STATUTORY INSTRUMENTS

2013 No. 2033

The Veterinary Medicines Regulations 2013

PART 5

Miscellaneous provisions, enforcement and offences

The Veterinary Products Committee

28.—(1) There shall continue to be a Veterinary Products Committee.

(2) The Secretary of State may appoint members of the Committee from professional people who are eminent in their field, and any lay members as the Secretary of State sees fit.

(3) The function of the Committee is to provide scientific advice on any aspect of veterinary medicinal products asked for by the Secretary of State and to carry out any functions specified in these Regulations.

(4) The Secretary of State may pay members of the Committee such amounts as the Secretary of State may decide.

(5) The Secretary of State may consult the Committee at any time.

Veterinary Products Committee appeals procedure

29.—(1) The following procedure applies when any person receives a notification from the Secretary of State informing that person (the appellant) of a right to an appeal to the Veterinary Products Committee.

(2) The appellant must inform the Secretary of State of an intention to appeal within 28 days of the notification which is the subject of the appeal.

(3) The appeal may be written or oral, or both, at the choice of the appellant.

(4) The appellant may not present to the Committee any new data not available to the Secretary of State at the time of the original decision.

(5) The Committee must consider the appeal and any representations made by the Secretary of State, and report its findings in writing to the Secretary of State together with its recommendations.

(6) The Secretary of State must send a copy of the report to the appellant on request.

(7) The Secretary of State must consider the report and then form a provisional decision.

(8) The Secretary of State must then notify the provisional decision to the appellant, together with the reasons for it.

Appeals to an appointed person

30.—(1) A person aggrieved by a provisional decision of the Secretary of State under regulation 29 may appeal against the decision to a person appointed for the purpose by the Secretary of State in accordance with this regulation.

(2) So may an applicant for—

(a) a manufacturing authorisation;

(b) appointment as a Qualified Person for the purposes of a manufacturing authorisation;

(c) authorisation for a person or premises to manufacture autogenous vaccines;

(d) an authorisation of a blood bank;

(e) authorisation of a person and premises to manufacture an unauthorised veterinary medicinal product for administration under the cascade;

(f) authorisation of an equine stem cell centre;

(g) a wholesale dealer's authorisation;

(h) the approval of premises for the supply of POM-VPS or NFA-VPS veterinary medicinal products by a suitably qualified person,

if such an application is refused.

(3) A holder of any of the above authorisations, appointment or approvals may appeal against a suspension or compulsory variation in the same way.

(4) The appointed person must consider the appeal (but may not consider any new data not available to the Secretary of State at the time of the original decision) and any representations made by the Secretary of State and report in writing, with a recommended course of action, to the Secretary of State.

(5) The Secretary of State must then reach a final decision and notify the appellant, together with the reasons for it.

Exports E+W+S

31.—(1) No person may export a veterinary medicinal product for use in another **[**F1country**]** unless the veterinary medicinal product may be lawfully supplied or administered in that **[**F1country**]**.

(2) If a veterinary medicinal product has been manufactured in accordance with a marketing authorisation, or if a product without a marketing authorisation has been manufactured under a manufacturing authorisation, and the product is intended for export F2..., the Secretary of State must, at the request of the exporter or the competent authorities of the country to which it is being exported, provide a certificate to that effect.

(3) When issuing the certificate the Secretary of State must take account of the model certificates issued by the World Health Organization(**1**).

(4) If the veterinary medicinal product is authorised in the United Kingdom the Secretary of State must ensure that the exporter or the competent authorities of the **[**F3importing**]** country has access to the summary of product characteristics.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F1 Word in reg. 31(1) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(6)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

(**1**) Published by the World Health Organization at: www.who.int/medicines/en.

F2 Word in reg. 31(2) omitted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(6)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Word in reg. 31(4) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(6)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Exports N.I.

31.—(1) No person may export a veterinary medicinal product for use in another **[**[F9]country**]** unless the veterinary medicinal product may be lawfully supplied or administered in that **[**[F9]country**]**.

