SCHEDULE 10 Regulation 54

CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

PART 1

ACTS OF PARLIAMENT

The Act

1.—(1) Section 3 of the Act (general functions of the Medicines Commission)(**1**) 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."

2. In section 4 of the Act (establishment of committees)(**2**), 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.".

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

(**1**) 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**) 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**) 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.

"(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.".

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(**4**).".

(4) In subsections (3) and (3A)(**5**), 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.".

5.—(1) Section 23 of the Act (special provisions as to the effect of manufacturer's licence)(**6**) 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.".

6. Section 31 of the Act shall be omitted

(**4**) OJNo. L214, 24.8.1993, p.1.
(**5**) Subsections (3A) to (3C) of section 8 were inserted by regulation 2(4) of S.I. 1993/834
(**6**) 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.

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".

15. In section 47 of the Act (standard provisions for licences or certificates), in subsection (2) and (4), omit "clinical trial certificate or".

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".

The Medicines Act 1971

20. In section 1 of the Medicines Act 1971 (fees payable for the purposes of Part II of the Act)(**7**) 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.".

(**7**) 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.

The Adults with Incapacity (Scotland) Act 2000

21. Section 51 of the Adults with Incapacity (Scotland) Act 2000(**8**) (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.".

PART 2

ORDERS AND REGULATIONS

1. In the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971(**9**)—

(a) in regulation 2 (interpretation), in the definition of "clinical trial certificate of right" and "animal test certificate of right", omit ""clinical trial certificate of right" and";

(b) in regulation 3 (standard provisions for licences and certificates), omit paragraph (2); and

(c) in Schedule 1, omit Part II (standard provisions for clinical trial certificates and clinical trial certificates of right).

2. In the Medicines (Surgical Materials) Order 1971(**10**), in article 3, for the words from ", the provisions contained in Parts I and II of the Act" to the end substitute—

(**8**) 2000 asp 4.
(**9**) S.I. 1971/972; regulation 3(3) and Part III of Schedule 1 are revoked insofar as they apply to animal test certificates by S.I. 2003/3309.
(**10**) S.I. 1971/1267, as amended by S.I. 1994/3119.

"(a) the provisions contained in Parts I and II of the Act, sections 62, 64, 65 and 67 of Part III of the Act, and the provisions contained in Parts V, VI and VIII of the Act shall have effect in relation to the said articles or substances described in the Schedule to this Order, as those provisions have effect in relation to medicinal products; and

(b) the provisions of the Clinical Trials Regulations shall have effect in relation to the said articles or substances.".

3.—(1) In the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972(**11**), article 4 shall be amended as follows.

(2) In paragraph (1)—

(a) for "sections 7, 31(2) and 32" substitute "sections 7 and 32";

(b) in subparagraph (a), omit "a clinical trial, or, as the case may be,".

(3) In paragraph (2)—

(a) in subparagraph (i)—

(i) in paragraph (a), omit "a clinical trial, or, as the case may be,",

(ii) in paragraph (b), omit "clinical trial or";

(b) in subparagraph (iii)—

(i) omit "the clinical trial or, as the case may be,",

(ii) omit the words from "the doctor or dentist" to "as the case may be,";

(c) in subparagraph (iv)—

(i) omit the words from "that the doctor or dentist" to "as the case may be,",

(ii) omit the words "the trial, or, as the case may be".

(4) Omit paragraph (3).

4. In the Medicines (Dental Filling Substances) Order 1975(**12**), in article 2, in paragraph (1), for the words from "the following provisions of the Act" to the end substitute—

"(a) the provisions contained in Parts I, II, III, V, VI and VIII of the Act shall have effect in relation to dental filling substances as those provisions have effect in relation to medicinal products; and

(b) the provisions of the Clinical Trials Regulations shall have effect in relation to those substances.".

