STATUTORY INSTRUMENTS

1999 No. 4

MEDICINES

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1999

Made - - - -	*5th January 1999*
Laid before Parliament	*11th January 1999*
Coming into force - -	*1st February 1999*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and agriculture in Wales and in Scotland respectively, 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 upon them by section 47(1) and 129(5) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by the said provisions and now vested in them(**2**) 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(**3**) 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 Regulations 1999 and shall come into force on 1st February 1999.

(2) In these Regulations, "the principal Regulations" means the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**4**).

Amendment of regulation 2(1) of the principal Regulations

2. Paragraph (1) of regulation 2 of the principal Regulations (interpretation) shall be amended as follows–

(a) after the definition of "the Act" there shall be inserted the following definition–

(**1**) 1968 c. 67. The expression "the Ministers" is defined in section 1(1) of that Act as amended by S.I. 1969/388, Schedule 1.

(**2**) 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); in the case of the Secretary of State concerned with agriculture in Wales by virtue of article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272); 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).

(**3**) *See* section 129(6) of the Medicines Act 1968.

(**4**) S.I. 1971/972. The relevant amending instruments are 1972/1226, 1977/1053, 1983/1730, 1992/2846 and 1993/833.

""the 1994 Regulations" means the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**5**);";

(b) after the definition of "clinical trial certificate of right" and "animal test certificate of right" there shall be inserted the following definition–

""exempt imported product" means a medicinal product as defined in article 1(2) of Council Directive 65/65/EEC(**6**) to which paragraph 1 of Schedule 1 to the 1994 Regulations applies, which was not manufactured in the United Kingdom and in relation to which no marketing authorisation has been granted;"; and

(c) after the definition of "licence holder" and "certificate holder" there shall be inserted the following definition–

""marketing authorisation" means

(a) a United Kingdom marketing authorisation granted by the licensing authority under the 1994 Regulations; or

(b) a Community marketing authorisation granted by the European Commission under Council Regulation (EEC) No. 2309/93(**7**); or

(c) a product licence which has effect as a United Kingdom marketing authorisation in accordance with paragraph 1 of Schedule 6 to the 1994 Regulations;".

Amendment of Schedule 3 to the principal Regulations

3.—(1) Schedule 3 to the principal Regulations (standard provisions for wholesale dealer's licences including wholesale dealer's licences of right) shall be amended in accordance with the following paragraphs.

(2) In paragraph 8(1), after the words "subject to sub-paragraphs (7)" there shall be inserted the words ", (7A)".

(3) In paragraph 8, after sub-paragraph (7) there shall be inserted the following sub-paragraph–

"(7A) The provisions of this paragraph shall also not apply where the imported proprietary product is an exempt imported product.".

(4) After paragraph 8A there shall be inserted the following paragraph–

"**8B.**—(1) Where the licence relates to exempt imported products, the licence holder shall only sell or supply such products in response to a bona fide unsolicited order to fulfil special needs, formulated in accordance with the specification of a doctor or dentist and for use by his individual patients on his direct personal responsibility and where the provisions set out in sub-paragraphs (2) to (9) are complied with.

(2) No later than 28 days prior to each importation of an exempt imported product, the licence holder shall give written notice to the licensing authority stating his intention to import that medicinal product and stating the following particulars–

(a) the name of the medicinal product, being the brand name or the common name, or the scientific name, and any name, if different, under which the medicinal product is to be sold or supplied in the United Kingdom;

(b) any trademark or name of the manufacturer of the medicinal product;

(**5**) S.I. 1994/3144; there are no amendments affecting the definition.
(**6**) OJ No. 22, 9.2.65, p. 369; there are no amendments affecting the definition.
(**7**) OJ No. L214, 24.8.93, p. 1.

(c) in respect of each active constituent of the medicinal product, any international non-proprietary name or the British approved name or the monograph name or, where that constituent does not have an international non-proprietary name, a British approved name or a monograph name, the accepted scientific name or any other name descriptive of the true nature of that constituent;

(d) the quantity of medicinal product which is to be imported which shall not exceed the quantity specified in sub-paragraph (6); and

(e) the name and address of the manufacturer or assembler of that medicinal product in the form in which it is to be imported and, if the person who will supply that medicinal product for importation is not the manufacturer or assembler, the name and address of such supplier.

