



STATUTORY INSTRUMENTS.

S.I. No. 36 of 2022

EUROPEAN UNION (VETERINARY MEDICINAL PRODUCTS AND
MEDICATED FEED) REGULATIONS 2022

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Contents

Part 1 – General

1. *Citation and commencement*
2. *Interpretation*
3. *Competent authorities*
4. *Revocations*

Part 2 - VMP Regulation - Infringements, penalties, authorisations

5. *Infringements - VMP Regulation*
6. *Penalties - VMP Regulation*
7. *Outer packaging, identification code, derogation, etc. - veterinary medicinal products*
8. *Authorisations, etc. - VMP Regulation*

Part 3 – Medicated Feed Regulation - Infringements, penalties, approvals

9. *Infringements - Medicated Feed Regulation*
10. *Penalties – Medicated Feed Regulation*
11. *Approvals - Medicated Feed Regulation*

Part 4 – Commission Implementing and Delegated Acts

12. *Implementing Regulation (EU) 2021/16*
13. *Delegated Regulation (EU) 2021/577*
14. *Delegated Regulation (EU) 2021/578*
15. *Implementing Regulation (EU) 2021/1248*
16. *Implementing Regulation (EU) 2021/1280*
17. *Implementing Regulation (EU) 2021/1281*
18. *Implementing Regulation (EU) 2021/1904*

Part 5 – Miscellaneous – VMP Regulation

19. *Determining and exemption of veterinary medicinal products*
20. *Prohibiting the supply of or recalling of veterinary medicinal products, recording product complaints, etc.*

21. *Certain animal disease situations*
22. *Return of unused, waste or expired veterinary medicinal products*
23. *Administration of veterinary medicinal products*
24. *Possession of veterinary medicinal product, etc.*
25. *Prohibition of false or misleading particulars.*
26. *Guidelines – Article 59 of VMP Regulation*

Part 6 – Enforcement

27. *Definitions (Part 6)*
28. *Inspection by authorised officers, etc.*
29. *Search warrant*
30. *Search of suspects and stopping of vehicles*
31. *Power of arrest*
32. *Saving for certain power*
33. *Obstruction.*
34. *Compliance notice*
35. *Appeal against compliance notice*
36. *Seizure and detention for non-compliance with compliance notice*
37. *Impersonation of an authorised officer, etc. and possession of certain identity documents*
38. *Evidence of class of veterinary medicinal product to which a contravention relates*
39. *Disposal of things seized*
40. *Evidence on certificate, etc.*
41. *Offences by bodies corporate, etc.*
42. *Fixed payment notice*
43. *Service of notices and notifications*
44. *Summary proceedings*
45. *Disqualification from keeping animals, veterinary medicinal products, etc.*
46. *Forfeiture of animal, veterinary medicinal product, or medicated feed, etc.*
47. *Recoupment of costs of certain disposals*
48. *Forgery*

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I, CHARLIE MCCONALOGUE, Minister for Agriculture, Food and the Marine, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) for the purpose of giving full effect to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018¹, and the European Commission implementing and delegated acts referred to in the following regulations adopted thereunder, and Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018², herby make the following regulations:

Part 1 - General

Citation and commencement

1. (1) These Regulations may be cited as the European Union (Veterinary Medicinal Products and Medicated Feed) Regulations 2022.

(2) These Regulations come into operation on 28 January 2022.

Interpretation

2. (1) In these Regulations —

“Article” unless otherwise indicated, means —

(a) in Part 2 (Regulations 5 to 8), an Article of the VMP Regulation;

(b) in Part 3 (Regulations 9, 10 and 11), an Article of the Medicated Feed Regulation;

“authorised officer” shall be construed in accordance with Regulation 28;

“competent authority” shall be construed in accordance with Regulation 3;

“Commission delegated act” means Delegated Regulation (EU) 2021/577 or Delegated Regulation (EU) 2021/578;

“Commission implementing act” means Implementing Regulation (EU) 2021/16, Implementing Regulation (EU) 2021/1248, Implementing Regulation (EU) 2021/1280, Implementing Regulation (EU) 2021/1281 or Implementing Regulation (EU) 2021/1904;

“Delegated Regulation (EU) 2021/577” means Commission Delegated Regulation (EU) 2021/577 of 29 January 2021³;

¹ OJ No. L 4, 7.1.2019, p.43

² OJ No. L 4, 7.01.2019, p.1

³ OJ No. L 123, 9.4.2021, p. 3

“Delegated Regulation (EU) 2021/578” means Commission Delegated Regulation (EU) 2021/578 of 29 January 2021⁴;

“Implementing Regulation (EU) 2021/16” means Commission Implementing Regulation (EU) 2021/16 of 8 January 2021⁵;

“Implementing Regulation (EU) 2021/1248” means Commission Implementing Regulation (EU) 2021/1248 of 29 July 2021⁶;

“Implementing Regulation (EU) 2021/1280” means Commission Implementing Regulation (EU) 2021/1280 of 2 August 2021⁷;

“Implementing Regulation (EU) 2021/1281” means Commission Implementing Regulation (EU) 2021/1281 of 2 August 2021⁸;

“Implementing Regulation (EU) 2021/1904” means Commission Implementing Regulation (EU) 2021/1904 of 29 October 2021⁹;

“HPRA” means the Health Products Regulatory Authority;

“Medicated Feed Regulation” means Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018²;

“Minister” means Minister for Agriculture, Food and the Marine;

“VMP Regulation” means Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018¹;

“veterinarian” means a veterinary practitioner registered under Part 4 of the Veterinary Practice Act 2005 (No. 22 of 2005).

(2) A word or expression that is used in these Regulations and is also used in the VMP Regulation or a Commission delegated or implementing act or the Medicated Feed Regulation has, unless the contrary intention appears, the same meaning in these Regulations as it has in the VMP Regulation or a Commission delegated or implementing act or the Medicated Feed Regulation.

Competent authorities

3. (1) The competent authority designated in the State to carry out tasks under the VMP Regulation is —

- (a) the HPRA, in the case of—
 - (i) marketing authorisations under Chapter II in accordance with the procedures laid down in Chapter III,
 - (ii) approval of clinical trials under Article 9,
 - (iii) in Chapter IV, Article 56, changing terms of marketing authorisations under Section 3, Articles 70, 71 and 72 and Sections 5 and 6,

⁴ OJ No. L 123, 9.4. 2021, p. 7

⁵ OJ No. L 7, 11.1. 2021, p. 1

⁶ OJ No. L 272, 30.7.2021, p. 46

⁷ OJ No. L 279, 3.8.2021, p. 1

⁸ OJ No. L 279, 3.8.2021, p. 15

⁹ OJ No. L 387, 3.11.2021, p. 133

- (iv) registration of homeopathic veterinary medicinal products under Chapter V,
 - (v) manufacturing authorisation under Chapter VI and in that Chapter (including making a decision under Article 88(2)), Article 91(3) in respect of recording manufacturing on the database, Articles 94, and 97(5) and 98,
 - (vi) registration of active substance manufacturers, importers and distributors in Article 95, and in respect of recording related information on the database pursuant to Article 91(3),
 - (vii) in Chapter VII, Articles 102, 123, 125, 126, 127, 128 and 129, 130 and
 - (viii) in Chapter IX, Articles 133, 134, 151, 152, 155, 157 and 159,
- and
- (b) the Minister, in the case of—
 - (i) collecting data under Article 57,
 - (ii) Article 91(3) in respect of recording wholesale distribution on the database,
 - (iii) granting wholesale distribution authorisation under Section 1 of Chapter VII and its suspension or revocation under Article 131, and
 - (iv) derogations under Articles 104(2), 110, 116 and 120(2).

(2) The HPRa may decide if a manufacturing authorisation is not required for the purposes of Article 88(2) of the VMP Regulation.

(3) The Minister is the competent authority in the State for the Medicated Feed Regulation.

Revocations

4. (1) The following are revoked:

- (a) the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S. I. No. 786 of 2007);
- (b) the European Communities (Animal Remedies) (Amendment) Regulations 2009 (S. I. No. 182 of 2009);
- (c) the European Communities (Animal Remedies) (Amendment) Regulations 2012 (S. I. No. 262 of 2012);
- (d) the European Communities (Animal Remedies) (Amendment) Regulations 2014 (S. I. No. 162 of 2014);
- (e) the European Communities (Animal Remedies) (Amendment) (No. 2) Regulations 2014 (S. I. No. 361 of 2014);

(f) the European Communities (Animal Remedies) (Amendment) Regulations 2016 (S. I. No. 278 of 2016).

(2) The European Communities (Animal Remedies and Medicated feedingstuffs) Regulations 1994 (S. I. No. 176 of 1994) are revoked.

Part 2 - VMP Regulation -Infringements, penalties, authorisations

Infringements - VMP Regulation

5. (1) A person who places on the market a veterinary medicinal product without holding a marketing authorisation granted by the competent authority or the European Commission for the product in contravention of Article 5(1) commits an offence.

