STATUTORY INSTRUMENTS

1971 No. 1200

MEDICINES

The Medicines (Control of Substances for Manufacture) Order 1971

Made - - - -	*23rd July 1971*
Laid before Parliament	*3rd August 1971*
Coming into Operation	*1st September 1971*

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 Health and Social Services for Northern Ireland, the Minister of Agriculture, Fisheries and Food and the Minister of Agriculture for Northern Ireland, acting jointly, in exercise of their powers under section 105(1)(a) of the Medicines Act 1968, as having effect subject to the provisions of article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(**1**) 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 and after taking into account the advice of the Committee on Safety of Medicines and the advice of the Veterinary Products Committee, hereby order as follows:—

Citation and commencement

1. This order may be cited as the Medicines (Control of Substances for Manufacture) Order 1971 and shall come into operation on 1st September 1971.

Interpretation

2.—(1) In this order unless the context otherwise requires:—

"the Act" means the Medicines Act 1968;

"Committee on Safety of Medicines" means the Committee established by the Medicines (Committee on Safety of Medicines) Order 1970(**2**);

"Veterinary Products Committee" means the Committee established by the Medicines (Veterinary Products Committee) Order 1970(**3**).

(**1**) (1969 I, p. 1070).
(**2**) (1970 II, p. 4098).
(**3**) (1970 III, p. 4335).

(2) The expressions used in Schedule 1 to this order have the meanings given to them in Schedule 2 to this order and other expressions have the same meaning as in the Act.

(3) The Interpretation Act 1889 shall apply to the interpretation of this order as it applies to the interpretation of an Act of Parliament.

Application of specified provisions of the Act to specified ingredients used in the manufacture of medicinal products

3. There are hereby specified the substances set out in numbered paragraphs in Column 1 of Schedule 1 to this order, as being substances which when not manufactured, sold, supplied, imported or exported for use for a medicinal purpose wholly or mainly in either or both of the ways specified in section 130(1) of the Act appear to the Ministers to be substances which are not in themselves medicinal products but are used as ingredients in the manufacture of medicinal products, and it is hereby directed that the provisions contained in Part II, sections 62, 66 and 67 of Part III of the Act, and the provisions contained in Parts V and VIII of the Act shall have effect in relation to each of those substances in the circumstances set out in the corresponding paragraph of Column 2 of the said Schedule, as those provisions have effect in relation to medicinal products.

Keith Joseph
22nd July 1971 — Secretary of State for Social Services

Peter Thomas
21st July 1971 — Secretary of State for Wales

Gordon Campbell
22nd July 1971 — Secretary of State for Scotland

W. K. Fitzsimmons
Minister of Health and Social Services for
22nd July 1971 — Northern Ireland

In Witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 22nd July 1971.

L.S.

J. M. L. Prior
Minister of Agriculture, Fisheries and Food

H. W. West
23rd July 1971 — Minister of Agriculture for Northern Ireland

SCHEDULE 1

Article 2(2) and Article 3

Column 1 Substances appearing to the Ministers to be substances which, as described in article 3 of this order, are not themselves medicinal products but which are used as ingredients in the manufacture of medicinal products	*Column 2* Circumstances in which the order applies to the substances referred to in Column 1
1. Amphotericin B	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
2. Bacitracin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
3. Capreomycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
4. Colistin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
5. Erythromycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
6. Gentamicin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
7. Heparin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
8. Hyaluronidase	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
9. Kanamycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
10. Neomycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in

Column 1	*Column 2*
	a medicinal product for parenteral injection into human beings or animals.
11. Penicillin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
12. Polymyxin B	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
13. Preparations of the pituitary (posterior lobe)	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
14. Streptomycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
15. The lincomycins	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
16. The rifamycins	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
17. The tetracyclines	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
18. Vancomycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
19. Viomycin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for parenteral injection into human beings or animals.
20. Oxytetracycline	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product which is to be administered to human beings or animals by means other than parenteral injection.
21. Tetracycline	
Substances appearing to the Ministers to be substances which, as described in article 3	Circumstances in which the order applies to the substances referred to in Column 1

Column 1	*Column 2*
of this order, are not themselves medicinal products but which are used as ingredients in the manufacture of medicinal products	
22. Dextrans	When manufactured, assembled, sold, supplied, imported or exported for use as ingredients of dextran injections for human or animal use.
23. Antigens	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
24. Antisera	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
25. Antitoxins	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
26. Chorionic gonadotrophin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
27. Corticotrophin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
28. Follicle-stimulating hormone	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
29. Insulin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
30. Sera	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
31. Streptodornase	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
32. Streptokinase	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
33. Toxins	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.
34. Vaccines	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.

Column 1	*Column 2*
35. Preparations of blood	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human use.
36. Plasma	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for administration to animals.
37. Any substances wholly or partly derived from animals not being substances specifically mentioned in any of the above paragraphs of this column.	

