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HOUSE OF COMMONS
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GENERAL COMMITTEES

Public Bill Committee

HEALTH SERVICE MEDICAL SUPPLIES (COSTS) BILL

Third Sitting

Tuesday 15 November 2016

(Afternoon)

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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

(Afternoon)

[Mark Pritchard *in the Chair*]

Health Service Medical Supplies (Costs) Bill

Clause 6

Provision and disclosure of information

2 pm

The Minister of State, Department of Health (Mr Philip Dunne): I beg to move amendment 1, in clause 6, page 4, line 4, at end insert—

"( ) References in this section to a UK producer are to a person who—

(a) manufacturers, distributes or supplies any UK health service products, and

(b) is not an excepted person."

This amendment is linked to amendments 2 to 16 and 19 to 35. It provides a definition of the term "UK producer" to be used in sections 264A to 265 of the National Health Service Act 2006.

The Chair: With this it will be convenient to discuss the following:

Government amendments 2 to 19.

Amendment 48, in clause 6, page 5, line 41, at end insert—

"(1A) Information provided by virtue of section 264A must be disclosed by the Secretary of State to any person listed in subsection (1) at that person's request."

Government amendments 20 to 36 and 38.

Mr Dunne: I apologise to the Committee for introducing quite so many amendments at this stage of our deliberations. As I explained in our pre-meeting before we went into line-by-line scrutiny, the amendments were tabled entirely to reflect the request from the devolved Administrations, with which we entirely agree, on how they want to apply this power in their territories. As a result of things beyond the control of the Committee, including elections in the devolved Administrations this spring, the European Union referendum and the summer recess, all of which interfered with the normal process of discussion between the Department and the devolved Administrations, we were not able to get instructions from them before the introduction of the Bill, which is why the amendments have only now been tabled.

I recognise that this is a large number of amendments, but they are all driving at the same objective. Some of the information requirements in the Bill that apply to England only could also apply to the territories of the devolved Administrations. The Government amendments therefore reflect the instructions of the devolved Administrations in that area. We have had constructive discussions with each Administration, and we have agreed that the UK Government will collect information from wholesalers and manufacturers for the whole of the UK. It would not make sense for each nation to collect its own information from wholesalers and manufacturers, because that would lead to duplication of effort to no apparent purpose. We have also agreed that each nation will collect information from its own pharmacies and GPs, to the extent that that is requested.

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.

While I am on my feet, I take the opportunity to clarify again the comments I made towards the end of our previous sitting, to ensure that they are properly on the record. They related to the distinctions between clauses 2 and 3. The Bill, as everyone in Committee knows, is concerned with the cost of health service medicines. We negotiated a voluntary scheme with industry that controls the cost of branded health service medicines. Any company that has branded medicines in its portfolio and chooses not to be a member of the voluntary scheme will automatically become a member of the statutory scheme.

The existing statutory scheme, which also applies only to branded health service medicines, is based on a price-cut mechanism. The Bill makes it clear that the Secretary of State may make regulations for a statutory scheme that is based on a payment mechanism, whereby a percentage of sales income is paid to the Government. Illustrative regulations, to which I referred this morning, and which include the payment mechanism alongside a price-freeze mechanism, have been provided to Committee members. Even though the Bill would not prevent us from applying the statutory scheme to unbranded generic medicines, that is not the Government's current intent.

I have some comments to make on Opposition amendment 48. Perhaps you would like me to do that after the amendment has been spoken to, Mr Pritchard.

The Chair: I think later would be helpful, thank you, Minister.

Dr Philippa Whitford (Central Ayrshire) (SNP): I want to raise a small, perhaps technical, issue on amendment 11, which it seems would insert the rules and definitions with respect to excepted persons for Scotland, Northern Ireland and Wales under a new subsection defining health service products for England. It seems out of place, and there is no definition of English excepted persons.

The amendment would insert new subsection (8A) into new section 264A, which clause 6 inserts into the National Health Service Act 2006. It seems out of place because the provision would deal with English health service products, then the definition of the excepted persons in the devolved nations, and then Scottish, Irish and Welsh health service products. It may just be a technical issue, but I wanted to raise it.

Mr Dunne: I am grateful to the hon. Lady for raising that issue. If we have time during the sitting, I shall respond more formally to her.

The Chair: I am sure that the hon. Lady knows, but if she wants to speak to amendment 48 now, she can do so.

Dr Whitford: My colleague will speak to that amendment.

