HOUSE OF LORDS

Library Note

Health Service Medical Supplies (Costs) Bill (HL Bill 81 of 2016–17)

The Health Service Medical Supplies (Costs) Bill was introduced into the House of Lords on 7 December 2016 and is due to receive its second reading on 21 December 2016. The Bill seeks to amend and extend the provisions of the National Health Service Act 2006 which relate to the control of the cost of both health service medicines and other medical supplies.

The NHS in England spent £15.2 billion on medicines during the financial year 2015/16; a rise of over 20 percent since 2010/11. Currently, the cost of branded medicines is regulated primarily through a voluntary scheme; manufacturers/suppliers who do not join the voluntary scheme automatically join a statutory scheme. Unbranded, or generic medicines, are not regulated and rely on competition to keep prices down. Recent price increases of some generic medicines have led to concern that not enough is being done to regulate their price. In addition, income from the voluntary scheme has reduced and some manufacturers/suppliers have chosen to join the statutory scheme, which does not involve the same payments to the Government under the voluntary scheme.

The Bill includes provisions to bring the current statutory medicines pricing scheme, which applies to branded medicines, into line with the voluntary scheme: the Pharmaceutical Price Regulation Scheme (PPRS). The Bill would also allow the Secretary of State to make regulations to limit prices of, or profits relating to, unbranded medicines. Currently, the Government cannot apply price controls to the unbranded generic medicines of those companies who are members of the PPRS; the Bill would remove this loophole. In addition, the Bill would introduce a new power regarding information provision, which would enable the Secretary of State to make regulations to obtain information about health service medicines and other supplies from all parts of the supply chain. The information would be used for defined purposes, set out in the Bill.

The Bill was broadly welcomed by Labour, the Scottish National Party and the Liberal Democrats. Several government amendments were made at committee stage and a new clause was added, relating to the information provision requirements in the Bill. A small number of government amendments were also made at report stage. No non-government amendments were successful at either committee or report stage. An amendment to ring fence the money collected through the voluntary scheme to invest in "access to new and innovative medicines and treatments", was defeated on division at committee stage, as was another to specify reporting requirements that the Secretary of State should follow in assessing the impact of the Bill. This briefing provides an overview of the clauses of the Bill and details its passage through the House of Commons in advance of the Bill's second reading in the House of Lords.

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1. Introduction

The Health Services Medical Supplies (Costs) Bills was introduced in the House of Lords on 7 December 2016, and is due to receive its second reading on 21 December 2016. The Bill seeks to amend the National Health Service Act 2006 (NHS Act) "to enable the Government to secure better value for money for the NHS from its spend on medicines".[1] This would be achieved by:

- Putting beyond doubt that the Government can require companies to make payments to control the cost of health service medicines.
- Enabling the Government to require companies to reduce the price of an unbranded generic medicine, or to impose other controls on that company's unbranded medicine, even if the company is in the voluntary scheme (the Pharmaceutical Price Regulation Scheme) for their branded medicines.
- Enabling the Government to make regulations to obtain information on sales and purchases of health service medicines, medical supplies and other related products from all parts of the supply chain, from manufacturer to pharmacy, for defined purposes.[2]

The Bill received broad support during its proceedings in the House of Commons, and there were no non-government amendments made to the Bill. Issues discussed included: ring-fencing the money rebated from schemes to control the prices of medicines; reporting on the impact of the Bill; the data sharing arrangements with devolved administrations arising from the information provisions in the Bill; and the treatment of repurposed off-patent drugs and 'specials'.

The Bill would extend and apply to England and Wales, Scotland and Northern Ireland with the exception of:

- Clause 7, which amends the NHS (Wales) Act and extends to England and Wales and applies to Wales only.
- Subsection 1 of clause 8 which amends the NHS (Scotland) Act extends and applies to Scotland only.

The majority of the provisions in the Bill would come into force as determined by regulations, which the Government will consult upon. The Department of Health has provided illustrative regulations relating to information provision and branded medicines.[3] The Minister of State for Health, Philip Dunne, has confirmed that consultation on the detailed regulations will start at royal assent, with implementation of the proposals is expected in autumn 2017.[4]

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[1] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[2] Department of Health, 'Guidance: Health Service Medical Supplies Costs', 8 November 2016.
[3] Department of Health, *Branded Health Services Medicines (Costs)* and *Provision of Information in Connection with Health Services Products*, November 2016.
[4] Public Bill Committee, Health Services Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 3rd sitting, col 74.

2. Policy Background

The Government estimates that the NHS in England spent £15.2 billion on medicines during the financial year 2015/16: with over £11.2 billion spent on branded medicine and nearly £4 billion on unbranded generic medicines; a rise of over 20 percent since 2010/11 and over 7 percent since last year.[5] The Government anticipates that "with advances in science and our ageing population, these costs can only continue to grow".[6]

Currently, the powers to control the prices of health service medicines and medical supplies are found in the NHS Act 2006. Branded medicines are regulated by one of two schemes; suppliers and manufacturers can choose to participate in the voluntary scheme—the Pharmaceutical Price Registration Scheme (PPRS)—and those who do not join the voluntary scheme automatically join the statutory scheme. The price of unbranded generic drugs is not currently controlled, and competition within the market is relied upon to control prices.

