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BRIEFING PAPER

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The Health Service Medical supplies (Costs) Bill (Bill 72 of 2016-17)

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Contents:

Contents

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Summary

The *Health Service Medical Supplies (Costs) Bill* was introduced on 15 September 2016. It is tabled to have its Second Reading on the 24 October 2016.

The Bill intends to make a number of amendments to the *National Health Service Act 2006* on matters related to the control of medicine prices.

The prices of the sale of NHS branded medicines is regulated in the UK through two schemes, the voluntary Pharmaceutical Price Regulation Scheme (PPRS) and a Statutory Scheme, both of which use measures to control the prices of branded medicines. Manufacturers and suppliers of NHS branded medicines can choose to sign up to the PPRS or will automatically fall under the control of the Statutory Scheme for their branded medicines. The prices of unbranded generic medicines are not controlled, competition within the market is relied upon to control prices.

The provisions within the Bill intend to address a number of concerns that the Government have expressed relating to medicines pricing. These include that the Statutory Scheme is providing lower savings for the NHS than the PPRS and the two schemes should be more aligned; and that a number of single source unbranded generic medicines manufacturers have recently been able to significantly increase prices, often by over 1000%.

The Bill would seek to provide powers for the Secretary of State for Health to:

- make changes to the statutory scheme to make it more aligned with the PPRS;
- control the prices of unbranded generic medicines; and
- require all medicines manufacturers and suppliers to provide information relating to prices.

This briefing paper will provide background on the issues, an outline of the contents of the Bill and relevant comment.

> The NHS is paying the extra £262 million a year for more than 50 drugs for which prices have increased greatly since 2010 — enough to pay for 7,000 junior doctors earning £37,000 each. (The Times, June 2016)

1. Background

New medicines launched in the UK following the granting of an EU or UK marketing authorisation may be priced at the discretion of the company on entering the market.[1] However, there are a number of schemes that regulate the prices of branded drugs sold to the NHS. The Association of the British Pharmaceutical Industry (ABPI) report that UK branded pharmaceutical prices are amongst the lowest, compared to other developed countries.[2]

While the price of branded medicines is regulated, the Government's policy on generic medicines, up until now, has been to allow manufacturers freedom of pricing for their products, relying on competition to deliver value for money. Any potential pricing abuses are a matter for the Competition and Markets Authority (CMA).[3]

In 2015, £9.3 billion was spent on NHS prescriptions dispensed in the community in England. In the 2014/15 period the overall NHS expenditure on medicines (in primary and secondary care) was £15.5 billion, an increase of 7.8 per cent from £14.4 billion in 2013/14.[4]

The term generic refers to medicines that are outside their patent period (usually 20 years). This means that a number of companies may make versions of the same medicine.

Box 1: Medicine pricing

While the everyday production and supply of medicines may often be relatively inexpensive, the price of a medicine will also take into account the research and development costs involved, clinical trials and the costs of the licensing process. It will also take account of the many substances that reach different stages of the development process but do not go on to become a successful medical product.

The ABPI report that the average time to develop a successful new medicine is 12 years, and the cost is £1.15 billion. More information is provided in this infographic, and in these articles from the Guardian and BBC News.

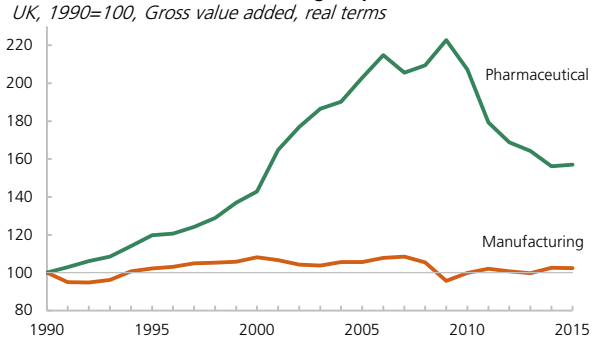
1.1 Contribution of the pharmaceutical industry

Economic output from the pharmaceutical industry[5] in the UK was worth £12.7 billion in 2015. This was 8% of the manufacturing sector's output, up from 5% in 1990, but down from 10% in 2011. As a

1 The UK is one of a minority of OECD countries, including Denmark, Germany, and the United States, where firms are not constrained in setting drug prices at market entry.
2 http://www.abpi.org.uk/our-work/policy-parliamentary/Documents/understanding_pprs2014.pdf
3 HC Written Question 25781 Thyroid gland: diseases, 8 February 2016
4 NHS Digital Prescriptions Dispensed in the Community in England 2015
5 The pharmaceutical industry is defined as the manufacturer of basic pharmaceutical products and pharmaceutical preparations (SIC code 21). Economic output is in terms of Gross Value Added (GVA) a measure similar to GDP. Output data are from ONS, *Quarterly National Accounts, Q2 2016*, Low Level Aggregates Table

proportion of the whole economy, the pharmaceutical industry's economic output was 0.8% in 2015.