5. In the Medicines (Specified Articles and Substances) Order 1976(**13**), in article 2, in paragraph (1), for the words from "the provisions of the Act" to the end substitute—

"(a) the provisions of the Act set out in Part I of the said Schedule 2 shall have effect in relation to such articles or substances as those provisions have effect in relation to medicinal products; and

(b) the provisions of the Clinical Trials Regulations shall have effect in relation to those articles or substances.".

6.—(1) The Medicines (Labelling) Regulations 1976(**14**) shall be amended as follows.

(**11**) S.I. 1972/1200.
(**12**) S.I. 1975/533, as amended by S.I. 1994/3119.
(**13**) S.I. 1976/968, as amended by S.I. 1994/3119.
(**14**) S.I. 1976/1726; the Regulations were revoked in so far as they relate to the labelling of containers and packages of medicinal products for administration in certain medicinal tests on animals by S.I. 1996/2194.

(2) In regulation 1 (citation and scope)(**15**), after "apply", insert "or a medicinal product which is an investigational medicinal product within the meaning of the Medicines for Human Use (Clinical Trials) Regulations 2003".

(3) In regulation 2 (commencement), in paragraph (b), in sub-paragraph (i), omit ", clinical trial certificate".

(4) Omit regulation 6 (clinical trials).

(5) In regulation 10 (surgical materials), omit the words from ", except that" to the end.

(6) In regulation 16 (provisions in licences, clinical trial certificates and animal test certificates)—

(a) in paragraph (1), for "a clinical trial certificate or animal test certificate " substitute "an animal test certificate";

(b) in paragraph (2), omit ", clinical trial certificate".

(7) Omit Schedule 2 (particulars required in the labelling of containers and packages of medicinal products for clinical trials).

7. In the Medicines (Fluted Bottles) Regulations 1978(**16**), in regulation 3 (exceptions)—

(a) after paragraph (e), insert the following paragraph—

"(ee) where medicinal products are investigational medicinal products within the meaning given by the Medicines for Human Use (Clinical Trials) Regulations 2004;"; and

(b) in paragraph (g), omit "clinical trial certificate or".

8. In Schedule 1 to the Medicines (Fixing of Fees Relating to Medicinal Products for Human Use) Order 1989(**17**), after paragraph 9A(**18**) insert the following paragraph—

"**9B.** Functions of the licensing authority which are functions of theirs by virtue of the Medicines for Human Use (Clinical Trials) Regulations 2004 and the functions of any person appointed under Schedule 5 or 8 to those Regulations.".

9. In the Medicines Act 1968 (Application to Radiopharmaceutical-Associated Products) Regulations 1992(**19**), in the Schedule—

(a) in the entry relating to section 44 of the Act, for """, or of a clinical trial certificate or animal test certificate,"" substitute """, or of an animal test certificate,"";

(b) in the entry relating to section 45 of the Act, omit "section 31,", in both places those words appear;

(c) in the entry relating to section 46 of the Act, for """or of a clinical trial certificate or animal test certificate"" substitute """or of an animal test certificate""; and

(d) in the entry relating to section 47 of the Act—

(i) for """any clinical trial certificate or animal test certificate"" substitute """any animal test certificate""", and

(ii) for """, or any clinical trial certificate or animal test certificate,"" substitute """, or any animal test certificate,"".

10. In the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994(**20**), in Schedule 4 (application of the provisions of the Act)—

(**15**) As amended by S.I. 1994/3144.
(**16**) S.I. 1978/40; regulation 3 was amended by S.I. 1994/3142 and 3144.
(**17**) S.I. 1989/684.
(**18**) Paragraph 9A was inserted by S.I. 1995/871.
(**19**) S.I. 1992/605.
(**20**) S.I. 1994/105.

(a) in the entry relating to section 23 of the Act, omit "clinical trials and";

(b) in the entry relating to section 44 of the Act, for "a clinical trial certificate or animal test certificate", in both places those words appear, substitute "an animal test certificate";

(c) in the entry relating to section 45 of the Act—

(i) omit "section 31,", and

(ii) for ""or of a clinical trial certificate or animal test certificate"" substitute ""or of an animal test certificate""; and

(d) in the entry relating to section 46 of the Act, for ""or of a clinical trial certificate or animal test certificate"" substitute ""or of an animal test certificate"".

