SCHEDULE 10 U.K.

CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

PART 1 U.K.

ACTS OF PARLIAMENT

The Act U.K.

1.—(1) Section 3 of the Act (general functions of the Medicines Commission) [F1] is amended as follows—

(2) In subsection (1), for the words from "advice" to "products, where" substitute—

"advice on matters—

(a) relating to the execution of this Act,

(b) relating to the exercise of any power conferred by this Act,

(c) relating to the execution of the Clinical Trials Regulations,

(d) relating to the exercise of any power conferred by those regulations, or

(e) otherwise relating to medicinal products,

where. "

(3) In subsection (2), after "by or under this Act" insert " or the Clinical Trials Regulations ".

(4) For subsection (2)(d) substitute—

"(d) to advise the licensing authority in cases where the authority—

(i) are required by the provisions of Part II of this Act, or by the provisions of the Clinical Trial Regulations, to consult the Commission with respect to any matter arising under those provisions; or

(ii) without being required to do so, elect to consult the Commission with respect to any matter arising under any of those provisions."

Textual Amendments

F1 Section 3 has effect as if any reference to the Act included a reference to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) ("the 1994 Regulations"); *see* regulation 9(1) of the 1994 Regulations.

2. In section 4 of the Act (establishment of committees) [F2], in subsection (2), for the words from "connected with" onwards substitute—

"connected with—

(a) the execution of this Act or the Clinical Trials Regulations, or

(b) the exercise of any power conferred by this Act or those regulations,

either generally or in relation to any particular class of substances or articles to which any provision of this Act or those regulations applies.".

Textual Amendments

F2 Section 4 has effect as if any reference to the Act included a reference to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) ("the 1994 Regulations"); *see* regulation 9(1) of the 1994 Regulations

3. In section 7 of the Act (restrictions as to dealings with medicinal products) [F3], after subsection (3), insert the following subsection—

"(3A) The restrictions imposed by subsections (2) and (3) of this section shall not apply where the medicinal product concerned is an investigational medicinal product within the meaning of the Clinical Trials Regulations.".

Textual Amendments

F3 Section 7 does not apply to "relevant medicinal products" within the meaning of regulation 1(2) of the 1994 Regulations; *see* regulation 9(2) of the 1994 Regulations.

4.—(1) Section 8 of the Act (provisions as to manufacture and wholesale dealing) shall be amended as follows.

(2) At the beginning of subsection (2), insert " Subject to subsection (2A) of this section ".

(3) After subsection (2) insert the following subsections—

"(2A) In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by subsection (2) of this section only apply—

(a) if the product has a product licence or marketing authorization, and

(b) to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that licence or authorization.

(2B) In subsection (2A) of this section—

"investigational medicinal product" has the meaning given by the Clinical Trials Regulations; and

"marketing authorization" means—

(a) a marketing authorization issued by a competent authority in accordance with Directive 2001/83/EC, or

(c) a marketing authorization granted by the European Commission under Council Regulation (EEC) 2309/93[F4].".

(4) In subsections (3) and (3A) [F5], for "subsection (3C)", in both places those words appear, substitute " subsections (3C) and (3D) ".

(5) After subsection (3C), insert the following subsection—

"(3D) The restrictions imposed by subsections (3) and (3A) of this section do not apply where the product concerned is an investigational medicinal product within the meaning given by the Clinical Trials Regulations.".

Textual Amendments

F4 OJ No. L214, 24.8.1993, p.1.

F5 Subsections (3A) to (3C) of section 8 were inserted by regulation 2(4) of S.I. 1993/834

5.—(1) Section 23 of the Act (special provisions as to the effect of manufacturer's licence) [F6] shall be amended as follows.

(2) In subsection (1)—

(a) omit "clinical trials and";

(b) for paragraph (b), substitute the following paragraph—

"(b) the products are manufactured or assembled to the order of—

(i) a person who is the holder of such a product licence, or

(ii) if the products are to be used for the purposes of a clinical trial, the sponsor of that trial,".

(3) After subsection (5), insert the following subsection—

"(6) In this section, "clinical trial" and "sponsor", in relation to a clinical trial, have the meaning given by Clinical Trials Regulations.".

Textual Amendments

F6 Section 23 of the Act has effect as if any reference in subsection (1) to a product licence included a reference to a marketing authorization; *see* regulation 9(1) of the 1994 Regulations.

6. Section 31 of the Act shall be omitted

7.—(1) Section 35 of the Act (supplementary provisions as to clinical trials and medicinal test on animals) shall be amended as follows.

(2) In subsection (1), omit "a clinical trial certificate or".

(3) In subsection (2), omit paragraph (a).

(4) In subsection (4), omit the words from the beginning to "; and".

(5) In subsection (5)—

(a) omit "a clinical trial or";

(b) for paragraph (a), substitute the following paragraph—

"(a) an animal test certificate has been issued and is for the time being in force in respect of that test, and the test is to be carried out in accordance with that certificate, and;"

(c) in paragraph (b), omit "trial or".

(6) In subsection (7)—

(a) for "sections 31 and 32" substitute " section 32 ";

(b) omit "of a clinical trial or"; and

(c) in paragraph (a), omit "trial or".

(7) In subsection (8), omit paragraph (a).

(8) In subsection (10), omit "any of the provisions of subsections (5) to (8) of section 31 of this Act, or".

