STATUTORY INSTRUMENTS

1977 No. 1053

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 3) Regulations 1977

Made - - - -	21*st June* 1977
Laid before Parliament	24*th June* 1977
Coming into Operation	15*th July* 1977

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 Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by section 47(1) of the Medicines Act 1968**(a)** and now vested in them**(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, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Standard Provisions for Licences and Certificates) Amendment (No. 3) Regulations 1977 and shall come into operation on 15th July 1977.

(2) These regulations shall be read as one with the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971**(c)** as amended**(d)** (hereinafter referred to as "the principal regulations").

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

2. In regulation 2(1) of the principal regulations (definitions) after the definition of "medicinal product" there shall be inserted the following definitions—

" "member" in the expression "member State" refers to membership of the European Economic Community;

"Second Council Directive" means Second Council Directive 75/319/EEC of 20th May 1975 (OJ No L147, 9.6.1975, p. 13);

(a) 1968 c. 67.

(b) In the case of the Secretaries of State concerned with health in England and in Wales by virtue of Article 2(2) of, and Schedule 1 to, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388 (1969 I, p. 1070)), and in the case of the Northern Ireland Departments by virtue of section 40 of, and Schedule 5 to, the Northern Ireland Constitution Act 1973 (c. 36), and section 1(3) of, and paragraph 2(1)(*b*) of Schedule 1 to, the Northern Ireland Act 1974 (c. 28).

(c) S.I. 1971/972 (1971 II, p. 2809).

(d) The relevant amending instrument is S.I. 1972/1226 (1972 II, p. 3708).

"imported proprietary product" means a proprietary medicinal product, imported other than from a member State;

"proprietary medicinal product" has the same meaning as in sections 7(7) and 8(4) of the Act, as amended(a);".

Amendment of Schedule 2 to the principal regulations

3. Schedule 2 to the principal regulations (standard provisions for manufacturer's licences) shall be amended as follows—

(*a*) in paragraph 7(*b*) after the word "assembled" there shall be inserted the words "including the person named as the qualified person for the purposes of paragraph 16 of this Part of this Schedule"

(*b*) in paragraph 8 after the word "thereon" there shall be inserted the words "including any register or other record referred to in paragraph 16(3)(*b*) of this Schedule"

(*c*) after paragraph 15 there shall be inserted the following paragraph—

"16.—(1) Subject to sub-paragraph (5) below, the licence holder shall at all times have at his disposal the services of a person who as respects qualifications and experience satisfies the provisions of Articles 23 and 24 of the Second Council Directive, to carry out the functions specified in sub-paragraph (3) below ("qualified person"). For the purposes of this paragraph, but without prejudice to sub-paragraph (4) below, the licence holder may regard a person as satisfying the provisions of the said Article 24 as respects formal qualifications if he produces evidence that he is a member of the Pharmaceutical Society or of the Royal Institute of Chemistry or of such other body as may appear to the licensing authority to be an appropriate body for the purpose, and that he is regarded by the body of which he is a member as so satisfying those provisions.

(2) The licence holder shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal to carry out the said functions.

(3) The functions to be carried out by the qualified person shall be as follows—

(*a*) to ensure that each batch of the medicinal product to which the licence relates has been manufactured or assembled and checked in compliance with the provisions of the Act and regulations made thereunder, the provisions of the licence and the provisions of the product licence which relates to the product;

(*b*) to certify in a register, or other record appropriate for the purpose, whether each production batch of the medicinal product to which the licence relates satisfies the requirements set out in (*a*) above and to ensure that such register or other record is regularly maintained, in particular that the appropriate entries in such register or other record are made as soon as practicable after each such batch has been manufactured.

(4) Where, after giving the licence holder and the person acting as a qualified person the opportunity of making representations to them (orally or in writing), the licensing authority are of the opinion that the

(a) See regulations 2 and 3 of the Medicines (Medicines Act 1968 Amendment) Regulations 1977 (S.I. 1977/1050 (1977 II, p. 2986)) and regulations 3 and 4 of the Medicines (Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1977 (S.R. of N.I. 1977/170).

person so acting does not satisfy the provisions of the said Articles 23 and 24 of the Second Council Directive as respects qualifications and experience, or that he is failing to carry out the functions specified in sub-paragraph (3) above, and have notified the licence holder accordingly in writing, the licence holder shall not permit that person to act as a qualified person so long as the said notification has not been withdrawn by the licensing authority.

(5) The provisions of this paragraph shall not apply in relation to veterinary drugs or to medicinal products consisting of vaccines, toxins or serums, medicinal products based on human blood or blood constituents, radioactive isotopes or medicinal products that are homoeopathic products.

(6) The provisions of this paragraph shall also not apply where the licence relates to manufacturing activity which—

(*a*) is limited to medicinal products to which Article 2 of the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971**(a)** as amended**(b)** applies, and consists solely of mixing together medicinal products and ingredients, other than active ingredients, on premises of which the licence holder is the occupier and which he is able to close so as to exclude the public, or

(*b*) is limited to assembly only, where all the products to be assembled are for sale or supply in the course of a business and are supplied, without any recommendation, for the purpose of administration to a particular person after the licence holder has been requested by or on behalf of that person, and in that person's presence, to use his judgment as to the treatment required.

