STATUTORY INSTRUMENTS

1972 No. 1226

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972

Made - - -	*8th August* 1972
Laid before Parliament	*16th August* 1972
Coming into Operation	*31st August* 1972

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 Secretary of State for Northern Ireland and the Minister of Agriculture, Fisheries and Food, 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 section 1(1)(*a*) of the Northern Ireland (Temporary Provisions) Act 1972(**c**)) 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, interpretation and commencement

1. These regulations, which may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1972, shall be read as one with the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**d**) (hereinafter referred to as "the principal regulations") and shall come into operation on 31st August 1972.

Amendment of regulation 2(1) *of the principal regulations*

2. Regulation 2(1) of the principal regulations (definitions) shall be amended by adding immediately before the definition of "medicinal product", the following definition:—

" 'licence holder' and 'certificate holder' shall be construed in the same manner as the holder of a licence or certificate is required to be construed under section 132(4) of the Act;".

Amendment of Part II of Schedule 1 *to the principal regulations*

3. In Part II of Schedule 1 to the principal regulations (standard provisions for clinical trial certificates) immediately after paragraph 3 there shall be added the following paragraphs:—

(**a**) 1968 c. 67.
(**b**) S.I. 1969/388 (1969 I, p. 1070).
(**c**) 1972 c. 22.
(**d**) S.I. 1971/972 (1971 II, p. 2809).

"4. The clinical trial in respect of which the clinical trial certificate has been issued shall be carried out in accordance with the outline of the clinical trial contained in the application for that certificate subject to any changes thereto which the licensing authority may from time to time approve.

5.—(1) The medicinal product to which the clinical trial certificate relates shall be administered only by or under the direction of a doctor or dentist named in the application for that certificate or by or under the direction of a doctor or dentist approved by the licensing authority for this purpose.

(2) Where the medicinal product to which the clinical trial certificate relates is to be administered by or under the direction of a doctor or dentist who has not been named in the application for that certificate or where it is intended that there shall be a change of the doctor or dentist so named, the certificate holder shall seek the approval of the licensing authority and for this purpose shall notify the licensing authority in writing of the name, address and qualifications of the doctor or dentist in question.

(3) In the event of any doctor or dentist ceasing to participate in the clinical trial in respect of which the clinical trial certificate has been issued, the certificate holder shall as soon as is reasonably possible inform the licensing authority and shall give the reason for such cessation.

6. Before any administration of the medicinal product to which the clinical trial certificate relates takes place, the certificate holder shall communicate the provisions of that certificate to each and every doctor or dentist who, in the course of the clinical trial in respect of which that certificate has been issued, is to administer or to direct the administration of that medicinal product.".

Amendment of Part III of Schedule 1 *to the principal regulations*

4. In Part III of Schedule 1 to the principal regulations (standard provisions for animal test certificates) immediately after paragraph 6 there shall be added the following paragraphs:—

"7. The medicinal test on animals in respect of which the animal test certificate has been issued shall be carried out in accordance with the outline of the medicinal test on animals contained in the application for that certificate subject to any changes thereto which the licensing authority may from time to time approve.

8.—(1) The medicinal product to which the animal test certificate relates shall be administered only by, or under the direction of, the person named in the application for that certificate as the person by whom it was proposed that the medicinal test on animals should be carried out or by or under the direction of such other person approved by the licensing authority for this purpose.

(2) Where the medicinal product to which the animal test certificate relates is to be administered by, or under the direction of, a person who has not been named in the application for that certificate or where it is intended that there shall be a change of the person so named, the certificate holder shall seek the approval of the licensing authority and for this purpose shall notify the licensing authority in writing of the name, address and qualifications of the person in question.

(3) In the event of any such named or approved person ceasing to participate in the medicinal test on animals in respect of which the animal test certificate has been issued, the certificate holder shall as soon as is reasonably possible inform the licensing authority and shall give the reason for such cessation.

9.—(1) The medicinal test on animals in respect of which the animal test certificate has been issued shall be carried out only at the location specified in the application for that certificate.

(2) Where the medicinal test on animals to which the animal test certificate relates is to be carried out at a location that has not been specified in the application or where it is intended that there shall be a change in the location so specified, the certificate holder shall seek the approval of the licensing authority and for this purpose shall notify the licensing authority in writing of the location in question.

10. Before any administration of the medicinal product to which the animal test certificate relates takes place, the certificate holder shall arrange that the particulars relating to the administration of that medicinal product together with any relevant safety precautions be communicated to each and every person who, in the course of the medicinal test on animals in respect of which that certificate has been issued, is to administer or to direct the administration of that medicinal product.".