Martyn Day (Linlithgow and East Falkirk) (SNP): It is a pleasure to serve under your chairmanship today, Mr Pritchard. I am somewhat reassured by many of the Minister's comments, and I thank him for his explanations. Much of this stuff is technical, and I hope he sees amendment 48 in a similar light. I think it would improve and strengthen the measure.

The clause does not currently set out a mechanism for the disclosure of information to devolved Administrations or bodies. For example, how will the information be disclosed, and by what means? Will it be only the Secretary of State who can disclose? In short, will the devolved Administrations be able to get the information when they want and need it, so that it ties in with the figures and statistics they are seeing and they can see patterns? It is about flexibility.

The amendment is fairly straightforward and we think it would help to strengthen and improve the Bill. I hope that the Minister agrees. We would like him to clarify whether the Government intend to leave disclosure to the discretion of the Secretary of State, on an ad hoc basis. Otherwise, what would the terms of disclosure be?

Rob Marris (Wolverhampton South West) (Lab): To tease out the amendment a little more, proposed new section 264B(1)(h) relates to the provision of information to

"any person who provides services to any person falling within any of paragraphs (a) to (g)".

Is the hon. Gentleman concerned that under his amendment there might be disclosure to other private providers; or is that covered because only paragraphs (a) to (g) are specified?

Martyn Day: I thank the hon. Gentleman for his intervention, and I hope that I can clarify my clarification. It is about timing—when the information is disclosed, not to whom it is disclosed. The Bill covers that and we are quite comfortable with that.

I was saying that we think our amendment would strengthen the clause. I am reminded that on Second Reading the Secretary of State referred to fact that there would be amendments—we are grateful to see many of them today—

"to reflect the agreement between the Government and the devolved Administrations, so that information from wholesalers and manufacturers can be collected by the Government for the whole of the UK and shared with the devolved Administrations."—[*Official Report*, 24 October 2016; Vol. 626, c. 80.]

We think our amendment would enable him to get his wish and provide a mechanism in the Bill.

We feel strongly about the matter and want to push it to a vote if we do not receive the necessary assurances from the Minister. I hope that he can provide them.

Justin Madders (Ellesmere Port and Neston) (Lab): I want to comment generally on the Minister's amendments. I agree that it would have been helpful if they had been published earlier, but reasons why that was not possible have been given, and the Committee will be pleased to hear that I do not intend to go through each of them. I take the Minister's assurances that there has been extensive dialogue with the devolved Administrations. I intend to direct my remarks not so much at those Administrations that have been taking responsibility for their health service for some time, but at those areas in England where they have embarked upon ambitious devolution arrangements that encompass health—Manchester is the most obvious and probably most advanced example. It is not at all clear to me how, if at all, the Bill will impact on them.

The Greater Manchester area has now been given a delegated budget of £6 billion per annum. I am sure that people there have made various representations about how that is short of the figure that they need, and a significant proportion of the annual budget will certainly be spent on pharmaceutical costs. Would it not be reasonable for the relevant proportion of the rebate to be returned to Manchester and such areas in the same manner as the initial funding is devolved down to them? Simon Wootton, who was the chief operating officer at the North Manchester clinical commissioning group, said that we have not had the PPRS money back into the local NHS in North Manchester.

I am not aware of any specific agreements as part of the devolution settlement for Greater Manchester, and nothing is in the Bill, so I would be grateful if the Minister, when he responds, set out whether there have been any discussions with local representatives in Manchester on the issue, and whether his intention is to ensure that, in common with other devolved Administrations, appropriate arrangements are put in place for the relevant proportion of the rebate to be paid directly to them.

Mr Dunne: First, in relation to amendment 11 and what the hon. Member for Central Ayrshire said, I think she made a perfectly reasonable point. As a lay reader of parliamentary drafting, if I may say so, it would be easy to be perplexed by the sequencing that she highlighted and brought to the attention of the Committee. I am advised, however, that the purpose of the amendment is to ensure that the UK Government collect information from English pharmacies and GP practices, but not from pharmacies in the areas of the devolved Administrations. Therefore, the reference to "Excepted person" includes pharmacies and GP practices in the devolved Administrations, but specifically does not include those in England, because their information is already collected by the UK Government. The terminology relates to where the GPs and pharmacies are and who is doing the collecting. I hope that helps.

