

Health Service Medical Supplies (Costs) Bill

EXPLANATORY NOTES

Explanatory notes to the Bill, prepared by the Department of Health, are published separately as Bill 72 – EN.

EUROPEAN CONVENTION ON HUMAN RIGHTS

Secretary Jeremy Hunt has made the following statement under section 19(1)(a) of the Human Rights Act 1998:

In my view the provisions of the Health Service Medical Supplies (Costs) Bill are compatible with the Convention rights.

Health Service Medical Supplies (Costs) Bill

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Make provision in connection with controlling the cost of health service medicines and other medical supplies; to make provision in connection with the provision of pricing and other information by those manufacturing, distributing or supplying those medicines and supplies, and other related products, and the disclosure of that information; and for connected purposes.

BE IT ENACTED by the Queen's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

Controlling cost of health service medicines

1 Voluntary schemes

- (1) Section 261 of the National Health Service Act 2006 (voluntary schemes for controlling the cost of health service medicines) is amended as follows.
- (2) In subsection (1) — 5
- (a) for “and 263” substitute “, 263 and 264A”,
 - (b) for “the purpose of” substitute “one or more of the following purposes”,
 - (c) omit the “or” before paragraph (b), and
 - (d) after paragraph (b) insert — 10
- “(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).”
- (3) In subsection (4) for “either” substitute “any”. 15
- (4) After subsection (8) insert —
- “(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. 20”

- (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 – 5
- (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)."

2 Power to control prices

For section 262(2) of the National Health Service Act 2006 (circumstances in which powers not exercisable) substitute – 10

- “(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.” 15

3 Statutory schemes

- (1) Section 263 of the National Health Service Act 2006 (statutory schemes for controlling the cost of health service medicines) is amended as follows.
- (2) In subsection (1) – 20
- (a) for “the purpose of” substitute “one or more of the following purposes”,
 - (b) omit the “or” before paragraph (b), and
 - (c) after paragraph (b) insert – 25
 - “(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).”
- (3) After subsection (5) insert – 30
- “(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.”
- (4) For subsection (7) substitute – 35
- “(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.”
- (5) After subsection (7) insert – 40
- “(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.”

4 Enforcement

- (1) The National Health Service Act 2006 is amended as follows.
- (2) Section 265 (enforcement) is amended as follows.
- (3) In subsection (4) –
 - (a) after “261(8)(b)” insert “or (9)”, and 5
 - (b) after “section 263(4), (5)” insert “, (5A)”.
- (4) After subsection (8) insert –

“(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.” 10
- (5) Section 266 (controls: supplementary) is amended as follows.
- (6) In subsection (1) (Secretary of State’s powers exercisable by making regulations or giving directions) for “(8)” substitute “(9)”.
- (7) In subsection (3) after “section 263(1)” insert “(a) or (b)”.
- (8) In subsection (4) after “section 263(1)” insert “(a) and (b)”. 15
- (9) After subsection (4) insert –

“(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 20
 - (b) the costs of research and development.”

*Controlling cost of other medical supplies***5 Control of maximum price of other medical supplies**

- (1) The National Health Service Act 2006 is amended as follows. 25
- (2) In section 260(1) (control of maximum price of medical supplies, other than health service medicines, required for the purposes of the Act) for “this Act” substitute “the health service”.
- (3) In section 265 (enforcement) –
 - (a) in subsection (1) for “regulations or directions under sections 261” substitute “orders, regulations or directions under sections 260”, 30
 - (b) in subsection (5) for “261” substitute “260”, and
 - (c) in subsection (8) for “261” substitute “260”.
- (4) In section 266(6) (interpretation) for “261” substitute “260”.
- (5) In section 278(3) (provisions which extend to Scotland and Northern Ireland) for “261” substitute “260”. 35
- (6) In Schedule 22 (which makes further provision in relation to section 260) omit paragraph 1 (which specifies provision which may be made by an order under section 260).

*Information about medical supplies etc***6 Provision and disclosure of information**

After section 264 of the National Health Service Act 2006 insert –

“264A Provision of information about health service products

- (1) Regulations may require any person who manufactures, distributes or supplies English health service products (an “English producer”) to – 5
 - (a) record and keep information which the Secretary of State may require for the purpose specified in subsection (2), and
 - (b) provide that information to the Secretary of State.
- (2) The purpose is that of enabling or facilitating any of the following – 10
 - (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 – 15
 - (i) adequate supplies of English health service products are available, and
 - (ii) the terms on which those products are available represent value for money.
- (3) Regulations may require any English producer or person who manufactures, distributes or supplies other UK health service products (an “other UK producer”) to – 20
 - (a) record and keep information which the Secretary of State may require for the purpose specified in subsection (4), and
 - (b) provide that information to the Secretary of State. 25
- (4) The purpose is that of enabling or facilitating either of the following –
 - (a) the exercise by the Secretary of State of any powers under sections 260 to 265;
 - (b) the operation of a voluntary scheme.
- (5) The information which the Secretary of State may require from an English producer or other UK producer by virtue of this section includes the following – 30
 - (a) the price charged or paid by the producer for the English health service products or other UK health service products, as the case may require (“the products”); 35
 - (b) the price charged or paid by the producer for delivery or other services in connection with the manufacturing, distribution or supply of the products;
 - (c) the discounts or rebates or other payments given or received by the producer in connection with the manufacturing, distribution or supply of the products; 40
 - (d) the revenue or profits accrued to 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 45

