STATUTORY RULES OF NORTHERN IRELAND

2011 No. 292

MEDICINES

The Medicines (Miscellaneous Amendments) Order 2011

Made - - - -	*24th May 2011*
Laid before Parliament	*27th May 2011*
Coming into force - -	*1st July 2011*

The Secretary of State and the Minister for Health, Social Services and Public Safety, acting jointly, make the following Order in the exercise of powers conferred upon them by sections 57(1) and (2), 58(4) and (5) and 129(4) of the Medicines Act 1968(**a**), or, in the case of the Minister, the powers conferred by those provisions and now vested in him(**b**).

In accordance with section 129(6) of that Act, they have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by this Order. In accordance with sections 58(6) and 129(6) and (7) of that Act, they have consulted and taken into account the advice of the Commission on Human Medicines(**c**).

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Medicines (Miscellaneous Amendments) Order 2011 and shall come into force on 1st July 2011.

(2) In this Order—

"the Act" means the Medicines Act 1968;

"the Pharmacy and General Sale Order" means the Medicines (Pharmacy and General Sale-Exemption) Order 1980(**d**);

"the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(**e**).

Amendment of Schedule 1 to the Pharmacy and General Sale Order

2.—(1) Schedule 1 to the Pharmacy and General Sale Order (exemptions for certain persons from sections 52 and 53) is amended as follows.

(**a**) 1968 c.67. The expression "the Ministers", which is relevant to the powers being exercised in the making of this Order, is defined in section 1 of the Act as amended by S.I. 1999/3142 and S.I. 2006/2407. Section 57(1) was amended by S.I. 2006/2407. Section 58(4) was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c.28), section 1; the Health and Social Care Act 2001 (c.15), section 63(1) and (4) and by S.I. 2002/253 and 2006/2407. Section 58(5) was amended by the Medicinal Products: Prescription by Nurses etc. Act 1992, section 1 and by the Health and Social Care Act 2001, section 63(1) and (6).

(**b**) By virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47); the Department for which the Minister was responsible was renamed by virtue of article 3(6) of S.I. 1999/283 (N.I.1).

(**c**) In section 58(6) of the Act, the expression "the appropriate committee" is defined in section 4(6) of the Act, as amended by S.I. 2005/1094; the word "Ministers" was substituted by S.I. 2006/2407.

(**d**) S.I. 1980/1924.

(**e**) S.I. 1997/1830.

(2) In Part 1, item 1A(**a**)—

(a) in column 1, after "chiropodists" insert "and podiatrists";

(b) for sub-paragraph (a) in column 2, substitute the following—

"(a) The following prescription only medicines—

(i) Amorolfine hydrochloride cream where the maximum strength of the Amorolfine in the cream does not exceed 0.25 per cent by weight in weight;

(ii) Amorolfine hydrochloride lacquer where the maximum strength of Amorolfine in the lacquer does not exceed 5 per cent by weight in volume;

(iii) Amoxicillin;

(iv) Co-Codamol;

(v) Co-dydramol 10/500 tablets;

(vi) Codeine Phosphate;

(vii) Erythromycin;

(viii) Flucloxacillin;

(ix) Silver Sulfadiazine;

(x) Tioconazole 28%;

(xi) Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight; and";

(c) for the entry in column 3, substitute—

"**1A.** The sale or supply shall be only in the course of their professional practice, and the medicinal product must have been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied.".

Amendment of Schedule 5 to the POM Order

3.—(1) Schedule 5 to the POM Order (exemption for certain persons from section 58(2) of the Act) is amended as follows.

(2) In Part 1 (exemption from restrictions on sale or supply)—

(a) in item 4(**b**)—

(i) in column 2, omit "Ergometrine maleate", "Lidocaine" and "Lidocaine Hydrochloride";

(ii) in column 3, omit the words after "professional practice";

(b) in item 5(**c**)—

(i) for the entry in column 2 substitute—

"**5.** Items which are—

(a) prescription only medicines which are not for parenteral administration and which—

(i) are eye drops and are prescription only medicines by reason only that they contain not more than 0.5 per cent of Chloramphenicol, or

(ii) are eye ointments and are prescription only medicines by reason only that they contain not more than 1.0 per cent Chloramphenicol, or

(iii) are prescription only medicines by reason only that they contain any of the following substances—

(**a**) Item 1A was inserted by S.I. 1998/107 and amended by S.I. 2006/2807.
(**b**) Relevant amending instruments are S.I. 1998/2081, 2010/1136.
(**c**) Item 5 was amended by S.I. 2005/765, 848, 1507.