

**Opening Statement of The Veterinary Council of Ireland to the Joint Oireachtas Committee on
Agriculture and the Marine on Tuesday, 27th April 2021**

The Veterinary Council is represented by Ms. Niamh Muldoon, Registrar and CEO of the Veterinary Council of Ireland, Mr. Joe Moffitt, President of the Veterinary Council of Ireland (Veterinary Practitioner), and Dr. Ailís Ní Riain, Deputy President of the Veterinary Council of Ireland (Medical Practitioner).

On behalf of the Veterinary Council, I welcome the opportunity to discuss this important topic of new EU Veterinary Medicines Regulation (2019/6) with the Joint Oireachtas Committee on Agriculture and the Marine, and I thank you for the invitation to speak before you today.

For information, I have set out in summary the public interest role of the Veterinary Council, as this is very relevant in the context of the discussion today.

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. We represent the public interest.

The Veterinary Council of Ireland is a statutory body set up under the Veterinary Practice Act 2005, as amended, and is under the aegis of the Minister of Agriculture, Food, and the Marine. 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 regulation of veterinary education, the maintenance of the Register of veterinary practitioners and veterinary nurses, the registration of veterinary premises, and through disciplinary action in cases of professional misconduct.

Registration

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 ethics 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 3,015 Veterinary Practitioners and 1,099 Veterinary Nurses 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.

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.

Background - EU Veterinary Medicines Regulation (2019/6)

The European Parliament and the European Council adopted Regulation (EU) 2019/6 in December 2018. The Regulation came into effect on 28 January 2019, following a 5-year period of negotiation. From 28 January 2022, this Regulation will apply directly to all EU Member States, including Ireland. Regulation EU 2019/6 contains new measures for increasing the availability and safety of veterinary medicines and enhances EU action against the threat of Antimicrobial Resistance (AMR).

The new Veterinary Medicines Regulation (EU) 2019/6 will change the existing rules on the authorisation and use of veterinary medicines in the European Union. Regulation 2019/6 replaces Directive 2001/82/ EC and amends the provisions of Regulation (EU) 726/2004 relating to the authorisation and supervision of veterinary medicines.

EU Regulation (2019/6) sets out rules for the sale, manufacture, import, export, supply, distribution, advertisement, control and use of veterinary medicinal products as stated aims in order to:

- stimulate the development of innovative veterinary medicines.
- strengthen EU action to fight Antimicrobial Resistance through specific measures ensuring prudent and responsible use of antimicrobials in animals, including reserving certain antimicrobials for the treatment of infections in people.
- Increase the availability and access to safe and high-quality medicines for veterinary practitioners, farmers and pet owners to treat and prevent the spread of disease in animals.
- Promote better incentives for developing new and innovative veterinary medicines.
- Provide new and enhanced rules to keep antimicrobials (including antibiotics) effective based on a '*One Health One Welfare*' approach for the benefit of animal and public health and every EU citizen.

A particular focus underpinning EU Regulation 2019/6 is a growing understanding of the risks of AMR. The World Health Organisation (WHO) has defined AMR as "a catastrophe that must be managed with the utmost urgency". In animal health, antibiotics are vital 'tools' to protect animal health and welfare in both companion and food producing animals. Reducing the use of antibiotics in both the human and animal health sectors is seen as a key intervention in tackling AMR. The aim of EU Regulation 2019/6 will be to respect these principles while also safeguarding public and animal health and the protection of the environment. The opportunity and challenge in implementing the regulations is to reserve the use of antimicrobials to appropriate circumstances, while ensuring that animal welfare and public health are equally protected.

Antimicrobial Resistance

One of the stated aims of the EU Regulation 2019/6 is to reduce antibiotic use in food producing animals (in particular preventative antibiotic use) in order to address the public health risk of antimicrobial resistance. Antimicrobials are medicine used to treat infections or disease and are essential in both human and animal health. Antimicrobial resistance (AMR) is resistance of a microorganism to an antimicrobial drug that was originally effective for treatment of an infection or disease.

