



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 [^{F1}the health service].

[^{F2}(1A) Before making an order under subsection (1) the Secretary of State must consult any body which appears to the Secretary of State appropriate to represent persons who manufacture, distribute or supply medical supplies falling within subsection (1).]

^{F3}(2)

^{F3}(3)

^{F3}(4)

(5) In this section ^{F4}...—

“medical supplies” includes surgical, dental and optical materials and equipment, ^{F5}...

^{F5}...

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

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Textual Amendments

- F1** Words in s. 260(1) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 7\(3\), 12\(3\)](#); S.I. 2017/809, reg. 2(f)
- F2** S. 260(1A) inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 7\(4\), 12\(3\)](#); S.I. 2017/809, reg. 2(f)
- F3** S. 260(2)-(4) omitted (7.8.2017) by virtue of [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 10\(3\)\(a\), 12\(3\)](#); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F4** Words in s. 260(5) omitted (7.8.2017) by virtue of [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 10\(3\)\(b\)\(i\), 12\(3\)](#); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F5** Words in s. 260(5) omitted (7.8.2017) by virtue of [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 10\(3\)\(b\)\(ii\), 12\(3\)](#); S.I. 2017/809, reg. 2(h) (with reg. 3)

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 ^[F6], 263 and 264A) as a “voluntary scheme”) made by the Secretary of State and the industry body for ^[F7]one or more of the following purposes] —
- (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, ^{F8}...
 - (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,
 - ^[F9](c) providing for any manufacturer or supplier to whom the scheme relates to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of any health service medicines (whether on the basis of net prices, average selling prices or otherwise).]
- (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 ^[F10]any] 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.

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^{F11}(7)

(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.

[^{F12}(9) The Secretary of State may provide for any amount payable in accordance with a voluntary scheme by any manufacturer or supplier to whom the scheme applies to be paid to the Secretary of State within a specified period.

(10) Neither of the following affects any liability of a manufacturer or supplier to pay amounts to the Secretary of State arising during a period when a health service medicine was covered by a voluntary scheme treated as applying to the person or the taking of any action in relation to any such liability—

- (a) the withdrawal of consent by the person to the scheme being treated as applying to the person;
- (b) the giving of notice to the person under subsection (4).]

Textual Amendments

- F6** Words in s. 261(1) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 3\(2\)\(a\), 12\(3\); S.I. 2017/809, reg. 2\(b\)](#)
- F7** Words in s. 261(1) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 3\(2\)\(b\), 12\(3\); S.I. 2017/809, reg. 2\(b\)](#)
- F8** Word in s. 261(1) omitted (7.8.2017) by virtue of [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 3\(2\)\(c\), 12\(3\); S.I. 2017/809, reg. 2\(b\)](#)
- F9** S. 261(1)(c) inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 3\(2\)\(d\), 12\(3\); S.I. 2017/809, reg. 2\(b\)](#)
- F10** Word in s. 261(4) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 3\(3\), 12\(3\); S.I. 2017/809, reg. 2\(b\)](#)
- F11** S. 261(7) omitted (7.8.2017) by virtue of [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 10\(4\), 12\(3\); S.I. 2017/809, reg. 2\(h\) \(with reg. 3\)](#)
- F12** S. 261(9)(10) inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\), ss. 3\(4\), 12\(3\); S.I. 2017/809, reg. 2\(b\)](#)

Commencement Information

- I1** S. 261(8) in force at 7.8.2017 immediately after 1999 c. 8, s. 33(8) comes into force by [S.I. 2017/810, art. 2\(a\)](#)

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

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- (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.

[^{F13}(2) If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine.]

