Health Act 1999

1999 CHAPTER 8

PART I

THE NATIONAL HEALTH SERVICE

Control of prices of medicines and profits

[F1 33 Powers relating to voluntary schemes.

(1) The powers conferred by this section may be exercised where there is in existence a scheme (referred to in this section and sections 34 and 35 as a voluntary scheme) made by the Secretary of State and the industry body for the purpose of—

(a) limiting the prices which may be charged by any manufacturer or supplier to whom the scheme relates for the supply of any health service medicines, or

(b) limiting the profits which may accrue to any manufacturer or supplier to whom the scheme relates in connection with the manufacture or supply of any health service medicines.

(2) For the purposes of this section and sections 34 and 35, a voluntary scheme is to be treated as applying to a manufacturer or supplier to whom it relates if—

(a) he has consented to the scheme being so treated (and has not withdrawn that consent), and

(b) no notice is in force in his case under subsection (4).

(3) For the purposes of this section a voluntary scheme has effect, in relation to a manufacturer or supplier to whom it applies, with any additions or modifications made by him and the Secretary of State.

(4) If any acts or omissions of any manufacturer or supplier to whom a voluntary scheme applies (a "scheme member") have shown that, in the scheme member's case, the scheme is ineffective for either of the purposes mentioned in subsection (1), the Secretary of State may by a written notice given to the scheme member determine that the scheme is not to apply to him.

(5) A notice under subsection (4) must give the Secretary of State's reasons for giving the notice; and the Secretary of State may not give a notice under that subsection until he has given the scheme member an opportunity to make representations about the acts or omissions in question.

(6) Consent under subsection (2)(a) must be given, or withdrawn, in the manner required by the Secretary of State.

(7) The Secretary of State may after consultation with the industry body require any manufacturer or supplier to whom a voluntary scheme applies to—

(a) record and keep any information, and

(b) provide any information to the Secretary of State,

which the Secretary of State may require for the purpose of enabling the scheme to operate or facilitating its operation or for the purpose of giving full effect to any provision made under subsection (8).

(8) The Secretary of State may—

(a) prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price charged by him for the supply of any health service medicine covered by the scheme without the approval of the Secretary of State, and

(b) provide for any amount representing any increase in contravention of that prohibition in the sums charged by that person for that medicine, so far as the increase is attributable to supplies to the health service, to be paid to the Secretary of State within a specified period.**]**

Textual Amendments

F1 S. 33 repealed by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 6, **Sch. 4** (with Sch. 2 Pt. 1), the repeal coming into force at 1.3.2007 to the extent that s. 33 is already in force at that date, and otherwise in accordance with s. 8(2)(4)(a)(5) of the repealing Act; 1999 c. 8, **s. 33** is re-enacted as 2006 c. 41, **s. 261**, which re-enactment comes into force immediately after and to the extent that s. 33 comes into force, see 2006 c. 41, **s. 277(4)**. The commencement of this provision of the Health Act 1999 (c. 8) brings into force its re-enactment in the National Health Service Act 2006 (c. 41) and also its repeal by virtue of provision in section 6 of, and Schedule 4 to, the National Health Service (Consequential Provisions) Act 2006 (c. 43)

Commencement Information

I1 S. 33 partly in force; s. 33 not in force at Royal Assent see s. 67(1); s. 33(1)-(6) in force for certain purposes at 1.9.1999 by S.I. 1999/2177, **art. 2(3)(a)**; s. 33(7) in force for certain purposes at 3.4.2007 by S.I. 2007/1179, **art. 2(a)**

I2 S. 33(8) in force at 7.8.2017 by S.I. 2017/810, **art. 2(a)**

34 Power to control prices.

F2 . . . . . .

Textual Amendments

F2 S. 34 repealed (1.3.2007) by National Health Service (Consequential Provisions) Act 2006 (c. 43), ss. 6, 8(2), **Sch. 4** (with Sch. 2 Pt. 1)

[F3 35 Statutory schemes.

(1) The Secretary of State may, after consultation with the industry body, make a scheme (referred to in this section and section 36 as a statutory scheme) for the purpose of—

(a) limiting the prices which may be charged by any manufacturer or supplier for the supply of any health service medicines, or

(b) limiting the profits which may accrue to any manufacturer or supplier in connection with the manufacture or supply of any health service medicines.

(2) A statutory scheme may, in particular, make any provision mentioned in subsections (3) to (6).

(3) The scheme may require any manufacturer or supplier to whom it applies to—

(a) record and keep information, and

(b) provide information to the Secretary of State.

(4) The scheme may provide for any amount representing sums charged by any manufacturer or supplier to whom the scheme applies, in excess of the limits determined under the scheme, for health service medicines covered by the scheme to be paid by that person to the Secretary of State within a specified period.

(5) The scheme may provide for any amount representing the profits, in excess of the limits determined under the scheme, accruing to any manufacturer or supplier to whom the scheme applies in connection with the manufacture or supply of health service medicines covered by the scheme to be paid by that person to the Secretary of State within a specified period.

