STATUTORY INSTRUMENTS

1999 No. 3463

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999

Made - - - -	*22nd December 1999*
Laid before Parliament	*30th December 1999*
Coming into force - -	*19th January 2000*

The Secretaries of State concerned with health in England, in Wales and in Scotland respectively, and as respects Northern Ireland, the Minister of Health, Social Services and Public Safety, acting jointly, in exercise of the powers conferred upon them by sections 58(1), (4) and (5) 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 sections 58(6) and 129(7) of that Act, hereby make the following Order:–

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Prescription Only Medicines (Human Use) Amendment (No. 2) Order 1999 and shall come into force on 19th January 2000.

(2) In this Order, "the principal Order" means the Prescription Only Medicines (Human Use) Order 1997(**3**).

Amendment of Schedule 1 to the principal Order

2. In Schedule 1 to the principal Order (which specifies substances which, if included in medicinal products make, those products prescription only medicines, and exemptions from restrictions on the sale and supply of prescription only medicines)–

(**1**) 1968 c. 67; the expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of the 1968 Act as amended by article 2(2) of, and Schedule 1 to, S.I.1969/388; section 58(4) and (5) of the 1968 Act has been amended by section 1 of the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28).

(**2**) 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; and in the case of the Minister of Health, Social Services and Public Safety, by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c. 47).

(**3**) S.I. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178, 2081, and 1999/1044.

(a) in relation to the substance Felbinac, in the entry in column 5, for " 30g" there is substituted "50g";

(b) there is inserted in column 1, at the appropriate place in the alphabetical order of the entries in that column, the substance "Levocarnitine", and, in column 3, in relation to that substance, there is inserted the entry " For dietary supplementation"; and

(c) there is inserted in column 1, at the appropriate place in the alphabetical order of the entries in that column, each of the following substances–

"Adapalene"

"Altretamine"

"Apraclonidine Hydrochloride"

"Bicalutamide"

"Calcipotriol Hydrate"

"Citalopram Hydrobromide"

"Dorzolamide Hydrochloride"

"Exemestane"

"Ferumoxsil"

"Moexipril Hydrochloride"

"Quinagolide Hydrochloride"

"Sparfloxacin"

"Tizanidine Hydrochloride"

"Valaciclovir Hydrochloride"

"Venlafaxine Hydrochloride"

"Zalcitabine".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
22nd December 1999 Department of Health

Signed by authority of the Secretary of State for Wales

David Hanson
Parliamentary Under Secretary of State, Welsh
20th December 1999 Office

John Reid
20th December 1999 Secretary of State, Scotland Office

Bairbre de Brún
Minister of Health, Social Services and Public Safety

22nd December 1999

EXPLANATORY NOTE

(This note is not part of the Order)

This Order further amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order") which specifies descriptions and classes of prescription only medicines (i.e. medicinal products which, subject to exemptions, may be sold or supplied by retail, only with a prescription given by an appropriate practitioner, and which may be administered only by or in accordance with the directions of such a practitioner). Under Schedule 1 to the principal Order, products are included in a class of medicines by reason of the substances contained in them, subject to their being excluded in specified circumstances.

The amendments made by this Order are as follows–

Amendment of the conditions under which products containing the substance Felbinac may be sold or supplied otherwise than as a prescription only medicine (to increase from 30g to 50g the maximum amount of medicinal product that may be contained in a container or package);

The inclusion in Schedule 1 to the principal Order of the substance Levocarnitine with an exemption where products are for use for dietary supplementation;

The inclusion in Schedule 1 to the principal Order of the substances Adapalene, Altretamine, Apraclonidine Hydrochloride, Bicalutamide, Calcipotriol Hydrate, Citalopram Hydrobromide, Dorzolamide Hydrochloride, Exemestane, Ferumoxsil, Moexipril Hydrochloride, Quinagolide Hydrochloride, Sparfloxacin, Tizanidine Hydrochloride, Valaciclovir Hydrochloride, Venlafaxine Hydrochloride and Zalcitabine.

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