Textual Amendments

F13 S. 262(2) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), **ss. 4, 12(3)**; S.I. 2017/809, reg. 2(c)

263 Statutory schemes

- (1) The Secretary of State may, after consultation with the industry body [^{F14}and any other person the Secretary of State thinks appropriate], make a scheme (referred to in this section and section 264 as a statutory scheme) [^{F15}one or more of the following purposes] —

- (a) limiting the prices which may be charged by any manufacturer or supplier for the supply of any health service medicines, ^{F16}...
- (b) limiting the profits which may accrue to any manufacturer or supplier in connection with the manufacture or supply of any health service medicines,
- [^{F17}(c) providing for any manufacturer or supplier of any health service medicines to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of those medicines (whether on the basis of net prices, average selling prices or otherwise).]

[^{F18}(1A) Consultation about the proposed exercise of a power under subsection (1) must include consultation about the following—

- (a) the economic consequences for the life sciences industry in the United Kingdom;
- (b) the consequences for the economy of the United Kingdom;
- (c) the consequences for patients to whom any health service medicines are to be supplied and for other health service patients.]

- (2) A statutory scheme may, in particular, make any provision mentioned in subsections [^{F19}(4)] to (6).

^{F20}(3)

- (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.

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[^{F21}(5A) The scheme may provide for any amount payable in accordance with the scheme by any manufacturer or supplier to whom the scheme applies to be paid 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.

[^{F22}(7) If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine.]

[^{F23}(8) Subsection (7) does not affect any liability of a person to pay amounts to the Secretary of State arising during a period when a health service medicine was covered by a statutory scheme applying to the person or the taking of any action in relation to any such liability.]

Textual Amendments

- F14** Words in s. 263(1) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(2)(a)**, 12(3); S.I. 2017/809, reg. 2(d)
- F15** Words in s. 263(1) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(2)(b)**, 12(3); S.I. 2017/809, reg. 2(d)
- F16** Word in s. 263(1) omitted (7.8.2017) by virtue of Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(2)(c)**, 12(3); S.I. 2017/809, reg. 2(d)
- F17** S. 263(1)(c) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(2)(d)**, 12(3); S.I. 2017/809, reg. 2(d)
- F18** S. 263(1A) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(3)**, 12(3); S.I. 2017/809, reg. 2(d)
- F19** Word in s. 263(2) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(5)(a)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F20** S. 263(3) omitted (7.8.2017) by virtue of Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(5)(b)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F21** S. 263(5A) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(4)**, 12(3); S.I. 2017/809, reg. 2(d)
- F22** S. 263(7) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(5)**, 12(3); S.I. 2017/809, reg. 2(d)
- F23** S. 263(8) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 5(6)**, 12(3); S.I. 2017/809, reg. 2(d)

Commencement Information

- I2** S. 263 in force at 7.8.2017 immediately after 1999 c. 8, s. 35 comes into force by S.I. 2017/810, **art. 2(b)**

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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.

^{F24}(2)

- (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.

Textual Amendments

F24 S. 264(2) omitted (7.8.2017) by virtue of [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), **ss. 10(6)**, 12(3); S.I. 2017/809, **reg. 2(h)** (with **reg. 3**)

Commencement Information

I3 S. 264 in force at 3.4.2007 in so far as not already in force immediately after 1999 c. 8, s. 36 comes into force by [S.I. 2007/1179](#), **art. 2(b)**

[^{F25}264A] Provision of information about health service products

- (1) References in this section to a UK producer are to a person who manufactures, distributes or supplies any UK health service products.
- (2) Regulations may require any UK producer to—
- (a) record and keep information which the Secretary of State may require for the purpose specified in subsection (3), and
 - (b) provide that information to the Secretary of State, (subject to subsection (9)).
- (3) The purpose is that of enabling or facilitating any of the following—
- (a) the determination of the payments to be made to any persons who provide primary medical services under Part 4;
 - (b) the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7;
 - (c) the consideration by the Secretary of State of whether—
 - (i) adequate supplies of English health service products are available, and
 - (ii) the terms on which those products are available represent value for money;
 - (d) the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the National Health Service (Wales) Act 2006;
 - (e) the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of that Act;
 - (f) the consideration by the Welsh Ministers of whether—
 - (i) adequate supplies of Welsh health service products are available, and