Amendment of Schedule 2 to the principal regulations

5. In Schedule 2 to the principal regulations (standard provisions for manufacturer's licences) immediately after paragraph 11 there shall be added the following paragraphs:—

"12.—(1) The licence holder who is not the holder of a product licence in respect of the medicinal product to which the manufacturer's licence relates, shall comply with any provisions of such a product licence that relates to the sale of that medicinal product and shall, by means of a label or otherwise, communicate the particulars of such provisions as relate to mode of sale, or restriction as to sale, to any person to whom the licence holder sells or supplies that medicinal product.

(2) Where the manufacturer's licence relates to the assembly of a medicinal product, and the licence holder sells or supplies that medicinal product at such a stage of assembly that does not fully comply with the provisions of the relevant product licence that relates to labelling, that licence holder shall communicate the particulars of those provisions to the person to whom that medicinal product has been so sold or supplied.

13. Where in his application for a manufacturer's licence the licence holder had specified a general classification of medicinal products in respect of which that licence was required or had given particulars of manufacturing operations and of substances or articles in accordance with paragraph 6 of Schedule 1 to the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971(**a**) and there has been, or it is proposed that there shall be, a change in such general classification or such particulars, the licence holder shall forthwith notify the licensing authority in writing of such change or proposed change.

(**a**) S.I. 1971/974 (1971 II, p. 2836).

14. Where the manufacturer's licence relates to the assembly of a medicinal product and that medicinal product is not manufactured by the licence holder, and where particulars as to the name and address of the manufacturer of, or of the person who imports, that medicinal product had been given by the licence holder to the licensing authority, the licence holder shall forthwith notify the licensing authority in writing of any changes in such particulars.

15. The licence holder, for the purpose of enabling the licensing authority to ascertain whether there are any grounds for suspending, revoking or varying any licence or certificate granted or issued under Part II of the Act, shall permit, and provide all necessary facilities to enable, any person duly authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the licence holder, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence or certificate.".

Amendment of Schedule 3 *to the principal regulations*

6. In Schedule 3 to the principal regulations (standard provisions for wholesale dealer's licences) immediately after paragraph 5 there shall be added the following paragraphs:-

"6.—(1) Subject to the provisions of sub-paragraph (2) of this paragraph, no medicinal product to which the wholesale dealer's licence relates shall be sold or offered for sale by way of wholesale dealing by virtue of that licence unless there has been granted in respect of that medicinal product a product licence which is for the time being in force and any sale or offer for sale shall be in conformity with the provisions of such product licence.

(2) The provisions of the preceding sub-paragraph of this paragraph shall not apply where—

(i) by virtue of any provisions of the Act or of any order made thereunder, the sale (other than sale by way of wholesale dealing) of the medicinal product to which the wholesale dealer's licence relates is not subject to the restrictions imposed by section 7(2) of the Act, or

(ii) the sale or offer for sale by way of wholesale dealing is of a medicinal product the dealings in which, at the time of its acquisition by the licence holder, were not subject to the said restrictions imposed by section 7(2) of the Act, or

(iii) at the time of such sale or offer for sale, the licence holder does not know, or could not by reasonable diligence and care have known, that such sale or offer for sale is of a medicinal product, or believes, on reasonable grounds, that the provisions of sub-paragraphs (2)(i) or 2(ii) of this paragraph apply in relation to such sale or offer for sale.

7. The licence holder, for the purpose of enabling the licensing authority to ascertain whether there are any grounds for suspending, revoking or varying any licence or certificate granted or issued under Part II of the Act, shall permit, and provide all necessary facilities to enable, any person duly

authorised in writing by the licensing authority, on production if required of his credentials, to carry out such inspection or to take such samples or copies, in relation to things belonging to, or any business carried on by, the licence holder, as such person would have the right to carry out or take under the Act for the purpose of verifying any statement contained in an application for a licence or certificate.".

Keith Joseph,
Secretary of State for Social Services.

3rd August 1972.

Peter Thomas,
Secretary of State for Wales.

7th August 1972.

Gordon Campbell,
Secretary of State for Scotland.

8th August 1972.

W. S. I. Whitelaw,
Secretary of State for Northern Ireland.

7th August 1972.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th August 1972.

(L.S.)

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

EXPLANATORY NOTE

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

These Regulations amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 and add to the Schedules to those regulations further standard provisions which may be incorporated in any licence or certificate. Regulations 3 and 4 provide for further standard provisions which may be incorporated in clinical trial and animal test certificates, regulation 5 provides for further standard provisions which may be incorporated in manufacturer's licences and regulation 6 provides further standard provisions which may be incorporated in wholesale dealer's licences. The remaining amendment (regulation 2) is of a minor character.

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