

## 1977 No. 2131

## MEDICINES

**The Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977**

*Made - - - - 20th December 1977*

*Laid before Parliament 5th January 1978*

*Coming into Operation 1st February 1978*

The Secretaries of State respectively concerned with health in England and in Wales, the Secretary of State concerned with health and with agriculture 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 section 62 of the Medicines Act 1968(a) as read with the Medicines (Extension to Antimicrobial Substances) Order 1973(b) and now vested in them (c) and 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 the following order, and after consulting and taking into account the advice of the Medicines Commission, hereby make the following order:—

*Citation, commencement and interpretation*

1.—(1) This order may be cited as the Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977 and shall come into operation on 1st February 1978.

(2) In this order—

(a) the classes of substances listed in numbered paragraphs in column 1 of Part II of Schedule 1 to this order shall have the meanings given to them in the correspondingly numbered paragraphs in column 2 of the said Part II;

(b) unless the context otherwise requires, “the Act” means the Medicines Act 1968;

and other expressions have the same meanings as in the Act.

(3) Except in so far as the context otherwise requires, any reference in this order to any enactment, order or regulations shall be construed as a reference

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(a) 1968 c. 67.

(b) S.I. 1973/367 (1973 I, p. 1270).

(c) 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 (1969 I, p. 1070)), 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).

to that enactment or order or to those regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order or regulations.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889<sup>(a)</sup> shall apply for the purposes of the interpretation of this order as they apply for the purposes of the interpretation of an Act of Parliament.

*Provisions prohibiting sale or supply*

2.—(1) Subject to the following provisions of this Article, the sale or supply of any substance specified in paragraph (2) of this Article, being a substance to which the provisions of the Medicines (Extension to Antimicrobial Substances) Order 1973 applies (“antimicrobial substance”), is hereby prohibited.

(2) The substances referred to in the foregoing paragraph of this Article are—

- (a) a substance listed in Part I of Schedule 1 to this order,
- (b) a substance falling within a class of substances listed in column 1 of Part II of the said Schedule,
- (c) a salt or derivative of the substances specified in the foregoing subparagraphs or a salt of a derivative of the said substances, or
- (d) a substance the chemical and biological properties of which are identical with or similar to a substance or a class of substances listed in Part I or Part II of the said Schedule which is produced by means other than the growth of specific organisms.

(3) The prohibition imposed by paragraph (1) of this Article shall apply whether or not the substance is contained in any other substance or article unless that other substance or article is either—

- (a) a medicinal product, or
- (b) an animal feeding stuff.

(4) The prohibition imposed by paragraph (1) of this Article shall be subject to the following exceptions, that is to say the sale or supply shall not, by virtue of the said paragraph (1), be prohibited—

- (a) where the sale or supply is of an antimicrobial substance listed in numbered paragraphs in column 1 of Schedule 2 to this order and the substance is sold or supplied for the purpose specified in the correspondingly numbered paragraphs of column 2 of the said Schedule and in the circumstances (if any) specified in relation to that purpose in column 3 of the said Schedule;
- (b) where the sale is to a person who buys it for one or more of the purposes specified in section 131(2) of the Act (wholesale) and such sale is to—
  - (i) a veterinary surgeon or veterinary practitioner,
  - (ii) a person lawfully conducting a retail pharmacy business,
  - (iii) a holder of a manufacturer’s licence granted under Part II of the Act, or
  - (iv) a person carrying on the business of selling by way of wholesale dealing;

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(a) 1889 c. 63.

- (c) where the sale or supply is to any of the following—
- (i) a public analyst appointed under section 89 of the Food and Drugs Act 1955(a), section 27 of the Food and Drugs (Scotland) Act 1956(b) or section 31 of the Food and Drugs Act (Northern Ireland) 1958(c),
  - (ii) an agricultural analyst appointed under section 67 of the Agriculture Act 1970(d),
  - (iii) a person duly authorised by an enforcement authority under sections 111 and 112 of the Act,
  - (iv) a sampling officer within the meaning of Schedule 3 to the Act,
  - (v) universities, other institutions concerned with higher education or institutions concerned with research.

