[F1SCHEDULE 9

Regulation 47(1)

MODIFICATIONS OF THE ENFORCEMENT PROVISIONS OF THE 2012 REGULATIONS SUBJECT TO WHICH THOSE PROVISIONS ARE APPLIED FOR THE PURPOSES OF THESE REGULATIONS

Textual Amendments

F1 Sch. 9 substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 64** (with Sch. 32)

1. The modifications of the 2012 Regulations mentioned in regulation 47 are as follows.

2. In regulation 2 (medicinal products)—

(a) at the beginning of paragraph (1) insert " Subject to paragraph (3), "; and

(b) after paragraph (2) insert the following paragraph—

"(3) "Medicinal product" includes any investigational medicinal product.".

2. In regulation 8(1) (interpretation)—

(a) the definition "assemble" is substituted by the definition of that expression in regulation 2(1) of these Regulations; and

(b) there is inserted in the appropriate position in alphabetical order a definition "container" in the same terms as the definition of that expression in regulation 2(1) of these Regulations; and

(c) the definition "qualified person" is substituted by the definition of that expression in regulation 2(1) of these Regulations.

3. In regulation 322(1) (validity of decisions and proceedings) omit "or" and insert a comma before " 8 (Article 126a authorisations) ", and after those words insert " or the Clinical Trials Regulations ".

4. In regulation 325(1) (rights of entry) insert after sub-paragraph (b) the following sub-paragraph—

"(ba) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations;".

5.—(1) Regulation 327 (powers of inspection, sampling and seizure) is amended as follows.

(2) In paragraph (1)—

(a) after sub-paragraph (b) omit "; or";

(b) after sub-paragraph (c) insert " ; or " and the following sub-paragraph—

"(d) in order to verify any statement contained in an application or request for an authorisation under the Clinical Trials Regulations.".

(3) After paragraph (2)(g) insert the following sub-paragraph—

"(h) information and documents relating to clinical trials".

(4) In paragraph (3)—

(a) omit "or" following sub-paragraph (a); and

(b) following paragraph (b) insert " ; or " and the following sub-paragraph—

"(c) a medicinal product used, or intended to be used, in a clinical trial".

(5) In paragraph (4)—

(a) after "require" insert " — (a) "; and

(b) after "control" insert " ; or " and the following sub-paragraph—

"(b) a person associated with a clinical trial to produce information or documents relating to the clinical trial which are in the person's possession or under the person's control".

(6) In paragraph (5)(a) for "(2)(f) or (g)" substitute " (2)(f), (g) or (h) ".

(7) After paragraph (9) insert the following paragraph—

"(10) In this regulation, "a person associated with a clinical trial means any of the following—

(a) the sponsor of a clinical trial (within the meaning of regulation 3 of the Clinical Trials Regulations);

(b) any person who, under arrangements made with the sponsor of a clinical trial, carries out functions of the sponsor of the trial;

(c) in investigator for a clinical trial (within the meaning of regulation 2(1) of the Clinical Trials Regulations);

(d) any person, other than an investigator, who conducts a clinical trial;

(e) any person occupying premises at which a clinical trial is being conducted; or

(f) any person who, in the course of employment with a person listed in any of sub-paragraphs (a) to (e), undertakes activities in connection with a clinical trial.".

(8) In regulation 335(6) (contravention due to fault of another person) omit "and" after sub-paragraph (e) and after sub-paragraph (f) insert " ; and " and the following sub-paragraph—

"(g) any obligation or prohibition under the Clinical Trials Regulations".

(9) In regulation 336(3) (warranty as defence) omit "and" after sub-paragraph (c) and after sub-paragraph (d) insert " ; and " and the following sub-paragraph—

"(e) regulation 46 of the Clinical Trials Regulations (labelling)".**]**

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, SCHEDULE 9.