	Voluntary Scheme—Pharmaceutical Price Regulation Scheme (PPRS)	**Statutory Scheme**
Background	The PPRS is a non-contractual voluntary scheme effective from the termination of the 2009 PPRS on 31 December 2013. It will continue to operate for five years starting from 1 January 2014. Exemptions for some medicines including dental anaesthetics and over the counter (OTC) sales small pharmaceutical companies (with sales worth less than £5 million a year). The scheme applies to branded medicines as well as branded generics and vaccines.	Sections 262–266 of the NHS Act 2006 allow the Secretary of State to establish a statutory scheme to control the price of medicines or the profit from the sale of those medicines. Manufacturers or suppliers of branded medicines default to the statutory scheme if they do not join the PPRS.
How it works	Introduces a limit on the growth in the overall cost of the branded medicines purchased by the NHS from members of the scheme. Scheme members make percentage payments to the Government based on the difference between allowed percentage growth and actual percentage growth in NHS expenditure on branded medicines.	Currently a fifteen percent cut in list price (the manufacturers published price) on maximum prices charged to the NHS on 1 December 2013. The price cut does not apply to products launched post December 2013.[7]
How many members	Total spend covered by the voluntary scheme in 2015 was £8,105 million.[8] The Government has previously estimated that around 75 percent of branded medicine sales are covered by the voluntary scheme.[9]	Total spend covered by the statutory scheme in 2015 was £942 million.[10] The Government has previously estimated that statutory scheme covered about 6 percent of branded medicine sales in the UK.[11]

[5] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[6] ibid.
[7] Department of Health, *Consultation on Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines*, September 2015, p 9.
[8] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[9] Department of Health, *Consultation on Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines*, September 2015, p 8.
[10] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[11] Department of Health, *Consultation on Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines*, September 2015, p 8.

	Voluntary Scheme—Pharmaceutical Price Regulation Scheme (PPRS)	Statutory Scheme
Unbranded/ Generics	The Government cannot currently apply price controls to unbranded, also known as generic, medicines, produced by members of the PPRS, even if the medicines themselves would otherwise fall within price control schemes.	The Government currently has the power under the 2006 Act to introduce controls on unbranded generic medicines, although to date the Government has not introduced these controls.

2.1 Voluntary and Statutory Schemes

As shown in the table above, the statutory scheme employs a fifteen percent cut in list price (the manufacturers published price) on medicines of suppliers or manufacturers in the statutory scheme. In contrast, the scheme members in the PPRS make percentage payments to the Government based on the difference between allowed percentage growth and actual percentage growth in NHS expenditure on branded medicines.[12]

The Government has expressed concern that the statutory scheme has delivered significantly lower savings for the NHS than the voluntary scheme; it has been estimated that "if the PPRS 2015 payment percentage of 10.36 percent applied to statutory scheme companies they would make payments of around £65 million, compared to around £23 million savings made through the 15 percent published list price cut".[13] The Government has argued that this gap is expected to widen.[14]

In addition, it is suggested that companies have divested individual products—or switched completely—into the statutory scheme, which has reduced savings through the PPRS. For the UK, in 2016/17, the Department of Health is estimated to receive £647 million in payments from the PPRS scheme; this is a reduction from the estimated £800 million in the 2015/16 period.[15] The Department of Health have estimated that since the current PPRS began in 2014, a total of £157m of sales have moved from the PPRS to the statutory scheme.[16] The Government estimates that, based on the current PPRS payment percentage and statutory 15 percent list price cut, the cost of companies switching from PPRS payments to sales in the statutory scheme could be £26 million per calendar year.[17]

In September 2015, the Government ran a consultation on strengthening the statutory scheme by requiring pharmaceutical companies to make payments to the Secretary of State on their NHS medicines sales. The preferred option was to replace the 15 percent list price cut imposed by the existing scheme with the payment on sales of medicines, similar to that in the PPRS. The consultation also sought views on how to address the problem of excessively priced

[12] For further information see, House of Commons Library, *Health Service Medical Supplies (Costs) Bill 2016–17*, 21 October 2016 and the Department of Health, *The Pharmaceutical Price Regulation Scheme 2014*, December 2013.
[13] Department of Health, *Consultation on Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines*, September 2015, p 9.
[14] ibid.
[15] House of Commons, 'Written Question: Pharmaceutical Price Regulation Scheme', 9 February 2016, 25939.
[16] Department of Health, *Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines: Consultation Response*, September 2016, p 7.
[17] Department of Health, *Health Service Medical Supplies (Costs) Bill Impact Assessment*, September 2016, p 13. Based on the current PPRS payment percentage profiled for 2016, 2017 and 2018 of 7.8 percent, and the current list price cut of 15 percent in the statutory scheme.

unbranded generic medicines.[18] The consultation closed in December 2015, and the Government published its response in September 2016.[19] The consultation response noted:

> Whilst NHS organisations were mainly positive, concerns were raised by the pharmaceutical industry—including as to whether the Secretary of State had the primary powers to impose a payment system. The Government reviewed the legislative powers and concluded that amendments should be made to the primary legislation (the National Health Service Act 2006) 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.[20]

The Department of Health's impact assessment for the Bill suggests that introducing a payment mechanism in the statutory scheme would generate savings of £88m per annum, when compared to leaving the scheme as it currently exists.[21]

2.2 Unbranded Generic Drugs

As outlined above, the prices of unbranded generic drugs are currently unregulated, with the Government instead relying on competition to regulate prices. The Competition and Markets Authority (CMA) is responsible for investigating and acting in cases of potential pricing abuses. In December 2016, the CMA imposed a record £84.2 million fine on the pharmaceutical manufacturer Pfizer, and a £5.2 million fine on the distributor Flynn Pharma.[22] It found that each broke competition law by "charging excessive and unfair prices" in the UK for an anti-epilepsy drug. The fines follow prices increasing by up to 2,600 percent overnight after the drug was de-branded in September 2012.