Dr Whitford: I understand that, but I could not find reference to that in the National Health Service Act 2006, and I thought that the aim was to bring everything together in this Bill, so it seemed odd that there was no mention of English excepted persons. That is fine—that information is already being collected—but the Bill still separates the definition of English health service products from the definition of the health service products of the

[Dr Philippa Whitford]

devolved nations. It seems an odd place to insert the amendment; it seems it is being attached to the definition of English health service products.

I totally accept that I am a complete novice, so there may be something I am not understanding, but to me, reading it logically, it does not seem to make total sense, and I thought that the aim of the Bill was to bring all the powers into one place. It seemed odd for there to be no definition of English excepted persons, even from an old Act, because what is happening here is that different things are being brought from the 2006 Act and from the Scotland Act 1978 into one place.

Mr Dunne: I thank the hon. Lady for that clarification. I hope that inspiration will arrive before I sit down.

To address the specific point made by the hon. Member for Ellesmere Port and Neston on devolution to Manchester, it is an interesting idea, which reflects some of the challenges arising from the increasing use of devolution of powers across our country. I can see why he might seek to secure a carve-out of income for Manchester. I would say, "Nice try", but at present the funding arrangements for Manchester and other devolved areas in England are agreed via NHS England. That applies to the totality of funding available for health provision within the Manchester area, so the allocation already includes income derived from the voluntary scheme, and it will not be ring-fenced as a subset of the funds, because there chaos would lie.

2.15 pm

Justin Madders: I appreciate that the Minister is not going to embark on a new area of debate and dialogue with Greater Manchester on this point, but will he advise whether future allocations intend to deal with the increased income from the rebate that is anticipated as a result of the Bill?

Mr Dunne: Each year, when NHS England agrees its commissioning budgets and tariffs with providers, an allocation is made. That is based on the overall sum received by NHS England. Increases in revenues that derive from the Bill will help to swell that pot relatively modestly, although every penny counts, and that will therefore be taken into account when determining allocations to all CCGs, including those in Manchester.

I will give the Government's response in relation to amendment 48; I do not have many comments to make. I sincerely hope that, before I reach the end of these remarks, I will be able to address the further point, on English exclusion, made by the hon. Member for Central Ayrshire.

Proposed new section 264B in clause 6 enables the Secretary of State to disclose the information collected to a range of bodies, which includes Government bodies such as NHS England, special health authorities, NHS Digital, other Departments and the devolved Administrations. It also enables the Secretary of State to prescribe representative bodies, or other persons in prescribed regulations, to whom he can disclose information in the future. For example, that might include certain information going to trade associations or other bodies that it might be appropriate to provide information to in future, with respect to the operations of the Bill.

The effect of the amendment tabled by the hon. Members for Central Ayrshire and for Linlithgow and East Falkirk would be that any of those bodies could in future access any information that the Government have collected. We do not believe that it would be right for representative bodies to be able to access information that the Secretary of State collects, primarily for purposes of commercial confidentiality. There are examples in other legislation in which we have taken specific steps to protect commercially sensitive information. I am not suggesting that one company would directly get access to information on another company's profitability, but third-party advisers, for example, might get access to that information.

We do not want to provide opportunities for risking breaches of commercial confidentiality, because that would undermine confidence in the information gathering for all the companies, which includes major multinational companies. We think that the amendment might open us up to criticism from the major suppliers that there was greater risk of that intervention, which we would not want to see.

Dr Whitford: If the Minister looks at our amendment, which is incredibly short, he will see that all it says is "at that person's request." We do not want to widen the list in any way at all; we are not looking to add to the list. All we are saying is that, if it is accepted that a devolved Government should be able to access this information, it should be at the request of that devolved Government. It should not be, "We will tell you every April how you're doing." If a devolved country sees a pattern emerging, it should be able to say, "Can we request our data?" The issue is that data are to be collected centrally but not belong to the devolved nations to which they pertain. We are not trying to add anyone; we are just trying to give the devolved countries the power to request.

Mr Dunne: I completely understand that that is the intent of the hon. Lady's amendment, and I think I have another way of addressing it, which I am now going to come on to. We think it entirely appropriate that at some point the devolved Administration might wish to change their information requirements. They might wish to add requests for information that they are not initially getting, which is a reasonable request.

We think that the right way to address that, rather than putting something in the Bill that might inadvertently allow other representative bodies access to information—I am sure the hon. Lady agrees that that might not be appropriate—is for a memorandum of understanding to be agreed between the Department of Health and each of the devolved Administrations that would allow requests for information to be submitted and dealt with in a manner agreeable to both parties. In the consultation process that will follow, we intend to enter into a memorandum of understanding that will include the procedures for requesting and sharing information.