11. In the Dangerous Substances and Preparations (Safety) (Consolidation) Regulations 1994(**21**), in regulation 1 (citation, commencement and interpretation), in paragraph (2), in the definition of "medicinal product"—

(a) for sub-paragraph (ii), substitute the following sub-paragraph—

"(ii) which is an "investigational medicinal product" within the meaning of regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003, or"; and

(b) omit sub-paragraph (iii).

12. In the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994(**22**)—

(a) in regulation 1—

(i) in paragraph (2), after the definition of "the Act" insert the following definition—

""the Clinical Trials Directive" means Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use;",

(ii) in paragraph (5), omit "and except in the case of "clinical trial,""; and

(b) in Schedule 1, in paragraph 2, for sub-paragraph (e)(**23**) substitute the following sub-paragraph—

"(e) the relevant medicinal product—

(i) is manufactured, assembled or imported by the holder of an authorization referred to in Article 40 of the 2001 Directive which relates specifically to the manufacture, assembly or import of relevant medicinal products to which paragraph 1 applies; or

(ii) has been manufactured, assembled or imported as an investigational medicinal product by the holder of an authorization referred to in Article 13 of the Clinical Trials Directive"; and.

13. In the Prescription Only Medicines (Human Use) Order 1997(**24**)—

(a) in article 1 (citation, commencement and interpretation), in paragraph (2), for the definition of "clinical trial exemption" substitute the following definition—

""clinical trial" has the meaning given by regulation 2(1) of the Medicines for Human Use (Clinical Trials) Regulations 2003;"; and

(**21**) S.I. 1994/2844; regulation 1(2) was substituted by S.I. 1996/2635.
(**22**) S.I. 1994/3144.
(**23**) Paragraph 2(e) of Schedule 1 was amended by SI 2002/236.
(**24**) S.I. 1997/1830; the relevant amending instrument is S.I. 2003/696.

(b) in article 3B (prescribing and administration by supplementary prescribers), in paragraph (3), in sub-paragraph (b), in head (ii), for the words from "and—" to the end substitute "which has been authorised, or is to be treated as having been authorised, by the licensing authority in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2003".

14. In the Ionising Radiation (Medical Exposure) Regulations 2000(**25**), in regulation 2 (interpretation), in paragraph (1), after the definition of "ionising radiation", insert the following definition—

""Local Research Ethics Committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004,

(b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000, or

(c) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State, the National Assembly for Wales or Scottish Ministers;".

15. In the Private and Voluntary Health Care (England) Regulations 2001(**26**), in regulation 24 (research), for paragraph (2) substitute the following paragraph—

"(2) For the purposes of paragraph (1)(a), "appropriate Research Ethics Committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004; or

(b) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State;".

16. In the Misuse of Drugs Regulations 2001(**27**), in regulation 18 (marking of bottles and other containers), for paragraph (3) substitute the following paragraph—

"(3) In this regulation—

"clinical trial" has the same meaning as in the Medicines for Human Use (Clinical Trials) Regulations 2003;

"medicinal test on animals" has the same meaning as in the Medicines Act 1968.".

17. In the Health Service (Control of Patient Information) Regulations 2002(**28**), in regulation 1 (citation, commencement, interpretation and extent), in paragraph (2), for the definition of "research ethics committee" substitute the following definition—

""research ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, or

(b) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State or the National Assembly for Wales;".

(**25**) S.I. 2000/1059.
(**26**) S.I. 2001/3968.
(**27**) S.I. 2001/3998.
(**28**) S.I. 2002/1438.

18. In the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002(**29**), in regulation 2 (interpretation), in paragraph (1), for the definition of "research ethics committee" substitute the following definition—

""research ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004, or

(b) any other committee established to advise on the ethics of research investigations on human beings and recognised for that purpose by or on behalf of the Secretary of State;".

(**29**) S.I. 2002/2375.