STATUTORY INSTRUMENTS

1993 No. 1227

MEDICINES

The Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1993

Made - - - -	*7th May 1993*
Laid before Parliament	*10th May 1993*
Coming into force - -	*31st May 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, 36 (as read with sections 24(4) and 38(3)) and 129(1) and (4) 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 1993 and shall come into force on 31st May 1993.

Interpretation

2. In these Regulations–

"the Act" means the Medicines Act 1968;

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

"medicinal product" includes, where a licence or certificate relates to any substance or article which is not a medicinal product, that substance or article;

(**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 the renewal of a product licence in consequence of a notice served on the licence holder 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 in writing and shall be signed by the applicant.

(2) Where the licensing authority have from time to time approved the form of renewal applications either for use generally or in respect of particular classes of renewal applications, every renewal application shall be made in such approved form.

(3) Subject to paragraph (4) below, six copies, or such lesser number as the licensing authority may direct, of each renewal application and of any accompanying particulars shall be supplied to the licensing authority in the English language and, where the renewal application or accompanying particulars have been translated from another language, also one copy of the renewal application or the accompanying particulars, as the case may be, in the original language, if the licensing authority so require.

(4) In the case of the renewal of a product licence of right, a further 20 copies of the renewal application and of any accompanying particulars shall be supplied to the licensing authority if the licensing authority so require.

(5) Except where the licensing authority otherwise direct, in the case of the renewal of a licence or certificate, a separate renewal application shall be made in respect of each medicinal product of a particular description to which such licence or certificate relates.

Conditions of renewal

4.—(1) Subject to paragraph (2) below, a renewal application shall be made only in respect of a licence or certificate where the licence or certificate is identical in all particulars with the existing licence or certificate.

(2) Notwithstanding paragraph (1) above, a renewal application may be made in respect of a licence or certificate where the only matters which are not identical with the existing licence or certificate relate to–

(a) any variation already incorporated since the date of issue; or

(b) any additional particulars required to be submitted to the licensing authority pursuant to regulation 5(1)(c) below and Part III of the Schedule.

Particulars to be contained in or to accompany renewal applications

5.—(1) Subject to the following provisions of these Regulations every renewal application shall contain or be accompanied by–

(a) the particulars specified in Part I of the Schedule except to the extent that the licensing authority have, in the case of any particular application or any class of renewal applications, otherwise directed;

(b) the particulars specified in Part II of the Schedule in relation to an application to which that Part applies, to the extent that the licensing authority have, in the case of any particular renewal application or any class of renewal applications, directed;

(c) the particulars specified in Part III of the Schedule in relation to an application to which that Part applies, if those particulars have not been submitted to the licensing authority at an earlier date.

(2) Subject to paragraph (3) below, any of the particulars, which by virtue of paragraph (1) above are required to be contained in or to accompany a renewal application, may be omitted if a statement of such omission and the reasons for it are contained in or accompany the renewal application.

(3) Any particulars omitted under paragraph (2) above shall be subsequently furnished to the licensing authority if the licensing authority so direct and such subsequently furnished particulars shall be deemed to have been contained in or to have accompanied the renewal application.

Time for submission of renewal applications

6. A renewal application for a licence or certificate shall be duly made only if it is made in the period at least 3 months and not more than 5 months before the expiry of the current licence or certificate.

Samples to accompany renewal applications

7. Every renewal application for a licence or certificate shall be accompanied by such samples of the medicinal product to which such licence or certificate relates, as the licensing authority have, in the case of any particular renewal application or class of renewal applications, directed.

Revocation

8. The Medicines (Renewal Applications for Licences and Certificates) Regulations 1974(**3**), the Medicines (Renewal Applications for Licences and Certificates) Amend-ment Regulations 1977(**4**) and the Medicines (Renewal Applications for Licences and Certificates) Amendment Regulations 1982(**5**) are hereby revoked to the extent that they relate to renewal applications for licences or certificates for veterinary drugs.

