



National Health Service Act 2006

2006 CHAPTER 41

PART 13

MISCELLANEOUS

Price of medical supplies

260 Control of maximum price of medical supplies other than health service medicines

- (1) The Secretary of State may by order provide for the control of maximum prices to be charged for any medical supplies, other than health service medicines, required for the purposes of this Act.
- (2) The Secretary of State may by direction given with respect to any undertaking, or by order made with respect to any class or description of undertakings, require persons carrying on the undertaking or undertakings of that class or description—
 - (a) to keep such books, accounts and records relating to the undertaking as may be prescribed by the direction, the order or a notice served under the order,
 - (b) to furnish at such times, in such manner and in such form as may be so prescribed such estimates, returns or information relating to the undertaking as may be so prescribed.
- (3) The power to make an order under this section includes power to provide for any incidental and supplementary provisions which the Secretary of State considers it expedient for the purposes of the order to provide.
- (4) Schedule 22 makes further provision in relation to this section.
- (5) In this section and Schedule 22—

“medical supplies” includes surgical, dental and optical materials and equipment, and

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“undertaking” means any public utility undertaking or any undertaking by way of trade or business, which is concerned with medical supplies required for the purposes of this Act,

and “equipment” includes any machinery, apparatus or appliance, whether fixed or not, and any vehicle.

261 Powers relating to voluntary schemes

- (1) The powers under this section may be exercised where there is in existence a scheme (referred to in this section and sections 262 and 263 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 262 and 263, a voluntary scheme must 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 does not 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

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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.

262 Power to control prices

- (1) The Secretary of State may, after consultation with the industry body—
 - (a) limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine, and
 - (b) provide for any amount representing sums charged by that person for that medicine in excess of the limit to be paid to the Secretary of State within a specified period.
- (2) The powers conferred by this section are not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies.

263 Statutory schemes

- (1) The Secretary of State may, after consultation with the industry body, make a scheme (referred to in this section and section 264 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

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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.

264 Statutory schemes: supplementary

- (1) The Secretary of State may, after consultation with the industry body, make any provision he considers necessary or expedient for the purpose of enabling or facilitating—
- (a) the introduction of a statutory scheme or of a limit under section 262, or
 - (b) the determination of the provision to be made in a proposed statutory scheme.
- (2) The provision may, in particular, require any person to whom such a scheme or limit may apply to—
- (a) record and keep information,
 - (b) provide information to the Secretary of State.
- (3) Where the Secretary of State is preparing to make or vary a statutory scheme, he may make any provision he considers necessary or expedient for transitional or transitory purposes which could be made by such a scheme.

265 Enforcement

- (1) Regulations may provide for a person who contravenes any provision of regulations or directions under sections 261 to 264 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 261(8)(b), 262(1)(b) or 263(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 261(8)(b), 262(1)(b) or 263(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 261 to 264 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 Deregulation and Contracting Out Act 1994 (c. 40), 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,

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- (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 261 to 264, may only be enforced under this section and may not be relied on in any proceedings other than proceedings under this section.
- (9) 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).

266 Controls: supplementary

- (1) Any power conferred on the Secretary of State by sections 261(6) to (8) and 262 to 264 may be exercised by—
 - (a) making regulations, or
 - (b) giving directions to a specific manufacturer or supplier.
- (2) Regulations under subsection (1)(a) may 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.
- (3) The powers to refuse approval under section 261(8)(a) or 263(6)(a) or to impose a limit under section 262(1)(a) or 263(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 262(1)(a) and 263(1) and (6)(a)) the Secretary of State and any other person must bear in mind, in particular—
 - (a) the need for medicinal products to be available for the health service on reasonable terms, and
 - (b) the costs of research and development.
- (5) The powers conferred by sections 261 to 264 do not affect any other powers of the Secretary of State to control prices or profits.

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(6) In this section and sections 261 to 265—

“health service” includes the health services within the meaning of the National Health Service (Scotland) Act 1978 (c. 29) and the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I.14)),

“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 Medicines Act 1968 (c. 67),

“supplier” means any person who supplies health service medicines,

and contravention of a provision includes a failure to comply with it, and supplying medicines includes selling them.

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