STATUTORY INSTRUMENTS

1983 No. 1730

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1983

Made - - - -	*21st November* 1983
Laid before Parliament	*30th November* 1983
Coming into Operation	*21st December* 1983

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Scotland and in Wales, 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 the 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 these regulations in accordance with section 129(6) of the said Act, hereby make the following regulations:—

Title, commencement and interpretation

1.—(1) These regulations may be cited in the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1983 and shall come into operation on 21st December 1983.

(2) In these regulations "the principal regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**c**).

Amendment of regulation 2(1) of the principal regulations

2. Regulation 2(1) of the principal regulations (interpretation) shall be amended as follows—

(*a*) for the definition of "member" there shall be substituted the following definition—

" "member" in the expression "member State" refers to membership of the European Communities;"; and

(**a**) 1968 c. 67.

(**b**) In the case of the Secretaries of State concerned with health in England and Wales by virtue of S.I. 1969/388, in the case of the Secretary of State concerned with agriculture in Wales by virtue of S.I. 1978/272 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; relevant amending instruments are S.I. 1972/1226, 1974/1523, 1977/1039, 1053.

(*b*) after the definition of "member" (as substituted) there shall be inserted the following definition—

" "the Council Directive" means the Council Directive 81/851/EEC of 28th September 1981 (OJ No. L317, 6.11.81, p.1);".

Amendment of Schedule 1 to the principal regulations

3. After paragraph 13 of part I of Schedule 1 to the principal regulations (standard provisions for product licences including product licences of right) there shall be inserted the following paragraph—

"**14.**—(1) The licence holder shall modify, in accordance with technical and scientific progress, the methods of control testing employed by him in relation to any medicinal product to which the licence relates, if such modification is needed to enable the medicinal product to be controlled with a greater degree of security.

(2) The provisions of this paragraph shall not apply in relation to—

(*a*) medicinal products which are manufactured, sold, supplied, imported or exported for use by being administered to human beings;

(*b*) veterinary drugs which—

(i) consist of vaccines, toxins or serums;

(ii) are based on radioactive isotopes;

(iii) are homoeopathic veterinary drugs; or

(iv) are additives for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply(**a**)."

Amendment of Schedule 2 to the principal regulations

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

(*a*) in paragraph 7(*b*) after the words "of paragraph 16" there shall be inserted the words "or 17, as the case may be,";

(*b*) in paragraph 8 after the words "in paragraph 16(3)(*b*)" there shall be inserted the words "or 17(3)(*b*), as the case may be,"; and

(*c*) after paragraph 16 there shall be inserted the following paragraph—

"**17.**—(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 31 and 32 of the 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 32 as respects formal qualifications if he produces evidence that he is a member of the Pharmaceutical Society or of the Royal Society of Chemistry or of such other body as may appear to the licensing

(**a**) OJ No. L270, 14.12.70, p.1.

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 person so acting does not satisfy the provisions of the said Articles 31 and 32 of the 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—

(*a*) medicinal products which are manufactured, sold, supplied, imported or exported for use by being administered to human beings;

(*b*) veterinary drugs which—

(i) consist of vaccines, toxins or serums;

(ii) are based on radioactive isotopes;

(iii) are homoeopathic veterinary drugs; or

(iv) are additives for animal feeding stuffs to which the provisions of Council Directive 70/524/EEC apply.

(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 (Exemptions from Licences) (Special and Transitional Cases) Order 1971(**a**) applies, and consists solely of mixing together medicinal prod-

(**a**) S.I. 1971/1450, as amended by S.I. 1972/1200.

ucts 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 animal or herd after the licence holder has been requested by the owner of that animal or herd to use his judgment as to the treatment required.

(7) The provisions of this paragraph shall not have effect until 9th October 1984 in relation to a licence which has been granted before the coming into operation of those regulations.".

Amendment of Schedule 3 to the principal regulations

5. In Schedule 3 to the principal regulations (standard provisions for wholesale dealer's licences) after paragraph 8 there shall be inserted the following paragraph—

"**9.**—(1) Subject to sub-paragraphs (7) and (8) below, where the licence relates to an imported proprietary veterinary drug or any imported ready-made veterinary drug 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 31 and 32 of the 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 32 as respects formal qualifications if he produces evidence that he is a member of the Pharmaceutical Society or of the Royal Society 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 production batch of any imported proprietary veterinary drug or imported ready-made veterinary drug 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 drug imported satisfies the requirements of the product licence which relates to the drug;

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

except 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 31 and 32 of the 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 veterinary drug or imported ready-made veterinary drug 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 veterinary drugs or imported ready-made veterinary drugs 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 veterinary drug or imported ready-made veterinary drug—

(*a*) in the course of the provision of facilities solely for the transport of the drug; or

(*b*) in the course of a business carried on by him as an import agent where he imports the drug 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 drug by way of wholesale dealing or in any other way intends to distribute the drug.

(9) For the purposes of this paragraph—

(*a*) "imported" means imported other than from a member State;

(*b*) "proprietary medicinal product" and "ready-made veterinary drug" have the same meaning as in sections 7(7) and 8(4) of the Act(**a**); and

(*c*) "proprietary veterinary drug" means a veterinary drug which is a proprietary medicinal product.

(10) The provisions of this paragraph shall not have effect until 9th October 1984 in relation to a licence which has been granted before the coming into operation of these regulations.".

Norman Fowler,
Secretary of State for Social Services.

21st November 1983.

George Younger,
Secretary of State for Scotland.

1st November 1983.

Nicholas Edwards,
Secretary of State for Wales.

2nd November 1983.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 26th October 1983.

Michael Jopling,
Minister of Agriculture, Fisheries and Food.

(L.S.)

(**a**) Sections 7(7) and 8(4) were inserted by S.I. 1977/1050 and S.R. (N.I.) 1977 No. 170 and amended by S.I. 1983/1724.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 10th day of November 1983.

N. Dugdale,
Permanent Secretary.

(L.S.)

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 10th day of November 1983.

W. H. Jack,
Permanent Secretary.

(L.S.)

EXPLANATORY NOTE

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

These Regulations further amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 which prescribed standard provisions which may be incorporated by the licensing authority in any licence or certificate granted or issued under Part II of the Medicines Act 1968.

The Regulations amend the 1971 Regulations by—

(1) prescribing an additional standard provision which may be incorporated in a product licence (Regulation 3);

(2) prescribing additional standard provisions which may be incorporated in a manufacturer's licence (Regulation 4);
and

(3) prescribing (in Regulation 5) additional standard provisions which may be incorporated in a wholesale dealer's licence relating to an imported proprietary veterinary drug or an imported ready-made veterinary drug (as defined in Regulation 5).

Regulations 4 and 5 do not come into operation until 9th October 1984 in relation to a licence which was granted before 21st December 1983.

The Regulations implement in part Council Directive 81/851/EEC (OJ No. L317, 6.11.81, p.1) on the approximation of the laws of the Member States relating to veterinary medicinal products.

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