Powers to regulate the price of unbranded drugs do currently exist in the statutory scheme, but are not used. In addition, the price of unbranded medicines cannot be regulated where a manufacturer or supplier is a member of the voluntary scheme.[23]

There has been increasing concern regarding whether competition in the market is sufficient to control prices. This follows several examples of high price increases where the unbranded generic medicines were sold/manufactured by one pharmaceutical company. The *Times* ran an investigation into examples of this practice in June 2016 and the issue was also noted by the House of Commons Health Committee in correspondence with the Secretary of State for Health, Jeremy Hunt.[24]

The Bill would amend the NHS Act 2006 to allow the Secretary of State to require companies to reduce the price of an unbranded generic medicine, or impose other controls on that company's unbranded generic medicines, even if the company is in the voluntary scheme for its branded medicines. The Government has stated that its intention is to "to use these new

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[18] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[19] Department of Health, *Changes to the Statutory Scheme to Control the Prices of Branded Health Service Medicines: Consultation Response*, September 2016, p 7.
[20] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[21] Department of Health, *Health Service Medical Supplies (Costs) Bill Impact Assessment*, September 2016, p 4.
[22] Competition and Markets Authority, 'Press Release: CMA Fines Pfizer and Flynn £90 Million for Drug Price Hike to NHS', 7 December 2016.
[23] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[24] For further information, see House of Commons Library, *Health Service Medical Supplies (Costs) Bill 2016–17*, 21 October 2016, pp 10–11.

powers where due to a lack of competition in the market, companies charge unreasonably high prices for unbranded generic medicines", and that "the Department will work with the industry representative body and the Competition and Markets Authority to determine when a price is 'unreasonably high'".[25]

2.3 Information Provisions

The Department of Health currently collects information about the prices of medicines from a range of sources. This includes information relating to sales of products and financial returns under the PPRS and for those within the statutory scheme. There are also several schemes that run in relation to unbranded generic medicines through which information is collected on a voluntary basis. The Government has stated that it does not have sufficient powers to collect information on the sale and purchase of health service medicines and other supplies by manufacturers, wholesalers, and dispensers (including pharmacies and GP practices that dispense or supply medicines and other supplies) in order to continue to run the drugs reimbursement system effectively and to provide transparency on the cost of drugs used by the health service. It has argued that this leads to asymmetry of information, which can enable actors in the supply chain to inappropriately increase NHS costs.[26]

The Bill would therefore amend the NHS Act 2006 to consolidate and expand the information collection that the Secretary of State can undertake, for specified purposes. It also details the way in which that data can be disclosed to others, including the devolved administrations.

3. Overview of the Bill

Most of the changes contained in the Bill relate to amending the NHS Act 2006 and the Department of Health has produced an 'unofficial' keeling schedule to show how the amended NHS Act would look.[27] The sections below provide an outline of the clauses of the Bill as introduced in the House of Lords.

3.1 Clauses 1–4: Control of the Price of Health Service Medicines

Clause 1: Statutory Powers under the Voluntary Scheme

Clause 1 would clarify that the statutory powers that the Secretary of State exercises in relation to voluntary schemes could also apply to a voluntary scheme which uses a payment mechanism. The clause would also extend the Secretary of State's power in relation to these schemes, for example to require a supplier or manufacturer who has not made payments in accordance with the terms of the voluntary scheme to make a payment to the Secretary of State within a specified time frame.

Clause 2: Power to Control Prices

Clause 2 would also allow the Secretary of State to make regulations to limit prices of, or profits relating to, unbranded medicines, also known as generic medicines. Currently, the

[25] Department of Health, *Health Service Medical Supplies (Costs) Bill Factsheet*, November 2016.
[26] Department of Health, *Health Service Medical Supplies (Costs) Bill Impact Assessment*, September 2016, p 19.
[27] Department of Health, *Health Service Medicines (Costs) Bill: Unofficial Keeling Schedule*, November 2016.

Government cannot apply price controls to the unbranded generic medicines of those companies who are members of the PPRS; the Bill would remove this loophole. Currently powers cannot be applied to suppliers or manufacturers who are members of the voluntary scheme. Clause 2 would amend the NHS Act 2006 to exempt medicines from these powers on an individual basis, rather than applying the exemption to all medicines produced by a manufacturer or supplier in the voluntary scheme; this would mean unbranded generic health would now be liable to the price controls within the voluntary scheme.

Clause 3: Statutory Schemes: Payment Mechanism

Clause 3 would clarify that the Secretary of State can introduce a payment mechanism scheme as part of the statutory schemes to regulate prices. The description mirrors clause 1 and clause 3 would also extends the statutory powers of the Secretary of State in similar ways to clause 1, for example, in allowing the Secretary of State to require a supplier or manufacturer who has not made payments in accordance with the terms of the voluntary scheme to make a payment to the Secretary of State within a specified time frame.

