

SCHEDULE 4

Regulation 21

Consequential amendments

Amendment of the Justification of Practices Involving Ionising Radiation Regulations 2004

1.—(1) The Justification of Practices Involving Ionising Radiation Regulations 2004(1) are amended as follows.

[^{F1}(2) For regulation 21 (saving for medical practices) substitute—

“21. Nothing in regulation 4(5) or 5(3) shall prevent anything permitted under regulation 11 of the Ionising Radiation (Medical Exposure) Regulations 2017 or regulation 11 of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.”.]

Textual Amendments

F1 Sch. 4 para. 1(2) substituted (6.2.2018) by The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 (S.I. 2018/121), regs. 1(2), 2(4)(a)

Commencement Information

I1 Sch. 4 para. 1 in force at 6.2.2018, see **reg. 1**

Amendment of the Human Medicines Regulations 2012

2.—(1) The Human Medicines Regulations 2012(2) are amended as follows.

[^{F2}(2) In regulation 173 (exemption for certain radiopharmaceuticals), for paragraph (d) substitute—

“(d) for administration—

- (i) in England and Wales and Scotland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;
- (ii) in Northern Ireland in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.”.]

[^{F3}(3) For regulation 240 (radioactive medicinal products), substitute—

“Radioactive medicinal products

240.—(1) Regulation 214(2) does not apply to—

- (a) a radioactive substance, administration of which results in a medical exposure; or
- (b) any other prescription only medicine if it is being administered in connection with a medical exposure,

if Conditions A to E are met.

(2) Condition A is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to—

- (a) in England and Wales and Scotland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2017 which apply to the exposure;

(1) S.I. 2004/1769; there are amending instruments but none is relevant.

(2) S.I. 2012/1916 as amended by S.I. 2014/490; there are other amending instruments but none is relevant.

Changes to legislation: There are currently no known outstanding effects for the The Ionising Radiation (Medical Exposure) Regulations 2017, SCHEDULE 4. (See end of Document for details)

- (b) in Northern Ireland, in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 which apply to the exposure.
- (3) Condition B is that the medical exposure has been authorised by—
 - (a) an IRME practitioner; or
 - (b) where it is not practical for an IRME practitioner to authorise the exposure, an operator acting in accordance with written guidelines issued by an IRME practitioner.
- (4) Condition C is that—
 - (a) in England and Wales and Scotland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017;
 - (b) in Northern Ireland, the IRME practitioner mentioned in sub-paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.
- (5) Condition D is that the prescription only medicine is not a product subject to special medical prescription.
- (6) Condition E is that, in the case of a prescription only medicine that is not a radioactive substance, it is specified in the protocols referred to in paragraph (2).
- (7) In this regulation—
 - “IRME practitioner” means—
 - (a) in relation to a medical exposure in England and Wales and Scotland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2017;
 - (b) in relation to a medical exposure in Northern Ireland, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;
 - “medical exposure” has the same meaning—
 - (a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;
 - (b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018;
 - “radioactive substance” has the same meaning—
 - (a) in England and Wales and Scotland as in the Ionising Radiation (Medical Exposure) Regulations 2017;
 - (b) in Northern Ireland as in the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.”.]

Textual Amendments

- F2** Sch. 4 para. 2(2) substituted (6.2.2018) by [The Ionising Radiation \(Medical Exposure\) \(Amendment\) Regulations 2018 \(S.I. 2018/121\)](#), regs. 1(2), **2(4)(b)(i)**
- F3** Sch. 4 para. 2(3) substituted (6.2.2018) by [The Ionising Radiation \(Medical Exposure\) \(Amendment\) Regulations 2018 \(S.I. 2018/121\)](#), regs. 1(2), **2(4)(b)(ii)**

Commencement Information

- I2** Sch. 4 para. 2 in force at 6.2.2018, see [reg. 1](#)

Amendment of the Ionising Radiations Regulations 2017

3.—(1) The Ionising Radiations Regulations 2017(3) are amended as follows.

(2) In regulation 2(1) (interpretation)—

(a) omit the definition of “carers and comforters”;

(b) insert after the definition of “calendar year”—

““carers and comforters” means individuals knowingly and willingly incurring an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone a medical exposure (other than as a carer and comforter);”;

(c) in the definition of “medical exposure”, after paragraph (d), insert—

“(e) carers and comforters;”.

(3) In regulation 3 (application)—

(a) in paragraph (2), omit “33”;

(b) omit paragraph (4).

(4) Omit regulation 33 (equipment used for medical exposure).

(5) In regulation 35(6) (duties of employees)—

(a) in sub-paragraph (a), after “overexposure;” insert “or”;

(b) in sub-paragraph (b), omit “or” the second time it appears;

(c) omit sub-paragraph (c).

(6) In regulation 38(2)(d) (exemption certificates)—

(a) before “25(2)” insert “and”;

(b) omit “and 33(1)”.

Commencement Information

I3 Sch. 4 para. 3 in force at 6.2.2018, see [reg. 1](#)

Changes to legislation:

There are currently no known outstanding effects for the The Ionising Radiation (Medical Exposure) Regulations 2017, SCHEDULE 4.