(2) If a veterinary medicinal product has been manufactured in accordance with a marketing authorisation, or if a product without a marketing authorisation has been manufactured under a manufacturing authorisation, and the product is intended for export outside the European Union, the Secretary of State must, at the request of the exporter or the competent authorities of the country to which it is being exported, provide a certificate to that effect.

(3) When issuing the certificate the Secretary of State must take account of the model certificates issued by the World Health Organization(**1**).

(4) If the veterinary medicinal product is authorised in the United Kingdom the Secretary of State must ensure that the exporter or the competent authorities of the third country has access to the summary of product characteristics.

Extent Information

E6 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F9 Word in reg. 31(1) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(7)**

Time limits

32.—(1) In any provision in these Regulations requiring the Secretary of State to issue an authorisation within a set time, the clock does not start to run until the Secretary of State has checked that the application dossier is in accordance with these Regulations and has validated the application.

(2) In calculating the period during which the Secretary of State must issue any authorisation requires the clock is stopped when the Secretary of State requires an applicant to provide further data until all the further data required have been provided.

(3) The clock is also stopped during any period that the applicant is given to provide oral or written explanations.

(4) The Secretary of State may stop the clock pending payment of outstanding fees.

(**1**) Published by the World Health Organization at: www.who.int/medicines/en.

Appointment of inspectors

33. The Secretary of State must appoint inspectors for the purposes of the enforcement of these Regulations and in these Regulations "inspector" means an inspector appointed under this regulation or a veterinary inspector appointed under the Animal Health Act 1981(**2**).

Powers of entry E+W+S

34.—(1) An inspector may, on giving reasonable notice, and on producing a duly authenticated authorisation if required, enter any premises at any reasonable hour for the purpose of ensuring that the provisions of these Regulations are being complied with; and in this regulation "premises" includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft.

(2) The requirement to give notice does not apply—

(a) where the entry is pursuant to any provision of an **[**F4enactment**]** which requires inspection without notice;

(b) where the requirement has been waived;

(c) where reasonable efforts to agree an appointment have failed;

(d) where an inspector has reasonable suspicion of a failure to comply with these Regulations; or

(e) in an emergency.

(3) Paragraph (1) does not apply in relation to any premises which are used wholly or mainly as a private dwelling, unless those premises, or any part of them, are approved, registered or authorised for the sale of veterinary medicines under paragraph 8, 10, 14(4) or 18 of Schedule 3 or for use as a feed business under paragraph 5(2)(e) or 7(2) of Schedule 5.

(4) Paragraphs (1) and (3) do not affect any right of entry conferred by a warrant issued by a justice of the peace.

[F5(5) An inspector may be accompanied by such other persons as the inspector considers necessary.**]**

(6) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises for the purposes of the enforcement of these Regulations, and either—

(a) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier;

(b) asking for admission, or the giving of such a notice, would defeat the object of the entry;

(c) the case is one of urgency; or

(d) the premises are unoccupied or the occupier is temporarily absent,

the justice may by signed warrant authorise an inspector to enter the premises, if need be by reasonable force.

(7) A warrant under this regulation is valid for one month.

(8) An inspector who enters any unoccupied premises must leave them as effectively secured against unauthorised entry as they were before entry.

(9) An inspector may enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and the premises of the marketing authorisation holder.

F6(10) . . . . . .

(**2**) 1981 c. 22.

(11) In this regulation, a reference to a justice of the peace —

(a) in Scotland includes a reference to the sheriff and to a magistrate; and

(b) in Northern Ireland, is a reference to a lay magistrate.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F4 Word in reg. 34(2)(a) substituted (E.W.S.) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(7)(a)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Reg. 34(5) substituted (E.W.S) (31.12.2020) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(7)(b)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Reg. 34(10) omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(b), **3(7)(c)** (as amended by S.I. 2020/1461, regs. 1(2)(a), **3(2)(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Powers of entry N.I.

