STATUTORY INSTRUMENTS

1992 No. 605

MEDICINES

The Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992

Made - - - -	*9th March 1992*
Laid before Parliament	*10th March 1992*
Coming into force in accordance with regulation 1(1)	
for certain purposes	*11th March 1992*
for all other purposes	*3rd April 1992*

The Secretary of State in exercise of powers conferred by section 2(2) of the European Communities Act 1972(**1**), being designated for the purposes of section 2(2) of that Act in respect of radioactive substances and the emission of ionising radiations(**2**) hereby makes the following regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992 and shall come into force—

(a) for the purpose of making Regulations under section 18 of the Act (including that section as applied by section 24(4) of the Act), on 11th March 1992; and

(b) for all other purposes, on 3rd April 1992.

(2) In these Regulations, unless the context requires otherwise—

"the Act" means the Medicines Act 1968(**3**);

"generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

"kit" means any preparation to be reconstituted or combined with radionuclides in a final radiopharmaceutical, usually prior to its administration;

(**1**) 1972 c. 68.
(**2**) S.I. 1977/1718.
(**3**) 1968 c. 67.

"precursor" means a radionuclide produced for the radio-labelling of another substance prior to administration, other than a radionuclide which is incorporated in, or produced from, a generator, or is included in a radiopharmaceutical;

"radiopharmaceutical" means any medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

"radiopharmaceutical-associated product" means a generator, kit or precursor which is not itself a medicinal product;

and any other expression used in these Regulations which is defined in the Act shall, unless the context requires otherwise, bear the meaning which it bears in the Act.

Application of the Act to radiopharmaceutical-associated products

2.—(1) Subject to paragraph (2) of this regulation, the provisions of the Act specified in column 1 of the Schedule to these Regulations shall have effect in relation to radiopharmaceutical-associated products as they have effect in relation to medicinal products.

(2) Where in relation to any provision specified in column 1 of the Schedule to these Regulations there is an entry in column 2 of that Schedule, that provision shall, in its application to radiopharmaceutical-associated products, have effect subject to the modification specified in that entry.

(3) For the purposes of Part I, sections 108 to 115,(**4**) 118, 119 and 125(**5**) of, and Schedule 3 to, the Act(**6**)—

(a) the provisions of the Act applied by paragraphs (1) and (2) of this regulation to radiopharmaceutical-asociated products, and the provisions of any regulations made under any of those provisions as so applied, shall be treated as provisions of, respectively, the Act and regulations made under it;

(b) any offence against any of those provisions shall be treated as an offence under the Act; and

(c) any reference in any of those provisions to medicinal products shall be treated as including a reference to radiopharmaceutical-associated products.

(4) The provisions of sections 1 and 132(**7**) of the Act (definitions) shall have effect in relation to radiopharmaceutical-associated products in so far as they relate to the provisions of the Act specified in column 1 of Schedule 1 to these Regulations.

(**4**) Sections 108 and 109 have been amended. Relevant amendments have been made by Schedule 3 to the Food Safety Act 1990 (c. 16). Section 110 has been amended by S.R. & O. (N.I.) 1973/211. Section 114 has been amended. Criminal penalties under the 1968 Act have been increased. Fines on summary conviction of offences triable either way under statutes passed before, or in the same Session as the Criminal Law Act 1977 (c. 45) were standardised in England and Wales by section 28 of the Criminal Law Act 1977, in Scotland by section 289B of the Criminal Procedure (Scotland) Act 1975 (c. 21), and in Northern Ireland by article 6 of the Fines and Penalties etc. (Northern Ireland) Order 1984 (S.I. 1984/703). "The statutory maximum" and "the prescribed sum" are now both £2000. Levels on the standard scale are presently fixed by the Criminal Penalties etc. (Increase) Order 1984 (E & W) (S.I. 1984/447), the Increase of Criminal Penalties etc. (Scotland) Order 1984 (S.) (S.I. 1984/526) and by the Criminal Penalties etc. (Increase) Order (Northern Ireland) 1984 (S.R. 1984/253). These instruments respectively amend section 37(2) and section 74 of the Criminal Justice Act 1982 (c. 48), sections 289B(6) and 289G(2) of the Criminal Procedure (Scotland) Act 1975 and articles 4 and 5 of the Fines and Penalties etc. (Northern Ireland) Order 1984. Section 289B was inserted by paragraph 5 of Schedule 11 to the Criminal Law Act 1977, and section 289G by section 54 of the Criminal Justice Act 1982.