(2) A person who conducts a clinical trial without approval under Article 9 commits an offence.

(3) A person who fails to comply with Section 4 of Chapter II of the VMP Regulation in respect of labelling and package leaflets commits an offence.

(4) The holder of a marketing authorisation or a registration of homeopathic veterinary medicinal products who fails to comply with Article 58, 76, 77 or 81 commits an offence.

(5) A qualified person responsible for pharmacovigilance who fails to comply with Article 78(1) commits an offence.

(6) A person who makes available a homeopathic veterinary medicinal product which is not registered in accordance with Chapter V of the VMP Regulation commits an offence.

(7) A person who engages in any of the activities referred to in Article 88(1) without holding a manufacturing authorisation commits an offence.

(8) The holder of a manufacturing authorisation who fails to comply with Article 93 commits an offence.

(9) An importer, manufacturer or a distributor of an active substance used as starting materials in veterinary medicinal products who fails to register their activity in accordance with Article 95 commits an offence.

(10) The holder of a manufacturing authorisation who fails to keep records in accordance with Article 96 commits an offence.

(11) The holder of a manufacturing authorisation or a qualified person who fails to comply with Article 97 commits an offence.

(12) A person who is not the holder of a wholesale distribution authorisation who carries out wholesale distribution of veterinary medicinal products commits an offence.

(13) A wholesale distributor who fails to comply—

(a) with the obligations of wholesale distributors under Article 101, or

(b) for the purpose of parallel trade in veterinary medicinal products, with Article 102,

commits an offence.

(14) A retailer of veterinary medicinal products who fails to comply with Article 103 commits an offence.

(15) A retailer of veterinary medicinal products retailing veterinary medicinal products at a distance who fails to comply with Article 104(1) or (5) commits an offence.

(16) A person who issues a veterinary prescription that fails to comply with the requirements set out in Article 105 commits an offence.

(17) A person who fails to comply with Article 106(1) by using a veterinary medicinal product other than in accordance with the terms of its marketing authorisation commits an offence.

(18) A person who fails to comply with Article 107 in the use of antimicrobial medicinal products commits an offence.

(19) The owner or keeper of a food-producing animal who fails to keep records in accordance with Article 108 commits an offence.

(20) A veterinarian referred to in Article 111(1) who fails to comply with that paragraph commits an offence.

(21) A veterinarian who fails to comply with Article 112, 113 or 114 when using medicinal products outside the terms of the marketing authorisations commits an offence.

(22) A veterinarian who fails to comply with Article 115 in respect of the withdrawal period for medicinal products used outside the terms of the marketing authorisation in food-producing animals commits an offence.

(23) A person who advertises veterinary medicinal products other than in accordance with Article 119 or 120 commits an offence.

(24) A person who promotes medicinal products used in animals in contravention of Article 121 commits an offence.

(25) The holder of a marketing authorisation who fails to comply with Article 127(1) or 128 in respect of the results of the control test carried out on a veterinary medicinal product commits an offence.

(26) A person who fails to comply with temporary safety restrictions imposed under Article 129 commits an offence.

(27) A person who supplies, fails to cease to supply or fails to recall a veterinary medicinal product the supply of which is prohibited or recalled under Article 134 commits an offence.

Penalties - VMP Regulation

6. A person who commits an offence under —
 - (a) paragraph (3), (4), (5), (6), (8), (9), (10), (11), (13), (23), (24) or (25) of Regulation 5, is liable on summary conviction to a class A fine, or

- (b) paragraph (1), (2), (7), (12), (14), (15), (16), (17), (18), (19), (20), (21), (22), (26) or (27) of Regulation 5, is liable —
 - (i) on summary conviction, to a class A fine, or
 - (ii) on conviction on indictment, to a fine not exceeding €300,000.

Outer packaging, identification code, derogation, etc. - veterinary medicinal products

7. (1) The HPRA may allow an identification code to be added on the immediate or outer packaging of a veterinary medicinal product in addition to the information referred to in Article 10(1) and 11(1).

(2) The HPRA may, on request by an applicant, allow on the immediate or outer packaging of a veterinary medicinal product additional useful information referred to in Article 13.

(3) A packaging leaflet shall be made available on paper and in addition, optionally electronically.

(4) A person who fails to comply with paragraph (3) commits an offence and is liable on summary conviction to a class A fine.

Authorisations, etc. - VMP Regulation

8. (1) A marketing, manufacturing or distribution authorisation or approval for clinical trial or parallel trade shall contain such terms as the competent authority decides. The authorisation or approval may be suspended or revoked if any of the terms attached to it are not complied with.

(2) The competent authority shall grant, refuse, suspend, revoke or amend by way of variation a marketing, manufacturing or distribution authorisation or clinical trial or parallel trade approval or registration of homeopathic veterinary medicinal products under the VMP Regulation.

(3) Applications to the competent authority for authorisation or approval or registration or amendments to such applications under the VMP Regulation shall be made in writing, or electronically to the competent authority in such form and manner as it decides accompanied by the fee to cover the costs of administration and such information as the competent authority decides.

(4) Decisions to grant, refuse, suspend, revoke or amend by way of variation a marketing authorisation, or a registration of a homeopathic veterinary medicinal product by the competent authority shall be published by the competent authority and in such form as it decides.

(5) Except in the circumstances set out in Section 6 of Chapter III or Section 6 of Chapter IV of the VMP Regulation, where the European Commission takes a decision, the competent authority shall inform the applicant of any proposed refusal, or the holder of an authorisation approval or registration of any proposed suspension, revocation or amendment by way of variation, of an authorisation, approval or registration under the VMP Regulation made by the competent authority. In relation to the competent authority's proposal, the applicant or

holder may within such period as the competent authority allows, being not less than 14 days, make representations in writing to the competent authority in relation to the proposal, who shall consider and inform the applicant or holder of its decision.

(6) If an applicant or holder is aggrieved by a decision of the competent authority under paragraph (5) in respect of representations made and considered, they may request the Minister or the HPRA's Advisory Committee for Veterinary Medicines, as the case may be, not later than 21 days after notification of the decision, to establish a panel to adjudicate on the matter. The Minister or the HPRA's Advisory Committee for Veterinary Medicines, unless they consider the request vexatious, shall establish a panel with one or more persons, who he or she considers are suitably qualified and independent to adjudicate on the matter. The panel shall set its own procedure and adjudicate on the matter. The decision of the panel is final, other than on a point of law, which lies with the High Court.

(7) Authorisations, approvals or registrations granted under the European Communities (Animal Remedies) (No. 2) Regulations 2007 (S. I. No. 786 of 2007) ("2007 Regulations") which are in force immediately before the commencement of these Regulations continue in force and are deemed to have been issued in accordance with the corresponding provision of the VMP Regulation and are, as such, subject to the relevant provisions of the VMP Regulation.

(8) Fees for applications for authorisations, approvals or registrations and inspections are not refundable.

(9) (a) A person who—

- (i) possesses or uses, or
- (ii) distributes, sells or supplies or imports, or possesses with the intention of distributing, selling or supplying,

a veterinary medicinal product which has not been granted a marketing authorisation by the competent authority or the European Commission, or the competent authority of another Member State, unless its use is permitted in the State, commits an offence.

(b) This paragraph does not apply to a veterinary medicinal product—

- (i) allowed under Article 110, 111 or 116 or used under 112, 113 or 114, or
- (ii) authorised under the European Union (Protection of animals used for Scientific Purposes) Regulations 2012 (S. I. No. 543 of 2012).

(10) A person who commits an offence under—

(a) paragraph (9)(a)(i), is liable on summary conviction to a class A fine, or

(b) paragraph (9)(a)(ii), is liable—

- (i) on summary conviction, to a class A fine, or

- (ii) on conviction on indictment, to a fine not exceeding €300,000.

(11) Where by way of derogation under Article 106(1) of the VMP Regulation—

- (a) the competent authority allows the use of an immunological veterinary medicinal product in accordance with Article 110(2, 3 or 5) or a veterinary medicinal product in accordance with Article 116, a person who fails to use the product in accordance with the allowance, or
- (b) a veterinarian who treats an animal in the circumstances referred to in Article 112, 113 or 114 with a product referred to in paragraph (1) of Article 112, 113 or 114, as the case may be, but fails to follow the steps for such treatment as set out in that Article,

commits an offence and is liable—

- (i) on summary conviction, to a class A fine, or
- (ii) on conviction on indictment, to a fine not exceeding €50,000.

Part 3 – Medicated Feed Regulation - Infringements, penalties, approvals

Infringements - Medicated Feed Regulation

9. (1) A feed business operator who fails to comply with Article 4 in respect of the manufacture, storage, transport or placing on the market of medicated feed or intermediate products commits an offence.

(2) A feed business operator manufacturing medicated feed or intermediate product who fails to comply with Article 5, 6, 7 or 8 commits an offence.

(3) A person who fails to comply with the specific labelling requirements of Article 9 commits an offence.

(4) A person who fails to comply with the packaging requirements of Article 10 commits an offence.