*David Ennals,*  
Secretary of State for Social Services.

15th December 1977.

*John Morris,*  
Secretary of State for Wales.

15th December 1977.

*Bruce Millan,*  
Secretary of State for Scotland.

15th December 1977.

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(a) 1955 (4 and 5 Eliz. 2)c.16  
(c) 1958 c. 27 (N.I.).

(b) 1956 c. 30.  
(d) 1970 c. 40.

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In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 15th December 1977.

(L.S.)

*John Silkin,*  
Minister of Agriculture,  
Fisheries and Food.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 19th day of December 1977.

(L.S.)

*N. Dugdale,*  
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 20th day of December 1977.

(L.S.)

*J. A. Young,*  
Permanent Secretary.

## Article 2(1)

## SCHEDULE 1

DESCRIPTIONS AND CLASSES OF ANTIMICROBIAL SUBSTANCES TO WHICH THE  
PROHIBITION IN ARTICLE 2(1) OF THIS ORDER APPLIES

## PART I

Amphotycin  
Bacitracin  
Candidin  
Capreomycin  
Chloramphenicol  
Cycloserine  
Erythromycin  
Framycetin  
Furaltadone  
Furazolidone  
Fusidic Acid  
Griseofulvin  
Hachimycin  
Nalidixic Acid  
Nitrofurantoin  
Nitrofurazone  
Novobiocin  
Nystatin  
Oleandomycin  
Paromomycin  
Spectinomycin  
Spiramycin  
Tylosin  
Vancomycin  
Viomycin  
Virginiamycin

## NOTE

In this Part of this Schedule—

- (a) a reference to any substance, other than furaltadone, shall be construed as a reference to the substance for which such name is shown in the current edition of the list of names prepared and published under section 100 of the Act, and
- (b) “furaltadone” means  $(\pm)$ -5-morpholino-methyl-3-(5-nitrofurylidene-amino)-2-oxo-oxazolidine.

## PART II

Column 1	Column 2
Class of substance	Meaning
1. Amphotericins	1. Antimicrobial substances or mixtures of such substances produced by <i>Streptomyces nodosus</i> .
2. Cephalosporins	2. Antimicrobial substances containing in their chemical structure a fused dihydrothiazine $\beta$ -lactam nucleus.
3. Gentamicins	3. Any antimicrobial basic substance or mixture of such substances produced by the strain <i>Micromonospora purpurea</i> which on 1st September 1967 was numbered NRRL 2953 in the culture collection of the Northern Utilisation Research and Development Branch of the United States Department of Agriculture.
4. Kanamycins	4. Any antimicrobial substance or mixture of such substances produced by <i>Streptomyces Kanamyceticus</i> .
5. Lincomycins	5. Antimicrobial substances produced by <i>Streptomyces lincolnensis</i> (var. <i>lincolnensis</i> ). These substances are the basic amides of hygric acid or of a substituted hygric acid with 6-amino-6, 8-dideoxy-1-thiogalacto-octopyranose or with substituted 6-amino-6, 8-dideoxy-1-thiogalacto-octopyranose.
6. Neomycins	6. Antimicrobial substances or mixtures of such substances produced by <i>Streptomyces fradiae</i> which are complex organic bases and which yield on hydrolysis with mineral acids the base neamine.
7. Penicillins	7. Any antimicrobial acid which contains in its structure a fused thiazolidine $\beta$ -lactam nucleus.
8. Polymixins	8. Any antimicrobial substance produced by any strain of <i>Bacillus polymyxa</i> .
9. Rifamycins	9. A group of related antimicrobial macrolactams produced by the growth of <i>Streptomyces mediterranei</i> and containing the chemical structure of 11-acetoxy-7,9, 15-trihydroxy-13-methoxy-2,6,8,10,12-pentamethylpentadeca-2,4, 14-trienoic acid amide attached by the nitrogen atom and by the oxygen atom in the 15-position respectively to the 7- and 2-positions of a 5,6, 9-trioxygenated 2, 4-dimethyl-1-oxo-naphtho (2, 1-b) furan.
10. Ristocetins	10. Antimicrobial substances produced by a strain of a <i>Nocardia</i> species referred to as <i>Nocardia lurida</i> .
11. Streptomycins	11. Any antimicrobial complex organic base or mixture of such bases produced by <i>Streptomyces griseus</i> which:— (a) yields on hydrolysis with mineral acids the base streptidine (meso-1 3-diguanidocyclohexane-2,4,5, 6-tetraol); and (b) yields on hydrolysis by a 4 per cent solution of sodium hydroxide the substance maltol (3-hydroxy-2-methyl-8-pyrone).

