STATUTORY INSTRUMENTS

2001 No. 3849

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2001

Made - - - -	*29th November 2001*
Laid before Parliament	*3rd December 2001*
Coming into force - -	*24th December 2001*

As respects England, Scotland and Wales, the Secretary of State concerned with health in England and the Minister of Agriculture, Fisheries and Food, and, as respects Northern Ireland, the Minister of Health, Social Services and Public Safety and the Minister of Agriculture and Rural Development, acting jointly, in exercise of the powers conferred on them by sections 53(4) and 129(1) and (5) of the Medicines Act 1968(**1**)or, as the case may be, the powers 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 taking into account the advice of the Committee on Safety of Medicines and 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 Regulations 2001 and shall come into force on 24th December 2001.

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 medicinal products on a general sale list)—

(**1**) 1968 c. 67; the expression "the Ministers" is defined in section 1(1) of that Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388, and by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142. The word "prescribed" in section 53(4) of that Act is defined in section 132(1) of that Act.

(**2**) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; in the case of the Minister of Agriculture, Fisheries and Food, by virtue of articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142; in the case of the Northern Ireland Ministers by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**3**) S.I. 1980/1923; relevant amending instruments are S.I. 1982/28, 1990/1124, 1994/2411, 1995/3215, 1997/2045, 1999/644 and 2510, and 2000/1070, 1918 and 2494.

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

(b) in paragraph (2), for sub-paragraph (b) there is substituted—

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

(i) where they are enteric-coated, contain aspirin only, and the amount of aspirin in each tablet does not exceed 75 milligrams, not more than 28 tablets,

(ii) where they contain aloxiprin, or aspirin or paracetamol or a combination of any or all of those substances, and do not satisfy the conditions specified in head (i) of this sub-paragraph, not more than 16 tablets;";

(c) in paragraph (2B) after sub-paragraph (d) add the following sub-paragraph—

"(e) in the case of liquid preparations of ibuprofen, individual unit doses of not more than 5 millilitres each to a maximum of 20 unit doses."; and

(d) after paragraph (2I) there are inserted the following paragraphs—

"(2J) Where a medicinal product for human use containing cetirizine 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 7 tablets.

(2K) Where a medicinal product for human use containing loratadine 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 7 tablets.

(2L) Where a medicinal product for human use containing ibuprofen lysine 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 16 tablets.".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under-Secretary of State,
28th November 2001 Department of Health

Whitty
Parliamentary Under-Secretary of State,
Department for Environment, Food and Rural
29th November 2001 Affairs

Bairbre de Brún
Minister of Health, Social Services and Public Safety

28th November 2001

Bríd Rodgers
Minister of Agriculture and Rural Development

29th November 2001

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 by amending regulation 8 of those Regulations (pack size on retail sale or supply of certain medicinal products on a general sale list) to—

(a) increase the maximum pack size of non-effervescent enteric-coated tablets containing low dose aspirin, up to 75 mg, on the general sale list which may be sold or supplied from outlets other than registered pharmacies from 16 tablets to 28;

(b) provide that liquid preparations containing ibuprofen which are on the general sale list may be sold or supplied from outlets other than registered pharmacies where the packaging or container of the product contains individual unit doses of the product to a maximum of 20 doses, of not more than 5 millilitres each;

(c) provide that medicinal products which contain cetirizine hydrochloride 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 7 tablets, that products which contain loratadine may be sold or supplied in the same circumstances in containers or packaging containing not more than 7 tablets, and that products which contain ibuprofen lysine may be sold or supplied in the same circumstances in containers or packaging containing not more than 16 tablets.

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 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.

Status:
Point in time view as at 24/12/2001.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2001.