34.—(1) An inspector may, on giving reasonable notice, and on producing a duly authenticated authorisation if required, enter any premises at any reasonable hour for the purpose of ensuring that the provisions of these Regulations are being complied with; and in this regulation "premises" includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft.

(2) The requirement to give notice does not apply—

(a) where the entry is pursuant to any provision of an EU instrument which requires inspection without notice;

(b) where the requirement has been waived;

(c) where reasonable efforts to agree an appointment have failed;

(d) where an inspector has reasonable suspicion of a failure to comply with these Regulations; or

(e) in an emergency.

(3) Paragraph (1) does not apply in relation to any premises which are used wholly or mainly as a private dwelling, unless those premises, or any part of them, are approved, registered or authorised for the sale of veterinary medicines under paragraph 8, 10, 14(4) or 18 of Schedule 3 or for use as a feed business under paragraph 5(2)(e) or 7(2) of Schedule 5.

(4) Paragraphs (1) and (3) do not affect any right of entry conferred by a warrant issued by a justice of the peace.

(5) An inspector may be accompanied by—

(a) such other persons as the inspector considers necessary; [F10]...

[F10](b) . . . . . .

(6) If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises for the purposes of the enforcement of these Regulations, and either—

(a) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier;

(b) asking for admission, or the giving of such a notice, would defeat the object of the entry;

(c) the case is one of urgency; or

(d) the premises are unoccupied or the occupier is temporarily absent,

the justice may by signed warrant authorise an inspector to enter the premises, if need be by reasonable force.

(7) A warrant under this regulation is valid for one month.

(8) An inspector who enters any unoccupied premises must leave them as effectively secured against unauthorised entry as they were before entry.

(9) An inspector may enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products, and the premises of the marketing authorisation holder.

(10) An inspector may carry out an inspection at the request of **[**F11a**]** member State, the European Commission or the Agency.

[F12(11) In this regulation, a reference to justice of the peace is a reference to a lay magistrate.**]**

Extent Information

E7 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F10 Reg. 34(5)(b) and word omitted (N.I.) (31.12.2020) by virtue of The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs., 1(3), 10(8(a)

F11 Word in reg. 34(10) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(8)(b)**

F12 Reg. 34(11) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(8)(c)**

Powers of an inspector

35.—(1) An inspector entering premises under the previous regulation may—

(a) inspect the premises, and any plant, machinery or equipment;

(b) search the premises;

(c) take samples;

(d) seize any computers and associated equipment;

(e) seize any veterinary medicinal product or any additive to which Schedule 5 applies, if it is not authorised in the United Kingdom;

(f) seize any premixture or feedingstuff that contains a veterinary medicinal product or additive to which Schedule 5 applies that is not authorised in the United Kingdom;

(g) seize any veterinary medicinal product, any additive to which Schedule 5 applies, any premixture or feedingstuff if—

(i) it has not been lawfully manufactured, incorporated or supplied in accordance with these Regulations;

(ii) it has been stored in a way that affects its safety, quality or efficacy; or

(iii) it is sold or offered for sale by a person not permitted to supply it under these Regulations;

(h) carry out any inquiries, examinations and tests;

(i) have access to, and inspect and copy or seize any documents or records (in whatever form they are held) relating to these Regulations; and

(j) have access to, inspect and check the operation of any computer and any associated apparatus or material that is or has been in use in connection with the records; and for this purpose may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford such assistance as may reasonably be required and, where a record is kept by means of a computer, may require the records to be produced in a form in which they may be taken away.

(2) The powers of seizure under sub-paragraph (1)(e), (f) and (g) include a power to seize anything which purports to be, or which an inspector reasonably believes to be, something the inspector is entitled to seize under these powers.

(3) An officer of any local authority who has entered premises exercising any statutory power of entry for the purposes of enforcing any legislation relating to food hygiene, feed hygiene or animal health, may inspect any records made under these Regulations (in whatever form they are held) relating to food-producing animals, and may remove them to enable them to be copied.

