SCHEDULE 10

CONSEQUENTIAL AND OTHER AMENDMENTS OF ENACTMENTS

PART 2

ORDERS AND REGULATIONS

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

(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(**2**), in article 3, for the words from ", the provisions contained in Parts I and II of the Act" to the end substitute—

"(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(**3**), 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).

(**1**) 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.
(**2**) S.I. 1971/1267, as amended by S.I. 1994/3119.
(**3**) S.I. 1972/1200.

4. In the Medicines (Dental Filling Substances) Order 1975(**4**), 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(**5**), 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(**6**) shall be amended as follows.

(2) In regulation 1 (citation and scope)(**7**), 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(**8**), 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(**9**), after paragraph 9A(**10**) insert the following paragraph—

(**4**) S.I. 1975/533, as amended by S.I. 1994/3119.
(**5**) S.I. 1976/968, as amended by S.I. 1994/3119.
(**6**) 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.
(**7**) As amended by S.I. 1994/3144.
(**8**) S.I. 1978/40; regulation 3 was amended by S.I. 1994/3142 and 3144.
(**9**) S.I. 1989/684.
(**10**) Paragraph 9A was inserted by S.I. 1995/871.

"**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(**11**), 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(**12**), in Schedule 4 (application of the provisions of the Act)—

(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(**13**), 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(**14**)—

(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

(**11**) S.I. 1992/605.
(**12**) S.I. 1994/105.
(**13**) S.I. 1994/2844; regulation 1(2) was substituted by S.I. 1996/2635.
(**14**) S.I. 1994/3144.

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)(**15**) 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(**16**)—

(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

(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(**17**), 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(**18**), 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

(**15**) Paragraph 2(e) of Schedule 1 was amended by SI 2002/236.
(**16**) S.I. 1997/1830; the relevant amending instrument is S.I. 2003/696.
(**17**) S.I. 2000/1059.
(**18**) S.I. 2001/3968.

(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(**19**), 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(**20**), 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;".

18. In the National Health Service (Functions of Strategic Health Authorities and Primary Care Trusts and Administration Arrangements) (England) Regulations 2002(**21**), 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;".

(**19**) S.I. 2001/3998.
(**20**) S.I. 2002/1438.
(**21**) S.I. 2002/2375.