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EXPLANATORY NOTE

These Regulations amend the Medicines Act 1968 so as to enable the implementation of certain Community obligations under two Council Directives Nos.65/65/EEC and 75/319/EEC which relate to proprietary medicinal products.

The amendments relate to—

(a) requirements to hold licences by persons responsible for placing proprietary medicinal products on the market and by distributors of such products imported from outside the European Economic Community (regulations 2 and 3);

(b) the treatment of dossiers forwarded to the licensing authority under Article 9 of Council Directive 75/319/EEC as applications for product licences (regulation 4(2));

(c)refusal, suspension and revocation of licences (regulation 4(3) and (5); and

(d)duration of licences which are not in accordance with Community obligations (regulation 4(4)).