

2006 No. 2806

MEDICINES

**The Medicines (Administration of Radioactive Substances)
Amendment Regulations 2006**

<i>Made</i>	- - - -	<i>19th October 2006</i>
<i>Laid before Parliament</i>		<i>26th October 2006</i>
<i>Coming into force</i>	- -	<i>17th November 2006</i>

The Secretary of State and the Department of Health, Social Services and Public Safety, acting jointly, make the following Regulations in the exercise of powers conferred upon them by sections 60(2) and 129(5) of the Medicines Act 1968(a), or, in the case of the Department, the powers conferred by those provisions and now vested in it(b).

In so far as these Regulations are not made under section 60(2) and 129(5) of the Medicines Act 1968, the Secretary of State makes these Regulations in exercise of the powers conferred upon her by section 2(2) of the European Communities Act 1972(c). The Secretary of State has been designated for the purposes of section 2(2) in relation to medicinal products(d).

In accordance with section 129(6) of the Medicines Act 1968, the Secretary of State and the Department of Health, Social Services and Public Safety have consulted such organisations as appear to them to be representative of interests likely to be substantially affected by these Regulations. In accordance with sections 60(7) and 129(7) of that Act, they have consulted and taken into account the advice of the Commission on Human Medicines(e).

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines (Administration of Radioactive Substances) Amendment Regulations 2006 and shall come into force on 17th November 2006.

(2) In these Regulations “the principal Regulations” means the Medicines (Administration of Radioactive Substances) Regulations 1978(f).

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- (a) 1968 c.67. The expression “the Ministers”, which is relevant to the powers being exercised in the making of these Regulations, is defined in section 1 of the Act as amended by Schedule 1 to S.I. 1969/388, paragraph 1(1) of the Schedule to S.I. 1999/3142 and paragraph 2 of Part 1 of Schedule 8 to S.I. 2006/2407; section 60 was amended by paragraph 33 of Part 1 of Schedule 8 to S.I. 2006/2407.
- (b) By virtue of the powers vested in the Minister in charge of that Department by virtue of section 95(5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47), which may now be exercised by the Department by virtue of section 1(8) of, and paragraph 4(1)(b) of the Schedule to, the Northern Ireland Act 2000 (c.1); the Department was renamed by virtue of Article 3(6) of S.I. 1999/283 (N.I.1.).
- (c) 1972 c.68.
- (d) S.I. 1972/181.
- (e) Section 60(7) was amended by paragraph 33(e) of Part 1 of Schedule 8 to S.I. 2005/1094; the expression “the appropriate committee”, which is referred to in section 60(7), is defined in section 4(6) of the Act as substituted by S.I. 2005/1094.
- (f) S.I. 1978/1006, amended by S.I. 1995/2147, 2005/2754 and 2006/2407.

Amendment of regulation 1 of the principal Regulations

2. In regulation 1 of the principal Regulations (citation, commencement and interpretation), in paragraph (2)—

- (a) after the definition of “directions”, insert the following definition—

““medical exposure” has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000(a);” and
- (b) after the definition of “notice”, insert the following definitions—

““operator” has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;

“practitioner” has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000;”

Substitution of regulation 2 of the principal Regulations

3. For regulation 2 of the principal Regulations (control of administration) substitute the following regulation—

“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 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) Paragraph (1) does not apply where the administration of a radioactive medicinal product would result in a medical exposure and the conditions specified in paragraph (3) are satisfied.

(3) The conditions referred to in paragraph (2) are that—

- (a) the medicinal product is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000 which apply to the exposure referred to in paragraph (1);
- (b) that medical exposure has been authorised by a practitioner or, where it is not practicable for a practitioner to authorise the exposure, an operator acting in accordance with written guidelines issued by a practitioner;
- (c) the practitioner is the holder of a certificate; and
- (d) the medicinal product is not a controlled drug.

(4) Where a certificate is issued to a doctor or dentist specifying particular descriptions or classes of radioactive medicinal products—

- (a) the doctor or dentist holding the certificate;
- (b) any person acting in accordance with his directions; and
- (c) an operator acting pursuant to his authorisation of a medical exposure or in accordance with his guidelines,

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.

(5) Where, in relation to a radioactive medicinal product specified in a certificate, the purpose for which the administration is also specified—

- (a) the doctor or dentist holding the certificate;

(a) S.I. 2000/1059, amended by S.I. 2004/1031 and 2006/2523.

- (b) any person acting in accordance with his directions; and
- (c) an operator acting pursuant to his authorisation of a medical exposure or in accordance with his guidelines,

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.

(6) Where a certificate issued to a doctor or dentist specifies both the persons to whom any descriptions or classes of radioactive medicinal product may be administered, and the descriptions or classes of radioactive medicinal product which may be administered—

- (a) the doctor or dentist;
- (b) any person acting in accordance with his directions; and
- (c) an operator acting pursuant to his authorisation of a medical exposure, or in accordance with his guidelines,

shall not under that certificate administer any such description or classes of radioactive medicinal product except for the purpose of diagnosis or treatment of a person specified in that certificate.”

Signed by authority of the Secretary of State for Health

17th October 2006

Andy Burnham
Minister of State,
Department of Health

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety

19th October 2006

Andrew McCormick
Permanent Secretary,
Department of Health, Social Services and Public Safety

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Medicines (Administration of Radioactive Substances) Regulations 1978 (“the principal Regulations”) which restrict the administration of radioactive medicinal products and implement a system of prior authorisation for administration of radioactive substances under Directive 76/579/Euratom^(a) (that Directive is no longer in force; the relevant provisions are now in Directive 96/29/Euratom^(b)).

Regulation 2 of the principal Regulations prohibits administration of radioactive medicinal products except by a doctor or dentist who holds the relevant certificate issued by the Ministers (“the certificate holder”) or by a person acting in accordance with his directions and makes other provisions relating to administration. Regulations 2 and 3 of these Regulations amend the principal Regulations in order to provide that radioactive medicinal products may be administered by a person who is not a certificate holder in the absence of such directions, in specified circumstances, where the administration involves a medical exposure under the Ionising Radiation (Medical Exposure) Regulations 2000 (“the IRME Regulations”). In particular, regulation 3 substitutes a new regulation 2 of the principal Regulations, so as to make provision for persons who are operators under the IRME Regulations to administer radioactive medicinal products. The operator must be acting in accordance with the relevant procedures and protocols under the IRME Regulations. In addition, he must be acting under the authorisation of, or in accordance with guidelines issued by, a person who is a practitioner under those Regulations and also a certificate holder.

A full regulatory impact assessment of the effect that this instrument will have on the costs of business is available from the Medicines and Healthcare products Regulatory Agency, Market Towers, 1 Nine Elms Lane, London SW8 5NQ. Copies of the assessment have been placed in the libraries of both Houses of Parliament.

(a) OJ No. L187, 12.7.1976, p1.

(b) OJ No. L159, 29.6.1996, p1.

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