Clause 4: Enforcement

Clause 4 of the Bill outlines the enforcement mechanisms for ensuring control of health service medicines, for example, the monetary penalties that could be incurred by a supplier or manufacturer. In addition, the clause would provide that the new payment mechanism in statutory schemes would be "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".[28]

3.2 Clause 5: Control of the Price of other Medical Supplies

Clause 5 would extend the territorial extent of the control of maximum prices for other medical supplies to Northern Ireland and Scotland. In addition, the clause would extend some of the enforcement powers in section 265 of the NHS Act 2006, which apply to medicines to other medical supplies.

3.3 Clauses 6–7: Provision and Disclosure of Information

Clause 6 would amend the NHS Act 2006 to provide 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. The Bill would also allow for the sharing of that information with specified persons for specified defined purposes. In England, the defined purposes would include "the determination of the payments to be made to any persons who provide primary medical services" or "pharmaceutical services", such as dispensing GPs or community pharmacists, and to enable the Secretary of State to consider whether adequate supplies of English health service products were "available and whether the terms on which those products are available represent value for money".[29]

[28] Explanatory Notes, p 11.
[29] ibid, p 13.

As agreed by the Department of Health and the devolved administrations that the Secretary of State would collect information from wholesalers and manufacturers from across the UK and that each nation would collect information from pharmacies and GP practices across their own territories.

Clause 7 of the Bill would insert new sections into the NHS (Wales) Act to allow Welsh ministers to request information from pharmacists or GPs for the purposes specified in the Bill, it would also allow Welsh ministers to disclose information to any person prescribed in regulations.

3.4 Clauses 8–10: Consequential Amendments, Extent and Commencement

Clause 8

Clause 8 would make a number of consequential amendments the NHS Act 2006. In addition, the clause would amend the NHS Act 2006 so that the power of the Secretary of State to make orders applies to the control of the price of medical supplies in the same way that it does to the control of the price of health service medicines.

Clause 9

Clause 9 outlines the extent of the Bill. This would extend and apply to England and Wales, Scotland and Northern Ireland with the exception of:

- Clause 7, which amends the NHS (Wales) Act and extends to England and Wales and applies to Wales only.
- Subsection 1 of clause 8 which amends the NHS (Scotland) Act extends and applies to Scotland only.

Legislative consent motions would need to be agreed in the devolved administrations for several of the clauses. Details can be found in Annex A of the Explanatory Notes.[30] The Explanatory Notes confirm that all of the legislative consent motions required, as outlined above, have been laid in their respective devolved institutions.[31]

Clause 10

Clause 10 relates to commencement. Clauses 9 (extent) and 11 (short title) would come into force on the day on which the Bill was passed. Clause 7, which relates to information provision to Welsh Ministers, would come into force on such day as the Welsh Minister may by order appoint. The other clauses in the Bill would come into force on a date provided in the regulations made by the Secretary of State.

[30] Explanatory Notes, p 21.
[31] Explanatory Notes, p 8.

4. Proceedings in the House of Commons

4.1 Second Reading

The Bill received its second reading in the House of Commons on 24 October 2016. Introducing what he described as a "short and focused Bill which is vitally important not only for the NHS but for patients",[32] the Secretary of State for Health, Jeremy Hunt, noted:

> The purpose of the Bill is to clarify and modernise provisions to control the cost of health service medicines and to ensure sales and purchase information can be appropriately collected and disclosed. These provisions will align the statutory and voluntary cost control mechanisms currently in existence, allow the Government to control the cost of excessively priced unbranded generic medicines, and ensure we have comprehensive data with which to reimburse people who dispense medicines. Taken together, these measures will enable us to secure better value for money for the NHS from its spend on medicines.[33]

While stressing the importance of the life sciences industry, "an industry which contributes £56 billion and tens of thousands of jobs to the UK economy every year", the Secretary of State outlined concerns about the growing cost of medicines to the NHS; during 2015/16 the NHS in England spent over £15.2 billion on medicines, a rise of nearly 20 percent since 2010/11.[34]

The Bill would, he argued, "put it beyond doubt that the Government can introduce a payment mechanism in the statutory scheme", whilst also amending "the 2006 Act so that it contains essential provisions for enforcement action".[35] In addition, the Bill would allow the Government to set prices of medicines where companies "charge unreasonably high prices for unbranded generic medicines", rather than relying solely on competition in the market to keep the prices of these drugs down.[36] The Secretary of State confirmed that the money generated by the current voluntary scheme, set up in 2014, was £1.24 billion, which "comes back to the Department of Health and is invested in the NHS".[37]

Speaking for the Opposition, Justin Madders, the Shadow Minister for Health, supported "the broad aims of the Bill".[38] However, he noted concerns from the medical technologies sector that the new information requirements might be onerous, and stressed the importance of monitoring the impact of the Bill on the supply chain.[39] In particular, he noted the importance of the pharmaceutical sector, and the concern about the potential unintended consequences of the Bill on investment in the pharmaceutical industry in the UK.[40] The Shadow Minster also

[32] HC *Hansard*, 24 October 2016, col 72.
[33] ibid.
[34] ibid.
[35] ibid, col 76.
[36] ibid, col 78.
[37] ibid, col 75.
[38] ibid, col 87.
[39] ibid, cols 83–4.
[40] ibid, col 86.