(5) A person who contravenes the prohibition of advertising medicated feed and intermediate products under Article 11(1) commits an offence.

(6) A person who fails to comply with the advertising, distribution or labelling requirements of Article 11 (2), (3), (4) or (5) commits an offence.

(7) A feed business operator distributing medicated feed or intermediate products who fails to comply with Article 12 commits an offence.

(8) A feed business operator manufacturing, storing, transporting or placing on the market medicated feed or intermediate products who fails to comply with the approval obligation under Article 13(1) commits an offence.

(9) A mobile mixer who fails to comply with Article 13(4) commits an offence.

(10) A person who fails to comply with the prescription requirements of Article 16 commits an offence.

(11) An animal keeper or other person who fails to use medicated feed in accordance with Article 17 commits an offence.

Penalties - Medicated Feed Regulation

10. A person who commits an offence under —

- (a) paragraph (2), (3), (4), (6), (7), (9) or (11) of Regulation 9, is liable on summary conviction to a class A fine, or
- (b) paragraph (1), (5), (8) or (10) of Regulation 9, is liable —
 - (i) on summary conviction, to a class A fine, or
 - (ii) on conviction on indictment, to a fine not exceeding €300,000.

Approvals – Medicated Feed Regulation

11. (1) Upon application to it in writing and in such form as it decides, the competent authority may approve in accordance with Article 13 establishments under the control of a feed business operator manufacturing, storing, transporting or placing on the market medicated feed or intermediate products.

(2) Applications for approvals under Article 13 shall be in writing made to the competent authority in such form and manner as it decides accompanied by the fee for such set out in Part 2 of the Schedule and such information as the competent authority decides.

(3) The competent authority, if it decides to refuse approval, shall inform the applicant of its decision. The applicant or holder may within such period as the competent authority allows, not being less than 14 days, make representations in writing to the competent authority, who shall consider and inform the applicant of its decision.

(4) If an applicant or holder is aggrieved by a decision of the competent authority under paragraph (3) in respect of representations made and considered, he or she may request the Minister, not later than 21 days after notification of the decision, to establish a panel to adjudicate on the matter. The Minister, unless he or she considers the request vexatious, shall establish a panel with one or more persons, who he or she considers are suitably qualified and independent to adjudicate on the matter. The panel shall set its own procedure and adjudicate on the matter. The decision of the panel is final, other than on a point of law, which lies with the High Court.

(5) Licenses granted under Regulation 4 of the European Communities (Animal Remedies and Medicated feedingstuffs) Regulations 1994 (S. I. No. 176 of 1994) which are in force immediately before the commencement of these Regulations continue in force and are deemed to have been approved under this Regulation.

Part 4 – Commission Implementing and Delegated Acts

Implementing Regulation (EU) 2021/16

12. (1) A holder of a market authorisation who fails to comply with Article 18(5), (6) or (8) of Implementing Regulation (EU) 2021/16 commits an offence.

(2) The holder of a marketing authorisation or an approval referred to in Article 18(9) of Implementing Regulation (EU) 2021/16 who fails to comply with that paragraph commits an offence.

(3) A person who commits an offence under this Regulation is liable on summary conviction to a class A fine.

Delegated Regulation (EU) 2021/577

13. (1) A veterinarian who prescribes or uses a veterinary medicinal product in contravention of Article 1 of Delegated Regulation (EU) 2021/577 as regards the content and format of the information necessary to apply Articles 112(4) and 115(5) of the VMP Regulation commits an offence and is liable on summary conviction to a class A fine.

Delegated Regulation (EU) 2021/578

14. (1) Veterinarians, retailers, pharmacies, feed mills and end-users (including farmers and breeders) shall upon request supply the competent authority with data on the use of the antimicrobial medicinal products referred to in Articles 3 and 4 of Delegated Regulation (EU) 2021/578 in respect of the animal species, categories and stages thereof referred to in Article 15 of that Regulation.

(2) A person referred to in paragraph (1) who fails to supply data when requested under that paragraph commits an offence and is liable on summary conviction to a class A fine.

Implementing Regulation (EU) 2021/1248

15. (1) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1248 who fails to comply with Chapter II of that Regulation in respect of the quality system commits an offence.

(2) A person responsible for wholesale distribution referred to in Article 101(3) of the VMP Regulation or a person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1248 shall comply with the obligations of such a person under Chapter III of Implementing Regulation (EU) 2021/1248.

(3) A person who operates a premises or storage facilities for storing veterinary medicinal products or equipment (including computerised systems) relating thereto or their distribution who fails to comply with Chapter IV of Implementing Regulation (EU) 2021/1248 commits an offence.

(4) A person involved in the distribution of veterinary medicinal products who fails to comply with the documentation, procedures or record keeping requirements of Chapter V of Implementing Regulation (EU) 2021/1248 commits an offence.

(5) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1248 who fails to comply with Article 20, 21(2) or 22 of Chapter VI of that Regulation commits an offence.

(6) A person responsible for receiving veterinary medicinal products who fails to comply with Article 21(1) or 23 of Chapter VI of Implementing Regulation (EU) 2021/1248 commits an offence.

(7) A person who fails to store veterinary medicinal products in accordance with Article 24 of Chapter VI of Implementing Regulation (EU) 2021/1248 commits an offence.

(8) A person who fails to destroy obsolete veterinary medicinal products in accordance with Article 25 of Chapter VI of Regulation (EU) 2021/1248 commits an offence.

(9) A person who fails to pick veterinary medicinal products in accordance with Article 26, or supply veterinary medicinal products in accordance with Article 27 or export veterinary medicinal products in accordance with Article 28, of Chapter VI of Implementing Regulation (EU) 2021/1248 commits an offence.

(10) A person who fails to comply with Article 29 in respect of complaints, Article 30 in respect of returns, Article 31 in respect of falsified veterinary medicinal products or Article 32 in respect of recalls, of Chapter VII of Implementing Regulation (EU) 2021/1248 commits an offence.

(11) A contract giver who fails to comply with Article 33 or a contract acceptor who fails to comply with Article 34 of Chapter VIII of Implementing Regulation (EU) 2021/1248 commits an offence.

(12) A person who fails to conduct or record self-inspections in accordance with Article 36 of Chapter IX of Implementing Regulation (EU) 2021/1248 commits an offence.

(13) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1248 who fails to comply with Chapter X of that Regulation in respect of transport requirements under Article 37, or containers, packaging or labelling under Article 38 or products requiring special conditions under Article 39 commits an offence.

(14) A person who commits an offence under this Regulation is liable on summary conviction to a class A fine.

Implementing Regulation (EU) 2021/1280

16. (1) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1280 who fails to comply with Chapter II of that Regulation in respect of the quality system commits an offence.

(2) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1280 who fails to comply with Chapter III of that Regulation in respect of personnel commits an offence.

(3) The operator of premises or equipment for active substances used as starting materials in veterinary medicinal products who fails to comply with Chapter IV of Implementing Regulation (EU) 2021/1280 commits an offence.

(4) A person who fails to comply with Chapter V of Implementing Regulation (EU) 2021/1280 in respect of documentation, procedures or record keeping commits an offence.

(5) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1280 who fails to comply with Chapter VI of that Regulation in respect of verification of eligibility or approval of suppliers under Article 14, receipt of active substances used as starting materials under Article 15, storage under Article 16, outsourced activities under Article 17, deliveries to customers under Article 18 or transfer of information under Article 19 commits an offence.

(6) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1280 who fails to comply with Chapter VII of that Regulation in respect of complaints under Article 20, returns under Article 21 or recalls under Article 22 commits an offence.

(7) A person referred to in Article 1(2) of Implementing Regulation (EU) 2021/1280 who fails to conduct or record self-inspection in accordance with Article 23 of that Regulation commits an offence.

(8) A person who commits an offence under this Regulation is liable on summary conviction to a class A fine.

Implementing Regulation (EU) 2021/1281

17. (1) A holder of a marketing authorisation Who fails to meet the requirements laid down in Chapter 1 of Implementing Regulation (EU) 2021/1281 in respect of the holder's pharmacovigilance system established and maintained in accordance with Article 77(1) of the VMP Regulation commits an offence.

(2) A holder of a marketing authorisation who fails to establish or implement in accordance with Chapter 2 of Implementing Regulation (EU) 2021/1281 an adequate or effective quality management system for the performance of the holder's pharmacovigilance activities commits an offence.

(3) A holder of a marketing authorisation who fails to set up or maintain a document management system in accordance with Article 5, provide training of personnel in accordance with Article 6, use relevant performance indicators in accordance with Article 7, perform audits in accordance with Article 8 or have a process in place to manage corrective or preventive actions in accordance with Article 9, of Chapter 2 of Implementing Regulation (EU) 2021/1281 commits an offence.

