2000 No. 3231

MEDICINES

The Prescription Only Medicines (Human Use) Amendment (No. 3) Order 2000

Made - - - - 8th December 2000

Laid before Parliament 12th December 2000

Coming into force - - 1st January 2001

As respects England, Scotland and Wales, the Secretary of State concerned with health in England, 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(4) and (5) and 129(4) of the Medicines Act 1968(a) or, as the case may be, those conferred by the said provisions and now vested in them(b), 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 Committee on Safety of Medicines pursuant to sections 58(6) and 129(7) of that Act, and after taking into account the advice of the Medicines Commission pursuant to section 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. 3) Order 2000 and shall come into force on 1st January 2001.
- (2) In this Order, "the principal Order" means the Prescription Only Medicines (Human Use) Order 1997(c).

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

⁽a) 1968 c. 67. The expression "the appropriate Ministers", and the expression "the Health Ministers" which is relevant to the powers being exercised in the making of this Order, are defined in section 1 of that Act as amended by article 2(2) of, and Schedule 1 to, S.I. 1969/388, and by article 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; section 58 was amended by section 1 of the Prescription by Nurses etc. Act 1992 (c. 28).

⁽b) In the case of the Secretary of State concerned with health in England, by virtue of article 2(2) of, and Schedule 1 to, S.I. 1969/388, and articles 2(1) and 5 of, and paragraph 1(1) of the Schedule to, S.I. 1999/3142; 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).

⁽c) S.I. 1997/1830, amended by S.I. 1997/2044, 1998/108, 1178 and 2081, 1999/3463, 2000/1917 and 2899.

the restrictions on the sale and supply of prescription only medicines), in relation to the substance Levonorgestrel, there are inserted the following entries—

in column 2—
"0.75mg"; and
in column 3—

"for use as an emergency contraceptive in women aged 16 years and over".

Yvette Cooper
Parliamentary Under Secretary of State for Public Health,
Department of Health

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

8th December 2000

4th December 2000

EXPLANATORY NOTE

(This note is not part of the Order)

This Order amends Schedule 1 to the Prescription Only Medicines (Human Use) Order 1997 (which specifies substances which, if included in medicinal products, make them prescription only medicines, and exemptions from the restrictions in section 58(2) on sale and supply of prescription only medicines) to provide that medicinal products consisting of or containing Levonorgestrel may be sold or supplied otherwise than as a prescription only medicine provided that they are at a maximum strength of 0.75 mg and are sold or supplied exclusively for use as an emergency contraceptive in women aged 16 years and over.

An assessment to 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 10-202 Market Towers, 1 Nine Elms Lane, London SW8 5NQ.



£1.50