STATUTORY INSTRUMENTS

2005 No. 764

MEDICINES

The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2005

Made - - - -	*16th March 2005*
Laid before Parliament	*17th March 2005*
Coming into force - -	*7th April 2005*

As respects England, Scotland and Wales, the Secretary of State, and, as respects Northern Ireland, the Department of Health, Social Services and Public Safety and the Department of Agriculture and Rural Development, acting jointly, in exercise of the powers conferred on them by sections 53(4), 61, 66(1) 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, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 2005 and shall come into force on 7th April 2005.

(2) In these Regulations, "the principal Regulations" means the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980(**3**).

(**1**) 1968 c. 67; the expression "the appropriate Ministers" and the expression "the Ministers", which are relevant to the powers being exercised in the making of these Regulations, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388, by articles 2(1) and 5 of, and the Schedule to, S.I. 1999/3142, and by article 5(1) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794.

(**2**) In the case of the Secretary of State, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, articles 2(1) of, and paragraph 1 of the Schedule to, S.I. 1999/3142, and articles 3(1)(c) and (7) of, and paragraph 15 of Schedule 1 to, S.I. 2002/794; in the case of the Northern Ireland Departments, the powers vested in the Ministers in charge of those Departments by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47) may now be exercised by the Departments by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c. 1); the Departments were renamed by virtue of article 3(4) and (6) of S.I. 1999/283 (N.I.1).

(**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, 2000/1070, 1918 and 2494, 2001/3849 and 2003/698.

Amendment of regulation 1 of the principal Regulations

2. In regulation 1 of the principal Regulations (citation, commencement and interpretation), in paragraph (2), in sub-paragraph (a)—

(a) in the definition of "relevant register"(**4**)—

(i) in paragraph (a), omit "and";

(ii) in paragraph (b), after "the Pharmacy (Northern Ireland) Order 1976(**5**);" insert "and"; and

(iii) after paragraph (b), insert—

"(c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(**6**) relating to—

(i) chiropodists and podiatrists;

(ii) physiotherapists; or

(iii) radiographers: diagnostic or therapeutic,

that register";

(b) in the definition of "supplementary prescriber"(**7**)—

(i) in paragraph (b), omit "or";

(ii) in paragraph (c), after "a registered midwife;", insert "or";

(iii) after paragraph (c), insert—

"(d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to—

(i) chiropodists and podiatrist;

(ii) physiotherapists; or

(iii) radiographers: diagnostic or therapeutic, or," and

(iv) after "an annotation" insert "or entry".

Amendment of regulation 5 of the principal Regulations

3. In regulation 5 of the principal Regulations (restrictions on persons to be supplied with certain medicinal products), in paragraph (2), in sub-paragraph (c), omit "eye ointment containing Oxyphenbutazone and"; "Framycetin sulphate", and "Thymoxamine hydrochloride".

Amendment of regulation 8 of the principal Regulations

4. In regulation 8 of the principal Regulations (pack size on retail sale or supply of certain medicinal products on a general sale list), in paragraph (2A)(**8**), for "20 tablets" substitute "50 tablets".

(**4**) The definition of "relevant register" was inserted by S.I. 2003/698 and amended by S.I. 2004/1771.
(**5**) S.I. 1976/1213 (N.I. 22).
(**6**) S.I. 2002/254.
(**7**) The definition of "supplementary prescriber" was inserted by S.I. 2003/698.
(**8**) Paragraph 2A was inserted by S.I. 1990/1124 and amended by S.I. 2000/2494.

Signed by authority of the Secretary of State for Health

Warner
Parliamentary Under Secretary of State,
16th March 2005 Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

Deirdre Kenny
A Senior Officer of the
Department of Health, Social Services and
15th March 2005 Public Safety

Sealed with the Official Seal of the Department of Agriculture and Rural Development

Gerald Lavery
A Senior Officer of the
Department of Agriculture and Rural
15th March 2005 Development

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 ("the principal Regulations") which impose restrictions on the sale and supply of medicinal products.

Regulation 2 amends the definition of "supplementary prescriber" in the principal Regulations to include chiropodists and podiatrists, physiotherapists and diagnostic or therapeutic radiographers. Schedule 2 to the principal Regulations makes provision for the particulars to appear in pharmacy records of supplies of prescription only medicines in pursuance of prescriptions given by such prescribers.

Regulation 3 amends regulation 5 of the principal Regulations to make changes to the prescription only medicines which may be sold or supplied by way of wholesale dealing to a registered ophthalmic optician.

Regulation 4 amends regulation 8 of the principal regulations. This regulation concerns the maximum number of tablets which may be contained in a pack of tablets for human use which are for sale elsewhere than at a registered pharmacy. The amendment changes the maximum number of tablets which may be contained in a pack containing Bisacodyl, from 20 to 50.

A Regulatory Impact Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament, and copies may be obtained from the Department of Health, Medicines and Healthcare products Regulatory Agency, Information Centre, Room 10-202, Market Towers, 1 Nine Elms Lane, London SW8 5NQ.