances, namely—

(a) the veterinarian undertakes to furnish a veterinary prescription within 72 hours of its dispensing,

(b) the medicinal product is dispensed in accordance with the directions of the veterinarian requesting it,

(c) the medicinal product is not a controlled drug (within the meaning of the Misuse of Drugs Act 1977 (No. 12 of 1977),

(d) the medicinal product is labelled in accordance with section 13(1) of the Act, other than the requirement under paragraph (b) of that subsection, and

(e) the pharmacist maintains the records required by Article 103(3) of the VMP Regulation in respect of dispensing the product.

(2) A veterinarian who makes a request in accordance with paragraph (1) shall issue a veterinary prescription for the medicinal product and shall at the same time ensure that the prescription is available to the pharmacist concerned and issues to the owner or keeper of the animal within the period specified in paragraph (1)(*a*).

(3) A pharmacist referred to in paragraph (2) shall ensure that the prescription once received is immediately endorsed as dispensed.

(4) If a veterinarian fails to comply with an undertaking under subparagraph (1)(*a*) or paragraph (2), the pharmacist concerned shall not, at any future date, dispense a medicinal product under this Regulation at the request of that veterinarian.

Dispensing and administering of veterinary medicinal products in a research environment

9. For the purposes of clinical or therapeutic treatment of an animal to which the Regulations of 2012 apply—

(a) a veterinary medicinal product prescribed may be dispensed by a veterinarian other than the prescribing veterinarian,

(b) a person may administer a veterinary medicinal product under the direct instruction of the prescribing veterinarian, notwithstanding

the terms of the marketing authorisation of that veterinary medicinal product, and

(c) notwithstanding paragraph (b), a prescription for pentobarbital sodium prescribed under this Regulation, for use by anyone other than a veterinary surgeon, may not exceed 1 gram of active substance.

Dispensing of veterinary medicinal products subject to prescription by persons other than a veterinarian or pharmacist

10. A retail responsible person from a premises to which a retailer's licence relates is permitted to dispense a veterinary medicinal product designated as prescription only medicine (POM), if the person requesting the product has a veterinary prescription relating to the product in his or her possession or a prescription is recorded for that person and for the product and is accessible on the national database, in the case of the following—

(a) an intramammary veterinary medicinal product,

(b) an antifungal veterinary medicinal product,

(c) an antiparasitic veterinary medicinal product,

(d) an immunological veterinary medicinal product,

(e) an injectable digestive stimulant, or

(f) an injectable vitamin and mineral.

Exemption from requirement for manufacturing authorisation

11. A retail responsible person from a premises to which a retailer's licence relates shall not require a manufacturing authorisation to divide or change the outer packaging of intramammary veterinary medicinal products for retail directly to the public.

Retail at distance of antiparasitic veterinary medicinal products subject to prescription

12. (1) A veterinarian or the holder of a licence granted under section 24(8) of the Act may retail at a distance antiparasitic veterinary medicinal products for food-producing animals subject to a prescription within the State.

(2) Subject to Regulation 6(1)(b), veterinary prescriptions shall be dispensed using the national database whenever retail over the internet occurs.

Storage and handling of veterinary medicinal products in retail premises

Receipt of veterinary medicinal products

13. (1) A holder of a retailer's licence shall ensure that—

(a) when receiving veterinary medicinal products—

(i) the arriving consignment is correct,

(ii) the veterinary medicinal products originate from approved suppliers, and

(iii) they have not been damaged during transport, and

(b) veterinary medicinal products requiring special storage or security measures shall be prioritised and, once appropriate checks have been conducted, those products shall immediately be transferred to appropriate storage facilities.

Storage and handling of veterinary medicinal products

(2) A holder of a retailer's licence shall ensure that—

(a) veterinary medicinal products are stored in accordance with the manufacturer's instructions and the summary of product characteristics,

(b) veterinary medicinal products—

(i) are stored separately from other products likely to alter them,

(ii) are protected from the harmful effects of light, temperature, moisture, and other external factors,

(iii) which require special storage conditions, are stored in accordance with those conditions,

(iv) are handled and stored in such a manner as to prevent spillage, breakage, contamination or mix-ups, and

(v) are not stored directly on the floor, unless the package is designed to allow for such storage.