SCHEDULE 2

Article 2(2)

"Amphotericin B" is any antimicrobial substance or mixture of such substances produced by *Streptomyces nodosus*. The expression includes any salt or derivative, or salt of a derivative, of amphotericin B and any substance the chemical and biological properties of which are identical with or similar to those of amphotericin B but which is produced by other means.

"Antigens" are substances which on administration to a human being or animal are capable of eliciting a specific immunological response.

"Antisera" are substances which consist wholly or partly of sera derived from animals which have been immunised against one or more micro-organisms, viruses or other antigens.

"Antitoxins" are substances which consist wholly or partly of immunoglobulins of antisera derived from animals which have been immunised against one or more toxins whether detoxified or not.

"Bacitracin" is any antimicrobial polypeptide produced by strains of *Bacillus licheniformis* and of *Bacillus subtilis* (var. *Tracey*), which yields on hydrolysis with mineral acids the amino acids L-cysteine, D-glutamic acid, L-histidine, L-isoleucine, L-leucine, L-lysine, D-ornithine, D-phenylalanine and DL-aspartic acid. The expression includes any salt or derivative, or salt of a derivative, of bacitracin and any substance the chemical and biological properties of which are identical with or similar to those of bacitracin but which is produced by other means.

"Capreomycin" is any antimicrobial polypeptide or mixture of such polypeptides produced by the strain of *Streptomyces capreolus* which on 1st September 1967 was numbered NRRL 2773 in the culture collection of the Northern Utilisation Research and Development Branch of the United States Department of Agriculture, and which yields on hydrolysis with mineral acids the amino acids α,β-diaminopropionic acids and α-(2-iminohexahydro-4-pyrimidyl)glycine together with serine, alanine and β-lysine. The expression includes any salt or derivative, or salt of a derivative, of capreomycin and any substance the chemical and biological properties of which are identical with or similar to capreomycin but which is produced by other means.

"Chorionic gonadotrophin" is a dry, sterile preparation of the gonad stimulating substance obtained from the urine of pregnant women.

"Colistin" is any antimicrobial polypeptide or mixture of such polypeptides produced by strains of *Bacillus polymyxa* (var. *colistinus*) which yields on hydrolysis with mineral acids only the amino acids leucine, threonine and α,Γ-diaminobutyric acid together with 6-methylheptanoic acid and 6-methyloctanoic acid. The expression includes any salt or derivative, or any salt of a derivative, of colistin and any substance the chemical and biological properties of which are identical with or similar to those of colistin but which is produced by other means.

"Corticotrophin" is a substance obtained from the anterior lobe of the pituitary gland and which contains the peptide hormone that increases the rate at which corticoid hormones are secreted by the adrenal gland.

"Dextrans" are the substances produced by the fermentation of sucrose by means of strains of *Leuconostoc mesenteroides*, or by means of purified enzymes derived from such strains being polymers of glucose in which the linkages between the glucose units are almost entirely of the α-1,6 type.

"Dextran injections" are preparations of solutions of dextrans in physiological saline or other vehicle suitable for intravenous injection of dextrans.

"Erythromycin" is any antimicrobial weakly basic substance or mixture of such substances produced by *Streptomyces erythreus* (Waksman) which has the following characteristics—

(a) it forms a dihydrate which has a melting point of about 135°C.;

(b) on mild acid hydrolysis it yields the base erythralosamine with a melting point of about 206°C.

The expression includes any salt or derivative, or salt of a derivative, of erythromycin and any substance the chemical and biological properties of which are identical with or similar to those of erythromycin but which is produced by other means.

"Follicle-stimulating hormone" is an extract of post-menopausal urine containing that hormone which has the property of stimulating growth and maturation of germinal follicles in the ovary. Such extract may contain substances with interstitial cell stimulating hormone activity.

"Gentamicin" is any antimicrobial basic substance or mixture of such substances produced by the strain of *Micromonospora purpurea* 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. The expression includes any salt or derivative, or salt of a derivative, of gentamicin and any substance the chemical and biological properties of which are identical with or similar to those of gentamicin but which is produced by other means.

"Heparin" is a substance containing the sodium salt of a sulphated polysaccharide obtained from mammalian tissues which has the property of prolonging the clotting time of blood in human beings or animals.

"Hyaluronidase" is a substance prepared from mammalian testicles or sperm or from other sources of the enzymes which diminish the viscosity of the hyaluronic acid present in mammalian tissues.

"Insulin" is a preparation of the specific antidiabetic principle of the pancreas.

"Kanamycin" is any antimicrobial substance or mixture of such substances produced by *Streptomyces kanamyceticus*. The expression includes any salt or derivative, or salt of a derivative, of kanamycin and any substance the chemical and biological properties of which are identical with or similar to those of kanamycin but which is produced by other means.

"The lincomycins" are the antimicrobial substances produced by *Streptomyces lincolnensis* (var. *lincolnensis*). 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. The expression includes any salt or derivative, or salt of a derivative, or salt of a derivative, of any lincomycin and any substance the chemical and biological properties of which are identical with or similar to those of any lincomycin but which is produced by other means.