The Regulation includes the following provisions:

- Antibiotics must not be applied routinely
- Antibiotics must not be used to compensate for poor hygiene
- Antibiotics must not compensate for inadequate animal husbandry
- Antibiotics must not compensate for poor farm management
- Antibiotics cannot be used for prophylaxis treatment (preventative treatment to healthy animals) except in exceptional circumstances.
- Antibiotic used for metaphylaxis treatment only when the risk of spread of an infection or of an infectious disease in the group of animals is high and where no other appropriate alternatives are available.
- Restriction of use of certain types of antibiotics (CIAs)
- Veterinary prescription based on clinical examination or other proper assessment
- Veterinary prescriptions only valid for 5 days for antimicrobial medicines
- Veterinary prescriptions limited to the amount required for the treatment concerned

Role of the Veterinary Council in offering definitions of terms in relation to EU Regulation 2019.6

The Veterinary Council, in its public interest role as regulator of the veterinary professions requested by the Department of Agriculture, Food and the Marine to consider offering definitions of the terms contained in the Veterinary Medicines Regulation 2019/6. The Veterinary Council as independent regulator regulating the veterinary professions, issues a Code of Professional Conduct by which all registrants are bound. The recitals to the Veterinary Medicines Regulation 2019/6 refer to national Codes of Professional Conduct for veterinary practitioners and it is a practical approach that such terms be defined in the Code of Professional Conduct for those prescribing veterinary medicines.

In considering these definitions, the Veterinary Council circulated draft definitions in December 2019 and engaged in a series of stakeholder engagements with a view to seeking input, observation and comment from stakeholders, ensuring the proposed definitions are fit for purpose and promote the highest ethical standards in the prescription of veterinary medicines in the interests of animal health and welfare, and public health.

To this end, the Veterinary Council convened meetings with various stakeholders over recent months on the proposed definitions, for inclusion in the VCI Code of Professional Conduct currently under review, on the implementation of Regulation (EU) 2019/6. The stakeholders with whom the Veterinary Council have engaged to date include the Health Products Regulatory Authority, Teagasc, Animal Health Ireland, UCD Subject Matter experts, Agricultural Consultants Association, Irish Farmers Association, Irish Creamery and Milk Suppliers Association, Irish Cattle and Sheep Association, Independent Licensed Merchants Association, Acorn Licensed Merchant Representative, Veterinary Ireland, Irish Pharmaceutical Union, and officials from the Department of Agriculture, Food and the Marine. The Veterinary Council wishes to note our thanks to all parties with whom we have enjoyed engaging and informative meetings with over recent months.

The Veterinary Council acknowledge the varying views on the proposed Veterinary Medicine Regulations 2019/6 held by stakeholders, and have provided definitions in the interests of animal health and welfare, and public health.

At its meeting on Friday, 16th April last, the Veterinary Council approved definitions set out below of the terms contained in the EU Veterinary Medicine Regulations (2019/6), in the interests of animal health and welfare and public health. The Veterinary Council will now focus on the development of guidance for veterinary practitioners regarding the use of dry cow therapy and parasite control, which guidance it is intended will be provided as appendices to the VCI Code of Professional Conduct, to support practitioners in navigating changes in practices in these areas.

A summary of these definitions and rationale is attached below for information.

In Conclusion

The Veterinary Council is the independent statutory body responsible for the regulation and management of the veterinary professions, including the regulation of prescribing of veterinary medicines in Ireland.

The Veterinary Council, having considered the scope and spirit of the of EU Veterinary Medicines Regulation (2019/6) believes the definitions offered by the Veterinary Council to the terms contained in the new Regulation will serve animal health and welfare and public health by reserving use of high-quality medicines to prevent the spread of disease in animals and help to mitigate against the growing threat of AMR.