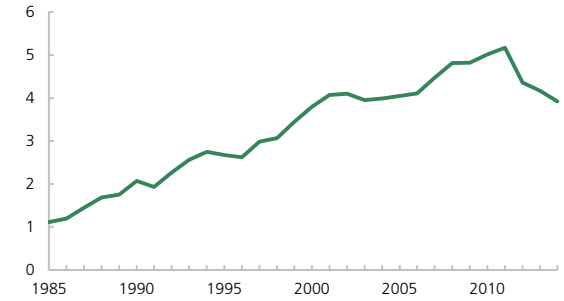
Pharmaceutical and manufacturing output
UK, 1990=100, Gross value added, real terms



The chart to the left shows how the pharmaceutical industry has performed over the last 35 years, compared with the whole manufacturing sector.

In 2014, UK pharmaceutical businesses spent just under £4 billion on R&D. This was 20% of all R&D expenditure in the UK.[6]

UK pharmaceutical businesses R&D spending
£ billions, 2014 prices



These figures are based on businesses based in the UK, not just UK-owned businesses. In 2014 two-thirds of this spending was from their own funds and most of the remaining third from overseas sources.

There were 34,000 employees in the pharmaceutical industry in 2015, roughly the same number as in 2009, but down 7,000 since 2011.[7]

The Government have emphasised the importance of the pharmaceutical industry to the UK. The Prime Minister has recently stated that *"it is hard to think of an industry of greater strategic importance to Britain."*[8]

However, concerns about increasing drug prices and the pressures this may put on the NHS budget have been the subject of much debate in recent years.[9] Most recently, it has been reported that a lack of competition has allowed single source unbranded generic medicines manufacturers to significantly increase prices, resulting in large increases in the NHS medicines costs.

6 ONS, *Business Enterprise Research and Development,* 2014
7 Employee data are from ONS, *Business Register and Employment Survey,* SIC 21
8 Conservatives, We can make Britain a country that works for everyone, July 2016
9 Financial Times, Drug prices: Tweaking the formula, April 2016

1.2 Pharmaceutical Price Regulation Scheme (PPRS)

The Pharmaceutical Price Regulation Scheme (PPRS) is a voluntary agreement that indirectly controls the prices of branded medicines sold to the NHS in the UK. It is negotiated between the Department of Health, acting on behalf of the UK Government and the devolved administrations, and the branded pharmaceutical industry, represented by the Association of the British Pharmaceutical Industry (ABPI). It is thought that the control of the prices of branded medicines to the NHS benefits both parties to the agreement, enabling the wider use of the latest medicines in the health service in the UK.

Following a consultation, a new five year scheme came into force on 1 January 2014. A November 2013 Ministerial Statement on the new PPRS highlights the changes that have been made since the previous scheme:[10]

> The new scheme will provide an unprecedented level of certainty on almost all the NHS branded medicines bill. The bill will stay flat over the next two years and will grow slowly after that. The industry will make compensating payments to the Department of Health if NHS spending on branded medicines exceeds the agreed growth rate. The agreement therefore provides stability and predictability to both the Government and the UK pharmaceutical industry, supporting the industry's global competitiveness. It will encourage the use of innovative and effective new medicines in the NHS.

The PPRS scheme covers the majority, by value, of the medicines used in the NHS in both primary and secondary care but does not cover unbranded generics or unlicensed products. Those pharmaceutical companies who do not sign up to the voluntary PPRS will automatically have the prices of branded medicines regulated through the Statutory Scheme (see section 1.2).

The purposes of the scheme as stated in the agreement are:

- to secure the provision of safe and effective medicines for the NHS at reasonable prices;
- to promote a strong and profitable pharmaceutical industry capable of such sustained research and development expenditure as should lead to the future availability of new and improved medicines;
- encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

A further discussion of the PPRS and how it is negotiated can be found in the Government document.[11]

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10 HC Deb 6 Nov 2013 WS19-20

11 Department of Health, Pharmaceutical Price Regulation Scheme 2014, December 2013

Previous PPRS schemes involved a cut in the list price of branded medicines. A new approach was taken in the 2014-2019 PPRS. It introduces a limit on the growth in the overall NHS spend on branded medicines. In short, the pharmaceutical industry has agreed to hold the branded medicines bill (as measured by scheme members' sales) flat for 2014 and 2015. The permitted growth in the last three years of the scheme is 1.8%, 1.8% and 1.9%. These growth levels are fixed. Retrospective quarterly payments will be paid to the Department of Health if the expenditure exceeds the permitted level.

