EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Medicines (Labelling) Regulations 1976 ("the Labelling Regulations") and the Medicines (Leaflets) Regulations 1977 ("the Leaflets Regulations") by implementing in part Council Directive 92/73/EEC (OJNo. L297, 13.10.1992, p. 8) ("the Directive") which widens the scope of Directives 65/65/EEC (OJ No.22, 9.2.1965, p. 369/65) and 75/319/EEC (OJ No. L147, 9.6.1975, p. 13) 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.

Regulations 2 to 4 amend the Labelling Regulations. Regulation 2 inserts a definition of "homoeopathic product to which Council Directive 92/73/EEC applies" into regulation 3(1) of the Labelling Regulations (Articles 1(1) and 2(1) of the Directive) and amends the definition of "product to which Chapters II to V of the 1965 Directive apply".

Regulations 3 and 4 insert a new regulation, 4F and a new Schedule, Schedule 9, which impose standard labelling requirements in respect of homoeopathic products to which Council Directive 92/73/EEC apply (Article 2(2) of the Directive) and (Schedule 9) those of them which are marketed in accordance with a certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S. I. 1994/105) (Article 7(2) of the Directive). New regulation 4F(3) disapplies specified provisions of the Labelling Regulations from the latter.

Regulations 5 to 10 amend the Leaflets Regulations. Regulation 5 inserts definitions of "certificate of registration", "homoeopathic medicinal product" and "homoeopathic product to which Council Directive 92/73/EEC applies" into regulation 2(1) of those Regulations (Articles 1(1) and 2(1) of the Directive) and makes consequential amendments to other definitions.

Regulations 7 and 10 insert a new regulation, 3B, and a new Schedule, Schedule 3, which set out the particulars required in leaflets relating to homoeopathic medicinal products which are marketed under a certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (Article 7(2) of the Directive). Regulations 6, 8 and 9 contain consequential amendments.

Other parts of the Directive are implemented by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 (S. I. 1994/105), the Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 1994 (S. I.1994/103) and the medicines Act 1968 (Amendment) Regulations 1994 (S. I.1994/101).