

EXPLANATORY NOTE

(This note is not part of the Rules)

Council Regulation (EEC) No. 1768/92 (“the EC Regulation”) (which is set out in Schedule 1 to these Rules) and which will take effect on 2nd January 1993, creates and sets out the conditions relating to applications for, and the grant of, a supplementary protection certificate for medicinal products (“the certificate”). The certificate, when granted, will extend the protection afforded by a patent in respect of a pharmaceutical product covered by it for a period which will not extend to a period more than five years from the date it takes effect.

The EC Regulation is directly applicable law in the United Kingdom and has effect so that the certificate confers the same rights and is subject to the same limitations and the same obligations as the basic patent; the decisions of the comptroller taken in respect of the certificate are open to the same appeals as those provided against similar decisions taken in respect of patents and, in the absence of specific procedural provisions in the EC Regulation or national laws, the procedural provisions applicable to the corresponding basic patent are to apply to the certificate.

These Rules are therefore necessary for implementation in part of the Community obligation to the extent that certain provisions of the EC Regulation enable the member States to make provision for the procedure applicable to the introduction of the certificate (in so far as that procedure is to differ from the procedure applicable to patents and applications for patents) (Article 18) and for the payment and the amount of fees (Articles 8(2) and 12).