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- (ii) the terms on which those products are available represent value for money;
 - (g) the determination of the payments to be made to any persons who provide primary medical services under section 2C(1) of the National Health Service (Scotland) Act 1978 (“the 1978 Act”);
 - (h) the determination of the remuneration to be paid to any persons who provide pharmaceutical care services under section 2CA(1) of the 1978 Act;
 - (i) the consideration by the Scottish Ministers of whether—
 - (i) adequate supplies of Scottish health service products are available, and
 - (ii) the terms on which those products are available represent value for money;
 - (j) the determination of the remuneration to be paid to any persons who provide primary medical services or pharmaceutical services under Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14));
 - (k) the consideration by a Northern Ireland department of whether—
 - (i) adequate supplies of Northern Ireland health service products are available, and
 - (ii) the terms on which those products are available represent value for money;
 - (l) the exercise by the Secretary of State of any powers under sections 260 to 264 and 265;
 - (m) the operation of a voluntary scheme.
- (4) The information which the Secretary of State may require from a UK producer by virtue of this section includes the following—
- (a) the price charged or paid by the producer for UK health service products;
 - (b) the price charged or paid by the producer for delivery or other services in connection with the manufacturing, distribution or supply of UK health service products;
 - (c) the discounts or rebates or other payments given or received by the producer in connection with the manufacturing, distribution or supply of UK health service products;
 - (d) the revenue or profits accrued to the producer in connection with the manufacturing, distribution or supply of UK health service products (including, in relation to profits, the costs incurred by the producer in connection with the manufacturing, distribution or supply of the products);
 - (e) such information about medicinal products, other medical supplies or other related products as is necessary to verify whether they are UK health service products and, if so, which of the following they are—
 - (i) English health service products;
 - (ii) Welsh health service products;
 - (iii) Scottish health service products;
 - (iv) Northern Ireland health service products.
- (5) Regulations under this section must require the Secretary of State to give a UK producer an information notice if information is required in respect of the costs incurred by the producer in connection with the manufacturing, distribution or supply

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of a particular UK health service product (other than costs which relate to any transaction between the producer and a UK producer for that product).

- (6) An information notice is a notice stating—
- (a) the period in relation to or for which, or intervals at which, information is required to be provided,
 - (b) the form and manner in which information is required to be provided,
 - (c) the time at which or period within which information is required to be provided, and
 - (d) that a right of appeal is conferred by virtue of section 265(5A).
- (7) Regulations under this section may require information which does not fall within subsection (5) to be provided—
- (a) in relation to or for a prescribed period or at prescribed intervals,
 - (b) in a prescribed form and manner, and
 - (c) at a prescribed time or within a prescribed period.
- (8) The provision of information by virtue of this section does not breach—
- (a) any obligation of confidence owed by the person providing it, or
 - (b) any other restriction on the provision of information (however imposed).
- (9) Regulations under this section may not do any of the following—
- (a) require any person who provides primary medical services under Part 4 of the National Health Service (Wales) Act 2006, or any person who provides pharmaceutical services under Part 7 of that Act, to record, keep or provide information relating to any Welsh health service products which are supplied by the person in providing the services in question;
 - (b) require any person who provides primary medical services under section 2C(1) of the 1978 Act, or any person who provides pharmaceutical care services under section 2CA(1) of that Act, to record, keep or provide information relating to any Scottish health service products which are supplied by the person in providing the services in question;
 - (c) require any person who provides primary medical services or pharmaceutical services under Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14)) to record, keep or provide information relating to Northern Ireland health service products which are supplied by the person in providing the services in question.
- (10) “English health service products” means any medicinal products used to any extent for the purposes of the health service continued under section 1(1) and any other medical supplies, or other related products, required for the purposes of that health service.
- (11) “Medical supplies” is to be read in accordance with section 260(5).
- (12) “Northern Ireland health service products” means any medicinal products used to any extent for the purposes of health care provided by virtue of the Health and Social Care (Reform) Act (Northern Ireland) 2009 and any other medical supplies, or other related products, required for the purposes of health care provided by virtue of that Act.
- (13) “Scottish health service products” means any medicinal products used to any extent for the purposes of the health service within the meaning of the 1978 Act and any other medical supplies, or other related products, required for the purposes of that health service.