noted that the PPRS rebate in Scotland had been used "to create a dedicated fund to give patients access to new medicines", and asked:

> Will the Minister consider investigating similar models and ensuring that the benefits of the scheme are used for the purpose of improving our frankly poor record in allowing patients to benefit from new medicines? We accept that there will always be challenges in matching funding to new drugs, but there is at least a degree of logic in allowing savings made in the drugs bill to be reinvested to enable new products to reach patients more quickly.[41]

Dr Philippa Whitford, Shadow SNP Westminster Group Leader (Health), was amongst several other speakers highlighting the importance of the pharmaceutical sector and paying tribute to importance of the research and development carried out by the industry.[42] She stated that the SNP welcomed the way the Bill would close "some of the loopholes faced by the NHS", with particular regard to the price of generic drugs.[43] She argued that data collection should be "simple and straightforward",[44] arguing "I have concerns about the involvement of the devolved administrations in the design of the schemes, access to data and ensuring that the funding for PPRS, which we use for our new drugs fund, is maintained".[45]

Norman Lamb, Liberal Democrat Spokesperson for Health, also welcomed the Bill, stating "I support this tidying-up measure and, in particular, the ending of the outrageous practice of a number of companies profiteering at the expense of NHS patients".[46]

4.2 Committee Stage

The Health Service Medical Supplies (Costs) Bill was considered during three sessions of the Public Bill Committee on 8 and 15 November 2016. The first sitting, on 8 November, heard evidence from several witnesses, including the Chief Pharmaceutical Officer of NHS England and representatives from the pharmaceutical industry. The Committee had also received several pieces of written evidence from the sector in advance of its sittings.[47]

No non-government amendments were made to the Bill during committee stage, although two Opposition amendments were defeated on division. The first sought to require funds obtained by the voluntary scheme to be invested in allowing access to new and innovative medicines and treatments. This would have altered the current situation outlined during second reading where funds are reinvested into the NHS more generally; in Scotland, funds are currently invested into a new medicines fund. The second was a proposed new clause to the Bill, which would have required the Secretary of State to report back to Parliament annually outlining the impacts of the Act, should it be passed, on a number of areas.

In addition, the Government made a number of amendments regarding information provision, particularly in relation to how the process would work in the devolved administrations. A new

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[41] ibid, col 85.
[42] ibid, col 89.
[43] ibid, cols 89–90.
[44] ibid, col 90.
[45] ibid, col 91.
[46] ibid, col 97.
[47] Written evidence submitted to the Public Bill Committee is available on its website, House of Commons Public Bill Committee on the Health Service Medical Supplies (Costs) Bill 2016–17.

clause, which became clause 7 in the Bill, was inserted to allow Welsh ministers the power to request and provide information. These are described in further detail below.

Clauses 1–4: Control of the Price of Health Service Medicines

During discussion of these clauses during committee, opposition parties moved several amendments, with one being defeated on division. Julie Cooper, Shadow Minister for Community Health, moved an amendment to clause 1 which would have required that funds generated by the voluntary scheme were used "for the purpose of investing in access to new and innovative medicines and treatments". Pointing to the "vague statement" made during second reading that money generated by the voluntary scheme was returned to the Department of Health and reinvested in the NHS, she argued that PPRS generated funds should be "retained within the portion of the health budget that relates specifically to the supply of medicines and medical supplies. We do not wish to see the savings lost in an NHS deficit black hole".[48] She noted that in Scotland rebates collected by the PPRS were earmarked to fund new medicines.

Dr Philippa Whitford, Shadow SNP Westminster Group Leader (Health), provided further details of the way in which the new medicines and rare diseases fund worked in Scotland, with money generated by PPRS rebates being committed to the fund. She argued:

> The pharmaceutical industry expects the rebates to be used to enable access to new medicines. One problem here is that the rebate goes into base funding, which means it disappears like water in the sand.[49]

Speaking for the Government, the Minister for State for Health, Philip Dunne, noted "some sympathy" with the motivations of the amendment, but outlined concerns that the income from voluntary and statutory schemes could fluctuate, thereby potentially leading to a shortfall in funds available for new medicines. He concluded "it is for NHS England and clinical commissioning groups to determine clinical priorities and to spend that money on what is clinically most important".[50] The amendment was defeated on division with by 9 votes to 8.[51]

The purpose of clause 2 was broadly welcomed in committee. In the evidence session during the first sitting of the Committee, on 8 November 2016, the Director General of the British Generic Manufacturers Association, Warwick Smith, argued that competition was a better way of controlling prices than intervention, arguing that a very small proportion of generic drugs had "made the front page of the Times".[52] However, speaking for the Association of the British Pharmaceutical Industry, David Watson supported the aims of the bill in addressing "price hikes, frankly in unbranded generic prices".[53] The clause was passed unamended.

During discussion of clause 3, Julie Cooper, Shadow Minister for Community Health, sought further clarification about how the payment mechanism for the statutory scheme would work,

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[48] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 2nd sitting, col 30.
[49] ibid, col 34.
[50] ibid, col 32.
[51] ibid, col 36.
[52] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 8 November 2016, session 2016–17, 1st sitting, col 9.
[53] ibid, col 20.

but withdrew an amendment that would have required that the same calculation was used for both voluntary and statutory schemes. Clauses 3 and 4 were passed unamended.