There are some exceptions where NHS spending on branded medicines is not included in the measurement of growth rate. These include exceptional procurement measures (such as stockpiling medications in preparation for a potential national pandemic), and for small pharmaceutical companies (with sales worth less than £5 million a year).

Following the agreement between the ABPI and the Department of Health on the PPRS 2014 scheme, the ABPI Chief Executive, Stephen Whitehead reported that the pharmaceutical industry has agreed to play its part in light of financial challenges to the NHS but expressed concerns about some parts of the scheme:

> "With this five year agreement industry has agreed to play our part, in light of the financial challenges facing the NHS. It's government's role to create an environment that encourages industrial growth and therefore we are disappointed that the Government has chosen not to maintain a taper for companies with NHS sales between £5 and £25 million. We now need the Government and the NHS to respond positively to this unique opportunity to demonstrate their active commitment to improving patients' access to the latest innovative medicines.
>
> "These have been the most complex negotiations we have ever had with Government and it should not be underestimated how difficult this will be for the industry. The commercial environment in the UK has an impact on its attractiveness for research and development investment and it's too early to say what impact this settlement will have on industry investment.[12]

PPRS payments

The process used to calculate PPRS payments is a complex one, but an NHS England guide to the PPRS provides a clear summary of the process:

> In essence, if NHS expenditure was to go above the agreed growth rates in branded medicines, offsetting industry payments would be made to DH which under the PPRS are phased over the remaining years of the agreement. So, for example, if the actual NHS spend were to exceed the agreed growth rate of 0% for 2014 and 2015, then the industry would make PPRS payments to DH on a quarterly basis. Each year the payment percentage for the following year will be adjusted based on previous years actual

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12 ABPI, ABPI agrees final details of new pricing agreement with Government, December 2013

> sales and modified estimates of the future trend. The actual sums paid are complex to calculate, due to re-forecasting effects.
>
> Alternatively, if the NHS expenditure on branded medicines were to be below the anticipated forecast growth rates, then there would be a similar downward correction to the profile of future industry payments. In effect the industry would have been paying excessive quarterly payments to DH and these would be offset through reduced payments over the remaining years. In year 5, if there is any difference between actual spend and anticipated spend, there is no mechanism to address the difference.[13]

Annex 5 of the PPRS document provides a more detailed explanation of the calculations involved.[14]

PPRS payments received by the Department of Health from the pharmaceutical industry are allocated to the devolved administrations. The method used to apportion the payments is based on primary care prescribing data relating to the spend on branded medicines in the period under consideration.[15]

The then Minister for Life Sciences, George Freeman, reported in February 2016 that the estimated UK income from PPRS payments would be £647 million in the 2016/17 period, with £518 million of this sum allocated to England.[16]

1.3 The Statutory Scheme

The *National Health Service Act 2006* provides the Secretary of State with the powers to establish a statutory scheme for the purpose of controlling the prices of medicines, or the profit from the sale of those medicines. Those manufacturers/suppliers of branded medicines who choose not to sign up to the PPRS are automatically subject to the statutory price regulation scheme.

The current statutory scheme, introduced through regulations, controls the price of branded medicines. Currently, there is a 15% reduction in the price of branded medicines that were on sale in December 2013. Medicines launched after this time are not subject to this reduction.

The 2015 NHS consultation on proposed changes to the statutory scheme provides information about what proportion of the medicines sold in the UK are controlled under the statutory scheme compared with the PPRS:

> In 2014 the statutory scheme covered around 6% of branded medicines sales in the UK – or around £710 million. This compared to £8,290 million – or around 75% of branded medicines sales – covered by the PPRS (there are exclusions from

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13 NHS England, Question and answer document for the NHS on the Pharmaceutical price regulation Scheme (PPRS), 2014

14 Department of Health, The Pharmaceutical Price Regulation Scheme 2014, December 2013 (page 74)

15 Department of Health, Pharmaceutical Price Regulation Scheme 2014: revised forecasts and profile of payment percentages at December 2015, December 2015

16 HC Written Question 25939 Pharmaceutical Price Regulation scheme, 9 February 2016

each scheme, for example parallel imports and wholesaler margins, which mean they do not together cover 100% of health service spend on branded medicines).[17]

1.4 Pricing of unbranded generic medicines

The Government's current policy on unbranded generic medicines is to allow manufacturers freedom of pricing for their products, relying on competition to deliver value for money. These are products that are outside of their patent period so can be manufactured and supplied by a number of companies.

The British Generics Manufacturers Association (BGMA) report that this pricing approach to the sales of generics medicines has "*led to a vibrant multi-source market, minimising the scope for shortages and delivering the lowest market prices in Europe.*"[18]

Through the Drug Tariff, the Department of Health reimburses pharmacists the cost of dispensing generic medicines. Reimbursement prices are set by the Department of Health and are based on the provision of sales information from generics manufacturers.

