STATUTORY INSTRUMENTS

1973 No. 367

MEDICINES

The Medicines (Extension to Antimicrobial Substances) Order 1973

Laid before Parliament in draft

Made - - -

1st March 1973

Coming into Operation

2nd April 1973

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 Secretary of State for Northern Ireland and the Minister of Agriculture, Fisheries and Food, acting jointly, in exercise of their powers under subsections (1)(b) and (2) of section 105 of the Medicines Act 1968(a) (as having effect subject to the provisions of Article 2(2) of and Schedule 1 to the Transfer of Functions (Wales) Order 1969(b) and section 1(1)(a) of the Northern Ireland (Temporary Provisions) Act 1972(c)) 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, and after having taken into account the advice of the Medicines Commission, hereby make the following order, a draft of which has been laid before Parliament and has been approved by resolution of each House of Parliament:—

Citation, commencement and interpretation

- 1.—(1) This order may be cited as the Medicines (Extension to Antimicrobial Substances) Order 1973 and shall come into operation on 2nd April 1973.
 - (2) In this order, unless the context otherwise requires—
 "the Act" means the Medicines Act 1968;

"antimicrobial properties" means the capacity to inhibit the growth of, or to destroy bacteria and other micro organisms whether in vitro or in vivo;

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

⁽a) 1968 c. 67.

⁽b) S.I. 1969/388 (1969 I, p. 1070).

⁽c) 1972 c. 22.

- (3) Except in so far as the context otherwise requires, any reference in this order to any enactment shall be construed as a reference to that enactment, amended or extended by any other enactment.
- (4) The Interpretation Act 1889(a) applies for the purposes of the interpretation of this order as it applies for the interpretation of an Act of Parliament.

Application of specified provisions of the Act to certain classes of substances

- 2.—(1) Subject to the provisions of paragraphs (2) and (3) of this Article, the classes of substances set out in the Schedule to this order are hereby specified as being classes of substances which are not in themselves medicinal products but in relation to which it appears to the Ministers that the conditions specified in paragraph (b) of section 105(1) of the Act are fulfilled in relation to all substances falling within those classes and it is hereby directed that, subject to such exceptions and modifications as are specified in paragraph (4) of this Article, the following provisions of the Act, that is to say Part I, section 6, section 7(1), (2) and (3), section 15(1) and (2), section 16(1), section 18, section 19(1)(a), sections 20 to 22, section 24, section 28(1), (2), (3)(a) to (3)(d), (3)(f), (3)(g) and (7), sections 29 and 30, sections 44 to 50, section 62, sections 66 to 68, Part V, section 92, section 93(2), (4) and (5)(b), section 95, section 97, and Part VIII shall have effect in relation to such classes of substances as those provisions have effect in relation to medicinal products.
- (2) The preceding paragraph of this Article shall not apply to any substance specified in any order made under section 104 or section 105 of the Act which is for the time being in force and which directs that Part II of the Act shall have effect in relation to such substances as that Part has effect in relation to a medicinal product.
- (3) Those provisions of Part II of the Act, which in paragraph (1) of this Article are directed to have effect in relation to the classes of substances to which that paragraph relates as those provisions have effect in relation to medicinal products, shall not have such effect in relation to a substance which falls within any of those classes which is incorporated in any animal feeding stuff in the circumstances described in section 42(1) of the Act.
- (4) The following provisions of the Act shall have effect in relation to any classes of substances to which this Article applies as aforesaid subject to the exceptions and modifications hereinafter specified:—
 - (a) in section 7(2) the words "and in circumstances to which this subsection applies" shall be omitted;
 - (b) in section 16(1) all words after the words "the first appointed day" shall be omitted, and section 16(1), as so modified, shall have effect in relation to any classes of substances to which this order applies where an order under that subsection is made which relates specifically to any classes of substances to which this order relates or to any substances falling within any such classes and which specifies a day, referred to as "the relevant appointed day", and any reference in the Act to "the first appointed day" in any provisions of the Act which by virtue of this Article are to have effect in relation to any classes of substances to which

this order relates, or to any substances falling within any such classes shall, in their application to such classes or substances, be construed as referring to the relevant appointed day which in relation to that class or substance is the relevant appointed day;

- (c) in section 28(3)(g) for the word "administered" there shall be substituted the word "used";
- (d) in Part VIII sections 104, 105, 117, 120, 130 and 131 shall be omitted.

Keith Joseph,
Secretary of State for Social Services.

22nd February 1973.

Peter Thomas, Secretary of State for Wales.

26th February 1973.

Gordon Campbell, Secretary of State for Scotland.

27th February 1973.

W. S. I. Whitelaw, Secretary of State for Northern Ireland.

28th February 1973.

In witness whereof the official seal of the Minister of Agriculture, Fisheries. and Food is hereunto affixed on 1st March 1973.

(L.S.) Joseph Godber,
Minister of Agriculture, Fisheries and Food.

Article 2(1)

SCHEDULE

Classes of Substances fulfilling the Conditions Contained in Section 105(1)(b) and (2) of the act

Substances which are not medicinal products, which are or contain:—

- 1. any of the substances commonly known as antibiotics being:—
- (a) substances synthesized by bacteria, fungi or protozoa which have antimicrobial properties, and derivatives of such substances possessing such properties,
- (b) substances which are synthesized in any other way and are identical with any substance described in sub-paragraph (a), of this paragraph,
- (c) any salt of any of the substances described in sub-paragraphs (a) and (b), of this paragraph;

- 2. any other substances which possess antigenic properties similar to the antigenic properties of any of the substances described in paragraph 1 of this Schedule;
- 3. sulphanilamide (being p-aminobenzenesulphonamide) or any derivative of sulphanilamide which possesses antimicrobial properties, and any salt of any such substance; or
- 4. any derivative of the nitrofurans which possesses antimicrobial properties, and any salt of any such derivative.

EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order extends certain specified provisions of the Medicines Act 1968 concerning such matters as the holding of licences, the provision of information, the commission of offences, the prohibition of sale, supply or importation, and the promotion of sales to the classes of substances set out in the Schedule to this Order, so that those provisions, subject to certain exceptions and modifications, will also apply to those classes of substances as those provisions apply to medicinal products.

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