# PARLIAMENTARY DEBATES

HOUSE OF COMMONS
OFFICIAL REPORT
GENERAL COMMITTEES

## Public Bill Committee

# HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

*Second Sitting*

*Tuesday 15 November 2016*

*(Morning)*

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**not later than**

**Saturday 19 November 2016**

**The Committee consisted of the following Members:**

*Chairs:* Mike Gapes, † Mark Pritchard

† Berry, James *(Kingston and Surbiton)* (Con)
† Churchill, Jo *(Bury St Edmunds)* (Con)
† Cooper, Julie *(Burnley)* (Lab)
† Cummins, Judith *(Bradford South)* (Lab)
† Davies, Dr James *(Vale of Clwyd)* (Con)
† Day, Martyn *(Linlithgow and East Falkirk)* (SNP)
† Dunne, Mr Philip *(Minister of State, Department of Health)*
† Foster, Kevin *(Torbay)* (Con)
Glen, John *(Salisbury)* (Con)
† Jones, Graham *(Hyndburn)* (Lab)
† Kendall, Liz *(Leicester West)* (Lab)
† McCartney, Karl *(Lincoln)* (Con)
† Madders, Justin *(Ellesmere Port and Neston)* (Lab)
† Marris, Rob *(Wolverhampton South West)* (Lab)
† Selous, Andrew *(South West Bedfordshire)* (Con)
† Spencer, Mark *(Sherwood)* (Con)
† Throup, Maggie *(Erewash)* (Con)
† Whitford, Dr Philippa *(Central Ayrshire)* (SNP)

Marek Kubala, Kenneth Fox, *Committee Clerks*

**† attended the Committee**

# Public Bill Committee

*Tuesday 15 November 2016*

*(Morning)*

[Mark Pritchard *in the Chair*]

## Health Service Medical Supplies (Costs) Bill

9.25 am

**The Chair:** Today we begin line-by-line consideration of the Health Service Medical Supplies (Costs) Bill. Before we begin, if Members wish to remove their jackets, they may do so. Even though it is winter, it is very warm in here, so I have asked for the windows to be opened at some point. I want people to feel comfortable and relaxed. Will Members and, indeed, members of the public make sure that their mobiles are switched to silent, so that we are not disturbed during our proceedings?

On the table to my left, the selection list of today's amendments—the order of business—is available for colleagues. It shows how the selected amendments have been grouped together for debate. Grouped amendments are generally on the same or a similar issue, as colleagues know, and the Member who puts his or her name to the lead amendment in a group is called first. Other Members are then free to catch my eye—to do so, please will you rise from your chair by more than one inch? That would be helpful. If called, Members may speak on any of the amendments in the group. A Member may speak more than once in a single debate.

I will work on the assumption that the Minister wishes the Committee to reach a decision on all Government amendments. Please note that decisions on amendments do not necessarily take place in the order in which they are debated; they take place in the order in which they appear on the amendment paper. In other words, debate occurs according to the selection and grouping list, but decisions are taken when we come to the clause that the amendment affects. I hope that that explanation is helpful to Members. I will use my discretion to decide whether to allow a separate stand part debate on individual clauses and schedules following the debate on the relevant amendments.

### Clause 1

Voluntary schemes

**Julie Cooper** (Burnley) (Lab): I beg to move amendment 44, in clause 1, page 1, line 14, at end insert—

"for the purpose of investing in access to new and innovative medicines and treatments."

**The Chair:** With this it will be convenient to discuss amendment 46, in clause 4, page 3, line 22, at end insert—

"(c) the NHS's duty to promote innovation."

*This amendment would introduce a requirement for the Secretary of State to take account of the NHS's legal duty to promote innovation, as set out in the Health and Social Care Act 2012.*

**Julie Cooper:** It is a pleasure to serve under your chairmanship, Mr Pritchard.

I will begin by outlining our overall priority for the Bill and, in particular, this clause. Our priority is to ensure that the Bill effectively controls the cost of medicines and medical supplies to the national health service while ensuring the best possible patient access to existing products and to new and innovative treatments. In that spirit, I would like to make some observations in support of amendments 44 and 46.

The clause will amend section 261 of the National Health Service Act 2006 and it is concerned with the powers related to the control of voluntary schemes. The stated aim of the clause is to give the Government new powers to require manufacturers or suppliers to pay the Secretary of State an amount that will be calculated on the basis of sales or estimated sales. The Opposition support the move to curtail excessive profits, thereby ensuring that the NHS achieves maximum value for money. Having said that we welcome saving vital NHS funds, we also wish to ensure that those funds are 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.

On Second Reading, the Secretary of State confirmed that £1.24 billion had been returned to the Department of Health through the rebate scheme. That is a considerable amount of money, and the figure will increase when this Bill is enacted. However, we were not reassured by his vague statement that the money returned to the Department would be reinvested in the NHS.

Also on Second Reading, the Secretary of State mentioned the considerable pressures facing the NHS and he suggested that one consequence of the Bill would be to transfer funding from the drugs bill to the frontline. I hope that the Minister present recognises that medication is often the frontline and that ensuring the timely access of appropriate medication often prevents hospitalisation and thus saves the NHS money. It is very much a case of a stitch in time.

In addition, it is a fact that community pharmacists the length and breadth of the country have offered to work with the Government to eradicate waste and to cut costs. As the experts on all medication matters, they are best placed to work with GPs and patients to achieve maximum efficiency. Sadly, the Government have responded by taking steps that are likely to lead to a reduction in the number of community pharmacies. This is a missed opportunity and that is regrettable.

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.

Recently, I have devoted a lot of time to supporting the campaign to achieve treatment for children suffering from the potentially life-threatening genetic condition of tuberous sclerosis. It is extremely distressing for parents to be informed that their child has been diagnosed with that incurable condition; it is even more distressing to learn that an effective pharmaceutical drug has been developed and licensed—Everolimus, marketed as Votubia—but is not available from the NHS for children in England. The drug is able to shrink the multitude of benign tumours that characterise that serious condition, thereby saving lives, improving quality of life for those affected and often removing the necessity for potentially damaging surgery.

That is one example, and there are many others. James Barrow from the Cystic Fibrosis Trust, speaking in support of the new medicine fund in Scotland, has said that using any reclaimed moneys in that way provides improved access and much needed transparency. Labour's amendment to the clause would introduce a duty to reinvest any rebates to improve access to new and innovative medicines and treatments, as I have outlined.

Further to that, amendment 46 refers specifically to the duty of the NHS to promote innovation under the Health and Social Care Act 2012. The UK is a world leader in the field of life sciences, and the British pharmaceutical industry is at the forefront of global research and development. In 2014, 20% of all the world's research and development into new medicines was carried out in the UK.

We have hitherto enjoyed significant benefits from European Union research funding. Given the outcome of the referendum, that is now at risk, and it is essential to ensure that we maintain our dominance in the sector, not least because the pharmaceutical industry employs close to 75,000 people. The promotion of innovation in the field is important not only for the health of the British people, but for the health needs of people worldwide. It is extremely important to the British economy, so it is vital that we do not take our eye off the ball. We need to put on record our continued commitment to research and to develop new treatments.

We face competition not only in Europe, but from emerging nations such as Brazil and China. We also need to ensure that the NHS does not trail in the take-up of those new drugs. Worryingly, the Office of Health Economics studied 14 high-income countries and found that the UK ranked ninth out of 14 across all the medicines studied. Successive studies have demonstrated relatively low take-up of new medicines in the UK compared with other countries. That is bad for patients and bad for our pharmaceutical industry.