I assure the Committee that the Government intend to continue to work constructively with the devolved Administrations to ensure that they have access to the relevant information collected in a format convenient to both sides, so that we do not end up with special data sets that are hard for an Administration to create because the data are not readily available from the information

provided. Aside from that, we would honour the reasonable requests of any devolved Administration to be able to get access to the data, which I acknowledge the Administration may not own if the information has been gathered by the Department of Health.

On that basis, I hope that the hon. Lady and the hon. Member for Linlithgow and East Falkirk will not press their amendment.

The Chair: If the SNP Front-Bench spokespersons want to press the amendment to a vote, that will happen later, but it would be helpful to the flow of the proceedings if they confirmed now whether they intended to do so.

Martyn Day: We are satisfied with the Minister's answer.

The Chair: I am grateful to the hon. Gentleman.

Amendment 1 agreed to.

Amendments made: 2, in clause 6, page 4, line 5, leave out from "any" to "to" in line 6 and insert "UK producer".

This amendment is linked to amendments 1, 3 to 16 and 19 to 35. It allows regulations to require the provision of information by a person who manufactures, distributes or supplies Welsh health service products, Scottish health service products or Northern Ireland health service products.

Amendment 3, in clause 6, page 4, line 19, at end insert—

"(d) the determination of the payments to be made to any persons who provide primary medical services under Part 4 of the National Health Service (Wales) Act 2006;

(e) the determination of the remuneration to be paid to any persons who provide pharmaceutical services under Part 7 of that Act;

(f) the consideration by the Welsh Ministers of whether—

(i) adequate supplies of Welsh health service products are available, and

(ii) the terms on which those products are available represent value for money;

(g) the determination of the payments to be made to any persons who provide primary medical services under section 2C(1) of the National Health Service (Scotland) Act 1978 ("the 1978 Act");

(h) the determination of the remuneration to be paid to any persons who provide pharmaceutical care services under section 2CA(1) of the 1978 Act;

(i) the consideration by the Scottish Ministers of whether—

(i) adequate supplies of Scottish health service products are available, and

(ii) the terms on which those products are available represent value for money;

(j) the determination of the remuneration to be paid to any persons who provide primary medical services or pharmaceutical services under Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14));

(k) the consideration by a Northern Ireland department of whether—

(i) adequate supplies of Northern Ireland health service products are available, and

(ii) the terms on which those products are available represent value for money;

(l) the exercise by the Secretary of State of any powers under sections 260 to 264 and 265;

(m) the operation of a voluntary scheme.".

This amendment is linked to amendments 1, 2, 4 to 16 and 19 to 35. It sets out the purposes for which a person may be required to record and provide information to the Secretary of State by virtue of regulations under section 264A(1) of the National Health Service Act 2006.

Amendment 4, in clause 6, page 4, leave out lines 20 to 29.

This amendment is linked to amendments 1 to 3, 5 to 16 and 19 to 35. It removes subsections (3) and (4) of section 264A of the National Health Service Act 2006 because the provision made by those subsections now appears in amendment 3.

Amendment 5, in clause 6, page 4, line 30, leave out

"an English producer or other"

and insert "a".

This amendment is linked to amendments 1 to 4, 6 to 16 and 19 to 35. It is a consequential amendment. A reference to an English producer is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Amendment 6, in clause 6, page 4, line 33, leave out from "for" to end of line 35 and insert "UK health service products".

This amendment is linked to amendments 1 to 5, 7 to 16 and 19 to 35. It is a consequential amendment. A reference to English health service products is no longer needed as those products will fall within the definition of "UK health service products" inserted by amendment 14.

Amendment 7, in clause 6, page 4, line 38, leave out "the" and insert "UK health service".

This amendment is linked to amendments 1 to 6, 8 to 16 and 19 to 35. It is a consequential amendment.

Amendment 8, in clause 6, page 4, line 41, leave out "the" and insert "UK health service".

This amendment is linked to amendments 1 to 7, 9 to 16 and 19 to 35. It is a consequential amendment.

Amendment 9, in clause 6, page 4, line 43, leave out second "the" and insert "UK health service".

This amendment is linked to amendments 1 to 8, 10 to 16 and 19 to 35. It is a consequential amendment.

Amendment 10, in clause 6, page 5, line 1, leave out from "whether" to "health" in line 2 and insert

"they are UK health service products and, if so, which of the following they are—

(i) English health service products;

(ii) Welsh health service products;

(iii) Scottish health service products;

(iv) Northern Ireland".

