HOUSE OF COMMONS LIBRARY

BRIEFING PAPER

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Health Service Medical Supplies (Costs) Bill: Committee Stage Report

By Sarah Barber

Contents:

Contents

Summary

The *Health Service Medical Supplies (Costs) Bill* was introduced on 15 September 2016 and had its Second Reading on the 24 October 2016. The Bill was considered in three sessions of the Public Bill Committee on 8 and 15 November. The remaining stages of the Bill have been tabled for 6 December 2016.

Full background on the Bill, and its provisions as originally presented, can be found in Library Briefing Paper, Commons Library analysis of the Health Service Medical Supplies (Costs) Bill.

The Bill

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 branded medicines for the NHS are 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 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 far fewer 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.

Government amendments

A number of Government amendments were added at Committee Stage in relation to information requirement processes in the devolved administrations. These specify that the UK Department of Health will collect information from manufacturers and suppliers across the UK, but the Devolved administrations will be responsible for collecting information from GPs and community pharmacies.

Other amendments

A number of Opposition and SNP amendments were discussed during Committee stage. These were related to:

- requiring that the funds from the PPRS be invested into new and innovative medicines in England;
- Ensuring the quality of medical supplies is not affected by the provisions in the Bill; and
- how the Department and devolved Administrations would share information.

A tracked changes version of the Bill showing changes made in Committee has been published on the Parliament website.

1. Background

The Health Service Medical Supplies (Costs) Bill was introduced on 15 September 2016. It followed a consultation on a number of medicines pricing issues in December 2015.[1]

The Bill and its explanatory notes are available on the Parliament website.

The Bill seeks to amend the National Health Service Act 2006 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.

Full background on the Bill, and its provisions as originally introduced is provided in Library Briefing paper 7744: Commons Library analysis of the Health Service Medical Supplies (Costs) Bill, 21 October 2016.

Following the Bill's Second Reading a number of Keeling Schedules were published by the Department of Health. These are documents prepared by the Government to show how a Bill would amend an Act or part of an Act:

- Amendment of the National Health Service Act 2006, 16 November 2016;
- Illustrative NHS Regulations - Branded Medicines, 16 November 2016; and
- Illustrative NHS Regulations – Information provision, 16 November 2016.

1.1 Public Bill Committee

The Public Bill Committee Stage started on 8 November 2016 and concluded on 15 November; it held three sittings. The membership of the Committee was as follows:

Chairs:

- Mike Gapes (Ilford South)
- Mark Pritchard (The Wrekin)

Membership:

- James Berry (*Kingston and Surbiton)*
- Jo Churchill (Bury St Edmunds)
- Julie Cooper (Burnley)
- Judith Cummins (Bradford South)

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

- Dr James Davies (Vale of Clwyd)
- Martyn Day (Linlithgow and East Falkirk)
- Mr Philip Dunne (Ludlow)
- Kevin Foster (Torbay)
- John Glen (Salisbury)
- Graham Jones (Hyndburn)
- Liz Kendall (Leicester West)
- Karl McCartney (Lincoln)
- Justin Madders (Ellesmere Port and Neston)
- Rob Marris (Wolverhampton South)
- Andres Selous (South west Bedfordshire)
- Mark Spencer (Sherwood)
- Maggie Throup (Erewash)
- Dr Philippa Whitford (Central Ayrshire)

The Public Bill Committee (PBC) received a number of written submissions and took evidence at its first sitting on 8 November 2016. The written evidence and the transcripts of the Committee's sitting are available on the Health Service Medical Supplies (Costs) Bill webpage on the Parliament website

A tracked changes version of the Bill showing changes made in Committee has been published on the Parliament website.

2. Summary of Second Reading

The *Health Service Medical Supplies (Costs) Bill* had its Second Reading on the 24 October 2016. There was general support on both sides of the House for the Bill. Issues raised in relation to the measures within the Bill included:

- That the information provisions should not place additional burdens on small businesses; and
- That funds from the Pharmaceutical Price Regulation Scheme should be used to fund innovative and new treatments in England.

