

2004 No. 2779

MEDICINES

**The Medicines (Vaccination Against Foot-and-Mouth Disease)
Order 2004**

<i>Made</i> - - - -	<i>25th October 2004</i>
<i>Laid before Parliament</i>	<i>29th October 2004</i>
<i>Coming into force</i> - -	<i>1st December 2004</i>

The Secretary of State, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development acting jointly in exercise of the powers conferred by sections 57(1) and (2) and 58(4) and (5) of the Medicines Act 1968(a), and now vested in them, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by this Order, and after consulting and taking into account the advice of the Veterinary Products Committee, make the following Order:

Title and commencement

1. This Order may be cited as the Medicines (Vaccination against Foot-and-Mouth Disease) Order 2004, and shall come into force on 1st December 2004.

Interpretation

2. In this Order—

“the Act” means the Medicines Act 1968;

“the appropriate authority” means in England the Secretary of State for Environment, Food and Rural Affairs, in Wales the National Assembly for Wales, in Scotland the Scottish Ministers and in Northern Ireland the Department of Agriculture and Rural Development;

“the Chief Veterinary Officer” means the officer appointed to that post in the Department for Environment, Food and Rural Affairs acting in connection with the Council Directive on FMD;

“the Council Directive on FMD” means Council Directive 2003/85/EC on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC(b);

(a) 1968 c. 67; and see paragraph 4(1)(b) of the Schedule to the Northern Ireland Act 2000 (c. 1), which has effect during suspension pursuant to section 1(8) of that Act: this paragraph provides that the functions of a Northern Ireland Minister who was in charge of a Northern Ireland Department immediately before the coming into force of section 1 of the Act may be discharged by that Department, subject, according to paragraph 4(1)(f) of the Schedule, to the direction and control of the Secretary of State. The Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland were renamed the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development by article 3(4) and (6) of the Departments (Northern Ireland) Order 1999 (S.I.1999/283 (N.I.1)).

(b) OJ No. L306, 22.11.2003, p. 1.

“establishment of a relevant risk” means the identification by the Chief Veterinary Officer of a relevant risk and communication by her or on her behalf of that identification in such manner and to such persons as she regards appropriate in the circumstances;

“FMD” means foot-and-mouth disease;

“FMD vaccine” means any veterinary drug presented for use in vaccination against FMD;

“lay vaccinator” means a person entitled by virtue of the Veterinary Surgery (Vaccination against Foot-and-Mouth Disease) Order 2004(a) to carry out a minor treatment under section 19(4)(e) of the Veterinary Surgeons Act 1966(b);

“relevant risk” means risk of outbreak of FMD in the United Kingdom which is posed in the circumstances described in Article 50.1(b) of the Council Directive on FMD;

“response to a relevant risk” means any act or sequence of acts to prevent an outbreak of FMD in the United Kingdom after the establishment of a relevant risk;

“response to an outbreak of FMD” means any act or sequence of acts to control or eradicate FMD in all or any part of the United Kingdom which is undertaken once an outbreak of FMD has occurred in the United Kingdom;

“RNA” means ribonucleic acid;

and other expressions have the same meanings as in the Council Directive on FMD.

Supply of FMD vaccine

3.—(1) The restrictions of sections 52 (“Sale or supply of medicinal products not on general sale list”) and 58(2)(a) (“Medicinal products on prescription only”) of the Act shall not apply to the supply of FMD vaccine by—

- (a) a person falling under any of the following categories if he acts within the terms of his engagement by the appropriate authority and does so as part of the appropriate authority’s response to an outbreak of FMD which has occurred in the United Kingdom or as part of the appropriate authority’s response to a relevant risk:
 - (i) officers of the appropriate authority;
 - (ii) lay vaccinators;
 - (iii) other persons engaged by the appropriate authority; or
- (b) a person who acts on the instructions of his employer if by virtue of sub-paragraph (a)(iii) the restrictions of sections 52 and 58(2)(a) of the Act do not apply to that employer when he gives those instructions.

