STATUTORY INSTRUMENTS

1992 No. 2845

MEDICINES

The Medicines (Manufacturer's Undertakings for Imported Products) Amendment Regulations 1992

Made - - - -	*12th November 1992*
Laid before Parliament	*20th November 1992*
Coming into force - -	*11th December 1992*

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and 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 upon them by sections 19(3)(b) and 129(1) and (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 and commencement

1. These Regulations may be cited as the Medicines (Manufacturer's Undertakings for Imported Products) Amendment Regulations 1992, and shall come into force on 11th December 1992.

Interpretation

2. In these Regulations, "the principal Regulations" means the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977(**4**).

(**1**) 1968 c. 67. The word "prescribed" in section 19(3)(b) is defined in section 132(1) as amended. The expression "the Ministers" used in section 129(1) of that Act is defined in section 1(1) as amended by S.I. 1969/388.

(**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 (c. 67).

(**4**) S.I. 1977/1038.

Amendment of regulation 2 of the principal Regulations

3. In regulation 2 of the principal Regulations (interpretation), after paragraph (1) there shall be inserted the following paragraph—

"(1A) In these regulations, "expiry date" means the date after which the medicinal product should not be used.".

Amendment of regulation 3 of the principal Regulations

4. At the beginning of regulation 3 of the principal Regulations (prescribed conditions for manufacturer's undertakings) there shall be inserted the words "Subject to regulation 4".

Insertion of regulation 4 into the principal Regulations

5. After regulation 3 of the principal Regulations there shall be inserted the following regulation—

"**Exception**

4. The conditions prescribed in these regulations shall not apply in relation to an application which indicates that the purposes for which the licence is required relate (wholly or partly) to medicinal products for human use which have been or are to be imported from a member State of the European Economic Community in so far as those purposes relate to those products.".

Amendment of the Schedule to the principal Regulations

6.—(1) The Schedule to the principal Regulations shall be amended in accordance with the following paragraphs of this regulation.

(2) After paragraph 2 there shall be inserted the following paragraph—

"**2A.** In relation to medicinal products for human use, the manufacturer shall provide and maintain a designated quality control department having authority in relation to quality control and being independent of all other departments.";

(3) After paragraph 3, there shall be inserted the following paragraph—

"**3A.** In relation to medicinal products for human use, the manufacturer shall maintain an effective pharmaceutical quality assurance system involving the active participation of the management and personnel of the different services involved.".

(4) In paragraph 7, after the word "destroyed" there shall be inserted the following—

"(a) in relation to a medicinal product for human use, for a period of five years from the date of release of the relevant batch, or for a period of one year after the expiry date of the relevant batch, whichever expires later,

(b) in any other case,".

(5) After paragraph 7 there shall be inserted the following paragraphs—

"**7A.** In relation to medicinal products for human use to which a product licence relates, the manufacturer shall keep readily available for examination by a person authorised by the licensing authority, samples of—

(a) each batch of finished products for at least a period of one year after their expiry date; and

(b) starting materials (other than solvents, gases or water) for at least a period of two years after release of the medicinal product of which the relevant starting materials formed part;

except where the manufacturer is authorised by the licensing authority to destroy such samples earlier.

7B.—(1) The manufacturer shall implement a system for recording and reviewing complaints in relation to medicinal products for human use to which a product licence relates together with an effective system for recalling promptly and at any time the medicinal products in the distribution network.

(2) The manufacturer shall record and investigate all complaints described in sub-paragraph (1) of this paragraph and shall immediately inform the licensing authority of any defect which could result in a recall from sale, supply or exportation or in an abnormal restriction on such sale, supply or exportation.".

Signed by authority of the Secretary of State for Health

Brian Mawhinney
Minister,
12th November 1992 Department of Health

David Hunt
12th November 1992 Secretary of State for Wales

Fraser of Carmyllie
12th November 1992 Minister of State Scottish Office

In witness, whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 12th November 1992.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 12th November 1992.

F. A. Elliott
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 12th November 1992.

W. J. Hodges
Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977 ("the 1977 Regulations") so implementing in part Commission Directive 91/356/EEC (OJNo. L193, 17.7.91, p.30) ("the Directive") so as to prescribe additional conditions to the undertakings given by or on behalf of manufacturers of imported medicinal products in connection with an application for the grant of a product licence.

In particular, these Regulations require manufacturers to undertake—

- to provide and maintain an independent quality control department (regulation 6(2), article 11(1) of the Directive);
- to maintain an effective pharmaceutical quality assurance system (regulation 6(3), article 6 of the Directive);
- to require the keeping of records for five years or until one year after the expiry date of the product (regulation 6(4), article 9 of the Directive);
- to retain samples of starting materials and finished products for the periods prescribed and to keep appropriate records (regulation 6(5), article 11(4) of the Directive); and
- to maintain an effective system whereby complaints are reviewed (regulation 6(5), article 13 of the Directive).

These Regulations also exclude from the scope of the 1977 Regulations applications relating to products imported from another member State of the European Economic Community (regulations 4 and 5).