The Secretary of State for Health, Jeremy Hunt, introduced the Bill and outlined its purpose:

> 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.[2]

He particularly highlighted the "*unethical and unacceptable practice*" of drug companies who are the sole supplier of certain unbranded generic drugs imposing significant price hikes. He noted one product where the price had increased by 12,000% between 2008 and 2016.[3] He said that the practice is not widespread but a handful of companies appear to be exploiting the current freedom of pricing for generic medicines in the UK.[4]

Jeremy Hunt described the powers proposed in the Bill as a "*modest addition*" to the powers already provided within the *National Health Service Act 2006*. He said they were necessary to ensure the Government could respond to changes in the commercial environment.[5] He said that the powers to control prices were only intended for use where there is not competition in the market and companies are charging the NHS an unreasonable price.[6]

The Shadow Secretary of State, Justin Madders said that the Opposition supported the broad aims of the Bill.[7] However, he said that he had concerns about the information requirement provisions of the Bill. He highlighted potential additional burdens on the medical technology sector. A number of Members raised similar concerns relating to excess burdens on small businesses, for example, James Davies said it was

2 HC Deb 24 October 2016 c72
3 HC Deb 24 October 2016 c73
4 HC Deb 24 October 2016 c78
5 HC Deb 24 October 2016 c76
6 HC Deb 24 October 2016 c79
7 HC Deb 24 October 2016 c82

important to avoid onerous data collection beyond what is already required by HMRC.[8]

With regards to this part of the Bill, the Secretary of State had said that these provisions were important to allow the Government to run a robust reimbursement system. He acknowledged concerns and said that the Government did not wish to place additional burdens on these companies:

> The 2006 Act already provides powers for the Government to require suppliers of medical technologies to keep and provide information on almost any aspect of their business. This Bill will clarify and modernise those powers, and I am committed to exercising them in a way that is fair and proportionate to companies, to the NHS and to taxpayers who rightly demand value for money from the supply chain. Companies are currently required to hold information on their income and sales for six years for tax purposes. We will work closely with industry to ensure that the requirement to keep and record data does not significantly increase this burden.[9]

Justin Madders also raised the idea of using the payments from the PPRS in a similar way to how they are used in Scotland where they are invested in a fund for new medicines. He said there was logic in allowing savings in the drugs bill to be reinvested in getting new drugs to patients quickly.[10]

The Health spokesperson for the Scottish National Party (SNP), Dr Philippa Whitford, said that the SNP welcomed that the Bill closed some of the loopholes around medicines pricing. She said that it was important to ensure that information collection is simple and straightforward, and that the devolved Administrations can access this information easily.[11]

8 HC Deb 24 October 2016 c100
9 HC Deb 24 October 2016 c80
10 HC Deb 24 October 2016 c85
11 HC Deb 24 October 2016 c91

3. Committee Stage

3.1 Controlling the costs of health service medicines (clauses 1-4)

Clauses 1-4 of the Bill would amend the *National Health Service Act 2006* (NHS Act) in relation to the prices of medicines.

Full background on the Bill, and its provisions as originally introduced is provided in Library Briefing paper 7744: Commons Library analysis of the Health Service Medical Supplies (Costs) Bill, 21 October 2016.

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.

This would amend the NHS Act to expand the types of schemes to which the Secretary of State can apply their powers. 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.

Clause 2 amends 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, 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 any 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. 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.

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.

There were no amendments made to these clauses at Committee stage. Opposition amendment 44, which would require the payments from the PPRS to be invested into access for new and innovative treatment, was pushed to a division where it was defeated by 9 votes to 8.[12]

Investing in new and innovative medicines

Julie Cooper introduced opposition amendment 44, which would amend Clause 1 to require that payments from the pharmaceutical companies through the PPRS be invested into access for new and innovative treatments in England. She highlighted that in Scotland, money from PPRS payments are already used in this way, and said that the Opposition were concerned that budget constraints limit access to new and innovative medicines:

> Amendment 44 would provide assurance by ensuring that rebates reclaimed against purchases of medicines were reinvested specifically in improving patient access to medicines. In Scotland, rebates collected by means of the voluntary prescription pricing regulation scheme are already specifically earmarked to fund new medicines. In essence, the Bill, which we support in principle, is to ensure that the NHS can procure medicines and medical supplies cost-effectively. I am sure that the intention is not to reduce funding to the NHS, so we cannot have a situation in which every pound repaid from the suppliers and manufacturers equates to £1 less of Treasury funding allocated to the NHS. We are concerned that, too often, budget constraints limit access to new and innovative medicines and treatments.[13]

SNP Health spokesperson, Dr Philippa Whitford recommended looking at the way the system works in Scotland; she said that the money going into general funding in England meant that the long term gain is to the treasury rather than the NHS.[14]

In responding to the amendment, the Under-Secretary of State for Health, Philip Dunne, agreed that investing in new and innovative treatments has the potential to transform care, but he said that it should be up to CCGs to determine their own clinical priorities. He also highlighted that income from the PPRS fluctuates, and allocating to a particular fund may mean that in some years the funding goes down:

