
STATUTORY INSTRUMENTS

1994 No. 3143

MEDICINES

The Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1994

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| <i>Made</i> | - - - - | <i>7th December 1994</i> |
| <i>Laid before Parliament</i> | | <i>9th December 1994</i> |
| <i>Coming into force</i> | - - | <i>1st January 1995</i> |

The Secretary of State concerned with health in England, the Secretaries of State 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(1), 36(1) (as read respectively with sections 24(4) and 38(3)) and 129(1) of the Medicines Act 1968(1) and now vested in them(2), and of all other powers enabling them in that behalf, 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 hereby make the following Regulations:

Title and commencement

1. These Regulations may be cited as the Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1994 and shall come into force on 1st January 1995.

Interpretation

2. In these Regulations—

“the Act” means the Medicines Act 1968;

“certificate” means an animal test certificate;

“licence” means a licence for a veterinary drug granted under Part II of the Act; and

(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).

“renewal application” means an application for the renewal of a licence under section 24 of the Act (other than a renewal application for a product licence to which the Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993⁽³⁾ apply (in consequence of a notice served under section 24(1A)), or an application for the renewal of a certificate under section 38 of the Act.

Form and manner of renewal application

3.—(1) Every renewal application shall be made to the licensing authority in writing and shall be signed by the applicant.

(2) The applicant shall supply six copies in the English language of each renewal application and of any accompanying particulars, or such lesser number as the licensing authority may direct, and if any document supplied has been translated from another language, one copy of that document in the original language shall also be supplied if the licensing authority require.

Particulars to be contained in or to accompany renewal applications

4.—(1) Every renewal application shall contain or be accompanied by particulars of—

- (a) the holder of the licence or certificate in respect of which the renewal application is made,
- (b) the product or class of products to which that licence or certificate relates,
- (c) the licence or certificate held, any variation thereof, and any notification to the licensing authority in accordance with the provisions of the licence or certificate, made since the grant of the licence or issue of the certificate as the case may be, or, if such licence or certificate has been renewed, since the date of the last renewal, and
- (d) any material changes, other than those submitted in accordance with sub-paragraph (c) above, in the information submitted in the application for the grant of the licence or issue of the certificate as the case may be, or, if such licence or certificate has been renewed, any such changes since the date of the last renewal.

(2) In the case of the renewal of a certificate, every renewal application shall be accompanied by up to date particulars of the progress of the medicinal test on animals to which the certificate relates.

Revocation

5. The Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1993⁽⁴⁾ are hereby revoked.

Signed by authority of the Secretary of State for Health.

5th December 1994

Tom Sackville
Parliamentary Under Secretary of State,
Department of Health

⁽³⁾ S.I.1993/2399.

⁽⁴⁾ S.I.1993/1227.

6th December 1994

Hector Monro
Parliamentary Under Secretary of State, Scottish
Office

Signed by authority of the Secretary of State for Wales.

6th December 1994

Gwilym Jones
Parliamentary Under Secretary of State, Welsh
Office

2nd December 1994

Angela Browning
Parliamentary Secretary, Ministry of Agriculture,
Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland
this

L.S.

6th day of December 1994.

F. A. Elliott
Permanent Secretary

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

L.S.

7th day of December 1994.

J. Murray
Permanent Secretary

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke and replace the Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1993 ([S. I.1993/1227](#)). They prescribe the form and manner of and the particulars to be contained in or to accompany renewal applications for licences for veterinary drugs and for animal test certificates. In the case of product licences, these Regulations apply to those licences which are not converted to marketing authorisations by virtue of the [Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, S. I. 1994/3142](#); but do not apply to product licences in respect of which renewal applications are made in consequence of a notice served under section 24(1A) of the Medicines Act 1968 (to which the Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993, [S. I.1993/2399](#), apply).