STATUTORY INSTRUMENTS

1985 No. 1403

MEDICINES

The Medicines (Control of Substances for Manufacture) Order 1985

Made - - - - -	*6th September* 1985
Laid before Parliament	*10th September* 1985
Coming into Operation	*1st October* 1985

The Secretary of State concerned with health in England, the Secretaries of State 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 section 105(1)(*a*) 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 Medicines Commission pursuant to section 129(7) of that Act, hereby make the following order:

Citation and commencement

1. This order may be cited as the Medicines (Control of Substances for Manufacture) Order 1985 and shall come into operation on 1st October 1985.

Interpretation

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

"the Act" means the Medicines Act 1968.

(2) The expressions used in Schedule 1 to this order have the meanings given to them in Schedule 2 to this order.

(a) 1968 c. 67.

(b) 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), 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).

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

3.—(1) 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, subject to the modifications specified in paragraph (2) of this Article, 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.

(2) In relation to the substances to which this Article applies, section 16(1) of the Act (transitional exemptions) shall have effect subject to the modification that for the words "the first appointed day" there shall be substituted "the relevant appointed day" and any reference to "the first appointed day" in any other provision of the Act which is to have effect in relation to those substances by virtue of this Article shall be construed, in its application to those substances, as referring to "the relevant appointed day".

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

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

29th August 1985.

Signed with the authority of the Secretary of State for Wales.

Mark Robinson,
Parliamentary Under-Secretary of State.

6th September 1985.

Gray of Contin,
Minister of State for Scotland.

3rd September 1985.

In witness whereof the official seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 4th September 1985.

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 3rd day of September 1985.

Maurice N. Hayes,
Permanent Secretary.

Sealed with the official seal of the Department of Agriculture for Northern Ireland this 3rd day of September 1985.

W. H. Jack,
Permanent Secretary.

SCHEDULE 1 Article 3(1)

Column 1	Column 2
Substances appearing to the Ministers to be substances which, as described in Article 3(1) of this order, are not themselves medicinal products but which are used as ingredients in the manufacture of medicinal products	Circumstances in which the order applies to the substances referred to in Column 1
1. Gentamicin	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.
2. Neomycin	" "
3. Nystatin	When manufactured, assembled, sold, supplied, imported or exported for use as an ingredient in a medicinal product for human or animal use.

SCHEDULE 2 Article 2(2)

"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.

"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.

"Nystatin" is any mixture of antifungal polyenes produced by the growth of *Streptomyces noursei* and containing the chemical structure 19-(3-amino-3,6-dideoxy-β-D-mannopyranosyloxy)-16-carboxy-3, 5, 7, 10, 11, 15, 17, 35-octahydroxy-34-methyl-13-oxo-octatriaconta-20, 24, 26, 30, 32-hexaen-37-olide. The expression includes any salt or derivative, or salt of a derivative, of nystatin and any substance the chemical and biological properties of which are identical with or similar to those of nystatin but which is produced by other means.

"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.

EXPLANATORY NOTE

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

This Order extends the application of specified provisions of the Medicines Act 1968 to the substances gentamicin, neomycin and nystatin, in circumstances where those substances are not in themselves medicinal products but are used as ingredients in the manufacture of medicinal products (Article 3(1)). Those substances are specified in Schedule 1 and defined in Schedule 2 to this Order.

The provisions of the Act which are applied to those substances by this Order relate to the holding of licences, the regulation of dealings with such substances, the commission of offences, requirements relating to containers and packages, and certain miscellaneous matters.

Those provisions already apply to gentamicin and neomycin in circumstances where they are for use as ingredients in medicinal products to be administered by parenteral injection, by virtue of the Medicines (Control of Substances for Manufacture) Order 1971 (S.I. 1971/1200). This Order applies those provisions to gentamicin and neomycin in circumstances where they are for use as ingredients in medicinal products which are to be administered by other means; further, it applies those provisions to nystatin in circumstances where that substance is for use as an ingredient in a medicinal product which is to be administered in any way.

This Order also modifies specified provisions of the Act, in the circumstances in which the Order applies, so as to provide for a transitional period of exemption before the provisions of the Act requiring the holding of licences shall have full effect (Article 3(2)).

SI 1985/1403
ISBN 0-11-057403-6