STATUTORY INSTRUMENTS

1977 No. 1038

MEDICINES

The Medicines (Manufacturer'S Undertakings for Imported Products) Regulations 1977

Made - - - -	*16th June 1977*
Laid before Parliament	*23rd June 1977*
Coming into Operation	*14th 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 19(3)(b) of the Medicines Act 1968 and now vested in them(**1**) 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 and commencement

1. These regulations may be cited as the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977 and shall come into operation on 14th July 1977.

Interpretation

2.—(1) In these regulations, unless the context otherwise requires, "medicinal product" includes, where a product licence relates to any substance or article which is not a medicinal product, the substance or article to which the licence relates or is intended to relate, and other expressions have the same meanings as in the Medicines Act 1968.

(2) Except in so far as the context otherwise requires, any reference in these regulations to any enactment shall be construed as a reference to that enactment as amended, extended or re-enacted by any other enactment or by any order or regulations.

(**1**) 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).

(3) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889 shall apply for the purposes of the interpretation of these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Prescribed conditions for manufacturer's undertakings

3. The prescribed conditions for the purposes of undertakings in accordance with section 19(3)(b) of the Medicines Act 1968 given by, or on behalf of, manufacturers of medicinal products which have been or are to be imported shall be those conditions set out in the Schedule to these regulations.

David Ennals
30th May 1977 — Secretary of State for Social Services

John Morris
2nd June 1977 — Secretary of State for Wales

Bruce Millan
14th June 1977 — Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 10th June 1977.

L.S.

John Silkin
10th June 1977 — Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 15th day of June 1977.

L.S.

N. Dugdale
Permanent Secretary

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 16th day of June 1977.

L.S.

J. A. Young
Permanent Secretary

SCHEDULE

Regulation 3

PRESCRIBED CONDITIONS FOR MANUFACTURER'S UNDERTAKINGS

1. The manufacturer shall provide and maintain such staff, premises, and plant as are necessary for the carrying out in accordance with the relevant product licences of such stages of the manufacture and assembly of the medicinal products to which the relevant product licences relate as are undertaken by him.

2. The manufacturer shall provide and maintain such staff, premises, equipment and facilities for the handling, storage and distribution of the medicinal products to which the relevant product licences relate which he handles, stores or distributes as are necessary to avoid deterioration of the medicinal products.

3. The manufacturer shall conduct all manufacture and assembly operations in such a way as to ensure that the medicinal products to which the relevant product licenses relate conform with the standards of strength, quality and purity applicable to them under the relevant product licences.

4. Where animals are used in the production of any medicinal product and the relevant product licences contain provisions relating to them the manufacturer shall arrange for the animals to be housed in premises of such a nature and to be managed in such a way as will facilitate compliance with such provisions.

5. The manufacturer shall make such adequate and suitable arrangements as are necessary for carrying out in accordance with the relevant product licences any tests of the strength, quality or purity of the medicinal products to which the licences relate.

6. The manufacturer shall inform the holder of the relevant product licences of any material alteration in the premises or plant used in connection with the manufacture or assembly of the medicinal products to which the relevant product licences relate or in the operations for which such premises or plant are so used and of any change, since the granting of the relevant product licences in respect of any person—

(a) responsible for supervising the production operations, or

(b) responsible for quality control of the medicinal products to which the relevant product licences relate, or

(c) in charge of the animals from which are derived any substance used in the production of the medicinal products to which the relevant product licences relate, or

(d) responsible for the culture of any living tissues used in the manufacture of the medicinal products to which the relevant product licences relate.

7. The manufacturer shall keep readily available for inspection by a person authorised by the licensing authority durable records of the details of manufacture and assembly of each batch of every medicinal product to which each relevant product licence relates and of the tests carried out thereon in such a form that the records will be easily identifiable from the number of the batch as shown on each container in which the medicinal product is exported from the country where it has been manufactured or assembled; the manufacturer shall permit the person authorised to take copies of or make extracts from such records. Such records shall not be destroyed for a period of five years from the date when the manufacture or assembly of the relevant batch of the medicinal product occurred.

8. The manufacturer shall inform the holder of the relevant product licence of any material change since the date upon which such licence was granted in respect of—

(a) the facilities and equipment available at each of the premises of the manufacturer for carrying out any stage of the manufacturer or assembly of the medicinal products to which the relevant product licences relate, or

(b) the facilities and equipment available in each of the premises of the manufacturer for the storage of the medicinal products to which the relevant product licences relate on, and distribution of the products from or between, such premises, or

(c) any manufacturing operations, not being operations in relation to the medicinal products to which the relevant product licences relate, which are carried on by the manufacturer on or near any of the premises on which such medicinal products are manufactured or assembled and the substances or articles in respect of which such operations are carried on, or

(d) the arrangements for the identification and storage of materials and ingredients before and during manufacture of the medicinal products to which the relevant product licences relate and the arrangements for the storage of the medicinal products after they have been manufactured or assembled, or

(e) the arrangements for ensuring a satisfactory turnover of stocks of medicinal products to which the relevant product licences relate, or

(f) the arrangements for maintaining production records and records of analytical and other testing procedures applied in the course of manufacture or assembly of the medicinal products to which the relevant product licences relate, or

(g) the arrangements for keeping reference samples of materials used in the manufacture of any medicinal products to which the relevant product licences relate and reference samples of such medicinal products.

EXPLANATORY NOTE

These Regulations made under section 19(3)(b) of the Medicines Act 1968 prescribe the conditions which are to be incorporated in undertakings given by or on behalf of overseas manufacturers of imported medicinal products where applicants are required by the licensing authority to produce the undertakings in connection with applications for product licences. The regulations relate to such matters as the provision of staff, premises and plant for the manufacture, handling and storage of medicinal products, record keeping and the supply of information to holders of product licences.