(c) verification of transported and stored veterinary medicinal products are carried out to ensure these products have not been or are not subjected to higher maximum exposure temperatures than those indicated by the manufacturer,

(d) retail operations are performed to ensure that appropriate storage conditions are maintained and allow for appropriate security of stocks,

(e) stock is rotated according to the 'first expiry, first out' principle,

(f) veterinary medicinal products, including immunological veterinary medicinal products subject to a prescription are not to be exposed for sale, on display or accessible to the general public,

(g) pest control measures are in place to prevent entry of rodents and other pests to the premises, and

(h) a risk assessment of delivery routes is used to determine where temperature controls are required as part of a delivery service provided.

Returns of veterinary medicinal products

(3) A holder of a retailer's licence shall ensure that—

(a) a returned veterinary medicinal product is handled according to a written, risk-based process, considering the nature of the veterinary medicinal product concerned, the reason for the return, any special storage conditions required and the time elapsed since it was supplied,

(b) the premises where veterinary medicinal products are stored has a secure, lockable, and separate quarantine area for the storage, prior to return or disposal, of expired, returned or damaged stock, and

(c) the quarantine area referred to in paragraph (b)—

(i) is also used for the temporary storage of products subject to recall due to quality defect or for reasons relating to pharmacovigilance provided for under the VMP Regulation, and

(ii) when recalled products are stored in this area, they are clearly segregated from other products stored in the same area and identified as recalled products.

Fees relating to licence or registration applications or alterations

14. The fee to accompany an application for, or alteration of, any of the following is—

(a) €250, in respect of a retailer's licence,

(b) €100, in respect of a retailer's internet licence,

(c) €50, in respect of entry on the Companion Animal Medicine Retailers' Register,

(d) €100, in respect of a licence issued under section 23(3) of the Act,

(e) €150, in respect of a licence issued under section 31(1)(a) of the Act, and

(f) €150, in respect of a licence issued under section 31(1)(b) of the Act.

Obligations in relation to recall or suspension of sale or supply of medicinal product

15. (1) A person who sells or supplies a medicinal product shall before any action is taken discuss with the HPRA or the Minister, as applicable, the details of any proposed recall or suspension from sale or supply and shall comply with any instructions provided by the HPRA or the Minister in relation to the action, including how it should be communicated.

(2) A person who sells or supplies a medicinal product shall notify the HPRA or the Minister, as applicable, of any action taken to suspend the sale or supply of the product or recall of the product, together with the reasons for the action, if it concerns the efficacy, safety (including the protection of public health), or quality of the product, or its compliance status with respect to the marketing authorisation.

Supply by holder of wholesale distribution authorisation

16. The holder of a wholesale distribution authorisation shall, in addition to those persons and entities set out in Article 101(2) of the VMP Regulation, supply veterinary medicinal products upon request to the following, namely—

(a) the Minister, the HPRA or a local authority (within the meaning of the Local Government Act 2001 (No. 37 of 2001)) concerned for the purposes of official controls or in the interests of public or animal health and welfare, and

(b) approved establishments under Article 13(1) of the Medicated Feed Regulation, but only with regard to a premix for a medicated feedingstuff.

Advertising of veterinary medicinal products

17. (1) The advertising of authorised immunological veterinary medicinal products or immunological veterinary medicinal products imported under a special import licence or special import notification, when subject to a prescription, is only permitted in respect of the owner or keeper of an animal, other than a domestic pet owner or keeper, and where the advertisement includes an express invitation to the owner or keeper to consult a veterinarian about the veterinary medicinal product being advertised.

(2) The advertising of non-immunological veterinary medicinal products imported under a special import licence or special import notification—

(a) for the purposes of use under Article 112, 113 or 114 of the VMP Regulation, is prohibited, and

(b) for the purposes of use under Article 116 of the VMP Regulation, is permitted only to veterinarians, pharmacists and those permitted to supply in accordance with the routes of retail (within the meaning of section 10 of the Act).

(3) Paragraphs (1) and (2) are penal provisions to which subsection (3) of section 30 of the Act applies.

Licensing of import of medicinal products in certain circumstances

18. (1) By way of derogation from 88(1)(c) of the VMP Regulation the import from a third country of a veterinary medicinal product to be used in accordance with Article 110, or of medicinal products to be used in accordance with Article 112, 113 or 114, of the VMP Regulation may be undertaken by holders of a wholesale distribution authorisation.

