STATUTORY INSTRUMENTS

# 1971 No. 974

# MEDICINES

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

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| *Made* - - - | *9th June* 1971 |
| *Laid before Parliament* | *24th June* 1971 |
| *Coming into Operation* | *1st July* 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 powers enabling them in that behalf, after consulting such organisations as appear to them to be representative of interests likely to be substantially affected, 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) Regulations 1971 and shall come into operation on 1st July 1971.

*Interpretation*

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

"the Act" means the Medicines Act 1968 ;

"application" means the request for the grant of a licence together with the particulars required by these regulations, but does not include a request to renew a licence ;

"a manufacturer's licence" does not include a manufacturer's licence of right ;

"a wholesale dealer's licence" does not include a wholesale dealer's licence of right ;

"standard provisions for licences" mean those standard provisions prescribed by the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**c**) ;

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

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

(**a**) 1968 c. 67.
(**b**) S.I. 1969/388 (1969 I, p. 1070).
(**c**) S.I. 1971/972. (1971 II, p. 2809).
(**d**) 1889 c. 63.

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

**3.**—(1) Every application for the grant of a manufacturer's licence shall contain or be accompanied by the particulars specified in Schedule 1 to these regulations.

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

*Supplementary provisions as to applications for manufacturer's licences and as to applications for wholesale dealer's licences*

**4.**—(1) Every application for the grant of a manufacturer's licence and every application for the grant of a wholesale dealer's licence shall specify which, if any, of the standard provisions for licences it is desired shall be excluded or modified in relation to the grant of the licence.

(2) Where, in any application for the grant of a manufacturer's licence or for the grant of a wholesale dealer's licence in accordance with these regulations, any required particulars are not furnished, the application shall state—

(*a*) that the required particulars are not applicable, or

(*b*) any other reason for their absence.

(3) The applicant for the grant of a manufacturer's licence or for the grant of a wholesale dealer's licence shall submit the application with the pages of the application including the accompanying particulars serially numbered, and the applicant shall supply the licensing authority with six copies in the English language of the application and of the accompanying particulars, and where the application or accompanying particulars have been translated from another language also one copy of the application or the particulars, as the case may be, in the original language.

(4) Every application for the grant of a manufacturer's licence and every application for the grant of a wholesale dealer's licence shall be signed by the applicant and where the application is made by a person other than the proposed licensee the application shall be signed by the proposed licensee.

*Keith Joseph,*
Secretary of State for Social Services.

19th May 1971.

Given under my hand on 20th May 1971.

*Peter Thomas,*
Secretary of State for Wales.

Given under my hand on 25th May 1971.

*Gordon Campbell,*
Secretary of State for Scotland.

Given under my hand on 4th June 1971.

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

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 27th May 1971.

(L.S.)

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

Given under my hand on 9th June 1971.

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

Regulation 3(1)

## SCHEDULE 1

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

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

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

3. 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.

4. A statement of the use for which the medicinal products are or are proposed to be manufactured, or assembled and whether the use is as stated in one or more of the following subparagraphs—

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

(*b*) for use by being administered to animals,

(*c*) for use in the form of 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*) for use by incorporation in any animal feeding stuff.

5.—(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 or are to be carried out.

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

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

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

from which, in either case, are to be 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 licensee proposes to store medicinal products or from which he proposes to distribute them.

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

(5) A separate statement in respect of each of the premises, of the manufacturing or assembling operations capable of being carried out at those premises with their existing facilities. Each statement shall specify the classes of medicinal products to which the operations are relevant.

(6) A separate statement in respect of each of the premises, of equipment available at those premises for carrying out each stage of the manufacturing or assembling operations described in subparagraph (5) of this paragraph.

6. A statement of any manufacturing operations, other than those to which the manufacturing licence is to relate, that are carried on by the proposed licensee on or near each of the premises referred to in paragraph 5 of this Schedule, and of the substances or articles which are the subject of any such operation.

7.—(1) The name and address and qualifications and experience of the production manager or other person whose duty it will be to supervise the production operations at each of the premises referred to in paragraph 5 of this Schedule, and the name and function of the person to whom he is responsible.

(2) The name and address and degrees, diplomas or other qualifications and experience of the person to be in charge of quality control over all the premises referred to in paragraph 5 of this Schedule and the extent of the authority to be delegated to him to reject unsatisfactory batches of medicinal products, and the name and function of the person to whom he is responsible. If ultimate responsibility for quality control is to be exercised by the holder of the product licence, this is to be stated.

(3) The name and address and degrees, diplomas or other qualifications of the person in charge of the animals referred to in paragraph 5(2) of this Schedule.

(4) The name and address and degrees, diplomas or other qualifications of the person to be responsible for the culture of any living tissue to be used in the manufacture of medicinal products.

8. An outline of the arrangements for the identification and storage of materials and ingredients before and during manufacture and for the storage of medicinal products after manufacture or assembly.

9. An outline of the arrangements at each of the premises where the licensee stores or proposes to store medicinal products for ensuring, so far as practicable, whether by maintaining records or other means, a satisfactory turn-over of stocks of medicinal products.

10. An outline of the arrangements—

(*a*) for maintaining production records,

(*b*) for maintaining records of analytical and other testing procedures applied in the course of manufacture or assembly for ensuring compliance of materials used in the manufacture of any medicinal products with the specification of such materials or medicinal products, and

(*c*) for keeping reference samples of materials used in the manufacture of any medicinal products and of the medicinal products.

Regulation 3(2)

## SCHEDULE 2

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

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

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 dealing includes 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 to be one or more of the following—

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

(*b*) for use by being administered to animals,

(*c*) for use in the form of 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*) for use by incorporation in any animal feeding stuff.

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

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

7. A statement indicating the facilities and equipment available at each of the 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 premises, whether by maintaining records or by other means, for ensuring, so far as practicable, a satisfactory turn-over of stocks of medicinal products.

## EXPLANATORY NOTE

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

These Regulations made under the Medicines Act 1968 relate to applications for the grant of manufacturer's licences and wholesale dealer's licences other than licences of right. They prescribe the form and manner in which such applications are to be made, and specify the information that shall accompany each application.

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