STATUTORY INSTRUMENTS

2013 No. 2033

The Veterinary Medicines Regulations 2013

PART 3

Records

Food-producing animals: proof of purchase of veterinary medicinal products

17. The keeper of a food-producing animal must keep proof of purchase of all veterinary medicinal products acquired for the animal (or, if they were not bought, documentary evidence of how they were acquired).

Food-producing animals: records of administration by a veterinary surgeon

- **18.** A veterinary surgeon who administers a veterinary medicinal product to a food-producing animal must [Flas soon as is reasonably practicable] either enter the following information personally in the keeper's records or give it to the keeper in writing (in which case the keeper must enter the following into those records)—
 - (a) the name of the veterinary surgeon;
 - (b) the name of the product and the batch number;
 - (c) the date of administration of the product;
 - (d) the amount of product administered;
 - (e) the identification of the animals treated; and
 - (f) the withdrawal period.

Textual Amendments

F1 Words in reg. 18 inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 11

Food-producing animals: records of acquisition and administration

- **19.**—(1) When a veterinary medicinal product is bought or otherwise acquired for a food-producing animal the keeper must, at the time, record—
 - (a) the name of the product and the batch number;
 - (b) the date of acquisition;
 - (c) the quantity acquired; and
 - (d) the name and address of the supplier.
- (2) At the time of administration (unless the administration is by a veterinary surgeon in which case the record must be in accordance with regulation 18) the keeper must record—

- (a) the name of the product;
- (b) the date of administration;
- (c) the quantity administered;
- (d) the withdrawal period; and
- (e) the identification of the animals treated.
- (3) A keeper who disposes of any or all of the veterinary medicinal product other than by treating an animal must record—
 - (a) the date of disposal;
 - (b) the quantity of product involved; and
 - (c) how and where it was disposed of.

Food-producing animals: retention of records

20. The keeper of a food-producing animal must keep the documentation on the acquisition of a veterinary medicinal product and the records relating to the product for at least five years following the administration or other disposal of the product, irrespective of whether or not the animal concerned is no longer in that keeper's possession or has been slaughtered or has died during that period.

Records by a holder of a manufacturing authorisation E+W+S

- **21.**—[F²(1) The holder of a manufacturing authorisation must record the following information in respect of any veterinary medicinal product supplied by the holder—
 - (a) the name of the veterinary medicinal product and marketing authorisation number if applicable;
 - (b) the pharmaceutical form and strength of the product;
 - (c) the quantity of product supplied;
 - (d) the batch number and expiry date;
 - (e) the date of the transaction under which the product was supplied;
 - (f) the company name and the permanent address or registered place of business of the recipient of the supply.]
- (2) The holder must keep with the record all certification provided by the qualified person (manufacture) in relation to that batch.
- (3) The holder must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market [F3 or for one year after the date of expiry of the batch, whichever is the longer.].

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

- **F2** Reg. 21(1) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **12(a)**
- **F3** Words in reg. 21(3) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **12(b)**

Records by a holder of a manufacturing authorisation N.I.

- **21.**—(1) A holder of a manufacturing authorisation must, as soon as is reasonably practicable, make a record of each batch of veterinary medicinal product manufactured, assembled or supplied, which must include—
 - (a) the name of the product;
 - (b) the quantity manufactured, assembled or supplied;
 - (c) the date of manufacture, assembly or supply;
 - (d) the batch number and expiry date; and
 - (e) in the case of supply, the name and address of the recipient.
- (2) The holder must keep with the record all certification provided by the qualified person (manufacture) in relation to that batch.
- (3) The holder must keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market.

Extent Information

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

Records by a holder of a wholesale dealer's authorisation E+W+S

- **22.** A holder of a wholesale dealer's authorisation must record the following as soon as is reasonably practicable after each incoming or outgoing transaction (including disposal) relating to a veterinary medicinal product—
 - (a) the date ^{F4}... of the transaction,
 - (b) the name of the veterinary medicinal product,
 - [F5(ba) the pharmaceutical form and strength of the product;]
 - (c) the F6... batch number,
 - (d) the expiry date,
 - (e) the quantity, and
 - [F7(f)] the company name and permanent address or registered place of business of—
 - (i) in respect of a purchase, the supplier, and
 - (ii) in respect of a sale, the recipient,

and must keep the records for at least [F8 five years].

