STATUTORY INSTRUMENTS

1971 No. 1448

MEDICINES

The Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences of Right) Regulations 1971

Made - - - -	27*th August* 1971
Laid before Parliament	2*nd September* 1971
Coming into Operation	1*st 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 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 Manufacturer's and Wholesale Dealer's Licences of Right) Regulations 1971 and shall come into operation on 1st September 1971.

Interpretation

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

"the Act" means the Medicines Act 1968;

"applicant" means an applicant for a manufacturer's licence of right or a wholesale dealer's licence of right;

"application" means the request for the grant of a manufacturer's licence of right or a wholesale dealer's licence of right together with the particulars required by these regulations, but does not include a request to renew such a licence;

"approved name" 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.

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

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

"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 a name which appears at the head of the relevant monograph;

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

"wholesale dealer's licence of right" means a wholesale dealer's licence to which an applicant is entitled by virtue of section 25 of the Act;

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.

Form of application for a manufacturer's licence of right and for a wholesale dealer's licence of right

3.—(1) Every application for the grant of a manufacturer's licence of right shall be in writing and shall contain the particulars specified in Schedule 1 to these regulations.

(2) Every application for the grant of a wholesale dealer's licence of right shall be in writing and shall contain the particulars specified in Schedule 2 to these regulations.

Supplementary provisions as to applications

4.—(1) Every application shall specify which, if any, of the standard provisions for licences it is desired shall be excluded or modified together with a statement of the reasons for such exclusion or modification.

(2) Where, in any application, any required particulars are not furnished, the application shall state—

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

(*b*) other reasons for their absence.

(3) The applicant shall submit the application with the pages serially numbered, and the applicant shall supply the licensing authority with six copies in the English language of the 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.

(a) 1889 c. 63.

(4) Every application shall be signed by the applicant and, where the application is made by a person other than the proposed holder of the licence, the application shall be signed also 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 1 Regulation 3(1)

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A MANUFACTURER'S LICENCE OF RIGHT

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. The period for which the licence is desired where it is for less than five years.

3. The name, and also the approved name or monograph name, if any, of the medicinal products to which the licence is to relate.

4. A statement of the manufacturing or assembling operations to which the licence is to relate, including a statement whether they include one or both of the following

(*a*) the manufacture of medicinal products, or

(*b*) the assembly of medicinal products.

5. A statement of the use for which the medicinal products are manufactured or assembled and whether the use is as stated in one or more of the following sub-paragraphs—

(*a*) by being administered to human beings,

(*b*) by being administered to animals,

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

(*d*) by being incorporated in any animal feeding stuff.

6.—(1) The address of each of the premises where the manufacturing or assembling operations to which the application relates, or both operations, including any testing associated with manufacture or assembly, are carried out.

(2) The address of each of the premises if different from those referred to in the preceding sub-paragraph—

(*a*) on which are kept any living animals, or

(*b*) on which are kept or from which are obtained any materials of animal origin

from which, in either case, are derived any substance or substances used in the production of the medicinal product whether human or veterinary to which the application relates.

(3) The address of each of the premises where the proposed holder of the licence stores medicinal products or from which he distributes them.

(4) A separate statement, in respect of each of the premises referred to in the preceding sub-paragraphs of this paragraph, of the manufacturing or assembling operations which are being or were carried out at those premises during the relevant period mentioned in section 16(4) of the Act (transitional exemptions) for the purpose of establishing entitlement to the grant of a manufacturer's licence of right, specifying in relation to each operation the medicinal products concerned.

7. A statement of any manufacturing operations, other than those to which the manufacturer's licence of right is to relate, that are carried on by the proposed holder of the licence on or near each of the premises referred to in paragraph 6 of this Schedule, and of the substances or articles which are the subject of any such operations.

8. A statement whether the proposed holder of the licence is the holder of a licence issued under the Therapeutic Substances Act 1956(a) or the Diseases of Animals (Therapeutic Substances) Order 1952(b) as amended(c), made under Part II of the Diseases of Animals Act 1950(d) in relation to any medicinal product to which the manufacturer's licence is to relate, and the name of each such therapeutic substance and the licence number.

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

9. In relation to products that are or are to be assembled but not manufactured by the proposed holder of the licence, the name and address of the person by whom they are or are to be manufactured.

10. The name and address and qualifications and experience of the production manager or other person whose duty it is to supervise the production operations at each of the premises referred to in paragraph 6 of this Schedule, and the name and function of the person to whom he is responsible.

11. A statement whether the proposed holder of the licence has appointed a person to be in charge of quality control over all the premises referred to in paragraph 6 of this Schedule, and whether that person has been authorised to reject unsatisfactory batches of medicinal products, and a statement whether the person, if any, appointed to be in charge of quality control is also the production manager or other person referred to in paragraph 10 of this Schedule.

12. An outline of the arrangements for maintaining production records and records of testing medicinal products, and also of the arrangements for keeping reference samples of medicinal products.

13. A statement indicating the grounds upon which the proposed holder of the licence is entitled to a licence of right.

Regulation 3(2)

SCHEDULE 2

PARTICULARS REQUIRED ON AN APPLICATION FOR THE GRANT OF A WHOLESALE DEALER'S LICENCE OF RIGHT

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. The period for which the licence is desired where it is for less than five years.

3. A statement of the wholesale dealings to which the licence is to relate, and whether they consist of—

(*a*) dealing in many kinds of medicinal products, and whether this includes dealing in herbal remedies,

(*b*) dealing only in such medicinal products as may be sold otherwise than at a registered pharmacy, or otherwise than by a practitioner or otherwise than at a hospital,

(*c*) dealing only in herbal remedies, or

(*d*) dealing only in particular classes of medicinal products not mentioned in the above sub-paragraphs, and a description of those classes.

4. Whether in any case mentioned in paragraph 3 of this Schedule the use of medicinal products is one or more of the following—

(*a*) by being administered to human beings,

(*b*) by being administered to animals,

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

(*d*) by being incorporated in any animal feeding stuff.

5. The address of each of the premises where the proposed holder of the licence stores or proposes to store medicinal products or from which he distributes or proposes to distribute them.

6. A statement indicating the general range of medicinal products stored or proposed to be stored at each of the said premises.

7. A statement indicating the facilities and equipment available at each of the said premises for storing the medicinal products on, and distributing them from or between, such premises.

8. An indication of the arrangements at each of the said premises, whether by maintaining records or by other means, for ensuring, so far as practicable, a satisfactory turn-over of stocks of medicinal products.

9. A statement indicating the grounds upon which the proposed holder of the licence is entitled to a licence of right.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations relate to applications for the grant of manufacturer's licences of right and to applications for the grant of wholesale dealer's licences of right, to which there is entitlement by virtue of section 25 of the Medicines Act 1968. They prescribe the form and manner in which such applications are to be made and specify the information that is to be contained in each application.