STATUTORY INSTRUMENTS

1974 No. 832

MEDICINES

The Medicines (Renewal Applications for Licences and Certificates) Regulations 1974

Made - - -	*9th May* 1974
Laid before Parliament	*21st May* 1974
Coming into Operation	*12th June* 1974

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture in Scotland, the Minister of Agriculture, Fisheries and Food, the Head of the Department of Health and Social Services for Northern Ireland and the Head of the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 18(1) and 36(1) of the Medicines Act 1968(**a**) (as read with sections 24(4) and 38(3) of that Act respectively) and now vested in them (**b**) 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 regulations, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974 and shall come into operation on 12th June 1974.

(2) In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"certificate" means a clinical trial certificate or an animal test certificate;

"licence" (except where that word occurs as part of the expression "product licence", "manufacturer's licence" or "wholesale dealer's licence") means a licence 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;

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388: 1969 I, p. 1070), and in the case of the Heads of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to the Northern Ireland Constitution Act 1973 (c. 36).

"renewal application" means an application for the renewal of a licence or certificate under section 24 or, as the case may be, under section 38 of the Act;

and other expressions have the same meanings as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any enactment or regulations shall be construed as a reference to that enactment or these regulations, as amended, extended or re-enacted by any other enactment, order or regulations.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(**a**) shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Form and manner of renewal application

2.—(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.

(4) In the case of the renewal of a product licence which is a 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 product 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.

Information relating to provisions of licences or certificates

3. Every renewal application shall specify—

(*a*) which, if any, of the standard provisions prescribed by regulations under section 47(1) of the Act (**b**) it is desired shall be excluded or modified in relation to the renewal of the licence or certificate in respect of which the renewal application is made, and

(**a**) 1889 c. 63.

(**b**) *See* S.I. 1971/972 (1971 II, p. 2809) as amended by S.I. 1972/1226 (1972 II, p. 3708).

(*b*) where it is desired that such licence or certificate and the licence or certificate as renewed shall not be subject to the same provisions (other than such standard provisions), the desired changes in such provisions and the reason for the changes.

Particulars to be contained in or to accompany renewal applications

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

(*a*) the particulars specified in paragraph 4 of Part I of the Schedule to these regulations,

(*b*) the other particulars specified in Part I of that 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, and

(*c*) the particulars specified in Part II of that Schedule to the extent that the licensing authority have, in the case of any particular renewal application or any class of renewal application, directed.

(2) Subject to paragraph (3) below, any of the particulars, which by virtue of paragraph 1(*b*) or (*c*) 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.

Renewal applications made earlier than 4 *months before expiry of licence or certificate*

5.—(1) Regulation 4 of these regulations shall not have effect in relation to any renewal application made before the commencement of the period of four months preceding the expiry of the licence or certificate in respect of which the renewal application is made.

(2) Every such renewal application shall contain or be accompanied by the particulars specified in Part I and Part II of the Schedule to these regulations.

(3) In the case of a renewal application to which this regulation applies, the applicant shall, before the commencement of the period of two months preceding the expiry of the licence or certificate in respect of which the renewal application has been made or before such other later date as the licensing authority may in any particular case allow, send to the licensing authority a notice in writing either certifying that the matters stated in the renewal application have not changed since the renewal application was made or, where there has been any change, giving particulars of any such change.

Notification of late renewal applications

6. In the case of a renewal application that is to be made during the period of two months preceding the expiry of the licence or certificate in respect of

which the renewal application is to be made, the licensing authority shall be notified in writing of the proposed renewal application before the commencement of that period or before such other later date as the licensing authority may in any particular case allow, and such notification shall include or be accompanied by the particulars specified in—

(*a*) paragraphs 1 and 4 of the Schedule to these regulations, and

(*b*) paragraphs 2, 3, 5, 7, 8 and 9 of that Schedule to the extent that the licensing authority have, in the case of any particular renewal application or any class of renewal applications, directed.

Samples to accompany renewal applications

7. Every renewal application for a product 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.

Barbara Castle,
Secretary of State for Social Services.

2nd May 1974.

John Morris,
Secretary of State for Wales.

2nd May 1974.

William Ross,
Secretary of State for Scotland.

3rd May 1974.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 3rd May 1974.

(L.S.)

Frederick Peart,
Minister of Agriculture, Fisheries and Food

Patrick J. Devlin,
Head of the Department of Health and Social Services for Northern Ireland.

8th May 1974.

Leslie J. Morrell,
Head of the Department of Agriculture for Northern Ireland.

9th May 1974.

SCHEDULE

Regulations 4(1), 5(2) and 6

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 which is a licence of right, the following further particulars:—

(*a*) particulars as to the specification and pharmaceutical form of the medicinal product to which the product 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 its 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 clinical trial or, as the case may be, the medicinal test on animals to which the certificate relates.

PART II

Product licences and certificates

7. In the case of the renewal of a product licence (other than such a licence which is a 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 product 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 safekeeping, 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 and facilities which are 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 safekeeping, and maintenance of adequate records in respect of medicinal products to be stored on or distributed from those premises.

EXPLANATORY NOTE

(*This Note is not part of the Regulations.*)

These Regulations prescribe the form and manner in which applications are to be made for the renewal of licences and certificates under Part II of the Medicines Act 1968. The regulations also specify the particulars, information and samples that shall be contained in or accompany such applications.

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