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STATUTORY INSTRUMENTS

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**1993 No. 2398**

**MEDICINES**

**The Medicines (Veterinary Medicinal Products)  
(Applications for Product Licences) 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 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:

**Title and commencement**

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

**Interpretation**

2.—(1) In these Regulations—

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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 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.

“the Act” means the Medicines Act 1968;

“application” means a request for the grant of a product licence and shall comprise all the documents submitted in support of it, and “applicant” shall be construed accordingly;

“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>(5)</sup> amended by Council Directive [90/676/EEC](#)<sup>(6)</sup>;

“Directive 81/852” means 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<sup>(7)</sup> amended by Council Directive [87/20/EEC](#)<sup>(8)</sup> and Commission Directive [92/18/EEC](#)<sup>(9)</sup>;

“Directive 90/677” means Council Directive [90/677/EEC](#) extending the scope of Directive [81/851/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products<sup>(10)</sup>;

“immunological product” means a veterinary medicinal product used in order to produce active or passive immunity or to diagnose the state of immunity, to which Directives 81/851 and 90/677 apply;

“product licence” means a product licence in relation to a veterinary medicinal product to which Directive 81/851 applies;

“standard provisions for licences” means the relevant standard provisions prescribed by regulations under section 47(1) of the Act<sup>(11)</sup>; and

“veterinary medicinal product” has the meaning assigned to that expression in Directive 81/851 and for the purposes of these Regulations shall be treated as a medicinal product within the meaning of section 130 of the Act.

(2) In these Regulations any reference to a numbered regulation or Schedule shall be construed as a reference to the regulation or Schedule so numbered in these Regulations.

### **Form and manner of application**

**3.—**(1) Every application shall be made in writing in the English language and shall be signed by the applicant.

(2) The applicant shall supply to the licensing authority four copies of each application, and shall supply a further twenty-two copies if the licensing authority so directs.

(3) Where the application, or any part thereof, has been translated from another language, the applicant shall supply to the licensing authority one copy of such application or part, as the case may be, in the original language if the licensing authority so directs.

### **Requirements as to application**

**4.—**(1) Subject to paragraphs (2) and (3) below, an applicant for a product licence shall submit to the licensing authority the particulars and documents required by Articles 5 and 5a of Directive 81/851 and—

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(5) OJ No. L317, 6.11.81, p.1.

(6) OJ No. L373, 31.12.90, p.15.

(7) OJ No. L317, 6.11.81, p.16.

(8) OJ No. L15, 17.1.87, p.34.

(9) OJ No. L97, 10.4.92, p.1.

(10) OJ No. L373, 31.12.90, p.26.

(11) The current Regulations are S.I. [1971/972](#) amended by S.I. [1972/1226](#), [1974/1523](#), [1977/675](#), [1039](#), [1053](#), [1983/1730](#).

- (a) if the application is in respect of a veterinary medicinal product other than an immunological product, shall comply with the requirements set out in Schedule 1, or
- (b) if the application is in respect of a veterinary medicinal product which is an immunological product, shall comply with the provisions of Article 2 of Directive 90/677 and the requirements set out in Schedule 2.

(2) An applicant shall not be required, by virtue of paragraph 10 of Article 5 of Directive 81/851, to provide the results of toxicological and pharmacological tests and clinical trials if he can demonstrate that he is entitled, subject to the provisions of that paragraph, to the benefit of any of sub-paragraphs (a)(i) to (iii) thereof.

(3) Paragraph (2) above shall not apply where the applicant claims the benefit of Article 5.10(a)(iii) of Directive 81/851, unless the product authorised within the European Economic Community to which the applicant refers has been so authorised for a period of not less than ten years before the making of the application.

### **Supplementary provisions as to application**

5.—(1) The applicant shall in making his application—

- (a) take account of the guidance published by the European Commission referred to in the first paragraph of the Introduction to the Annex to Directive 81/852, and
- (b) include all information relevant to the evaluation of the product to which the application relates, whether favourable or unfavourable, including all relevant details of any incomplete or abandoned test or trial relating to the product,

and shall confirm in writing that he has done so.

(2) The applicant shall confirm in writing that he has complied with the requirements of the Animals (Scientific Procedures) Act 1986<sup>(12)</sup> which are relevant to his application.