(4) A holder of a marketing authorisation who fails to provide a record management system in accordance with Article 10, collect or maintain detailed records in accordance with Article 11, record adverse events in accordance with Article 12, 13 or 14, post-marketing surveillance studies requested in accordance with Article 15, provide a risk management system in accordance with Article 16, perform signal management process in accordance with Article 17, monitor benefit-risk balance in accordance with Article 18, record a conclusion of a benefit-risk balance in accordance with Article 19 or provide a communication plan in accordance with Article 20, of Chapter 3 of Implementing Regulation (EU) 2021/1281 commits an offence.

(5) A holder of a marketing authorisation who—

- (a) fails to maintain the holder's pharmacovigilance system master file in accordance with Chapter 4, or
- (b) fails to communicate a corrective and preventive action plan when required under Article 27,

of Implementing Regulation (EU) 2021/1281 commits an offence.

(6) A holder of a marketing authorisation who commits an offence under this Regulation is liable on summary conviction to a class A fine.

Implementing Regulation (EU) 2021/1904

18. (1) A person offering veterinary medicinal products for sale at a distance who fails to display the logo model set out in the Annex to Implementing Regulation (EU) 2021/1904 or clearly display the logo on websites offering veterinary medicinal products for sale at a distance commits an offence.

(2) A person who commits an offence under this Regulation is liable on summary conviction to a class A fine.

Part 5 – Miscellaneous – VMP Regulation

Determining and exemption of veterinary medicinal products

19. (1) The HPRA may, on application, determine that a product does not come within the scope of the VMP Regulation.

(2) An application under paragraph (1) shall be made in such form and accompanied by any material and any fee to cover the costs of administration contain any particulars that the HPRA decides.

(3) If, following evaluation of an application under paragraph (1), the HPRA proposes to classify a product as a veterinary medicinal product within the scope of the VMP Regulation, it shall—

- (a) notify the applicant in writing of the proposal and that he or she may make representations to the HPRA in relation to the proposal within 14 days of notification,

- (b) consider any representation made before deciding whether to proceed with, modify or withdraw the proposal, and
- (c) notify the applicant of the decision and the reasons for it.

(4) Where the HPRA makes a determination under paragraph (1) it shall notify both the applicant and the Minister.

(5) The HPRA, under and in accordance with Article 5(6) of the VMP Regulation, may allow exemptions from Article 5 of any veterinary medicinal product intended for animals referred to in that paragraph.

(6) Application for exemption referred to in paragraph (5) shall be made in such form and accompanied by any fee and any material and contain any particulars that the HPRA decides.

(7) Where the HPRA allows an exemption under Article 5(6) it shall publish the exemption in such manner as it decides.

Prohibiting the supply of or recalling of veterinary medicinal products, recording product complaints, etc.

20. (1) The HPRA, if prohibiting the supply of or recalling a veterinary medicinal product under Article 134 of the VMP Regulation shall issue a notice to the marketing authorisation holder or supplier concerned stating the reasons for the prohibition or recall and include any terms of compliance.

(2) The HPRA may modify or withdraw a notice.

(3) A person shall comply with a notice (including a notice subject to representation under paragraph (8)).

(4) A person who fails to comply with a notice commits an offence and is liable—

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €300,000.

(5) Where a notice is issued by the HPRA, the holder of a marketing authorisation or supplier concerned shall consult with and agree to a requirement or amendment notified by the HPRA regarding the contents of the notice or to the publication of the notice.

(6) Records of a veterinary medicinal product prohibited or recalled by a notice shall be made available for inspection on request to an authorised officer by the person to whom the notice is issued.

(7) Without prejudice to paragraph (8), where the HPRA proposes to issue a notice, it shall—

- (a) notify the person concerned in writing of the proposal and of the reasons for it and he or she may, within 7 days of the notification, make representations to the HPRA in relation to the proposal,
- (b) consider any representation made before deciding whether to proceed with, modify or withdraw the proposal, and
- (c) notify the person of the decision and the reasons for it,

and the notice shall not have effect until the HPRA issues a notification of its decision in accordance with subparagraph (c).

(8) Where the HPRA, for urgent public or animal health reasons, issues a notice, it shall—

- (a) in the notice inform the person of the decision and the reasons for it and that the notice takes effect immediately, but the person may within 7 days of the notice, make representations to the HPRA in relation to the decision,
- (b) consider any representations duly made, and
- (c) confirm, modify or withdraw the notice and notify the person and the reasons for it,

and the notice has effect upon its issue

(9) The holder of a marketing authorisation, registration for homeopathic veterinary medicinal products or products referred to in Article 5(6) or a supplier shall maintain a system for recording and reviewing complaints concerning reported defects associated with a veterinary medicinal product to which the authorisation relates and the outcome of any investigation carried out in respect of each complaint.

(10) The holder of a marketing authorisation, registration for homeopathic veterinary medicinal products or products referred to in Article 5(6) or a supplier shall keep such documents as will facilitate the withdrawal or recall from placing on the market, distribution, sale or supply of a veterinary medicinal product to which the authorisation relates. The documents shall be readily available for inspection by an authorised officer.

(11) A holder of an authorisation or a supplier who fails to comply with paragraph (9) or (10) commits an offence and is liable on summary conviction to a class A fine.

(12) In this Regulation “notice” means a notice prohibiting the supply of or recalling a veterinary medicinal product under Article 134 of the VMP Regulation.

Certain animal disease situations

21. (1) These Regulations, in so far as they relate to an animal under the care of a veterinarian, do not apply to the administration of a veterinary medicinal product, if the product is administered for the purpose of, or in the course of an official or voluntary 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 for the determination of the health or status of that animal.

(2) An animal to which a veterinary medicinal product has been administered under and in accordance with a scheme or programme under paragraph (1) is considered, subject to the terms and conditions of the scheme or programme, to have had a veterinary medicinal product administered to it.

Return of unused, waste or expired veterinary medicinal products

22. (1) The owner, or where the animals are not kept by the owners, keepers of food-producing animals shall return an unused, waste or expired veterinary medicinal product to the person from whom he or she purchased the product and shall record this in records kept for the purposes of Article 108 of the VMP Regulation.

(2) A person who fails to comply with this regulation commits an offence and is liable on summary conviction to a class A fine.

Administration of veterinary medicinal products

23. (1) Subject to the VMP Regulation or a Commission delegated or implementing act, a person shall not administer or cause or permit administration of a veterinary medicinal product to an animal unless—

- (a) there is in force a marketing authorisation in respect of the veterinary medicinal product,
- (b) the administration is carried out in accordance with the terms of the authorisation or in accordance with the derogation provided for under Article 112, 113 or 114,
- (c) the authorisation authorises administration of the product to the animal, class of animal or species or in accordance with the derogation provided for under Article 112, 113 or 114,
- (d) the VMP Regulation or a Commission delegated or implementing act has been complied with in respect of the product, and
- (e) in relation to veterinary medicinal products subject to a prescription it has been prescribed by a registered veterinary practitioner and, the person administering the product has a veterinary prescription in his or her possession relating to that veterinary medicinal product.

(2) A person shall not—

- (a) administer to a food producing animal, a veterinary medicinal product which consists of or contains a substance, the administration of which to the animal, species or class of animal, is not permitted under the terms of the marketing authorisation relating to the product, or is not in accordance with the derogation provided for under Articles 113 or 114,
- (b) import, export, sell, supply, or slaughter for human consumption, a food producing animal to which a veterinary medicinal product has been administered in contravention of subparagraph (a),
- (c) import, export, sell or supply for human or animal consumption meat, milk, eggs or honey derived from, or produced by, an

animal to which a veterinary medicinal product has been administered in contravention of subparagraph (a),

- (d) process meat, milk, eggs or honey referred to in subparagraph (c) or import, export or sell produce of any meat, milk, eggs or honey prepared from, or with, such meat, milk, eggs or honey, or
- (e) have in his or her possession or under his or her control a food producing animal to which a veterinary medicinal product has been administered in contravention of subparagraph (a) or meat, milk, eggs or honey derived from, or produced by, the animal.

(3) The owner or keeper of an animal to which a veterinary medicinal product has been administered shall—

- (a) comply with the conditions of use of the veterinary medicinal product to be complied with after administration, and
- (b) ensure that the animal is not slaughtered in order to be offered for human consumption (or sold, supplied or exported in order to be so offered) before the end of the withdrawal period and that produce obtained from the animal before the end of a withdrawal period is not disposed of with a view to being offered for human consumption.

(4) If a person, other than the owner or keeper of an animal, administers a veterinary medicinal product to that animal, he or she shall inform the owner or person in charge of the animal of its administration.

(5) In paragraph (3), “conditions of use” means information and directions that, pursuant to a marketing authorisation, are required to appear on the container, outer package and package leaflet of the veterinary medicinal product.

(6) A person who fails to comply with this Regulation (other than paragraph (4)) commits an offence and is liable—

- (a) on summary conviction, to a class A fine, or to imprisonment for a term not exceeding 6 months, or to both,
- (b) on conviction on indictment, to a fine not exceeding €300,000, or to imprisonment for a term not exceeding 2 years, or to both.

(7) A person who fails to comply with paragraph (4) commits an offence and is liable on summary conviction to a class A fine.

