STATUTORY INSTRUMENTS

1971 No. 972

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971

Made - - -	9*th June* 1971
Laid before Parliament	24*th June* 1971
Coming into Operation	1*st 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 section 47(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 regulations, hereby make the following regulations :—

Citation and commencement

1. These regulations may be cited as the Medicines (Standard Provisions for Licences and Certificates) 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 ;

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

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

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

(2) The Interpretation Act 1889(**c**) 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**) 1889 c. 63.

Standard provisions for licences and certificates

3. The standard provisions for the purposes of Part II of the Act shall be the following—

(1) for product licences, including product licences of right, those provisions set out in Part I of Schedule 1 to these regulations;

(2) for clinical trial certificates, including clinical trial certificates of right, those provisions set out in Part II of Schedule 1 to these regulations;

(3) for animal test certificates, including animal test certificates of right, those provisions set out in Part III of Schedule 1 to these regulations;

(4) for manufacturer's licences, including manufacturer's licences of right, those provisions set out in Schedule 2 to these regulations;

(5) for wholesale dealer's licences, including wholesale dealer's licences of right, those provisions set out in Schedule 3 to these regulations.

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 of 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.

SCHEDULE 1 Regulation 3(1)

PART I

Standard provisions for product licences including product licences of right

1. The licence holder shall forthwith report to the licensing authority any change in his name and address and in any address at which there is carried on a business to which the licence relates.

2.—(1) The licence holder shall forthwith inform the licensing authority of any material change that has been made or that he proposes to make, or that he proposes that another person shall make, in the particulars contained in or furnished in connection with his application, in relation to any medicinal product to which the licence relates, that is to say—

(*a*) in the specification of the medicinal product,

(*b*) in the specification of any of the constituents of the medicinal product,

(*c*) in the composition of the medicinal product, or of any of the constituents of the medicinal product,

(*d*) in the methods of manufacture or assembly of the medicinal product, or of any of the constituents of the medicinal product,

(*e*) in the methods and procedures described in the application for ensuring compliance with such specifications, or

(*f*) in the arrangements described in the application for storage of the medicinal product.

(2) Where the particulars of any of the matters mentioned in the licence differ from the particulars relating to the corresponding matters contained in or furnished in connection with the application for the licence, the licence holder shall forthwith inform the licensing authority of any change to a material extent in the matters mentioned in the licence that he proposes to make, or that he proposes that another person shall make.

3. The licence holder shall forthwith inform the licensing authority of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with, the application for the product licence for the purpose of being taken into account in assessing the safety, quality or efficacy of any medicinal product to which the licence relates.

4. The licence holder shall maintain a record of reports of which he is aware of adverse effects in one or more human beings or animals associated in those reports with the use of any medicinal product to which the licence relates, which shall be open to inspection by a person authorised by the licensing authority, who may take copies thereof, and if the licensing authority so directs, the licence holder shall furnish the licensing authority with a copy of any such reports of which he has a record or of which he is or subsequently becomes aware.

5. The licence holder shall keep readily available for inspection by a person authorised by the licensing authority durable records of his arrangements—

(i) for procuring the sale, supply, manufacture, assembly or importation of any medicinal product to which the licence relates, and

(ii) for obtaining materials for the purpose of the manufacture or the assembly by him or on his behalf of any medicinal product to which the licence relates, and

(iii) for tests to be carried out on the materials used for manufacture or assembly of any medicinal product and on any medicinal product to which the licence relates,

and shall permit the person authorised to take copies of, or to make extracts from, such records. The records shall not be destroyed for a period of five years from the date when the sale, supply or exportation of the relevant batch of the medicinal product was authorised by or on behalf of the licence holder, without the consent of the licensing authority.

6. The licence holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal product to which the licence relates.

7. Where the licence holder has been informed by the licensing authority that any batch of any medicinal product to which the licence relates has been found not to conform as regards strength, quality or purity with the specification of that product or with the provisions of the Act or of any regulations under the Act that are applicable to the medicinal product, he shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such period not exceeding six weeks as may be specified by the licensing authority.

