SCHEDULE 12 Regulation 56

TRANSITIONAL PROVISIONS

Ethical approval given before 1st May 2004

1.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004;

(b) no ethics committee has given a favourable opinion in relation to that trial in accordance with regulation 15; and

(c) a committee established or recognised for the purpose of advising on the ethics of research investigations on human beings has before 1st May 2004 given a favourable ethical opinion in relation to that trial.

(2) Subject to the following sub-paragraphs, where sub-paragraph (1) applies—

(a) the trial shall be treated for the purposes of these Regulations as if an ethics committee has given a favourable opinion in relation to that trial in accordance with regulation 15;

(b) regulations 12, 24(3) and 29 shall apply in relation to the trial with the modification that references to the application for an ethics committee opinion shall be read as references to the application for approval made to the committee referred to in sub-paragraph (1)(c); and

(c) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee referred to in sub-paragraph (1)(c).

(3) This sub-paragraph applies where the committee referred to in sub-paragraph (1)(c) has not been recognised by the Authority in accordance with regulation 7—

(a) for the area in which the trial sites are situated, or

(b) for the description or class of clinical trial into which the trial falls,

before 1st September 2004.

(4) Where sub-paragraph (3) applies—

(a) the sponsor of the clinical trial may make an application to an ethics committee established or recognised by the Authority in accordance with Part 2—

(i) for the area in which the trial sites are situated, or

(ii) for the description or class of clinical trial into which the trial falls,

for an amendment to the protocol for the trial within the meaning of Part 3 of these Regulations; or

(b) the chief investigator may make an application to an ethics committee in accordance with regulation 14.

(5) Where an ethics committee receives an application for an amendment in accordance with sub-paragraph (4)(a), it shall consider the amendment as if it was a valid notice of amendment under regulation 24.

(6) Where an ethics committee gives a favourable opinion in relation an application for amendment made pursuant to sub-paragraph (4)(a)—

(a) sub-paragraph (2)(c) shall cease to apply; and

(b) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee which gave that favourable opinion.

(7) Where an ethics committee gives a favourable opinion in relation to an application pursuant to sub-paragraph (4)(a), sub-paragraph (2) shall cease to apply in relation to that trial

(8) Where sub-paragraph (3) applies and before 1st May 2006 no favourable opinion has been given as specified in sub-paragraphs (6) and (7), sub-paragraph (2) and (4) shall cease to apply from that date.

(9) If the committee referred to in sub-paragraph (1)(b) is abolished or ceases operation before 1st May 2006—

(a) the Authority shall nominate an ethics committee as responsible for the work of the committee which is abolished or which ceases operation; and

(b) regulations 24, 25, 27, 30 to 35 and 48 shall apply in relation to the trial with the modification that references to the relevant ethics committee shall be read as references to the committee so nominated.

Applications for ethical approval prior to 1st May 2004

2.—(1) This sub-paragraph applies where a person has made an application for an ethical opinion in relation to a clinical trial before 1st May 2004 to a committee established or recognised for the purpose of advising on the ethics of research investigations on human beings.

(2) Where—

(a) sub-paragraph (1) applies;

(b) the committee has not given its opinion before 1st May 2004; and

(c) the committee has been recognised by the Authority in accordance with regulation 7 for the area in which the trial sites are situated, or for the description or class of clinical trial into which the trial falls,

the committee shall consider the application as if it had been made in accordance with regulation 14.

Clinical trial exemptions or notifications prior to 1st May 2004

3.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004; and

(b) immediately before 1st May 2004, a clinical trial certificate was in force and the trial was being conducted in accordance with that certificate.

(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 application for the clinical trial certificate.

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.

(**1**) S.I. 1995/2808.

(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 .

5.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted after 30th April 2004;

(b) the investigational medicinal product used in the trial is a product with a marketing authorization;

(c) the trial has before 1st May 2004 been notified to the licensing authority by the person supplying the product for the purposes of that trial; and

(d) the licensing authority has before 1st May 2004 notified that person that—

(i) the trial appeared to fall within the terms of the Medicines (Exemption from Licences) (Clinical Trials) Order 1974(**2**), and

(ii) the authority agreed to the trial proceeding.

(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 notification referred to in sub-paragraph (1)(c).

6.—(1) This sub-paragraph applies where—

(a) a clinical trial is conducted 30th April 2004; and

(b) immediately before 1st May 2004, the exemption conferred by article 2(2) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(**3**) 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 notification to the licensing authority specified in article 2(3)(c) or (4)(a) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972.

(**2**) S.I. 1974/498.
(**3**) S.I. 1972/1200.

Applications for clinical trial exemptions or notifications prior to 1st May 2004

7.—(1) This sub-paragraph applies where—

(a) an application for a clinical trial certificate has been made in accordance with section 36 of the Act and the licensing authority has not before 1st May 2004 determined whether to issue a certificate;

(b) the licensing authority has received a notice pursuant to article 4(1)(a) of the Medicines (Exemption from Licences) (Clinical Trials) Order 1995 and on 1st May 2004—

(i) the specified period within the meaning of article 4(2) of that Order has not expired, and

(ii) the authority has not given or sent a notice pursuant to article 4(1)(b); or

(c) the licensing authority has received a notice pursuant to article 4(2)(iv) of the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972 and on 1st May 2004—

(i) the period specified in article (2)(v) of that Order has not expired, and

(ii) the authority has not given a direction pursuant to that article.

(2) Where sub-paragraph (1) applies the licensing authority shall treat the application or notice as a valid request for authorisation to conduct the clinical trial to which the application or notice relates under regulation 17.