STATUTORY INSTRUMENTS

1971 No. 1447

MEDICINES

The Medicines (Applications for Product Licences of Right and Clinical Trial and Animal Test Certificates of Right) Regulations 1971

Made - - - -	*27th August* 1971
Laid before Parliament	*2nd September* 1971
Coming into Operation	*1st September* 1971

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 Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland, acting jointly, in exercise of their powers under Sections 18, 36 and 129(1) of the Medicines Act 1968(a), as having effect subject to the provisions of Article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(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 following regulations, hereby make the following regulations:—

Citation and commencement

1. These regulations may be cited as the Medicines (Applications for Product Licences of Right and Clinical Trial and Animal Test Certificates of Right) Regulations 1971 and shall come into operation on 1st September 1971.

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

"the Act" means the Medicines Act 1968;

"applicant" means an applicant for a product licence of right or a clinical trial certificate of right or animal test certificate of right;

"application" means a request for the grant of a product licence of right or the issue of a clinical trial certificate of right or animal test certificate of right together with the particulars of the product or products which may be the subject of one request in accordance with regulation 3 of these regulations but does not include a request to renew a product licence of right or a clinical trial certificate of right or animal test certificate of right;

(a) 1968 c. 67. (b) S.I. 1969/388 (1969 I, p. 1070).

"approved name" in relation to a constituent is the name of the substance or article which appears in the current edition (as defined in section 103(5) of the Act) of the list prepared and published in accordance with section 100 of the Act as in force at the date of the application;

"clinical trial certificate of right" and "animal test certificate of right" mean certificates to which an applicant is entitled by virtue of section 37(4) of the Act;

"the Committee on Safety of Drugs" means the committee appointed in June 1963 by the Ministers concerned with health in England and Wales, in Scotland and in Northern Ireland respectively to advise on the safety, quality and efficacy of medicinal products and to promote the collection of reports of adverse reactions and to assess their significance;

"medicinal product" includes substances or articles specified in orders made under section 104 or section 105 of the Act which are for the time being in force and which direct that Part II of the Act shall have effect in relation to such substances or articles as that Part has effect in relation to medicinal products within the meaning of the Act;

"monograph" means a monograph in any edition of the European Pharmacopoeia or of any compendium published by the Ministers under Section 99 of the Act or of the British Pharmacopoeia or of the British Pharmaceutical Codex or of the British Veterinary Codex, and "monograph name" means, in relation to a constituent, the name which appears at the head of the relevant monograph;

"product licence of right" means a product licence to which an applicant is entitled by virtue of section 25 of the Act;

"proprietary designation" means a word or words used in connection with the sale of a medicinal product, substance or article or constituent for the purpose of indicating that they are the goods of a particular person by virtue of manufacture, selection, certification, dealing with or offering for sale;

"standard provisions" mean those conditions prescribed by regulations made under section 47(1) of the Act which are for the time being in force;

"the Veterinary Products Safety Precautions Scheme" means the scheme drawn up in 1964 following discussions between the Minister of Agriculture, Fisheries and Food, the Minister of Health, the Secretary of State concerned with agriculture and with health in Scotland and representatives of professional and commercial organisations for the purpose of safeguarding human beings and animals against risks arising from the use of veterinary products;

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

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

(3) The Interpretation Act 1889(a) shall apply to the interpretation of these regulations as it applies to the interpretation of an Act of Parliament.

(a) 1889 c. 63.

Form and manner of application

3.—(1) An application shall be in writing and may relate to one or more medicinal products, substances or articles where each medicinal product, substance or article is separately identifiable by its name and particulars.

(2) An applicant shall supply the licensing authority with six copies in the English language of his application and where any parts of the application have been translated from another language also one copy of those parts of the application in their original language.

(3) An applicant shall submit the application with the pages serially numbered and headed with the applicant's own reference number.

(4) An application shall be signed by the applicant, and, where the application is made by a person other than the proposed holder of the licence or certificate, the application shall be signed also by the proposed holder of the licence or certificate.

Material to be contained in or to accompany an application

4.—(1) Every application for the grant of a product licence of right for a medicinal product, substance or article other than those to which the succeeding sub-paragraph of this regulation applies, shall contain the particulars specified in Part I of Schedule 1 to these regulations.