The Bill therefore needs to achieve a balance. We need to ensure the best possible patient access to medication at the fairest price, and we need to encourage the pharmaceutical industry to continue to invest in research and development. Therefore, it is right that the Bill should outline our commitment to promote innovation. We look forward to hearing the Minister's comments, but we are minded to press amendment 44 to a Division.

**The Minister of State, Department of Health (Mr Philip Dunne):** Mr Pritchard, thank you for calling me and, more particularly, for taking time out of your schedule to chair this important sitting.

On amendment 44, I was interested in the comments of the hon. Lady about the motivation behind it, with which I have some sympathy. I hope that what I say will reassure her that her amendment is unnecessary.

The amendment would require income from the pharmaceutical price regulation scheme and the statutory scheme to be ring-fenced to fund and increase access to new and innovative medicines and treatments. As a Government, we are committed to ensuring that patients have faster access to new and innovative medicines and treatments—I mention briefly the accelerated access scheme that we have introduced.

The hon. Lady touched on the compelling and sometimes tragic cases of individual constituents, friends and relatives seeking to get access to innovative drugs, in particular once those drugs have become authorised. Between 1 March 2000 and 30 June 2016, NICE, the National Institute for Health and Care Excellence, made individual recommendations for 646 separate propositions, 81% of which were recommended or optimised, so there is a steady track record of introducing innovative treatments and, in particular, drugs into our health service. That is done, properly, through the independent NICE structure. I am sure we will talk more about that in Committee.

**Rob Marris** (Wolverhampton South West) (Lab): On the number of drugs to which the Minister referred, will he give an indication now or later of how many, if any, of those drugs were repurposed? I am thinking, for example, of a drug that has recently had a lot of publicity; it is primarily used for osteoporosis, but there are indications that it may be very helpful with breast cancer. What about such repurposed drugs, as opposed to brand new drugs?

**Mr Dunne:** I do not have that figure in my head, as the hon. Gentleman might expect. I hope to get inspiration during the sitting and will try to address that question later.

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.

**Rob Marris:** The Minister was talking about such decisions being clinically led. Will he therefore assure the Committee that the decision to cut spending on public health in England, to put the money into frontline medical services, was a clinical decision?

**Mr Dunne:** As the hon. Gentleman knows, decisions to allocate spending across the responsibilities of the Health Department were determined as a result of the spending review last year. The decisions within the NHS that I am talking about, on treatments, rather than preventive public health, are determined by clinicians.

Separate to the Bill, Government are taking action to secure the UK's future as an attractive place for the life sciences sector and to support faster patient access to medical innovations. For example, the recently published accelerated access review sets out ways to increase the speed at which 21st century innovations in medicines, medical technologies and digital products get to NHS patients and their families. Recommendations included bringing together organisations from across the system in an accelerated access partnership and creating a strategic commercial unit within NHS England that can work with industry to develop commercial access arrangements. We are considering those recommendations with partners and will respond in due course.

NHS England and NICE are jointly consulting on a number of proposed changes to NICE standard technology appraisals and highly specialised technology appraisals, including around speeding up the appraisal process. The Department of Health continues to work closely with NHS England and other stakeholders to improve uptake of new medicines. A key element of that is the innovation scorecard, published quarterly. It is designed to help users—clinicians, patients, commissioning groups, Government and other stakeholders—to understand and monitor the uptake of innovations in the NHS and should ultimately be used to promote an equitable spread of clinically effective, cost-effective innovations.

I hope that having heard in particular what I said about the way in which income from these schemes does not rise in a continuum but fluctuates, the hon. Member for Burnley will recognise that the amendment could have the adverse consequence of leading to a reduction in funding available for medicines.

**Julie Cooper:** Will the Minister give way on that point?

**Mr Dunne:** I was about to ask the hon. Lady to withdraw her amendment, but if she has something to add, I am happy to give way.

**Julie Cooper:** Is the Minister aware of problems with the administration of the scheme in Scotland? Is he aware of what the experience has been in Scotland?

**Mr Dunne:** Fortunately, the Committee has the benefit of the Scottish National party's spokesperson on health, the hon. Member for Central Ayrshire, who I am sure would be happy to give us her experience. The fact is that we have had some experience in England of fluctuating income from these schemes, which is the primary basis for our position.

**Justin Madders** (Ellesmere Port and Neston) (Lab): I am grateful to the Minister for his explanation. On the money that is received from the rebate from PPRS, responses I have had to written questions suggest that that is considered part of the baseline budget. With respect to the debate we have had recently about the £10 billion extra, or the £4.5 billion extra—whichever version we prefer—could he advise whether the rebate is included within that extra money, or is it part of the baseline funding?

**Mr Dunne:** The Department of Health receives income from a number of different sources. It mostly deals with expenditure but also receives income from activities conducted through the NHS. One source of income is the rebate through these schemes, which forms part of the funding available to the Department. We have committed that funds available out of the scheme will go into the NHS. The hon. Gentleman raised the issue of the £10 billion. I gently remind him that, in 2014-15, the funds available to the NHS from the Department of Health were £98.1 billion, and by 2021 that figure will be £119.9 billion, which in cash terms is a £20 billion increase and in real terms is a £10 billion increase.

**Dr Philippa Whitford** (Central Ayrshire) (SNP): As the hon. Member for Burnley said, the system functions quite differently in Scotland. We have a new medicines and rare diseases fund, rather than a cancer drugs fund, which means that the use of funding to access new medicines is not limited to one cohort of patients. Our fund is £90 million, which, given that we are less than 10% of the UK population, means it is proportionately almost three times the size of the cancer drugs fund. As was mentioned, this is very much funded by the PPRS. It is committed to that. 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.

We have so many debates in this House about patients who are struggling to access new treatments. Amendment 46 talks about innovation and research, which we support in Scotland. We are quite a research-oriented country. Our research funding to our universities is 30% higher, in proportion to our population. The NHS in Scotland commissions research, particularly on things like informatics and data management around health and social care, which are the big challenges we face in the future.

The Scottish Medicines Consortium, which makes our decisions in the same way as NICE, was reformed in 2013. Since then, we have had a 40% increase in drugs being passed. What we see in England is that even if a drug is passed at the level of NICE, it sometimes does not come into use in the NHS, because the funding is simply not earmarked to make it available.

9.45 am

We talk a lot in this country about being a research-orientated nation and wanting to support that, for economic and science benefits, but the problem is that if, at the end of the day, patients cannot access a drug and clinicians cannot use it, that is very undermining. Having been involved with drug trialling for breast cancer, I can tell hon. Members that clinicians may spend a couple of years doing huge amounts of paperwork to take part in a trial, which means that their patients can get the drug, and then suddenly, when the trial is finished and they start to go through the process, they find that

they cannot use it any more. In those circumstances, many clinicians will think, "Well, what was the point in all that work?".

The two have to go together: if we are to support innovation, we have to think of a pathway that goes all the way to the patient. At the moment, that is not the case. Just putting the money into base funding means that the long-term gain is to the Treasury rather than the NHS, so I recommend looking at how the system works in Scotland. That has increased our access to drugs. We do face challenges, as we leave the European Union, with the loss of Horizon 2020 and the European Medicines Agency. It is therefore important to have a partnership approach among academia, the pharmaceutical industry and the NHS to ensure that we push new drugs, but can then access them as well.

**The Chair:** Before we move on, I have a couple of housekeeping points. First, I thank the Doorkeeper for his tenacity and the engineers for getting the windows open. I think that we are all happier for that. Secondly, because we have Health questions today, we will seek to adjourn at about 11.10 am. I will allow the Government Whip to suggest the appropriate minute at which to do that. I now ask the Opposition whether they want to press the amendment.