8. The licence holder shall notify the licensing authority forthwith of any decision to withdraw from sale, supply or exportation any medicinal product to which the licence relates, and shall state the reason for that decision.

Regulation 3(2) **PART II**

Standard provisions for clinical trial certificates and clinical trial certificates of right

1. The certificate holder shall forthwith report to the licensing authority any change in his name and address and in any address at which there is carried on a business to which the clinical trial certificate relates.

2. The certificate holder shall forthwith inform the licensing authority of any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with, the application for the clinical trial certificate for the purpose of being taken into account in assessing the safety, quality or efficacy of any medicinal products to which the certificate relates for the purpose for which the certificate holder proposed that it may be used.

3. The certificate holder shall forthwith inform the licensing authority of any decision to discontinue the trial of any medicinal product to which the certificate relates and shall state the reason for the decision.

Regulation 3(3) **PART III**

Standard provisions for animal test certificates and animal test certificates of right

1. The certificate holder shall forthwith report to the licensing authority any change in his name and address and in any address at which there is carried on a business to which the animal test certificate relates.

2. The certificate holder shall forthwith inform the licensing authority of any proposed change in the arrangements for the supervision of the performance of the medicinal test on animals to which the certificate relates.

3. The certificate holder shall forthwith furnish the licensing authority with any information received by him that casts doubt on the continued validity of the data which was submitted with, or in connection with, the application for the animal test certificate for the purpose of being taken into account in assessing the safety, quality or efficacy of any medicinal product to which the certificate relates for the purpose for which the certificate holder proposed that it may be used.

4. The certificate holder shall maintain a record of any report received by him of adverse effects in any animal or animals associated in the report with the use of any medicinal product to which the certificate relates, which shall be open to inspection by a person authorised by the licensing authority, who may take copies thereof, and the certificate holder, unless requested by the licensing authority not to do so, shall forthwith furnish the licensing authority with a copy of any such reports that have been received by him.

5. The certificate holder shall keep readily available for inspection by a person authorised by the licensing authority durable records of his arrangements,

(i) for procuring the sale, supply, manufacture, assembly or importation of any medicinal product to which the certificate relates, and

(ii) for obtaining materials for the purpose of the manufacture or assembly by him, or on his behalf, of any medicinal product to which the certificate relates, and

(iii) for tests to be carried out on the materials used for manufacture or assembly of any medicinal products and on any medicinal products to which the certificate relates;

and shall permit the person authorised to take copies or to make extracts from such records. Such records shall not, without the consent of the licensing authority, be destroyed for a period of one year from the date of the expiry of the last certificate for the medicinal test on animals to which such records relate.

6. The certificate holder shall forthwith notify the licensing authority of any decision to discontinue the test of any medicinal product to which the certificate relates and shall inform the licensing authority of the reason for the decision.

SCHEDULE 2 Regulation 3(4)

Standard provisions for manufacturer's licences and manufacturer's licences of right

1. The licence holder shall provide and maintain such staff, premises and plant as are necessary for the carrying out in accordance with his licence and the relevant product licences of such stages of the manufacture and assembly of the medicinal products as are undertaken by him, and he shall not carry out any such manufacture or assembly except at the premises specified in his manufacturer's licence.

2. The licence holder shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products which he handles, stores or distributes under his licence as are necessary to avoid deterioration of the medicinal products and he shall not use for such purposes premises other than those specified in the licence or which may be approved from time to time by the licensing authority.

3. The licence holder shall conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products conform with the standards of strength, quality and purity applicable to them under the relevant product licences.

4. The licence holder, where animals are used in the production of any medicinal products and the relevant product licences contain provisions relating to them, shall arrange for the animals to be housed in premises of such a nature and to be managed in such a way as will facilitate compliance with such provisions.

5. The licence holder shall either

(*a*) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with the relevant product licences any tests of the strength, quality or purity of the medicinal products that he manufactures under his manufacturer's licence as required by those product licences, and when animals are used for such tests they shall be suitably housed and managed, or

(*b*) make arrangements with a person approved by the licensing authority for such tests to be carried out in accordance with the relevant product licences on his behalf by that person.