Column 1	Column 2
Class of substance	Meaning
12. Sulphanilamide	12. Sulphanilamide being p-aminobenzenesulphonamide, having any of the hydrogen atoms of either or both nitrogen atoms substituted by an equal number of univalent atoms or radicals.
13. Tetracyclines	13. Antimicrobial bases which contain the chemical structure naphthacene-2-carboxamide, hydrogenated to any extent and having each of the positions 1,3,10,11,12 and 12a substituted by a hydroxyl or an oxo group.

Article 2(4)(a)

## SCHEDULE 2

EXCEPTIONS FROM THE PROHIBITION IMPOSED  
BY ARTICLE 2(1) OF THIS ORDER

Column 1	Column 2	Column 3
Substance	Purpose	Circumstances
1. Sulphanilamide	<p>1(1) When, as the derivative sulphaquinoxaline, it is—</p> <p>(a) contained in a product which is for the destruction of rats and mice, or</p> <p>(b) sold or supplied for use in the manufacture of a product for the destruction of rats and mice.</p> <p>(2) When, as the derivative methyl 4-aminobenzene-sulphonyl carbamate, it is—</p> <p>(a) contained in a product which is for use as a herbicide, or</p> <p>(b) sold or supplied for use in the manufacture of herbicides.</p>	<p>(a) The amount of sulphaquinoxaline in the product shall not exceed 0.5 per cent of the product and the product shall also contain warfarin or its sodium or triethanolamine derivative.</p> <p>(a) Only when sold or supplied for agricultural, horticultural or forestry purposes or for use in or near water or on uncultivated land.</p>
2. Griseofulvin	2(1) When contained in a product which is for use as a fungicide.	(1) When sold or supplied for horticultural purposes and containing ingredients other than that referred to in column 1 of this paragraph in such a quantity as to render the product unfit for any medicinal purpose and unpalatable to such a degree as to prevent consumption by human beings.

Column 1	Column 2	Column 3
Substance	Purpose	Circumstances
3. Streptomycins	<p>(2) When sold or supplied for use in the manufacture of fungicides.</p> <p>3(1) When contained in a product which is for use as a fungicide.</p> <p>(2) When sold or supplied for use in the manufacture of fungicides.</p>	<p>(1) When sold or supplied for horticultural purposes and containing ingredients other than those referred to in column 1 of this paragraph in such a quantity as to render the product unfit for any medicinal purpose and unpalatable to such a degree as to prevent consumption by human beings.</p>

## EXPLANATORY NOTE

*(This Note is not part of the Order.)*

This Order is made under section 62 of the Medicines Act 1968 and prohibits the sale or supply of the antimicrobial substances specified in Article 2(2) of the order. Section 62 was made to apply to antimicrobial substances by the Medicines (Extension to Antimicrobial Substances) Order 1973 as that section applies to medicinal products. Exceptions from the prohibition referred to above are provided. These include exceptions for the sale or supply of antimicrobial substances when contained in medicinal products or animal feeding stuffs and exceptions for the sale or supply of Griseofulvin, Streptomycins and certain compounds based on Sulphanilamide when sold or supplied for the purposes and in the circumstances set out in Schedule 2 to the order.

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