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 Words in reg. 22(a) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 13(a)
- F5 Reg. 22(ba) inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **13(b)**

- **F6** Word in reg. 22(c) omitted (E.W.S.) (17.5.2024) by virtue of The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 13(c)
- F7 Reg. 22(f) substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **13(d)**
- F8 Words in reg. 22 substituted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), 13(e)

Records by a holder of a wholesale dealer's authorisation N.I.

- **22.** A holder of a wholesale dealer's authorisation must record the following as soon as is reasonably practicable after each incoming or outgoing transaction (including disposal) relating to a veterinary medicinal product—
 - (a) the date and nature of the transaction,
 - (b) the name of the veterinary medicinal product,
 - (c) the manufacturer's batch number,
 - (d) the expiry date,
 - (e) the quantity, and
 - (f) the name and address of the supplier or recipient,

and must keep the records for at least three years.

Extent Information

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

Records of the receipt or supply of prescription products E+W+S

- **23.**—[F9(1) Any person permitted under these Regulations to supply a veterinary medicinal product classified as POM-V or POM-VPS or prescribed under the cascade who receives or supplies any such veterinary medicinal product must keep all documents relating to the transaction which show—
 - (a) the date of the transaction under which the product was received or supplied;
 - (b) the name of the veterinary medicinal product;
 - (c) the pharmaceutical form and strength of the product;
 - (d) the batch number;
 - (e) the quantity of product received or supplied;
 - (f) the company name and the permanent address or registered place of business of—
 - (i) in respect of a purchase, the supplier;
 - (ii) in respect of a sale, the recipient;
 - (g) if there is a written prescription the name and contact details of the prescriber;
 - (h) the expiry date.
- (1A) Where the duty in paragraph (1) applies in respect of a veterinary medicinal product for a non-food producing animal, the duty in respect of sub-paragraph (d) is satisfied by recording the batch number—
 - (a) on the date on which the batch is received, or

- (b) on the date on which a veterinary medicinal product from the batch is first supplied.]
- (2) If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction.
- (3) As an alternative to paragraphs (1) and (2) that person may make a record of all the information required there provided that this is done as soon as is reasonably practicable following the transaction.
 - (4) The documentation and records must be kept for at least five years.

Textual Amendments

F9 Reg. 23(1)(1A) substituted for reg. 23(1) (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **14**

Records of the receipt or supply of prescription products N.I.

- **23.**—(1) Any person permitted under these Regulations to supply a veterinary medicinal product classified as POM-V or POM-VPS who receives or supplies any such veterinary medicinal product must keep all documents relating to the transaction that show—
 - (a) the date;
 - (b) the name of the veterinary medicinal product;
 - (c) the batch number (except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date of receipt of the batch or the date a veterinary medicinal product from the batch is first supplied);
 - (d) the quantity;
 - (e) the name and address of the supplier or recipient; and
 - (f) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription.
- (2) If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction.
- (3) As an alternative to paragraphs (1) and (2) that person may make a record of all the information required there provided that this is done as soon as is reasonably practicable following the transaction.
 - (4) The documentation and records must be kept for at least five years.

Records of products administered to a food-producing animal under the cascade

- **24.** A veterinary surgeon administering a veterinary medicinal product to food-producing animals under the cascade, or permitting another person to administer it under that veterinary surgeon's responsibility, must, as soon as is reasonably practicable, record—
 - (a) the date of examination of the animals;
 - (b) the name and address of the owner;
 - (c) the identification and number of animals treated;
 - (d) the result of the veterinary surgeon's clinical assessment;
 - (e) the trade name of the product if there is one;
 - (f) the manufacturer's batch number shown on the product if there is one;
 - (g) the name and quantity of the active substances;

- (h) the doses administered or supplied;
- (i) the duration of treatment; and
- (j) the withdrawal period,

and must keep the record for at least five years.

[F10Reporting of sales and usage data in relation to antibiotics

- **24A.**—(1) Where the Secretary of State serves a notice in writing on any person mentioned in paragraph (2) requiring that person to provide any information held by that person in relation to sales and usage of antibiotics from any records made for the purposes of these Regulations the person must provide that information.
 - (2) The persons are—
 - (a) the holder of a manufacturing authorisation;
 - (b) the holder of a marketing authorisation;
 - (c) the holder of a wholesale dealer's authorisation;
 - (d) a keeper of food-producing animals;
 - (e) a feedingstuffs manufacturer;
 - (f) a veterinary surgeon.]

Textual Amendments

F10 Reg. 24A inserted (E.W.S.) (17.5.2024) by The Veterinary Medicines (Amendment etc.) Regulations 2024 (S.I. 2024/567), regs. 1(1), **15**

Changes to legislation:There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, PART 3.