(4) Where an inspector has entered any premises and it is not reasonably practicable to determine at the time whether documents on those premises are relevant to these Regulations, the inspector may seize them to ascertain whether or not they are relevant.

Inspection of pharmacies

36. In relation to a pharmacy, all the powers of an inspector to enforce these Regulations may also be exercised by an officer of the General Pharmaceutical Council appointed for the purpose.

Obstruction

37. No person may—

(a) intentionally obstruct any person acting in the execution of these Regulations;

(b) without reasonable cause, fail to give to any person acting in the execution of these Regulations any assistance or information that that person may reasonably require under these Regulations;

(c) furnish to any person acting in the execution of these Regulations any information knowing it to be false or misleading; or

(d) fail to produce a record when required to do so to any person acting in the execution of these Regulations.

Improvement notices

38.—(1) An inspector who has reasonable grounds for believing that any person is failing to comply with these Regulations may serve a notice on that person (in these Regulations referred to as an "improvement notice") that—

(a) states the inspector's grounds for believing this;

(b) specifies the matters that constitute the failure to comply;

(c) specifies the measures that, in the inspector's opinion, the person must take in order to secure compliance; and

(d) requires the person to take those measures, or measures at least equivalent to them, within the period (being not less than 14 days) specified in the notice.

(2) An improvement notice must state—

(a) the right of appeal to a magistrates' court or to the sheriff; and

(b) the period within which such an appeal may be brought.

Appeals against improvement notices E+W+S

39.—(1) Any person who is aggrieved by an improvement notice may appeal to a magistrates' court or, in Scotland, to the sheriff.

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980(**3**) applies to the proceedings.

(3) An appeal to the sheriff under paragraph (1) is by summary application.

(4) The period within which an appeal may be brought is 28 days or the period specified in the improvement notice, whichever ends the earlier.

(5) A court may suspend an improvement notice pending an appeal.

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Appeals against improvement notices N.I.

39.—(1) Any person who is aggrieved by an improvement notice may appeal to a magistrates' court [F13]....

(2) The procedure on an appeal to a magistrates' court under paragraph (1) is by way of complaint, and the Magistrates' Courts Act 1980(**3**) applies to the proceedings.

[F14](3) . . . . . .

(4) The period within which an appeal may be brought is 28 days or the period specified in the improvement notice, whichever ends the earlier.

(5) A court may suspend an improvement notice pending an appeal.

Extent Information

E8 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

(**3**) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c.39), section 47.
(**3**) 1980 c. 43; sections 51 and 52 have been substituted by the Courts Act 2003 (c.39), section 47.

Textual Amendments

F13 Words in reg. 39(1) omitted (N.I.) (31.12.2020) by virtue of The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(9)(a)**

F14 Reg. 39(3) omitted (N.I.) (31.12.2020) by virtue of The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(9)(b)**

Powers of a court on appeal

40. On an appeal against an improvement notice, the court may either cancel the notice or confirm it, with or without modification.

Seizure notices E+W+S

41.—(1) An inspector must follow the procedures set out in this regulation when seizing anything under these Regulations.

(2) The inspector must serve on the person appearing to be in charge of the seized product a notice (referred to in these Regulations as a "seizure notice")—

(a) giving the grounds for seizing the product; and

(b) informing that person of the rights under this regulation to make a claim, and the address for the service of the claim.

(3) An inspector who is not able to remove products seized immediately may mark the products in any way, and serve a notice on the person in charge of the products identifying them, and prohibiting the removal of the products from the premises until they are collected by an inspector, and no person other than an inspector may remove products identified under this paragraph from the premises.

(4) The person on whom the seizure notice was served or the owner of the seized product may, within 28 days of seizure, notify any claim that the product was not liable to seizure to the Secretary of State at the address specified in the seizure notice, setting out the grounds in full.

(5) If a notification of a claim is not received within 28 days, the Secretary of State may destroy the product.