(3) Subject to sub-paragraph (4), the licence holder shall not import the exempt imported product if, before the end of 28 days from the date on which the licensing authority sends or gives the licence holder an acknowledgement in writing by the licensing authority that they have received the notice referred to in sub-paragraph (2) above, the licensing authority have notified him in writing that the product should not be imported.

(4) The licence holder may import the exempt imported product referred to in the notice where he has been notified in writing by the licensing authority, before the end of the 28-day period referred to in sub-paragraph (3), that the exempt imported product may be imported.

(5) Where the licence holder sells or supplies exempt imported products, he shall, in addition to those records mentioned in paragraph 4B of this Schedule make and maintain written records relating to–

(a) the batch number of the batch of the product from which the sale or supply was made; and

(b) details of any adverse reaction to the product so sold or supplied of which he becomes aware.

(6) The licence holder shall import no more on any one occasion than such amount as is sufficient for 25 single administrations, or for 25 courses of treatment where the amount imported is sufficient for a maximum of three months' treatment and on any such occasion shall not import more than the quantity notified to the licensing authority under sub-paragraph (2)(d).

(7) The licence holder shall inform the licensing authority forthwith of any matter coming to his attention which might reasonably cause the licensing authority to believe that the medicinal product can no longer be regarded either as a product which can safely be administered to human beings or as a product which is of satisfactory quality for such administration.

(8) The licence holder shall not issue any advertisement, catalogue, price list or circular relating to the exempt imported product or make any representations in respect of that product.

(9) The licence holder shall cease importing or supplying an exempt imported product if he has received a notice in writing from the licensing authority directing that, as from a date specified in that notice, a particular product or class of products shall no longer be imported or supplied.

(10) In this paragraph–

"British approved name" means the name which appears in the current edition of the list prepared by the appropriate body in accordance with section 100 of the Act and published by the Ministers on the recommendation of the Medicines Commission and

"current" in this definition means current at the time the notice is sent to the licensing authority;

"common name" means the international non-proprietary name or, if one does not exist, the usual common name;

"international non-proprietary name" means a name which has been selected by the World Health Organisation as a recommended international non-proprietary name and in respect of which the Director-General of the World Health Organisation has given notice to that effect in the World Health Organisation Chronicle; and

"monograph name" means the name or approved synonym which appears at the head of a monograph in the current edition of the British Pharmacopoeia, the British Pharmaceutical Codex, the European Pharmacopoeia or a foreign or international compendium of standards and "current" in this definition means current at the time the notice is sent to the licensing authority.".

Frank Dobson
Secretary of State for Health,
21st December 1998 Department of Health

Signed by authority of the Secretary of State for Wales

Jon Owen Jones
Parliamentary Under Secretary of State,
4th January 1999 Welsh Office

Signed by authority of the Secretary of State for Scotland

Sam Galbraith
Parliamentary Under Secretary of State,
22nd December 1998 Scottish Office

Jeff Rooker
22nd December 1998 Ministry of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

D.C. Gowdy
5th January 1999 Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on

L.S.

P. Small
22nd December 1998 Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 ("the principal Regulations"). They provide that holders of wholesale dealer's licences who import medicinal products for the purpose of sale and supply in specified circumstances where marketing authorisations are not required under The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (S.I. 1994/3144) must meet specified requirements. These are equivalent to those imposed on people exempt from the requirement to hold a product licence by virtue of The Medicines (Exemption from Licences) (Importation) Order 1984 (S.I. 1984/673).

The requirements are imposed in a new paragraph 8B of Schedule 3 to the principal Regulations which is inserted by regulation 3(4). Under the new paragraph, holders of wholesale dealer's licences relating to exempted products (as defined in regulation 2(3) which inserts the new definition into regulation 2(1) of the principal Regulations) must only sell or supply such products in specified circumstances and where they have complied with the provisions set out in regulation 3(4) of these Regulations. The provisions require notification of the licensing authority concerning the importation of the products, record-keeping and set maximum quantities for import.

Under regulation 3(3) (which inserts a new paragraph 8(7A) into Schedule 3), exempted products are also not required to undergo controls carried out by a qualified person.

An assessment of the cost to business has been carried out and these Regulations impose no new costs on business.