

SCHEDULE 4

Regulation 19

APPLICATION OF PROVISIONS OF THE ACT

(1) Provision of the Medicines Act 1968	(2) Modification
section 6	as though in subsection (1) for “this Part of this Act” there were substituted “Part II of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”; as though “licences and” were omitted; and as though after “certificates” there were inserted “of registration”;
	as though in subsection (2) for “this Act” there were substituted “the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”
section 21	as though in subsections (1), (2) and (3), “or the Commission” and “or Commission”, in any place where those words appear, were omitted; as though in subsection (1) for “subsection (3) of section 20 of this Act” there were substituted “regulation 5(2) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”; as though for the word “licence” in both places where it appears there were substituted “certificate of registration”; and as though for “that subsection” there were substituted “regulation 5(2) of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”;
	as though in subsections (3) and (4) for “licence”(in any place where it appears) there were substituted “certificate of registration”;
	as though in subsection (4) “, in a case where the applicant has not been heard by, or made representations to, the Commission under subsection (1) of this section” were omitted and as though for “he” in the first place where it appears, there were substituted “the applicant”;
	as though in paragraph (a) of subsection (5), “subsection (2) or” were omitted;
	as though for paragraph (d) of subsection (5) there were substituted “propose on grounds not relating to safety or quality to refuse to grant the certificate”

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(1) Provision of the Medicines Act 1968	(2) Modification
section 22	as though in subsection (1) for “licence under this Part of this Act” there were substituted “certificate of registration”;
section 23	as though in subsection (2) “or propose to grant a licence otherwise than in accordance with the application” were omitted and for “licence” there were substituted “certificate of registration”
section 29	as though in subsection (1) “to the provisions of this Part of this Act relating to clinical trials and medicinal tests on animals and” were omitted; as though subsection (4) were omitted
section 44	as though in subsection (1) for “section 28 of this Act” there were substituted “regulation 9 of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”; and as though in subsection (2) for “, revoke or vary”, in both places in which they appear, there were substituted “or revoke” and for “, revocation or variation” there were substituted “or revocation” and as though for “licence” (in any place where it appears) there were substituted “certificate of registration”
section 44	as though in subsection (1) for “licence under this Part of this Act (including a licence of right) or for a clinical trial certificate or animal test certificate (including a certificate to which a person is entitled by virtue of section 37(4) of this Act” there were substituted “certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”; as though in subsection (2) for “licence under this Part of this Act” there were substituted “certificate of registration” and as though “, or of a clinical trial certificate or animal test certificate,” were omitted; as though in subsection (3) the words from the beginning to “subsection (4) of this section,” were omitted and as though “licence or” and “varied,” were omitted;

(1) Provision of the Medicines Act 1968	(2) Modification
section 45(1)	as though subsection (4) were omitted; as though in subsection (5) “other than a licence of right” were omitted and for “licence” (in both places where it appears) there were substituted the word “certificate” as though in subsection (1) before “section 8”, for “,” there were substituted “or” and as though “, section 31, section 32, section 34 or section 40” and “or animal feeding stuff” were omitted and as though for “any of those sections” there were substituted “either of those sections”; as though subsection (2) were omitted; as though in subsection (3) “or of a clinical trial certificate or animal test certificate” were omitted and, in paragraph (a), for “licence or certificate” there were substituted “certificate of registration”; as though subsections (4) and (5) were omitted; as though in subsection (8) for “(1) to (6)” there were substituted “(1), (3) and (6)”
section 46(2)	as though “or of a clinical trial certificate or animal test certificate” (wherever those words appear) were omitted; as though in subsection (1), for “any substance or article” to “product manufactured or assembled)” there were substituted “a medicinal product which has been manufactured or assembled”; and as though for “that licence or” there were substituted “that certificate”; as though in paragraph (a) of subsection (2) “applicable to them” were omitted; as though in paragraph (b) of subsection (2) “or certificate” were omitted

(1) As regards subsection (8), see Magistrates' Courts Act 1980 (c. 43), section 32(2) and S.I. 1984/447. As regards subsection (9), see Criminal Justice Act 1982 (c. 48), sections 37, 38 and 46; S.I. 1984/447; and the Criminal Justice Act 1991 (c. 53), sections 17 and 18.

(2) Section 46 was amended by Schedule 1 to the Animal Health and Welfare Act 1984 (c. 26).

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(1) Provision of the Medicines Act 1968	(2) Modification
section 58A ⁽³⁾	as though “and” were inserted at the end of subsection (1)(a) and subsection (1)(b) were omitted
section 59	as though in paragraph (c) of subsection (1) for “that licence” there were substituted “that certificate” and as though for subsection (3) where it first appears there were substituted “(2B)”
section 92	as though in paragraph (b) of subsection (4) for “licence” there were substituted “certificate” and as though for “subsection (3)” where those words first appear there were substituted “(2B)”
section 93	as though subsections (2), (4) and (10) were omitted and as though paragraph (b) of subsection (5) were omitted
section 94	as though in subsection (1) for “product licence under this Act” there were substituted “certificate of registration” and for “licence” in both places where it appears there were substituted “certificate of registration”
section 96	
section 97	
section 107	as though in subsection (1) for “Part II of this Act” there were substituted “the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1993” and as though “or of a Minister under section 75 of this Act” and “licence or” were omitted;
	as though in subsection (2) for “this Act” (in the first two places in which those words appear) there were substituted “the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” and as though “or of any regulations made under this Act” were omitted;
	as though in subsection (4) “licence or” (wherever those words appear) were omitted
section 108 ⁽⁴⁾	as though at the end of subsection (1) there were inserted “and of the Medicines

⁽³⁾ Section 58A was inserted by regulation 2 of [S.I. 1992/3271](#).

