EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Applications for Product Licences and Clinical Trial Certificates and Animal Test Certificates) Regulations 1971 and the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974 by adding to the requirements as to particulars to be contained in, or to accompany, an application for the grant or renewal of a product licence, so implementing in part Council Directives—

89/342/EEC relating to immunological products (OJNo. L142, 25.5.1989, p.14) (Regulations 2(a), 2(b), 3 and 4 which implement articles 1, 2 and 3 of that Directive);

89/343/EEC relating to radiopharmaceuticals (OJ No. L142, 25.5.1989, p.16) (Regulations 2(c), 3 and 4 which implement in part articles 1, 2, 3 and 4 of that Directive); and

89/381/EEC relating to medicinal products derived from human blood or human plasma (OJ No. L181, 28.6.1989, p.44) (Regulations 2(a), 3 and 4 which implement articles 1 and 2 of that Directive);

by imposing special conditions for applications for product licences in respect of these types of product.

These Directives extend 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) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, to cover such products which had previously been excluded byArticle 34 of Council Directive 75/319/EEC.