

STATUTORY INSTRUMENTS

1984 No. 756

MEDICINES

**The Medicines (Products Other Than Veterinary Drugs)
(Prescription Only) Amendment Order 1984**

<i>Made</i> - - - -	31st May 1984
<i>Laid before Parliament</i>	11th June 1984
<i>Coming into Operation</i>	2nd July 1984

The Secretary of State concerned with health in England, the Secretaries of State respectively concerned with health and with agriculture in Wales and in Scotland, the Minister of Agriculture, Fisheries and Food, the Department of Health and Social Services for Northern Ireland and the Department of Agriculture for Northern Ireland, acting jointly, in exercise of powers conferred by sections 58(1) and (4), and 129(4) of the Medicines Act 1968(a) 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(c) pursuant to sections 58(6) and 129(7) of that Act, hereby make the following order:—

Citation, interpretation and commencement

1. This order, which may be cited as the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment Order 1984, amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(d) (hereinafter referred to as “the principal order”) and shall come into operation on 2nd July 1984.

Amendment of Article 1 of the principal order

2.— (1) Article 1 of the principal order (interpretation) is amended in accordance with the following provisions of this Article.

(a) 1968 c. 67; sections 58(1) and (4) and 129(4) were applied to cyanogenetic substances by S.I. 1984/187.

(b) 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, the Transfer of Functions (Wales) Order 1969 (S.I. 1969/388), in the case of the Secretary of State concerned with agriculture in Wales by virtue of Article 2(3) of, and Schedule 1 to, the Transfer of Functions (Wales) (No. 1) Order 1978 (S.I. 1978/272) and in the case of the Northern Ireland Departments 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).

(c) See S.I. 1970/1257.

(d) S.I. 1983/1212.

(2) In paragraph (2)(a) of that Article—

(a) the following definition is inserted immediately after the definition of “controlled drug”—

“‘cyanogenetic substances’ means preparations which—

- (i) are presented for sale or supply under the name of, or as containing, amygdalin, laetrile or vitamin B17 or
- (ii) contain more than 0.1 per cent by weight of any substance having the formula either α -Cyanobenzyl-6-*O*- β -D-glucopyranosyl- β -D-glucopyranoside or α -Cyanobenzyl- β -D-glucopyranosiduronic acid;”;

(b) for the definition of “medicinal product” there is substituted the following definition—

“‘medicinal product’ includes any article or substance in respect of which section 58 of the Act has effect by virtue of an order made under section 104 of the Act, but does not include—

- (i) a medicinal product which is a veterinary drug as defined in section 132(1) of the Act or
- (ii) an article or substance in respect of which section 58 has such effect where that article or substance is only for administration to animals;”.

(3) After the reference to the abbreviation for gram in paragraph (3)(c) of that Article there is inserted the following—

“‘iu’ for international unit of activity;”.

Amendment of Article 3(1) of the principal order

3. At the end of Article 3(1) of the principal order (medicinal products on prescription only) there is added the following sub-paragraph—

“(f) cyanogenetic substances other than preparations for external use.”

Amendment of Part I of Schedule 1 to the principal order

4. In Part I of Schedule 1 to the principal order (which lists substances which render a medicinal product a prescription only medicine except in circumstances also listed), after the entry relating to Viomycin Sulphate, there are inserted in columns 1, 3 and 4 the entries set out in columns 1, 3 and 4 respectively in the Schedule to this order.

Signed by authority of the Secretary of State for Social Services.

John Patten,
Parliamentary Under-Secretary of State,
Department of Health and Social Security.

16th May 1984.

George Younger,
Secretary of State for Scotland.

23rd May 1984.

Nicholas Edwards,
Secretary of State for Wales.

21st May 1984.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed this 24th day of May 1984.



Michael Jopling,
Minister of Agriculture, Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 21st day of May 1984.



Maurice N. Hayes,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 31st day of May 1984.



J. C. Chalmers,
Under Secretary.

SCHEDULE

Article 4

ENTRIES ADDED TO PART I OF SCHEDULE 1 TO THE PRINCIPAL ORDER(a)

Column 1	Circumstances excluding medicinal products from the class of prescription only medicines		
	Column 2	Column 3	Column 4
Substance	Maximum strength	Use, pharmaceutical form or route of administration	Maximum dose and maximum daily dose
Vitamin A		(1) Internal	(1) 7500 iu (2250 mcg Retinol equivalent) (MDD)
		(2) External	
Vitamin A Acetate		(1) Internal	(1) Equivalent to 7500 iu Vitamin A (2250 mcg Retinol equivalent) (MDD)
		(2) External	
Vitamin A Palmitate		(1) Internal	(1) Equivalent to 7500 iu Vitamin A (2250 mcg Retinol equivalent) (MDD)
		(2) External	

(a) Note: all columns appearing in the principal order are set out in this order, although no entries are added by this order to column 2.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This order amends the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 (the principal order) which specifies descriptions and classes of prescription only medicines, that is to say medicinal products which (subject to exemptions) may be sold or supplied by retail only in accordance 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.

Article 2 extends the definition of "medicinal product" in Article 1(2) of the principal order to include articles and substances for human use to which section 58 of the Medicines Act 1968 has been applied by an order under section 104 of that Act. Article 2 also inserts a definition of cyanogenetic substances in paragraph (2) of Article 1 of the principal order and a reference to the abbreviation for international unit of activity in paragraph (3) of that Article.

Article 3 extends Article 3 of the principal order to provide that cyanogenetic substances may be sold or supplied by retail only on the prescription of an appropriate practitioner and administered only under the directions of such a practitioner.

Article 4 and the Schedule add Vitamin A, Vitamin A Acetate and Vitamin A Palmitate to those medicines listed in Part I of Schedule 1 to the principal order. Except where a maximum dose or a maximum daily dose is set out on the label of the container or package of a medicinal product containing those substances and that dose does not exceed the limits set out in column 4 of Part I of that Schedule, the principal order will apply to the sale, supply and administration of that product.

SI 1984/756
ISBN 0-11-046756-6



780110467566