Possession of veterinary medicinal product, etc.

24. (1) A person shall not have in his possession or under his control—

- (a) a veterinary medicinal product or any ingredient for a veterinary medicinal product for the purpose of selling or otherwise supplying it to another person in contravention of the VMP Regulation or a Commission delegated or implementing act,
- (b) an animal, knowing it to be an animal to which a veterinary medicinal product or an ingredient for such a product has been administered, and has possession or control for the purposes of—

- (i) selling or otherwise supplying any produce for human consumption which is derived in whole or in part from the animal,
 - (ii) slaughtering the animal for human consumption, or
 - (iii) selling or otherwise supplying the animal to another person, where such slaughter, sale or supply would be in contravention of the VMP Regulation or a Commission delegated or implementing act, or
- (c) (i) an animal to which a veterinary medicinal product or an ingredient a veterinary medicinal product has been administered, or
- (ii) the carcass of such an animal,
- where such possession or control or the manner of such possession or control by the person is prohibited by the VMP Regulation or a Commission delegated or implementing act.
- (2) (a) Where a person has possession or control of an animal, being an animal to which a veterinary medicinal product or an ingredient for such a product has been administered, for the purpose of—
- (i) slaughtering the animal, or
 - (ii) selling or otherwise supplying the animal to another person for the purpose of slaughtering it,
- it shall be presumed, until the contrary is shown, that—
- (I) the animal would have been slaughtered for the purpose of human consumption, and
 - (II) the person knew it to be an animal to which a veterinary medicinal product or an ingredient for such a product has been administered.
- (b) Where a person has possession or control of an animal, being an animal to which a veterinary medicinal product or an ingredient for such a product has been administered, for the purpose of selling or otherwise supplying any produce for human consumption which is derived in whole or in part from the animal, it shall be presumed, until the contrary is shown, that—
- (i) the animal was at all material times in the person's possession or control for the purpose of selling or otherwise supplying such produce for human consumption, and
 - (ii) the person knew it to be an animal to which a veterinary medicinal product or an ingredient for such a product has been administered.
- (3) A person who contravenes this Regulation commits an offence and is liable—
- (a) on summary conviction, to a class A fine, or to imprisonment for a term not exceeding 6 months, or to both,

- (b) on conviction on indictment, to a fine not exceeding €300,000, or to imprisonment for a term not exceeding 2 years, or to both.

(4) Where in any proceedings for an offence under this Regulation it is shown that a person was in possession of a veterinary medicinal product or an ingredient for a veterinary medicinal product and the court concerned, having regard to the quantity of the product or the ingredient which the person possessed or such other matter as the court considers relevant, is satisfied that it is reasonable to assume that the product or ingredient was possessed for the purpose of supplying it to another person otherwise than in accordance with the VMP Regulation or a Commission delegated or implementing act, it shall be presumed until the contrary is shown that the product or ingredient was so possessed.

Prohibition of false or misleading particulars

25. (1) The particulars required by or under the VMP Regulation to be given in connection with any placing on the market, sale, importation or advertisement or other promotion of a veterinary medicinal product and any other particulars (including the brand name or trade name of such product) given in connection with such placing on the market, sale, importation or advertisement or other promotion shall not be so given by any person as to convey or be likely to convey a false or misleading indication or impression of the composition, medicinal value or effectiveness of such product.

(2) A person who fails to comply with paragraph (1) commits an offence and is liable —

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €300,000.

Guidelines – Article 59 of VMP Regulation

26. The Minister or, at his or her request, the HPRA shall issue guidelines or take appropriate measures to advise small and medium-sized enterprises on compliance with the requirements of the VMP Regulation.

Part 6 – Enforcement

Definitions (Part 6)

27. In this Part—

“applicable (EU) Regulation” means the VMP Regulation, the Medicated Feeds Regulation or a Commission implementing or delegating act;

“authorised officer” means a person appointed under paragraph (1) or deemed appointed under paragraph (2) of Regulation 28;

“officer of customs” has the meaning assigned to it in the Customs Act 2015 (No. 18 of 2015);

“record” has the meaning assigned to it in section 2(1) of the Animal Health and Welfare Act 2013 (No. 15 of 2013).

Inspection by authorised officers, etc.

28. (1) The Minister may for the purpose of enforcing an applicable (EU) Regulation appoint in writing such persons or class of persons, as he or she considers appropriate, to be authorised officers for the exercise of the functions conferred on an authorised officer under this Part.

(2) A person appointed as an authorised officer under section 10 of the Animal Remedies Act 1993 (No. 23 of 1993) is deemed to be appointed as an authorised officer to exercise the functions conferred on an authorised officer under this Part.

(3) An authorised officer appointed under this Regulation shall be furnished with a warrant of his or her appointment and, when exercising a function conferred on him or her as an authorised officer, the officer shall, if requested by a person affected, produce the warrant, or other evidence (including an identity document relating to the officer under section 17 of the Animal Remedies Act 1993) that he or she is such an officer, for inspection.

(4) An authorised officer or a member of the Garda Síochána or an officer of customs may carry out the controls on the persons referred to in Article 123 and carry out inspections referred to in Article 123(6) and for that purpose exercise the powers conferred on such officer or member under paragraph (6).

(5) An authorised officer may carry out inspections of pharmacovigilance systems of veterinary medicinal products for the purposes of Article 126 and exercise the powers conferred on such officer under paragraph (6).

(6) For the purposes of enforcing an applicable (EU) Regulation and carrying out the controls on persons referred to in Article 123 of the VMP Regulation where an authorised officer or a member of the Garda Síochána or an officer of customs has reasonable grounds for believing that—

- (a) the manufacture, placing on the market, importation, preparation, handling, storage, transport, exportation, distribution, sale, supply, marketing, advertising or use of a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate products or pharmacovigilance activities is taking place or has taken place in, on, under or from any land, premises or in, on or from any vehicle,
- (b) an offence is being or has been committed under these Regulations in, on, under or from any land, premises or in, on or from any vehicle,
- (c) any land, vehicle or premises is used for or in connection with the breeding, rearing, feeding, keeping, exhibiting, selling or transporting of animals,
- (d) any land or premises is a slaughterhouse or is used for or in connection with the slaughter of animals,

- (e) in, on, under or from any land or premises or in, on or from any vehicle, there is or was any animal of any species to which a veterinary medicinal product is being or has been administered or there is or was any food derived from such an animal or any carcase of such an animal, or
- (f) in, on, under or from any land or premises or in, on or from any vehicle, there is or was any veterinary medicinal product or any ingredients for veterinary medicinal products, or medicated feed or intermediate products or any machinery (including any computerised information management system), instrument, equipment, container, record or other thing used in the manufacture, preparation, handling, storage, transport, placing on the market, exportation, distribution, sale, supply or use of veterinary medicinal products or ingredients for veterinary medicinal products or medicated feed or intermediate products,

the authorised officer, member of the Garda Síochána or officer of customs (in this section referred to as the “relevant person”) may, stop, subject to paragraph (7), any such vehicle or enter (if necessary by force) any such land or premises, or land or premises used in connection with such land or premises, or any such vehicle, and there, or at any other place, and with such other authorised officers, members of the Garda Síochána and officers of customs (if any) as the relevant person considers appropriate—

- (i) search for and examine, inspect or test any animals, food derived from animals or carcasses of animals or anything believed to be a veterinary medicinal product or an ingredient for a veterinary medicinal product, medicated feed or intermediate products or anything to which subparagraph (f) relates,
- (ii) take such specimens (including blood, urine, faeces, tissue, hair or remains of implants) from any animals, food derived from animals or carcasses of animals, and may for that purpose perform or cause to be performed any procedure (including surgery) as is considered necessary on such animals, food or carcasses,
- (iii) take, without payment, samples of, or from, any substances, or of or from a thing which may be considered appropriate for the purposes of an applicable (EU) Regulation, as he or she may reasonably require and carry out or cause to be carried out on the sample such tests, analyses, examination or inspections as he or she considers necessary or expedient and mark or otherwise identify it.
- (iv) seize and detain anything to which subparagraph (f) relates or anything which is believed to be or to contain a veterinary medicinal product or an ingredient for a veterinary medicinal product or medicated feed or intermediate products kept, used or intended to be used in

contravention of an applicable (EU) Regulation, as the case may be,

- (v) search for and examine any record and take extracts from and copies of any such record,
- (vi) seize and detain an animal in respect of which it is, with reasonable grounds, believed by the relevant person that a prohibited veterinary medicinal product or ingredient for a veterinary medicinal product has been administered to it in contravention of an applicable (EU) Regulation,
- (vii) require any person who is suspected to be, or to have been engaged in the importation, manufacture, preparation, handling, storage, transport, exportation, distribution, sale, supply or use of, or any person who is suspected to have possession or control of or to have kept or to keep, any veterinary medicinal product, ingredient for a veterinary medicinal product, animal, food derived from animals, carcasses of animals or medicated feed or intermediate products or anything to which subparagraph (f) relates, or any person who is suspected to be, or to have been, engaged in the breeding, rearing, feeding, keeping, exhibiting, selling or transporting or in the possession or control of any animal—
 - (I) in the case of any documents in the possession or control of that person or any such veterinary medicinal product, ingredient, animal, food, carcase or thing or medicated feed or intermediate products, to produce them to the relevant person or any authorised officer, member of the Garda Síochána or officer of customs,
 - (II) in the case of any information (including passwords) in relation to such document, veterinary medicinal product, animal, food, carcase, information management system, or thing or medicated feed or intermediate products which may be required (including the source of that document, product, animal, food, carcase or thing), to furnish them to the relevant person or any authorised officer, member of the Garda Síochána or officer of customs,
- (viii) require any person, being the owner or the person in charge of animals or, the owner or occupier of, or employed in or on lands or premises so entered to give assistance, to carry out such instructions and to give such information as may be reasonably necessary for the purposes of subparagraphs (i) to (vii), and
- (ix) require any person who is for the time being in charge or control of any vehicle so stopped or entered—
 - (I) to refrain from moving it, and

- (II) to give assistance, to carry out such instructions and to give such information as may be reasonably necessary for the purposes of subparagraphs (i) to (vii).