**Mr Dunne:** I would like your guidance, Mr Pritchard, on whether I can comment on the second amendment in the group now or whether you would like to take the—

**The Chair:** You can comment on it now. I understand that there will not be a vote on amendment 46, but if there is, it will be later. We will be taking amendment 44, but you can comment on amendment 46 now, Minister.

**Mr Dunne:** Thank you, Mr Pritchard. Amendment 46 was also raised by the hon. Member for Burnley, for which I thank her.

We agree that the promotion of innovation, as the hon. Member for Central Ayrshire said, is an important part of what we like to do in this country. The role that we see for the Government is in sustaining the UK not just industrially, but by generating innovation to make our population healthier. That is vital in securing the best possible, evidence-based care and treatment for patients. I am talking about the rapid progress that is being made and technological advance through innovation. That is why the duty to promote innovation was placed not only on NHS England but on clinical commissioning groups and NICE through the Health and Social Care Act 2012.

Supporting innovation brings in many factors beyond the scope of the Bill, as is set out in the accelerated access review, which I have touched on. Supporting innovation is much more about better horizon scanning, faster licensing and assessment, and cutting-edge clinical practice than it is about pricing. It is precisely because this is such a broad area that it is not appropriate for the NHS duty to be linked to the provisions in the Bill. As drafted, the provisions in the Bill focus on the specific issue of the cost of medicines and medical supplies, but in doing so, they take account of the need to balance access to a product, which may be supported by lower prices, and the need for companies to support the costs of research and development.

To attempt to link these measures to the much wider duty on the NHS would be to distort the objectives of the cost control scheme. The Bill has an important role to play in securing the best possible care for patients, but I would like to assure the Committee that the Government, together with NHS England and others, place a very high priority on supporting innovation.

**The Chair:** We have the privilege of having two shadow Ministers. I do not know whether either of them wants to respond on amendment 44 or amendment 46, or whether the hon. Lady wants to press amendment 44.

**Julie Cooper:** I am grateful to the Minister for his comments, but I am still keen to press amendment 44 to a Division. The lack of transparency in what is currently available is unacceptable, and there is a danger that the Bill will be contrary to what I am sure is its real intention and cut funding to front-line medication. The amendment would prevent that.

I take the Minister's point about fluctuation in funding, but I am sure he will agree that if this can be made to work in Scotland, it can be made to work here. I do not want us to fall behind on that. We are all aware of the massive deficit within the NHS. It is very important that funding recouped from pharmaceutical profits is not lost for the NHS and for the real purpose of providing new medicines, and that people in England do not lose because of the Bill. I thank the Minister for his comments, but I will press the amendment to a Division.

*Question put,* That the amendment be made.

*The Committee divided:* Ayes 8, Noes 9.

**Division No. 1]**

**AYES**

| | |
|---|---|
| Cooper, Julie | Kendall, Liz |
| Cummins, Judith | Madders, Justin |
| Day, Martyn | Marris, Rob |
| Jones, Graham | Whitford, Dr Philippa |

**NOES**

| | |
|---|---|
| Berry, James | McCartney, Karl |
| Churchill, Jo | Selous, Andrew |
| Davies, Dr James | Spencer, Mark |
| Dunne, Mr Philip | Throup, Maggie |
| Foster, Kevin | |

*Question accordingly negatived.*

**Julie Cooper:** I beg to move amendment 45, in clause 1, page 1, line 14, at end insert—

"(2A) After subsection (1) insert—

'(1A) In exercising functions in relation to the controls on the costs of health service medicines, the Secretary of State must ensure that any medicine covered by a voluntary or statutory scheme that requires payments calculated by reference to sales of that medicine shall be made available to all NHS patients if recommended by a qualified NHS clinician.'"

The amendment continues in the vein of amendment 44, given our concern to ensure the best access to medicines. We are very much aware of the barriers that exist and are keen that every piece of legislation takes the opportunity to remove those barriers and make medicines more accessible to patients. It is important that the Bill does

*[Julie Cooper]*

not inadvertently become a way of restricting that access. Where a clinician deems medicines necessary and desirable, patients should have access to them.

I was worried on Second Reading to hear the Secretary of State's comment that the prescribing of some medicines is "not strictly necessary". That questioning of the clinical judgment of the medical profession is not just inappropriate but could be suggestive of a dangerous precedent. We must never reach a stage where politicians decide which medication is appropriate and when. I assume that that was not the Secretary of State's intention, but we would like to ensure that drugs approved by the National Institute for Health and Care Excellence are made available to patients if so desired by a qualified NHS practitioner.

There is already an agreed fixed limit on NHS spend on branded medicines, with any additional expenditure above that level paid for by the pharmaceutical companies via the clawback by the Department of Health. Currently, NICE assesses new medicines for cost-effectiveness, which provides a further restraint on pricing. There is therefore no reason for the NHS to deny patients any treatment covered by the scheme. We would like the Minister to look favourably on the amendment. We will not press it to a Division, but we are very concerned about the issues I have outlined.

**Mr Dunne:** Again, I understand the hon. Lady's intent. I was a little confused by her interpretation of the Secretary of State's remarks on Second Reading as meaning that politicians are involved in making decisions on prescribing. I assure her that, although I have been in the Department for a short amount of time, there has been no suggestion at any point that any politician should get involved in making decisions about which drugs should be prescribed.

**Julie Cooper:** I thought it inappropriate that the Secretary of State for Health expressed an opinion on which medications are necessary and which are not. I question his qualification to make that comment.

**Mr Dunne:** I do not have complete recollection of what the Secretary of State said, but he may have been referring to things such as the over-prescription of antibiotics, which we know is a problem globally. A great deal of work is being undertaken right across the NHS and with other health bodies around the world to reduce the scale of antibiotic prescription.

**Dr Whitford:** Is it not the case, however, that we seem to be developing this additional rationing system between NICE and patients of the NHS? I am talking about NICE's recommendations being accepted but not funded. The hepatitis C drugs are basically being rationed to a certain number of patients per month, even though they have been passed by NICE and trying to eliminate the viral load in the community can be more effective in the long term.

**Mr Dunne:** Inevitably, some decisions have to be taken when introducing new drugs as to the extent to which they are applicable. Those are clinically-led decisions. There is not a completely bottomless funding pot for the prescription of medicine, so those decisions have to be taken by ordinary clinicians within their practices and within the infrastructure of approvals, which is entirely independent and led by NICE in England.

**Dr Whitford:** With respect to the Minister, that is not what I am hearing from clinicians who work in the field of HIV and hepatitis C. They are being told, "You can have"—for example—"50 patients a month," and they are having to pick who gets the drugs and who does not.

**Mr Dunne:** I will not be drawn into the detail on a specific drug, because the hon. Lady may have access to information that I do not, but in relation to hepatitis C, as she has raised it, there has been a discussion between the trust and NICE. As I understand it, the trust is continuing to work with NHS England collaboratively to discuss the issue of access to the new hepatitis C drugs. We will always have some discussions about applicability when a new treatment is introduced, to see whether it is appropriate for all conditions; it may be that only some benefit from the drug. I think that that is as far as I can go on this issue.

To return to the Government's view of the amendment, we are concerned that it would in effect circumvent the critical system of checks and balances around clinicians' prescribing freedoms. That would present a danger to patients and the sustainability of the NHS. It is also not the purpose of the Bill to address matters other than the cost of medicines and medical supplies.