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- (14) “UK health service products” means any English health service products, Welsh health service products, Scottish health service products or Northern Ireland health service products.
- (15) “Welsh health service products” means any medicinal products used to any extent for the purposes of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006 and any other medical supplies, or other related products, required for the purposes of that health service.
- (16) Until the coming into force of the repeal of section 27 of the 1978 Act by schedule 3 to the Smoking, Health and Social Care (Scotland) Act 2005 the references in subsections (3)(h) and (9)(b) to pharmaceutical care services under section 2CA(1) of the 1978 Act are to be read as references to pharmaceutical services under section 27(1) of that Act.

Textual Amendments

F25 Ss. 264A-264C inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), **ss. 8, 12(3)**; [S.I. 2017/809](#), **reg. 2(g)**

264B Disclosure of information

- (1) Information provided by virtue of section 264A may be disclosed by the Secretary of State to any of the following persons—
 - (a) [^{F26}NHS England];
 - (b) any Special Health Authority;
 - ^{F27}(c)
 - (d) any government department;
 - (e) the Welsh Ministers;
 - (f) the Scottish Ministers;
 - (g) the Common Services Agency for the Scottish Health Service constituted under section 10 of the 1978 Act;
 - (h) a Northern Ireland department;
 - (i) the Regional Business Services Organisation established under section 14 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;
 - (j) any person who provides services to any person falling within any of paragraphs (a) to (i);
 - (k) any prescribed body appearing to the Secretary of State to represent UK producers;
 - (l) such of the following as may be prescribed—
 - (i) an NHS foundation trust;
 - (ii) any health service body within the meaning of section 9(4) (not falling within any of paragraphs (a) to (k) above).
- (2) A person to whom any confidential or commercially sensitive information is disclosed under subsection (1) may not—
 - (a) use the information for any purpose other than the purpose specified in relation to that person in subsection (3), or
 - (b) disclose the information to another person (subject to subsection (4)).
- (3) For the purposes of subsection (2)—

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- (a) in relation to a person falling within subsection [F28(1)(a) or (b)], the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(a) to (c), (l) or (m);
 - (b) in relation to a person falling within subsection (1)(d), the purpose is that of—
 - (i) exercising functions connected with any of the matters specified in section 264A(3)(a) to (c), (l) or (m), or
 - (ii) preventing, detecting or investigating any unlawful activities;
 - (c) in relation to a person falling within subsection (1)(e), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(d) to (f), (l) or (m);
 - (d) in relation to a person falling within subsection (1)(f) or (g), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(g) to (i), (l) or (m);
 - (e) in relation to a person falling within subsection (1)(h) or (i), the purpose is that of exercising functions connected with any of the matters specified in section 264A(3)(j) to (m);
 - (f) in relation to a person falling within subsection (1)(j), the purpose is that of providing services in connection with any purpose specified in relation to the person for whom the services are provided in any of paragraphs (a) to (e) above;
 - (g) in relation to a person falling within subsection (1)(k) or (l), the purpose is any prescribed purpose connected with any of the matters specified in section 264A(3).
- (4) The Welsh Ministers may disclose any confidential or commercially sensitive information disclosed to them under subsection (1) to any of the following persons—
- (a) a Local Health Board or other person appointed under section 88(3)(b) of the National Health Service (Wales) Act 2006 to exercise the functions of a determining authority under Part 7 of that Act;
 - (b) a National Health Service trust established under section 18 of the National Health Service (Wales) Act 2006;
 - (c) any person who provides services to the Welsh Ministers or to any person falling within paragraph (a) or (b).
- (5) A person to whom any confidential or commercially sensitive information is disclosed under subsection (4) may not—
- (a) use the information for any purpose other than the purpose of exercising functions connected with any of the matters specified in section 264A(3)(d) to (f), (l) or (m), or
 - (b) disclose the information to another person.