The latest data on primary care prescribing from NHS Digital indicates that in 2015 a total of 1,084 million prescription items were dispensed in the community in England at a total cost of £9.3 billion. Of these items, the majority were prescribed generically – 807 million items (74%).[19]

The average net ingredient cost (the cost of the drug without the addition of dispensing costs) per generic item was much lower than for brand items - £4.33 for generic compared with £17.99 for branded. However, the annual increase in generic costs in 2015 was higher than that for brand items. Compared with 2014 prices, the average cost of a generically prescribed item increased by 14.4% in 2015 compared with a 5.5 % increase in brand items.[20]

The Competitions and Marketing Authority (CMA) are responsible for investigating and acting in the cases of potential pricing abuses. In a recent example of where the CMA have taken action against pharmaceutical companies with regards to generic pricing, GlaxoSmithKline and a number of other companies were fined £45 million when it was found that payments had been made in order to prevent the anti-depressant medication paroxetine being offered on the generics market.[21]

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17 Department of Health, Consultation outcome: Branded medicines: controlling prices, December 2015
18 BGMA, Key Issues: Freedom in market prices [accessed 18 October 2016]
19 NHS Digital Prescriptions Dispensed in the Community in England 2015
20 NHS Digital Prescriptions Dispensed in the Community in England 2015
21 CMA, CMA fines pharma companies £45 million, February 2016

However, there have been concerns expressed recently that this approach is allowing large price increases in single source generic medicines (those manufactured/sold by one company).

1.5 Generic drug price increases

In the case of unbranded generic medicines that are sold/manufactured solely by one pharmaceutical company (single source generics), there have been a number of high profile examples of significant price increases.

The Times newspaper have recently conducted an investigation into the price increases of a number of unbranded generic drugs. They reported in June 2016 that certain pharmaceutical companies were buying the production rights of medicines that were out of patent, producing and marketing them as unbranded generics (as the sole supplier) and substantially increasing prices. It reported that the prices of a number of unbranded generic drugs had increased to the point where the NHS was paying an extra £262million a year. *The Times* also stated that some drugs had increased in price by over 1000%:

> Over the past five years 32 medicines have risen in price by more than 1,000 per cent while the cost of a further 196 has at least doubled. In the most extreme case, the price of hydrocortisone 10mg tablets rose by 12,500 per cent, from 70p a packet in 2008 to £85 this year.[22]

The Chair of the Commons Health Select Committee, Dr Sarah Wollaston has also highlighted this issue.[23] In correspondence with the Secretary of State for Health regarding the reports published in *The Times*, she asked what measures would be introduced to tackle this. In his response the Secretary of State stated that for the most part, the system in place around the pricing of generic medicines had worked well, but he was aware of recent price increases and was concerned about potential adverse effects on the NHS budget. He highlighted a 2015 consultation into medicines pricing schemes and stated that he was considering putting new measures in place to monitor and control generics prices.[24] (see section 1.5)

As the table below shows, in 2015 both the total net ingredient cost[25] and the cost per item for generic items showed the largest recorded increase over the past decade:

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22 The Times, 'Extortionate' prices add £260m to NHS drug bill Four firms exploit loophole to make fortunes at taxpayers' expense, 3 June 2016

23 Letter from Chair of the Commons Health Select Committee, Dr Sarah Wollaston MP to the Secretary of State for Health on generic medicines price increases, 13 June 2016

24 Letter from Secretary of State for Health to the Chair of the Commons Health Select Committee on generic medicine price increases,

25 The net ingredient cost (NIC) is the basic price of a drug i.e. the price listed in the Drug Tariff or price lists. NIC refers to the basic cost of the drug and does not include any dispensing costs, fees or discount. It does not include any adjustment for income obtained where a prescription charge is paid at the time the prescription is dispensed or where the patient has purchased a pre-payment certificate. The figures

Net ingredient cost (NIC) and average NIC per prescription item by class of preparation, 2005 - 2015

	Net ingredient cost				Net ingredient cost per item			
	Generic		Proprietary		Generic		Proprietary	
	Cost £millions	Annual % change	Cost £millions	Annual % change	Cost £millions	Annual % change	Cost £millions	Annual % change
2005	1,978.1		2,189.9		4.77		15.68	
2006	2,275.0	15.0%	2,172.7	-0.8%	5.01	5.1%	16.31	4.0%
2007	2,284.8	0.4%	2,218.2	2.1%	4.61	-7.9%	16.44	0.8%
2008	2,036.3	-10.9%	2,317.5	4.5%	3.83	-17.0%	16.31	-0.8%
2009	2,253.3	10.7%	2,400.2	3.6%	3.96	3.4%	16.18	-0.8%
2010	2,430.6	7.9%	2,525.9	5.2%	4.01	1.3%	16.25	0.4%
2011	2,429.2	-0.1%	2,587.3	2.4%	3.78	-5.7%	16.27	0.1%
2012	2,711.0	11.6%	2,640.5	2.1%	3.84	1.6%	16.57	1.9%
2013	2,877.2	6.1%	2,733.5	3.5%	3.84	-0.1%	16.98	2.5%
2014	2,975.6	3.4%	2,780.6	1.7%	3.79	-1.3%	17.05	0.4%
2015	3,499.3	17.6%	2,987.0	7.4%	4.33	14.4%	17.99	5.5%

