

**EXPLANATORY MEMORANDUM TO THE  
MEDICINES (VACCINATION AGAINST FOOT-AND-MOUTH DISEASE) ORDER**

**2004 No. 2779**

1. This explanatory memorandum has been prepared by Defra and is laid before Parliament by Command of Her Majesty.

**2. Description:**

2.1 This Order forms part of contingency plans for future outbreaks of foot-and-mouth disease and will allow vaccine to be supplied and administered by lay vaccinators without delay in the event of a future outbreak. The Order extends the provisions contained in the Medicines Act to allow the distribution of vaccine to be handled by non-vets. To ensure proper handling we will require all concerned in the vaccine distribution chain to comply with the requirements of the “Rules and Guidance for Pharmaceutical Manufacturers and Distributors”.

**3. Matter of special interest to the Joint Committee on Statutory Instruments/Select Committee on Statutory Instruments:**

3.1 None.

**4. Legislative Background:**

This Order extends the provisions contained in the Medicines Act to allow the distribution of foot-and-mouth vaccine to be handled by non-vets. To ensure proper handling we will require all concerned in the vaccine distribution chain to comply with the requirements of the “Rules and Guidance for Pharmaceutical Manufacturers and Distributors”.

**5. Extent:**

5.1 The Order applies to the whole of the UK.

**6. European Convention on Human Rights:**

6.1 Not applicable.

**7. Policy Background:**

7.1 The Medicines Act 1968 places a number of restrictions on the sale, supply and distribution of vaccine which we consider need to be amended in the case of foot-and-mouth vaccine to provide the necessary flexibility to implement a Government decision to implement an emergency vaccination policy. Without change, this requires us to restrict the supply of foot-and-mouth vaccine to vaccination teams by the veterinary surgeon who has the animals under his/her care, and require a prescription. This would seriously affect our ability to effectively and swiftly implement a vaccination campaign, as it would significantly restrict the numbers of people who could supply vaccination teams with vaccine in an outbreak

7.2 An equivalent Order is also being made under the Veterinary Surgeons Act 1966 to allow lay vaccinators – who must be deemed competent to administer vaccine by, and act under the direction of, a veterinary surgeon - to vaccinate animals against foot-and-mouth disease (which although defined as a minor treatment normally has to be carried out by a veterinary surgeon).

**8. Impact:**

8.1 See attached Regulatory Impact Assessment.

**9. Contact:**

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## REGULATORY IMPACT ASSESSMENT

### 1. Title of proposed measures

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

### 2. Purpose and intended effects

#### Objective

2.1 This proposal forms part of contingency plans for future outbreaks of foot-and-mouth disease. The intention is to make the legislative amendment after consultation, which will allow vaccine to be supplied to and administered by lay vaccinators without delay in the event of a future outbreak.

#### Background

2.2 The vaccination of animals against foot-and-mouth disease is defined as a minor treatment which normally has to be carried out by a veterinary surgeon, under the Veterinary Surgeons Act 1966. The Medicines Act 1968 provides that a vaccine may not be sold or supplied except in accordance with a prescription given by an appropriate practitioner and that no person shall administer such a medicinal product unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner. During the outbreak of foot-and-mouth disease in the UK during 2001, plans were developed (but not implemented), to vaccinate livestock against foot-and-mouth disease. Since there is a finite supply of veterinary surgeons, who were fully occupied on other essential disease control duties during the outbreak, draft legislation was prepared to allow lay vaccinators to carry out this task. We are now planning to put in place an Order amending the Veterinary Surgeons Act 1966 that will allow lay vaccination of livestock in the event of a future outbreak of foot-and-mouth disease. An equivalent Order under the Medicines Act 1968 is also being planned to allow the supply of foot-and-mouth vaccine otherwise than by pharmacists and vets and without a prescription to Defra and its appointed contractors in the event of a decision to vaccinate animals in a designated area.

#### Devolution

2.3 Legislation under the Veterinary Surgeons Act is made jointly by the Secretary of State for the Environment, Food and Rural Affairs and by the Department of Agriculture and Rural Development NI and in the case of the legislation under the Medicines Act by the Secretary of State for the Environment, Food and Rural Affairs, the Department of Agriculture and Rural Development NI and the Department of Health, Social Services and Public Safety (also in NI) acting jointly. The Orders will be subject to negative resolution procedure.