(6) If a notification of a claim is received within 28 days, then, unless the product seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal investigation, the Secretary of State must either return the product or take proceedings for an order for the confirmation of the seizure notice and the destruction of the veterinary medicinal product in a magistrates' court (or, in Scotland, the sheriff court), and if the court confirms the notice it must order its destruction.

(7) The procedure in a magistrates' court under this regulation is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings.

(8) The procedure before the sheriff is by summary application.

(9) The person on whom the seizure notice was served is liable for the costs of transport, storage for up to 28 days and destruction of the product seized unless a claim is made to a court and the court directs otherwise.

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Seizure notices N.I.

41.—(1) An inspector must follow the procedures set out in this regulation when seizing anything under these Regulations.

(2) The inspector must serve on the person appearing to be in charge of the seized product a notice (referred to in these Regulations as a "seizure notice")—

(a) giving the grounds for seizing the product; and

(b) informing that person of the rights under this regulation to make a claim, and the address for the service of the claim.

(3) An inspector who is not able to remove products seized immediately may mark the products in any way, and serve a notice on the person in charge of the products identifying them, and prohibiting the removal of the products from the premises until they are collected by an inspector, and no person other than an inspector may remove products identified under this paragraph from the premises.

(4) The person on whom the seizure notice was served or the owner of the seized product may, within 28 days of seizure, notify any claim that the product was not liable to seizure to the Secretary of State at the address specified in the seizure notice, setting out the grounds in full.

(5) If a notification of a claim is not received within 28 days, the Secretary of State may destroy the product.

(6) If a notification of a claim is received within 28 days, then, unless the product seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal investigation, the Secretary of State must either return the product or take proceedings for an order for the confirmation of the seizure notice and the destruction of the veterinary medicinal product in a magistrates' court [F15]..., and if the court confirms the notice it must order its destruction.

(7) The procedure in a magistrates' court under this regulation is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings.

[F16](8) . . . . . .

(9) The person on whom the seizure notice was served is liable for the costs of transport, storage for up to 28 days and destruction of the product seized unless a claim is made to a court and the court directs otherwise.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F15 Words in reg. 41(6) omitted (N.I.) (31.12.2020) by virtue of The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(10)(a)**

F16 Reg. 41(8) omitted (N.I.) (31.12.2020) by virtue of The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(10)(b)**

Publication

42.—(1) The Secretary of State must publicise all improvement notices and seizure notices issued under these Regulations and the suspension or revocation of anything issued under these Regulations, and may do so in such manner as the Secretary of State sees fit.

(2) This does not apply in relation to a seizure notice issued to a common carrier who does not own the seized goods.

Offence

43. It is an offence(**4**) to fail to comply with—

(a) regulation 4(1) or (2);

(b) regulation 5(1);

(c) regulation 7(2), (3), (4) or (5);

(d) regulation 8;

(e) regulation 9(1);

(f) regulation 10(1) or (2);

(g) regulation 11(1);

(h) regulation 13;

(i) regulation 17;

(j) regulation 18

(k) regulation 19

(l) regulation 20

(m) regulation 21

(n) regulation 22

(o) regulation 23

(p) regulation 24;

(q) regulation 25(1);

(r) regulation 26(1), (2) or (6);

(s) regulation 27(1);

(t) regulation 31(1);

(u) regulation 37;

(v) an improvement notice issued under regulation 38; or

(w) regulation 41(3).

Penalties

44.—(1) A person guilty of an offence under these Regulations is liable—

(a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or both, or

(b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

(2) Where a body corporate is guilty of an offence under these Regulations, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of—

(a) a qualified person appointed as such for the purposes of these Regulations;

(b) any director, manager, secretary or other similar person of the body corporate; or

(**4**) Other offences are set out at the end of Schedules 1, 2, 3, 4 and 5.

(c) any person who was purporting to act in any such capacity,

that person is guilty of the offence as well as the body corporate.

(3) If an offence under these Regulations committed by a partnership is shown—

(a) to have been committed with the consent or connivance of a partner; or

(b) to be attributable to any neglect on their part,

the partner as well as the partnership is guilty of the offence and liable to be proceeded against and punished accordingly.