(Source: NHS Digital Prescriptions Dispensed in the Community in England 2015)

The table below provides details of the ten highest price increases observed over the past decade in drugs which can be prescribed generically:

Top 10 price increases for drugs available generically in the past decade, England

	Net ingredient cost £000s			Net ingredient cost per item prescribed			
	2005	2015	% Change	2005	2015	Increase	% Change
Doxepin	283	5,122	1707%	£2.36	£126.91	£124.56	5281.3%
Tranylcypromine Sulfate	201	5,443	2608%	£13.98	£632.96	£618.98	4427.3%
Cloral Betaine	116	1,130	877%	£3.14	£138.01	£134.87	4295.1%
Chlortalidone	135	647	379%	£2.29	£71.93	£69.64	3044.6%
Dicycloverine Hydrochloride	994	13,000	1207%	£4.71	£126.71	£122.00	2589.6%
Dipipanone Hydrochloride	360	2,946	718%	£11.07	£295.90	£284.83	2572.9%
Liothyronine Sodium	518	22,189	4181%	£11.58	£287.57	£275.99	2383.8%
Trifluoperazine	961	3,229	236%	£2.54	£48.23	£45.69	1797.6%
Menthol	18	1,011	5583%	£0.79	£12.03	£11.23	1413.7%
Carbimazole	1,968	31,269	1489%	£5.40	£63.20	£57.80	1071.3%
Ascorbic Acid	470	5,040	972%	£2.20	£24.45	£22.25	1012.2%

Source: NHS Digital Prescriptions Dispensed in the Community in England 2015

are in £s and pence. (HSCIC, *General Practice Prescribing Data (Presentation Level) Glossary of Terms*, 2015)

1.6 Department of Health consultation on medicines pricing

The Government consulted on a number of issues relating to drug prices in 2015.

Better aligning the statutory scheme with the PPRS

The Government consulted on reforming the statutory scheme. It reported that it was currently providing lower savings for the NHS in comparison to the PPRS, and that it should be more equal for companies under the two schemes. The Government proposed a number of new approaches to the scheme. The preferred option was the introduction of a percentage payment on the sale of products. This would also apply to medicines put on the market since December 2013 (previously exempt from the statutory scheme).

Following the consultation, the Government decided to proceed with its preferred option, more information on the responses to the consultation are provided in the consultation document. However, of particular note is that responses to this part of the consultation by members of the pharmaceutical industry suggested that the Government did not have the legal powers in existing legislation to implement these changes.

The Government stated they would legislate to amend the National Health Service Act 2006 to "*put beyond doubt*" that the Secretary of State has the powers to require a payment mechanism in the Statutory Scheme. These amendments are within the Health Service Medical Supplies Bill. The Government have reported that following the passing of the Bill, a further consultation will be conducted seeking views on the operation of the proposed payment mechanism. It is expected that changes will not be introduced until the 2017/18 financial year.[26]

The Government have reported that introducing the new payment approach within the statutory scheme will save the NHS an estimated £80 million.[27]

Small companies and OTC medicines

Over the counter (OTC) medicines are those that can be bought without a prescription.

Within the consultation, the Government committed to retaining the exemption for small companies (those with medicine sales below £5 million) from any new payment mechanism. They also stated that they would keep the small company exemption at the current level.

The Government also concluded they would exclude the sales of OTC medicines from the future payments mechanism and to disregard these sales when calculating whether a company has sales under £5 million.

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[26] Department of Health, Consultation outcome: Branded medicines: controlling prices, December 2015

[27] Department of Health, Health Service Medical Supplies (Costs) Bill Impact Assessment, September 2016

Single source generics

The Government consulted on proposals to introduce measures to control the prices of generic medicines where there is insufficient competition to control prices (as highlighted in section 1.4 above).

Currently, those manufacturers and suppliers that are members of the PPRS, are excluded from other price controls of their products that are not part of the PPRS (i.e. unbranded generic medicines). In contrast, under the Statutory Scheme, the Secretary of State could introduce controls on unbranded generic medicines produced but to date the Government have not introduced such controls; they report that the approach to generic medicines has worked well on the whole.