⁽⁴⁾ Section 108 was amended by the Local Government Act 1972 (c. 70), Schedule 30, the Animal Health and Welfare Act 1984 (c. 40), section 16 and Schedule 1, [S.I. 1968/1699](#) and the Food Safety Act 1990 (c. 16), section 59(1) and Schedule 3.

(1) Provision of the Medicines Act 1968	(2) Modification
	<p>(Homoeopathic Medicinal Products for Human Use) Regulations 1994”</p> <p>as though in subsection (6), in paragraph (a) “40,” and from “and of any regulations” to the end of the paragraph were omitted and as though paragraph (c) were omitted;</p> <p>as though in subsection (8) paragraph (b) were omitted;</p> <p>as though in subsection (11) paragraph (a) and, in paragraph (b), “in all other respects”, were omitted</p>
section 109(5)	as though at the end of subsection (1) there were inserted “and of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”
section 110(6)	as though at the end of subsection (1) there were inserted “and of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” and as though subsection (4) were omitted
section 111	<p>as though in paragraph (a) of subsection (1) after “any provisions of” there were inserted “the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994 or”;</p> <p>as though in subsection (3) for “licence or certificate under Part II of the Act” there were substituted “certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” and as though “licence or” were omitted</p>
section 112	as though in subsection (7) for the words “licence or certificate under Part II of the Act” there were substituted “certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” and as though the words “licence or” were omitted
section 118	as though in paragraph (b) of subsection (1) for “this Act” there were substituted “the

(5) Section 109 was amended by Schedule 27 to the Local Government (Scotland) Act 1973 (c. 65) and by Schedule 3 to the Food Safety Act 1990.

(6) Section 110 was amended by S.R. & O. (N.I.) 1973/211.

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(1) Provision of the Medicines Act 1968	(2) Modification
section 119	Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” as though for “this Act” (in the first place in which those words appear) there were substituted “the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” and in the other places in which they appear there were substituted “those Regulations”
section 121	as though in subsection (4) for “90” there were substituted “89”
section 122	as though in subsection (2) for “65,” there were substituted “65 and” and as though “and section 90” were omitted
section 124	as though subsection (2) were omitted
section 126	as though in subsection (1) paragraph (a) were omitted; and as though “animal feeding stuff or” (in both places where those words appear) and “animal feeding stuffs or” were omitted; as though in subsection (2) “or animal feeding stuff” and “or of animal feeding stuffs” were omitted; as though in subsection (3) from “, to any of those provisions” to the end were omitted; as though in subsection (4) “, or of so much of subsection (2) of section 90 of this Act as relates to leaflets” and “or of animal feeding stuffs in which medicinal products have been incorporated” were omitted; in paragraph (a) as though “or” were omitted; and as though paragraph (b) were omitted
section 127	as though for “this Act” there were substituted “the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”
Schedule 2	as though for “the licence” or “licence” (wherever those words appear) there were substituted “certificate”; as though paragraph 1 were omitted; as though in paragraphs 2 and 4, “or the Commission” and “or Commission” (wherever those words appear) were omitted;

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(1) Provision of the Medicines Act 1968	(2) Modification
	as though in paragraph 2 for “the preceding paragraph” there were substituted “paragraph (2) of regulation 9 of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994” and for “, revoked or varied” there were substituted “or revoked”;
	as though in paragraph 3 “or the Commission, as the case may be,” were omitted;
	as though in paragraph 4 “, or to be varied so as to contain provisions specified in their advice” were omitted;
	as though in paragraph 5 as though “, in a case where the holder of the licence has not been heard by, or made representations to, the Commission under paragraph 2 of this Schedule” were omitted;
	as though in sub-paragraph (a) of paragraph 6 “paragraph 3 or” were omitted and as though in sub-paragraph (d) for “, revoke or vary” there were substituted “or revoke”;
	as though in paragraph 8 for “section 28 of this Act” there were substituted “paragraph (2) of regulation 9 of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994”; as though sub-paragraph (a) were omitted; and in sub-paragraph (b) for “, revoke or vary” there were substituted “or revoke”, and for “, revocation or variation” there were substituted “or revocation”;
	as though in paragraphs 11, 13 and 14 for “paragraphs 1 to 9” there were substituted “paragraphs 2 to 9”;
	as though for paragraph 12 there were substituted “The licensing authority shall report the suspension forthwith to the appropriate committee.”;
	as though in paragraph 13 for the words from the beginning to “the Commission” there were substituted “if the licensing authority are advised by the appropriate committee” and for “, or ought to be revoked or varied” there were substituted “or revoked”;

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(1) Provision of the Medicines Act 1968	(2) Modification as though paragraph 15 were omitted
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