(4) For the purposes of paragraph (2) above, "director", in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate.

(5) Where an offence that has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, the partner as well as the partnership is guilty of the offence.

Northern Ireland E+W+S

[F7]45. . . . . . .

Textual Amendments

F7 Reg. 45 omitted (E.W.S.) (31.12.2020) by virtue of The Veterinary Medicines and Residues (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1461), regs. 1(2)(b), **4(6)**

Northern Ireland N.I.

45.—(1) This regulation has effect in relation to the enforcement of these Regulations in Northern Ireland.

(2) The Department of Agriculture and Rural Development or the Department of Health, Social Services and Public Safety (or both Departments acting jointly) instead of the Secretary of State exercise the powers of the Secretary of State in—

(a) regulation 33 (appointment of inspectors);

(b) regulation 41 (seizure notices);

(c) regulation 42 (publication); and

(d) sub-paragraph (4) of paragraph 14 of Schedule 3 (approval of premises for suitably qualified persons).

(3) The Department of Agriculture and Rural Development is the competent authority for—

[[F17](a) Regulation (EC) No 178/2002;**]**

[[F18](b) Regulation (EC) No 1831/2003;**]**

[[F19](c) Regulation (EU) 2017/625; and**]**

[[F20](d) Regulation (EC) No 183/2005.**]**

(4) In relation to pharmacies, an officer of the Pharmaceutical Society of Northern Ireland appointed by the Society for the purpose has all the powers of an inspector to enforce these Regulations.

(5) In proceedings in a magistrates' court relating to an improvement notice under regulation 38 or a seizure notice under regulation 41, the Magistrates' Courts (Northern Ireland) Order 1981(**5**) applies.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F17 Reg. 45(3)(a) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(3)(a)**

F18 Reg. 45(3)(b) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(3)(b)**

F19 Reg. 45(3)(c) substituted (N.I.) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(11)**; and substituted (N.I.) (31.12.2020) by The Official Controls (Animals, Feed and Food, Plant Health etc.) (Amendment) (EU Exit) (No. 2) Regulations 2020 (S.I. 2020/1631), regs. 1(2), **3(3)**

F20 Reg. 45(3)(d) substituted (26.3.2019) by The Veterinary Medicines and Animals and Animal Products (Examination of Residues and Maximum Residue Limits) (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/676), regs. 1(2)(a), **2(3)(d)**

Review E+W+S

46.—(1) Before the end of each review period, the Secretary of State must—

(a) carry out a review of these Regulations other than the fees provisions;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the EU instruments, or provisions of EU instruments, to which this regulation applies are implemented in other member States.

(3) The EU instruments, and provisions of EU instruments, to which this regulation applies are—

(a) Council Directive 90/167/EEC laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation (EC) No 183/2005(**6**);

(b) Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**7**);

(c) Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**8**);

(d) Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety

(**5**) S.I. 1981/1675 (N.I. 26).
(**6**) OJ No L 92, 7.4.1990, p. 42.
(**7**) OJ No L 228, 17.8.1991, p. 70.
(**8**) OJ No L311, 28.11.2001, p. 1; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ No L188, 18.7.2009, p. 14).

Authority and laying down procedures in matters of food safety, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(e) Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(f) **[**[F8]Regulation (EU) 2017/625 of the European Parliament and of the Council on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products;**]**

(g) Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(h) Commission Regulation (EC) No 1234/2008(**9**);

(i) Regulation (EC) No 470/2009 of the European Parliament and of the Council(**10**);

(j) Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and Articles 15 and 17 of that Regulation as they refer to the labelling requirements for feedingstuffs containing specified feed additives(**11**); and

(k) Commission Regulation (EU) No 37/2010(**12**).

(4) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, other than the fees provisions;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(5) In this regulation—

(a) "review period" means the period of five years beginning with the day on which these Regulations come into force, and, subject to paragraph (6), each successive period of five years thereafter; and

(b) "the fees provisions" means regulation 16 and Schedule 7.

