STATUTORY INSTRUMENTS

1992 No. 605

The Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992 and shall come into force—

(a) for the purpose of making Regulations under section 18 of the Act (including that section as applied by section 24(4) of the Act), on 11th March 1992; and

(b) for all other purposes, on 3rd April 1992.

(2) In these Regulations, unless the context requires otherwise—

"the Act" means the Medicines Act 1968(**1**);

"generator" means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be removed by elution or by any other method and is to be used in a radiopharmaceutical;

"kit" means any preparation to be reconstituted or combined with radionuclides in a final radiopharmaceutical, usually prior to its administration;

"precursor" means a radionuclide produced for the radio-labelling of another substance prior to administration, other than a radionuclide which is incorporated in, or produced from, a generator, or is included in a radiopharmaceutical;

"radiopharmaceutical" means any medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose;

"radiopharmaceutical-associated product" means a generator, kit or precursor which is not itself a medicinal product;

and any other expression used in these Regulations which is defined in the Act shall, unless the context requires otherwise, bear the meaning which it bears in the Act.

(**1**) 1968 c. 67.