#### Risk Assessment

2.4 The risk that the proposed regulations address is that there may not be enough veterinary surgeons available to be deployed on minor treatments such as vaccination during a future outbreak of foot-and-mouth disease, as there will be a host of other urgent duties which they will be required to undertake in such a situation.

### 3. Options

Option 1: do nothing, leave legislation unchanged and hope sufficient veterinary surgeons will be available to carry out vaccination.

Option 2: amend the legislation to allow suitable trained lay vaccinators to receive and administer foot-and-mouth disease vaccine under veterinary direction in the event of an outbreak of the disease, thus allowing veterinary surgeons to perform other urgent tasks. The Royal College of Veterinary Surgeons defines “direction” as meaning the veterinary surgeon instructs the vaccinator as to the treatment to be administered but is not necessarily present.

The legislation will also be amended to allow the supply of the vaccine other than through a veterinary practitioner or pharmacist direct to Defra officers, Defra appointed contractors or lay vaccinators without prescriptions in the event of a future outbreak.

#### **4. Benefits**

##### **Identify the benefits**

Option 1 – would have no additional benefit for animal health or the veterinary profession.

Option 2 – would free veterinary surgeons to carry out other essential tasks during an outbreak of foot-and-mouth disease and would allow more rapid completion of an emergency vaccination programme. Speed is essential in carrying out emergency vaccination, to help reduce the scale of an outbreak.

##### **Quantifying and valuing the options and benefits**

Option 1 is estimated to have no benefits. Should emergency vaccination be employed as a disease control measure in the event of an outbreak of foot-and-mouth disease, it would have to be carried out as rapidly as possible in order to contain the possible spread of the disease. The inability to employ lay vaccinators would seriously limit the ability to vaccinate in a short time frame.

Option 2 would allow suitable trained lay vaccinators to administer foot-and-mouth disease vaccine. This would permit a reduction in costs compared with using veterinarians. The Government has made a commitment to consider the use of emergency vaccination in the event of a future outbreak and the recently adopted EU Council Directive on Foot-and-mouth Disease also moves emergency vaccination to the forefront of disease control strategies.

#### **5. Compliance Costs for Businesses, Charities and Voluntary Organisations**

5.1 The new regulations will not have any direct effect other than on veterinary surgeons and pharmacists, and then only if emergency vaccination was used during an outbreak of foot-and-mouth disease.

##### **Policy Costs**

5.2 The proposal would not involve any additional costs.

##### **Implementation Costs**

5.3 None.

#### **6. Consultation with Small Businesses**

Over 300 interested organisations were consulted in drawing up these proposals. 36 positive responses were received.

## **7. Other Costs**

There are no other costs to be incurred.

## **8. Results of Consultations**

Further to paragraph 6, the Royal College of Veterinary Surgeons was consulted and supported the proposed order under the Veterinary Surgeons Act but expressed reservations over the need to amend the Medicines Act. These concerns were taken account of in putting forward recommendations to Ministers.

## **9. Summary and Recommendations**

It is recommended that Option 2 be adopted. This will amend the legislation to allow suitably competent persons to administer foot-and-mouth disease vaccine in the event emergency vaccination is used during a future outbreak of the disease. It will also allow distribution of the vaccine to vaccination centres. This proposal is not expected to impose any additional costs on any sector; rather it will benefit the community as a whole in helping to speed up vaccination and hence assist in limiting the extent of any future outbreak, as well as possibly reducing the numbers of livestock to be culled.

## **10. Enforcement, Sanctions, Monitoring and Review**

The proposal provides for a veterinary surgeon to direct the person carrying out the vaccination. The veterinary surgeon must be satisfied that the person is competent to administer vaccine. Should foot-and-mouth vaccine be supplied otherwise than in accordance with the Medicines (Vaccination Against Foot-and-Mouth Disease) Order 2004, such supply would be contrary to either or both of sections 52 and 58 of the Medicines Act 1968, breach thereof being a criminal offence under section 67(2) of the Act, the maximum penalty being either or both of an unlimited fine or up to two years' imprisonment. The enforcement power in respect of these offences lies with the Secretary of State by virtue of section 108 of the Act.

## **11. Regulatory Quality**

### **DECLARATION**

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the Minister responsible: Ben Bradshaw  
Parliamentary Under-Secretary of State  
Department for Environment, Food and Rural Affairs

Date: 14<sup>th</sup> October 2004

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### **Date of Preparation**

8 October 2004