(3) The applicant shall state which, if any, of the standard provisions for licences it is desired shall be excluded or modified in relation to any product licence granted as a result of the application.

(4) The licensing authority may require the applicant to submit such samples as they may specify—

- (a) of the veterinary medicinal product, its active ingredients and its intermediate products or other constituent materials for testing by a laboratory designated for the purposes of Article 9.2 of Directive 81/851, in order to ensure that the applicant's control testing methods within the meaning of Article 5.9 of that Directive are satisfactory, or
- (b) of substances necessary to verify the analytical detection methods to trace residues proposed in the application documents in pursuance of Article 5.8 of that Directive.

### **Revocation**

6. The Regulations set out in Schedule 3 are hereby revoked in so far as they relate to applications for product licences for veterinary medicinal products.

21st September 1993

*Tom Sackville*  
Parliamentary Under Secretary of State,  
Department of Health

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(12) 1986 c. 14.

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**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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21st September 1993

*Hector Monro*  
Parliamentary Under Secretary of State, Scottish  
Office

24th September 1993

*John Redwood*  
Secretary of State for Wales

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on

L.S.

20th September 1993.

*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

L.S.

23rd day of September 1993.

*F. A. Elliott*  
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this

L.S.

30th day of September 1993.

*W. J. Hodges*  
Permanent Secretary

## SCHEDULE 1

Regulation 4(1)(a)

### REQUIREMENTS OF APPLICANTS FOR PRODUCT LICENCES IN RESPECT OF VETERINARY MEDICINAL PRODUCTS OTHER THAN IMMUNOLOGICAL PRODUCTS

#### Interpretation

1. References in this Schedule to requirements are those requirements set out in Title I of the Annex to Directive 81/852.

#### Requirements

2. The applicant shall comply with the requirements set out in Part 1 (administrative data, summary of product characteristics, expert reports).

3.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 2 (analytical (physico-chemical, biological or microbiological) tests).

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the licensing authority, the applicant shall obtain from the manufacturer—

- (a) all the data necessary for him to take responsibility for the product,
- (b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process or specifications, and
- (c) written confirmation that the manufacturer will supply to the licensing authority all documents and particulars which may be required by the authority relating to any such modification,

and shall submit the data and confirmations received to the licensing authority.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the licensing authority considers that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the authority on request a more appropriate specification.

4. The applicant shall comply with the requirements set out in Part 3 (safety and residues testing), and shall supply a copy of any certificate issued by a laboratory which carried out any such test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in the second paragraph of Part 3.

5.—(1) Subject to sub-paragraph (2) below, the applicant shall comply with the requirements set out in Part 4 (pre-clinical and clinical testing).

(2) In the case of a trial of a product conducted in the United Kingdom, unless the trial is one under which the product is not to be identified, the labelling of any container and package of the product shall comply with the requirements contained in regulations relating to such product made under section 85(1) of the Act for the time being in force(13).

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(13) The current Regulations are S.I. 1976/1726 (amended by S.I. 1977/996, 2168, 1981/1791, 1983/1729, 1985/2008 and 1989/1183) and S.I. 1988/1009.

## SCHEDULE 2

Regulation 4(1)(b)

REQUIREMENTS OF APPLICANTS FOR PRODUCT  
LICENCES IN RESPECT OF IMMUNOLOGICAL PRODUCTS**Interpretation**

1. References in this Schedule to requirements are those requirements set out in Title II of the Annex to Directive 81/852.

**Requirements**

2. The applicant shall comply with the requirements set out in Part 5 (administrative data, summary of product characteristics, expert reports).

3.—(1) Subject to sub-paragraphs (2) and (3) below, the applicant shall comply with the requirements set out in Part 6 (analytical (physico-chemical, biological or microbiological) tests).

(2) Where at the request of the applicant a manufacturer of an active ingredient of the product submits details concerning the method of manufacture, quality control during manufacture and process validation directly to the licensing authority, the applicant shall obtain from the manufacturer—

- (a) all the data necessary for him to take responsibility for the product,
- (b) written confirmation that the manufacturer will ensure batch to batch consistency and inform the applicant before he modifies the manufacturing process or specifications, and
- (c) written confirmation that the manufacturer will supply to the licensing authority all documents and particulars which may be required by the authority relating to any such modification,

and shall submit the data and confirmations received to the licensing authority.

