

amended by SI 1995/2147

STATUTORY INSTRUMENTS

1978 No. 1006

MEDICINES

**The Medicines (Administration of Radioactive Substances)
Regulations 1978**

<i>Made</i>	- - -	17th July 1978
<i>Laid before Parliament</i>		27th July 1978
<i>Coming into Operation</i>		
<i>Regulations 1 and 3</i>		1st January 1979
<i>All other Regulations</i>		1st July 1980

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 60 of the Medicines Act 1968(a) and now vested in them(b) and the said Secretaries of State together with the Secretary of State for Northern Ireland being designated(c) for the purposes of section 2(2) of the European Communities Act 1972(d) in relation to medicinal products and safety measures in regard to radioactive substances and the emission of ionising radiation, acting jointly, in exercise of powers conferred on them by the said section 2(2) and in each case in exercise 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 regulations, and after consulting and taking into account the advice of the Medicines Commission, hereby make the following regulations:—

Citation, commencement and interpretation

1.—(1) These regulations may be cited as the Medicines (Administration of Radioactive Substances) Regulations 1978 and shall come into operation as respects regulations 1 and 3 on 1st January 1979 and as respects all other regulations on 1st July 1980.

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

“the Act” means the Medicines Act 1968;

(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) S.I. 1972/1811 and S.I. 1977/1718.

(d) 1972 c. 68.

[H78-608]

“medicinal product” includes any substance or article specified in the Medicines (Dental Filling Substances) Order 1975(a) or in the Medicines (Radioactive Substances) Order 1978(b);

“purpose” in relation to the administration of a radioactive medicinal product means the purpose of diagnosis, treatment or research;

“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;

“radioactive medicinal product” means a medicinal product which is, which contains or which generates a radioactive substance and which is, contains or generates that substance in order, when administered, to utilize the radiation emitted therefrom;

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

(3) Except in so far as the context otherwise requires, any reference in these regulations to any enactment, order or regulations shall be construed as a reference to that enactment or order or to those regulations, as the case may be, as amended, extended or re-enacted by any other enactment, order or regulations.

(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 these regulations as they apply for the purposes of the interpretation of an Act of Parliament.

Control of administration

2.—(1) No person shall administer to a human being (otherwise than to himself) any radioactive medicinal product unless he is a doctor or a dentist holding a certificate issued by the Health Ministers for the purposes of section 60 of the Act in respect of radioactive medicinal products (hereinafter referred to as a “certificate”) or a person acting in accordance with the directions of such a doctor or dentist.

(2) Where a certificate is issued to a doctor or a dentist specifying particular descriptions or classes of radioactive medicinal products the doctor or dentist holding the certificate and any person acting in accordance with his directions shall not administer any radioactive medicinal product unless it is a radioactive medicinal product of a description or falling within a class specified in the certificate.

(3) Where, in relation to a radioactive medicinal product specified in a certificate, the purpose for which the administration is authorised is also specified, the doctor or dentist holding the certificate and any person acting in accordance with his directions shall not administer the said radioactive medicinal product unless it is for the purpose so specified.

Advisory committee

3.—(1) The Health Ministers may appoint a committee to be called the Administration of Radioactive Substances Advisory Committee to advise them with respect to the grant, renewal, suspension, revocation and variation of certificates in those cases where, in the opinion of the Health Ministers, certificates should not be granted, renewed, suspended or varied without the

(a) S.I. 1975/533.

(b) S.I. 1978/1004.

(c) 1889 c. 63.

advice of the said committee and generally in connection with the system of prior authorisation envisaged by Article 5(a) of Council Directive 76/579/Euratom(a).

(2) The members of the Administration of Radioactive Substances Advisory Committee, of whom a majority shall be doctors, shall be appointed by the Health Ministers and shall include persons appearing to the Health Ministers to have wide and recent experience appropriate and relevant to advising on the administration of radioactive medicinal products and related scientific and radiological safety matters.

(3) The Health Ministers shall appoint one of the members of the Administration of Radioactive Substances Advisory Committee, being a doctor, to be chairman of the said committee.

(4) The provisions of regulations made under paragraph 1(a) of Schedule 1 to the Act in respect of committees established under section 4 of the Act shall apply to the Administration of Radioactive Substances Advisory Committee as they apply to such committees.

Issue of certificates

4.—(1) A certificate may specify—

- (a) particular descriptions or classes of radioactive medicinal products, and
- (b) in relation to particular descriptions or classes of radioactive medicinal products, the purpose for which they may be administered.