Treatments that do not demonstrate efficacy, safety and value for money should not be routinely available on the NHS. The National Institute for Health and Care Excellence, an internationally respected organisation that provides evidence-based guidance to the NHS, ensures that the treatments recommended for patients deliver value for money and improved patient outcomes. NICE's recommendations are developed free from political interference and help NHS organisations to design services that are in line with the best available evidence and that meet the needs of their local populations.

**Rob Marris:** The Minister read out what I understood to be the role of NICE. May I focus for a moment on the words "value for money"? My understanding is that if NICE in England says that a particular medicine—perhaps a new medicine or a repurposed medicine—is value for money, then because that cost-benefit analysis has taken place, the drug should be freely available to clinicians to prescribe in medically appropriate cases. However, we are hearing quite a lot of stories, particularly about the prophylactic HIV drug or hepatitis C drugs, of when that is not the case. In other words, NICE says that a drug is value for money, but clinicians are blocked from prescribing it, even when they think it would be medically efficacious for their patient. Why is that?

10 am

**Mr Dunne:** From time to time, local circumstances may mean that clinicians do not have access to the drugs. They may be newly innovated, and given the scale of the NHS in this country, not all clinicians will get the information they need to provide new drugs as rapidly as some patients may like. It can take time to introduce a new drug, as the hon. Gentleman will understand. I recognise that it is the role of clinicians to prescribe in the best interests of their patients, and I know that local or national commissioning policies or

technology assessments by NICE will mean that in some cases patients are unable to access the treatment that their clinician has recommended, but it is important to recognise that local and national scrutiny and the independent assessments of NICE are essential to promote evidence-based prescribing, protect patients and secure value for money. Undermining that system of checks and balances, as I am afraid the amendment tabled by the hon. Member for Burnley would, could endanger patients and result in significant variation in prescribing practices. I ask her to withdraw the amendment, since she has indicated that she does not intend to press it to a vote.

**Julie Cooper:** I beg to ask leave to withdraw the amendment.

*Amendment, by leave, withdrawn.*

*Question proposed,* That the clause stand part of the Bill.

**Mr Dunne:** Clause 1 will amend the powers relating to voluntary schemes in section 261 of the National Health Service Act 2006. The voluntary scheme referred to in that section is the pharmaceutical price regulation scheme. Although the scheme itself is voluntary, there are statutory powers that can be used in relation to its operation. Other than with respect to the entry and exit mechanisms, the Government do not currently use those powers for the 2014 PPRS, but we wish to retain the option of making regulations or directions with respect to those powers in future. The Government do not intend the amendments to the 2006 Act to affect the operation of the current 2014 voluntary scheme.

The amendments to the 2006 Act will put it beyond doubt that the Secretary of State's existing powers can apply for the purposes of operating a voluntary scheme that includes only a payment system. They are part of our policy to align the powers relating to voluntary and statutory schemes, which we will come on to when we consider later clauses of the Bill. They will also ensure that when a company leaves the voluntary scheme, it is still able to make payments covering the period in which it was a member. That will clarify the requirements and ensure that there will be no loophole that companies can exploit to avoid making payments that are due after they have left the scheme.

It may also be helpful if I clarify a point that arose on Second Reading. In response to a question from my hon. Friend the Member for South West Wiltshire (Dr Murrison), the Secretary of State inadvertently indicated that the Bill would prevent companies that are part of the current voluntary pharmaceutical price regulation scheme from parallel importing of medicines. I would like to clarify that statement, because it did not completely accurately reflect our intent. Parallel imports made in accordance with the EU single market rules are a legitimate part of the medicines market, and the Government have no intention of taking action to prevent such trade. The Bill does not exclude the possibility of parallel import prices being controlled; they could be covered through regulation at a later date if the evidence warranted action. I hope that helps the Committee in its consideration. I commend the clause to the Committee.

**The Chair:** I thank the Minister for correcting the record.

*Question put and agreed to.*

*Clause 1 accordingly ordered to stand part of the Bill.*

## Clause 2

POWER TO CONTROL PRICES

*Question proposed,* That the clause stand part of the Bill.

**Mr Dunne:** Clause 2 will amend the power to control prices in section 262 of the National Health Service Act 2006. That section already allows the Secretary of State to limit the price of any health service medicines except when the manufacturer or supplier is in the voluntary scheme, the PPRS. Section 266 of the 2006 Act allows the prices of health service medicines to be controlled by way of regulation or directions. Clause 2's amendments to the 2006 Act will enable us to address unreasonably high-priced unbranded generic medicines. Most manufacturers of unbranded generic medicines are members of the PPRS for their branded medicines, and we therefore cannot currently limit the prices of their unbranded generic medicines if they charge excessive prices. We rely on competition in the market to keep the prices of those medicines down. It generally works well and, in combination with high levels of generic prescribing, has led to significant savings for the NHS.

I am grateful for the contributions made on Second Reading by almost everyone who spoke. The intent behind the clause was widely recognised across the House as appropriate and desirable. Members were aware from their own experience, and particularly from a *Times* article in the summer, that in some instances where there has been no competition to keep prices down, a small number of companies have raised their prices to what look like unreasonable and unjustifiable levels.

There are some clear examples of price increases. The most egregious was one product whose price increased by 12,000% between 2008 and 2016. If the price had stayed the same, the NHS would have spent £58 million less on that medicine last year alone. Another medicine increased in price by 3,600% between 2011 and 2016; the NHS would have spent £2.1 million less on that single medicine had the price stayed the same.

**Justin Madders:** I am grateful for the Minister's explanation. As he said, we support the broad thrust of the aims behind the clause. Has he engaged in any research or discussions with the developers to understand the reason for those rapid price rises?

**Mr Dunne:** We have had discussions with the trade association for the generic manufacturers. The trade association, which gave evidence to the Committee on a day when I was, unfortunately, not able to attend, made it clear that the generic medicine producers industry as a whole thinks it appropriate that we take this action. We are grateful for that support. Discussions are under way through other bodies. In particular, the Competition and Markets Authority has indicated that it is in discussions with some companies, one of which voluntarily issued a press release last month to tell the market that the Competition and Markets Authority is investigating it.

**Justin Madders:** What I was trying to elicit was whether anything had been put forward to explain any specific price increases. We are concerned that the clause will have the unintended consequence of limiting supply.

**Mr Dunne:** We are anxious to ensure that we do not inadvertently introduce a regime that might cause difficulty when there might be a valid reason for increasing a drug's price significantly. That was the justification in the past for not addressing the issue, because abuses were seen to be pretty isolated. However, in the past two or three years, the prices of more drugs have risen seemingly unjustifiably. That is the justification for introducing these measures.

I recognise that there may be occasions when a manufacturer incurs some additional costs: for instance, if a production run or line has finished and the manufacturer must start a new line or restart an old one, that would lead to a justifiable price increase. The clause allows us to take action where we suspect a price has risen excessively. The rest of the Bill provides opportunities for the Department to gain information about the cost of supplies, which allows us to get a better handle on when we think an increase has been unjustifiable, and identify that more rapidly. *[Interruption.]* Does the hon. Member for Wolverhampton South West want to intervene, or is he just poised in an energetic way?

**Rob Marris:** I am always ready.

**Mr Dunne:** Then I will continue.

Certain companies appear to have made it their business model to buy the marketing authorisations for medicines without any patents outstanding. They then de-brand the medicines and abuse the existing freedom of pricing for unbranded generic medicines. Although the practice is not widespread, it must be addressed, which is the reason for the clause.