- whether or not they are English health service products or other UK health service products.
- (6) Regulations under this section may require information to be provided in such form and manner, and at such time or within such period, as may be prescribed. 5
- (7) 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). 10
- (8) “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.
- (9) “Medical supplies” is to be read in accordance with section 260(5). 15
- (10) “Other UK health service products” means —
- (a) any medicinal products used to any extent for the purposes of —
 - (i) the health service continued under section 1(1) of the National Health Service (Wales) Act 2006,
 - (ii) the health service within the meaning of the National Health Service (Scotland) Act 1978, or
 - (iii) health care provided by virtue of the Health and Social Care (Reform) Act (Northern Ireland) 2009, or
 - (b) any other medical supplies, or other related products, required for the purposes of anything specified in sub-paragraphs (i) to (iii) of paragraph (a). 20 25

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) the Board; 30
 - (b) any Special Health Authority;
 - (c) the Health and Social Care Information Centre;
 - (d) any government department;
 - (e) the Welsh Ministers;
 - (f) the Scottish Ministers; 35
 - (g) a Northern Ireland department;
 - (h) any person who provides services to any person falling within any of paragraphs (a) to (g);
 - (i) any prescribed body appearing to the Secretary of State to represent English producers or other UK producers; 40
 - (j) any other prescribed person.
- (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. 45

- (3) For the purposes of subsection (2) –
- (a) in relation to a person falling within subsection (1)(a) to (c), the purpose is that of exercising functions connected with any of the matters specified in section 264A(2) or (4);
 - (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(2) or (4), or
 - (ii) preventing, detecting or investigating any unlawful activities;
 - (c) in relation to a person falling within subsection (1)(e) to (g), the purpose is that of exercising functions connected with either of the matters specified in section 264A(4);
 - (d) in relation to a person falling within subsection (1)(h), 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 (c) above;
 - (e) in relation to a person falling within subsection (1)(i) or (j), the purpose is any prescribed purpose connected with any of the matters specified in section 264A(2) or (4).

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 English producers or other 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 the Data Protection Act 1998.
- (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.”

Supplementary and final provisions

7 Consequential amendments

- (1) The National Health Service Act 2006 is amended as follows.
- (2) In section 260 (control of maximum price of medical supplies other than health service medicines) –
 - (a) omit subsections (2) to (4), and
 - (b) in subsection (5) omit –
 - (i) “and Schedule 22”, and
 - (ii) the definition of “undertaking” (and the “and” before it).
- (3) In section 261 (powers relating to voluntary schemes) omit subsection (7).
- (4) In section 263 (statutory schemes) –
 - (a) in subsection (2) for “(3)” substitute “(4)”, and
 - (b) omit subsection (3).
- (5) In section 264 (statutory schemes: supplementary) omit subsection (2).

- (6) Section 265 (enforcement) is amended in accordance with subsections (7) to (12).
- (7) In subsection (1) for “264” substitute “264A”.
- (8) In subsection (5) —
 - (a) the words from “conferring” to the end become paragraph (a), and 5
 - (b) after paragraph (a) insert “, and
 - (b) conferring on English producers and other UK 10
 - producers a right of appeal against enforcement
 - decisions taken in respect of them in pursuance of
 - section 264A and this section.”
- (9) In subsection (7)(a) and (d) after “supplier” insert “, or other person who is an English producer or other UK producer,”.
- (10) In subsection (8) for “264” substitute “264A”.
- (11) For subsection (9) substitute —
 - “(9) Before making any regulations under this section the Secretary of State 15
 - must consult the industry body and any other body which appears to
 - the Secretary of State appropriate to represent English producers or
 - other UK producers.”
- (12) After subsection (10) insert —
 - “(11) In this section “English producer” and “other UK producer” are to be 20
 - read in accordance with section 264A.”
- (13) In section 271 (territorial limit of exercise of functions), in subsection (3)(i) omit “and Schedule 22”.
- (14) In section 272 (orders, regulations, rules and directions) omit subsection (9).
- (15) In section 278 (extent), in subsection (3), after “supplies)” insert “, and this Part 25
- to the extent that it applies to those sections,”.
- (16) In Schedule 22 (provisions in relation to section 260) omit paragraphs 2 to 11.

8 Extent

This Act extends to England and Wales, Scotland and Northern Ireland.

9 Commencement 30

- (1) Section 8, this section and section 10 come into force on the day on which this Act is passed.
- (2) The remaining provisions of this Act come into force on such day as the Secretary of State may by regulations appoint.
- (3) Regulations under this section may make — 35
 - (a) different provision for different purposes, and
 - (b) transitional, transitory or saving provision.
- (4) Regulations under this section are to be made by statutory instrument.

10 Short title

This Act may be cited as the Health Service Medical Supplies (Costs) Act 2016.

Health Service Medical Supplies (Costs) Bill

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B I L L

To make provision in connection with controlling the cost of health service medicines and other medical supplies; to make provision in connection with the provision of pricing and other information by those manufacturing, distributing or supplying those medicines and supplies, and other related products, and the disclosure of that information; and for connected purposes.

*Presented by Secretary Jeremy Hunt
supported by
The Prime Minister,
Mr Chancellor of the Exchequer,
Secretary Greg Clark,
Mr Philip Dunne and
Nicola Blackwood.*

*Ordered, by The House of Commons,
to be Printed, 15 September 2016.*

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HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Health Service Medical Supplies (Costs) Bill as introduced in the House of Commons on 15 September 2016 (Bill 72).

