

STATUTORY INSTRUMENTS

1982 No. 425

MEDICINES

The Medicines (Control of Substances for Manufacture) Order
1982

<i>Made</i> - - - - -	22nd March 1982
<i>Laid before Parliament</i>	30th March 1982
<i>Coming into Operation</i>	20th April 1982

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 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 the following order in accordance with section 129(6) of the said Act and after taking into account the advice of the Veterinary Products Committee (c) in accordance with section 129(7) of the said Act, hereby order as follows:—

Citation and commencement

1. This order may be cited as the Medicines (Control of Substances for Manufacture) Order 1982 and shall come into operation on 20th April 1982.

Interpretation

2. In this order:—

“the Act” means the Medicines Act 1968;

“Benzestrol” means 4,4'-(1,2-diethyl-3-methyltrimethylene)diphenol and salts and esters thereof;

“Dienoestrol” means 4,4'-(diethylideneethylene)diphenol and salts and esters thereof;

(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).

(c) A committee established under section 4 of the Medicines Act 1968 by virtue of the Medicines (Veterinary Products Committee) Order 1970 (S.I. 1970/1304).

“Hexoestrol” means 4,4'-(1,2-diethylethylene)diphenol and salts and esters thereof;

“Stilbenes” means substances which consist wholly of any of the following:—

- (a) Benzestrol,
- (b) Dienoestrol,
- (c) Hexoestrol, or
- (d) Stilboestrol;

“Stilboestrol” means (*E*)- α,β -diethylstilbene-4,4'-diol and salts and esters thereof;

“Thyrostatic substances” means anti-thyroid substances with a depressant effect on thyroid activity and thyroid hormone production for use by administration to animals to increase their bodyweight.

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 the numbered paragraphs in Column 1 of the Schedule 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 sections 62(1)(a), 62(2) to (7) and 67 of Part III of the Act, and the provisions contained in Part VIII of the Act shall have effect in relation to each of those substances in the circumstances set out in Column 2 of the said Schedule, as those provisions have effect in relation to medicinal products.

Norman Fowler,
Secretary of State for Social Services.

16th March 1982.

Nicholas Edwards,
Secretary of State for Wales.

11th March 1982.

George Younger,
Secretary of State for Scotland.

4th March 1982.

In Witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 2nd March 1982.



Peter Walker,
Minister of Agriculture, Fisheries and Food.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland this 22nd day of March 1982.



N. Dugdale,
Permanent Secretary.

Sealed with the Official Seal of the Department of Agriculture for Northern Ireland this 19th day of March 1982.



J. A. Young,
Permanent Secretary.

SCHEDULE

Article 3

Column 1	Column 2
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	Circumstances in which the order applies to the substances referred to in Column 1
1. Stilbenes 2. Thyrostatic substances ...	When sold or supplied for use as an ingredient in the manufacture of a medicinal product for use by being administered to animals.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order extends the provisions contained in sections 62 (except for the provisions contained in section 62(1)(b)) and 67 of the Medicines Act 1968, and the provisions contained in Part VIII of that Act, concerning, in relation to medicinal products, the prohibition of the sale, supply or importation of such products, offences and certain miscellaneous matters, so that those provisions will also relate to stilbenes and thyrostatic substances in the circumstances specified in the Schedule to the Order. The extension of those provisions will enable the implementation in part of Council Directive 81/602/EEC (O.J. No. L222, 7.8.81, p.32) concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, by an order made under section 62 of the Act as so extended.

SI 1982/425
ISBN 0-11-026425-8