Currently, our only recourse is to refer such cases to the Competition and Markets Authority, as I mentioned. When the CMA investigates, we must wait for the outcome, and in the meantime the NHS continues to have to pay high prices. The Department consulted on the issue as part of the consultation on the statutory scheme that was launched in December 2015. The Department has been working closely with the Competition and Markets Authority and has referred cases to it. The CMA is about to issue a decision in a case on a high-priced unbranded generic medicine. As I have just said, it has also recently opened another investigation.

The powers under section 262 of the 2006 Act to limit prices of health service medicines can be exercised through directions or regulations. The Government's intent is to work with directions, which will enable us to limit the price of a specific medicine from a specific manufacturer. The Government are obliged to consult the industry representative body when we want to direct the price of a medicine. In the case of high-priced generics it would be the representative body of the unbranded industry—currently the British Generic Manufacturers Association, which appeared before the Committee last week.

The Government would of course also engage with the company involved before issuing a direction that limited the price of a medicine. As I have indicated, there may be good reasons for a price increase, and it is important that the Government understand the reason behind a price increase before issuing a direction. As I said, the new information powers will help us with that.

My officials have initiated talks with the unbranded generic medicines industry representative body and the CMA to explore how in practice we would determine what should be considered a reasonable price. Any decision by the CMA in the cases that I highlighted earlier could help set a useful precedent. I can reassure the Committee that companies charging unreasonably high prices for unbranded generic medicines is not a common practice. The Government do not intend to use the power where competition in the market for unbranded generic medicines is working. However, the Government need the right legislative tool to be able to address unreasonably high prices of unbranded generic medicines. The clause will give us that tool, and I ask the Committee to agree to it.

**Dr Whitford:** Basically, we welcome the measures in clause 2 to try to close the specific loophole whereby companies that are part of the PPRS voluntary scheme and that also produce generic medicines are able to increase the prices of generic medicines. However, the Minister talked about the British Generic Manufacturers Association—largely companies that focus on generic medicines—which would be more to do with clause 3. My understanding is that the change will close the specific loophole relating to large pharmaceutical companies that also produce generic medicines, rather than companies that focus only on generic medicines, which we will come on to in clause 3. We welcome the closing of that loophole, but those two things are quite different and we should therefore not conflate them. It is not the competition authority that would tackle them. That is much more related to purely generic companies.

**Mr Dunne:** We will obviously come on to clause 3 shortly. The primary intent behind clause 3 is to modernise the statutory scheme, rather than to address the difference between one type of company that produces only generics and another that produces generics and branded medicines. I am not sure that I agree with the hon. Lady's distinction.

**Dr Whitford:** My point is just that what the Minister has described applies more to clause 3, on companies that produce purely generic medicines, so the attempt would be to strengthen the statutory scheme that they might be part of. It is the production of generics by the group of companies under the PPRS scheme, the big pharmaceutical companies, that is getting under the wire. That is covered by clause 2(2). The Minister was talking about the Competition and Markets Authority and the British Generic Manufacturers Association, and I think clause 3 is more relevant to that. Clause 2 is more of a surgical change, which we absolutely support.

**The Chair:** The Minister can respond either now or later.

**Mr Dunne:** I am grateful for your guidance, Mr Pritchard —I will respond now. The current statutory scheme does not capture generics, so amendments to the statutory scheme to allow generics to be brought into it are appropriate. If I am giving the Committee information that covers two clauses, rather than just one, I hope that is helpful.

**The Chair:** Very good added value from the Minister, I am sure.

*Question put and agreed to.*

*Clause 2 accordingly ordered to stand part of the Bill.*

**Clause 3**

STATUTORY SCHEMES

10.15 am

**Julie Cooper:** I beg to move amendment 43, in clause 3, page 2, line 27, at end insert—

'(2A) An amount calculated under subsection (2) may only be calculated using the same methodology as an amount payable by any member of a scheme made under Section 261 of the National Health Service Act 2006 (voluntary schemes for controlling the cost of health service medicines) is calculated."

We support clause 3 in principle and the amendment aims to clarify that. Under the current system, following the National Health Service Act 2006, two schemes operate to control prices of medicines: the statutory scheme and the PPRS voluntary scheme. It is important to align those two schemes, because since 2014 there has been a significant movement of companies deciding to shift from the PPRS scheme to the statutory scheme to reduce the level of rebate payable. That has reduced savings to the NHS, so it requires urgent revision.

We agree with 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. We are concerned, however, that the Bill is not specific about how payments would be calculated under the statutory scheme. We agree with the Secretary of State that the purpose of the Bill is to clarify and modernise provisions to control the cost of health service medicines.

The amendment seeks to clarify beyond doubt that the Bill is in line with the stated aim of achieving equivalence between the two price-control schemes, by ensuring that under the statutory scheme members' rebates are calculated using the same methodology as for PPRS members. We commend the amendment, but will not push it to a Division. I am interested to hear the Minister's comments.

**Dr Whitford:** One issue arises because the statutory scheme was based on prices in December 2013. The further on in time we are, the less proportional the return. Whether it is the same or a similar mechanism, we should avoid having a price rebate to the NHS stuck in time, which might be five years ago, and does not reflect the actual costs of the drugs.

**Mr Dunne:** The voluntary schemes are introduced and refreshed every five years. The current scheme was negotiated in 2014, so we are two years into that. One reason for having a time limit on the scheme, from the Government and NHS perspective, is that companies like to find ways during the course of time to adjust their commercial behaviour for their benefit. Having the opportunity to renegotiate the voluntary scheme every few years enables us to try to avoid the circumstances referred to by the hon. Lady.

**Dr Whitford:** If I could clarify, the voluntary scheme runs for five years but what I was talking about, with regard to clause 3, is the statutory scheme and the price rebate related to a requirement for a percentage reduction from the price in December 2013. That is how the rebate in the statutory scheme is defined. The further one gets away from that date point, the less one gains. It is the statutory scheme I am talking about rather than the voluntary one.

**Mr Dunne:** My understanding is that under the statutory scheme, the percentage applies based on sales achieved in the previous year. Therefore, the percentage reduction that we seek for the statutory scheme can be adjusted year by year. That is the intent of what we seek to do. I will seek further inspiration to ensure that I have exactly addressed the point that the hon. Lady makes.

Amendment 43 would have the effect of linking the payment mechanisms of the statutory and voluntary schemes. I understand why that might appear a desirable objective, so I understand the intention behind the amendment. 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.

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.

There are also provisions on the uptake of new medicines by the NHS, such as making NICE-approved medicines available within 90 days of a NICE decision. We are keen to encourage that. By contrast, the statutory scheme is intended to be a more straightforward approach. As such, the payment percentage applied may be slightly different from that applied to any voluntary scheme, in order to achieve a broadly similar level of savings once all elements of the schemes are taken into account.

As we heard in oral evidence last week, the freedom to negotiate the voluntary scheme is greatly valued by both industry and Government. We intend that any future voluntary scheme should be established through such negotiation, but linking the payment mechanisms would inevitably restrict that flexibility and freedom for both sides. In addition, while the Government welcome the collaborative approach of a voluntary scheme, we cannot guarantee that Government will always want two schemes in future. The amendment would constrain the Government's discretion to run a single scheme if they and the House thought it best to do so. For those reasons, I urge the hon. Member for Burnley to withdraw her amendment.

**Julie Cooper:** I beg to ask leave to withdraw the amendment.

*Amendment, by leave, withdrawn.*

*Question proposed,* That the clause stand part of the Bill.