(2) Every application for the grant of a product licence of right to import a medicinal product for use by the importer for administration to animals or incorporation in any animal feeding stuff for a medicinal purpose, shall contain the particulars specified in Part II of Schedule 1 to these regulations.

(3) Every application for the issue of a clinical trial certificate of right shall contain the particulars specified in Schedule 2 to these regulations.

(4) Every application for the issue of an animal test certificate of right shall contain the particulars specified in Schedule 3 to these regulations.

Supplementary provisions as to applications

5.—(1) Where, in any application in accordance with these regulations, any required particulars are not furnished, the applicant shall state—

(*a*) that the required particulars are not applicable, if such is the case, or

(*b*) other reasons for their absence.

(2) Every applicant for the grant of a product licence of right or the issue of a clinical trial certificate of right or animal test certificate of right shall supply the licensing authority with a sample of the medicinal product, substance or article to which the application relates if requested to do so by the licensing authority for the purpose of determining the application.

(3) Every applicant for the grant of a product licence of right shall submit with the application evidence that the appropriate provisions of subsections (2) or (3) of section 16 of the Act have effect in relation to him.

(4) Every applicant for the issue of a clinical trial certificate of right or animal test certificate of right shall submit with the application evidence that the provisions of section 37(4) of the Act have effect in relation to him.

(5) Every application for the grant of a product licence of right shall include a document in the form approved from time to time by the licensing authority which shall state the following particulars—

(*a*) the reference number, if any, allotted to the proposed holder of the licence by the Committee on Safety of Drugs in respect of submissions made by him to that committee in relation to any medicinal products, substances or articles to which the application relates or the reference and date of any letter from the Ministry of Agriculture, Fisheries and Food indicating that it had no objection under the Veterinary Products Safety Precautions Scheme to any medicinal product, substance or article to which the application relates,

(*b*) a statement whether the application is the first application for a product licence of right made by or on behalf of the proposed holder of the licence and, if it is not the first application, the reference numbers allotted by the licensing authority in respect of previous applications,

(*c*) a statement whether it is intended to submit further applications for licences of right,

(*d*) a statement of the total number of separate descriptions of medicinal products, substances and articles to which the application relates,

(*e*) a statement of the number of pages comprising the application, and

(*f*) a statement whether any of the descriptions of medicinal products, substances or articles to which the application relates falls within the following categories—

(i) imported medicinal products,

(ii) substances or articles to which section 43 of the Act applies, or

(iii) medicinal products, substances or articles not manufactured by the proposed holder of the licence.

Signed by authority of the Secretary of State for Social Services.

Paul Dean,
Parliamentary Under Secretary of State,
Department of Health and Social Security.

13th August 1971.

Signed by authority of the Secretary of State for Wales.

David Gibson-Watt,
Minister of State Welsh Office.

27th August 1971.

Gordon Campbell,
Secretary of State for Scotland.

25th August 1971.

W. K. Fitzsimmons,
Minister of Health and Social Services
for Northern Ireland.

16th August 1971.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th August 1971.

(L.S.)

J. M. L. Prior,
Minister of Agriculture, Fisheries and Food.

H. W. West,
Minister of Agriculture for Northern Ireland.

17th August 1971.

SCHEDULE I

PART I

Regulation 4(1)

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A PRODUCT LICENCE OF RIGHT FOR ANY MEDICINAL PRODUCT, SUBSTANCE OR ARTICLE OTHER THAN THOSE TO WHICH PART II OF THIS SCHEDULE APPLIES

1. The name and address of the applicant ,and, where the applicant is not the proposed holder of the licence, the name and address of the proposed holder of the licence.

2.—(1) A statement whether the proposed holder of the licence is

(*a*) the person responsible for the composition of the medicinal product, substance or article, or

(*b*) the person who has, or will have, procured the importation of the medicinal product, substance or article, or

(*c*) the person who has, or will have, imported the medicinal product, substance or article, or

(*d*) in the case where the provisions of section 43 of the Act apply the person who first sells, supplies or exports the substance or article for use as a medicinal product.

(2) Where the application is made by or on behalf of a person to whom the provisions of section 43 of the Act apply, a statement whether that person is engaged in retail sale or in supply in circumstances corresponding to retail sale and whether he has assembled the substance or article for the purpose of being sold or supplied by him for a medicinal purpose.