Brian Mawhinney
Minister of State
7th May 1993 Department of Health

Hector Monro
Parliamentary Under Secretary of State, Scottish
6th May 1993 Office

David Hunt
7th May 1993 Secretary of State for Wales

(**3**) S.I. 1974/832.
(**4**) S.I. 1977/180.
(**5**) S.I. 1982/1789.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 6th May 1993.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 7th day of May 1993.

L.S.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 6th day of May 1993.

L.S.

W. J. Hodges
Permanent Secretary

SCHEDULE Regulation 5(1)

RENEWAL APPLICATION PARTICULARS

PART I

Standard particulars for all licences and certificates

1. Particulars of the holder of the licence or certificate in respect of which the renewal application is made.

2. Particulars of the licence or certificate in respect of which the renewal application is made, including particulars of any variation of such licence or certificate that has been made since such licence or certificate was granted or issued and of any notification which has been made to the licensing authority in accordance with the provisions applicable to such licence or certificate.

3. Particulars of any changes of any material extent in the matters stated in the application for the grant of the licence or the issue of the certificate in respect of which the renewal application is made and of any such changes in any application for the variation of such licence or certificate.

4. Particulars of the medicinal products of the description to which the licence or certificate, in respect of which the renewal application is made, relates.

Product licences of right

5. In the case of the renewal of a product licence of right, the following further particulars–

(a) particulars as to the specification and pharmaceutical form of the medicinal product to which the licence in respect of which the renewal application is made relates, including the qualitative and quantitative composition of such medicinal product covering all active ingredients, all colouring matter, flavouring agents and perfumes and all other ingredients;

(b) particulars as to the manufacture of such medicinal product and of the active ingredients of such medicinal product;

(c) particulars of the quality control procedures and methods used to ensure compliance with the specification of such medicinal product;

(d) particulars as to the procedures for testing or ascertaining the purity, potency and stability of such medicinal product;

(e) particulars as to the containers and labelling of such medicinal product and as to the leaflets to be enclosed in the containers or packages of such medicinal product;

(f) particulars as to reports and evaluations of experimental and biological studies and of other preclinical and laboratory studies carried out with such medicinal product and its ingredients;

(g) particulars of the indications for the administration of such medicinal product, the dosage, methods and routes of administration, and of any contra-indications and warnings; and

(h) in the case of such medicinal product which is to be incorporated in any animal feeding stuff, particulars as to the feeding stuff in question, and in relation to the medicinal product in question, particulars as to its compatibility or incompatibility with other substances or articles, its stability in animal feeding stuffs, methods of incorporation and rates of inclusion in animal feeding stuffs and particulars as to the method of analysis in relation to such incorporation or inclusion.

Certificates

6. In the case of the renewal of a certificate, further particulars as to the progress of the medicinal test on animals to which the certificate relates.

PART II

Product licences (other than product licences of right) and certificates

7. In the case of the renewal of a product licence (other than a product licence of right) or a certificate, the following further particulars–

(a) particulars as to the specification and pharmaceutical form of the medicinal product to which the licence or certificate in respect of which the renewal application is made, relates, including the qualitative and quantitative composition of such medicinal product covering all active ingredients, all colouring matter, flavouring agents and perfumes and all other ingredients;

(b) particulars as to the manufacture of such medicinal product and of the active ingredients of such medicinal product;

(c) particulars of the quality control procedures and methods used to ensure compliance with the specification of such medicinal product;

(d) particulars as to the procedures for testing or ascertaining the purity, potency and stability of such medicinal product;

(e) particulars as to the containers and labelling of such medicinal product and as to the leaflets to be enclosed in the containers or packages of such medicinal product;

(f) particulars as to reports and evaluations of experimental and biological studies and of other preclinical and laboratory studies carried out with such medicinal product and its ingredients;

(g) particulars of the indications for the administration of such medicinal product, the dosage, methods and routes of administration, and of any contra-indications and warnings; and

(h) in the case of such medicinal product which is to be incorporated in any animal feeding stuff, particulars as to the feeding stuff in question, and in relation to the medicinal product in question, particulars as to its compatibility or incompatibility with other substances or articles, its stability in animal feeding stuffs, methods of incorporation and rates of inclusion in animal feeding stuffs and particulars as to the method of analysis in relation to such incorporation or inclusion.

