STATUTORY INSTRUMENTS

1997 No. 2045

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment (No. 2) Regulations 1997

Made - - - -	*21st August 1997*
Laid before Parliament	*26th August 1997*
Coming into force	
except for regulation 2(b)(ii) and (iii)	*16th September 1997*
regulation 2(b)(ii) and (iii)	*16th September 1998*

The Secretary of State concerned with health in England, the Secretaries of State concerned with health and with 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 the powers conferred upon them by sections 53(4) and 129(1) and (5) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by those 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 pursuant to section 129(6) of that Act, and after consulting and taking into account the advice of the Medicines Commission pursuant to section 129(7) of that Act, hereby make the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment (No. 2) Regulations 1997 and shall come into force—

(a) except for regulation 2(b)(ii) and (iii), on 16th September 1997; and

(**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. The word "prescribed" in section 53(4) is defined in section 132(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).

(b) for the purposes of regulation 2(b)(ii) and (iii) on 16th September 1998.

Amendment of regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980

2. In regulation 8 of the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**3**) (pack size on retail sale or supply of certain products on a general sale list)—

(a) in paragraph (1), for "paragraphs (2) to (2C) and (3)" there is substituted "paragraphs (2) to (2E) and (3)";

(b) in paragraph (2)—

(i) for "aloxiprin, aspirin, paracetamol or salicylamide" there is substituted "aloxiprin, aspirin or paracetamol",

(ii) for subparagraph (b) there is substituted—

"(b) in the case of tablets that are not effervescent—

(i) where they do not contain aspirin or paracetamol, not more than 25 tablets,

(ii) where they contain aspirin, paracetamol or both of those substances, not more than 16 tablets;",

(iii) for subparagraph (d) there is substituted—

"(d) in the case of capsules—

(i) where they do not contain aspirin or paracetamol, not more than 25 capsules,

(ii) where they contain aspirin, paracetamol or both of those substances, not more than 16 capsules; and",

(iv) after subparagraph (d) add the following subparagraph—

"(e) in the case of liquid preparations of paracetamol—

(i) which are intended for persons aged 12 years and over, not more than 160 millilitres of the product, or

(ii) which are intended for persons aged less than 12 years, individual unit doses of not more than 5 millilitres each, to a maximum of 20 unit doses."; and

(c) after paragraph (2C) there are inserted the following paragraphs—

"(2D) Where a medicinal product for human use containing sodium picosulphate is sold by retail in the course of a business elsewhere than at a registered pharmacy or is so offered or exposed for sale by retail or so supplied in circumstances corresponding to retail sale, the product shall be presented for sale in a separate and individual container or package containing not more than 60 millilitres of the product.

(2E) Where a medicinal product for human use containing loperamide hydrochloride is sold by retail in the course of a business elsewhere than at a registered pharmacy or is so offered or exposed for sale by retail or so supplied in circumstances corresponding to retail sale, the product shall be presented for sale in a separate and individual container or package containing not more than 6 tablets or capsules.".

(**3**) S.I. 1980/1923; relevant amending instruments are S.I. 1982/28, 1990/1124, 1994/2411 and 1995/3215.

Frank Dobson,
12th August 1997 Secretary of State for Health

Win Griffiths,
Parliamentary Under-Secretary of State,Welsh
20th August 1997 Office

Sam Galbraith,
Parliamentary Under-Secretary of State,The
21st August 1997 Scottish Office

Jeff Rooker,
Minister of State, Ministry of Agriculture,
19th August 1997 Fisheries and Food

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

L.S.

D. C. Gowdy
20th August 1997. Permanent Secretary

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

L.S.

P. J. Small
19th August 1997. Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980.

The Regulations:

(a) remove the provision relating to pack sizes for salicylamide with effect from 16th September 1997;

(b) reduce the maximum pack size of non-effervescent tablets and capsules containing aspirin or paracetamol or both on the general sale list which may be sold or supplied from outlets other than registered pharmacies from 25 tablets or capsules to 16 with effect from 16th September 1998;

(c) with effect from 16th September 1997 provide that liquid preparations containing paracetamol which are on the general sale list may be sold or supplied from outlets other than registered pharmacies on the following conditions. Where they are intended for use by persons aged 12 years and over the packaging or container of the product shall contain not more than 160 millilitres of the product and where they are intended for use by persons aged under 12 years the packaging or container of the product shall contain individual unit doses of the product to a maximum of 20 doses, of not more than 5 millilitres each; and

(d) with effect from 16th September 1997 provide that medicinal products which contain sodium picosulphate and which are on the general sale list may be sold or supplied from outlets other than registered pharmacies in containers or packaging containing not more than 60 millilitres of the product and that products which contain loperamide hydrochloride may be sold or supplied in the same circumstances in containers or packaging containing not more than 6 tablets or capsules.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in the libraries of both Houses of Parliament. Further copies may be obtained from the Department of Health, Medicines Control Agency, Information Centre, Room 1207 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.