- These Explanatory Notes have been prepared by the Department of Health in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill.

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Overview of the Bill

- 1 The Health Service Medical Supplies (Costs) Bill amends and extends existing provisions of the National Health Service Act 2006 (“the NHS Act”) which relate to:
 - the control of the cost of health service medicines and other medical supplies;
 - the provision of pricing and other information to the Secretary of State by those manufacturing, distributing or supplying health service medicines or other related products required for the purposes of the health service; and
 - the disclosure of the information referred to in the preceding paragraph in specified circumstances.

Clauses relating to the control of the cost of health service medicines

- 2 Clauses 1 to 4 of the Bill relate to the control of the cost of health service medicines¹. The provisions in the Bill clarify that the Secretary of State may make regulations or directions to limit the costs of health service medicines by requiring manufacturers and suppliers of health service medicines to make payments calculated by reference to sales or estimated sales of those medicines. The provisions in the Bill will enable the Secretary of State to recover and enforce those payments.

Clause relating to the control of the cost of other medical supplies

- 3 Section 260 of the NHS Act provides the Secretary of State with the power to control the maximum price of medical supplies other than health service medicines. Clause 5 makes the enforcement provisions and the territorial extent provisions relating to section 260 consistent with the enforcement and territorial extent provisions relating to the powers to control the cost of health service medicines.

Clause relating to the provision and disclosure of information

- 4 Clause 6 will introduce a new power to enable the Secretary of State to make regulations to obtain information from any person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purposes of the health service, for purposes specified in the Bill. The provisions in the Bill will also allow the information to be disclosed in specified circumstances.

¹ "Health service medicine" means a medicinal product used to any extent for the purposes of the health service, as defined in section 266(6) of the National Health Service Act 2006

Policy background

Clauses relating to the control of the cost of health service medicines

- 5 The Secretary of State primarily controls the cost of most branded health service medicines by way of a voluntary scheme agreed with industry. The current voluntary scheme is the 2014 Pharmaceutical Price Regulation Scheme (PPRS). Companies that are members of the scheme make payments to ensure that spending on branded health service medicines stays at the agreed level.
- 6 The powers under the NHS Act allow the Secretary of State, after consultation with the appropriate industry body², to make a statutory scheme for the purpose of limiting the prices of, or profits accruing from, the sales of health service medicines by companies that choose not to be members of the voluntary scheme.
- 7 Currently, manufacturers or suppliers of health service medicines can choose (primarily based on the nature of their business) to be controlled either by the voluntary scheme or the statutory scheme.

Voluntary scheme

- 8 There has been a succession of voluntary schemes agreed between the Secretary of State and the Association of the British Pharmaceutical Industry (ABPI) since the 1950s. The schemes are normally agreed on a five-year term.
- 9 The current PPRS was agreed in January 2014, and includes for the first time a payment mechanism requiring members of the scheme to pay a defined percentage of the value of their sales revenue from specified branded health service medicines to the Secretary of State, provided that the growth in health service expenditure on branded health service medicines exceeds a pre-agreed level set out in the scheme.
- 10 Section 261 of the NHS Act refers to the existence of voluntary schemes made between the Department of Health and industry for the purpose of 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 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. Although the scheme itself is voluntary, section 261 provides the Secretary of State with specific statutory powers in relation to members of such voluntary schemes.

Statutory scheme

- 11 Sections 262 to 266 of the NHS Act provide the Secretary of State with the power, including by way of a statutory scheme, to limit the prices which may be charged by any manufacturer or supplier for the supply of any health service medicine, or to limit the profits which may accrue to any manufacturer or supplier in connection with the manufacture or supply of any health service medicines by way of regulations or directions. Currently, these regulations or

² For example the Association of the British Pharmaceutical Industry (ABPI)

directions cannot apply to members of a voluntary scheme which are made for the purposes set out in section 261 of the Act.

- 12 The current statutory scheme is set out in regulations³ and applies to any manufacturer or supplier of branded health service medicines who is not a member of the voluntary scheme. The current statutory scheme operates through a cut in list price (i.e. the manufacturer's published price).

Background to proposed amendments

- 13 While current arrangements allow manufacturers and suppliers to choose which scheme to be controlled by, since 2013 it has become clear that the mechanism of controlling prices in the statutory scheme is less effective in terms of the level of saving it makes than the mechanism in the voluntary scheme, leading to some companies leaving the voluntary scheme in favour of the statutory scheme.
- 14 The Government consulted on introducing the same kind of mechanism that exists in the voluntary scheme into the statutory scheme in the autumn of 2015. Industry responses queried whether the Government had sufficient power to introduce a statutory payment similar to that which forms part of the agreed voluntary scheme, and some have made clear that they would challenge this view in the courts. The Government has therefore concluded that amendments should be made to the NHS Act to put beyond doubt that the Secretary of State has the power to require a payment mechanism in the statutory scheme to limit the cost of health service medicines.