3. Where the application is in respect of a licence to procure the sale or supply of a medicinal product, substance or article in the United Kingdom or to procure the importation or exportation of a medicinal product, substance or article, the name and address of the person who sells, supplies, imports or exports the medicinal product, substance or article.

4.—(1) Except where it is desired that the licence shall come into operation on the date specified in an order made under Section 17 of the Act, upon which date subsection (2) or (3) of Section 16 of the Act shall cease to have effect in relation to the medicinal product, substance or article to which the application relates, the date on which it is desired that the licence shall come into operation.

(2) The period for which the licence is desired where it is for less than 5 years.

5. A statement of the activities to which the licence is to relate, that is to say, whether it is one or more of the following—

(*a*) to sell or supply the medicinal product, substance or article in the United Kingdom,

(*b*) to procure the sale or supply by another person of the medicinal product, substance or article in the United Kingdom,

(*c*) to import the medicinal product, substance or article,

(*d*) to procure the importation by another person of the medicinal product, substance or article,

(*e*) to export the medicinal product, substance or article,

(*f*) to procure the exportation by another person of the medicinal product, substance or article,

(*g*) to procure the manufacture or assembly by another person of the medicinal product, substance or article for the purposes of any of the activities referred to in subparagraphs (*a*), (*b*), (*c*), (*d*), (*e*) or (*f*) of this paragraph.

6. The name under which the medicinal product, substance or article is sold, supplied, imported or exported together with the approved name or monograph name, if any.

7. A description of the pharmaceutical form of the medicinal product, substance or article and a statement whether—

(*a*) it is for use by being administered to human beings or animals, or

(*b*) it is in the form of an ingredient for use in the preparation of a substance or article which is to be administered to human beings or animals for a medicinal purpose, or

(*c*) it is in the form to be used for incorporation in any animal feeding stuff.

8. A statement of the composition of the medicinal product, substance or article in terms of its active constituents.

9. A description of the physical characteristics of the medicinal product, substance or article.

10. A statement of—

(*a*) the indications suggested by the proposed holder of the licence for the administration of the medicinal product,

(*b*) methods and routes of administration, and

(*c*) recommended dose or dosage, as appropriate

(i) for adults,

(ii) for children and infants by age groups, and

(iii) for animals.

11. A statement whether, and, if so, which of the standard provisions it is desired should be excluded or modified together with a statement of the reasons for such exclusion or modification.

12. In the case of an imported medicinal product, substance or article, the name and the address of the importer.

13. In the case of any medicinal product, substance or article—

(*a*) a statement of the manufacturing or assembling operations relating to the medicinal product, substance or article carried out by the proposed holder of the licence or any other persons, and

(*b*) a statement of the address of each place of manufacture or assembly in the United Kingdom,

(*c*) the names and addresses of the persons, if any, other than the proposed holder of the licence responsible for any stage of the manufacture or assembly and a statement of the operations for which each such person is responsible,

(*d*) a statement of the arrangements made for storage of the medicinal product, substance or article by the proposed holder of the licence or on his behalf, and

(*e*) a statement of the address of each place of storage of the medicinal product, substance or article.

14. In the case of a medicinal product, substance or article manufactured or assembled in the United Kingdom, a statement whether precautions are taken during manufacture or assembly to control the quality of the medicinal product, substance or article and whether the proposed holder of the licence is responsble for deciding that any batch of the medicinal product, substance or article is of acceptable quality for sale, supply or exportation, and, if not, who is responsible.

15. In the case of an imported medicinal product, substance or article, a statement whether precautions are taken during manufacture or assembly both before and after importation to control the quality of the medicinal product, substance or article and whether the proposed holder of the licence is responsible for deciding that any batch of the medicinal product, substance or article is of acceptable quality for sale, supply or exportation, and, if not, who is responsible.

16. In respect of each constituent, whether active or not—

(*a*) the approved name or the monograph name, or

(*b*) where there is no approved name or monograph name, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub-paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

17. A description of the nature of the containers used for the medicinal product, substance or article and a statement of any special directions necessary for storage and transport.

18. Any directions, contra-indications and warnings on the container label, the package label and in any leaflet inserted in the package, and particulars contained in any informative literature.

