STATUTORY INSTRUMENTS

1999 No. 2510

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment (No. 2) Regulations 1999

Made - - - - -	*8th September 1999*
Laid before Parliament	*9th September 1999*
Coming into force - -	*30th September 1999*

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 on them by sections 53(4) and 129(1) and (5) of the Medicines Act 1968() or, as the case may be, those conferred by those provisions and now vested in them(), 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 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 1999 and shall come into force on 30th September 1999.

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() (pack size on retail sale or supply of certain medicinal products on a general sale list)—

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

(b) after paragraph (2E) there is inserted—

(**a**) 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).

(**b**) In the case of the Secretaries of State concerned with health in England and Wales, by virtue of article 2(2) of, and Schedule 1 to, 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, 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).

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

"(2F) Where a medicinal product for human use containing ranitidine 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 12 tablets.".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
6th September 1999 Department of Health

David Hanson
Parliamentary Under Secretary of State,
8th September 1999 The Welsh Office

John Reid
Secretary of State,
8th September 1999 The Scotland Office

Hayman
Parliamentary Under Secretary of State, Ministry of
8th September 1999 Agriculture, Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 8th September 1999

L.S.

D. C. Gowdy
Permanent Secretary

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland on 7th September 1999

L.S.

P. Small
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 by amending regulation 8 of those Regulations (pack size on retail sale or supply of certain medicinal products on a general sale list) to provide that medicinal products containing ranitidine hydrochloride and which are on the general sale list may be sold or supplied from outlets other than registered pharmacies only in separate and individual containers or packages containing not more than 12 tablets.

An assessment of the cost to business of complying with these Regulations has been made, copies of which have been placed in 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.

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