(3) Where the applicant refers to a specification in a monograph in a pharmacopoeia but the licensing authority considers that such specification is insufficient to ensure the quality of the product, the applicant shall submit to the authority on request a more appropriate specification.

4.—(1) Subject to sub-paragraph (2) below, the applicant shall comply with the requirements set out in Parts 7, 8 and 9 (safety testing and efficacy trials), and shall supply a copy of any certificate issued by a laboratory which carried out a safety test certifying that the test was carried out in conformity with the principles of good laboratory practice as referred to in paragraph 3 of Section A of Part 7.

(2) In the case of an efficacy trial of a product conducted in the United Kingdom, unless the trial is one under which the product is not to be identified, the labelling of any container and package of the product shall comply with the requirements contained in regulations relating to such product made under section 85(1) of the Act for the time being in force<sup>(14)</sup>.

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(14) The current Regulations are S.I. 1976/1726 (amended by S.I. 1977/996, 2168, 1981/1791, 1983/1729, 1985/2008 and 1989/1183) and S.I. 1988/1009.

## SCHEDULE 3

Regulation 6

Regulations revoked	References	Extent of revocation
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971	S.I. <a href="#">1971/973</a>	The whole Regulations insofar as they relate to applications for product licences for veterinary medicinal products.
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1972	S.I. <a href="#">1972/1201</a>	The whole Regulations insofar as they relate to applications for product licences for veterinary medicinal products.
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1975	S.I. <a href="#">1975/681</a>	The whole Regulations insofar as they relate to applications for product licences for veterinary medicinal products.
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1977	S.I. <a href="#">1977/1051</a>	The whole Regulations insofar as they relate to applications for product licences for veterinary medicinal products.
The Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1983	S.I. <a href="#">1983/1726</a>	The whole Regulations insofar as they relate to applications for product licences for veterinary medicinal products.

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

These Regulations implement Articles 5 and 5a of Council Directive 81/851/EEC (OJNo. L317, 6.11.81, p.1) (“Directive 81/851”) as amended by Council Directive [90/676/EEC](#) (OJ No. L373, 31.12.90, p.15) on the approximation of the laws of the Member States relating to veterinary medicinal products, Council Directive [81/852/EEC](#) (OJ No. L317, 6.11.81, p.16) (“Directive 81/852”) as amended by Council Directive [87/20/EEC](#) (OJ No. L15, 17.1.87, p.34) and Commission Directive [92/18/EEC](#) (OJ No. L97, 10.4.92, p.1) on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products, and Article 2 of Council Directive [90/677/EEC](#) (OJ No. L373, 31.12.90, p.26) (“Directive 90/677”) extending the scope of Directive [81/851/EEC](#) on the approximation of the laws of the Member States relating to veterinary medicinal products and laying down additional provisions for immunological veterinary medicinal products.

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

The Regulations apply to applications for product licences in relation to veterinary medicinal products to which Directive 81/851 applies (see Article 2 of the Directive). Such products are to be treated as medicinal products within the meaning of section 130 of the Medicines Act 1968 for the purposes of the Regulations (see the definitions of “product licence” and “veterinary medicinal product” in regulation 2(1)).

The Regulations prescribe the form and manner of an application (regulation 3), require the applicant to submit to the licensing authority the particulars and documents set out in Articles 5 and 5a of Directive 81/851, to comply with the provisions of Article 2 of Directive 90/677 in relation to immunological products and to comply with the requirements set out in the Annex to Directive 81/852 (regulation 4 and Schedules 1 and 2, which apply to veterinary medicinal products other than immunological products and veterinary medicinal products which are immunological products respectively).

An applicant is required to confirm to the licensing authority that he has taken account of certain guidance published by the European Commission referred to in the Introduction to the Annex to Directive 81/852 (regulation 5(1)(a)). This guidance is at present contained in a publication entitled “The Rules Governing Medicinal Products in the European Community”, Volume V/B, “Notice to applicants for marketing authorisation for veterinary medicinal products in the European Community”, Revised Edition, January 1993 (ISBN 92-826-5780-9), which may be obtained from Her Majesty’s Stationery Office or from the Office for Official Publications of the European Communities, L/2985, Luxembourg.

The Regulations revoke the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971, as amended, in so far as they relate to applications for product licences for veterinary medicinal products (regulation 6 and Schedule 3).