(6) The scheme may—

(a) prohibit any manufacturer or supplier to whom the scheme applies from increasing, without the approval of the Secretary of State, any price charged by him for the supply of any health service medicine covered by the scheme, and

(b) provide for any amount representing any increase in contravention of that prohibition in the sums charged by that person for that medicine, so far as the increase is attributable to supplies to the health service, to be paid to the Secretary of State within a specified period.

(7) A statutory scheme may not apply to a manufacturer or supplier to whom a voluntary scheme applies.**]**

Textual Amendments

F3 S. 35 repealed by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 6, **Sch. 4** (with Sch. 2 Pt. 1), the repeal coming into force in accordance with s. 8(2)(4)(a)(5) of the repealing Act. [Note: the repeal is therefore wholly prospective as at the in-force date of the repealing Act, s. 35 not having been brought into force to any extent by that date]; 1999 c. 8, **s. 35** is re-enacted as 2006 c. 41, **s. 263**, which re-enactment comes into force immediately after and to the extent that s. 35 comes into force, see 2006 c. 41, **s. 277(4)**. The commencement of this provision of the Health

Act 1999 (c. 8) brings into force its re-enactment in the National Health Service Act 2006 (c. 41) and also its repeal by virtue of provision in section 6 of, and Schedule 4 to, the National Health Service (Consequential Provisions) Act 2006 (c. 43)

Commencement Information

I3 S. 35 in force at 7.8.2017 by S.I. 2017/810, **art. 2(b)**

36 Statutory schemes: supplementary.

F4 . . . . . .

Textual Amendments

F4 S. 36 repealed by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 6, **Sch. 4** (with Sch. 2 Pt. 1), the repeal coming into force at 1.3.2007 to the extent that s. 36 is already in force at that date, and otherwise at 3.4.2007 in accordance with s. 8(2)(4)(a)(5) of the repealing Act

Commencement Information

I4 S. 36 wholly in force at repeal; s. 36 not in force at Royal Assent; s. 36 in force for certain purposes at 3.8.1999 by S.I. 1999/2177, **art. 2(2)(b)**; s. 36 otherwise in force at 3.4.2007 by S.I. 2007/1179, **art. 2(b)**

[F5 37 Enforcement.

(1) Regulations may provide for a person who contravenes any provision of regulations or directions under sections 33 to 36 to be liable to pay a penalty to the Secretary of State.

(2) The penalty may be—

(a) a single penalty not exceeding £100,000, or

(b) a daily penalty not exceeding £10,000 for every day on which the contravention occurs or continues.

(3) Regulations may provide for any amount required to be paid to the Secretary of State by virtue of section 33(8)(b), 34(1)(b) or 35(4) or (6)(b) to be increased by an amount not exceeding 50 per cent.

(4) Regulations may provide for any amount payable to the Secretary of State by virtue of provision made under section 33(8)(b), 34(1)(b) or 35(4), (5) or (6)(b) (including such an amount as increased under subsection (3)) to carry interest at a rate specified or referred to in the regulations.

(5) Provision may be made by regulations for conferring on manufacturers and suppliers a right of appeal against enforcement decisions taken in respect of them in pursuance of sections 33 to 36 and this section.

(6) The provision which may be made by virtue of subsection (5) includes any provision which may be made by model provisions with respect to appeals under section 6 of the M1 Deregulation and Contracting Out Act 1994, reading—

(a) the references in subsections (4) and (5) of that section to enforcement action as references to action taken to implement an enforcement decision,

(b) in subsection (5) of that section, the references to interested persons as references to any persons and the reference to any decision to take enforcement action as a reference to any enforcement decision.

(7) In subsections (5) and (6), "enforcement decision" means a decision of the Secretary of State or any other person to—

(a) require a specific manufacturer or supplier to provide information to him,

(b) limit, in respect of any specific manufacturer or supplier, any price or profit,

(c) refuse to give his approval to a price increase made by a specific manufacturer or supplier,

(d) require a specific manufacturer or supplier to pay any amount (including an amount by way of penalty) to him,

and in this subsection "specific" means specified in the decision.

(8) A requirement or prohibition, or a limit, under sections 33 to 36 may only be enforced under this section and may not be relied on in any proceedings other than proceedings under this section.

(9) In this section "regulations" means regulations made by the Secretary of State, and the Secretary of State must consult the industry body before making any regulations under this section.