(7) An authorised officer may only stop a vehicle for the purposes of paragraph (6) in a public place (within the meaning of the Road Traffic Act 1961 (No. 24 of 1961)) if accompanied by a member of the Garda Síochána and the officer requests the member to stop the vehicle.

(8) The functions of a relevant person under this Regulation may only be exercised in respect of a dwelling or so much of a vehicle or premises as constitutes a dwelling where the relevant person has reasonable cause to suspect that, before a search warrant could be sought in relation to the dwelling under Regulation 29, anything to which paragraph (6) relates—

- (a) is being destroyed or disposed of, or
- (b) is likely to be destroyed or disposed of.

(9) An authorised officer, a member of the Garda Síochána or an officer of customs accompanying the relevant person may exercise all the functions conferred on the relevant person by virtue of this Regulation.

(10) An authorised officer when exercising a power under this Regulation may be accompanied by another person, and may take with him or her, or that person may take with them, any equipment or material to assist the officer in the exercise of the power.

(11) An authorised officer may use reasonable force, if necessary, to enter land or premises to exercise his or her powers under this Regulation.

(12) Where in the course of exercising a power under this Regulation, an authorised officer finds or comes into possession of anything that the officer has reasonable grounds for believing to be evidence of an offence or suspected offence under these Regulations, the officer may seize and retain it for use as evidence in proceedings for an offence under these Regulations.

Search warrant

29. (1) Where a judge of the District Court is satisfied by information on oath of an authorised officer, a member of the Garda Síochána or an officer of customs that there is reasonable cause for suspecting that—

- (a) evidence of or relating to the commission or intended commission of an offence under these Regulations is to be found in, on or under any land or premises or in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling,
- (b) there is or was or is intended to be in, on or under any land or premises, in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling, any veterinary medicinal product or ingredient for a veterinary medicinal

product in relation to which a contravention of these Regulations, is being or has been or is intended to be committed, or

- (c) a document directly or indirectly relating to, or connected with, a transaction or dealing which was, or an intended transaction or dealing which would if carried out be, an offence under these Regulations, is in the possession or under the control of a person in, on or under any land or premises or in or on any vehicle and that such land, premises or vehicle or any part thereof consists of a dwelling,

the judge may issue a search warrant under this Regulation.

(2) A search warrant issued under this Regulation shall be expressed and operate to authorise a named authorised officer, named member of the Garda Síochána or named officer of customs, accompanied by such authorised officers, members of the Garda Síochána and officers of customs or other persons as the named officer or member thinks necessary, at any time or times within one month from the date of issue of the warrant, on production if so requested of the warrant to enter (if necessary by force) the land, premises or vehicle named in the warrant.

(3) Where any premises, land or vehicle is entered pursuant to a warrant issued under this Regulation, an authorised officer, a member of the Garda Síochána or an officer of customs so entering may—

- (a) stop and detain any person found in, on or under such land or premises, or in or on such vehicle, for the purpose of searching that person and to search or cause to be searched that person, and
- (b) exercise all or any of the powers referred to in Regulation 28.

Search of suspects and stopping of vehicles

30. (1) Where a member of the Garda Síochána or an officer of customs has reasonable grounds for believing that a person is in possession, in contravention of these Regulations, of a veterinary medicinal product or an ingredient for a veterinary medicinal product or medicated feed or intermediate products, the member or officer may without warrant—

- (a) search, or cause to be searched by such a member or officer, the person and, if the member or officer considers it necessary for that purpose, detain the person for such time as is reasonably necessary to carry out the search,
- (b) search, or cause to be searched by such a member or officer, any vehicle in which the member or officer suspects that such product or feed may be found and for the purpose of carrying out the search, if any such member or officer thinks fit, require the person who is, for the time being, in charge or control of the vehicle to bring it to a stop and when stopped to refrain from moving it or, in case the vehicle is already stationary, to refrain from moving it, or

- (c) seize and detain, or cause to be seized and detained by such a member or officer, anything found in the course of a search under this Regulation which any such member or officer reasonably suspects to be something which might be required as evidence in proceedings for an offence under these Regulations.

(2) Where a member of the Garda Síochána or an officer of customs decides to search or cause to be searched a person under this Regulation, the member or officer may require the person to accompany that member or officer to either a Garda Síochána station or a customs office for the purpose of being so searched at that station or office. If the person refuses the member may arrest the person without warrant.

(3) A member of the Garda Síochána or an officer of customs may stop a vehicle, vessel or aircraft for the purposes of these Regulations and may require it to be moved for inspection to such place as the member directs.

(4) A person who, without reasonable excuse, fails to comply with a request of a member of the Garda Síochána or an officer of customs under paragraph (2) or (3) commits an offence and is liable on summary conviction to a class A fine.

(5) Nothing in this Part operates to prejudice any power to search or to stop, or to seize or detain property, which may, apart from this Part, be exercised by a member of the Garda Síochána or an officer of customs.

Power of arrest

31. Where with reasonable cause a member of the Garda Síochána—

- (a) suspects that an offence under these Regulations has been committed or attempted, and
- (b) suspects a person of having committed the offence or having made the attempt,

the member may arrest the person without warrant if—

- (i) with reasonable cause the member suspects that the person, unless arrested, either will abscond for the purposes of evading justice or will obstruct the course of justice, or
- (ii) having enquired of the person, the member has reasonable doubts as to the person's identity or place of abode, or
- (iii) having enquired of the person, the member knows that the person does not ordinarily reside in the State or has reasonable doubts as to whether the person so resides.

Saving for certain power

32. Nothing in these Regulations shall operate to prejudice any power to search, or to seize or detain property, which may, apart from these Regulations, be exercised by a member of the Garda Síochána or an officer of customs.

Obstruction

33. A person who —

- (a) obstructs or impedes an authorised officer, member of the Garda Síochána or officer of customs or any person who accompanies such officer or member, in the exercise of any of the functions conferred on or exercisable by the officer or member under Regulation 28,
- (b) fails, without reasonable excuse, to comply with a requirement of an authorised officer, member of the Garda Síochána or officer of customs under Regulation 28,
- (c) purporting to give information to an authorised officer under Regulation 28 for the exercise of the officer's or member's functions under that Regulation—
 - (i) makes a statement that he or she knows to be false or misleading in a material particular or recklessly makes a statement which is false or misleading in a material particular, or
 - (ii) intentionally fails to disclose a material particular,

commits an offence and is liable on summary conviction to a class A fine.

Compliance notice

34. (1) Where an authorised officer is of the opinion that a person is not complying, or has not complied with an applicable (EU) Regulation or any authorisation, approval or registration under such, the officer may serve on the person a notice (“compliance notice”) stating that opinion on the person.

(2) A compliance notice shall—

- (a) require the person on whom it is served to take such action as specified in the notice,
- (b) inform the person on whom it is served that he or she may appeal the notice to the District court under Regulation 35, and
- (c) state that if the person on whom the notice is served fails to comply with the notice, he or she commits an offence and is liable to the penalty set out in paragraph (7).

(3) A person on whom a compliance notice is served shall—

- (a) comply with the notice until it expires or is annulled under Regulation 35, and
- (b) not cause or permit another person to contravene the terms of the notice.

(4) A compliance notice may specify a time limit within which the action specified in the notice is to be complied with.

(5) A compliance notice may be modified or withdrawn by a further notice and the earlier notice has effect subject to the modification or withdrawal.

(6) A compliance notice shall include an address for the service of an appeal under Regulation 35.

(7) A person on whom a compliance notice is served who fails to comply with, or causes another person to contravene, the notice commits an offence and is liable—

- (a) on summary conviction, to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €50,000.

Appeal against compliance notice

35. (1) A person on whom a compliance notice is served may, not later than 10 days from the date of the service of the notice, appeal the notice to the judge of the District Court having jurisdiction in the District Court district—

- (a) where the veterinary medicinal product or animal feed to which the notices relates is situated, or
- (b) where the person bringing the appeal ordinarily resides or carries on business.