(2) A person may not supply or use a medicinal product imported under special import licence other than in accordance with the conditions of the licence.

Record keeping for owners and keepers of food producing animals

19. (1) The record of all medicinal products to be kept in accordance with Articles 108 and 109 of the VMP Regulation by the owner or keeper of a food producing animal shall also include medicinal products not subject to a prescription.

(2) In addition to paragraph (1) the following must also be kept by the owner or keeper of a food producing animal, namely –

(a) the name of the person who administered a medicinal product to such an animal,

(b) date of expiry of the withdrawal period,

(c) the quantities of expired or waste medicinal products and unused, expired or waste medicated feed and intermediate products, and

(d) the method of disposal of that referred to in subparagraph (c).

(3) Records referred to in this Regulation, including copies of veterinary prescriptions, shall be kept by the owner or keeper of a food producing animal for a period of at least 5 years and those records shall be made available on request to an authorised officer.

Disposal of unused and unopened, expired or recalled veterinary medicinal products or medicated feed

20. (1) The following persons, namely—

(a) the holder of a veterinary medicinal product marketing authorisation, or a person carrying out activities on his or her behalf, and

(b) a person who imports a veterinary medicinal product under a special import licence or special import notification,

shall maintain a system designed to ensure, in accordance with Article 117 of the VMP Regulation, that a veterinary medicinal product including the immediate packaging supplied by him or her in the State, which is unused and unopened, expired or recalled, is disposed of.

(2) A person referred to in paragraph (1) shall put in place the necessary arrangements with –

(a) a holder of a wholesale distribution authorisation,

(b) a veterinarian,

(c) a pharmacist,

(d) a holder of a veterinary medicinal product retailer's licence, or

(e) a person registered as a companion animal medicines seller,

to whom he or she supplies a veterinary medicinal product, to receive a veterinary medicinal product that is unused and unopened, expired or recalled from those persons.

(3) A holder of a wholesale distribution authorisation, veterinarian, pharmacist, holder of a veterinary medicinal product retailer's licence, person registered as a companion animal medicines seller shall have in place the necessary systems to receive from those they supply to, a veterinary medicinal product that is unused and unopened, expired or recalled for the return to the person from whom they purchased or to a place designated by the Minister, that veterinary medicinal product and in addition take steps to ensure that customers are aware of the arrangements.

(4) The owner or keeper of an animal—

(a) shall ensure an —

(i) unused and unopened, expired or recalled veterinary medicinal product, or

(ii) unused and unopened, expired or recalled medicated feed, or intermediate product,

including its immediate packaging, is disposed of in an appropriate manner, and

(b) may return such products or feed to—

(i) the person from whom the owner or keeper purchased that product or feed, or

(ii) a place designated by the Minister in respect of such owners and keepers of animals specified by the Minister.

(5) Manufacturers of medicated feed or intermediate products approved in accordance with Article 13 of the Medicated Feed Regulation, must have in place systems to receive from those they supply to, unused and unopened, expired, or recalled medicated feed and intermediate products, ensure they are disposed of safely to the satisfaction of the Minister, having regard to the environment, public health and any guidelines issued by the Minister on such disposal, and in addition take steps to ensure that customers are aware of the arrangements.

(6) Records of the return or disposal of unused and unopened, expired or recalled veterinary medicinal products, unused and unopened, expired or recalled medicated feed or intermediate products shall be kept by those referred to in this Regulation for a period of at least 5 years and be made available on request to an authorised officer.

(7) In this Regulation "expired" in relation to a veterinary medicinal product medicated feed or intermediate product, means the product or feed in addition to being expired, has not been opened or used and is non-hazardous, other than where it is being returned from the owner or keeper of an animal to the veterinarian from whom they have been supplied with such product or to a place designated by the Minister.

National database

Electronic prescriptions

21. (1) An electronic veterinary prescription for a medicinal product shall contain the elements listed in Article 105 of the VMP Regulation and Regulation 3(2).

(2) An electronic veterinary prescription for medicated feed shall contain the elements listed in Annex V to the Medicated Feed Regulation.