**Mr Dunne:** The clause amends the provisions relating to statutory schemes in section 263 of the National Health Service Act 2006, which describes the purposes for which the Secretary of State can make statutory schemes. The amendments make it clear that a statutory scheme may require companies to make payments to the Government, based on their health service sales. For those companies not in the voluntary scheme, the Government operate a statutory scheme. That is currently based on a cut to the list price of products, rather than a payment mechanism on company sales, as in the voluntary scheme. The cut to the list price has delivered fewer savings to date than the payment mechanism under the voluntary scheme.

**Dr Whitford:** That was the point I was trying to make earlier. One is a percentage return on sales and profits, and the other is a cut in price. The further we are from the time set, which was December 2013, the less value we have from that in proportion to current prices.

**Mr Dunne:** I am grateful to the hon. Lady for making that clear to the Committee. The different approaches to price control between the voluntary and statutory schemes have led to some companies making commercial decisions to divest products from the voluntary scheme and sell them through the statutory scheme, thereby reducing the effectiveness of the voluntary scheme and savings to the NHS. The introduction of a payment mechanism in the statutory scheme would save the health services across the UK an estimated £90 million a year, as set out in the impact assessment.

In response to the Government's consultation on introducing a payment mechanism in the statutory scheme, the pharmaceutical industry queried whether the Government had the powers to introduce a statutory payment system. The clause clarifies the existing powers to make it clear that the Government have the power to introduce a payment mechanism in the statutory scheme. The ability to make the statutory scheme by way of regulations rather than setting out the detail in primary legislation provides us with the flexibility to respond to changes in the wider economy, the medicines market and patient needs. We have provided illustrative regulations to support scrutiny of this delegated power.

The clause makes a further amendment to section 263 of the National Health Service Act 2006. Currently, the power to make a statutory scheme cannot be applied to members of a voluntary scheme, which means that if the Government introduced a statutory scheme for unbranded generic medicines—although we have no current plans to do so—we would be unable to apply the scheme to manufacturers of unbranded generic medicines that have a mixed portfolio of branded and unbranded generic medicines, and are members of the voluntary scheme. The clause therefore amends the Act in such a way that the power to make a statutory scheme cannot be applied to products covered by the voluntary scheme rather than member companies of the voluntary schemes.

The Government's view is that, for the most part, competition works well to keep down the price of unbranded generic medicines. Should that situation change, this amendment would enable the Government to use their clause 2 powers to take action beyond individual products or companies. I hope that is clear to the Committee. If so, I ask the Committee to agree that clause 3 should stand part of the Bill.

**Rob Marris:** What a pleasure to appear before you for the first time, Mr Pritchard. As you know, my mother is one of your constituents and was quite a frequent correspondent. She is now in quite frail health so I suspect that you have not heard from her recently, but I thank you for your courtesy in your replies to her over the years. It is a particular pleasure to appear opposite a fellow west midlands MP, the Minister, who represents Ludlow, the constituency in which my mother used to live. She is still in the same house, but the constituency boundaries have changed.

**Mr Dunne:** She may move back again.

**Rob Marris:** Indeed. I very much welcome clause 3 because it is to do with extending the statutory scheme. The helpful library briefing cites the Department of Health consultation from December 2015, which points out:

> "In 2014 the statutory scheme covered around 6% of branded medicines sales in the UK",

in contrast to the voluntary scheme, which covered about 75%. Those are the relative sizes of the schemes.

The Minister said—forgive me that this is not an exact quote, but I do not write that fast—that one of the effects of the clause 3 changes will be to broaden the statutory scheme to cover companies that have a mixed portfolio of branded and unbranded drugs, and are members of the voluntary scheme. As he pointed out, the clause clarifies the power of the Secretary of State to make the statutory scheme—something that was debated or contested by some companies.

In particular, I welcome the clause philosophically or ideologically because it amends section 263 of the National Health Service Act 2006—a Labour Act for which I voted proudly. Section 263(1) of that Act provides the Secretary of State with the power to make a statutory scheme for the purposes of "limiting the prices" or, as in section 263(1)(b) "limiting the profits". This is something of a damascene conversion for this Government.

I hope, Mr Pritchard, that you will give me a bit of latitude, as I am about to read a quotation from this morning's edition of *The Times*. An article entitled "Energy companies face caps on 'rip-off' tariffs" says:

> "Measures designed to cap the household energy bills of millions of British families on 'rip-off' standard variable tariffs are being considered by ministers."

I think we heard about that in my party's manifesto at the general election; there has been a damascene conversion by the Government. That article also says:

> "Greg Clark, the business and energy secretary, said: 'I have made clear to the big firms that they must treat customers properly or be made to do so.'"

10.30 am

That is a big step forward for the Government. It is almost Churchillian for the Minister and the Secretary of State to say that the Conservative Government are

going to embrace price controls—something I am not sure any Conservative Government has done since 1945 when we had price controls during the war. I warmly commend the Government on the Bill, particularly as crystallised in the design of, and powers under, clause 3, which ensures that the Secretary of State has the power to make a statutory scheme, which can limit not only prices but profits.

**Andrew Selous** (South West Bedfordshire) (Con): Many Conservative Members may see the Bill as limiting the ability of drug companies to rip off the Government in a wholly unacceptable way, rather than as introducing price controls in the manner to which the hon. Gentleman refers.

**Rob Marris:** With respect to the hon. Gentleman, that is precisely what price controls do: they stop rip-offs. If one has price controls for other reasons, that is a separate debate. The price controls discussed in the Bill and in the 2006 Act are, as I understand it, precisely to stop rip offs. It appears that the Secretary of State for Business, Energy and Industrial Strategy is now looking at the same thing, as the newspaper quote suggested. It may be an incorrect quote—I give that caveat—but it is a direct quote from the Secretary of State to say that the Government are looking at these things. That does not necessarily mean that they will do them, but it is an ideological watershed for a Conservative Government to look quite rightly at legislating to stop rip-off Britain with regard to prices, but also with regard to limiting profits.

That is what a statutory scheme has the power to do under section 263(1) of the 2006 Act. As I understand it—the Minister can correct me if I am wrong—clause 3, which is at the heart of this provision, does not say, "There has been a debate about whether we can have a statutory scheme or not". For the sake of certainty, we are saying in clause 3 that the Government will have the power to make a statutory scheme, but I do not hear the Minister going on to say, "But that statutory scheme will have nothing to do with limiting profits."

In the absence of the Minister's saying that, he appears ideologically to encompass the concept that I embrace, which is that, in certain circumstances in capitalism, it is incumbent and right for a Government to intervene in the market to limit not only prices—rip-off Britain and so on—but profits. On certain occasions, the Government should have that power, and I think a pharmaceutical supplier to the NHS is one such example. There is a very narrow range of things I could see this happening in, but in pharmaceuticals it is possible.

I congratulate the Government on coming over to a socialist perspective, not only on pharmaceuticals but apparently, if *The Times* report is right, coming our way on energy companies. Long may that continue. Perhaps we can look at rail fares next. Will the Minister have a word with his fellow Ministers on that?

**The Chair:** If the Minister is in Churchillian mode—I do not take a view on that; I am completely neutral as Chair—that is something I have always wanted to see. In fact, we have two Churchills in the debate, as Members will recognise. That is probably a first, which is great.

**Mr Dunne:** Thank you very much indeed, Mr Pritchard. I hope I am not going to disappoint you, given that build-up.

As ever, I am delighted to see the hon. Member for Wolverhampton South West, who is almost my parliamentary neighbour and with whom I served on countless Finance Bill Committees when he was previously in this place. He always entertained the Committee with his interventions, some of which were occasionally on the subject of the Bill, rather like on this occasion. He has craved your indulgence, Mr Pritchard, and I am glad that you allowed him to point out what I am going to take a stage further, if you will indulge me a little.