(2) Notice of an appeal shall contain a statement of the grounds upon which it is alleged that the compliance notice is unreasonable having regard to the applicable (EU) Regulation concerned and shall be served on the Minister at the address included on the notice in accordance with Regulation 34(6) not later than 2 days prior to the appeal.

(3) A copy of a notice of an appeal shall be lodged with the District Court clerk not later than 2 days prior to the hearing of the appeal.

(4) A compliance notice in respect of which an appeal is brought under this Regulation has effect pending the making of an order under paragraph (5).

(5) On the hearing of an appeal the judge may confirm, modify or annul the compliance notice concerned.

(6) A person, including a person on whom a compliance notice has been served, shall not—

- (a) pending the determination of the appeal, deal with any veterinary medicinal product or animal feed to which the notice relates, other than in accordance with the terms of the compliance notice, or
- (b) if the notice is confirmed or modified on appeal, deal with any veterinary medicinal product or animal feed to which the notices relates other than in accordance with the terms of the compliance notice as confirmed or modified.

(7) A person who fails to comply with paragraph (6) commits an offence and is liable—

- (a) on summary conviction to a class A fine, or
- (b) on conviction on indictment, to a fine not exceeding €50,000.

(8) In this Regulation “appeal” means an appeal under paragraph (1).

Seizure and detention for non-compliance with compliance notice

36. (1) Without prejudice to an appeal under Regulation 35, where —

- (a) the owner, occupier or person in charge of land or premises, or the owner or person in possession or control of a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate product fails to comply with a compliance notice within the time specified in the notice,
- (b) an authorised officer has reasonable grounds for believing that a compliance notice, whether or not modified under Regulation 35(5), will not be complied with, or
- (c) a compliance notice has been confirmed with or without modification under Regulation 35(5) and the notice has not been complied with,

then the authorised officer may seize and detain the product or feed and any means of transport or other thing used in connection with such.

(2) Where a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate product, means of transport or other thing is seized and detained under paragraph (1), an authorised officer may—

- (a) sell, destroy or dispose of the product, feed or other thing or cause it to be sold, destroyed or disposed of, or
- (b) take such other measures in relation to the product, feed, means of transport or other thing as the authorised officer considers appropriate, in the circumstances.

(3) The profits, if any, arising out of the sale, destruction or disposal of a veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate product, means of transport or other thing seized and detained under paragraph subsection (1) shall be paid to the owner of the product, feed, means of transport or other thing less any expenses (including ancillary expenses) incurred in connection with the seizure, detention, sale, destruction or disposal.

(4) The costs (including ancillary costs) of a measure taken under this section may be recovered by the Minister—

- (a) as a simple contract debt in a court of competent jurisdiction from the person who was the owner of the veterinary medicinal product or any ingredient for a veterinary medicinal product or medicated feed or intermediate or means of transport or other thing at the time the measure was carried out, or
- (b) by deducting the costs from any moneys due, or becoming due, and payable by the Minister to the person on whom the compliance notice concerned was served.

(5) Where the Minister proposes to recover the costs of anything done under this Regulation the Minister shall—

- (a) inform by notice the person concerned of the costs (including, but not limited to, salaries, subsistence, hiring of vehicles, machinery or equipment, feeding and veterinary fees) the reason for the costs and that he or she may make representations in relation to the proposal not later than 14 days from the date of the notice,
- (b) consider any representations duly made, and
- (c) make a decision and inform by notice the person concerned, stating the decision and the reasons for the decision.

Impersonation of an authorised officer, etc. and possession of certain identity documents

37. (1) A person who, with the intention to deceive—

- (a) purports to be, or
- (b) acts in a manner that would lead another person to believe that he or she is,

a person duly appointed as an authorised officer or other officer of the Minister either generally or for the purposes of these Regulations commits an offence and is liable on summary conviction to a class A fine or to imprisonment for a term not exceeding 6 months, or both.

(2) A person who, without lawful excuse, has in his or her possession any document which—

- (a) has been,
- (b) purports to be, or
- (c) could lead another person to believe that it has been,

duly issued for the purpose of identifying the person in possession of the document as a person duly authorised by, or a duly authorised officer or other officer of the Minister either generally or for the purposes of these Regulations commits an offence and is liable on summary conviction to a class A fine or to imprisonment for a term not exceeding 6 months, or both.

Evidence of class of veterinary medicinal product to which a contravention relates

38. In any proceedings for an offence under these Regulations in which it is alleged that a contravention of these Regulations has occurred in relation to a class of veterinary medicinal product or a class of ingredient for a veterinary medicinal product or a class of medicated feed or intermediate products, it shall not be necessary to show that the contravention relates to a particular veterinary medicinal product or ingredient for a veterinary medicinal product or a particular medicated feed or intermediate product where it can be shown that it relates to a thing which is a member of such a class of veterinary medicinal product or class of ingredient for a veterinary medicinal product or medicated feed or intermediate product.

Disposal of things seized

39. If, in the course of exercising a power under this Part, a person, being an authorised officer, a member of the Garda Síochána or an officer of customs, finds or comes into possession of any thing which such a person believes to be evidence of any offence or suspected offence under these Regulations, it may be seized and retained for use in evidence in any criminal proceedings, for such period from the date of seizure as is reasonable or, if proceedings are commenced in which the thing so seized is required for use in evidence, until the conclusion of the proceedings, and thereafter it shall be returned to its owner, unless—

- (a) returning it would cause the owner to be in possession of the seized item contrary to law,
- (b) the expiry date of a seized medicine has expired,
- (c) the person from whom it was seized cannot be found within in a period of 30 days, or
- (d) an order from the court has been obtained to otherwise dispose of it,

and an authorised officer may, other than where paragraph (c) or (d) applies, approve the disposal, without payment or compensation of the thing following the issuing of a disposal notice to the owner giving him or her 10 days to appeal the decision to the Minister to dispose.

Evidence on certificate, etc.

40. (1) In proceedings for an offence under these Regulations consisting of a contravention of an applicable (EU) Regulation, a certificate purporting to be signed by a person employed at a laboratory named in the certificate stating the capacity in which that person is so employed and stating one or more of the following, namely—

- (a) that the person received a sample submitted to the laboratory,
- (b) that, for a period as is specified in the certificate, the person had in his or her custody a sample so submitted,
- (c) that the person gave to such other person as is specified in the certificate a sample so submitted,
- (d) that the person carried out a laboratory examination for the purpose of detecting the presence, in a sample so submitted, of a substance, ingredient for a veterinary medicinal product or medicated feed or intermediate product or a veterinary medicinal product or medicated feed or intermediate product, or
- (e) that a particular substance, ingredient for a veterinary medicinal product or medicated feed or intermediate product or a veterinary medicinal product or medicated feed or intermediate product was present in the sample,

is, unless the contrary is shown, evidence of the matters stated in the certificate.

(2) A certificate purporting to be signed by an officer of the Minister and to certify that on a specific day or days or during the whole of a specified period-

- (a) a particular person or organisation did not hold a marketing, manufacturing or distribution authorisation, clinical trial or parallel trade approval or registration of homeopathic veterinary medicinal products,
- (b) a marketing, manufacturing or distribution authorisation, clinical trial or parallel trade approval or registration of homeopathic veterinary medicinal products is suspended or has been revoked,
- (c) a person or organisation was or was not the holder of a marketing, manufacturing or distribution authorisation, clinical trial or parallel trade approval or was not authorised, or
- (d) that a particular authorisation, approval or registration, referred to in this paragraph, was subject to a particular condition or conditions,

is, without proof of the signature of the person purporting to sign the certificate or that he or she is an officer of the Minister, evidence, unless the contrary is shown, of the matters stated in the certificate.

(3) In proceedings for an offence under these Regulations the court may, if it considers that the interests of justice so require, direct that oral evidence of any matter stated in a certificate under paragraph (1) or (2) be given, and the court may for the purpose of receiving oral evidence adjourn the matter.

Offences by bodies corporate, etc.

41. (1) Where an offence under these Regulations has been committed by a body corporate and it is proved to have been so committed with the consent or connivance of or to be attributable to any willful neglect on the part of any person who, when the offence was committed, was a director, manager, secretary or other officer of the body corporate, or a person purporting to act in any such capacity, that person, as well as the body corporate, shall be guilty of an offence and shall be liable to be proceeded against and punished as if guilty of the first-mentioned offence.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) shall apply in relation to the acts and defaults of a member in connection with the functions of management as if such a member were a director or manager of the body corporate.

Fixed payment notice

42. (1) Where an authorised officer has reasonable grounds for believing that a person is committing or has committed an offence referred to in paragraph (a) of Regulation 6 or paragraph (a) of Regulation 10 or under Regulation 7(4), 20 (11) or 22(2) or Part 4, he or she shall report this to another officer of the competent authority concerned authorised in that behalf.