(2) The Health Ministers may grant to any doctor or dentist a certificate if—

- (a) an application for the grant of a certificate has been made—
 - (i) in writing,
 - (ii) signed by the applicant, and
 - (iii) where the Health Ministers have from time to time approved the form of application for certificates, in that approved form;
- (b) the application contains the following particulars—
 - (i) the name, address, qualifications and relevant experience of the applicant and the post or position which the applicant holds or is to hold and in which he proposes to administer the radioactive medicinal products specified in the application,
 - (ii) the particular descriptions or classes of radioactive medicinal products the applicant proposes to administer or to have administered and the purpose for which they are to be administered,
 - (iii) information as to the equipment, facilities and staff available to the applicant for the proposed administration of radioactive medicinal products,
 - (iv) such other information as the Health Ministers may reasonably require; and
- (c) they are reasonably satisfied—
 - (i) that the applicant is fitted by reason of his knowledge, experience, competence and skill to hold a certificate and to administer the radioactive medicinal products specified therein,

(a) O.J. No. L187, 12.7.76 p.5.

- (ii) as to the radiation hazards associated with the use of the radioactive medicinal products specified in the application in relation to the purpose for which it is stated they are to be administered, and
- (iii) that the applicant has available to him suitable equipment and facilities and the services of suitably qualified staff to enable him to administer safely the radioactive medicinal products specified in the application.

Duration and renewal of certificates

5.—(1) Subject to paragraph (3) below, a certificate shall remain in force for a period of 5 years or for such shorter period as may be specified in the certificate.

(2) The Health Ministers may renew a certificate—

- (a) if an application for the renewal of the certificate is made in writing to the Health Ministers containing or accompanied by particulars of any changes in the matters stated in the application for the grant of the certificate in respect of which the application for renewal is made, and
- (b) if they remain satisfied as to the matters specified in regulation 4(2)(c) of these regulations.

(3) Where an application for the renewal of a certificate has been duly made the certificate shall not cease to be in force before the Health Ministers have determined the said application.

Suspension, revocation and variation of certificates

6.—(1) The Health Ministers may suspend for such period as they may determine or revoke a certificate on one or more of the following grounds, that is to say—

- (a) that a material change has occurred in relation to any of the matters stated in the application;
- (b) that they are no longer satisfied that the holder of the certificate has available to him either or both of the following—
 - (i) suitable equipment or facilities,
 - (ii) the services of suitably qualified staff.

(2) The Health Ministers may vary a certificate—

- (a) by adding thereto particular descriptions or classes of radioactive medicinal products and the purpose for which they may be administered or, in relation to descriptions and classes of radioactive medicinal products already specified in the certificate, an additional purpose for which they may be administered;
- (b) by deleting therefrom particular descriptions or classes of radioactive medicinal products or the purpose for which such radioactive medicinal products may be administered in both cases if they are no longer satisfied as to the radiation hazards associated with their use and where only one description or one class of radioactive medicinal product is specified in the certificate, the Health Ministers may revoke the certificate.

Hearings and written representations

7.—(1) If the Health Ministers propose—

- (a) to refuse to grant or renew a certificate, or
- (b) to suspend, revoke or vary a certificate

they shall serve notice on the applicant for or the holder of the certificate stating their proposals and the reasons for them and before determining the application or suspending, revoking or varying the certificate as the case may be, if the applicant or the holder of the certificate has within the time allowed notified the Health Ministers of his desire either to be heard or to make representations in writing, the Health Ministers shall afford to the applicant or the holder of the certificate an opportunity of appearing before, and being heard by, a person appointed for the purpose by the Health Ministers or of making representations in writing to the Health Ministers with respect to the proposal.

(2) Where the applicant or the holder of the certificate has availed himself of the opportunity either of being heard by a person appointed for that purpose or of making representations in writing to the Health Ministers and the Health Ministers then determine either—

- (a) to refuse to grant or renew the certificate, or
- (b) to suspend, revoke or vary the certificate

they shall serve on the applicant for or the holder of the certificate, as the case may be, a notice stating the reasons for their decision.

(3) The provisions of subsection (7) of section 21 of the Act shall have effect in relation to a person appointed under paragraph (1) of this regulation as they have effect in relation to a person appointed under subsection (5) of that section.

(4) In this regulation “the time allowed” means the period of twenty-eight days after the service of a notice under paragraph (1) of this regulation or such extended period as the Health Ministers may in any particular case allow.

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.

Roy Mason
Secretary of State for Northern Ireland.

14th July 1978.

Scaled 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.

EXPLANATORY NOTE

(This Note is not part of the Regulations.)

These Regulations prohibit the administration of radioactive medicinal products except by doctors or dentists holding a certificate issued by the Health Ministers in respect of radioactive medicinal products or persons acting under the directions of such a doctor or dentist. The regulations also—

- (1) include provision as to the grant, duration, renewal, suspension, variation and revocation of certificates,
- (2) provide for the appointment of a committee to advise the Health Ministers, and
- (3) provide a procedure enabling applicants for or holders of a certificate to make representations in writing or to be heard by a person appointed before a certificate is refused, suspended, varied or revoked as the case may be.

The regulations are made in pursuance of Council Directive 76/579/Euratom which lays down the revised standards for the health protection of the general public and workers against the dangers of ionising radiation. They implement Article 5(a) of the Directive which provides that a system of prior authorisation must be applied in respect of the administration of radioactive substances to persons for the purposes of diagnosis, treatment or research.

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