EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement in part Council Directive 92/73/EEC (OJ L297, 13.10.92, p.8) ("the Directive") which widens the scope of Directives 65/65/EEC (OJ No. 22, 9.2.1965, p.369/65) ("the 1965 Directive") and 75/319/EEC (OJ No. L147, 9.6.1975, p.13) ("the 1975 Directive") on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homoeopathic medicinal products.

References to the 1965 Directive are brought in by Article 7(4) of the Directive and references to the 1975 Directive are brought in by Article 4 of the Directive.

These Regulations bring into operation, in respect of homoeopathic medicinal products for human use, the special, simplified registration procedure provided for in Article 7 of the Directive (excluding products defined in Article 1(4) and (5) of the 1965 Directive), or satisfying the criteria in Article 2(4) of that Directive (regulation 2).

Part II of the Regulations sets out the procedure for applying for certificates of registration (regulation 4, Schedule 1; Article 8 of the Directive) and for determining such applications (regulation 5(1), (2) and (3); Article 7(1) of the Directive and Article 5 of the 1965 Directive). It sets time limits for dealing with applications (regulation 5(4) and (5); Article 7 of the 1965 Directive) and specifies the conditions for suspension or revocation of certificates (regulation 9; Article 11 of the 1965 Directive) and for withdrawal of products from the market (regulation 11; Article 28 of the 1975 Directive).

Part II also contains further provisions relating to the grant and revocation of certificates (regulation 6; Article 7(1) of the Directive, Article 12 of the 1965 Directive) and requirements in respect of controls (regulation 7; Article 27 of the 1975 Directive).

Regulation 8 provides for the expiry of certificates after five years and for their renewal (Article 10 of the 1965 Directive); and regulation 11 provides for the variation of certificates.

Part III of, and Schedule 2 to, these Regulations specify the fees payable in connection with applications for the grant of (regulation 13), or variations to (regulation 14), certificates and the fees payable in connection with the holding of certificates (regulation 15).

Regulation 16 and Schedule 3 provide as to time of payment of fees (regulation 16), refund and waiver of fees in specified circumstances (regulation 17) and recovery of unpaid fees (regulation 18).

Part IV of, and Schedule 4 to, these Regulations apply specified provisions of the Medicines Act 1968 to certificates of registration so as to apply provisions concerning the marketing of medicinal products under product licences. In particular, procedures identical to those set out in that Act apply where an application for the grant of a certificate is refused or where a certificate is suspended or revoked, and for enforcement of these Regulations.

Other parts of the Directive are implemented by the Medicines (Labelling and Leaflets) Amendment Regulations 1994 (S. I. 1994/104), the Medicines Act 1968 (Amendment) Regulations 1994 (S. I. 1994/101) and the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994 (S. I. 1994/103).