

SCHEDULE 12

TRANSITIONAL PROVISIONS

Clinical trial exemptions or notifications prior to 1st May 2004

- 4.—(1) This sub-paragraph applies where—
- (a) a clinical trial is conducted after 30th April 2004; and
 - (b) immediately before 1st May 2004, the exemption conferred by article 3 of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995⁽¹⁾ applied in respect of the sale or supply of medicinal products for the purposes of that trial.
- (2) Where sub-paragraph (1) applies—
- (a) the trial shall be treated for the purposes of these Regulations as having been authorised by the licensing authority;
 - (b) regulations 17 to 21 shall not apply in relation to the trial; and
 - (c) regulations 11, 24(2), 29, 31 and 45(1), and Schedule 7, shall apply in relation to the trial with the modification that references to the request for authorisation shall be read as references to the notice to the licensing authority specified in article 4(1)(a) of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 .

⁽¹⁾ S.I. 1995/2808.