The responses in the consultation varied on this matter; Responses from the health service supported the proposals whereas industry responses stated that there had been insufficient consultation on the issue, that there could be unintended consequences of introducing price controls and that the CMA already had powers in this area. More information on this is provided in the consultation document.

The Government stated in response to the consultation that it intended to amend legislation to allow for the introduction of price controls on generic medicines, should this be necessary.

1.7 Information provision

The Department of Health collect information under the PPRS in order to operate the scheme. This includes information relating to the sales of products and financial returns.

Under the Statutory Scheme, regulations allow for the collection of sales information relating to the companies that are not members of the PPRS.

There are a number of voluntary schemes that currently exist to allow for the collection and reporting of information about the sales of unbranded generic medicines.

Scheme M is a voluntary agreement between the Secretary of State and the British Generic Manufacturers Association (BGMA) representing the generic medicine industry.[28] It applies to manufacturers and suppliers but not distributers of generic medicines. It includes a number of provisions relating to the submission of information relating to sales and prices of medicines to the Department of Health. The department of use this information to assess what the reimbursement price will be for these drugs in the Drug Tariff.

[28] Department of Health, Revised long-term arrangements for reimbursement of generic medicines, Scheme M, 2010

There is a similar scheme that apply to wholesalers of generic medicines (Scheme W).[29] These schemes are made under Section 261 of the *National Health Service Act 2006.*

The Department of Health have reported that there are limitations to these schemes- because it is voluntary not all manufacturers will submit information and that means the information received is inconsistent and not fully representative of the industry.[30]

The response to the consultation on NHS medicines pricing stated that the Government would seek to legislate to require all manufacturers, suppliers and distributors to keep and supply information to the Secretary of State on generic medicine prices and sales.

1.8 The National Health Service Act 2006

The *National Health Service Act 2006* consolidated a number of pieces of legislation relating the health service and social care.

Sections 260-266 of the act relate to control of the pricing of health service medicines and other medical supplies. This includes providing the Secretary of State with powers:

- to control prices within a voluntary scheme relating to medicine prices i.e the PPRS;
- to establish a statutory scheme; and
- to require NHS medicines manufacturers/suppliers to provide information relating to prices of medicines.

It also provides information relating to the enforcement measures and penalties.

The *Health Service Medical Supplies (Costs) Bill* intends to amend a number of the sections in this Act.

[29] Department of Health, New long-term arrangements for reimbursement of generic medicines, Scheme W, 2010

[30] Health Service medical Supplies (Costs) Bill, Explanatory notes

2. The Bill

The Health Service Medical Supplies (Costs) Bill (the Bill) had its First Reading on 15 September 2016 and is tabled for its Second Reading on 24 October 2016.

The Bill page on the Parliament website provides links to the Bill, explanatory notes and debates on the Bill. An Impact Assessment was published by the Department of Health in September 2016.

The Department of Health has produced a useful factsheet on the Bill which outlines the different elements of the Bill and how it will change the pricing of medicines.

In short, Department of Health state that the Bill will:

1. put beyond doubt that the government can require companies to make payments to control the cost of health service medicines
2. enable 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
3. enable 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[31]

2.1 Devolution issues

Health is generally a devolved issue. However, regulation of the price of medicines used in the NHS in England, Scotland and Wales is reserved.

This is not reserved in Northern Ireland, but the *National Health Service Act 2006* (the legislation that regulates medicines pricing) applies across the UK. A Legislative Consent Motion will be required from Northern Ireland for the Bill to apply across the UK.

2.2 Content of the Bill

This section provides an overview of the main provisions in the Bill. A more detailed description of the content of the Bill is provided in the Bill's explanatory notes.

The Bill would make a number of amendments to the *National Health Service Act 2006* (hereafter referred to as the *NHS Act).*

[31] Department of Health Guidance: Health service medical supplies costs [accessed 18 October 2016]

Controlling the cost of health service medicines

The Department of Health factsheet provides a short summary of the measures in clauses 1-4 of the Bill in relation to statutory medicines pricing schemes and high priced generic medicines:

> The Bill would amend the National Health Service Act 2006 to put beyond doubt that the government can require companies in the statutory scheme to make payments to control the cost of health service medicines. These payments can be either instead of, or in combination with measures to limit prices directly or control their profits. The Bill would also allow the government to apply penalties for non-compliance and to recover any payments owed through the courts following a right of appeal to a tribunal. The penalties can be a single penalty not exceeding £100,000 or a daily penalty not exceeding £10,000.
>
> […]The Bill would amend the National Health Service Act 2006 to enable the government to require companies to reduce the price of a generic medicine, or to impose other controls on that company's unbranded medicine, even if the company is in the voluntary scheme, the PPRS 2014, for their branded medicines.
>
> The government intends to use this power to limit the price of unbranded medicines where competition in the market fails and companies charge the NHS unreasonably high prices for generic medicines.[32]

Clause 1 would amend section 261 of the NHS Act which provides the Secretary of State for Health with powers in relation to voluntary schemes. The PPRS is a voluntary scheme, but there are statutory powers under the NHS Act in relation to the scheme.

