STATUTORY INSTRUMENTS

2013 No. 2033

The Veterinary Medicines Regulations 2013

PART 3

Records

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

- **21.**—[F1(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 [F2 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

- F1 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)**
- **F2** 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;

Status: There are multiple versions of this provision on screen. These apply to different geographical extents. Skip to: E+W+S - England, Wales and Scotland extent N.I. - Northern Ireland extent Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Section 21. (See end of Document for details)

- (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

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

Status:

There are multiple versions of this provision on screen. These apply to different geographical extents.

Skip to:

- E+W+S England, Wales and Scotland extent
- N.I. Northern Ireland extent

Changes to legislation:

There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Section 21.