6. The licence holder shall provide such information as may be requested by the licensing authority for the purposes of the Act, about the products currently being manufactured or assembled under his licence and of the operations being carried out in relation to such manufacture or assembly.

7. The licence holder shall inform the licensing authority before making any material alteration in the premises or plant used under his licence, or in the operations for which they are used, and he shall inform the licensing authority of any change that he proposes to make in any personnel named in his licence as respectively

(*a*) responsible for supervising the production operations, or

(*b*) responsible for quality control of the medicinal products being manufactured or assembled, or

(*c*) in charge of the animals from which are derived any substances used in the production of the medicinal products being manufactured or assembled, or

(*d*) responsible for the culture of any living tissues used in the manufacture of the medicinal products being manufactured or assembled.

8. The licence holder shall keep readily available for inspection by a person authorised by the licensing authority durable records of the details of manufacture and assembly of each batch of every medicinal product being manufactured or assembled under his licence and of the tests carried out thereon, in such a form that the records will be easily identifiable from the number of the batch as shown on each container in which the medicinal product is sold, supplied or exported, and he shall permit the person authorised to take copies or make extracts from such records. Such records shall not be destroyed for a period of five years from the date when the manufacture or assembly of the relevant batch occurred, without the consent of the licensing authority.

9. The licence holder shall keep such documents as will facilitate the withdrawal or recall from sale, supply or exportation of any medicinal products to which the licence relates.

10. Where the licence holder has been informed by the licensing authority that any batch of any medicinal product to which his licence relates has been found not to conform as regards strength, quality or purity with the specification of the relevant product or with the provisions of the Act or of any regulations under the Act that are applicable to the medicinal product, he shall, if so directed, withhold such batch from sale, supply or exportation, so far as may be reasonably practicable, for such a period not exceeding six weeks as may be specified by the licensing authority.

11. The licence holder shall ensure that any tests for determining conformity with the standards and specifications applying to any particular product used in the manufacture shall, except so far as the conditions of the relevant product licence may otherwise provide, be applied to samples taken from the medicinal product after all manufacturing processes have been completed, or at such earlier stage in the manufacture as may be approved by the licensing authority.

SCHEDULE 3 Regulation 3(5)

Standard provisions for wholesale dealer's licences including wholesale dealer's licences of right

1. The licence holder shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products which he handles, stores or distributes under his licence, as are necessary to avoid deterioration of the medicinal products and he shall not use for such purposes premises other than those specified in the licence or which may be approved from time to time by the licensing authority.

2. The licence holder shall provide such information as may be requested by the licensing authority concerning the type and quantity of any medicinal product which he currently handles, stores or distributes.

3. The licence holder shall inform the licensing authority of any proposed structural alterations to, or discontinuance of use of, premises to which the licence relates or premises which have been approved from time to time by the licensing authority.

4. The licence holder shall keep such documents relating to his transactions by way of the sale of medicinal products to which the licence relates as will facilitate the withdrawal or recall from sale or exportation of such products.

5. Where the licence holder has been informed by the licensing authority or by the holder of the product licence that any batch of any medicinal product to which the wholesale dealer's licence relates has been found not to conform as regards strength, quality or purity with the specification of that product or with the provisions of the Act or of any regulations under the Act that are applicable to the medicinal product, he shall, if so directed, withhold such batch from sale or exportation, so far as may be reasonably practicable, for such period not exceeding six weeks as may be specified by the licensing authority.

EXPLANATORY NOTE

(*This Note does not form part of the Regulations.*)

These Regulations, made under section 47 of the Medicines Act 1968, contain the standard provisions which may be incorporated in any licence or certificate. Schedule 1 contains in Part I standard provisions for product licences, in Part II standard provisions for clinical trial certificates and in Part III standard provisions for animal test certificates. Schedule 2 contains standard provisions for manufacturer's licences and Schedule 3 contains standard provisions for wholesale dealer's licences.