(2) An officer who receives a report under paragraph (1), if he or she considers it appropriate, may serve on the person a notice in writing (“fixed payment notice”) stating that—

- (a) the person is alleged to have committed the offence,
- (b) the person may during the period of 28 days beginning on the date of the notice make to the Minister, at the address specified in the notice, a payment of €250 accompanied by the notice (if required in the notice),
- (c) the person is not obliged to make the payment, and
- (d) a prosecution in respect of the alleged offence will not be instituted during the period specified in the notice and, if the payment specified in the notice is made during that period, no prosecution in respect of the alleged offence will be instituted.

(3) Where a fixed payment notice is served under paragraph (2)—

- (a) the person to whom the notice applies may, during the period specified in the notice, make to the Minister at the address specified in the notice the payment specified in the notice accompanied by the notice (if required in the notice),
- (b) the Minister may receive the payment, issue a receipt for it and retain the money so paid, and any payment so received shall not be recoverable in any circumstances by the person who made it, and
- (c) a prosecution in respect of the alleged offence shall not be instituted in the period specified in the notice, and if the payment so specified is made during that period, no prosecution in respect of the alleged offence shall be instituted.

(4) In proceedings for an offence referred to in paragraph (1) the onus of proving that a payment in accordance with a fixed payment notice has been made lies on the person on whom the fixed payment notice was served.

(5) In proceedings for an offence referred to in paragraph (1) it is a defence for the accused to show that he or she has made a payment in accordance with this section pursuant to a fixed payment notice issued in respect of that offence.

Service of notices and notifications

43. (1) Subject to paragraph (2), any notice, notification or document required or authorised by virtue of an applicable (EU) Regulation to be given to any person by the competent authority or required to be given under these Regulations shall be addressed to the person concerned by name and may be given —

- (a) by delivering it to the person,
- (b) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address,

- (c) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address, or
- (d) by electronic communication, if the person concerned has agreed to service of notices, notifications or documents by such means, provided that there is a facility for confirming receipt of the electronic communication and that such receipt has been confirmed.

(2) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 (No. 38 of 2014) shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

Summary proceedings

44. Proceedings for an offence may be brought and prosecuted summarily by—

- (a) in any case, the Minister, or
- (b) in a case where the HPRA is the competent authority, the HPRA.

Disqualification from keeping animals, veterinary medicinal products, or medicated feed, etc.

45. (1) A person who is convicted on indictment of an offence under these Regulations may, in addition to the penalty imposed thereunder—

- (a) be disqualified from keeping, dealing in or having charge or control, directly or indirectly, of either or both—
 - (i) any animal or class or classes of animal, and
 - (ii) any veterinary medicinal product or medicated feed or class or classes of a veterinary medicinal product or medicated feed or any ingredient thereof,
- or
- (b) be disqualified from working in or having charge or control of any one or more of the following, that is to say, the manufacture, importation, preparation, handling, storage, transport, exportation, distribution, sale or supply of either or both food intended for human consumption and food intended for animal consumption or of any class or classes of either or both such foods,

for such period, including where appropriate for the life of the person, as the court thinks fit.

(2) In this Regulation “control” includes, in relation to a body corporate, the power of the person concerned to secure, by means of holding shares or the possession of voting power in or in relation to that or any other body corporate, or by virtue of powers conferred by articles of association or other document regulating that or any other body corporate, that the affairs of the first-mentioned body corporate are conducted in accordance with the wishes of that person.

Forfeiture of animal, veterinary medicinal product, etc.

46. (1) Where—

- (a) a veterinary medicinal product,
- (b) an ingredient for a veterinary medicinal product,
- (c) an animal to which a veterinary medicinal product has been administered,
- (d) any thing used in connection with an unauthorised veterinary medicinal product or any thing directly used in connection with any other veterinary medicinal product, or
- (e) any thing used in connection with an animal to which a prohibited veterinary medicinal product has been administered or any thing directly used in connection with an animal to which any other veterinary medicinal product has been administered,

has come into the possession of an authorised officer in respect of which an offence is with reasonable cause suspected by the officer of having been committed under these Regulations, or where an offence has been committed or is alleged to have been committed under these Regulations in respect of any of the matters referred to in paragraph (a), (b), (c), (d) or (e), and on the application before a court of—

- (i) the Minister, or
- (ii) where criminal proceedings have been instituted, the person who instituted those proceedings,

the appropriate court may, at its discretion and where it is satisfied that an offence has been committed (whether or not any person has been convicted of the offence) order the forfeiture of any such animal, veterinary medicinal product, ingredient for a veterinary medicinal product, or other thing, as the case may be.

(2) Any thing ordered by the appropriate court to be forfeited under this Regulation shall be disposed of as the Minister thinks fit, and any moneys arising from such disposal shall, without prejudice to it being taken into account (where appropriate) for the purposes of Regulation 47, be paid into or disposed of for the benefit of the Exchequer in such manner as the Minister for Finance shall direct.

(3) (a) In this section—

“appropriate court” means—

- (i) in case the estimated value of the animal, veterinary medicinal product, ingredient for a veterinary medicinal product or other thing to be forfeited does not exceed €15,000, the District Court,
- (ii) in case the estimated value aforesaid does not exceed €75,000, the Circuit Court,
- (iii) in any case, the High Court;

“estimated value”, in relation to the thing sought to be forfeited, means the estimated amount of money which, in the opinion of the court, a willing purchaser would pay to a willing seller when such a thing could be sold legally and after deduction for—

- (I) the estimated costs incidental to such a sale, and
- (II) the estimated amount of any tax or duty owing to the State in respect of that thing,

and when it cannot be sold legally then such estimated value, if any, as the court considers appropriate.

- (b) (i) If, in relation to an application under this section to the District Court, that court becomes of the opinion during the hearing of the application that—

- (I) the estimated value aforesaid will exceed €15,000, or
- (II) that for any reason it should decline jurisdiction,

it may, if it so thinks fit, transfer the application to the Circuit Court or the High Court, whichever it considers appropriate having regard to the estimated value aforesaid or to such other matters that it considers appropriate.

- (ii) If, in relation to an application under this section to the Circuit Court, that court becomes of opinion during the hearing of the application that—

- (I) the estimated value aforesaid will exceed €75,000, or
- (II) that for any reason it should decline jurisdiction,

it may, if it so thinks fit, by order transfer the application to the High Court.

- (c) An application under this section shall be brought in a summary manner.

- (4) (a) An order shall not be made by a court under this section unless the court is satisfied that in the circumstances all practicable steps have been taken to notify any person of the proceedings relating to the application for the order and who, in the opinion of the court, should be given the opportunity of being heard by it on that application.

- (b) The court concerned may make such order as to the costs of the parties to or heard by the court in proceedings relating to an

application for an order under this section as it considers appropriate.

Recoupment of costs of certain disposals

47. Where any thing which is seized from or forfeited by a person under these Regulations is duly disposed of by or on behalf of the State, the costs of such disposal, less any moneys arising from such disposal, shall (except where such costs have been waived in writing) be recoverable from such person as a simple contract debt in any court of competent jurisdiction.

Forgery

48. (1) A person shall not forge a document purporting to be—

- (a) a veterinary prescription,
- (b) an authorisation or approval or registration under the VMP Regulation, or
- (c) a record required to be kept under, or any other document issued or maintained under, an applicable EU Regulation or these Regulations,

(which is, in this Regulation, referred to as a “forged document”).

(2) A person shall not forge an endorsement or other entry purporting to be for any purpose of an applicable EU Regulation on any document whatsoever required to be kept for the purposes of an applicable EU Regulation (which document with such entry in this Regulation is referred to as a “falsely endorsed document”).

(3) A person shall not, with intent to deceive, alter—

- (a) a veterinary prescription,
- (b) an authorisation or approval or registration under the VMP Regulation, or
- (c) a record required to be kept or any other document issued or maintained under an applicable EU Regulation,

(which document if so altered is, in this Regulation, referred to as an “altered document”).

(4) A person shall not utter a forged document, a falsely endorsed document or an altered document.

(5) A person shall not have in his or her possession or under his or her control, a forged document, a falsely endorsed document or an altered document.

(6) Paragraph (5) does not apply to—

- (a) an authorised officer or a member of the Garda Síochána or an officer of customs, when acting in the course of his or her duty, or

(b) a person who has taken into his or her possession a document for the purpose of—

(i) preventing another from committing or continuing to commit an offence, or

(ii) delivering it into the custody of a person specified in subparagraph (a).

(7) A person who contravenes this Regulation commits an offence and is liable—

(a) on summary conviction, to a class A fine, or to imprisonment for a term not exceeding 6 months, or to both,

(b) on conviction on indictment, to a fine not exceeding €50,000, or to imprisonment for a term not exceeding 2 years, or to both.



GIVEN under my Official Seal,
27 January, 2022.

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 give effect to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018, and the European Commission implementing and delegated acts referred to in the following regulations adopted thereunder on veterinary medicinal products, and Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and use of medicated feed by providing for offences and penalties for contravention of such and enforcement measures.

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