Manufacturer's licences

8. In the case of the renewal of a manufacturer's licence, the following further particulars–

(a) particulars of operations to be carried out in pursuance of the licence as renewed;

(b) particulars of the premises in which those operations are to be carried out;

(c) particulars of the equipment which is or will be available on those premises for carrying out those operations;

(d) the names and qualifications of the persons under whose supervision those operations will be carried out; and

(e) particulars of the arrangements made or to be made for securing the safe-keeping, and maintenance of adequate records in respect of medicinal products to be manufactured or assembled in pursuance of the licence as renewed.

Wholesale dealer's licences

9. In the case of the renewal of a wholesale dealer's licence, the following further particulars–

(a) particulars of the premises on which will be stored medicinal products of the description to which the licence as renewed will be intended to relate;

(b) particulars of the equipment which is or will be available for storing medicinal products on those premises;

(c) particulars of the equipment which is or will be available for distributing medicinal products from those premises; and

(d) particulars of the arrangements made or to be made for securing the safe-keeping, and maintenance of adequate records in respect of medicinal products to be stored on or distributed from those premises.

PART III

Additional particulars for product licences (other than product licences of right or product licences in relation to products used in order to produce active or passive immunity or to diagnose the state of immunity)

10. In the case of renewal of a product licence (other than a product licence of right or a product licence in relation to a product used in order to produce active or passive immunity or to diagnose the state of immunity), the following additional particulars–

(a) a statement of the address of each place or proposed place of manufacture or assembly of the medicinal product outside the United Kingdom;

(b) particulars of the shelf life of the medicinal product, if more than 3 years, together with a scientific justification for that shelf life;

(c) a statement of any special directions necessary for the disposal of–

(a) waste from the medicinal product, including any unused product, and

(b) any container in which traces of the medicinal product may remain; and

(d) a summary of the product characteristics as specified in Article 5a of Council Directive81/851/EEC(**6**) as amended by Council Directive 90/676/EEC(**7**).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974, as amended, insofar as they relate to veterinary drugs.

The Regulations reproduce the provisions of the revoked Regulations only in respect of veterinary drugs and are amended in part to take account of Council Directive 90/676/EEC (OJNo. L373,

(**6**) OJ No. L317, 6.11.81, p.1.
(**7**) OJ No. L373, 31.12.90, p.15.

31.12.90, p.15) which amends Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p.1) on the approximation of the laws of the Member States relating to veterinary medicinal products.

The principal changes are–

(1) the Regulations do not apply to an application for the renewal of a product licence in consequence of a notice served on the licence holder under section 24(1A) of the Medicines Act 1968 (notice of expiry where grant would contravene a Community obligation) (see definition of "renewal application" in regulation 2);

(2) a licence or certificate can now only be renewed where its terms are identical with the existing licence or certificate and the only additional particulars to be included are those pursuant to the provisions of these Regulations (regulation 4);

(3) additional particulars are prescribed which must be submitted with applications for the renewal of product licences (other than product licences of right or product licences in relation to products used in order to produce active or passive immunity or to diagnose the state of immunity) if never submitted before (regulation 5(1)(c) and Part III of the Schedule, Articles 5 and 5a of the amended Directive);

(4) the period during which renewal applications can be submitted has been changed to the period at least 3 months and not more than 5 months before the expiry of the current licence or certificate (regulation 6, Article 15 of the amended Directive).