SCHEDULES

SCHEDULE 34

Amendments to existing law

PART 4

The Medicines for Human Use (Clinical Trials) Regulations 2004

52. The Medicines for Human Use (Clinical Trials) Regulations 2004 [M1] are amended as follows.

Marginal Citations

M1 S.I. 2004/1031, as amended by S.I. 2005/2754. There are other amendments, but none is relevant.

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

(a) before the definition "the Act" insert the following definition—

""the 2012 Regulations" means the Human Medicines Regulations 2012;";

(b) for the definition "appropriate committee" substitute—

""appropriate committee" for the purposes of any provision of these Regulations under which a function falls to be performed means whichever the licensing authority considers to be appropriate of—

(a) the Commission on Human Medicines; or

(b) an expert committee appointed by the licensing authority;";

(c) insert in the appropriate position in alphabetical order the following definition—

""the Commission on Human Medicines" means the Commission on Human Medicines within the meaning of regulation 9 of the 2012 Regulations;";

(d) in the definition "licensing authority" for "section 6 of the Act" substitute " regulation 6 of the 2012 Regulations ";

(e) for sub-paragraph (a) of the definition "marketing authorisation" substitute—

"(a) a UK marketing authorisation granted by the licensing authority under the 2012 Regulations,"; and

(f) for the definition "medicinal product" substitute—

""medicinal product" means a medicinal product within the meaning of regulation 2(1) of the 2012 Regulations."

54. In regulation 4(3) (responsibility for functions under the Directive) for "the Act" substitute " the 2012 Regulations ".

55. In regulation 19(10) (authorisation procedure for clinical trials involving medicinal products for gene therapy etc) omit "established by section 2A of the Act".

56. In regulation 46(2)(c) (labelling) for words from "Schedule 5" to the end of the sub-paragraph substitute " Part 13 of the 2012 Regulations that apply in relation to medicinal products sold or supplied in accordance with a prescription given by a person who is an appropriate practitioner within the meaning of regulation 214(3) to (6) of those Regulations ".

57. In regulation 47 (application of enforcement provisions of the Act)—

(a) for "the Act" in the heading substitute " the 2012 Regulations "; and

(b) for paragraph (1) substitute—

"(1) Regulations 2, 8(1), 322, 323(1), 324(1), 325 to 330, 332 to 339, 343 and Schedule 31 of the 2012 Regulations ("those provisions") shall apply for the purposes of these Regulations as they apply for the purposes of the 2012 Regulations, but with the modifications specified in Schedule 9, and any reference in those provisions to the 2012 Regulations includes a reference to these Regulations."; and

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

"(3) In those provisions as applying by virtue of paragraph (1), any reference to, or relating to, a requirement, a power, a function, a right, a duty, an entitlement, or a protection shall be read as a reference to, or relating to, that requirement, power, function, right, duty, entitlement, or protection as applied by this regulation.".

58. In regulation 48(5) (infringement notices) for "sections 108 to 110 of the Act" substitute " regulation 323(1) or 324(1) of the 2012 Regulations ".

59. In regulation 49(5) (offences) for "the Act" substitute " the 2012 Regulations ".

60. In regulation 53(3) (construction of references to specified publications) for "section 103(1) of the Act" substitute " regulation 321(1) of the 2012 Regulations ".

61. In paragraph 4(2) of Schedule 5 (procedural provisions relating to the refusal or amendment of, or imposition of conditions relating to, clinical trial authorisations and the suspension or termination of clinical trials)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert " , the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister ".

62. In Schedule 7 (standard provisions for manufacturing authorisations)—

(a) in Part 2—

(i) in paragraph 5 for "the Act" substitute " the 2012 Regulations ",

(ii) in paragraph 9 for "the Act or any regulations under the Act" substitute " or the 2012 Regulations ", and

(iii) in paragraph 13—

(aa) for "Part II of the Act" substitute " Parts 3 to 8 of the 2012 Regulations ", and

(bb) for "the Act" in the second place where it occurs substitute " the 2012 Regulations "; and

(b) in Part 3—

(i) in paragraph 6 for "the Act" in the first place where it occurs substitute " the 2012 Regulations ", and

(ii) in paragraph 8—

(aa) for "Part II of the Act" substitute " Parts 3 to 8 of the 2012 Regulations ", and

(bb) for "the Act" in the second place where it occurs substitute " the 2012 Regulations ".

63. In paragraph 5(2) of Schedule 8 (procedural provisions relating to proposals to grant, refuse to grant, vary, suspend or revoke manufacturing authorisations)—

(a) in sub-paragraph (a), for paragraphs (i) to (iii) substitute—

"(i) the Commission on Human Medicines,

(ii) an expert committee appointed by the licensing authority,

(iii) an expert advisory group within the meaning of regulation 14 of the 2012 Regulations,

(iv) the British Pharmacopoeia Commission referred to in regulation 11 of the 2012 Regulations, or any of its sub-committees,

(v) the Medicines Commission formerly established under section 2 of the Act, or any of its committees,

(vi) the Advisory Board on the Registration of Homoeopathic Products formerly established under section 4 of the Act, or any of its sub-committees, or

(vii) the Herbal Medicines Advisory Committee formerly established under section 4 of the Act, or any of its sub-committees, and"; and

(b) in sub-paragraph (b) after "Crown" insert " , the Scottish Ministers, the Welsh Ministers or a Northern Ireland Minister ".

64. For Schedule 9 substitute the following Schedule—

"SCHEDULE 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

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 Human Medicines Regulations 2012, PART 4.