STATUTORY INSTRUMENTS

1998 No. 2368

MEDICINES

The Medicines (Pharmacy and General Sale —Exemption) Amendment (No. 2) Order 1998

Made - - - -	*22nd September 1998*
Laid before Parliament	*25th September 1998*
Coming into force - -	*19th October 1998*

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred upon them by sections 57(1) and (2) and 129(4) 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 this Order 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 Order:

Citation and commencement

1. This Order may be cited as the Medicines (Pharmacy and General Sale—Exemption) Amendment (No. 2) Order 1998 and shall come into force on 19th October 1998.

Amendment of the Medicines (Pharmacy and General Sale—Exemption) Order 1980

2. The Medicines (Pharmacy and General Sale—Exemption) Order 1980(**3**) shall be amended as follows–

(a) in article 1(2)(a), the following definition is inserted after the definition of "prescription only medicine"–

> ""registered homoeopathic medicinal product for human use" means a homoeopathic medicinal product in respect of which a certificate of registration

(**1**) 1968 c. 67. The expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1(1)(a) and (2) of that Act as amended by S.I.1969/388, Schedule 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 Department of Health and Social Services for Northern Ireland 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. 1980/1924; relevant amending instruments are S.I. 1994/2409, 1994/3144 and 1998/107.

granted pursuant to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**4**) is in force,";

(b) in article 2, paragraphs (3) and (4) are revoked,

(c) after article 6, the following article is inserted–

"Exemption for certain registered homoeopathic medicinal products for human use

6A.—(1) The restrictions imposed by sections 52 and 53 shall not apply to the sale or supply, offer or exposure for sale or supply of a registered homoeopathic medicinal product for human use other than an excluded product if and so long as the person selling or supplying the registered homoeopathic medicinal product for human use has been requested by or on behalf of a particular person and in that person's presence to use his own judgment as to the treatment required.

(2) The restrictions imposed by section 52 shall not apply to the sale or supply, offer or exposure for sale or supply of a registered homoeopathic medicinal product for human use other than an excluded product if and so long as the conditions specified in section 53 are fulfilled.

(3) For the purposes of paragraphs (1) and (2) above a product is an excluded product if it is–

(a) a prescription only medicine,

(b) a controlled drug, or

(c) in a class specified in Schedule 3 to the Medicines (General Sale List) Order 1984(**5**).", and

(d) in Part I of Schedule 1, in paragraph 11–

(i) in the entry in column 1, there are inserted, after the words "holders of marketing authorizations within the meaning of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994", the words ", holders of certificates of registration granted pursuant to the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994", and

(ii) in the entry in column 2, the word "or" is deleted and there are inserted, after the words "marketing authorizations", the words "or certificates of registration".

Signed by authority of the Secretary of State for Health

Hayman
Parliamentary Under Secretary of State,
15th September 1998 Department of Health

Jon Owen Jones
Parliamentary Under Secretary of State, Welsh
22nd September 1998 Office

(**4**) S.I. 1994/104; amended by S.I. 1994/899.
(**5**) S.I. 1984/769; relevant amending instruments are S.I. 1985/1540 and 1987/910.

Sam Galbraith
Parliamentary Under Secretary of State, The
22nd September 1998 Scottish Office

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

L.S.

D.C. Gowdy
22nd September 1998. Permanent Secretary

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Medicines (Pharmacy and General Sale—Exemption) Order 1980 which specifies exemptions from the general requirements as to retail sale or supply set out in sections 52 (pharmacy sale) and 53 (conditions for sale of products on a general sale list) of the Medicines Act 1968.

It provides for certain homoeopathic products for human use which have a current certificate of registration to be exempt:

from the requirements of sections 52 and 53 where they are sold by a person who has been requested by or on behalf of a patient and in the patient's presence to use his judgment as to the treatment required; and

from the requirements of section 52 where they are sold by a person who meets the conditions for general sale set out in section 53.

The Order revokes article 2(3) and (4) which provided a temporary exemption in respect of registered homoeopathic medicinal products.

The exemptions do not apply to registered homoeopathic products for human use which are prescription-only medicines specified in an order made under section 58(1) of the Medicines Act, which are controlled drugs covered by the Misuse of Drugs Act 1971, or which are in a class specified in Schedule 3 to the Medicines (General Sale List) Order 1984.