Textual Amendments

- F25** Ss. 264A-264C inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), **ss. 8**, 12(3); S.I. 2017/809, reg. 2(g)
- F26** Words in Act substituted (1.7.2022) by [Health and Care Act 2022 \(c. 31\)](#), s. 186(6), Sch. 1 para. 1(1)(2); S.I. 2022/734, reg. 2(a), Sch. (with regs. 13, 29, 30)
- F27** S. 264B(1)(c) omitted (1.2.2023) by virtue of [The Health and Social Care Information Centre \(Transfer of Functions, Abolition and Transitional Provisions\) Regulations 2023 \(S.I. 2023/98\)](#), reg. 1(2), **Sch. para. 10(8)(a)** (with reg. 3)

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F28 Words in s. 264B(3)(a) substituted (1.2.2023) by [The Health and Social Care Information Centre \(Transfer of Functions, Abolition and Transitional Provisions\) Regulations 2023 \(S.I. 2023/98\)](#), reg. 1(2), [Sch. para. 10\(8\)\(b\)](#) (with reg. 3)

264C Sections 264A and 264B: supplementary

- (1) Before making regulations under section 264A or 264B the Secretary of State must consult any body which appears to the Secretary of State appropriate to represent UK producers.
- (2) Nothing in section 264A or 264B requires information to be provided, or authorises information to be disclosed or used, in contravention of [^{F29}the data protection legislation].
- (3) Nothing in section 264A or 264B affects any duties, obligations or powers to require or authorise information to be provided, disclosed or used which exist apart from that section.

[In this section, “the data protection legislation” has the same meaning as in the Data ^{F30}(4) Protection Act 2018 (see section 3 of that Act).]

Textual Amendments

- F25** Ss. 264A-264C inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), [ss. 8, 12\(3\)](#); S.I. 2017/809, reg. 2(g)
- F29** Words in s. 264C(2) substituted (25.5.2018) by [Data Protection Act 2018 \(c. 12\)](#), s. 212(1), [Sch. 19 para. 115\(2\)](#) (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)
- F30** S. 264C(4) inserted (25.5.2018) by [Data Protection Act 2018 \(c. 12\)](#), s. 212(1), [Sch. 19 para. 115\(3\)](#) (with ss. 117, 209, 210); S.I. 2018/625, reg. 2(1)(g)

265 Enforcement

- (1) Regulations may provide for a person who contravenes any provision of [^{F31}orders, regulations or directions under sections 260] to [^{F32}264A] 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) [^{F33}or (9)], 262(1)(b) or 263(4), (5) [^{F34}, (5A)] 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

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- [^{F35}(a)] conferring on manufacturers and suppliers a right of appeal against enforcement decisions taken in respect of them in pursuance of sections [^{F36}260] to 264 and this section [^{F37}, and
- (b) conferring on UK producers a right of appeal against enforcement decisions taken in respect of them in pursuance of section 264A and this section (other than enforcement decisions falling within subsection (5A)).]
- [^{F38}(5A) Provision must be made by regulations for conferring on UK producers a right of appeal against enforcement decisions taken in respect of them in pursuance of section 264A and this section if the enforcement decisions relate to information notices given by virtue of section 264A(5).]
- (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,
- (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 [^{F39}, or other person who is a UK producer,] 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 [^{F40}, or other person who is a UK producer,] 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 [^{F41}260] to [^{F42}264A], may only be enforced under this section and may not be relied on in any proceedings other than proceedings under this section.
- [^{F43}(8A) Subsection (8) does not apply to any action by the Secretary of State to recover as a debt any amount required to be paid to the Secretary of State by virtue of any of sections 261 to 263 or this section.]
- [^{F44}(9) Before making any regulations under this section the Secretary of State must consult the industry body and any other body which appears to the Secretary of State appropriate to represent UK producers.]
- (10) The Secretary of State may by order increase (or further increase) either of the sums mentioned in subsection (2).
- [^{F45}(11) In this section “UK producer” is to be read in accordance with section 264A.]

