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STATUTORY INSTRUMENTS

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**1992 No. 3274**

**The Medicines (Leaflets) Amendment Regulations 1992**

**Insertion of regulation 3A into the principal Regulations**

4. After regulation 3 of the principal Regulations (standard requirements relating to leaflets), there shall be inserted the following regulation—

**“Standard requirements relating to leaflets for radiopharmaceuticals and radiopharmaceutical-associated products**

**3A.** Subject to the following provisions of these regulations, any leaflet which is enclosed with the packaging of a proprietary medicinal product which is a radiopharmaceutical or a radiopharmaceutical-associated product shall, in addition to containing any particulars required by any other provision of these regulations, contain—

- (a) details of any precautions to be taken by the user and the patient during the preparation and administration of the product;
- (b) details of any special precautions to be taken in respect of the disposal of the container and its unused contents.”.