Clause 5: Medical Supplies

Clause 5 would allow the Secretary of State to make an order to control the maximum price of medical supplies. The clause would also amend some of the enforcement powers in the NHS Act 2006, so that the enforcement regime was the same as that agreed for medicines, rather than containing criminal sanctions.

Giving evidence to the Committee on 8 November 2016, Philip Kennedy, chair of the Association of British Healthcare Industries, stated:

> I believe that the addition of medical devices and any other items was relatively late in the consideration. In that regard, I wonder whether there has been a proper assessment of the impact that that would have. We would welcome further work on the potential impact. It is very clear for pharmaceuticals, but extremely unclear for medical devices.[54]

During discussion of clause 5, Dr Philippa Whitford, Shadow SNP Westminster Group Leader (Health), moved a probing amendment that would have required the Secretary of State to conduct a consultation on the potential impact of the clause on the quality of medical supplies. Explaining her amendment, she noted:

> When controlling the price of drugs, the quality of those drugs is controlled by the Medicines and Healthcare Products Regulatory Agency so that pushing down the price does not result in loss of quality. My concern is that, beyond a kitemark or a CE mark, we do not have anything in the United Kingdom that controls quality, particularly of consumables such as swabs and gloves.[55]

Justin Madders, Shadow Minister for Health, supported the amendment. He said:

> We need to be confident that the Bill poses no risk of any reduction in quality, but we would have been more confident about that if there had been a proper consultation on that element in the first place.[56]

The Minister of State for Health, Philip Dunne, described the amendment as "an issue for which we have considerable sympathy".[57] He noted that, while in relation to the costs of medicines the Bill did explicitly state that industry should be consulted, this was not the case for medical supplies. He invited Dr Whitford to withdraw the amendment, undertaking to work with her to amend the amendment "to give it the effect that she seeks". The Minister added:

> We will consult with industry on the impact of the Bill on medical supplies. Although I am not going to give the hon Lady an absolute assurance that we can introduce a threshold for quality, which is quite hard to prescribe given the immense variety of supplies we are talking about […] The intent is not to buy substandard equipment to

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[54] Public Bill Committee, Health Services Medical Supplies (Costs) Bill, 8 November 2016, session 2016–17, 1st sitting, col 8.
[55] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 2nd sitting, col 50.
[56] ibid, col 51.
[57] ibid, col 51.

> treat patients, but to remove variability in pricing for the same equipment depending on different purchasers, which is inappropriate and means effectively the taxpayer is the funder of all these different entities.[58]

The amendment was withdrawn.[59]

Clause 6: Provision and Disclosure of the Information

Clause 6 would give the secretary of state power to make regulations to request information, and also outlines the purposes for which information can be required. It also provides for information to be disclosed in some instances.

There were several government amendments made to clause 6 during committee stage, something which had been foreshadowed by the Secretary of State during second reading.[60] As outlined by the Minister of State for Health, Philip Dunne:

> The amendments were tabled entirely to reflect the request from the devolved Administrations, with which we entirely agree, on how they want to apply this power in their territories […] they are all driving at the same objective. Some of the information requirements in the Bill that apply to England only could also apply to the territories of the devolved Administrations. The government amendments therefore reflect the instructions of the devolved administrations in that area. We have had constructive discussions with each administration, and we have agreed that the UK Government will collect information from wholesalers and manufacturers for the whole of the UK. It would not make sense for each nation to collect its own information from wholesalers and manufacturers, because that would lead to duplication of effort to no apparent purpose. We have also agreed that each nation will collect information from its own pharmacies and GPs, to the extent that that is requested.[61]

Martyn Day (SNP MP for Linlithgow and East Falkirk) sought clarification regarding "what information will be disclosed and by what means", commenting:

> In short, will the devolved administrations be able to get the information when they want and need it, so that it ties in with the figures and statistics they are seeing and they can see patterns? It is about flexibility. The amendment is fairly straightforward and we think it would help to strengthen and improve the Bill. I hope that the Minister agrees. We would like him to clarify whether the Government intend to leave disclosure to the discretion of the Secretary of State, on an ad hoc basis? Otherwise, what would the terms of disclosure be?[62]

Responding for the Government, Philip Dunne argued that the amendment might lead to more organisations having access to any information that the Government collected and therefore

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[58] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 2nd sitting, col 52.
[59] ibid, col 53.
[60] HC *Hansard*, 24 October 2016, col 80.
[61] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 3rd sitting, cols 57–8.
[62] ibid, col 59.

more opportunities for risking breaches of commercially confidential information. Instead, he argued, that the issue could be addressed in:

> […] a memorandum of understanding to be agreed between the Department of Health and each of the devolved administrations that would allow requests for information to be submitted and dealt with in a manner agreeable to both parties. In the consultation process that will follow, we intend to enter into a memorandum of understanding that will include the procedures for requesting and sharing information.[63]

The amendment was withdrawn and the clause was agreed.

The Committee also considered new clause 1, which became clause 7 of the Bill as introduced in the House of Lords. Clause 7 would insert new sections into the NHS (Wales) Act 2006 to allow Welsh Ministers to request information from pharmacists or GPs for the purposes specified in the Bill. It would also allow Welsh ministers to disclose information to any person prescribed in regulations. The clause was agreed.