Proposed amendments to the NHS Act

- 15 The Bill makes provision for amendments to the NHS Act to clarify that the Secretary of State can also make a statutory scheme for the purpose of requiring any manufacturer or supplier to whom the scheme applies to pay to the Secretary of State an amount calculated by reference to sales or estimated sales of any health service medicines.
- 16 Additionally, the Bill provisions clarify that the powers relating to voluntary schemes are exercisable in relation to voluntary schemes whereby scheme members make payments based on their sales of health service medicines. The Bill makes provision for a new power to enable the Secretary of State to require a voluntary scheme member to pay a sum due under that scheme. If the scheme member fails to pay, the existing provisions (section 265) which allow recovery through the courts will apply. The Bill provisions make clear that payments owed whilst the manufacturer or supplier was a member of the voluntary scheme may be recovered notwithstanding that a member of a voluntary scheme moves to the statutory scheme or vice versa.
- 17 Currently, provisions in the NHS Act state that regulations or directions made under sections 262 or 263 for the purposes of limiting prices of, or profits accrued from health service medicines cannot apply to members of a voluntary scheme. This is the case, even if the regulations or directions are directed at health service medicines manufactured or supplied by that scheme member which are not covered by the voluntary scheme. For example, the current PPRS covers branded health service medicines. However, a member of the PPRS may

³ The Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007

also manufacture unbranded health service medicines. The current provisions in the NHS Act prevent the Secretary of State from making regulations or directions to limit prices or profits that apply to a member of the PPRS, even if the regulations or directions are directed at the member's unbranded medicines. The Bill therefore amends the provisions of the NHS Act, so that the Secretary of State can make directions or regulations under section 262 or 263 to limit the prices of, or profits relating to, health service medicines of a manufacturer or supplier in the voluntary scheme, as long as their health service medicine to which the directions or regulations relate is not covered by the voluntary scheme. The Secretary of State will continue to be able to exercise their power in relation to a supplier not in the voluntary scheme even where the health service medicine has already been subject to controls under the voluntary scheme by virtue of the manufacturer of the health service medicine being a member of the voluntary scheme.

Clause relating to the control of cost of other medical supplies

- 18 Section 260 of the NHS Act provides the Secretary of State with the power to control the maximum price of medical supplies other than health service medicines. Clause 5 of the Bill amends sections 260, 265 and 278 so that the enforcement provisions at section 265 (which currently only apply to health service medicines) and the relevant territorial extent provisions at section 278 (which currently only extend the health service medicines provisions to the United Kingdom) also apply to other medical supplies.

Clause relating to the provision and disclosure of information

- 19 The Government currently collects information, under a variety of voluntary and statutory arrangements, from suppliers and manufacturers of health service medicines. These arrangements have certain limitations. In particular, where the arrangements are voluntary, not all manufacturers, wholesalers or other suppliers participate. This inevitably means the Department's information is inconsistent. In addition the extent and conditions under which that information can be shared, and the purposes for which it can be shared, are uncertain.
- 20 The Bill therefore provides for a single information gathering power in relation to health service products which will replace the existing statutory information gathering powers relating to the statutory and voluntary schemes, providing a clearer basis for collecting and using that information. The Bill also makes provision for the sharing of that information with various bodies for defined purposes.
- 21 The Bill makes provision for amendments to the NHS Act to remove existing powers to request information under sections 260 to 264, and introduces a new section to the Act to allow the Secretary of State to make regulations to require any person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purposes of the health service, to keep and supply information with regards to those products.
- 22 The Secretary of State will therefore be able to request information from all persons in the supply chain involved in the supply of health service medicines, or other related products required for the purposes of the health service, and will be able to use that information for the purposes specified in the Bill.
- 23 It will also be possible for the Secretary of State to disclose that information in specified circumstances (see commentary on clause 6 below).

Legal background

24 The relevant legal background is explained in the policy background section of these Notes.

Territorial extent and application

- 25 By virtue of clause 8, the clauses in the Bill extend to England, Wales, Scotland and Northern Ireland.
- 26 Regulation of the price of medicines and medical supplies used for the purpose of the health services in England, Scotland and Wales is reserved with regards to Scotland and Wales. The regulation of the price of medicines and medical supplies is not reserved with regards to Northern Ireland.
- 27 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom. The table also summarises the position regarding legislative consent motions and matters relevant to Standing Orders Nos. 83J to 83X of the Standing Orders of the House of Commons relating to Public Business.

Clauses relating to the control of the cost of health service medicines

- 28 The current legislation relating to the control of the cost of health service medicines extends and applies to the United Kingdom. These existing powers are being amended and will therefore require a Legislative Consent Motion (“LCM”) to be agreed by the Northern Ireland Assembly.

Clause relating to the control of cost of other medical supplies

- 29 The current legislation relating to the control of the cost of medical supplies extend to England and Wales but will be amended to extend to Scotland and Northern Ireland as well. An LCM will require agreement from the Northern Ireland Assembly for this purpose.

Clause relating to the provision and disclosure of information

- 30 The current legislation relating to the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the NHS Act (for example, dispensing GPs) and the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of the NHS Act is not reserved with regards to Scotland, Wales and Northern Ireland. Clause 6 includes some subsections relating to the provision of information for these purposes and also for the consideration by the Secretary of State of whether adequate supplies of English health service products are available, and the terms on which those products are available represent value for money. Currently, these provisions of Clause 6 apply to ‘English producers’ only (for specific details see commentary on clause 6).
- 31 Clause 6 also includes provisions which, with regards to Scotland and Wales, relate to reserved matters concerning the health service in the United Kingdom (again for specific details see commentary on clause 6). An LCM agreed by the Northern Ireland Assembly for these provisions is required.
- 32 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom. The table also summarises the position regarding legislative consent motions and matters relevant to Standing Orders Nos. 83J to 83X of the Standing Orders of the House of Commons relating to Public Business.

