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STATUTORY INSTRUMENTS

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**1994 No. 2157**

**MEDICINES**

**The Medicines (Veterinary Medicinal Products) (Applications for Product Licences) (Amendment) Regulations 1994**

<i>Made</i>	- - - -	<i>10th August 1994</i>
<i>Laid before Parliament</i>		<i>18th August 1994</i>
<i>Coming into force</i>	- -	<i>8th September 1994</i>

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and 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 and 129(1) and (4) of the Medicines Act 1968<sup>(1)</sup> and now vested in them<sup>(2)</sup>, 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<sup>(3)</sup> for the purposes of section 2(2) of the European Communities Act 1972 <sup>(4)</sup> 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:

**Citation and commencement**

1. These Regulations, which implement article 1.9 of Council Directive [93/40/EEC](#) amending Directives [81/851/EEC](#) and [81/852/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products <sup>(5)</sup>, may be cited as the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) (Amendment) Regulations 1994 and shall come into force on 8th September 1994.

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- (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 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](#).
- (5) OJ No. L214, 24.8.93, p. 31.

### **Amendment to the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993**

2.—(1) The Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993<sup>(6)</sup> shall be amended in accordance with this Regulation.

(2) In regulation 2(1) (interpretation) for the definition of “Directive 81/851” there shall be substituted the following definition:

““Directive 81/851” means Council Directive [81/851/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products<sup>(7)</sup> as amended by Council Directives [90/676/EEC](#)<sup>(8)</sup> and [93/40/EEC](#).”.

(3) In regulation 4(1) (Requirements as to application) for the words “Subject to paragraphs (2) and (3) below” there shall be substituted the words “Subject to paragraphs (2), (3) and (4) below”.

(4) After paragraph (3) of regulation 4 there shall be added the following paragraph—

“(4) In the circumstances described in article 15.2 of Directive 81/851, an applicant for a product licence shall submit to the licensing authority all relevant data available to the applicant.”.

Department of Health  
27th July 1994

*Tom Sackville*  
Parliamentary Under Secretary of State,

Scottish Office  
27th July 1994

*Hector Monro*  
Parliamentary Under Secretary of State,

Signed by authority of the Secretary of State for Wales:

Welsh Office  
27th July 1994

*Gwilym Jones*  
Parliamentary Under Secretary of State,

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 3rd August 1994.

*William Waldegrave*  
Minister of Agriculture, Fisheries and Food

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<sup>(6)</sup> S.I. [1993/2398](#).

<sup>(7)</sup> OJ No. L317, 6.11.81, p. 1.

<sup>(8)</sup> OJ No. L373, 31.12.90, p. 15.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 9th day of August 1994.

L.S.

*F. A. Elliott*  
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 10th day of August 1994.

*P. T. Toal*  
Assistant Secretary

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations amend the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993 (S.I.1993/2398) so as to implement article 1.9 of Council Directive [93/40/EEC](#) (amending Directives [81/851/EEC](#) and [81/852/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products, OJNo. L214, 24.8.93, p. 31) which article removes and replaces the second paragraph of article 15 of Council Directive [81/851/EEC](#). They permit an applicant for a product licence for a veterinary medicinal product to submit, in certain circumstances, all relevant data available to him rather than a full data dossier.