

Written Submission of The Veterinary Council of Ireland to the Joint Oireachtas Committee on Agriculture, Food and the Marine to inform their pre-legislative scrutiny of the Veterinary Medicinal Products Medicated Feed and Fertilisers Regulation Bill 2022.

11th October 2022

The Veterinary Council of Ireland welcomes the invite from the Joint Oireachtas Committee on Agriculture, Food and the Marine to make a written submission on the matters currently under consideration by the Committee, relating to their pre-legislative scrutiny of the Veterinary Medicinal Products Medicated Feed and Fertilisers Regulation Bill 2022 (“the Bill”). Our submission will be brief however the Veterinary Council remains at the disposal of the Joint Oireachtas Committee to inform or assist their deliberations at any time.

Independent Statutory Regulator

The Veterinary Council is the independent statutory body responsible for the regulation and management of the veterinary professions, being veterinary practitioners and veterinary nurses in Ireland.

The principal function of the Veterinary Council is to regulate the practise of veterinary medicine and veterinary nursing in the Republic of Ireland, in the interest of animal health and welfare and in the interest of public health.

The functions of the Veterinary Council include protection of the public through the supervision of veterinary education, the maintenance of the Register of veterinary practitioners and veterinary nurses, the registration of veterinary practice premises, and through disciplinary action in cases of professional misconduct.

General Comment on Bill / EU 2019 Requirements

The general purpose of the Bill is to safeguard public and animal health and protect the environment. There is an increasing awareness of the requirement for prudence in the use of medicines in the human and animal domains; it is acknowledged that human, animal and environmental health are inextricably linked. This link is through consumption of animal products, water quality and other environmental matters. Restrictions on veterinary medicinal products in foodstuffs of animal origin have long been in place so that foodstuffs obtained from animals treated with veterinary medicinal products do not contain residues of that medicine or its metabolites which might constitute a health hazard for the consumer.

This Bill is required to give effect to some matters arising as a result of the EU Veterinary Medicinal Products Regulations 2019/6.

The Bill provides for:

- The making of regulations on the retailing of veterinary medicinal products including sales on the internet which are not expressly provided for in the Veterinary Medicinal Products Regulations and will be regulated for in secondary legislation by the Minister in accordance with the provisions of the Bill.
- The making of regulations on the licencing of the importation of certain veterinary medicinal products and medicated feed in circumstances permitted under EU law.
- The making of regulations on the possession, administration and storage of veterinary medicinal products and medicated feed and the enforcement powers of authorised officers.
- The repeal of the Animal Remedies Act 1993.
- The creation of a national database, to be known as the *National Veterinary Prescription System*, a digital online system which will facilitate and obligate the recording of veterinary prescriptions by veterinarians and the dispensing of the veterinary medicinal product/medicated feed by a registered dispensing outlet, Co-Op (Licenced Merchant), Pharmacy or Feed Mill. This NVPS system arises to meet two requirements, firstly to assist DAFM in their medicine usage reporting requirements to Europe, and second to ensure competition in the market for the supply of veterinary medicinal products, where antiparasitic products will require a veterinary prescription from 1 December 2022, the stated date for the legislative requirement to come into force.
- In addition to veterinary medicinal products and medicated feed, the Bill, we understand that the Bill, when enacted, will enable the Minister to capture and process information on the import, manufacture, sale, supply and use of fertiliser in the State. It will enable data related to fertilisers and lime to be collected from the point of import into the country until sale to end user. It will provide for the establishment of a National Fertiliser Database which will encompass the registration of "fertiliser economic operators" and "professional fertiliser end users".

It is also relevant to note the Report of the Task Force on the method of supply of antiparasitic veterinary medicinal products that are intended for food-producing species, established by the Health Products Regulatory Authority (the "HPRA") and report published in December 2019. That Task Force determined that there is widespread resistance to antiparasitic medicines in parasites of livestock in Ireland, recommending that antiparasitic products supplied without a veterinary prescription do not comply with all of the criteria in Article 34 of the Veterinary Medicinal Products Regulations. This in effect determined that a previous

derogation relied upon was no longer valid due to increasing resistance rates and thus recommending that a veterinary prescription will be required for antiparasitic products, to increase the regulation of the products, in the interests of animal health and welfare and public health.

The National Veterinary Prescription System, as developed by the Department of Agriculture, Food and the Marine, will ensure access and competition in relation to the supply and availability of medicinal products, enabling any customer with a veterinary prescription, to obtain the medicinal products from a supplier of their choice, such as a pharmacy, licensed merchant or the prescribing veterinary practitioner.

