

MEMORANDUM OF UNDERSTANDING

between

the Health Products Regulatory Authority

and

the Veterinary Council of Ireland

CONCERNING COOPERATION IN THE REGULATION OF VETERINARY MEDICINAL PRODUCTS

1 BACKGROUND

The Veterinary Council of Ireland ('VCI') established by the Veterinary Practice Act 2005, and the **Health Products Regulatory Authority ('HPRA')** established by the Irish Medicines Board Acts 1995 and 2006 (hereinafter referred to as the '**Participants**') wish to establish a framework for cooperation in the regulation of veterinary medicinal products ('**VMPs**').

2 OBJECTIVES

2.1 The objectives of this Memorandum of Understanding ('**MOU**') in respect of VMPs are:

2.1.1 to promote an understanding between the Participants of each other's regulatory roles, requirements and processes;

2.1.2 to facilitate the exchange of information and documentation relating to the regulation of VMPs and areas of common interest;

2.1.3 to facilitate collaborative activities between the Participants;

2.1.4 to enhance the ability of the Participants in the provision of their respective roles relating to or in connection with animal or public health.

2.2 This MOU represents the understanding reached by the Participants, in particular that:

2.2.1 each Participant has jurisdiction over different areas. This MOU is intended to cover areas of common interest and permit meaningful collaboration between the Participants.

2.2.2 each Participant may limit the scope of disclosure of information to the other Participant particularly if the disclosure may be prejudicial to the commercial interests

of a third party, breach the duty of confidence or privacy, disclose a trade secret, is contrary to the public interest or the interests of the Participant concerned, would be in breach of or inconsistent with statutory obligations or requirements or other obligations and requirements imposed by law.

3 DEFINITIONS

3.1 With respect to this MOU:

- **Data Protection Law** means all data protection and privacy legislation, regulations and guidance applicable from time to time including, without limitation and as applicable:
 - the Data Protection Acts 1988 to 2018 (as amended, supplemented or replaced time to time);
 - EU General Data Protection Regulation (EU) 2016/679 (as amended, supplemented or replaced from time to time) (the "**GDPR**");
 - any applicable guidance or codes of practice issued by the Article 29 Working Party, the European Data Protection Board or the Data Protection Commission from time to time (all as amended, updated or re-enacted from time to time).
- **veterinary medicinal product ("VMP")** means 'veterinary medicinal product' as defined in Regulation (EU) 2019/6

3.2 For the avoidance of doubt, all legislation referred to in this MOU includes all supplements, amendments, and any subsequent replacements that may occur from time to time.

4 AREAS OF COOPERATION

4.1 The Participants having reached the above understanding will:

- 4.1.1 establish avenues of communication with each other to facilitate the exchange of information about their respective fields of regulation and operation of their organisations;
- 4.1.2 establish avenues of communication to facilitate the exchange of information in situations where each Participant obtains information which could be considered relevant to the other Participant's functions;
- 4.1.3 where appropriate, share information, including in support of law enforcement activities; and
- 4.1.4 undertake collaborative activities consistent with this MOU.

5 CONFIDENTIALITY

HPRA

- 5.1 Nothing in this MOU requires the HPRA to release personal data or confidential information to the VCI, except in accordance with law.
- 5.2 The HPRA will make all reasonable efforts to inform the VCI of any effort made by a judicial, legislative or other authority to obtain personal data or confidential information that has been provided by the VCI to the HPRA. If disclosure is required by law, where time allows, the HPRA will consult with the VCI in advance of releasing such information and in all cases will take all reasonable measures to ensure that the information received from the VCI will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.
- 5.3 Unless otherwise required by law, the HPRA will not disclose any information received from the VCI under this MOU, except with the written consent of the VCI.
- 5.4 Unless otherwise required by law, the HPRA will not use the information disclosed to it under this MOU for any other purpose than the performance of its regulatory functions.

VCI

- 5.5 Nothing in this MOU requires the VCI to release personal data or confidential information to the HPRA, except in accordance with law.
- 5.6 The VCI will make all reasonable efforts to inform the HPRA of any effort made by a judicial, legislative or other authority to obtain personal data or confidential information that has been provided by the HPRA to the VCI. If disclosure is required by law, where time allows, the VCI will consult with the HPRA in advance of releasing such information and in all cases the VCI will take all reasonable measures to ensure that the information received from the HPRA will be disclosed in a manner that protects the information from any disclosure that is not required or authorised by law.
- 5.7 Unless otherwise required by law, the VCI will not disclose any information received from the HPRA under this MOU, except with the written consent of the HPRA.
- 5.8 Unless otherwise required by law, the VCI will not use the information disclosed to it under this MOU for any other purpose than the performance of its regulatory functions.

6 DATA PROTECTION

The Participants will comply with their duties as applicable under Data Protection Law and will give each other all reasonable assistance as appropriate or necessary to enable the other to comply with their duties as applicable under Data Protection Law.

7 FINANCIAL ARRANGEMENTS

Each Participant will be solely responsible for the administration and expenditure of its own resources associated with activities conducted under this MOU.

8 VARIATION

- 8.1 The Participants agree to keep the suitability of this MOU under review, and to formally review the MOU every three years from the effective date.
- 8.2 Any provision of this MOU may be amended at any time by the mutual consent in writing of the Participants via their respective signatories.

9 STATUS OF MEMORANDUM OF UNDERSTANDING

This MOU reflects the intentions of the Participants and both Participants recognise the importance of maintaining the confidentiality of confidential material and observing Data Protection Law and will take particular care to do so in respect of any materials shared pursuant to this MOU.

10 EFFECTIVE DATE

This MOU will come into effect upon the date of signature of both signatories and will continue in effect until terminated in accordance with clause 12.

11 DESIGNATED CONTACTS

- 11.1 The liaison officers of the Participants responsible for the administration of this MOU are:
 - 11.1.1 for the HPRA, the person holding the position of **[to be inserted]**;
 - 11.1.2 for the VCI, the person holding the position of **[to be inserted]**.

12 TERMINATION

- 12.1 Either Participant may, at any time, give written notice of termination to the other Participant. This MOU (excepting clause 5 and obligations under Data Protection Law) will terminate six months after the date of receipt of the notice of termination.
- 12.2 The termination of this MOU will not affect the confidentiality undertakings expressed by the Participants in this MOU.

12.3 The termination of this MOU will not affect any commitments given under or as a consequence of this MOU in respect of any arrangement or action taken during the period before the termination takes effect.

Signed 

on this 4th day of November 2024



by Lorraine Nolan, Chief Executive, the Health Products Regulatory Authority (HPRA)

on this 4th day of November 2024



by Niamh Muldoon Chief Executive, the Veterinary Council of Ireland (VCI)