EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision for renewal applications for product licences for veterinary drugs in consequence of notices of expiry served on the holders of such licences by the licensing authority under section 24(1A) of the Medicines Act 1968.

These notices are served on holders of licences which do not comply with the provisions of Council Directive 81/851/EEC on the approximation of the laws of the Member States relating to veterinary medicinal products (OJNo. L317, 6.11.81, p.1) as amended by Council Directive 90/676/EEC (OJ No. L373, 31.12.90, p.15), and Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ No. L317, 6.11.81, p.16) as amended by Commission Directive 92/18/EEC (OJ No. L97, 10.4.92, p.1). The Regulations thus implement the requirements of Article 2.5 of Council Directive 90/676/EEC and, in respect of immunological products, Article 6.4 of Council Directive 90/677/EEC extending the scope of Directive 81/851/EEC and laying down additional provisions for immunological veterinary medicinal products (OJ No. L373, 31.12.90, p.26) to extend the Directives' provisions progressively to existing products.

Except where the renewal application is permitted to be accompanied by documents and particulars already submitted to another member state, regulation 3 provides for such renewal applications to be made in accordance with the provisions of the Medicines (Veterinary Medicinal Products) (Applications for Product Licences) Regulations 1993 (S.I.1993/2398).