Specific requested amendments to the Bill

There are a number of elements to the Bill which the VCI believe could be enhanced to better protect and safeguard access to these medicines and we would welcome consideration on proposals in relation to the sections of the Bill highlighted below.

1. National Database

Section 7(4) Information held on the national database –

(a) May be shared with the following persons:

- (i) the Food Safety Authority of Ireland for the purpose of performing its regulatory functions
- (ii) the Health Products Regulatory Authority in their role as a competent authority for the VMP regulation
- (iii) the Veterinary Council of Ireland for purposes relating to fitness to practice hearings

It is suggested that Section 7(4) (iii) this should read "*the Veterinary Council for purposes associated with its regulatory functions*" to bring it in line with the wording for the Food Safety Authority of Ireland or alternatively "*for the performance of its functions as set out in the Veterinary Practice Act, 2005*". This is for reasons including that the Veterinary Council has additional statutory functions for which this information will be needed, including the power to investigate (via Authorised Officers) and prosecute for various offences under Part 10 of our legislation, the Veterinary Practice Act 2005 (as amended), which is largely unconnected with fitness to practise hearings. It would be important that there are no inadvertent limitations to prevent this information being provided to us, or to curtail our use of it.

2. Proposed inclusion of reference to veterinary premises, COS, exempted place or state premises

Section 7(5) provides that "*The Minister may make regulations in relation to the operation of the national database including inter alia –*

- (a) specifying the manner, method or form of recording information on the national database*
- (b) determining the form of the electronic prescription or notification of the existence of a prescription on the national database*
- (c) ...*
- (d) ...*
- (e) Providing for the registration of veterinarians or other specified persons on the national database"*

In accordance with section 106 of our legislation, the Veterinary Practice Act 2005, a registered veterinary practitioner can only practise at or from a premises with a certificate of suitability, with some limited exceptions (e.g., a State premises). Some registered practitioners are non-practising (e.g., retired) but any veterinary practitioner who is practising will have a certificate of suitability number for the premises at or from which they practise, or will be associated with a state premises or exempted place. This certificate of suitability number, relevant to all veterinary practitioners in private practice, should be recorded in the national database, together with the identity and registration number of each practitioner.

Similarly, we anticipate that when regulations are made under section 6 of the Bill, they will specify that a certificate of suitability number be included as information that must be contained on a veterinary prescription, written by a veterinary practitioner in private practice, or capturing any prescriptions issued by those persons in the employment of the state, categorising their association with any state premises or exempted place.

3. Definitions (Part 2, Chapter 3)

Generally, a lack of definitions in primary legislation can be problematic for those endeavouring to comply and for those tasked with enforcement functions. We make the following comments in relation to the definitions in the Bill.

- A. A veterinary nurse is defined as a person registered with the VCI. However, a veterinarian is not, and it would be useful to have a similar definition for the vet as registered with the VCI included here. In addition, it would seem sensible for the term "veterinary practitioner" to be used throughout the Bill, rather than "veterinarian", given this is the term for vets in the Veterinary Practice Act 2005.

Suggested inclusion: *"Veterinarian means a veterinary practitioner registered under Part 4 of the Veterinary Practice Act 2005".*

OR

Amend to use the phrase "veterinary practitioner" throughout with a definition of *"Veterinary practitioner means a veterinary practitioner registered under Part 4 of the Veterinary Practice Act 2005."*

- B. The term **animal under care**, (i.e., an animal under the care of a veterinary practitioner/practice, where a client patient practice relationship exists to enable the safe treatment and care of an animal based on a threshold of knowledge) is referenced throughout the Bill but not defined. There is a definition in the Animal Health and Welfare (Animal Remedies Veterinary Practice and Veterinary Medicine) Regulations 2017 (which appears to be still in force), where regulation 4(9) provides that:

For the purpose 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.*

For consistency, and to avoid the inevitable confusion as to what is meant by "under the care" in the absence of a definition, the same wording that appears in the 2017 regulations, as recited above, should be included in the Bill.

- C. The term "companion animal" is used in the Bill and should be defined. The following is the definition in S.I. No 786/2007 – European Communities (Animal Remedies) (No. 2) Regulations 2007, which has been revoked – "*companion animal includes a domestic dog, cat, rabbit (other than a rabbit kept for human consumption), a small rodent, cage bird, homing pigeon, terrarium animal and an aquarium fish or an equid declared as not intended for use as food for human consumption in accordance with the European Communities (Equine Stud-Book Competition) Regulations 2004 (S.I. No. 399 of 2004)*";

- D. Similarly, a definition of "food producing animal" should be inserted. The following is the definition in the revoked S.I. No 786/2007 – European Communities (Animal Remedies) (No. 2) Regulations 2007 – *"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 intended for use as food for human consumption in accordance with the European Communities (Equine Stud-Book and Competition) Regulations 2004, (S.I. No. 399 of 2004)"*;
- E. In a similar vein, we recommend the inclusion of a definition of "veterinary prescription" along the lines of the following – *"a written prescription issued by a registered veterinary practitioner in respect of an animal under his or her care that provides for the administration of a veterinary medicinal product to the animal"*. A similar definition existed in the aforementioned S.I. No 786/2007.

