EXPLANATORY NOTE

These Regulations further amend the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971 by prescribing requirements as to specimens or mock-ups of containers, packages and leaflets and documentary evidence of authorisations obtained in other countries in relation to the manufacturer or assembly or the sale, supply or placing on the market of Medicinal products to be furnished with applications for product licences. To the extent that the regulations relate to proprietary medicinal products they implement certain Community obligations under two Council Directives Nos.65/65/EEC and 75/319/EEC.