STATUTORY INSTRUMENTS

1978 No. 41

The Medicines (Labelling and Advertising to the Public) Regulations 1978

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Labelling and Advertising to the Public) Regulations 1978 and shall come into operation on 1st February 1978.

(2) In these regulations, unless the context otherwise requires—

"the Act" means the Medicines Act 1968;

"advertisement" has the same meaning as in section 92(1) and (2) of the Act;

"certified midwife" has the same meaning as in section 11(2) of the Act;

"commercially interested party" has the same meaning as in section 92(4) of the Act;

"local authority" means:

(a) in relation to England and Wales, the Greater London Council, a county council, a London borough council, a district council or the Common Council of the City of London;

(b) in relation to Scotland, a regional, islands or district council;

(c) in relation to Northern Ireland, a district council;

"registered nurse" has the same meaning as in section 11(2) of the Act;

"representation" has the same meaning as in section 92(5) of the Act;

"spermicidal contraceptive" means a contraceptive substance or article (not being a veterinary drug) which acts wholly or mainly by chemical spermicidal means, but does not include—

(a) a contraceptive substance or article which is administered orally,

(b) an intra-uterine contraceptive device, or

(c) a spermicidal lubricant which is or is to be applied to a condom, cap, or diaphragm;

"venereal disease" means syphilis, gonorrhoea or soft chancre;

and other expressions have the same meanings as in the Act.

(3) Except in so far as the context otherwise requires, any reference in these regulations to any provision of any enactment shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(4) 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.

Prohibition of advertisements for medicinal products and other substances and articles referring to specified diseases

2.—(1) Subject to the following provisions of these regulations, no advertisement shall be issued which is likely to lead to the use of any medicinal product or other substance or article—

(a) for the purpose of the treatment of human beings for any disease specified in Schedule 1 to these regulations, the diagnosis of any such disease, except under the instruction of a doctor or dentist, or

(b) for the purpose of procuring the miscarriage of women.

(2) The prohibition imposed by paragraph (1) of this regulation does not apply in relation to the issue of an advertisement which relates to a medicinal product or other substance or article which is sold or supplied as a food or dietary supplement for persons suffering from diabetes.

(3) For the purposes of this regulation the following shall be included among the acts taken to constitute the issue of an advertisement, that is to say—

(a) the sale or supply or offer or exposure for sale or supply, of a medicinal product in a labelled container or package;

(b) the supply, with a medicinal product of any description, of a leaflet relating solely to medicinal products of that description.

Prohibition of advertisements for medicinal products on prescription only

3. Subject to the following provisions of these regulations, no advertisement shall be issued likely to lead to the use of any medicinal product which is for use by being administered to human beings and is of a description or falling within a class specified—

(a) in any order made under section 58(1) of the Act (medicinal products on prescription only) which is subject to the restrictions imposed by section 58(2) of the Act, or

(b) in any order made under section 62(1) of the Act which prohibits the retail sale or the supply in circumstances corresponding to retail sale of that medicinal product except where such sale or supply—

(i) takes place on premises which are a registered pharmacy and is by or under the supervision of a pharmacist in accordance with a prescription given by a doctor or a dentist, or

(ii) is by a doctor or dentist to his patient or to a person responsible for the care of his patient.

Prohibition of advertisements relating to medicinal products for the purpose of treatment of specified diseases

4.—(1) Subject to the following provisions of these regulations, no advertisement shall be issued relating to any medicinal product which is for use by being administered to human beings, not being a medicinal product of a description or falling within a class specified in regulation 3 of these regulations, which is likely to lead to the use of such a medicinal product—

(a) for the purpose of the treatment of human beings for, or the prevention in human beings of—

(i) any disease of a description specified in column 1 of Part I of Schedule 2 to these regulations, except a purpose specified in column 2 of that Part of that Schedule, subject to the restrictions (if any) specified in column 3 of that Part of that Schedule, or

(ii) any disease of any system or part of the body specified in column 1 of Part II of that Schedule, except a purpose specified in column 2 of that Part of that Schedule, subject to the restrictions (if any) specified in column 3 of that Part of that Schedule, or

(iii) any adverse condition specified in column 2 of Part III of that Schedule opposite a system or part of the body specified in column 1 of that part of that Schedule, except a purpose specified in column 3 of that Part of that Schedule;

(b) for the purpose of the treatment of human beings for any physical injury specified in column 1 of Part IV of that Schedule except where the medicinal product is in a form and used for a purpose specified in column 2 of that Part of that Schedule;

(c) for any purpose specified in Part V of that Schedule.

