

1978 No. 1004

MEDICINES

The Medicines (Radioactive Substances) Order 1978

Laid before Parliament in draft.

Made - - - - 17th July 1978

Coming into Operation 1st January 1979

The Secretaries of State respectively concerned with health in England, in Wales and in Scotland and the Department of Health and Social Services for Northern Ireland, acting jointly, in exercise of powers conferred by section 104(1) 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 order, and after taking 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 (Radioactive Substances) Order 1978 and shall come into operation on 1st January 1979.

(2) In this order, unless the context otherwise requires—

“the Act” means the Medicines Act 1968;

“radioactive substance” means any substance that contains one or more radionuclides of which the activity or the concentration cannot be disregarded as far as radiation protection is concerned;

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 provision of any enactment shall be construed as a reference to that provision as amended or extended by any enactment or instrument and as including a reference to any provision which may re-enact or replace it.

(4) The rules for the construction of Acts of Parliament contained in the Interpretation Act 1889(c) 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.

(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), and in the case of the Department of Health and Social Services for Northern Ireland 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) 1889 c. 63.

Application of specified provisions of the Act to certain substances or articles consisting of or containing radioactive substances

2.—(1) For the purposes of section 104(1) of the Act, the articles or substances described in the Schedule to this order are hereby specified as being articles or substances appearing to the Health Ministers to be articles or substances which are not medicinal products but are manufactured, sold, supplied, imported or exported for use wholly or partly for a medicinal purpose and it is hereby directed that, subject to the modification specified in paragraph (2) of this Article, the following provisions of the Act, that is to say the provisions contained in Part I, sections 60 and 67(2) and (4) and Part VIII shall have effect in relation to such articles or substances as those provisions have effect in relation to medicinal products.

(2) In relation to any apparatus as is described in paragraph 3 of the Schedule to this order, section 130(9) of the Act (definition of “administer”) shall have effect as if the definition included the exposure of the body or any part of the body to the neutrons emitted by the apparatus.

David Ennals,

Secretary of State for Social Services.

10th July 1978.

John Morris,

Secretary of State for Wales.

12th July 1978.

Bruce Millan,

Secretary of State for Scotland.

13th July 1978.

Sealed with the official seal of the Department of Health and Social Services for Northern Ireland this 17th day of July 1978.

(L.S.)

N. Dugdale,

Permanent Secretary.

Article 2

SCHEDULE

1. Interstitial and intracavitary appliances (other than nuclear powered cardiac pacemakers) which contain or are to contain a radioactive substance sealed in a container (otherwise than solely for the purpose of storage, transport or disposal) or bonded solely within material and including the immediate container or bonding that are designed to be inserted into the human body or body cavities.

2. Surface applicators, that is to say plates, plaques and ophthalmic applicators which contain or are to contain a radioactive substance sealed in a container (otherwise than solely for the purpose of storage, transport or disposal) or bonded solely within material and including the immediate container or bonding that are designed to be brought into contact with the human body.

3. Any apparatus capable of administering neutrons to human beings when the neutrons are administered in order to generate a radioactive substance in the person to whom they are administered for the purpose of diagnosis or research.

4. Other substances or articles (not being an instrument, apparatus or appliance) which consist of or contain or generate a radioactive substance and which—

- (a) consist of or contain or generate that substance in order, when administered, to utilise the radiation emitted therefrom, and
 - (b) are manufactured, sold or supplied for use wholly or mainly by being administered to one or more human beings solely by way of a test for ascertaining what effects it has when so administered.
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EXPLANATORY NOTE

(This Note is not part of the Order.)

This Order extends the application of specified provisions of the Medicines Act 1968 to certain articles and substances that are, contain or generate radioactive substances. These provisions include section 60 of that Act which enables regulations to be made prohibiting the sale, supply or administration of medicinal products specified in the regulations except by practitioners holding a certificate issued for the purposes of section 60. The Order also modifies the definition of "administer" for the purposes of the order.

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