The Conservative party is the party of the working man in Britain in 2016. As the hon. Gentleman may have heard, because he is a keen student of these things and because the Conservative party conference was held in Birmingham this year, which is not too far from his constituency, the Home Secretary made it clear that she regards the Conservative party as the party of the consumer in 2016. I will take that one step further.

**Rob Marris:** Do you mean the Prime Minister?

**Mr Dunne:** No, I mean the Home Secretary.

We believe that competition is the best way to drive prices of medicines down for the NHS, and generally speaking that works well. In the case of the specific unbranded generics where there is a single supplier, we have seen that there is an opportunity for market abuse, and I agree with my hon. Friend the Member for South West Bedfordshire that the clauses are designed to use the device of price controls to avoid excess profit abuse by individuals in British companies, which we have seen.

I gently remind the hon. Member for Wolverhampton South West that successive Governments since 1957, including the Government whom he proudly supported for many years, had price controls in place for the cost of medicines.

**Dr Whitford:** The Minister was obviously not happy with the amendment on aligning the two schemes, but he talks about a mechanism of price control under clause 4. Will he give us even the broad principle of what he thinks the price control mechanism in the statutory scheme will be?

**Mr Dunne:** The mechanism in the statutory scheme will be to allow the discount to be changed periodically. That will be determined through consultation with industry in the same way as applies in the voluntary scheme.

**Dr Whitford:** To clarify, therefore will the situation continue to be that the statutory scheme is based on a price reduction as opposed to a percentage above a mark being returned to the NHS, as in the voluntary scheme? Will it be a similar mechanism to what we have today?

**Mr Dunne:** I believe that that is the case, but if I have misunderstood the hon. Lady's question I shall clarify that later in the sitting, if I may. Our intention is to consult on the matter, so the precise mechanism has not yet been finalised; hence there is some uncertainty.

**Rob Marris:** On the detail, while the Minister is pondering, we talked about the date of December 2013 for the 15% price reduction—the questioning of the hon. Member for Central Ayrshire particularly related to that—but I understand that medicines launched after that date are not in the statutory scheme.

*[Rob Marris]*

At some point—perhaps later in the sitting—will the Minister clarify whether the Government intend that medicines launched after December 2013 could be in the statutory scheme? Might it be altered in that way to encompass that possibility?

**Mr Dunne:** Companies are free to join the voluntary scheme. If they choose not to, but they want to sell unbranded generics into the NHS, they will be caught within the statutory scheme. The statutory scheme is the default scheme under which unbranded generics are sold into the NHS. It will pick up new unbranded generics as they come forward, unless their manufacturers are in the voluntary scheme and choose to have them dealt with through it.

*Question put and agreed to.*

*Clause 3 accordingly ordered to stand part of the Bill.*

## Clause 4

ENFORCEMENT

*Question proposed,* That the clause stand part of the Bill.

**Mr Dunne:** The clause amends sections 265 and 266 of the 2006 Act in relation to enforcement. It ensures that the existing enforcement provisions in the Act apply to the contravention of any of the new powers in clauses 1, 2, 3 and 5. The maximum penalties are a single penalty of £100,000 or £10,000 per day for the duration of the contravention. The Secretary of State has the power under the 2006 Act to increase or further increase, by order, those maximum penalties.

The clause also ensures that provision can be made in regulations for companies to appeal any enforcement decisions under the new information powers in clause 6. That simply extends the possibility of appealing any enforcement decision under the information powers. Furthermore, clause 4 clarifies the fact that payments or penalties can be recovered as a civil debt through the courts.

In light of the Secretary of State's flexibility to amend the penalty amounts in future, I hope the Committee will recognise that the proposed penalties are appropriate, but in the event they are deemed not to be appropriate, there is sufficient flexibility in the clause to allow the Government of the day to amend the penalties to whatever they deem appropriate.

On that basis, I ask the Committee to agree that the clause stand part of the Bill.

**Rob Marris:** Will the Minister—if not now, later—give other examples of where a Secretary of State has such apparently wide-ranging powers to set a penalty? In any judicial system there is often discretion among the judiciary as to the penalty imposed on a wrongdoer, but this is not a judicial system. It is a quasi-judicial system, at best. The Government seem to be taking broad powers, and it may be that Governments, including Governments under which I served, have done so in the past, but I cannot think of any examples.

I hope the Minister can provide clarity, because the Secretary of State will be able to exercise the new powers not only by making regulations—such regulations, of course, would come before the House—but by giving directions, which is a much more elastic and broader term. A little clarity on that would be helpful.

**Mr Dunne:** I can help the hon. Gentleman directly with a specific example. The Secretary of State already has those powers under the 2006 Act, which the hon. Gentleman's Government enacted.

*Question put and agreed to.*

*Clause 4 accordingly ordered to stand part of the Bill.*

## Clause 5

CONTROL OF MAXIMUM PRICE OF OTHER MEDICAL SUPPLIES

**Dr Whitford:** I beg to move amendment 47, in clause 5, page 3, line 39, at end insert—

'(7) Before making regulations under Clause 5 the Secretary of State must conduct a consultation on the potential effect of this clause on the maintenance of quality of those medical supplies, and seek representations from manufactures, suppliers and distributors of medical supplies as part of the consultation.".

This is a probing amendment on an issue of concern. The Secretary of State has obviously had powers since 2006, and perhaps earlier, to seek to control the price of medical supplies. That power has not really been utilised, and neither have the informatics of that. 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. As a surgeon for 30-odd years, I can tell the Committee that the range in quality of things such as surgical gloves can be immense. A surgeon might use two or three pairs of gloves during an operation. If there is a leak in those gloves that is not visible, it might be only when the surgeon washes their hands afterwards that they see they have blood on their finger, which means that staff are exposed to blood contamination. Poor-quality swabs might result in thread or fluff coming off inside a patient, which can contribute to sepsis. There is no quality controller specific to medical supplies, so if we just drive down the price, we may drive down the quality.

We use a lot of central procurement in Scotland, and NHS National Procurement has helped us to control our prices for everything from consumables through to major machine purchases, which is already saving money for the NHS in Scotland. If there were a reduction in quality, our concern is that it would be UK-wide. It would be something that producers were doing, which would in turn undermine what the devolved Government were trying to do. Procurement remains devolved, but if the quality started to drop overall, that would affect all the devolved health services, as well as NHS England.

The amendment calls for consultation and for consideration of some form of quality regulation or control that would mean those items having to be way above the very basic CE level, at a point considered high enough quality for NHS use.

10.45 am

**Justin Madders:** I support the hon. Lady's amendment. She spoke with great personal experience, which we all appreciate, about the importance of maintaining the quality and reliability of products in the NHS. Over the weekend, there were reports of the vast sums paid out by the NHS in clinical negligence costs. I am sure we all agree that that money would be better spent on patient care. Of course, many of those claims are down to human error, or to events that were in some other way avoidable. However, one obvious example of an area where we need to be reassured that the Bill will not have unintended consequences is infection control. About 300,000 people a year—about one in every 16 patients—get an infection while being cared for in the NHS. That causes additional suffering, inconvenience and, sometimes, serious illness or death. It also has a wider impact on the NHS, because patients with hospital-acquired infections spend two and a half times longer in hospital than uninfected patients, on average: they are usually admitted for approximately 11 days.