(2) For the purposes of paragraph (1) an outbreak of FMD has occurred in the United Kingdom where—

- (a) the situation described in any of paragraphs 1 to 4 of the Schedule applies in the United Kingdom, and an analysis establishing the finding referred to in that paragraph is confirmed by the Chief Veterinary Officer or on her behalf in such manner and to such persons as she regards appropriate in the situation; or
- (b) the situation described in paragraph 5 of the Schedule applies and the Chief Veterinary Officer’s satisfaction described in that paragraph is communicated by her or on her behalf in such manner and to such persons as she regards appropriate in the situation.

14th October 2004

Ben Bradshaw
Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

(a) S.I. 2004/2780
(b) 1966 c. 36.



Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

D.C. Gowdy
Permanent Secretary

Department of Health, Social Services and Public Safety

25th October 2004



Sealed with the Official Seal of the Department of Agriculture and Rural Development

Pat Toal
Permanent Secretary

Department of Agriculture and Rural Development

25th October 2004

SCHEDULE

Article 3(2)

Situations amounting to an outbreak of foot-and-mouth disease

1. FMD virus has been isolated from an animal, any product derived from that animal, or its environment.

2. Clinical signs consistent with FMD are observed in an animal of a susceptible species, and the viral antigen or viral RNA specific to any serotype of FMD virus has been detected and identified in samples collected from the animal or animals of the same epidemiological group.

3. Clinical signs consistent with FMD are observed in an animal of a susceptible species and the animal or its cohorts are positive for antibody to FMD virus structural or non-structural proteins, in circumstances where previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

4. Viral antigen or viral RNA specific to any serotype of FMD virus has been detected and identified in samples collected from animals of susceptible species, and the animals are positive for antibody to FMD virus structural or non-structural proteins, in circumstances where, in the case of antibodies to structural proteins, previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity.

5. The Chief Veterinary Officer is satisfied that an epidemiological link has been established between a place in the United Kingdom where animals susceptible to FMD may be held or found and an outbreak of FMD outside of the United Kingdom which has been confirmed by the competent authority in the country concerned, and that any of the following sub-paragraphs applies in respect of any place where that outbreak is identified outside of the United Kingdom:

- (a) any animal is positive for antibody to FMD virus structural or non-structural proteins, in circumstances where previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity;
- (b) viral antigen or viral RNA specific to any serotype of FMD virus has been detected and identified in samples collected from any animal of a susceptible species;
- (c) serological evidence of active infection with FMD by detection of seroconversion from negative to positive for antibody to FMD virus structural or non-structural proteins has—
 - (i) except where paragraph (ii) applies, been established in any animal of a susceptible species; or

- (ii) where a previously seronegative status cannot be reasonably be expected, been established in any animal of a susceptible species following detection of seroconversion carried out in paired samples collected from the same animals on two or more occasions at least 5 days apart, in the case of structural proteins, and at least 21 days apart, in the case of non-structural proteins,
and previous vaccination, residual maternal antibodies or non-specific reactions can be excluded as possible causes of seropositivity; or
- (d) clinical signs consistent with FMD are observed in any animal of a susceptible species.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order is made under the Medicines Act 1968 and applies to all of the United Kingdom. It exempts specified government officers and other persons (such as contractors and volunteers and their employees) from the general restrictions of the Medicines Act 1968 as to the supply of pharmacy only and prescription only medicines. The exemption applies only when they supply foot-and-mouth vaccine as part of the government's response to an outbreak in the United Kingdom of foot-and-mouth disease (defined, as specified in Annex I to Council Directive 2003/85/EC on Community measures for control of foot-and-mouth disease, to include an established epidemiological link between a place in the United Kingdom and an outbreak elsewhere), or to the risk of an outbreak occurring in the United Kingdom in the circumstances envisaged by Article 50.1(b) of Council Directive 2003/85/EC, which covers risk of the disease spreading to the United Kingdom from another Member State owing to its geographical situation or the prevailing meteorological conditions. The exemption also applies in the same limited circumstances to lay vaccinators, that is, persons covered by the Veterinary Surgery (Vaccination against Foot-and-Mouth Disease) Order 2004.

A Regulatory Impact Assessment has been prepared and placed in the library of each House of Parliament. Copies can be obtained from the Department for Environment, Food and Rural Affairs (Animal Welfare Division, Branch D), 6th Floor, 1A Page Street, London SW1P 4PQ.

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