Commentary on provisions of Bill

- 33 The Bill is made up of ten clauses. The substantive clauses make amendments to, or insert new provisions into, the Act. The first four clauses relate to the provisions of the Act which deal with the control of the costs of health service medicines. Clause 5 relates to the control of cost of other medical supplies and clause 6 concerns the provision and disclosure of information relating to health service products. Clause 7 makes certain consequential amendments. Clause 8 relates to the territorial extent of the provisions. Clause 9 makes provision for the commencement of the Bill and clause 10 provides for the short title of the Bill.

Part 1: Controlling cost of health service medicines

Clause 1: Voluntary Schemes

- 34 Clause 1 amends section 261 (Powers relating to voluntary schemes) of the Act.
- 35 Section 261(1) of the Act refers to the existence of a voluntary scheme made by the Secretary of State and Industry 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.
- 36 Subsections (2) to (8) of section 261 of the Act provides the Secretary of State with specific statutory powers in relation to members of such voluntary schemes.
- 37 Subsection (2) of clause 1 of the Bill amends section 261(1) of the NHS Act to add a new paragraph (c) to expand the description of the kinds of schemes which are within the scope of the powers of the Secretary of State relating to voluntary schemes. New paragraph (c) refers to a scheme which provides 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 health service medicines.
- 38 Subsection (3) of clause 1 clarifies that a voluntary scheme, as referred to in section 261 of the Act, and to which the powers in the Act relate, can include any or all of the purposes set out at paragraphs (a) to (c) of section 261(1) namely price control, profit control or a requirement to make payments.
- 39 Subsection (4) of clause 1 adds new subsection (9) to section 261 which will enable the Secretary of State, by regulations or directions (see section 266(1)), to require a manufacturer or supplier who has not made payments in accordance with the terms of a voluntary scheme, to make a payment to the Secretary of State within a time period specified in the regulations or directions.
- 40 Subsection (4) of clause 1 also adds new subsection (10) to section 261 of the Act. This provision provides that where a manufacturer or supplier leaves the voluntary scheme, that does not affect any liability to make payments which arose during the period that the health service medicine was covered by the voluntary scheme when the manufacturer or supplier was a member of the voluntary scheme.

Clause 2: Power to control prices

- 41 Section 262 of the NHS Act provides the Secretary of State with the power to limit prices of health service medicines and to provide for any amount representing sums charged for that medicine, in excess of the limit, to be paid to the Secretary of State. Section 266(1) of the NHS Act allows the Secretary of State to do this by way of regulations or directions.
- 42 Clause 2 amends section 262(2) so that if at any time a health service medicine is covered by a voluntary scheme that applies to its manufacturer or supplier, the powers in section 262 cannot be exercised in relation to that manufacturer or supplier as regards that medicine. This allows the Secretary of State to make directions or regulations under section 262 to limit the prices of health service medicines of a manufacturer or supplier in the voluntary scheme, as long as their health service medicine is not covered by the voluntary scheme.

Clause 3: Statutory schemes

- 43 Clause 3 amends section 263 (Statutory Schemes) of the Act.
- 44 Section 263(1) provides the Secretary of State with the power to make 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.
- 45 Subsection (2) of clause 3 amends section 263(1) of the Act to add a new paragraph (c) which clarifies that the Secretary of State can make a statutory scheme for the purpose of 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 health service medicines.
- 46 Subsection (3) of clause 3 adds a new subsection (5A) to section 263 which will enable the Secretary of State by regulations or directions to require a manufacturer or supplier who has not made payments in accordance with the statutory scheme, to make a payment to the Secretary of State within a time period specified in the regulations or directions.
- 47 Subsection (4) of clause 3 substitutes section 263(7) which currently has the effect that the power to create a statutory scheme cannot be applied to a manufacturer or supplier to whom the voluntary scheme applies even if the price of the medicine they supply is not controlled by the voluntary scheme. The effect of the amendment is that if, at any time, a health service medicine is covered by a voluntary scheme that applies to its manufacturer or supplier, the power in section 263 cannot be exercised in relation to that manufacturer or supplier as regards that medicine. The Secretary of State will continue to be able to exercise the power in section 263 in relation to a supplier who is not in the voluntary scheme even where the health service medicine has already been subject to controls under the voluntary scheme by virtue of the manufacturer of the health service medicine being a member of the voluntary scheme.
- 48 Subsection (5) of clause 3 also adds new subsection (8) to section 263 of the Act. This provision provides that any liability of a manufacturer or supplier to pay amounts that arose at a time when the health service medicine was covered by a statutory scheme which applied to the manufacturer or supplier is not affected by the manufacturer or supplier joining a voluntary scheme.