(2) The restrictions imposed by paragraph (1) of this regulation shall not apply in relation to the issue of an advertisement in a newspaper or journal or to the transmission of any advertisement by the Independent Broadcasting Authority under the Independent Broadcasting Act 1973 where the holder of a product licence has, as soon as is reasonably possible, complied with or taken all necessary steps to ensure compliance with any direction in writing given by the licensing authority to the effect that an advertisement relating to medicinal products of the particular description to which such product licence relates ought not to be issued for any of the purposes to which paragraph (1) relates.

(3) For the purposes of this regulation the following shall be included among the acts taken to constitute the issue of an advertisement, that is to say—

(a) the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled container or package;

(b) the supply, with a medicinal product of any description, of a leaflet relating solely to medicinal products of that description.

Prohibition of representations

5.—(1) Subject to the following provisions of these regulations no representation shall be made by a commercially interested party which is likely to lead to the use of a medicinal product or other substance or article to which regulation 2 of these regulations applies for a purpose specified in regulation 2, or a medicinal product to which regulation 4 of these regulations applies for a purpose specified in regulation 4, if the representation—

(a) is made in connection with the sale or supply, or offer for sale or supply, of a medicinal product or other substance or article to which regulation 2 applies, or a medicinal product to which regulation 4 applies, or

(b) is made to any person for the purpose of inducing him to purchase a medicinal product or other substance or article to which regulation 2 applies or a medicinal product to which regulation 4 applies from a person selling by retail medicinal products or other substances or articles to which regulation 2 or regulation 4 applies, or

(c) in the case of medicinal products to which regulation 2 or regulation 4 applies, is made to the patient of a doctor or dentist for the purpose of inducing him to request the doctor or dentist to prescribe medicinal products of that description.

(2) The prohibition imposed by sub-paragraph (a) or sub-paragraph (b) of paragraph (1) above does not apply to any representation—

(a) which is made by a pharmacist in relation to the sale or supply of a medicinal product where—

(i) the pharmacist dispenses the medicinal product in accordance with a prescription given by a doctor or dentist; or

(ii) the pharmacist is requested by or on behalf of a person to sell or supply the medicinal product in accordance with the pharmacist's own judgment as to the treatment required; or

(b) which is made by a chiropodist registered by the Chiropodists Board under the Professions Supplementary to Medicine Act 1960 to a person who is a patient of his in relation to a medicinal product for the purpose of treatment by being administered to the surface of the foot; or

(c) which is made to a patient in relation to a medicinal product by a registered nurse or a certified midwife.

Prohibition of advertisements for, and containers and packages of, spermicidal contraceptives and leaflets

6.—(1) Subject to the following provisions of these regulations, no advertisement shall be issued relating to a spermicidal contraceptive which contains any statement or suggestion that the spermicidal contraceptive to which the advertisement relates is a highly reliable means of contraception when used or applied otherwise than in conjunction with another method of contraception.

(2) Subject to the following provisions of these regulations, every advertisement relating to a spermicidal contraceptive shall contain, and every container and package of a spermicidal contraceptive shall be labelled to show, and any leaflet which is supplied, or is intended to be supplied, with a spermicidal contraceptive shall contain, the warning specified in paragraph 1 of Schedule 3 to these regulations. Such warning shall be clearly legible and shall appear conspicuously and in a prominent position in the advertisement, labelled container or package or leaflet.

(3) An advertisement, labelled container or package or leaflet to which paragraph (2) above applies may include a reference to a contraceptive substance, article, instrument, apparatus or appliance of any kind other than a spermicidal contraceptive, but shall not contain any recommendation for the use of a diaphragm or cap as a means of contraception where such diaphragm or cap is made of any substance which would be likely to be deleteriously affected if used in conjunction with the spermicidal contraceptive to which that advertisement, labelled container, labelled package or leaflet relates.

(4) Any container or package of, and any leaflet supplied, or intended to be supplied with, a spermicidal contraceptive shall also show or contain the warning specified in paragraph 2 of Schedule 3 to these regulations. Such warning shall appear in bold face, not less than the size of type used in the greater part of the printed text of the label on the container or package or the printed text of the leaflet.

Prohibition of advertisements containing certain words or phrases

7. No advertisement shall be issued relating to any medicinal product which is for use by being administered to human beings which contains any reference to the Commission, an appropriate committee or the licensing authority unless the licensing authority specifically require such reference.

General exceptions

8.—(1) The prohibitions, restrictions and requirements imposed by any provision of these regulations do not apply to any advertisement relating to a medicinal product where the holder of the product licence which relates to the medicinal product has sent or delivered a copy of the advertisement to the licensing authority and the authority have not within the period of 42 days

commencing with the date of receipt of the advertisement by the authority notified the holder of the product licence that the advertisement ought not to be issued.