(3) Notification to the owner or keeper of an animal of the existence of a veterinary prescription being available for dispensing on the national database shall be issued by short messaging service (SMS) message or electronic mail or both and shall contain the prescription identifier.

(4) Notifications as referred to in paragraph (3) are not veterinary prescriptions and shall not contain all of the elements of a veterinary prescription detailed in paragraph (1).

(5) A veterinary prescription that is fully dispensed at the time of issuing must be marked and recorded as such by the prescribing veterinarian before issuing to the owner or keeper of an animal.

(6) An undispensed or part dispensed electronic veterinary prescription may only be issued by way of the national database.

Information transmission to and from national database

(7) If recorded on another database, the method of transfer of data to and from the national database shall be by application programming interface (API) technology.

Registration of persons on national database

(8) The following persons require registration on the national database in order to use and access it—

(a) owners or keepers of an animal (other than a companion animal),

(b) veterinary premises,

(c) veterinarians,

(d) administration employees at a veterinary premises,

(e) holders of a retailer's licence,

(f) retail responsible persons or veterinary nurses operating from a licenced retail premises or a pharmacy,

(g) retail pharmacy businesses (within the meaning of the Pharmacy Act 2007 (No. 20 of 2007)),

(h) pharmacists,

(i) persons providing computer software to veterinary practices to write prescriptions, and

(j) persons providing computer software to dispense veterinary prescriptions.

Regulation 5

SCHEDULE

Proper Assessment Protocol for the prescribing of antiparasitic veterinary medicinal products

Requirements of the Protocol

The Proper Assessment Protocol shall –

(a) be drawn up by the prescribing veterinarian,

(b) be in writing (including in electronic format),

(c) include the prescribing veterinarian's Veterinary Council of Ireland registration number,

(d) include the date the protocol was drawn up,

(e) include the prescription number, and

(f) contain at least the following information set out in the form below.

Proper Assessment Protocol for the prescribing of antiparasitic veterinary medicinal products

1. Herdowner name and herd number details

2. Confirm that the animal owner/keeper has affirmed that no animals are currently showing clinical signs of disease

3. Category of animals

(Provide details of age, sex, weight, breed(s) and system of farming. If developing a Proper Assessment Protocol for different groups/categories of animals, where there are different risks and/or control strategies, these must be described and accounted for separately.)

4. Farm details

(Provide details of farm relevant to potential parasitic risk including but not limited to size, soil type, stocking rate, system(s) of production, grazing patterns/systems or feeding system.)

5. Use of antiparasitic veterinary medicinal products

(Provide details of general farm use of antiparasitics in the previous 12 months including treatment of all categories of animals on farm and products used. Provide any diagnostic evidence of worm or ectoparasite burdens, such as faecal egg count, skin scrape, assessment of treatment effectiveness (faecal egg count reduction test) etc.

6. Evidence of antiparasitic resistance (shall contain any evidence of confirmed antiparasitic resistance on farm e.g. FECRT)

7. Investigate and record details of intervention strategies and previous treatment for the parasite(s) class/category now being considered (provide details of previous treatment(s) for parasite to be targeted in the last 3 years. Provide any previous clinical history of parasite to be targeted in recent years.)

8. Antiparasitic husbandry practices

(Provide details of on farm husbandry practices focused on reducing antiparasitic resistance,

such as refugia, grazing patterns, biosecurity.)

9. Recommendation of treatment

(Shall include a statement outlining the justification for antiparasitic product to be prescribed as well as any other husbandry/grazing/management recommendations for control of parasites.)

L.S.

GIVEN under my Official Seal,
12 September, 2024.

CHARLIE MCCONALOGUE,
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 supplement in Irish law Regulation (EU) 2019/6 relating to veterinary medicinal products and Regulation (EU) 2019/4 relating to medicated feed and provide for the following:

- the issuing and dispensing of medicinal products subject to a veterinary prescription;
- the operation of a parasite control programme;
- record keeping for veterinarians and owners and keepers of food-producing animals;
- matters on the retail and wholesale of veterinary medicinal products;
- retail at a distance of such products;
- storage of such products;
- advertising of such products;
- setting fees in relation to licences issued;
- matters to be provided under national law in the above EU Regulations;
- the operation of the national database.

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