(**5**) Section 125(1) has been amended by Schedule 7 to the Magistrates Courts Act 1980 (c. 43), subsection (2) has been amended by section 460(1)(b) of the Criminal Procedure (Scotland) Act 1975 and subsection (6) by S.R. & O (N.I.) 1973/211.

(**6**) Schedule 3 has been amended by S.I. 1968/1699, S.R. & O (N.I.) 1973/211, the Food Act 1984 (c. 30), S.I. 1989/846, the Food Safety Act 1990 (c. 16) and S.I. 1991/762.

(**7**) Section 132 has been amended. Relevant amendments have been made by Schedule 3 to the Food Safety Act 1990.

Transitional provision

3. These Regulations shall not render unlawful anything done before 31st December 1992 in relation to a radiopharmaceutical-associated product if—

(a) products of that description were sold or supplied, or procured to be sold, supplied, manufactured or assembled, at any time before 3rd April 1992; and

(b) products of that description were effectively on the market in the United Kingdom immediately before 3rd April 1992.

Signed by authority of the Secretary of State for Health.

Virginia Bottomley
Minister of State,
Department of Health

9th March 1992

SCHEDULE Regulation 2(1) and (2)

(1) *Provision of the Medicines Act 1968*	(2) *Modification*
section 6	as though in subsection (1) the words "and certificates" were omitted
section 7(1)(a), (2), (4), (5) and (6)(**8**)	as though for the words ", supply or export", ", supply or exportation" and ", supplying or exporting" there were substituted throughout the section "or supply", "or supply" and "or supplying" respectively; as though in subsection (5) for paragraphs (a) and (b) there were substituted "is responsible for the placing of the product on the market in the United Kingdom"
section 14	as though for "sections 7 and 8" there were substituted "section 7"
section 18(**9**)	as though in subsection (1) there were added at the end "for the purpose of implementing Directive 89/343/EEC"(**10**)
section 19(1) to (3)	
sections 20(**11**) to 22	
section 24(**12**)	
section 28(1), (2), (3) and (7)(**13**) as though in subsection (3) in paragraph (e) the words "manufactured, assembled or", and paragraphs (f), (i) and (j) were omitted	
sections 29 and 30	
section 44(1) to (3)	as though in subsection (1) the words from "(including a licence of right)" to "section 37(4) of this Act)" were omitted; as though in subsection (2) the words ", or of a clinical trial certificate or animal test certificate," were omitted; and as though in subsection (3) the words from the beginning to "subsection 4 of this section" and the words "or certificate" were omitted
section 45(1), (2) and (6) to (9)(**14**)	as though in subsection (1) the words ", section 8, section 31, section 32, section 34 or

(**8**) Section 7 was amended by S.I. 1977/1050 and 1983/1724.
(**9**) Section 18 was amended by S.I. 1983/1724.
(**10**) OJ No. L142, 25.5.1989, p. 16.
(**11**) Section 20 was amended by S.I. 1977/1050.
(**12**) Section 24 was amended by S.I. 1977/1050.
(**13**) Relevant amendments were made to section 28 by S.I. 1975/1169.
(**14**) See footnote relating to regulation 2(3) concerning the amendment of section 114 supra.