(2) The prohibitions, restrictions and requirements imposed by any provision of these regulations do not apply to—

(a) any letter written to a person in reply to a specific inquiry made by or on behalf of that person in relation to a medicinal product of a particular description;

(b) any letter or other communication specifically addressed to a member of either House of Parliament or of the Northern Ireland Assembly;

(c) any representation made by a commercially interested person or any advertisement sent or supplied exclusively, or any advertisement included in a journal or other publication supplied or directed mainly or exclusively to, or any cinematographic film or sound recording played to—

(i) persons who in the usual course of their business or profession may lawfully prescribe, sell, supply, manufacture, assemble or administer the medicinal product or other substance or article to which that advertisement relates, or

(ii) persons who in the course of such business or profession provide training or instruction to persons undergoing training with a view to obtaining a qualification in such business or profession, or

(iii) persons who in the course of such business or profession as aforesaid are engaged in the preparation or publication of printed matter, cinematograph film, sound recording or matter intended for sound broadcasting or television in relation to the medicinal product or other substance or article to which that advertisement relates or in relation to the treatment or prevention of any disease to which any provision of these regulations applies, or

(iv) a Minister of the Crown, a Government Department, a local authority, or a charitable, educational or scientific body, in relation to any of the functions of any of such bodies relating to medicinal products or other substances or articles, or the treatment, prevention or diagnosis of any of the diseases specified in Schedule 1 or Schedule 2 to these regulations;

(d) any reference to a medicinal product of a description or falling within a class specified in regulation 3 of these regulations where such reference is contained in a statutory report circulated to members of a company formed and registered under the Companies Act 1948 or the Companies Act (Northern Ireland) 1960 or formed and registered under or incorporated by or under any other Act of Parliament or any other report, circular, notice or announcement prepared solely for the purpose of providing information about a company's affairs;

(e) any printed matter, photograph, cinematograph film, sound recording, sound broadcasting, television broadcast or sound or television programme transmitted to subscribers to a diffusion service (in this paragraph referred to as "the material"), if—

(i) the material has not been prepared or issued by or on behalf of or at the request of a commercially interested party, and

(ii) the material has not been prepared or issued for the purposes of inducing any person to purchase, or to request a doctor or dentist to prescribe, a medicinal product or other substance or article;

(f) any notice displayed for the purpose of encouraging employees to participate in a health care programme.

(3) The prohibitions, restrictions and requirements imposed by any provision of these regulations do not apply for the period up to and including the 1st January 1981 to the use of the name of a

medicinal product where such name is that shown in the product licence issued in respect of such product.

Exceptions for labels and leaflets

9.—(1) The prohibitions, restrictions and requirements imposed by any provision of these regulations do not apply to any labelled container or package of a medicinal product or any other substance or article or any leaflet supplied with such product where that product is prepared or dispensed with a view to administration to a person in accordance with the prescription of a doctor or dentist.

(2) The prohibition imposed by regulation 4(1) of these regulations does not apply to a labelled container or package of a medicinal product or to a leaflet supplied, or intended to be supplied with a medicinal product which—

(a) is a herbal remedy, not being a herbal remedy of a description, or falling within a class, specified in any order made under section 56(3) of the Act (exceptions in respect of herbal remedies), or

(b) consists of one or more of the dilutions of unit preparations of any substance having been diluted to at least one part of a million (6x),

(c) is a medicinal product prepared and dispensed by a pharmacist in accordance with his own judgment for the treatment required by the person to whom that medicinal product is to be administered if—

(i) he prepares or dispenses that medicinal product at the request of that person, and

(ii) that person is present in the pharmacy in which that medicinal product is so prepared at the time of making such request,

and the conditions specified in paragraph (3) below are satisfied.

(3) The conditions referred to in paragraph (2) above are—

(a) that the labelled container and package of, and any leaflet supplied with, a medicinal product to which that paragraph applies shall not include any word or phrase specified in Schedule 4 to these regulations except in so far as the inclusion of any such word or phrase is necessary to explain the contra-indications or precautions or the action to be taken in the event of over-dosage of the medicinal product;

(b) that every container and package of such medicinal product shall be labelled to show, and every leaflet supplied with such medicinal product shall include, such of the phrases and particulars specified in paragraph 1 of Schedule 5 to these regulations as may be appropriate in any particular case and the warning specified in paragraph 2 of that Schedule, which shall be completed in the manner specified in paragraph 3 of that Schedule;

(c) that the labelled container and package of, and any leaflet supplied, or intended to be supplied with, the medicinal product shall not contain any reference to any disease or purpose in respect of which the issue of advertisements is prohibited by the provisions of these regulations, other than the name of any disease which is required to be shown on containers and packages and included in leaflets in accordance with the requirements imposed by sub-paragraph (b) above and Schedule 5 to these regulations;

(d) that the warning required to be shown on containers and packages and leaflets in accordance with sub-paragraph (b) above shall be within a rectangle within which there shall be no other matter of any kind.