Proposed New Clauses: Reporting, Specials and Repurposed Off-Patent Drugs

New clause 2, moved by, Justin Madders, Shadow Minister for Health, would have required the Secretary of State to produce an annual report on the impact of the Act, with particular reference to the availability and cost of medicines and other medical supplies to the health service and the terms upon which they are made available; research and development; and the NHS's duty to promote innovation. Commenting on the proposed clause, Mr Madders noted:

> While we agree that it is vital that those who abuse the system to drive obscene profits for themselves are dealt with, we do not wish to find the UK becoming a less attractive place for research and investment because other countries have made themselves more attractive. We ask that the report become an annual feature of the Secretary of State's duties to ensure that we can judge the effectiveness of the Bill. The converse point is that if we continue to see price increases, we want to be assured that the regulations are effective in driving best value for the NHS.[64]

Speaking for the SNP, Dr Philippa Whitford echoed some of the sentiments relating to the UK's pharmaceutical industry, arguing, "it is incumbent upon Government to ensure that the Bill has no unintended consequences".[65]

Responding for the Government, Philip Dunne argued that the requirements for an annual report were already intended and were included in the illustrative regulations which the Government had provided to show how regulations under the Bill would be drafted.[66] Pushing the amendment to a division, Justin Madders stated "that having draft regulations that have not yet been consulted on is not an adequate substitute for the assurances that we are seeking".[67] The new clause was defeated on division by 9 votes to 5.[68]

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[63] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 3rd sitting, col 62.
[64] ibid, cols 77–8.
[65] ibid, col 78.
[66] The Department of Health has provided illustrative regulations on *Branded Health Services Medicines (Costs)* and *Provision of Information in Connection with Health Services Products*, November 2016.
[67] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 3rd sitting, col 81.

New clause 3 was moved by Dr Philippa Whitford for the SNP and dealt with the issue of 'specials', this relates to unlicensed preparations, often topical medicines, often used for severe skin conditions such as hard-to-control psoriasis. She noted that "The British Association of Dermatologists reports that patients in England, Wales and Northern Ireland are struggling to get them prescribed, because the costs have spiralled out of control".[69] The Minister confirmed that the manufacturers of 'specials' were often not in the voluntary scheme, and that the Government therefore had power to regulate the prices of these medicines. However, he noted:

> I am interested in exploring why we have chosen not to take advantage of the power that we already have in that case, because on the face of it, it would appear to be an example of where the power perhaps ought to be used.[70]

Withdrawing her amendment, Dr Whitford noted:

> I wanted to try to draw attention to this matter. The Minister has said that the Government have had the power all of this time and not used it. In part it is about bringing powers into line and creating consistency. I call on him to use those powers. Even though only a relatively small percentage of drugs are affected, the impact on patients from not being able to access them is significant.[71]

Dr Philippa Whitford also moved new clause 4, which sought to deal with repurposed off-patent drugs (drugs designed for a particular use that contribute in relation to another condition). She highlighted concerns that where new purposes for a drug were discovered "some companies would license a drug and totally change the price or to manufacture that drug simply as a generic with a massive price".[72] She stated that "the new clause is to raise an issue that is not covered in the Bill and to see if it has been considered at all by the Government".[73] The Minister confirmed that the Bill's provisions "will apply to those drugs whether they are licensed branded medicines or generic medicines" and therefore to repurposed off-patent drugs. He also updated the Committee on work which had been undertaken on the area of repurposing drugs. The new clause was withdrawn.

4.3 Report and Third Reading

Report

During report stage many of the same issues discussed during committee stage were revisited. This included amendments to:

- Insert a new clause to require the Secretary of State to report on the impact of the Act on specific issues (new clause 1).
- Ring-fence the funds rebated by the voluntary scheme (amendment 8).

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[68] ibid, col 81.
[69] Public Bill Committee, Health Service Medical Supplies (Costs) Bill, 15 November 2016, session 2016–17, 3rd sitting, col 82.
[70] ibid, col 83.
[71] ibid, col 85.
[72] ibid, col 86.
[73] ibid.

- Require the Secretary of State to consult on the potential impact of controlling the prices of medical supplies on quality (amendment 9).

- Obtain further clarity regarding how the information sharing arrangements would work with regard to the devolved administrations (amendment 10).

Government amendments to clause 6 were agreed to without division. These were amendments 1–5, which sought to address a "potential loophole in the Bill", and a "minor consequential amendment" (amendment 6), which added the Regional Business Services Organisation in Northern Ireland to the list of people to whom the Secretary of State could disclose information.[74]

The Shadow Health Minister, Justin Madders moved new clause 1, which would have required the Secretary of State to place a report before Parliament on: the impact of the Act on the pricing and availability of medicines and other medical supplies; research and development; and the NHS's legal duty to promote innovation. The clause was similar to that which was moved and defeated on division during committee stage. Noting that "the Opposition do not oppose the Bill", Justin Madders argued that a review was necessary to measure the impact of the Act on the pharmaceutical sector and on accessing drugs, stating:

> […] prudence requires that such a review take place within a reasonable timeframe to ensure there are no unintended consequences and that we can remain confident that the pharmaceutical sector in this country will continue to be at the forefront.[75]

Dr Philippa Whitford, Shadow SNP Westminster Group Leader (Health), stated that the SNP would "not obstruct the Bill, because we support the basic aim to control prices in order to achieve a good return to the NHS from the drugs that it uses".[76] She voiced the SNP's support for the principle of the new clause, although noting that "six months might be a little early technically to bring things together". Responding for the Government, the Minister of State for Health, Philip Dunne, argued that the requirements to report on the impact of the Bill, which were already included in the illustrative regulations, would be more far-reaching.[77] The proposed new clause was withdrawn.

