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

Radioactive medicinal products

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

(a) a radioactive medicinal product, 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 the following conditions 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 in regulation 4(1) and (2) of the Ionising Radiation (Medical Exposure) Regulations 2000(**1**) 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, by an operator acting in accordance with written guidelines issued by an IRME practitioner.

(4) Condition C is that the IRME practitioner mentioned in paragraph (a) or (b) of paragraph (3) is the holder of a certificate granted pursuant to the Medicines (Administration of Radioactive Substances) Regulations 1978(**2**).

(5) Condition D is that the prescription only medicine is not a controlled drug.

(6) Condition E is that, in the case of a prescription only medicine that is not a radioactive medicinal product, it is specified in the protocols referred to in paragraph (2).

(7) In this regulation—

"IRME practitioner" means, in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000;

"medical exposure" has the same meaning as in the Ionising Radiation (Medical Exposure) Regulations 2000; and

(**1**) S.I. 2000/1059, as amended by S.I. 2006/2523.
(**2**) S.I. 1978/1006.

"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.