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12 Health Service Medical Supplies (Costs) Bill Committee, 15 November 2016
13 PBC 15 November 2016, c30
14 PBC 15 November 2016, c35

> We know that investing in new and innovative medicines and treatments, where they are proven to work and are a clinical priority, has the potential to transform the care of patients and to improve outcomes, which is what we all want. However, it is a fundamental principle of NHS funding that it should be allocated according to clinical priorities based on the judgment of clinical commissioners. That may include new treatments, but it may include scaling up older effective treatments—through repurposing, as indicated by the hon. Gentleman—or investing in more staff.
>
> We understand the intention behind the amendment, but it is for NHS England and clinical commissioning groups to determine clinical priorities and to spend that money on what is clinically most important. It is also important to point out to the hon. Lady that income from the voluntary and statutory schemes can fluctuate from year to year, so allocating such income by means of a ring fence to a specific area, such as new medicines, brings risk because in some years the income received may go down. The perverse consequence of the amendment's ring-fencing may therefore mean less money being spent in a subsequent year, in the event of the scheme not generating an increase in income. That would disadvantage patients by making treatment dependent on income from medicine pricing schemes, which we do not think should be the determinant of available medicine.[15]

The amendment was pushed to a division where it was defeated by 9 votes to 8.[16] A similar Opposition amendment has been tabled for Report Stage of the Bill.[17]

Types of payment mechanisms

Opposition amendment 43 to clause 3 was described by Julie Cooper as seeking to clarify that payment mechanisms under the Statutory scheme use the same approach as the PPRS. She said that the Opposition supported the principles of the Bill on "*ensuring that both schemes achieve the same level of savings and that the system is not open to abuse.*" However, they had concerns that the Bill is not specific about how payments will be calculated under the Statutory Scheme. [18]

The Minister said that whilst there should be some alignment between the two schemes, to require them to be the same would remove some of the flexibility that currently exists in allowing for the renegotiation of the PPRS, and some of the benefits associated with having two schemes:

> We think there is merit in aligning the two schemes in some respects. However, to require them to be the same is inappropriate, because it removes some flexibility that the Government have, and from which the NHS benefits, in being able to negotiate the voluntary scheme on a periodic basis. The voluntary scheme has other aspects beyond pure price. Aligning the two in what will become a statutory scheme would restrict the scope for the two schemes to operate in a complementary manner.

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15 PBC 15 November 2016 c32
16 PBC 15 November 2016 c36
17 Health Service Medical Supplies (Costs) Bill, Notice of amendments given up to and including 29 November 2016
18 PBC 15 November 2016 c43

> The voluntary scheme is a matter for negotiation with industry on a periodic basis. As such, there is scope to include a range of measures. Those measures may change with each iteration of the scheme, to reflect the priorities of each side at the time of renegotiation. To illustrate that, the current voluntary scheme includes a range of provisions developed through negotiation with industry that sit alongside the payment mechanism. That includes price modulation, which enables companies to put prices up and down as long as the overall effect across their portfolio is neutral. That may have benefits for them, not only for their sales to the NHS but in the pricing references used by selling to the NHS in jurisdictions in other countries. That is of potential commercial value to companies, which may be willing to accept a higher payment percentage as a result—in other words, a higher discount to the NHS.[19]

3.2 Controlling the costs of other medical supplies (clause 5)

Clause 5 of the Bill 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.

No amendments were added to the Bill during Committee Stages. No amendments were pushed to a division.

Maintaining the quality of medical supplies

Amendment 47 to clause 5 was a probing amendment introduced by Dr Philippa Whitford (SNP). It would require the Secretary of State to conduct a consultation on the potential effect of controlling the prices of medical supplies on the quality of these products. She expressed concerns that using the powers in the bill to control the prices of medical supplies could result in an impact on the quality of those supplies, for example, surgical gloves. [20]

The Minister thanked Dr Whitford for her amendment and said that the Government were looking to introduce a more centralised purchasing across the NHS, similar to that in Scotland. He said he hoped she would withdraw the amendment at this stage, but he invited her to work with him in addressing this issue. He reported that Department of Health officials will look at the right way to amend the Bill to give the same effect but in a way that works in the context of the Bill.[21]

The Minister also said that the Government will consult with industry on the impact of the Bill on medical supplies. He stated that whilst he couldn't provide an absolute assurance, there is an intent that

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19 PBC 15 November 2016 c44
20 PBC 15 November 2016 c50
21 PBC 15 November 2016 c51

equipment has to meet a quality threshold to be acceptable to a clinician:

> 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, there is a clear intent that, if we are centralising procurement of equipment, that equipment has to meet a quality threshold in order to be acceptable to the clinician. I understand the point she makes. The intent is not to buy substandard equipment to 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.[22]

3.3 Information provision (clause 6)

Clause 6 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. 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. It 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.