Clause 4: Enforcement

- 49 Clause 4 amends sections 265 (Enforcement) and section 266 (Controls: supplementary) of the Act.
- 50 Subsection (3) of clause 4 makes consequential amendments to section 265 of the Act, which sets out the enforcement mechanism for the control of the cost of health service medicines provisions of the Act. In particular, subsection (3) of clause 4 ensures that the enforcement provisions of the Act apply to the new provisions inserted into sections 261, 262 and 263. This includes the power to apply a penalty where there has been a breach of any of the provisions and the power to provide for any amount payable to the Secretary of State by virtue of new sections 261(8) (voluntary schemes) and new section 263(5A) (statutory schemes) to carry interest at a rate specified or referred to in the regulations.
- 51 Subsection (4) of clause 4 clarifies subsection (8) of section 265 of the NHS Act by inserting subsection (8A) into section 265. Subsection (8) of section 265 of the Act provides that a prohibition or requirement under sections 261 to 264 may not be relied upon in any proceedings other than proceedings under sections 265. Subsection (8) was capable of being misconstrued in such a way that it might be said that the Secretary of State could not enforce payments that are due in a Court. New subsection (8A) makes clear that that is not the case. It explains that 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 by virtue of the enforcement provisions in section 265.
- 52 Subsections (5) to (9) make consequential amendments to section 266 of the Act. Section 266 makes supplementary provisions for sections 261-265 which relate to the control of costs of health service medicines. Subsections (5) to (9) ensure that the supplementary provisions of the Act apply to new provisions inserted into sections 261 (voluntary schemes), section 262 (power to control prices) and 263 (statutory schemes) of the Act. This includes enabling the Secretary of State to exercise the new powers by making regulations or giving directions to a specific manufacturer or supplier, clarifying that the powers which relate to a direct limit of prices or profits, continue only to apply to provisions which directly limit prices or profits, and inserting new subsection (4A) so that the new power in subsection 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 the need for medicinal products to be available for the health service on reasonable terms as well as the costs of research and development.

Part 2: Controlling cost of other medical supplies

Clause 5: Control of maximum price of other medical supplies

- 53 Section 260 of the NHS Act enables the Secretary of State to make an order to provide for the control of maximum prices to be charged for any medical supplies other than health service medicines which are required for the purposes of the Act. Schedule 22 makes further provision in relation to section 260 of the Act.
- 54 The territorial extent of section 260 is extended by virtue of subsection (5) of clause 5 so that, as a result of an amendment to section 278(3), it extends to Scotland and Northern Ireland as well as England and Wales. Subsection (2) of clause 5 therefore also amends section 260 so that it refers to “medical supplies...required for the purposes of the health service” rather than “for the purposes of this Act”. The definition of “health service” here includes the health services in England, Wales, Scotland and Northern Ireland.

- 55 Subsection (3) of Clause 5 amends section 265 so that some of the enforcement powers in section 265 which currently apply to health service medicines also apply to other medical supplies. In particular, section 265(1) of the NHS Act is amended so that penalties can be applied to any person who breaches any provisions made by way of an order under section 260.
- 56 As mentioned in relation to the enforcement provisions, subsection (8) of section 265 of the Act provides that a prohibition or requirement under sections 261 to 264 may not be relied upon in any proceedings other than proceedings under sections 265 and new subsection (8A) explains that 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 by virtue of the enforcement provisions in section 265. Subsection (3) of clause 5 amends subsection (8) of section 265 so that it also applies to section 260.
- 57 Subsection (4) of clause 5 amends section 266(6) (interpretation) of the NHS Act so that the definitions in this section also apply to section 260. Section 266(6) defines health service, health service medicine, the industry body, manufacture, medicinal product and supplier.
- 58 Subsection (6) of clause 5 omits reference to paragraph 1 of Schedule 22. Paragraph 1 provides further detail as to the contents of an order. This paragraph is no longer necessary for the purposes of applying section 260.

Part 3: Information about medical supplies etc.

Clause 6: Provision and disclosure of information

- 59 Clause 6 inserts new sections 264A, 264B and 264C into the Act.

New section 264A

- 60 Section 264A will allow the Secretary of State to make regulations to require any person who manufactures, distributes or supplies health service medicines, medical supplies or other related products required for the purpose of the health service to record, keep and provide information to the Secretary of State for specified purposes.
- 61 The information may include but will not be limited to:
- a. The price charged or paid for the products;
 - b. The price charged or paid for the delivery or other services in connection with the manufacturing, distribution or supply of those products;
 - c. The discounts or rebates or other payments given or received in connection with the manufacturing, distribution or supply of those products;
 - d. The revenue or profits accrued in connection with manufacturing, distribution or supply of those products;
 - e. Such information about medicinal products, other medical supplies, or other related products as is necessary to verify whether or not they are products which have been supplied to the health service in England or the United Kingdom.

- 62 The Secretary of State will be able to require that manufacturers, distributors and suppliers of English health service products (medicinal products used to any extent for the health service in England, medical supplies or other related products, required for the purposes of the health service in England to record, keep and provide information for the purposes of enabling or facilitating:
- a. the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the Act (such as dispensing GPs);
 - b. the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of the Act (such as community pharmacists); or
 - c. the consideration by the Secretary of State of whether adequate supplies of English health service products are available and whether the terms on which those products are available represent value for money.
- 63 The Secretary of State will be able to require that manufacturers, distributors and suppliers of English Health Service Products or other UK health service products (health service medicines, medical supplies or other related products required for the purposes of the health service in the United Kingdom) to record, keep and provide information for the purposes of enabling or facilitating:
- a. the exercise by the Secretary of State of any powers under sections 260 to 265 (these sections relate to the control of the cost of health service medicines and supplies); or
 - b. the operation of a voluntary scheme.
- 64 Clause 6 also provides that:
- a. regulations made under new section 264A may set out the form and manner, and the time or period within which information is to be provided; and
 - b. the provision of information under the section does not breach any obligation of confidentiality owed by a person providing the information nor can it breach any other restriction that may have been imposed on the disclosure of that information to the Secretary of State.
- 65 Subsections (8), (9) and (10) of new section 264A, inserted by Clause 6, define various terms used in the new section. In particular they define what is meant by “English health service products” and “Other UK health service products” by setting out the distinction between the meaning of “health service” in England and the rest of the UK by reference to the relevant legislation in Wales, Scotland and Northern Ireland. In explaining what is meant by “products” the subsections clarify that the term includes medicinal products used for those health services and any other medical supplies or other related products required for the purposes of those health services.
- 66 The meaning of “medical supplies” is confirmed by reference to section 260(5) (Control of maximum price of medical supplies other than health service medicines) so that the meaning includes surgical, dental and optical materials and equipment.