Textual Amendments

F31 Words in s. 265(1) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), ss. 7(5)(a), 12(3); S.I. 2017/809, reg. 2(f)

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- F32** Word in s. 265(1) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(8)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F33** Words in s. 265(4) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 6(3)(a)**, 12(3); S.I. 2017/809, reg. 2(e)
- F34** Word in s. 265(4) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 6(3)(b)**, 12(3); S.I. 2017/809, reg. 2(e)
- F35** S. 265(5)(a): words in s. 265(5) renumbered as s. 265(5)(a) (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(9)(a)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F36** Word in s. 265(5)(a) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 7(5)(b)**, 12(3); S.I. 2017/809, reg. 2(f)
- F37** S. 265(5)(b) and preceding word inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(9)(b)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F38** S. 265(5A) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(10)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F39** Words in s. 265(7)(a) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(11)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F40** Words in s. 265(7)(d) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(11)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F41** Word in s. 265(8) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 7(5)(c)**, 12(3); S.I. 2017/809, reg. 2(f)
- F42** Word in s. 265(8) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(12)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F43** S. 265(8A) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 6(4)**, 12(3); S.I. 2017/809, reg. 2(e)
- F44** S. 265(9) substituted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(13)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)
- F45** S. 265(11) inserted (7.8.2017) by Health Service Medical Supplies (Costs) Act 2017 (c. 23), **ss. 10(14)**, 12(3); S.I. 2017/809, reg. 2(h) (with reg. 3)

Commencement Information

- I4** S. 265(10) in force at 7.8.2017 immediately after 1999 c. 8, s. 37(10) comes into force by S.I. 2017/810, **art. 2(c)**

266 Controls: supplementary

- (1) Any power conferred on the Secretary of State by sections 261(6) to [F46(9)] 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)[F47(a) or (b)] 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,

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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)[^{F48}(a) and (b)] 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.

[^{F49}(4A) The power under section 263(1)(c) is exercisable only with a view to requiring payments to be made which would be reasonable in all the circumstances, bearing 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.

(6) In this section and sections [^{F50}260] 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.

Textual Amendments

- F46** Word in s. 266(1) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), [ss. 6\(6\)](#), 12(3); S.I. 2017/809, [reg. 2\(e\)](#)
- F47** Words in s. 266(3) inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), [ss. 6\(7\)](#), 12(3); S.I. 2017/809, [reg. 2\(e\)](#)
- F48** Words in s. 266(4) inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), [ss. 6\(8\)](#), 12(3); S.I. 2017/809, [reg. 2\(e\)](#)
- F49** S. 266(4A) inserted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), [ss. 6\(9\)](#), 12(3); S.I. 2017/809, [reg. 2\(e\)](#)
- F50** Word in s. 266(6) substituted (7.8.2017) by [Health Service Medical Supplies \(Costs\) Act 2017 \(c. 23\)](#), [ss. 7\(6\)](#), 12(3); S.I. 2017/809, [reg. 2\(f\)](#)

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- I5** S. 266 in force at 3.4.2007 for specified purposes immediately after 1999 c. 8, s. 38 comes into force by [S.I. 2007/1179](#), [art. 2\(c\)](#)
- I6** S. 266 in force at 7.8.2017 in so far as not already in force immediately after 1999 c. 8, s. 38 comes into force by [S.I. 2017/810](#), [art. 2\(d\)](#)

Changes to legislation:

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Changes and effects yet to be applied to the whole Act associated Parts and Chapters:

Whole provisions yet to be inserted into this Act (including any effects on those provisions):

- s. 3B(1)(aa) inserted by [2022 c. 31 Sch. 3 para. 2\(b\)](#)
- s. 3B(1)(za) inserted by [2022 c. 31 Sch. 3 para. 2\(a\)](#)
- s. 13G(4) words omitted by virtue of 2012 c. 7, Sch. 14 para. 4A (as inserted) by [2014 c. 23 s. 120\(18\)\(a\)](#)
- s. 35(3A)(3B) inserted by [2012 c. 7 s. 159\(4\)](#)
- s. 35(3A) words substituted by [2022 c. 31 Sch. 5 para. 12\(4\)](#) (This amendment not applied to legislation.gov.uk. The insertion of s. 35(3A) by 2012 c. 7 s.159(4) not yet in force.)
- s. 40(4)-(4B) substituted for s. 40(4) by [2012 c. 7 Sch. 14 para. 5](#)
- s. 42(1A) inserted by [2012 c. 7 Sch. 14 para. 6](#)
- s. 65F(2A)-(2F) inserted by [2012 c. 7 Sch. 14 para. 15\(4\)](#) (This amendment is itself amended before it comes into force by 2014 c. 23, ss. 85(15), 120(18)(b)(c), 127(1); S.I. 2014/1714, art. 3(2)(b)(c))
- s. 65H(10A) inserted by [2012 c. 7 Sch. 14 para. 17\(4\)](#)
- s. 65H(10A) omitted by [2022 c. 31 Sch. 8 para. 7\(7\)](#) (This amendment not applied to legislation.gov.uk. 2012 c. 7 Sch. 14 revoked at 1.7.2022 by 2022 c. 31, s. 186(6), Sch. 7 para. 13 before the insertion of s. 65H(10A) could come into effect.)
- s. 82A-83A and cross-heading substituted for s. 83 and cross-heading by [2022 c. 31 Sch. 3 para. 3](#)
- s. 84(4)-(4B) substituted for s. 84(4) by [2022 c. 31 Sch. 3 para. 4\(4\)](#)
- s. 92(5A) inserted by [2022 c. 31 Sch. 3 para. 9\(4\)](#)
- s. 94(3)(ca)(cb) substituted for s. 94(3)(ca) by [2022 c. 31 Sch. 3 para. 11\(3\)](#)
- s. 98A98B substituted for s. 98A by [2022 c. 31 Sch. 3 para. 14](#)
- s. 98BC-99B and cross-heading substituted for s. 99 and cross-heading by [2022 c. 31 Sch. 3 para. 15](#)
- s. 100(3A)(3B) inserted by [2022 c. 31 Sch. 3 para. 16\(4\)](#)
- s. 109(3)(ca)(cb) substituted for s. 109(3)(ca) by [2022 c. 31 Sch. 3 para. 23\(3\)](#)
- s. 112(1)(za) inserted by [2022 c. 31 Sch. 3 para. 24\(2\)\(b\)](#)
- s. 114A114B substituted for s. 114A by [2022 c. 31 Sch. 3 para. 26](#)
- s. 114C and cross-heading inserted by [2022 c. 31 Sch. 3 para. 27](#)
- s. 116A116B and cross-heading inserted by [2022 c. 31 Sch. 3 para. 30](#)
- s. 117(4)(4A) substituted for s. 117(4) by [2022 c. 31 Sch. 3 para. 31\(4\)](#)
- s. 125A125B substituted for s. 125A by [2022 c. 31 Sch. 3 para. 39](#)
- s. 223C(1)(c)(d) inserted by [2022 c. 31 s. 28](#)
- s. 223LA inserted by [2022 c. 31 s. 30\(3\)](#)
- Sch. 15 para. 4(1)(b) and word omitted by [2012 c. 7 Sch. 14 para. 39\(3\)](#)