"Lincomycin" is one of the lincomycins which incorporates *trans*-L-4-propylhygric acid and a methylthio group in the pyranose ring.

"Neomycin" is any antimicrobial substance or mixture of such substances produced by *Streptomyces fradiae* which are complex organic bases and which yield on hydrolysis with mineral acids the base neamine. The expression includes any salt or derivative, or salt of a derivative, of neomycin and any substance the chemical and biological properties of which are identical with or similar to those of neomycin but which is produced by other means.

"Oxytetracycline" is 4-dimethylamino-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxonaphthacene-2-carboxamide. The expression includes any salt of oxytetracycline.

"Parenteral injection" in relation to any substance includes any administration of the substance by insertion into the body by any route other than that of the gastro-intestinal tract but does not include any application of the substance to the skin.

"Penicillin" is any antimicrobial acid, any salt thereof, or any derivative which is obtained therefrom which contains in its structure a fused thiazolidine β-lactam nucleus.

"Plasma" means the fluid element of uncoagulated blood.

"Polymyxin B" is any antimicrobial polypeptide or mixture of such polypeptides produced by strains of *Bacillus polymyxa* which yields on hydrolysis with mineral acids only the amino acids leucine, phenylalanine, threonine and α,Γ-diaminobutyric acid together with 6-methylheptanoic acid and 6-methyloctanoic acid. The expression includes any salt or derivative, or salt of a derivative, of polymyxin B and any substance the chemical and biological properties of which are identical with or similar to those of polymyxin B but which is produced by other means.

"Preparations of blood" include whole blood from human beings or animals, serum or plasma made from such blood, any protein or other substance separated from such blood and any dried product prepared from any such serum, plasma, protein or other substance.

"Preparations of the pituitary (posterior lobe)" include the active principles thereof (whether obtained by fractionation of the gland or by synthesis) and derivatives of those principles with the same specific biological action.

"The rifamycins" are a group of related antimicrobial macrolactams produced by the growth of *Streptomyces mediterranei* 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-oxonaphtho[2,1-*b*] furan. The expression includes any salt or derivative, or salt of a derivative, of any rifamycin and any substance the chemical and biological properties of which are identical with or similar to those of any rifamycin but which is produced by other means.

"Rifamide" is an antimicrobial base produced from a rifamycin known as rifamycin B and has 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 5,6-dihydroxy-2,4-dimethyl-1-oxonaphtho[2,1-*b*] furan-9-oxyacetic acid diethylamide.

"Sera" means the fluid element of coagulated blood.

"Streptodornase" is the substance produced by strains of streptococcus which catalyzes the depolymerisation of deoxyribonucleic acid.

"Streptokinase" is the substance produced by strains of streptococcus which activates an inactive precursor of a fibrinolytic enzyme present in plasma.

"Streptomycin" is any antimicrobial complex organic base or mixture of such bases produced by *Streptomyces griseus* 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-Γ-pyrone).

The expression includes any salt or derivative, or salt of a derivative, of streptomycin and any substance the chemical and biological properties of which are identical with or similar to those of streptomycin but which is produced by other means.

"The tetracyclines" are the 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 an hydroxyl or an oxo group.

"Tetracycline" is 4-diamethylamino-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxonaphthacene-2-carboxamide. The expression includes any salt of tetracycline.

"Toxins" are substances used in the diagnosis, prevention or treatment of disease and consisting wholly or partly of poisonous substances derived from specific micro-organisms, plants or animals.

"Vaccines" are substances which consist wholly or partly of—

(a) any micro-organisms, viruses or other organisms in any state,

(b) any toxins of microbial origin which have been detoxified, or

(c) any extracts or derivatives of any micro-organisms or of any viruses,

being substances which, when administered to human beings or animals, are used for the prevention or treatment of specific diseases.

"Vancomycin" is any mixture of antimicrobial substances produced by *Streptomyces orientalis*. The expression includes any salt or derivative, or salt of a derivative, of vancomycin and any substance the chemical and biological properties of which are identical with or similar to those of vancomycin but which is produced by other means.

"Viomycin" is any antimicrobial organic base produced by the growth of *Streptomyces griseus* (var. *purpureus*), which yields on hydrolysis with mineral acids urea, L-serine, αβ-diaminopropionic acid and 3,6-diaminohexanoic acid. The expression includes any salt or derivative, or salt of a derivative, of viomycin and any substance the chemical and biological properties of which are identical with or similar to those of viomycin but which is produced by other means.

EXPLANATORY NOTE

This Order extends certain specified provisions of the Medicines Act 1968, concerning, in relation to medicinal products, the holding of licences and certificates, the regulation of dealings, offences and penalties, labelling, leaflets and containers, and certain miscellaneous matters, so that those provisions will also relate to the substances described in Schedule 1 to this order in the circumstances there specified.