(7) The provisions of this paragraph shall not have effect until 22nd November 1977 in relation to a licence which has been granted before the coming into operation of these regulations.".

Amendment of Schedule 3 to the principal regulations

4. In Schedule 3 to the principal regulations (standard provisions for wholesale dealer's licences) after paragraph 7 there shall be inserted the following paragraph—

"8.—(1) Subject to sub-paragraphs (7) and (8) below, where the licence relates to imported proprietary products the licence holder shall at all times have at his disposal the services of a person who as respects qualifications and experience satisfies the provisions of Articles 23 and 24 of the Second Council Directive to carry out the functions specified in sub-paragraph (3) below ("qualified person"). For the purposes of this paragraph, but without prejudice to sub-paragraph (6) below, the licence holder may regard a person as satisfying the provisions of the said Article 24 as respects formal qualifications if he produces evidence that he is a member of the Pharmaceutical Society or of the Royal Institute of Chemistry or of such other body as may appear to the licensing authority to be an appropriate body for the purpose, and that he is regarded by the body of which he is a member as so satisfying those provisions.

(2) The licence holder shall at all times provide and maintain such staff, premises, equipment and facilities as will enable the qualified person who is at his disposal to carry out the said functions.

(a) S.I. 1971/1450 (1971 III, p. 4118).
(b) S.I. 1972/1200 (1972 II, p. 3553).

(3) The functions to be carried out by the qualified person shall be as follows:—

(*a*) to ensure that each production batch of any imported proprietary product to which the licence relates has undergone a full qualitative analysis, a quantitative analysis of at least all the active ingredients and all other tests or checks necessary to ensure that the quality of the product imported satisfies the requirements of the product licence which relates to the product;

(*b*) to certify in a register, or other record appropriate for the purpose, whether each batch of the imported proprietary product to which the licence relates satisfies the requirements set out in (*a*) above and to ensure that such register or other record is regularly maintained:

Provided that the above functions shall be deemed to be carried out in respect of a batch which had entered the territory of another member State prior to its importation if there is available evidence in writing, signed by a person carrying out the functions of a qualified person in that member State, that the batch in question satisfies the requirements set out in (*a*) above.

(4) The licence holder shall keep the said register or other record readily available for inspection by a person authorised by the licensing authority and such register or other record shall not be destroyed for a period of five years from the date of the certification referred to in sub-paragraph (3)(*b*) above.

(5) The licence holder shall notify the licensing authority of the name and address and degrees, diplomas or qualifications and experience of the person who will carry out the functions of a qualified person and shall notify the licensing authority of any change as to the qualified person and shall not permit any person to act as a qualified person except the person named in his licence as the qualified person for the purposes of this paragraph or, subject to the provisions of paragraph (6) below, any other such person whose name is notified to the licensing authority.

(6) Where, after giving the licence holder and the person acting as a qualified person the opportunity of making representations to them (orally or in writing), the licensing authority are of the opinion that the person so acting does not satisfy the provisions of the said Articles 23 and 24 of the Second Council Directive as respects qualifications and experience, or that he is failing to carry out the functions specified in sub-paragraph (3) above, and have notified the licence holder accordingly in writing, the licence holder shall not permit that person to act as a qualified person so long as the said notification has not been withdrawn by the licensing authority.

(7) The provisions of this paragraph shall not apply where the imported proprietary product that is to be sold or offered for sale or in any other way distributed has been in the possession of a person in the course of his business who is the holder of a wholesale dealer's licence which relates to imported proprietary products of the same description in circumstances by virtue of which that licence holder is required to comply with the provisions of this paragraph.

(8) The provisions of this paragraph shall also not apply where the licence holder handles the imported proprietary product—

(*a*) in the course of the provision of facilities solely for the transport of the medicinal product, or

(*b*) in the course of a business carried on by him as an import agent where he imports the medicinal product solely to the order of another person who intends, in the course of a business carried on by him, to sell, or offer for sale the medicinal product by way of wholesale dealing or in any other way intends to distribute the medicinal product.

(9) The provisions of this paragraph shall not have effect until 22nd November 1977 in relation to a licence which has been granted before the coming into operation of these regulations.".

David Ennals,
Secretary of State for Social Services.

13th June 1977.

John Morris,
Secretary of State for Wales.

14th June 1977.

Bruce Millan,
Secretary of State for Scotland.

16th June 1977.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 17th June 1977.

(L.S.)

John Silkin,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 20th day of June 1977.

(L.S.)

N. Dugdale,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 21st day of June 1977.

(L.S.)

J. A. Young,
Permanent Secretary.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations further amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 and add to the Schedules to those regulations. Regulation 3 provides for further standard provisions which may be incorporated in manufacturer's licences. Regulation 4 provides for further standard provisions which may be incorporated in wholesale dealer's licences. To the extent that the regulations apply to proprietary medicinal products they implement certain Community obligations under two Council Directives Nos. 65/65/EEC and 75/319/EEC.

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