
STATUTORY INSTRUMENTS

2008 No. 2297

MEDICINES

^{F1}The Veterinary Medicines Regulations 2008

<i>Made</i>	- - - -	<i>26th August 2008</i>
<i>Laid before Parliament</i>		<i>1st September 2008</i>
<i>Coming into force</i>	- -	<i>1st October 2008</i>

The Secretary of State is a Minister designated⁽¹⁾ for the purposes of making Regulations under section 2(2) of the European Communities Act 1972⁽²⁾ in relation to measures in the veterinary and phytosanitary fields for the protection of public health.

The Secretary of State has carried out the consultation required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽³⁾.

In accordance with section 56(1) of the Finance Act 1973⁽⁴⁾, the Treasury consent to the making of these Regulations.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 and by section 56(1) of the Finance Act 1973.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, [45](#) (with [reg. 3](#))

^{F1}PART 1

Introduction

Title and commencement

1.

(1) S.I. 1999/2027.
(2) 1972 c. 68.
(3) OJ No. L31, 1.2.2002, p. 1.
(4) 1973 c.51.

Definition of “veterinary medicinal product”, interpretation and scope

2.

Products to which these Regulations do not apply

3.

^{F1}PART 2

Authorised veterinary medicinal products

Placing a veterinary medicinal product on the market

4.

Manufacture of veterinary medicinal products

5.

The finished product

6.

Classification, supply and possession of the product

7.

Administration of the product

8.

Importation of authorised veterinary medicinal products

9.

Advertising the product

10.

Advertising of prescription products and products containing psychotropic drugs or narcotics

11.

Defence of publication in the course of business

12.

Wholesale dealing

13.

Feedingstuffs

14.

Exemptions

15.

Fees

16.

^{F1}PART 3

Records

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

17.

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

18.

Food-producing animals: records of acquisition and administration

19.

Food-producing animals: retention of records

20.

Records by a holder of a manufacturing authorisation

21.

Records by a holder of a wholesale dealer's authorisation

22.

Records of the receipt or supply of prescription products

23.

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

24.

^{F1}PART 4

Unauthorised veterinary medicinal products

Importation of an unauthorised veterinary medicinal product

25.

Possession of an unauthorised veterinary medicinal product

26.

Supply of an unauthorised veterinary medicinal product

27.

PART 5

Miscellaneous provisions, enforcement and offences

The Veterinary Products Committee

^{F1}28.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Veterinary Products Committee appeals procedure

^{F1}29.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Appeals to an appointed person

^{F1}30.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Exports

^{F1}31.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Time limits

^{F1}32.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Appointment of inspectors

^{F1}33.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Powers of entry

^{F1}34.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Powers of an inspector

^{F1}35.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Inspection of pharmacies

^{F1}36.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Obstruction

^{F1}37.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Improvement notices

^{F1}38.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Appeals against improvement notices

^{F1}39.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Powers of a court on appeal

^{F1}40.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Seizure notices

^{F1}41.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Publication

^{F1}42.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Penalties

^{F1}43.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Northern Ireland

^{F1}44.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009 \(S.I. 2009/2297\)](#), regs. 1, **45** (with [reg. 3](#))

Revocations and consequential amendment

45.—^{F1}(1)

(2) In section 1 of the Medicines Act 1971⁽⁵⁾ (fees), in subsection (3), for “as amended by the Transfer of Functions (Wales) Order 1969 have the same meanings in this section as in that Act as so amended” substitute “(as amended) have the same meanings in this section as in that Act (as amended)”.

F1 Regulations revoked (except reg. 45(2)) (1.10.2009) by [The Veterinary Medicines Regulations 2009](#) (S.I. 2009/2297), regs. 1, **45** (with [reg. 3](#))

Jonathan Shaw
Parliamentary Under Secretary of State
Department for Environment, Food and Rural
Affairs
Dave Watts
Alan Campbell
Two of the Lords Commissioners of Her
Majesty’s Treasury

⁽⁵⁾ 1971 c.69, as amended by section 21 of the Health and Medicines Act 1988 (c. 49) and S.I. 1994/3144, 2004/1031, 2005/2750 and 2006/2407.

