STATUTORY INSTRUMENTS

1993 No.2399

MEDICINES

The Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993

Made - - - -	*30th September 1993*
Laid before Parliament	*8th October 1993*
Coming into force - -	*29th October 1993*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of the powers conferred by sections 18 (as read with section 24(4)) and 129(1) of the Medicines Act 1968(**1**) and now vested in them(**2**), after consulting such organisations as appear to them to be representative of interests likely to be substantially affected by the following Regulations in accordance with section 129(6) of that Act, and the Secretary of State and the Minister of Agriculture, Fisheries and Food, being Ministers designated(**3**) for the purposes of section 2(2) of the European Communities Act 1972(**4**) in relation to medicinal products and the common agricultural policy of the Economic Community, acting jointly, in exercise of the powers conferred on them by the said section 2(2), and of all other powers enabling them in that behalf, hereby make the following Regulations:

Title and commencement

1. These Regulations may be cited as the Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993 and shall come into force on 29th October 1993.

(**1**) 1968 c. 67; *see*the definition of "prescribed" in section 132(1); "the Ministers" referred to in section 129(1) is defined in section 1 (see also the following footnote).
(**2**) In the case of the Secretaries of State concerned with health in England and Wales by virtue of S.I. 1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of S.I. 1978/272 and in the case of the Northern Ireland Departments by virtue of the Northern Ireland Constitution Act 1973 (c. 36), section 40 and Schedule 5, and the Northern Ireland Act 1974 (c. 28), section 1(3) and Schedule 1, paragraph 2(1)(b).
(**3**) S.I. 1972/1811.
(**4**) 1972 c. 68.

Interpretation

2. In these Regulations—

"the Act" means the Medicines Act 1968;

"Directive 81/851" means Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products(**5**) amended by Council Directive 90/676/EEC(**6**) and extended by Council Directive 90/677/EEC extending the scope of Directive 81/851/EEC and laying down additional provisions for immunological veterinary medicinal products(**7**);

"licence" means a product licence for a veterinary drug under Part II of the Act;

"renewal application" means an application for the renewal of a licence under section 24 of the Act in consequence of a notice served on the holder of the licence by the licensing authority under section 24(1A)(**8**) thereof.

Requirements as to renewal application

3.—(1) Subject to paragraph (2) below, every renewal application shall be made in accordance with the provisions of the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993(**9**) as if such application were an application to which those Regulations apply.

(2) If the product the subject of the licence for which a renewal application is made is for the time being authorised in accordance with Directive 81/851 for sale or supply in another member state, or is the subject of an application for such authorisation, the requirements of regulation 4 of the Regulations referred to in paragraph (1) above shall be deemed to have been complied with if the renewal application is accompanied by such documents and particulars as have been submitted to that other member State, unless the licensing authority otherwise directs.

Tom Sackville
Parliamentary Under Secretary of State,
21st September 1993 Department of Health

Hector Munro
Parliamentary Under Secretary of State, Scottish
21st September 1993 Office

John Redwood
24th September 1993 Secretary of State for Wales

(**5**) OJ No. L317, 6.11.81, p.1.
(**6**) OJ No. L373, 31.12.90, p.15.
(**7**) OJ No. L373, 31.12.90, p.26.
(**8**) Section 24(1A) was inserted by regulation 4(4) of S.I. 1977/1050.
(**9**) S.I.1993/2398.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 20th September 1993.

L.S.

Gillian Shephard
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 23rd day of September 1993.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 30th day of September 1993.

L.S.

W. J. Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for renewal applications for product licences for veterinary drugs in consequence of notices of expiry served on the holders of such licences by the licensing authority under section 24(1A) of the Medicines Act 1968.

These notices are served on holders of licences which do not comply with the provisions of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (OJNo. L317, 6.11.81, p.1) as amended by Council Directive 90/676/EEC (OJ No. L373, 31.12.90, p.15), and Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ No. L317, 6.11.81, p.16) as amended by Commission Directive 92/18/EEC (OJ No. L97, 10.4.92, p.1). The Regulations thus implement the requirements of Article 2.5 of Council Directive 90/676/EEC and, in respect of immunological products, Article 6.4 of Council Directive 90/677/EEC extending the scope of Directive 81/851/EEC and laying down additional provisions for immunological veterinary medicinal products (OJ No. L373, 31.12.90, p.26) to extend the Directives' provisions progressively to existing products.

Except where the renewal application is permitted to be accompanied by documents and particulars already submitted to another member state, regulation 3 provides for such renewal applications to be made in accordance with the provisions of the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993 (S.I.1993/2398).