The Bill would allow the Secretary of State to disclose the information provided by manufacturers and suppliers in certain circumstances, including to:

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

The Bill would require the Secretary of State to consult with representatives of the pharmaceutical industry before making regulations under new sections 264A and B of the *NHS Act*.

There were a number of Government amendments added to this part of the Bill during Committee Stage.

Government amendments

The Minister introduced a number of Government amendments to Clause 6. He explained that these were the result of discussions with the devolved Administrations on how they would like the information requirement powers to be applied in their territories. He said that discussion between the Government and the devolved Administrations had led to an agreement that the UK government will collect

[22] PBC 15 November 2016 c52

information from wholesalers and manufacturers across the UK.[23] It was also agreed that each nation will collect the information from GPs and pharmacies for which they have responsibility:

> Amendments 1 to 36 and 38 therefore enable the Secretary of State to collect information from UK producers for devolved purposes, with the exception of pharmacies and GPs in the devolved territories. The amendments will enable the Secretary of State to share the information with the devolved Administrations and other bodies in the devolved Administrations, and enable them all to use the information for devolved purposes: reimbursement of pharmacies and GPs; and to assess value for money in relation to the supplies. I hope that the Committee will therefore accept those Government amendments.[24]

Disclosure of information to devolved Administrations

SNP amendment 48 to clause 6 would provide that information provided under the Bill must be disclosed by the Secretary of State to any of the persons entitled to see this information (as listed in the Bill) at their requests.

It was introduced by Martyn Day who said that, as currently drafted, Clause 6 does not provide a mechanism for disclosure of information. He asked if the Minister could clarify whether disclosure will be at the discretion for the Secretary of State and what the terms would be.[25]

The Minister responded to the amendment. He said that he understood the intent of the amendment, but that it would be best to address this in a Memorandum of Understanding between the Department of Health and each of the devolved Administrations. He said this would allow requests for information to be dealt with in a way to suit both parties.[26] The amendment was withdrawn.

Information requirements

Rob Marris (Labour) requested clarification on the provision of information by producers of medical supplies. In evidence to the Public Bill Committee, the Chair of the Association of British Healthcare Industries had said that there were concerns in the medical technology industry that the requirements of the Bill could introduce additional burdens on smaller businesses.[27]

The Minister stated that the intention was not to place additional burdens on medical device producers and suppliers. He said the Government will consult with the trade associations, and publicly; and would look at the current definition of SME in the regulations, as this was not the same as used elsewhere. He drew attention to the illustrative regulations produced for consideration, and the provision made for SMEs within these:

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23 PBC 15 November 2016 c57
24 PBC 15 November 2016 c58
25 PBC 15 November 2016 c59
26 PBC 15 November 2016 c63
27 PBC 8 November 2016 c5

> The illustrative regulations that the Government have provided to help the Committee scrutinise the clause demonstrate our intentions in this area. The regulations distinguish between routine collection and non-routine collection of information. Routine collections mostly include information that we are already collecting under voluntary arrangements. On a non-routine basis, we would collect information to satisfy ourselves that the supply chain provides value for money. We do that at present through sampling collections from time to time, particularly among the smaller providers and pharmacies. We will consult with stakeholders to determine whether the obligation to keep and record information will be any more burdensome than the existing obligation to keep these data for tax purposes, as I have said.
>
> Committee members will see that we have made provision for SMEs in the illustrative regulations, which I touched on in response to my hon. Friend the Member for Erewash. For the purposes of the illustrative information regulations, SMEs can, where appropriate, provide the Government with the information requested by providing us with invoices. That is how we currently collect information from pharmacies, which we believe places a proportionate and modest burden on them.[28]

3.4 New clauses not added to the Bill

Reporting requirements (New Clause 2)

Opposition New Clause 2 would introduce a requirement for the Secretary of State to present an annual report to Parliament on the impact of the Act on the prices and availability of medicines, and other supplies; and on research and development.[29]

In introducing the new clause, Justin Madders (Labour) said that the amendment gave an opportunity for Parliament to scrutinise the effectiveness of the Bill. He said there had been some unease about the impact of the Bill, and of Brexit on the pharmaceutical industry:

> 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.[30]

The Minister said key industry stakeholders had supported the provisions in the Bill, and outlined what the Government were doing outside the Bill for the life sciences sector. He said that the illustrative regulations to the Bill contained a requirement for an annual report on the impact of the regulations. He accepted that a reporting requirement is important but that to set it out in the Bill would be too restrictive.

