STATUTORY INSTRUMENTS

1992 No. 2844

MEDICINES

The Medicines (Exemption from Licensing) (Radiopharmaceuticals) Order 1992

Made - - - -	*12th November 1992*
Laid before Parliament	*20th November 1992*
Coming into force - -	*11th December 1992*

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 the powers conferred upon them by section 15(1) of the Medicines Act 1968(**1**) or, as the case may be, those conferred by that provision and now exercisable by them(**2**) and of all other powers enabling them in that behalf, after consultation with such organisations as appear to them to be representative of interests likely to be substantially affected by this Order(**3**), hereby make the following Order:

Citation, interpretation and commencement

1.—(1) This Order may be cited as the Medicines (Exemption from Licensing) (Radiopharmaceuticals) Order 1992 and shall come into force on 11th December 1992.

(2) In this Order—

"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;

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

(**1**) 1968 c. 67. The expressions "the appropriate Ministers" and "the Health Ministers" are defined in section 1 of that Act as amended by S.I.1969/388.

(**2**) In the case of the Secretaries of State concerned with health in England and 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).

(**3**) See section 129(6) of the Medicines Act 1968.

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

Exemption for certain radiopharmaceuticals assembled at the time of administration

2. Section 7 of the Medicines Act 1968 (requirements as to product licences) shall not apply to anything done in relation to a radiopharmaceutical for human use—

(a) which is prepared at the time at which it is intended to be administered; and

(b) which is prepared, in accordance with the manufacturer's instructions and by the person by whom it is to be administered, exclusively from a kit, generator or precursor (or from more than one of these) in respect of which a product licence is in force; and

(c) the administration of which is not a contravention of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978(**4**).

Signed by authority of the Secretary of State for Health

Brian Mawhinney
Minister,
12th November 1992 Department of Health

David Hunt
12th November 1992 Secretary of State for Wales

Fraser of Carmyllie
12th November 1992 Minister of State Scottish Office

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 12th November 1992

L.S.

F. A. Elliott
Permanent Secretary

(**4**) S.I. 1978/1006.

EXPLANATORY NOTE

(This note is not part of the Order)

This Order exempts from the restrictions imposed by section 7 of the Medicines Act 1968 (product licences) a radiopharmaceutical product for human use if it is prepared from a kit, generator or precursor which itself has a product licence, where the radiopharmaceutical product is prepared at the time of its administration and where that administration is not a contravention of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978.

This Order implements in part article 2 of Council Directive 89/343/EEC (OJNo. L142 25.5.89 p.16) which extends the scope of Council Directives 65/65/EEC (OJ No. 22 9.2.1965 p.369/65) and 75/319/EEC (OJ No. L147 9.6.1975 p.13) and which lays down additional provisions for the control of radiopharmaceuticals.