New Section 264B

- 67 Section 264B allows the Secretary of State to disclose the information obtained from manufacturers, distributors and suppliers by virtue of new section 264A in specified circumstances.
- 68 It allows the information obtained to be disclosed to certain health service bodies including NHS England, any special health authority (such as the NHS Business Services Authority) and

the Health and Social Care Information Centre. If the information disclosed to the health service bodies is confidential or commercially sensitive, they can only use the information for the purpose of exercising their functions, and only if those functions are connected with the matters specified in section 264A(2) or (4) of the Bill. These include matters relating to the control of the cost of health service medicines in the United Kingdom, payments to persons who provide primary care services (such as dispensing GPs) in England, the determination of remuneration paid to those who provide pharmaceutical services in England and the consideration by the Secretary of State of whether adequate supplies of English health service products are available and whether the terms on which those products are available represent value for money.

- 69 Section 264B also allows the information obtained under section 264A to be disclosed to any government department. If the information is confidential or commercially sensitive they will only be able to use the information for either the purpose of exercising their functions, and again only if those functions are connected with the matters specified in section 264A(2) or (4) as set out at paragraph 68 above, or for the purpose of preventing, detecting or investigating any unlawful activities.
- 70 Section 264B allows the information under section 264A to be disclosed also to Welsh Ministers, Scottish Ministers and a Northern Ireland Department. If the information is confidential or commercially sensitive, they can only use that information for the purpose of exercising their functions if their functions are connected to matters specified in section 264A(4), which are matters relating to the control of the cost of health service medicines in the United Kingdom.
- 71 Section 264B allows information obtained under section 264A to be disclosed to any persons who provide services to NHS England, any Special Health Authority, the Health and Social Care Information Centre, any government department, Welsh Ministers, Scottish Ministers or a Northern Ireland Department. If the information is confidential or commercially sensitive, the information can only be used for the purpose for which the person whom they are providing services to is allowed to use the information, as specified in the Bill.
- 72 Section 264B also provides the Secretary of State with the power to make regulations to disclose information obtained under section 264A to a body that represents manufacturers, suppliers and distributors of health service medicines, medical supplies and other related products required for the purposes of the health service, or to any other person. If the information is confidential or commercially sensitive, the representative body or the other person can only use the information for purposes prescribed in regulations and for matters connected to sections 264A(2) or (4), as set out above.

New Section 264C

- 73 Section 264C supplements new sections 264A and 264B. In particular, it requires the Secretary of State to consult any body (such as the Association of the British Pharmaceutical Industry) which appears to the Secretary of State to represent manufacturers, distributors and suppliers of health service medicines, medical supplies or other related products required for the purposes of the health service in England or the United Kingdom before making any regulations under section 264A or 264B.
- 74 Section 264C also clarifies that regulations made under section 264A cannot require information to be provided or for disclosure of information under section 264B to be in contravention of the Data Protection Act.
- 75 Finally, section 264C clarifies that regulations for the provision of information made under 264A or the disclosure of information by virtue of section 264B does not affect any other

existing powers, obligations or duties that already exist to require or authorise information to be provided, disclosed or used.

Part 4: Supplementary and final provisions

Clause 7: Consequential amendments

- 76 Clause 7 makes a number of consequential amendments to sections 260-266 of the Act and omits paragraphs 2-11 of Schedule 22 of the Act.

Existing information provisions

- 77 Clause 7 removes any existing information gathering powers under sections 260, 261, 263 and 264 which have been rendered unnecessary as a consequence of new section 264A.

Section 260 and Schedule 22

- 78 Section 260 enables the Secretary of State to make an order to provide for the control of maximum prices to be charged for any medical supplies other than health service medicines which are required for the purposes of the Act. Schedule 22 makes further provision in relation to section 260 of the Act.
- 79 Subsection (2) of clause 7 omits reference to ‘undertakings’ from section 260. This definition is no longer accurate for the purposes of defining the persons that may be affected by section 260.
- 80 Subsection (2) of clause 7 in relation to section 260 of the NHS Act, and subsection (14) of clause 7 in relation to section 271 (Territorial limit of exercise of functions) of the NHS Act omit reference to Schedule 22. This is because paragraph 1 of Schedule 22 is omitted by subsection (6) of clause 5 (as referred to in the description of clause 5 above) and the remaining paragraphs of Schedule 22 by subsection (16) of clause 7. Paragraphs 2 to 11 of Schedule 22 provide further detail as to the delivery or service of documents where required for the purposes of section 260, the territorial extent of section 260, the restrictions on disclosing information, the criminal offences committed by corporations under section 260 or Schedule 22, the circumstances in which documents must be produced and the penalties for offences. The enforcement provisions in Schedule 22 are inconsistent with the enforcement provisions in section 265 which relate to the control of the cost of health service medicines. The other provisions in Schedule 22, which are not related directly to enforcement, are unnecessary for the purpose of exercising the powers in section 260.
- 81 Subsection (8) of clause 7, amends section 265(5) of the Act so that provisions can be made by way of regulations for conferring on manufacturers and suppliers a right of appeal where an enforcement decision has been made in respect of section 260.

