

## EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order exempts from the restrictions imposed by section 7 of the Medicines Act 1968 (product licences) a radiopharmaceutical product for human use if it is prepared from a kit, generator or precursor which itself has a product licence, where the radiopharmaceutical product is prepared at the time of its administration and where that administration is not a contravention of regulation 2 of the Medicines (Administration of Radioactive Substances) Regulations 1978.

This Order implements in part article 2 of Council Directive [89/343/EEC](#) (OJNo. L142 25.5.89 p.16) which extends the scope of Council Directives [65/65/EEC](#) (OJ No. 22 9.2.1965 p.369/65) and [75/319/EEC](#) (OJ No. L147 9.6.1975 p.13) and which lays down additional provisions for the control of radiopharmaceuticals.