Changes to legislation: There are currently no known outstanding effects for the
The Veterinary Medicines Regulations 2008. (See end of Document for details)

^{F1}SCHEDULE 1 Regulation 4(3)

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^{F1}SCHEDULE 2 Regulation 5(2)

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^{F1}SCHEDULE 3 Regulation 7

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^{F1}SCHEDULE 4 Regulation 8

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^{F1}SCHEDULE 5 Regulation 14

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^{F1}SCHEDULE 6 Regulation 15(4)

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^{F1}SCHEDULE 7 Regulation 16

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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and remake with amendments the Veterinary Medicines Regulations 2007.

Principal changes to the 2007 Regulations

The new Regulations introduce a fee for the registration of veterinary premises for the supply of veterinary medicinal products.

They provide comprehensive rights of appeal to an appointed person when applications for the authorisation or approval of manufacture or retail premises are refused.

They introduce new controls on the collection and supply of equine stem cells.

They introduce compulsory variations by the Secretary of State for manufacturers and wholesale dealers.

They allow suitably qualified persons to supply veterinary medicines to retail customers from pharmacies or registered veterinary premises without dual registration.

They introduce record-keeping requirements in relation to adverse reactions to products marketed under the small animals exemption scheme.

They update fees.

They have been changed so that the drafting is now gender-neutral.

They make an amendment to the Medicines Act 1971 arising from veterinary medicinal products no longer being licensed under the Medicines Act 1968.

The Regulations

The Regulations make provision for the authorisation, manufacture, classification, distribution and administration of veterinary medicinal products.

They implement Directive [2001/82/EC](#).

They enforce Regulations [\(EC\) No. 178/2002](#), No. 1831/2003, No. 882/2004 No. 183/2005, in so far as they apply to veterinary medicinal products used in feedingstuffs, and to some specified feed additives used in feedingstuffs.

They implement Council Directive 90/167 so far it is not superseded by Regulation [\(EC\) No. 183/2005](#).

They provide that a veterinary medicinal product must have a marketing authorisation granted by the Secretary of State before being placed on the market, and make provision for the grant of a marketing authorisation (regulation 4 and Schedule 1).

They specify that a veterinary medicinal product must be manufactured by a person holding a manufacturing authorisation, and make provision for granting an authorisation (regulation 5 and Schedule 2).

They regulate supply and possession of veterinary medicinal products, and introduce new classifications of those products (regulation 7 and Schedule 3).

They provide that a veterinary medicinal product may only be administered as specified in its marketing authorisation or, in the case of administration by a veterinary surgeon, administration under the rules of the “cascade” (regulation 8 and Schedule 4).

They control bringing a veterinary medicinal product into the United Kingdom (regulation 9) and advertising (regulation 10 to 12).

They control wholesale dealing (regulation 13 and Schedule 3).

They control medicated feedingstuffs and feedingstuffs containing additives specified in the Regulations (regulation 14 and Schedule 5).

They provide for exemptions (regulation 15 and Schedule 6).

They provide for fees (regulation 16 and Schedule 7).

Changes to legislation: There are currently no known outstanding effects for the
The Veterinary Medicines Regulations 2008. (See end of Document for details)

They require records to be kept (regulations 17 to 24).

They create offences of importation, possession and supply of unauthorised veterinary medicinal products (regulations 25 to 27).

They make provision for the existence of the Veterinary Products Committee (regulation 28). They make provision for an appeals procedure in the case of a refusal, etc., of a marketing authorisation (regulation 29).

They create administrative arrangements for the enforcement of the Regulations (regulations 32 to 41).

Under regulation 43 breach of the Regulations is an offence punishable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or both, or
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both.

A full impact assessment has been prepared and placed in the libraries of both Houses of Parliament. It is available, together with a transposition note and a table showing fee changes, on www.vmd.gov.uk at “Publications, Veterinary Medicines Regulations and Guidance”.

Changes to legislation:

There are currently no known outstanding effects for the The Veterinary Medicines Regulations 2008.