4. Restriction on Use of Premises (typographical error to be corrected)

Section 17(1) provides that *"A person shall not use a premises to store a veterinary medicinal product for the purpose of retail unless the premises is*

(d) a premises to which a certificate of suitability granted under section 19 applies "

This should read *"section 109"* of the Veterinary Practice Act 2005.

5. Veterinary Medicinal product retailer's licence

Section 18(3) provides that *"A person, other than a veterinarian supplying their own clients or a pharmacist from a pharmacy shall not retail a veterinary medicinal product from a premises unless the person holds a retailer's licence to retail the product from premises mentioned in the licence"*.

Reference to supplying "their own clients" ought to be amended to refer to "animals under their care" which is the language used in section 15(b) and 23(2) of the Bill. As referred to above, the definition of "under the care" which appears in the Animal Health and Welfare (Animal Remedies Veterinary Practice and Veterinary Medicine) Regulations 2017 should also be inserted. If these changes are made, this would remove the prospect of non-practising veterinary practitioners, such as those without the benefit of professional indemnity insurance and such requirements in the public interest under the Veterinary Practice Act 2005, inadvertently being permitted to supply or retail a veterinary medicinal product to their own clients, as distinct from animals under their care.

6. Use of term "certificate of suitability"

Section 20(4) of the Bill provides that a person who has completed a training course in the proper and safe handling and storage of veterinary medicinal products will be provided with a "certificate of suitability". This term has an important and specific meaning for the Veterinary Council and registered veterinary practice premises, where it relates to a premises at or from which a registered veterinary practitioner can practice veterinary medicine. It is defined in the Veterinary Practice Act 2005. We respectfully suggest a different term is used here to avoid confusion between a veterinary practice premises the subject of a Certificate of Suitability issued by the Veterinary Council, such as a veterinary clinic or hospital etc, and a Licensed Merchant premises the subject of a retail licence issued by the Department of Agriculture, Food and the Marine. Alternative terms such as approved retail premises or certified retail premises might be more appropriate for use in this regard for the avoidance of any confusion.

7. Fixed Premises

Section 23(1) A person shall not retail a veterinary medicinal product other than from a fixed premises-

Section 23 (2) Subsection 1 does not apply to the retail of a veterinary medicinal product in the course of the provision of a veterinary service by a veterinarian for the treatment of an animal under his or her care, with the suggested addition [*associated with a Certificate of Suitability, exempted place or state premises*].

8. Retail at distance

Section 25(9) provides that "*The Minister may grant a licence to –*

(c) a veterinarian supplying his or her own clients"

Reference to supplying "his or her own clients" ought to be amended to refer to "animals under their care", as referred to previously.

9. Forgery (possession of forged documents)

Section 54 (6) (a) appears to excuse Authorised Officers (under the Bill), an officer of customs and members of An Garda Síochána from the offence of having in their possession or control a forged document. Authorised Officers under the Veterinary Practice Act 2005 may also have some documents in their possession. We suggest either

referring to this, or alternatively referring to "those authorised by law" as being exempt from this prohibition.

10 Schedule Part 1 Routes of retail (page 84 of the draft Bill)

1 Prescription only – a medicinal product designated “prescription only” may only be retailed by –

(a) A veterinarian where the animal to which the product is to be administered is under his or her care and he or she has issued a veterinary prescription for the veterinary medicinal product, [*and is associated with a veterinary premises the subject of a Certificate of Suitability granted under section 109 of the Veterinary Practice Act 2005*] (suggested inclusion in italics)

2 (b) A veterinarian where the animal to which the product is to be administered is under his or her care [*and is associated with a veterinary premises the subject of a Certificate of Suitability granted under section 109 of the Veterinary Practice Act 2005*]

3(b) by a veterinarian where the animal to which the product is to be administered is under his or her care [*and is associated with a veterinary premises the subject of a Certificate of Suitability granted under section 109 of the Veterinary Practice Act 2005*]

4(b) by a veterinarian [*and is associated with a veterinary premises the subject of a Certificate of Suitability granted under section 109 of the Veterinary Practice Act 2005*]

Practise of Veterinary Medicine

The Veterinary Council is the statutory body responsible for regulating the practice of veterinary medicine in the State, in the interest of animal health and welfare and in the interest of public health. The practise of veterinary medicine may only be carried out by a veterinary practitioner, suitably qualified and registered with the VCI, with some limited exceptions allowable in relation to research or such projects, authorised or licensed by the Health Products Regulatory Authority.

