STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

CHAPTER 3

Exemptions

Exemptions in relation to specific kinds of product

[F1Radioactive 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).

(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

F1 Reg. 240 substituted (6.2.2018) by The Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322), reg. 1, **Sch. 4 para. 2(3)** (as substituted (6.2.2018) by S.I. 2018/121, regs. 1(2), **2(4)(b)(ii)**)

Changes to legislation:
There are currently no known outstanding effects for the The Human Medicines Regulations 2012, Section 240.