(10) The Secretary of State may by order increase (or further increase) either of the sums mentioned in subsection (2).**]**

Textual Amendments

F5 S. 37 repealed by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 6, **Sch. 4** (with Sch. 2 Pt. 1), the repeal coming into force at 1.3.2007 to the extent that s. 37 is already in force at that date, and otherwise in accordance with s. 8(2)(4)(a)(5) of the repealing Act; 1999 c. 8, **s. 37** is re-enacted as 2006 c. 41, **s. 265**, which re-enactment comes into force immediately after and to the extent that s. 37 comes into force, see 2006 c. 41, **s. 277(4)**. The commencement of this provision of the Health Act 1999 (c. 8) brings into force its re-enactment in the National Health Service Act 2006 (c. 41) and also its repeal by virtue of provision in section 6 of, and Schedule 4 to, the National Health Service (Consequential Provisions) Act 2006 (c. 43)

Commencement Information

I5 S. 37 partly in force; s. 37 not in force at Royal Assent see s. 67(1); s. 37 in force for certain purposes at 3.8.1999 by S.I. 1999/2177, **art. 2(2)(c)**; s. 37(1)-(9) in force at 1.11.1999 insofar as not already in force by S.I. 1999/2177, **art. 2(4)(a)**

I6 S. 37(10) in force at 7.8.2017 by S.I. 2017/810, **art. 2(c)**

Marginal Citations

M1 1994 c.40.

[F6 38 Controls: supplementary.

(1) Any power conferred on the Secretary of State by sections 33(6) to (8) and 34 to 36 may be exercised by—

(a) making regulations, or

(b) giving directions to a specific manufacturer or supplier,

and the regulations may themselves confer power for the Secretary of State to give directions to a specific manufacturer or supplier; and in this subsection "specific" means specified in the direction concerned.

(2) Any power to make regulations under any of those provisions or section 37 may be exercised generally in relation to manufacturers or suppliers of health service medicines or be exercised in relation to any class of manufacturers or suppliers.

(3) The powers to refuse approval under section 33(8)(a) or 35(6)(a) or to impose a limit under section 34(1)(a) or 35(1) are exercisable only with a view to limiting by reference to the prices or profits which would be reasonable in all the circumstances—

(a) the prices which may be charged for, or

(b) the profits which may accrue to any manufacturer or supplier in connection with,

the manufacture or supply for the purposes of the health service of health service medicines.

(4) In so exercising those powers (in the case of sections 34(1)(a) and 35(1) and (6)(a)) the Secretary of State and any other person must bear in mind, in particular, the need for medicinal products to be available for the health service on reasonable terms and the costs of research and development.

(5) Section 57 of, and Schedule 11 to, the 1977 Act and section 49 of, and Schedule 10 to, the 1978 Act (maximum prices of medical supplies) are to cease to have effect in relation to health service medicines; but the powers conferred by sections 33 to 36 do not affect any other powers of the Secretary of State to control prices or profits.

(6) This subsection and subsections (7) and (8) apply for the interpretation of sections 33 to 37 and this section—

"health service" means any of the health services within the meaning of the 1977 Act, the 1978 Act or the [M2]Health and Personal Social Services (Northern Ireland) Order 1972,

"health service medicine" means a medicinal product used to any extent for the purposes of the health service,

"the industry body" means any body which appears to the Secretary of State appropriate to represent manufacturers and suppliers,

"manufacture" includes assemble and "manufacturer" means any person who manufactures health service medicines,

"medicinal product" has the meaning given by section 130 of the [M3]Medicines Act 1968,

"supplier" means any person who supplies health service medicines.

(7) References to contravention of a provision include failure to comply with it.

(8) References to supplying medicines include selling them.**]**

Textual Amendments

F6 S. 38 repealed by National Health Service (Consequential Provisions) Act 2006 (c. 43), s. 6, **Sch. 4** (with Sch. 2 Pt. 1), the repeal coming into force at 1.3.2007 to the extent that s. 38 is already in force at that date, and otherwise in accordance with s. 8(2)(4)(a)(5) of the repealing Act; 1999 c. 8, **s. 38** is re-enacted as 2006 c. 41, **s. 266**, which re-enactment comes into force immediately after and to the extent that s. 38 comes into force, see 2006 c. 41, **s. 277(4)**. The commencement of this provision of

the Health Act 1999 (c. 8) brings into force its re-enactment in the National Health Service Act 2006 (c. 41) and also its repeal by virtue of provision in section 6 of, and Schedule 4 to, the National Health Service (Consequential Provisions) Act 2006 (c. 43)

Commencement Information

I7 S. 38 in force at 7.8.2017 in so far as not already in force by S.I. 2017/810, **art. 2(d)**

I8 S. 38 partly in force; s. 38 not in force at Royal Assent see s. 67(1); s. 38(6) in force for certain purposes at 3.8.1999 by S.I. 1999/2177, **art. 2(2)(d)**; s. 38 in force for certain purposes at 1.9.1999 by S.I. 1999/2177, **art. 3(b)**; s. 38(5) in force at 1.11.1999 by S.I. 1999/2177, **art. 2(4)(a)**; s. 38 in force for certain purposes at 1.11.1999 by S.I. 1999/2177, **art. 2(4)(b)**; s. 38 in force for certain purposes at 3.4.2007 by S.I. 2007/1179, **art. 2(c)**

Marginal Citations

M2 S.I. 1972/1265 (N.I.14).

M3 1968 c.67.

Changes to legislation:
There are currently no known outstanding effects for the Health Act 1999, Cross Heading: Control of prices of medicines and profits.