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)).