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28 PBC 15 November 2016 c70
29 PBC 15 November 2016 c77
30 PBC 15 November 2016 c78

In response, Justin Madders said he felt *"having draft regulations that have not yet been consulted on is not an adequate substitute for the assurances that we are seeking."*[31]

He pressed the new clause to a division where it was defeated by 9 votes to 5.[32]

Controlling the price of 'specials' (New Clause 3)

Dr Philippa Whitford (SNP) introduced New Clause 3 to introduce a requirement for a review into how effective the powers in the *NHS Act* are to control the prices of unlicensed medical products (specials).

'Specials' are unlicensed medical products that can be prescribed and produced/imported for use by a specific patient, where no alternative licensed medical product is available.

Dr Whitford drew attention to specific 'specials' (often used in treating skin conditions) where costs have "*spiraled out of control.*" She said that the new clause was to look at whether 'specials' are covered.[33]

The Minister responded. He said that, under the *NHS Act*, the Government currently have the power to limit the price of any medicine, so long as the producer is not a part of the PPRS. However, this power has not been used to control the price of 'specials.'

He said it should be recognised that often these types of products are expensive to produce, and by setting the reimbursement price on the drugs tariff, the Government does encourage pharmacies to source 'specials' as cheaply as possible.[34]

The new clause was withdrawn.

Off-patent drugs (New Clause 4)

Dr Whitford (SNP) introduced new clause 4 to require a review on whether the provisions of the Bill extend to the regulation of the prices of repurposed off-patent drugs.[35] She highlighted a Private Members Bill that was introduced in 2015, *The Off-patent Drugs Bill.* This had sought to ensure that off-patent drugs could be used in new unlicensed indications. The Commons library briefing paper, produced for the Bill's Second Reading provides more information on the Bill and background issues. The Bill did not progress beyond Second Reading.

Dr Whitford said that the clause was to raise this issue, and to see if it had been considered by the Government.

The Minister said that the *NHS Act's* provisions already apply to this group of drugs. He also provided some information on the Government's action in supporting the use of off-patent drugs. This included the establishment of a working group at the Department,

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31 PBC 15 November 2016 c81
32 PBC 15 November 2016 c81
33 PBC 15 November 2016 c82
34 PBC 15 November 2016 c83
35 An off-patent drug is the term used to describe a drug where the patent period has expired. At this time, a number of pharmaceutical companies may be producing versions of the same drug (generics).

improved GMC guidance and NICE guidance on use of off-patent drugs:

> Since November last year, a range of organisations have come together to work collaboratively to examine the issues at play in drug repurposing and to develop positive ways of handling those issues to ensure that patients benefit from robust research outcomes.
>
> Officials in the Department have been working on the issue with the Association of Medical Research Charities and many of its members, as well as with NHS England, NICE, the publishers of the "British National Formulary" and the Medicines and Healthcare Products Regulatory Agency. All are committed to taking non-legislative measures to make sure that there is a clear and accessible pathway to ensuring that robust evidence showing new uses for existing drugs can be brought more systematically into clinical practice to benefit patients. That working group has made significant progress, and I would like to thank the organisations that have come together in a true spirit of co-operation to achieve rapid progress.
>
> The General Medical Council has provided better advice for doctors about prescribing drugs outside their licensed indications, when that is clinically indicated. The "British National Formulary" has introduced new processes to ensure that information about repurposed drugs is captured more systematically and is therefore much more readily available for the clinical prescribers whom the hon. Lady referred to as the people at the forefront of this innovation. The Committee has heard from Dr Keith Ridge about the role that regional medicines optimisation committees will be asked to take in supporting prescribers to take up and use new evidence, particularly about unlicensed medicine use. Significant work has also been done on the development of a pathway that maps the routes from research result into clinical practice, which will help researchers and clinicians ensure safe and timely implementation.
>
> NICE has published more than 50 evidence summaries for unlicensed and off-label uses of medicines. Although I said I did not want to go into detail, there are a couple of examples that the hon. Lady will be familiar with but other members of the Committee might be less so. NICE has made recommendations and guidelines on the use of tamoxifen to prevent familial breast cancer, and on the use of antidepressants—selective serotonin reuptake inhibitors—to treat irritable bowel syndrome.[36]

[36] PBC 15 November 2016 c87

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