If an unauthorised or unqualified persons carries out an act of veterinary medicine, he or she has committed an offence, contrary to the public interest and will be liable to prosecution by the VCI before the District Court. Section 54 of the Veterinary Practice Act 2005, as amended, sets out offences in relation to the practise of veterinary medicine or use of title, which states that “*a person, other than a veterinary practitioner, shall not, do or perform any act, matter or thing, the doing or performance of which forms part of the practice of veterinary medicine*”.

The term “Veterinary” is a protected term and may only be used by those persons qualified, insured or indemnified, and authorised to practise veterinary medicine in the State, to protect

both the animal owners and animals in receipt of such treatment and care, ensuring treatment from suitably qualified, insured, competent and regulated professional persons.

Under the Veterinary Practice Act 2005, section 53 sets out that the practice of veterinary medicine includes diagnosing disease, injury, pain, deformity, defect or state of health of an animal, identifying and carrying out treatment, whether surgical or medical in nature, or any such matters, and performing a surgical procedure on an animal.

Pursuant to section 106 of the Veterinary Practice Act 2005, the practice of veterinary medicine must only be undertaken from a premises for which a certificate of suitability has been issued by the Veterinary Council, a state premises, a premises such as a farm where care and treatment is being delivered to an animal under the care of a veterinary practitioner or from an exempted place.

Registration Numbers

The VCI maintains registers of veterinary practitioners, veterinary nurses and veterinary practice premises for which a certificate of suitability has been issued, following inspection by the Veterinary Council. The Veterinary Council ensures that all registered persons meet the necessary standards in terms of education, skill, competence, and professional conduct, to perform their duties, in accordance with the prescribed Codes of Professional Conduct and in accordance with legislative requirements. Any practitioner must be registered with the Veterinary Council to practise as a Veterinary Practitioner or Veterinary Nurse. The Veterinary Council safeguard access and maintenance of the Registers. There are currently 3,379 Veterinary Practitioners and 1,216 Veterinary Nurses and 742 veterinary practice premises registered with the Veterinary Council.

Programmes of Education

The Veterinary Council develops and publishes accreditation standards for programmes of veterinary medicine and veterinary nursing education in Ireland. The Veterinary Council sets the accreditation standards required for any programmes of veterinary education in Ireland to obtain VCI accreditation as a programme of education, graduates of which are entitled to enter the Register of Veterinary Practitioners in Ireland.

The Council works to ensure veterinary education and training remains up to date and is benchmarked to the highest international standards. The Veterinary Council also requires that all veterinary practitioners and veterinary nurses fulfil ongoing professional education requirements to ensure maintenance of competence, knowledge and skills throughout their professional lives. There are currently 5 programmes of veterinary nursing and 1 programme of veterinary medicine accredited by the Veterinary Council in Ireland.

The Veterinary Council provides guidance to veterinary registrants on matters relating to conduct and ethics through their Codes of Professional Conduct for registered Veterinary Practitioners and Veterinary Nurses. The Code of Professional Conduct consists of the rules

and principles which govern veterinary practitioners and veterinary nurses, in the exercise of their profession. The Code of Professional Conduct is binding on all registrants.

Disciplinary

The Veterinary Council is also the designated body to which members of the public may make a complaint against a veterinary practitioner or veterinary nurse. One of the functions of the Veterinary Council is to take disciplinary action in cases of professional misconduct. In 2021, the Veterinary Council received 65 complaints against registered persons and convened 4 Fitness to Practise Inquiries to consider allegations of professional misconduct.

Conclusion

The Veterinary Council is the body tasked with acting in the interest of animal health and welfare and public health, to ensure that services proffered in the delivery of veterinary care and treatment to animals are of a minimum standard, from certified veterinary premises based on educational qualifications and continued professional development and competence, on which members of the public and animal owners can safely rely.

We highlight that the Veterinary Council will always act in the best interests of animal health and welfare and public health, in a reasonable and proportionate manner, discharging our duties as required, through investigation and/or prosecution as appropriate in the public interest.

The Veterinary Council, as an independent statutory body, will continue to work to ensure that the high standards expected and enjoyed in the veterinary industry are upheld, and that the quality of veterinary care in Ireland is provided by those persons suitably qualified and authorised to deliver such services, in the best interests of animal health and welfare, and the public interest.

We remain available to assist the Committee in any matter.

Niamh Muldoon

Registrar & Chief Executive Officer