STATUTORY INSTRUMENTS

1995 No. 2147

MEDICINES

The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995

Made - - - -	*15th August 1995*
Laid before Parliament	*16th August 1995*
Coming into force - -	*11th September 1995*

The Secretary of State, in exercise of the powers conferred upon him by section 2(2) of the European Communities Act 1972(**1**), being designated(**2**) for the purposes of that section in relation to medicinal products and safety measures in regard to radioactive substances and the emission of ionising radiation, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medicines (Administration of Radioactive Substances) Amendment Regulations 1995 and shall come into force on 11th September 1995.

Amendments to Regulations

2.—(1) The Medicines (Administration of Radioactive Substances) Regulations 1978(**3**) are amended in accordance with the following paragraphs.

(2) In regulation 1 (citation, commencement and interpretation) in paragraph (2)—

(a) after the definition of "the Act" there is inserted the following definition—

> ""directions" in relation to any directions given on or after 11th September 1995 means directions in writing;";

(b) after the definition of "medicinal product" there is inserted the following definition—

> ""notice" in relation to any notice served on or after 11th September 1995 means notice in writing;".

(3) In regulation 2 (control of administration) after paragraph (3) there is inserted—

> "(4) A doctor or dentist who holds a certificate which specifies both—

(**1**) 1972 c. 68.
(**2**) S.I. 1972/1811 and 1977/1718.
(**3**) S.I. 1978/1006.

(a) the persons to whom any descriptions or classes of radioactive medicinal product may be administered, and

(b) the descriptions or classes of radioactive medicinal product which may be so administered,

and any person acting in accordance with the directions of such a doctor or dentist, shall not under that certificate administer any such description or class of radioactive medicinal product except for the purpose of diagnosis or treatment of a person specified in that certificate.".

(4) In regulation 4 (issue of certificates)—

(a) in paragraph (1)(b) after the word "administered" there are added the words "and, where it is proposed to administer any of those descriptions or classes of radioactive medicinal product for the purpose of diagnosis or treatment, particulars relating to the persons to whom they may be administered";

(b) after paragraph (2)(b)(iii) there is inserted—

"(iiiA) where the application relates to a proposal to administer a description or class of radioactive medicinal product to particular persons, information sufficient to enable those persons to be identified,";

(c) after paragraph (2) there is inserted—

"(3) Where the Health Ministers are considering an application which—

(a) is made by a doctor or dentist who holds a certificate which specifies descriptions or classes of radioactive medicinal products other than those specified in the application; and

(b) in accordance with a requirement under paragraph (2)(b)(iv) contains information relating to particular named persons to whom it is proposed to administer a radioactive medicinal product for the purpose of diagnosis or treatment,

nothing in paragraph (2)(c) requires the Health Ministers, for the purposes of granting a certificate which specifies only one or more of those persons as persons to whom a description or class of radioactive medicinal products may be administered, to reconsider a matter previously considered by them in connection with the grant of the certificate already held by the applicant.".

(5) In regulation 6 (suspension, revocation and variation of certificates) after paragraph (2) there is inserted—

"(3) Without prejudice to any requirement of regulation 7 of these Regulations as to the service of notices, where in the exercise of any power conferred by this regulation the Health Ministers suspend, revoke or vary a certificate, they shall serve notice on the holder of the certificate giving particulars of the suspension, revocation or variation and of the reasons for their decision to suspend, revoke or vary the certificate.".

(6) In regulation 7 (hearings and written representations)—

(a) at the beginning of paragraph (1) there is inserted "Subject to paragraph (5) below,";

(b) after paragraph (4) there is inserted—

"(5) This regulation shall not apply to a proposal to vary a certificate so as to include any additional description or class of radioactive medicinal product which was specified in, or which falls within a class which was specified in, the application for that certificate.".

(7) After regulation 7 there is added—

"**Application of provisions of the Act**

8.—(1) Section 6(2) of the Act shall apply to functions conferred on the Health Ministers by these Regulations as it applies to functions conferred on the licensing authority by or under the Act.

(2) In so far as these Regulations are not made under section 60 of the Act they shall be treated for the purposes of section 67(2) and (4) and Part VIII of the Act, and of any Order or regulations made under the Act, as though they were regulations made under section 60 of the Act and any certificate issued under these Regulations shall be treated as being issued for the purposes of that section.".

Stephen Dorrell
One of Her Majesty's Principal Secretaries of State,
Department of Health

15th August 1995

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Administration of Radioactive Substances) Regulations 1978 ("the 1978 Regulations"), which prohibit the administration of radioactive medicinal products except by doctors or dentists holding a certificate issued by the Health Ministers (as defined in the Medicines Act 1968) or persons acting under the directions of such a doctor or dentist. The 1978 Regulations also make provision for the grant, duration, renewal, suspension, variation and revocation of certificates, for the appointment of an advisory committee (the Administration of Radioactive Substances Advisory Committee) and for various procedural matters.

The 1978 Regulations were made in pursuance of Council Directive 76/579/Euratom and implement Article 5(a) of that Directive, which provides that a system of prior authorization must be applied in respect of the administration of radioactive substances to persons for the purposes of diagnosis, treatment or research.

These Regulations make provision for—

(a) directions and notices to be given in writing (regulation 2(2));

(b) the grant of further certificates, to authorise the administration of descriptions or classes of radioactive substances for the purpose of diagnosis or treatment of persons specified in those certificates, to those doctors and dentists who already hold certificates (regulation 2(3) and (4));

(c) the administration of descriptions and classes of radioactive medicinal products under those further certificates to particular patients (regulation 2(3));

(d) the giving of written particulars to a doctor or dentist about the suspension, revocation or variation of his certificate (regulation 2(5));

(e) the cessation of certain procedural requirements where a certificate is varied to include a description or class of radioactive medicinal product which was included in the application for that certificate (regulation 2(6));

(f) the functions of Health Ministers under the 1978 Regulations to be performed by any one of them or by any two or more of them acting jointly (regulation 2(7));

(g) the application of section 67(2) and (4) and Part VIII of that Act (provisions which relate to offences etc.) to the 1978 Regulations (also regulation 2(7)).