These definitions and their implications for prescribing veterinary practitioners will be published in the Council's Code of Professional Conduct, which is currently undergoing review and is due for publication later this year.

The Veterinary Council will continue to play their part in the public interest of animal health and welfare and public health, as our nation navigates the implementation of EU Veterinary Medicines Regulation (2019/6). The Veterinary Council will continue to foster best professional practice, in the interests of animal welfare and public interest. The Veterinary Council will continue to work to ensure that the high standards expected in the veterinary professions are upheld, and that quality of veterinary care is continuously improving into the future.

Finally, I would like to thank the Chair and members of this Committee for the invitation to address you today. The President of the Veterinary Council, Mr. Joe Moffitt, the Deputy President, Dr. Ailís Ní Riain, and I would be happy to address any questions the Committee may have.

Niamh Muldoon

Registrar, Veterinary Council of Ireland

Definitions

'Diagnosis of the infectious disease'

This relates to a diagnosis performed by a veterinarian and is based on information gleaned from a variety of sources including:

- i) Findings from a clinical examination
- ii) Interview with the owner or custodian of the animal
- iii) Veterinary history of the patient and its cohorts
- iv) Paraclinical findings as reported by pertinent laboratory tests and radiological studies.

'Clinical examination' by a veterinarian.

A clinical examination of a patient can include measurement of physiological parameters, palpation, auscultation, and percussion as well as any other methodology at the discretion of the attending veterinary practitioner. The clinical examination is interpreted within the context of the clinical history, examination of the environment and if necessary clinico-pathological test results. Any such examination must be undertaken with reasonable care. The Council regards the carrying out of this procedure as a day one competence of all Registrants.

'Any other Proper Assessment of the Health Status of the animal(s) by a veterinarian'

An assessment is a process for obtaining and/or interpreting information relating to the health status of the animal or group of animals by a veterinary practitioner. In the absence of immediate prior clinical examination, any other proper veterinary assessment is only possible within a current Client Patient Practice Relationship and where conditions of ethical veterinary practise have been met.

All such assessments should be based on first-hand knowledge of the historical and current risks to the health of the animal(s) entrusted to the care of the veterinarian. Relevant information includes records of management and health history along with results of ancillary tests, post-mortems, epidemiological investigations along with any other information deemed necessary by the attending veterinary practitioner.

The extent of the information required to make such an assessment for an individual or group of animals is the responsibility of the attending veterinary practitioner and must be undertaken with reasonable care.

All veterinary advice and/or treatments prescribed or carried out on foot of either clinical or other assessments should optimise animal welfare outcomes, clinical success, and public health protection. Animal remedies designated as Prescription Only Medicines (POM) shall not be prescribed solely on the basis of an assessment of animal records or diagnostic test results in the absence of a Client Patient Practice Relationship.

'Justification'

Justification for all veterinary prescriptions and especially antimicrobials rests with the prescribing veterinary practitioner. Whether following a clinical or other proper assessment of the health status of the animal(s) by a veterinary practitioner, there should exist contemporaneous veterinary medical records that demonstrate on-going direct clinical contact with the animal(s). These records, the ancillary information outlined above, and any other information deemed appropriate by the veterinary practitioner should provide the rational justification for all prescriptions in keeping with current prudent prescribing guidelines and legislation.

A '**Veterinarian**' means a veterinary practitioner registered with the Veterinary Council of Ireland, entitled to practise in the Republic of Ireland, and operating within the terms of the Veterinary Practice Act, 2005 (as amended) and the Animal Remedies Regulations and the definition of the Animals under Veterinary Care Guidance issued by the Veterinary Council of Ireland.

A '**Client Patient Practice Relationship**' is an agreement between an animal owner (or designated keeper) and a veterinary practitioner(s) within a veterinary practice to provide veterinary services that demonstrate real and on-going clinical veterinary practitioner/animal contact, as detailed under the Council's '*Animals under Veterinary Care*' Guidance.