1977 No. 170

MEDICINES

Medicines (Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1977

Made . . . . . 21*st June* 1977

Coming into operation . . . . 15*th July* 1977

The Department(a) of Agriculture for Northern Ireland and the Department(a) of Health and Social Services for Northern Ireland being the departments designated by the European Communities (Designation) Order 1972(b) acting jointly in exercise of the powers conferred on them by section 2(2) of the European Communities Act 1972(c), hereby make the following regulations:

Citation and commencement

1. These regulations may be cited as the Medicines (Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1977 and shall come into operation on 15th July 1977.

Interpretation

2.—(1) In these regulations "the Act" means the Medicines Act 1968(d) and other expressions have the same meaning as in the Act.

(2) The Interpretation Act (Northern Ireland) 1954(e) shall apply for the interpretation of these regulations as it applies for the interpretation of a Measure of the Northern Ireland Assembly.

Amendment of section 7 of the Act

3.—(1) Section 7 of the Act (product licences) shall be amended in accordance with this regulation.

(2) In subsection (5) for the words "is responsible for the composition of the product" there shall be substituted the words—

"(*a*) is responsible for the composition of the product, or

(*b*) in the case of a proprietary medicinal product, is responsible for the placing of that product on the market in the United Kingdom.".

(3) At the end of the section there shall be inserted the following subsection—

"(7) In this section—

(*a*) "proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack,

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(a) Formerly Ministry: *see* 1973 c. 36 Sch. 5 para. 8
(b) S.I. 1972/1811 (1972 III, p. 5216)
(c) 1972 c. 68
(d) 1968 c. 67
(e) 1954 c. 33 (N.I.)

(*b*) for the purposes of paragraph (*a*) "medicinal product" does not include—

(i) vaccines, toxins or serums,

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(iii) homoeopathic medicinal products, or

(iv) veterinary drugs.".

(4) This regulation shall come into force on 1st September 1977.

Amendment of section 8 of the Act

4.—(1) Section 8 of the Act (manufacture and wholesale dealing) shall be amended in accordance with this regulation.

(2) For subsection (3) (wholesale dealer's licence) there shall be substituted the following subsections—

"(3) No person shall, in the course of a business carried on by him—

(*a*) sell, or offer for sale, any medicinal product by way of wholesale dealing, or

(*b*) distribute, otherwise than by way of sale, any proprietary medicinal product which has been imported, but was not consigned from a member State,

except in accordance with a licence granted for the purposes of this subsection (in this Act referred to as a "wholesale dealer's licence").

(4) In this section—

(*a*) "proprietary medicinal product" means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack,

(*b*) for the purposes of paragraph (*a*) "medicinal product" does not include—

(i) vaccines, toxins or serums,

(ii) medicinal products based on human blood or blood constituents or radioactive isotopes,

(iii) homoeopathic medicinal products, or

(iv) veterinary drugs.".

(3) This regulation shall come into force on 1st September 1977.

Amendments of other provisions of Part II of the Act

5.—(1) In Part II of the Act (licences and certificates relating to medicinal products) there shall be made the further amendments provided for by paragraphs (2) to (5) below.

(2) After section 18(2) (applications for licences) there shall be inserted the following subsection—

"(3) Where documents that constitute a dossier for the purposes of Article 9 of Second Council Directive 75/319/EEC of 20 May 1975 are forwarded to the licensing authority under and in accordance with the said Article, such forwarding shall be deemed to be an application for the grant of a product licence under this Part of this Act."

OJ No. L147 9.6.1975, p. 13

(3) In section 20(1)(*b*) (grant or refusal of licences) after the word "Act" there shall be inserted the words "and any Community obligation".

(4) After subsection (1) of section 24 (duration of licences) there shall be inserted as subsection (1A)—

> "(1A) Where any licence has been granted under this Part of this Act and the licensing authority subsequently consider that it would no longer be possible to grant that licence without contravening a Community obligation, the licence shall (notwithstanding subsection (1) above) expire on such date as may be specified in a notice served on the holder of the licence by the licensing authority.",

and in subsection (2) of that section for the words "such licence" there shall be substituted the words "licence granted under this Part of this Act".

(5) At the end of section 28(3) (suspension, revocation and variation of product licences) there shall be inserted after paragraph (i) (as added(f))—

> "(*j*) that, in relation to medicinal products of any description to which the licence relates any of the provisions contained in regulations which—
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> (i) are made under section 85 of this Act (labelling and marking of containers and packages), and
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> (ii) impose requirements which give effect to Community obligations,
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> has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble such medicinal products.".

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 20th June 1977.

(L.S.) *N. Dugdale*
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 21st June 1977.

(L.S.) *J. A. Young*
Permanent Secretary

(f) Paragraph (i) was added by the Medicines (Medicines Act 1968 Amendment) Regulations (Northern Ireland) 1975 S.R. 1975 No. 197 (II, p. 1022)

EXPLANATORY NOTE

(This note is not part of the regulations but is intended to indicate their general purport.)

These regulations amend the Medicines Act 1968 so as to enable the implementation of certain Community obligations under two Council Directives Nos. 65/65/EEC and 75/319/EEC which relate to proprietary medicinal products.

The amendments relate to—

(*a*) requirements to hold licences by persons responsible for placing proprietary medicinal products on the market and by distributors of such products imported from outside the European Economic Community (regulations 3 and 4);

(*b*) the treatment of dossiers forwarded to the licensing authority under Article 9 of Council Directive 75/319/EEC as applications for product licences (regulation 5(2));

(*c*) refusal, suspension and revocation of licences (regulation 5(3) and (5));

(*d*) duration of licences which are not in accordance with Community obligations (regulation 5(4)).