(6) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F8 Reg. 46(3)(f) substituted (E.) (14.12.2019) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) Regulations 2019 (S.I. 2019/1488), regs. 1(1), 27(c); and substituted (W.) (31.1.2020) by The Official Controls (Animals, Feed and Food, Plant Health Fees etc.) (Wales) Regulations 2020 (S.I. 2020/44), regs. 1(2), **24(1)(c)**

(**9**) OJ No L334, 12.12.2008, p. 7.
(**10**) OJ No L152, 16.6.2009, p. 11.
(**11**) OJ No L229, 1.9.2009, p. 1, last amended by Commission Regulation (EU) No 939/2010 (OJ L277, 21.10.2010, p. 14).
(**12**) OJ No L293, 11.11.2010, p.72; corrected at OJ L293, 11.11.2010, p. 72.

Review **N.I.**

46.—(1) Before the end of each review period, the Secretary of State must—

(a) carry out a review of these Regulations other than the fees provisions;

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the EU instruments, or provisions of EU instruments, to which this regulation applies are implemented in [F21]... member States.

(3) The EU instruments, and provisions of EU instruments, to which this regulation applies are—

(a) Council Directive 90/167/EEC laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, so far it is not superseded by Regulation (EC) No 183/2005(**6**);

(b) Commission Directive 91/412/EEC laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products(**7**);

(c) Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products(**8**);

(d) Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(e) Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition, in so far as it applies to veterinary medicinal products used in feedingstuffs;

[[F22](f) Regulation (EU) 2017/625;**]**

(g) Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene, in so far as it applies to veterinary medicinal products used in feedingstuffs;

(h) Commission Regulation (EC) No 1234/2008(**9**);

(i) Regulation (EC) No 470/2009 of the European Parliament and of the Council(**10**);

(j) Article 8 of Regulation (EC) No 767/2009 of the European Parliament and of the Council, and Articles 15 and 17 of that Regulation as they refer to the labelling requirements for feedingstuffs containing specified feed additives(**11**); and

(k) Commission Regulation (EU) No 37/2010(**12**).

(4) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by these Regulations, other than the fees provisions;

(b) assess the extent to which those objectives are achieved; and

(**6**) OJ No L 92, 7.4.1990, p. 42.
(**7**) OJ No L 228, 17.8.1991, p. 70.
(**8**) OJ No L311, 28.11.2001, p. 1; last amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council (OJ No L188, 18.7.2009, p. 14).
(**9**) OJ No L334, 12.12.2008, p. 7.
(**10**) OJ No L152, 16.6.2009, p. 11.
(**11**) OJ No L229, 1.9.2009, p. 1, last amended by Commission Regulation (EU) No 939/2010 (OJ L277, 21.10.2010, p. 14).
(**12**) OJ No L293, 11.11.2010, p.72; corrected at OJ L293, 11.11.2010, p. 72.

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(5) In this regulation—

(a) "review period" means the period of five years beginning with the day on which these Regulations come into force, and, subject to paragraph (6), each successive period of five years thereafter; and

(b) "the fees provisions" means regulation 16 and Schedule 7.

(6) If a report under this regulation is published before the last day of the review period to which it relates, the following review period is to begin with the day on which that report is published.

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F21 Word in reg. 46(2) omitted (N.I.) (31.12.2020) by virtue of The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(12)(a)**

F22 Reg. 46(3)(f) substituted (N.I) (31.12.2020) by The Animals (Health, Identification, Trade and Veterinary Medicines) (Amendment) (EU Exit) Regulations (Northern Ireland) 2020 (S.R. 2020/353), regs. 1(3), **10(12)(b)**

Revocations

47. The following Regulations are revoked—

(a) the Veterinary Medicines Regulations 2011(**13**); and

(b) the Veterinary Medicines (Amendment) Regulations 2012(**14**).

(**13**) S.I. 2011/2159.
(**14**) S.I. 2012/2711.

Changes to legislation:
There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 5.