
STATUTORY INSTRUMENTS

1995 No. 3215

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1995

Made - - - - *11th December 1995*
Laid before Parliament *11th December 1995*
Coming into force - - *1st January 1996*

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 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, those conferred by the said 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, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1995 and shall come into force on 1st January 1996.

(2) In these Regulations “the principal Regulations” means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980⁽³⁾.

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

Amendment of regulation 8 of the principal Regulations

2. In regulation 8 of the principal Regulations (pack size on retail sale or supply of certain medicinal products on a general sale list)—

(a) in paragraph (1), for “paragraphs (2), (2A) and (3)” there is substituted “paragraphs (2) to (2C) and (3)”;

(b) after paragraph (2A) there are inserted the following paragraphs—

“(2B) Where a medicinal product for human use containing ibuprofen 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—

(a) in the case of tablets, not more than 12 tablets;

(b) in the case of capsules, not more than 12 capsules;

(c) in the case of powder or granules, not more than 12 sachets;

(d) in the case of a product for topical use, not more than 2.5 grams of ibuprofen.

(2C) Where a medicinal product for topical human use containing clotrimazole 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 500 milligrams of clotrimazole.”.

Signed by authority of the Secretary of State for Health

4th December 1995

Gerald Malone
Minister of State
Department of Health

11th December 1995

William Hague
Secretary of State for Wales

6th December 1995

James Douglas Hamilton
Minister of State The Scottish Office

6th December 1995

Angela Browning
Parliamentary Secretary, Ministry of Agriculture,
Fisheries and Food

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on

L.S.

7th December 1995.

F. A. Elliott
Permanent Secretary

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

L.S.

5th December 1995.

J. Murray
Permanent Secretary

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 with respect to regulation 8 (which limits the pack size on retail sale or supply of certain medicinal products on a general sale list) so as to provide that tablets, capsules, powder and granules and topical presentations of ibuprofen and topical presentations of clotrimazole which are medicinal products for human use on a general sale list may be sold or supplied by retail elsewhere than at a registered pharmacy only in separate and individual containers or packages not containing more than specified amounts of the product. In the case of ibuprofen tablets or capsules, the specified amount is 12; in the case of ibuprofen powder or granules, it is 12 sachets; and in the case of topical presentations of ibuprofen, it is 2.5 grams of ibuprofen. In the case of topical presentations of clotrimazole, the specified amount is 500 milligrams of clotrimazole.