As well as the devastating impact on the patients affected, there is a significant financial impact on the NHS. I have referred to the costs incurred from clinical negligence claims. The most recent reliable estimate of costs from infections, which appeared in the Plowman report, put the figure at £1 billion a year. According to Professor Briggs's report "Getting It Right First Time", if someone gets an infection from an orthopaedic operation, it costs the NHS an extra £100,000 to put it right. 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.

**Mr Dunne:** Rather unusually, I start by thanking the hon. Lady for proposing the amendment. She has raised an issue for which we have considerable sympathy. She touched on the way in which medical products are procured in Scotland. I can confirm that we are looking to introduce more centralised purchasing across the NHS under the efficiency proposals made by Lord Carter in the other place. One of the areas of focus was the variability, in purchasing terms, of standard commodity items. She mentioned surgical gloves—I will not go into detail on those with her, because she has obviously used them considerably more than I can conceive of and is therefore very experienced when it comes to the variability not just in price but in quality of such commodity products. We are looking to introduce closer central purchasing—I think 12 items are currently being trialled or introduced in parts of NHS England.

We recognise that, as currently drafted, the Bill does not explicitly state in relation to section 260 that the Government are obliged to consult industry. I am aware that the 2006 Act, in relation to controlling the cost of medicines, does explicitly state that there is an obligation on the Government to consult. The hon. Lady's amendment is appropriate in its intent. I invite her to withdraw it at this stage, but I undertake to work with her. My officials will consider how to amend the amendment to give it the effect that she seeks, but in a way that works in the context of the Bill. There are technical drafting issues with the amendment that mean that it would give us some unintended difficulties. That is the Government's position on the amendment; I hope she is happy with that.

The hon. Lady referred to the effect of any pricing controls for medical supplies on the maintenance of those products' quality. I can assure the Committee that the Government will take into account all relevant factors, including any concerns raised by industry about the quality of medical supplies, when making and consulting on price controls if they were to apply to medical supplies. The Government would not be in favour of putting any of those many factors in the Bill, because it may unnecessarily constrain the conduct of future Governments or the NHS.

**Dr Whitford:** If there is a move to more central procurement, will the Minister consider some form of quality control regulation or power at that point, so that central procurement is not just driven to accept the lowest price and there is some safety mechanism, in the same way we have the MHRA for drugs?

**Mr Dunne:** 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.

**Rob Marris** *rose—*

**Mr Dunne:** I think the hon. Gentleman is looking to intervene—or is he stretching again?

**Rob Marris:** I urge the Minister to have a greater familiarity with the quality of surgical gloves, which are great for delivering leaflets. They give a bit of weather protection. You don't have to lick your finger to get the next leaflet, you don't get letterbox knuckle, and—best of all—the dog gets latex, not flesh.

**Mr Dunne:** Again the hon. Gentleman strays, but not too far beyond his brief, because surgical gloves have been raised now by three members of the Committee. I am grateful for that tip. With the onset of winter weather, that could be quite useful for those of us who will be going to Sleaford and North Hykeham over the next few weeks to leaflet. I will take it upon myself to bring a box of surgical gloves when I visit.

With your indulgence, Mr Pritchard, I will take this opportunity to pick up the points made by the hon. Member for Central Ayrshire about the way the statutory scheme is intended to operate. To be crystal clear, clause 2 relates to unbranded generics and allows us to make regulations and directions to specific companies, while clause 3 relates currently only to branded medicines but could, if we wanted it to, also relate to unbranded medicines in future. The statutory scheme will be used where a company is not a member of the voluntary scheme, as I indicated to the hon. Member for Wolverhampton South West. The statutory scheme is intended to operate through setting a percentage of sales to be paid to the Government.

*[Mr Dunne]*

Details of the scheme's operation will be set out in regulations. A draft of the illustrative regulations is available to the Committee.

I will revert to the hon. Lady's amendment 47. The Government do not currently control prices of medical supplies. As was referred to earlier, the MHRA is responsible for the safety, efficacy and quality of medical supplies. That provides some check of quality in relation to not only medicines but medical supplies.

**Rob Marris:** The Minister has lost me there. It is probably my ignorance, but I thought he just said that the Government do not currently control the cost of medical supplies. If that is what he said, is that because they do not use the power they already have under section 260(1) of a 10-year-old Act?

**Mr Dunne:** Yes, I think that is the correct answer. We do have those powers under the 2006 Act, but they have not been used, partly because generally speaking medical supplies is a competitive market. We have not seen the kind of abusive price behaviour that we are trying to address elsewhere in the Bill.

**Dr Whitford:** Will the Minister give way?

**Mr Dunne:** I am about to conclude but I will happily give way.

**Dr Whitford:** I would like to clarify the reason for introducing this, if there has not been a problem in the market, as we have seen with the price hikes in generics, and it is much harder to do. Why are the Government extending a power they have had for 10 years but never used?

**Mr Dunne:** In essence, we are trying to bring the regimes for medical supplies and drugs into the same environment, so that we are able in future to use the powers, which we are introducing for the first time for drugs, for medical supplies on the same basis, so that we do not have to treat one thing under one Act and the other under another. I hope that is clear.

**Justin Madders:** I am sorry to push this point, but are there any examples? We obviously have clear examples, for example, in the pharmaceutical sector. Is there anything in the supplies sector that would be equivalent?

**Mr Dunne:** I am not aware of any particular examples of medical supplies that we are concerned about at this point. However, I am sure that, if there are people outside watching who have good examples, they will let the Committee know before we conclude our deliberations.

Reverting to the hon. Lady's amendment 47, we understand the intent behind it. We are not fully convinced that the current drafting would have precisely the effect that she is hoping. I invite her to work with me and my officials between now and Report. The Government will be happy to consider how we could best introduce the requirement to consult in relation to section 260. On that basis, I invite her to withdraw the amendment.

**Dr Whitford:** I beg to ask leave to withdraw the amendment.

*Amendment, by leave, withdrawn.*

*Question proposed,* That the clause stand part of the Bill.

**Mr Dunne:** Clause 5 amends section 260 of the 2006 Act, which enables the Secretary of State to control the maximum prices of medical supplies other than health service medicines. As we have just discussed, the Government have powers to control prices of medical supplies and we are not currently using those powers. It is important that we continue to have those powers, should we decide it is necessary to control prices of medical supplies in the event of market abuse.

With an increasing spend on healthcare products, the Government need the tools to be able to control prices, if there is any indication that medical suppliers do not provide value for money to the NHS and the taxpayer. The measures would ensure that the same enforcement and territorial extent provisions apply to controlling the cost of medical supplies and health service medicines.

Existing enforcement provisions in relation to medical supplies are draconian compared with those for medicines. Currently, a contravention or a failure to comply is in fact a criminal offence in relation to medical supplies, whereas it is not in relation to medicines. We are aligning the enforcement provisions to those for medicines and making them much more proportionate. That is done through clause 7, through consequential amendments. On that basis, I ask the Committee to agree that clause 5 stand part of the Bill.

**Rob Marris:** May I again congratulate the Government? This appears to be the only piece of criminal legislation I have ever heard of that apparently has a 100% deterrence rate. That is, the Government have the power to penalise a course of action and, as far as the Government are aware, no company is pursuing such a course of action, meaning that Government do not have to exercise their powers, criminal or otherwise. What a great piece of legislation passed by the Labour Government in 2006.

*Question put and agreed to.*

*Clause 5 accordingly ordered to stand part of the Bill.*

*Ordered,* That further consideration be now adjourned. —*(Mark Spencer.)*

11 am

*Adjourned till this day at Two o'clock.*