(4) In this regulation "unit preparation" means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being further diluted tenfold, or serially in multiple powers of ten, in an inert diluent, and then used either in this diluted form

or, where applicable, by impregnating tablets, granules, powders or other inert substances for the purpose of being administered to human beings.

Exceptions for advertisements for certain classes of medicinal products

10. The prohibitions, restrictions and requirements imposed by regulations 2, 4 and 5 of these regulations do not apply to any advertisement or representation relating to a medicinal product, or any labelled container or package of a medicinal product, or any leaflet supplied, or intended to be supplied, with a medicinal product if such advertisement, representation, labelled container or package or leaflet corresponds with the terms of the provisions of the product licence which relates to the medicinal product and the product licence—

(a) is or was granted on or after 17th March 1976, not being a licence the number of which, as allocated by the licensing authority, includes the figures "59" as the fifth and sixth digits respectively of that number (being a licence granted under circumstances corresponding to those applying upon the grant of a licence of right), or

(b) is a product licence which has been varied as to indications on or after 17th March 1976.

Temporary and transitional provisions

11.—(1) The provisions of these regulations other than regulation 2 shall not apply to the issue of any advertisement before 1st August 1978.

(2) The provisions of these regulations shall not have effect in relation to labelled containers and packages of, or leaflets supplied, or intended to be supplied, with a medicinal product to which a product licence has been granted before the coming into operation of these regulations or, where such licence has been granted thereafter—

(a) in the case of a spermicidal contraceptive, until 30th September 1978;

(b) in the case of any other product, until 30th September 1979.

(3) Where a person, in the course of a business carried on by him, sells or supplies or has in his possession for sale or supply by way of wholesale dealing such a medicinal product as is mentioned in paragraph (2) above in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation, but not with the requirements of these regulations, and the product is assembled in the same labelled container in which the product is to be sold by retail or supplied in circumstances corresponding to retail sale, for the purposes of the application of these regulations in relation to such sale or supply or possession during the period until and including 31st December 1979 the requirements of these regulations shall be regarded as having been complied with.

(4) Where a person, in the course of a business carried on by him, sells by retail, supplies in circumstances corresponding to retail sale, or has in his possession for the purpose of such sale or supply such a medicinal product as is mentioned in paragraph (2) above in such circumstances as to comply with all requirements as to labelling which applied to that product immediately before these regulations came into operation, but not with the requirements of these regulations, for the purposes of the application of these regulations in relation to such sale or supply or possession during the period until and including 31st December 1980 the requirements of these regulations shall be regarded as having been complied with.

Offences

12. Any person who contravenes these regulations or who contravenes the provisions of section 85(3) or section 86(2) of the Act shall be guilty of an offence and—

(a) shall be liable on summary conviction to a fine not exceeding £400, and

(b) shall be liable on conviction on indictment to a fine or to imprisonment for a term not exceeding 2 years or to both.

Amendment of regulation 19 of the Medicines (Labelling) Regulations 1976

13.—(1) Regulation 19 of the Medicines (Labelling) Regulations 1976, as amended(**1**), shall be further amended in accordance with the following paragraphs of this regulation.

(2) In paragraph (1)(c), for the words "30th June 1978" there shall be substituted the words "31st December 1979", and for the words "30th June 1979" there shall be substituted the words "31st December 1979".

(3) In paragraph (1)(d), for the words "30th June 1979" there shall be substituted the words "31st December 1980", and for the words "30th June 1980" there shall be substituted the words "31st December 1980".

David Ennals
3rd January 1978 — Secretary of State for Social Services

John Morris
10th January 1978 — Secretary of State for Wales

Bruce Millan
10th January 1978 — Secretary of State for Scotland

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 11th January 1978.

L.S.

John Silkin
Minister of Agriculture, Fisheries and Food

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 13th day of January 1978.

L.S.

N. Dugdale
Permanent Secretary

(**1**) S.I. 1977/996.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 16th day of January 1978.

L.S.

J. A. Young
Permanent Secretary