

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.

(2) For regulation 21 (saving for medical practices) substitute—

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

Amendment of the Human Medicines Regulations 2012

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

(2) In regulation 173 (exemption for certain radiopharmaceuticals)—

(a) in paragraph (d), at the beginning insert “in Northern Ireland”;

(b) after paragraph (d) insert—

“(e) in England and Wales and Scotland, for administration in accordance with a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017”.

(3) In regulation 240 (radioactive medicinal products)—

(a) for paragraph (1)(a) substitute—

“(a) either—

(i) in Northern Ireland, a radioactive medicinal product, administration of which results in a medical exposure; or

(ii) in England and Wales and Scotland, a radioactive substance, administration of which results in a medical exposure; or”;

(b) in paragraph (2), after “Condition A” insert “in Northern Ireland”;

(c) after paragraph (2) insert—

“(2A) Condition A in England and Wales and Scotland is that the prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 6(1) and (4) of the Ionising Radiation (Medical Exposure) Regulations 2017.”;

(d) in paragraph (4), after “condition C” insert “in Northern Ireland”;

(e) after paragraph (4A) insert—

“(4) Condition C in England and Wales and Scotland is that the IRME practitioner mentioned in paragraph (a) or (b) of paragraph (3) is the holder of a licence issued under the Ionising Radiation (Medical Exposure) Regulations 2017.”;

(f) in paragraph (6) after “Condition C” insert “in Northern Ireland”;

(g) after paragraph (6) insert—

“(6A) Condition D in England and Wales and Scotland is that the prescription only medicine is not a radioactive substance.”.

(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.

- (h) for paragraph (7) substitute—
 - “(7) In this regulation—
 - “IRME practitioner” means—
 - (a) in Northern Ireland, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000;
 - (b) in England and Wales and Scotland, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2017;
 - “medical exposure”—
 - (a) in Northern Ireland has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000; and
 - (b) in England and Wales and Scotland has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2017; and
 - “radioactive medicinal product” means a medicinal product which consists of, contains or generates a radioactive substance so that, when the product is administered, the radiation it emits may be used.”.

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)”.