Other consequential information provisions

- 82 Subsection (7) of clause 7 amends section 265(1) of the Act so that the Secretary of State can apply penalties to breaches of the information provisions made by regulations under new section 264A.
- 83 Subsection (8) of clause 7 amends section 265(5) so that manufacturers, distributors and suppliers referred to in new section 264A who have had an enforcement decision made against them have the right to appeal.
- 84 Subsection (9) amends section 265(7)(a) and (d) so that the definition of “enforcement decision” includes decisions made against manufacturers, distributors and suppliers referred

to in new section 264A.

- 85 Subsection (11) replaces the existing consultation requirement so that the Secretary of State must consult not only the industry body, as is already the case, but also any other body which appears to the Secretary of State appropriate to represent persons who distribute health service medicines or persons who manufacture, distribute or supply any other medical supplies, or other related products, required for the purposes of the health service.
- 86 Subsection (12) confirms the definition of “English producer”, “medical supplies” and “other UK producer”, by referring to the relevant definitions in other clauses of the Bill and sections of the Act.
- 87 Subsection (14) of clause 7 omits subsection (9) from section 272 (orders, regulations, rules and directions) of the NHS Act, so that subsections (7) and (8) of 272, which relate to the exercise of the power to make orders apply to section 260 of the NHS Act, in the same way they do the health service medicines provisions.
- 88 Subsection (15) of clause 7 amend section 278 of the NHS Act so that the supplementary provisions in the NHS Act also extent to Scotland and Northern Ireland, to the extent that the supplementary provisions apply to sections 260- 266 of the NHS Act.

Clause 8: Extent

- 89 The Act will extend to England and Wales, Scotland and Northern Ireland.

Clause 9: Commencement

- 90 Other than the provisions which relate to extent (clause 8) and the short title (clause 10) the provisions will come into force on a date determined by the Secretary of State by way of Regulations.

Financial implications of the Bill

Clauses relating to the control of the cost of health service medicines

- 91 The Bill will amend primary legislation only. No policies will be directly implemented as a result of these changes. The objective is to allow the Government to implement a statutory scheme for controlling the cost of medicines based on a payment mechanism, in order to better align the way the statutory scheme and voluntary 2014 Pharmaceutical Price Regulation Scheme work. The Impact Assessment accompanying the Bill provides further information on the potential financial implications.

Clause relating to the provision and disclosure of information

- 92 The Bill’s information measures will amend primary legislation only. No policies will be directly implemented as a result of these changes. Their implementation would require additional future changes to secondary legislation and additional Impact Assessments to assess their cost effectiveness. The Department expects to be able to absorb the cost of managing the new information power within existing administrative resources and there may be further efficiency savings as a result of changes indirectly emerging from the information gathered.

Parliamentary approval for financial costs or for charges imposed

93 The House Authorities do not consider that a Ways and Means resolution is required.

Compatibility with the European Convention on Human Rights

94 The department does not consider that the provisions of the Bill engage Convention rights.

Related documents

95 The following documents are relevant to the Bill and can be read at the stated locations:

- Impact assessment:
<https://www.gov.uk/government/publications/health-service-medical-supplies-costs>

Annex A - Territorial extent and application in the United Kingdom

- Clauses 1 to 5 apply and extend to England, Wales, Scotland and Northern Ireland.
- Clause 6 extends to England, Wales, Scotland and Northern Ireland. Some of the subsections of clause 6 apply to England only, whilst other subsections apply to the United Kingdom.
- As none of the clauses apply to England only, or to England and Wales only, the Department considers that the EVEL standing orders do not apply to any of the clauses in the Bill.
- See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.⁴

Provision	Extends to E & W and applies to England?	Extends to E & W and applies to Wales?	Extends and applies to Scotland?	Extends and applies to Northern Ireland?	Would corresponding provision be within the competence of the National Assembly for Wales?	Would corresponding provision be within the competence of the Scottish Parliament?	Would corresponding provision be within the competence of the Northern Ireland Assembly?	Legislative Consent Motion needed?
Clause 1	Yes	Yes	Yes	Yes	No	No	Yes	Yes (NI)
Clause 2	Yes	Yes	Yes	Yes	No	No	Yes	Yes (NI)
Clause 3	Yes	Yes	Yes	Yes	No	No	Yes	Yes (NI)
Clause 4	Yes	Yes	Yes	Yes	No	No	Yes	Yes (NI)
Clause 5	Yes	Yes	Yes	Yes	No	No	Yes	Yes (NI)
Clause 6	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (NI)
Clause 7	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (NI)
Clause 8	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (NI)
Clause 9	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (NI)
Clause 10	Yes	Yes	Yes	Yes	N/A	N/A	N/A	Yes (NI)

⁴ References in this Annex to a provision being within the legislative competence of the Scottish Parliament, the National Assembly for Wales or the Northern Ireland Assembly are to the provision being within the legislative competence of the relevant devolved legislature for the purposes of Standing Order No. 83J of the Standing Orders of the House of Commons relating to Public Business.

HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

EXPLANATORY NOTES

These Explanatory Notes relate to the Health Service Medical Supplies (Costs) Bill as introduced in the House of Commons on 15 September 2016 (Bill 72).

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