

## SCHEDULE 4

### Consequential amendments

#### **Amendment of the Human Medicines Regulations 2012**

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

[<sup>F1</sup>(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.”;]

[<sup>F2</sup>(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;
- (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).

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(1) 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, Paragraph 2.* (See end of Document for details)

(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.”.]

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#### **Textual Amendments**

- F1** 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)**
- F2** 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)**

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#### **Commencement Information**

- I1** Sch. 4 para. 2 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, Paragraph 2.