19. A statement whether, before the first appointed day, the medicinal product, substance or article was available—

(*a*) for general sale, or

(*b*) for sale in Great Britain in the premises of an authorised seller of poisons within the meaning of the Pharmacy and Poisons Act 1933(a), and in Northern Ireland in premises for which an annual licence is in force under section 17 of the Pharmacy and Poisons Act (Northern Ireland) 1925(b),

(i) in accordance with a prescription given by a practitioner, or

(ii) without a prescription given by a practitioner,

(*c*) for sale through any other channels.

20. A statement whether it is proposed to make any change in the methods of sale or supply of the medicinal product, substance or article and particulars of the intended change, if any.

21. A statement indicating the grounds on which the proposed holder of the licence is entitled to a licence.

22. A statement whether the proposed holder of the licence is the holder of a licence issued under the Therapeutic Substances Act 1956(c) or the Diseases of Animals (Therapeutic Substances) Order 1952(d) as amended(e), made under Part II of the Diseases of Animals Act 1950(f) in relation to the medicinal product, substance or article which is the subject of the application and, if so, the licence number and the name of the therapeutic substance.

(a) 1933 c. 25.
(b) 1925 (N.I.) c. 8.
(c) 1956 c. 25.
(d) S.I. 1952/1933 (1952 I, p. 129).
(e) The amending Orders are not relevant to the subject matter of these Regulations.
(f) 1950 c. 36.

Regulation 4(2) PART II

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A PRODUCT LICENCE OF RIGHT TO IMPORT A MEDICINAL PRODUCT FOR USE BY THE IMPORTER BY BEING ADMINISTERED TO ANIMALS OR INCORPORATED IN ANY ANIMAL FEEDING STUFF FOR A MEDICINAL PURPOSE

1. The name and address of the applicant, and, where the applicant is not the proposed holder of the licence, the name and address of the proposed holder of the licence, namely the importer of the medicinal product.

2. (*a*) The name and address of the manufacturer or assembler of the medicinal product in the form in which it is imported,

(*b*) the name and address of any person in the United Kingdom other than the proposed holder of the licence taking part in the manufacture or assembly of the medicinal product after importation.

3.—(1) Except where it is desired that the licence shall come into operation on the date specified in an order made under Section 17 of the Act upon which date subsection (3) of Section 16 shall cease to have effect in relation to the medicinal product to which the application relates, the date on which it is desired that the licence shall come into operation.

(2) The period for which the licence is desired where it is for less than 5 years.

4. The name of the medicinal product together with the approved name or monograph name, if any.

5. A description of the pharmaceutical form in which the medicinal product is administered to animals or is for use by incorporation in any animal feeding stuff.

6. A statement of the composition of the medicinal product in terms of its active constituents.

7. A description of the physical characteristics of the medicinal product.

8. A statement of the purpose in relation to which the medicinal product is imported and whether it is—

(*a*) for use by being administered to animals, or

(*b*) for incorporation in any animal feeding stuff.

9. Particulars of the recommended dose or dosage, methods and routes of administration.

10. A statement whether, and, if so, which of the standard provisions it is desired should be excluded or modified together with a statement of the reasons for such exclusion or modification.

11. A description of the method of manufacture or assembly of the medicinal product both before and after importation.

12. A statement whether precautions are taken during manufacture or assembly both before and after importation to control the quality of the medicinal product and whether the proposed holder of the licence is responsible for deciding that any batch of the medicinal product is of acceptable quality for sale, supply or exportation, and, if not, who is responsible.

13. In respect of each constitutent, whether active or not—

(*a*) the approved name or the monograph name, or

(*b*) where there is no approved name or monograph name, the non-proprietary designation or other descriptive appellation by which it can be readily identified, or

(*c*) where there is no name or descriptive appellation as described in sub-paragraphs (*a*) and (*b*) of this paragraph, the proprietary designation.

14. A description of the nature of the containers used for the medicinal product and a statement of any special directions necessary for storage and transport.

15. Particulars of the indications suggested by the proposed holder of the licence for the administration of the medicinal product whether or not incorporated in animal feeding stuffs.

16. A statement indicating the grounds on which the proposed holder of the licence is entitled to a licence.

17. A statement whether the proposed holder of the licence is the holder of a licence issued under the Diseases of Animals (Therapeutic Substances) Order 1952 as amended, made under Part II of the Diseases of Animals Act 1950 in relation to the medicinal product which is the subject of the application and, if so, the licence number and the name of the therapeutic substance.