Clause 1 would amend the NHS Act to expand the types of schemes to which the Secretary of State can apply their powers. A third type of scheme would be added to subsection 1 of section 261 of the Act- where manufacturers or suppliers are required to pay the Secretary of State a certain amount in relation to the sales or estimated sales of medicines.

This would mean that the powers in section 261 of the NHS Act will apply to any scheme which requires:

- Price control
- Profit control; or
- A requirement to make payments.

Subsection 4 would provide that the Secretary of State can make regulations to require a manufacturer/supplier to make a payment within a specified time period where they have failed to make a payment in line with the requirements of the scheme.

This subsection also would provide that where a manufacturer/supplier leaves a voluntary scheme they will still remain liable to make any

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[32] Department of Health, Health Service Medical Supplies (Costs) Bill factsheet, September 2016

payments owed from the time during which the medicine was covered by the scheme.

This would mean that the Secretary of State can make regulations to require the members of the PPRS to make payments calculated with reference to the sales (or estimated sales) of medicines.

Clause 2 amends Section 262 of the NHS Act which provides the Secretary of State with the powers to make regulations to:

- limit the prices of medicines; and
- require that any amount paid to manufacturers/suppliers in excess of the set price to be paid to Secretary of State.

Currently, the powers in Section 262 cannot be exercised against any manufacturer/supplier who is covered by a voluntary scheme, whether the medicine in question is controlled under the scheme or not. Clause 2 would amend this to provide that the powers can be applied to the company where the medicine in question is not controlled by a voluntary scheme, irrespective of whether the manufacturer/supplier has other medicines controlled under the voluntary scheme.

If a manufacturer is a member of the PPRS, any medicine produced by them that is not covered by the scheme (for example, an unbranded generic medicine) is be exempt from price controls. This clause would mean that it will now be possible for the Secretary of State to control the prices of these medicines. This will mean that medicines that are not subject to the PPRS can be controlled through the Statutory Scheme (subject to existing exceptions).

As it is already possible for the prices of unbranded generic medicines to be controlled through the Statutory Scheme, this would now mean that the unbranded generic medicines produced by members of the PPRS could also be controlled.

Clause 3 would amend section 263 of the Act which currently provides powers to the Secretary of State to make a statutory scheme to limit medicine prices and limit the profits received in relation to the sale/manufacture of a medicine. Responses to the 2015 Government consultation from the pharmaceutical industry had suggested that the Government did not have powers to introduce a scheme relating to a payment requirement

Clause 3 would extend the powers in section 263 to ensure that the Secretary of State can make a statutory scheme that may require any manufacturer/supplier to pay a certain amount relating to the sales or estimated sales of a medicine.

The clause would also provide powers for the Secretary of State to make regulations to require a payment to be made within a specified time period where they have failed to make a payment in line with the requirements of the scheme. With this in place, it would allow, for example, the Government to introduce a Statutory Scheme to control overall spend as was proposed in the 2015 consultation response.

Subsection 4 seeks to replace subsection 7 of Section 263. This would mean that where a medicine is controlled under a voluntary scheme, the statutory scheme will not apply, but only in relation to that medicine. Medicines produced by the same manufacturer that are not controlled under the voluntary scheme could now be controlled under a statutory scheme.

Clause 4 would amend sections 265 and 266 of the NHS Act in relation to enforcement. It ensures that the enforcement provisions within the Act apply to the new provisions. The penalty that can be applied by the Government in the case that the provisions are not complied with are either a single penalty of up to £100,000 or up to £10,000 a day.

The costs of other medical supplies

Clause 5 would amend section 260 of the NHS Act which provides powers for the Secretary of State to make orders to control the maximum price of medical supplies other than medicines. Medical supplies is defined under section 260 as including "*surgical, dental and optical materials and equipment.*"

Clause 5 would extend the territorial extent of Section 260 to Scotland and Northern Ireland as well as England and Wales. It also extends some of the enforcement powers within Section 265 that currently apply to medicines to other medical supplies.

Information provision

The Department of Health factsheet on the Bill provides a short summary of the measures in Clause 6:

> The Bill would bring together the information requirements for health service medicines and other supplies in one place in the NHS Act. It would also enable the government to make regulations to obtain information on sales and purchases of health service medicines and other medical supplies from all parts of the supply chain, from manufacturer to pharmacy, for defined purposes.
>
> The Bill would strengthen and expand the statutory footing for existing data collections, which would enable the government to access to data on more products and from more parts of the supply chain which would improve the data which informs the reimbursement arrangements for community pharmacy and GP practices.
>
> The Bill would also enable the government to obtain information on sales and purchases from across the supply chain to evaluate whether the supply chain as a whole, a specific sector, or specific product groups provide value-for-money to the NHS.[33]

Clause 6 would insert a number of new sections to the NHS Act.

