

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, Paragraph 5. (See end of Document for details)

SCHEDULE 2

The manufacture of veterinary medicinal products

PART 1

Manufacturing authorisations

[^{F1}Suspension, revocation etc] of the authorisation **E+W+S**

5.—(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder—

- (a) has not complied with these Regulations;
- (b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;
- (c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; ^{F2}...
- (d) no longer has suitable premises or equipment.

[^{F3}(e) has failed to carry out the activity specified in the authorisation for a period of five years or more; or

- (f) has not paid any fee required under these Regulations]

[^{F4}(2) The Secretary of State may also suspend, vary or revoke the authorisation on being satisfied that the qualified person (manufacturer), the person responsible for quality control or the person with responsibility for production is not fulfilling that person's duties under these Regulations.

(3) In particular, the Secretary of State may—

- (a) suspend the manufacture or import of veterinary medicinal products;
- (b) suspend, revoke or vary the manufacturing authorisation for one or more pharmaceutical forms;
- (c) suspend, revoke or vary the manufacturing authorisation for one or more activities in one or more manufacturing sites.]

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** Words in Sch. 2 para. 5 heading substituted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(c)**
- F2** Word in Sch. 2 para. 5(1) omitted (E.W.S.) (17.5.2024) by virtue of [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(a)(i)**
- F3** Sch. 2 para. 5(1)(e)(f) inserted (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(a)(ii)**
- F4** Sch. 2 para. 5(2)(3) substituted for Sch. 2 para. 5(2) (E.W.S.) (17.5.2024) by [The Veterinary Medicines \(Amendment etc.\) Regulations 2024 \(S.I. 2024/567\)](#), regs. 1(1), **85(b)**

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Changes to legislation: There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2013, Paragraph 5. (See end of Document for details)

Suspension, variation or revocation of the authorisation **N.I.**

5.—(1) The Secretary of State may suspend, vary or revoke a manufacturing authorisation if the holder—

- (a) has not complied with these Regulations;
- (b) has manufactured a veterinary medicinal product not authorised by the manufacturing authorisation;
- (c) has produced a veterinary medicinal product outside the terms of a marketing authorisation; or
- (d) no longer has suitable premises or equipment.

(2) The Secretary of State may also suspend, vary or revoke it on being satisfied that the qualified person (manufacture) is not fulfilling their duties under these Regulations.

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, Paragraph 5.