SCHEDULE 2 Regulation 4(3)

Particulars Required on an Application for the Issue of a Clinical Trial Certificate of Right

1. The name and address of the applicant, and, where the applicant is not the proposed holder of the certificate, the name and address of the proposed holder of the certificate.

2. In the case of an application for a clinical trial certificate of right relating to a clinical trial a proposal for which has been agreed by the Committee on Safety of Drugs, a statement covering—

(*a*) the reference number allotted to the proposed holder of the certificate in connection with the clinical trial by the Committee on Safety of Drugs, and

(*b*) the date on which the Committee on Safety of Drugs gave notice of its agreement to the clinical trial, and

(*c*) a description of the medicinal products to which the application relates.

3. In the case of an application for a clinical trial certificate of right relating to a clinical trial which has not been agreed to by the Committee on Safety of Drugs, a statement of the activities to which the certificate is to relate, and in respect of each medicinal product which is the subject of the application, whether it is one or more of the following—

(*a*) to sell or supply the medicinal product for the purpose of a clinical trial,

(*b*) to procure the sale or supply of the medicinal product for the purpose of a clinical trial,

(*c*) to procure the manufacture or assembly of the medicinal product for sale or supply for the purpose of the clinical trial and whether or not in addition to the purposes specified in sub-paragraphs (*a*) or (*b*) of this paragraph.

4. In the case of an application for a clinical trial certificate of right relating to a clinical trial which has not been agreed to by the Committee on Safety of Drugs, a description of the clinical use to be investigated and an outline of the proposed trial.

5. A statement indicating the grounds on which the proposed holder of the certificate is entitled to a certificate.

6. A statement whether the proposed holder of the certificate is the holder of a licence issued under the Therapeutic Substances Act 1956(a) in relation to the medicinal product, which is the subject of the application and, if so, the licence number and the name of the therapeutic substance.

Regulation 4(4)

SCHEDULE 3

Particulars Required on an Application for the Issue of an Animal Test Certificate of Right

1. The name and address of the applicant, and, where the applicant is not the proposed holder of the certificate, the name and address of the proposed holder of the certificate.

2. In the case of an application for an animal test certificate of right relating to a medicinal test on animals a proposal for which has been agreed under the Veterinary Products Safety Precautions Scheme, a statement covering—

(*a*) the reference and date of the letter from the Ministry of Agriculture, Fisheries and Food indicating that it had no objections to the holding of the test, and

(*b*) a description of the medicinal products, substances or articles to which the application relates.

3. In the case of an application for an animal test certificate of right relating to a medicinal test on animals a proposal for which has not been agreed under the Veterinary Products Safety Precautions Scheme a statement of the activities to which the certificate is to relate, and in respect of each medicinal product substance or article which is the subject of the application, whether it is one or more of the following—

(*a*) to sell or supply the medicinal product for the purpose of a medicinal test on animals, or

(*b*) to procure the sale or supply of the medicinal product for the purpose of a medicinal test on animals, or

(*c*) to procure the manufacture or assembly of the medicinal product for sale or supply for the purpose of a medicinal test on animals and whether in addition to the purpose specified in sub-paragraph (*a*) or (*b*) of this paragraph, or

(*d*) to administer the medicinal product, substance or article for the purpose of a medicinal test on animals.

(a) 1956 c. 25.

4. In the case of an application for an animal test certificate of right other than one to which paragraph 2 of the Schedule relates, a description of the medicinal test on animals, its location, and a statement of the investigations being carried out.

5. A statement indicating the grounds on which the proposed holder of the certificate is entitled to a certificate.

6. A statement whether the proposed holder of the certificate is the holder of a licence issued under the Diseases of Animals (Therapeutic Substances) Order 1952 as amended, made under Part II of the Diseases of Animals Act 1950 in relation to the medicinal product, substance or article which is the subject of the application and, if so, the licence number and the name of the therapeutic substance.

EXPLANATORY NOTE

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

These Regulations relate to the grant of product licences for which there is entitlement by virtue of section 25 of the Medicines Act 1968 (which relates to medicinal products effectively on the market before 1st September 1971) and to the issue of clinical trial certificates and animal test certificates for which there is entitlement by virtue of section 37(4) of the Act (which relates to trials or tests in progress immediately before 1st September 1971) with respect to medicinal products and certain substances and articles including those for incorporation in animal feeding stuffs. They prescribe the form and manner in which such applications are to be made and specify the information and documents that shall accompany each application.