New section 264A would provide powers for the Secretary of State to make regulations to require any manufacturer, supplier of medicines or medical supplies to provide information to the Secretary of State. The

[33] Department of Health, Health Service Medical Supplies (Costs) Bill factsheet, September 2016

sections provide examples that this information may be related to prices, discounts or rebates, revenue or profits but the powers are not limited to this.

Clause 6 would also provide that regulations can be made regarding the time frame by which this information should be provided and the form it should take.

New section 264A would also establish that the information provided can only be used for certain purposes, including assessing payments to those providing primary care services, controlling the costs of health service medicines in the UK and, assessing whether adequate supplies of NHS products are available.

New section 264B would allow the Secretary of State to disclose the information provided by manufacturers and suppliers under Section 264A in certain circumstances, including to:

- certain health service bodies, for example NHS England;
- Government departments;
- Ministers in Wales, Scotland and Northern Ireland;

The section would also provide the Secretary of State with the powers to make regulations to share the information with bodies that represent the pharmaceutical industry.

This section also provides that if the information is confidential or commercially sensitive, the information can only be used by the Secretary of State or the recipients of the information for the purposes prescribed in regulations or listed in Section 264A.

New section 264C would require the Secretary of State to consult with representatives of the pharmaceutical industry before making regulations under new sections 264A and B.

These amendments would mean that the Secretary of State has powers to require that all manufacturers and suppliers of medicines and medical supplies to provide information on pricing.

Territorial extent and commencement

Clause 8 provides that the Act will apply across the UK. More specific information about where specific clauses will apply is provided in annex A to the explanatory notes to the Bill:

- 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.

A Legislative Consent Motion will be need to be agreed by the Northern Ireland Assembly for the Bill to apply across the UK.

Clause 9 provides that (except for clause 8 and clause 10) the provisions of the Bill will come into force on a date provided in regulations made by the Secretary of State.

2.3 Comment on the Bill

The Pharmaceutical Journal have reported that the ABPI was currently looking at the Bill to ensure the Government's response is proportionate and appropriately targeted. They include the following comment from the ABPI:

> "The ABPI acknowledges the need for clarity on pricing on older medicines and has been calling on the government to take action on the issue of significant price rises in a small number of those medicines where a competitive market is not working as effectively," says Richard Torbett, executive director of commercial at the ABPI.

The Director General of the British Generics Manufacturers Association (BGMA) has published the following response to the Bill. It states that generic competition saves the NHS over £13 billion a year and expresses concerns that new measures to control the prices of unbranded generic medicines may not be justified:

> "We understand the Government's desire to monitor and control the prices of NHS medicines where they are not effectively limited by competition. But we must recognise that the UK benefits from one of the most competitive generic medicines markets in Europe delivering some of the lowest prices available. Generic competition saves the NHS more than £13billion every year, increasing access by allowing more patients to be treated as a result. Allowing flexibility of pricing ensures that the market attracts numerous suppliers, which in turn maintains downward pressure on prices as manufacturers compete for market share.
>
> "Prices of generic medicines controlled by competition in this way has been a core element of the UK's success, often reducing factory gate prices by 90% or more compared with the original branded equivalent. It is important that the success of the UK's arrangements in delivering these very low prices across a large number of products is not undermined by action designed to deal with recent price increases in 1% of generic medicines, which may or may not be justified. Experience in other markets that lack flexibility due to more rigid price setting policies shows that shortages of medicines are more common, putting patient care at risk, and as well as delivering prices that are on average higher than in the UK.
>
> "Where competition is not controlling prices, our arrangements provide for the Department of Health to intervene and if necessary they can refer cases to the Competition and Markets Authority. We need to make this intervention work effectively in these rare extreme cases and not put at risk a system which generally works extremely well for patients and the NHS."

One of the companies that had been the subject of *the Times* investigation into price increases in unbranded generic medicines has also commented on the Bill. Concordia International, a US company which owns AMCo in the UK (formed by the merger of Amdipharm and Mercury) was reported to have fallen by 28% in its share price which

was attributed to the introduction of the Bill.[34] The Chairman and Chief Executive of Concordia said that the company supports any action to ensure safe and effective medicines for patients and that they would monitor the Bill and evaluate what impact it may have on the business.

[34] Bloomberg, Drugmaker Concordia Drops to 2013 Low on U.K. Bill, Index Exit, September 2016

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