In addition, the Opposition proposed an amendment (amendment 8) to ring-fence the money collected through the voluntary scheme so that it would be used for the purpose of improving access to new and innovative medicines and treatments. Justin Madders stated "it is our fear that this new money, which could have delivered a step-change in access to treatments to the benefit of patients and the life sciences sector, will instead be simply added to the baseline, with every £1 from the pharmaceutical sector meaning £1 less coming from the Treasury".[78] The proposal was welcomed by the SNP, with Dr Whitford commenting that it "advocates the same approach that we have in Scotland" which has a new medicines and rare diseases fund.[79] Responding for the Government, Philip Dunne argued that "it is for NHS England and clinical

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[74] HC *Hansard*, 6 December 2016, cols 168–9.
[75] ibid, col 151.
[76] ibid, col 156.
[77] ibid, col 162.
[78] ibid, col 153.
[79] ibid, col 156.

commissioning groups to determine clinical priorities and spend the money on what is clinically most important". He went on to state:

> The income from the voluntary and statutory schemes can and does fluctuate; that is the biggest problem with ring-fencing, which could bring risks in this area. For example, the annual income from the PPRS has varied between £310 million and £839 million in a full financial year in England, so there is the potential for the income that it generates to vary widely, which could disadvantage patients by making treatment dependent on income from a pricing scheme with unsteady income generation.[80]

Dr Whitford, again, spoke to her proposed amendment 9, dealing with the issue of medical supplies and ensuring quality. Referring to discussions which had happened during committee, Dr Whitford stated, "I am slightly disappointed that we did not manage to get this amendment adopted, so I raise again the issue of quality control and ask the Government to consult on it".[81] The amendment would have required the Government to consult upon the potential effect of the clause 5 on the maintenance of quality. Justin Madders welcomed the proposed amendments from the SNP, noting that controls on other medical supplies "were notably lacking from the initial consultation, so there is still considerable anxiety within the sector about how the controls will be used".[82] Rob Marris (Labour MP for Wolverhampton South West) commented:

> I had understood him [the Minister], perhaps wrongly, to say in committee that he liked what the SNP was putting forward in terms of quality, but he did not think the wording was quite right, so he hoped to be able to come back on report with an amendment relating to quality. I may have misunderstood or misremembered what he said, but if my memory is correct, I hope that he can explain why I cannot see on the Order Paper a Government amendment relating to quality. Perhaps he proposes to table an amendment at a later stage.[83]

Responding for the Government, Philip Dunne noted:

> A similar amendment was tabled by the hon Lady in Committee. I want to reiterate that I am happy to consider with her how we could best introduce a general requirement to consult industry in section 260. Indeed, my officials have been in discussions with her, and I am grateful for her time and constructive comments […] If she will continue to work with me and my officials, the Government would be happy to consider, while the Bill is in the other place, how we could best introduce the requirement to consult into section 260.[84]

The SNP also moved an amendment (amendment 10) regarding information sharing of the data collected using the Bill's new powers. The amendment sought to ensure "that any such data that relates to the devolved administrations—essentially, their data—is freely accessible to them" and sought further clarity about the Government's proposed memorandum of understanding.[85] Responding for the Government, Philip Dunne outlined some of the issues relating to data sharing, noting "we need to get into the detail of that in discussion on the

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[80] HC *Hansard*, 6 December 2016, col 166.
[81] ibid, col 157.
[82] ibid, col 153.
[83] ibid, col 161.
[84] ibid, cols 167–8.
[85] ibid, col 158.

memorandum of understanding, rather than committing that to the Bill at this stage".[86] The amendment was withdrawn.

Third Reading

Speaking at third reading the Minister of State for Health, Philip Dunne, stated "it has been a pleasure to take this short, albeit technical, Bill through the House with such a wide degree of consensus from all participating parties".[87] The Minister thanked opposition members for their contributions, concluding:

> The Bill will help to secure better value for money for the NHS from its spending on medicines, while ensuring that the decisions made by the Government are based on more accurate and robust information.[88]

Justin Madders, the Shadow Health Minister, indicated Labour's support for the Bill and thanked the Minister for his "reasonable and constructive" manner, commenting:

> There is much in the Bill to be welcomed. We certainly want an end to the playing of the system that has been going on. We hope that the Bill will finally put an end to such antics and deliver a mechanism that ensures consistency in appropriate circumstances. We support the rationale behind aligning the statutory and voluntary schemes, which will create a more level playing field between companies and offer a much better chance of delivering greater savings and value for money to the taxpayer. We support measures to tackle the small number of cases where we have seen companies disgracefully exploiting loopholes in the regulations to hike the price of medicines, sometimes by more than 10,000 percent.[89]

Dr Philippa Whitford, speaking for the SNP, also welcomed the Bill, but highlighted two issues which she had raised at committee, regarding 'specials' and repurposed off-patent drugs, stating "I hope that the two issues raised by my new clauses will be dealt with".[90]

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[86] HC *Hansard*, 6 December 2016, col 169.
[87] ibid, col 171.
[88] ibid, col 173.
[89] ibid, col 174.
[90] ibid, col 176.