8. In section 36 of the Act (application for, and issue of, certificate)—

(a) in subsection (1), omit "a clinical trial certificate or";

(b) in subsection (2), omit "clinical trial or";

(c) in subsection (3), omit "clinical trial certificates or".

9.—(1) Section 37 of the Act (transitional provisions as to clinical trials and medicinal tests on animals) shall be amended as follows.

(2) In subsection (1), omit "31, ".

(3) In subsection (2), for "sections 31 and 32" substitute " section 32 ".

(4) In subsection (3)—

(a) omit paragraph (a);

(b) for "section 31 or section 32 of this Act do not apply to anything done in relation to medicinal products of that description or (as the case may be)" substitute " section 32 of the Act do not apply to anything done ".

(5) In subsection (4)—

(a) omit "a clinical trial certificate or";

(b) in paragraph (a), for the words from the beginning to "so specified" substitute " substances or articles specified in the application ".

10. In section 38 of the Act (duration and renewal of certificate)—

(a) in subsections (1) and (4), omit "clinical trial certificate or";

(b) in subsections (5) and (6), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ".

11. In section 39 of the Act (suspension, revocation or variation of certificate)—

(a) in subsections (1), (3) and (4), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ";

(b) in subsection (2)(c) and (e), omit "clinical trial or".

12. In section 44 of the Act (provision of information to licensing authority), in subsections (1) and (2), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ".

13. In section 45 of the Act (offences under Part II)—

(a) in subsections (1) and (2), omit "section 31,";

(b) in subsection (3), for "a clinical trial certificate or animal test certificate" substitute " an animal test certificate ".

14. In section 46 of the Act (special defences under section 45), for "a clinical trial certificate or animal test certificate" (in each place) substitute " an animal test certificate ".

[F7]15. . . . . . .

Textual Amendments

F7 Sch. 10 para. 15 revoked (1.10.2010) by The Health and Social Care Act 2008 (Commencement No.16, Transitory and Transitional Provisions) Order 2010 (S.I. 2010/807), art. 1(1)(b), **Sch. 2**

16. In section 50 of the Act (certificates for exporters of medicinal products), after paragraph (b) insert

", and

(c) to the provisions of the Clinical Trials Regulations and to any authorisation granted or other thing done by virtue of those regulations.".

17. In section 104 of the Act (application of Act to certain articles and substances), in subsection (1), after "such provisions of this Act" insert " , or the Clinical Trials Regulations, ".

18. In section 105 of the Act (application of Act to certain other substances which are not medicinal products), in subsection (1), after "such provisions of this Act" insert " , or the Clinical Trials Regulations, ".

19. In section 132 of the Act (general interpretation provisions)—

(a) in subsection (1)—

(i) omit the entry defining "clinical trial" and "clinical trial certificate", and

(ii) before the definition of "the Commission" insert the following definition—

""the Clinical Trials Regulations" means the Medicines for Human Use (Clinical Trials) Regulations 2004;"; and

in subsection (3), omit "a clinical trial certificate or".

20. In section 1 of the Medicines Act 1971 (fees payable for the purposes of Part II of the Act) [F8] after subsection (2) insert the following subsection—

"(2A) In subsections (1) and (2)(b) above, any reference to a licence under Part II of the principal Act shall be taken to include a reference to a manufacturing authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004.".

Textual Amendments

F8 Section 1 of the Medicines Act 1971 has effect as if any reference in subsection (1) to any application in pursuance of the Act for a licence under Part II of the Act (or for the variation or renewal of such a licence) included a reference to any application under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994 (S.I. 1994/3144) for a marketing authorization (or for the variation or renewal of such an authorization) and any reference in subsection (2)(b) to a licence under Part II of the Act included a reference to a marketing authorization; *see* regulation 9(12) of the those Regulations.

21. Section 51 of the Adults with Incapacity (Scotland) Act 2000 [F9] (authority for research) shall be amended as follows—

(a) in subsection (2), at the beginning of paragraph (b) insert " Subject to subsection (3A), ";

(b) after subsection (3), insert the following subsection—

"(3A) Where the research consists of a clinical trial of a medicinal product, the research may be carried out—

(a) without being approved by the Ethics Committee, if a favourable opinion on the trial has been given by an ethics committee, other than the Ethics Committee, in accordance with regulation 15 of the Medicines for Human Use (Clinical Trials) Regulations 2004; and

(b) without the consent of any guardian or welfare attorney, or the adult's nearest relative, if—

(i) it has not been practicable to contact any such person before the decision to enter the adult as a subject of the clinical trial is made, and

(ii) consent has been obtained from a person, other than a person connected with the conduct of the clinical trial, who is—

(A) the doctor primarily responsible for the medical treatment provided to that adult, or

(B) a person nominated by the relevant health care provider."; and

(c) at the end insert the following subsection—

"(9) In this section—

"clinical trial on a medicinal product" means a clinical trial as defined by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2004;

"an ethics committee" has the meaning given by that regulation;

"person connected with the conduct of the trial" and "relevant health care provider" have the meanings given by Schedule 1 to those regulations.".

Textual Amendments

F9 2000 asp 4.

Changes to legislation:
There are currently no known outstanding effects for the The Medicines for Human Use (Clinical Trials) Regulations 2004, PART 1.