(1) *Provision of the Medicines Act 1968*	(2) *Modification*
	section 40" and "or animal feeding stuff" were omitted and for "any of those sections" there were substituted "that section"; as though in subsection (2) the words "or animal feeding stuff", ", section 31, section 32 or section 40" and "or feeding stuff" were omitted; and as though in subsection (8) for "subsections (1) to (6)" there were substituted "subsections (1), (2) or (6)"
section 46(1)(**15**)	as though the words "or of a clinical trial certificate or animal test certificate" and "or certificate" were omitted and for the words from "any substance or article" to "product manufactured or assembled)" there were substituted "a medicinal product which has been manufactured or assembled"
section 47(1) to (4), (6) and (7)	as though in subsection (1) after "Ministers may" there were inserted "for the purpose of implementing Directive 89/343/EEC"; as though in subsection (2) the words "any clinical trial certificate or animal test certificate" were omitted; and as though in subsection (4) the words ", or any clinical trial certificate or animal test certificate," and "or certificate", in both places where they occur, were omitted; and as though in subsection (6) the words "or certificate", in both places where they occur, were omitted
section 50	as though after "any description" there were inserted "to another member State of the European Economic Community"
section 86	as though in subsection (1), for the words "for any of the purposes specified in section 85(2) of this Act" there were substituted "for the purpose of implementing Directive 89/343/EEC"
section 91(**16**)\	as though in subsection (1) for the words ", section 85(5), section 86(3) or section 90(2)" there were substituted "section 86(3)";

(**15**) Section 46 was amended by Schedule 1 to the Animal Health and Welfare Act 1984 (c. 26). SCHEDULE — continued
(**16**) See footnote relating to regulation 2(3) concerning the amendment of section 114 supra.

(1) *Provision of the Medicines Act 1968*	(2) *Modification*
	as though in subsection (2) for the words from "section 85(3)" to "section 90(1)" there were substituted "section 86(2)"; and as though in subsection (3) for "sections 85 to 87" there were substituted "section 86" and the words from "and any power to make regulations conferred by those sections" to the end of the subsection were omitted
section 107	as though in subsection (1) there were omitted the words "or of a Minister under section 75 of this Act" and "or certificate"; as though in subsection (4) the words "or certificate" were omitted in all three places where they occur
section 121	as though in subsection (4) for the words from "section 63" to the end there were substituted "section 86 and the provisions of any regulations made under it"
section 122	as though in subsection (2) for the words from "the following provisions" to the end there were substituted "the provisions of section 86 and of any regulations made under it"
section 124(1) and (3)	
section 126(4)	as though there were omitted the words "or subsection (3)", ", or so much of subsection (2) of section 90 of this Act as relates to leaflets", "or of animal feeding stuffs in which medicinal products have been incorporated" and paragraph (b) and the word "or" immediately preceding it
section 127	
section 128	
section 129(1) to (3) and (5)	as though in subsection (2) the words "orders or" and the words from "or any order or regulations made in relation to Northern Ireland" to "section 120 of this Act" were omitted; and as though in subsection (3) paragraphs (a) and (b) were omitted and in paragraph (c) the words ", other than section 79," were omitted
sections 133 and 134(**17**)	

(**17**) Section 134(2) was repealed by section 41 of, and Part I of Schedule 6 to, the Northern Ireland (Constitution) Act 1973 (c. 36). Section 37(1) of that Act abolished the Joint Exchequer Board and transferred its functions to the Treasury.

(1) *Provision of the Medicines Act 1968*	(2) *Modification*
Schedule 2	as though in paragraph 8 sub-paragraph (a) were omitted; as though in paragraph 12 the words "if the licence is a product licence," were omitted; as though in paragraph 13 the words "in the case of a product licence)" were omitted; and as though the provisions of section 21 so far as applied by paragraph 16 were incorporated in Schedule 2

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations apply, with necessary modifications, certain provisions of the Medicines Act 1968 (notably those relating to product licences) to radiopharmaceutical kits, generators and precursors, thereby implementing in part Council Directive 89/343/EEC relating to radiopharmaceuticals (OJ No. L142 25.5.1989 p. 16) (regulation 2 and the Schedule). They include transitional protection until 31st December 1992 for products on the market in the United Kingdom immediately before 3rd April 1992 (regulation 3).