This amendment is linked to amendments 1 to 9, 11 to 16 and 19 to 35. It is a consequential amendment. It enables regulations to require a UK producer to provide information about products for verifying whether they are Welsh, Scottish or Northern Ireland health service products.

Amendment 11, in clause 6, page 5, line 14, at end insert—

"(8A) "Excepted person" means any of the following—

(a) a person who provides primary medical services under Part 4 of the National Health Service (Wales) Act 2006;

(b) a person who provides pharmaceutical services under Part 7 of that Act;

(c) a person who provides primary medical services under section 2C(1) of the 1978 Act;

(d) a person who provides pharmaceutical care services under section 2CA(1) of the 1978 Act;

(e) a person who provides primary medical services or pharmaceutical services under Part 2 or 6 of the Health and Personal Social Services (Northern Ireland) Order 1972 (S.I. 1972/1265 (N.I. 14)).".

This amendment is linked to amendments 1 to 10, 12 to 16 and 19 to 35. It lists the persons who are excepted from being a "UK producer" for the purposes of the definition inserted by amendment 1.

Amendment 12, in clause 6, page 5, line 15, at end insert—

"( ) "Northern Ireland health service products" means any medicinal products used to any extent for the purposes of health care provided by virtue of the Health and Social Care (Reform)

[The Chair]

Act (Northern Ireland) 2009 and any other medical supplies, or other related products, required for the purposes of health care provided by virtue of that Act.".

This amendment is linked to amendments 1 to 11, 13 to 16 and 19 to 35. It provides a definition of "Northern Ireland health service products" for the purposes of section 264A of the National Health Service Act 2006.

Amendment 13, in clause 6, page 5, line 15, at end insert—

"( ) "Scottish health service products" means any medicinal products used to any extent for the purposes of the health service within the meaning of the 1978 Act and any other medical supplies, or other related products, required for the purposes of that health service.".

This amendment is linked to amendments 1 to 12, 14 to 16 and 19 to 35. It provides a definition of "Scottish health service products" for the purposes of section 264A of the National Health Service Act 2006.

Amendment 14, in clause 6, page 5, leave out lines 16 to 26 and insert—

"( ) "UK health service products" means any English health service products, Welsh health service products, Scottish health service products or Northern Ireland health service products.".

This amendment is linked to amendments 1 to 13, 15, 16 and 19 to 35. It provides a definition of "UK health service products" for the purposes of section 264A of the National Health Service Act 2006.

Amendment 15, in clause 6, page 5, line 26, at end insert—

"( ) "Welsh health service products" means any medicinal products used to any extent for the purposes of the health service continued under section 1(1) of the National Health Service (Wales) Act 2006 and any other medical supplies, or other related products, required for the purposes of that health service."

This amendment is linked to amendments 1 to 14, 16 and 19 to 35. It provides a definition of "Welsh health service products" for the purposes of section 264A of the National Health Service Act 2006.

Amendment 16, in clause 6, page 5, line 26, at end insert—

"( ) Until the coming into force of the repeal of section 27 of the 1978 Act by schedule 3 to the Smoking, Health and Social Care (Scotland) Act 2005 the references in subsections (2)(h) and (8A)(d) to pharmaceutical care services under section 2CA(1) of the 1978 Act are to be read as references to pharmaceutical services under section 27(1) of that Act.".

This amendment is linked to amendments 1 to 15 and 19 to 35. It makes transitional provision in relation to references to pharmaceutical care services under section 2CA(1) of the National Health Service (Scotland) Act 1978.

Amendment 17, in clause 6, page 5, line 35, at end insert—

"(fa) the Common Services Agency for the Scottish Health Service constituted under section 10 of the 1978 Act;".

This amendment adds the Common Services Agency for the Scottish Health Service to the persons listed in section 264B(1) of the National Health Service Act 2006. This means that information provided by virtue of section 264A of that Act may be disclosed to that Agency.

Amendment 18, in clause 6, page 5, line 36, at end insert—

"(ga) the Regional Business Services Organisation established under section 14 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;".

This amendment adds the Regional Business Services Organisation to the persons listed in section 264B(1) of the National Health Service Act 2006. This means that information provided by virtue of section 264A of that Act may be disclosed to that Organisation.

Amendment 19, in clause 6, page 5, line 40, leave out "English producers or other".

This amendment is linked to amendments 1 to 16 and 20 to 35. It is a consequential amendment. A reference to English producers is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Amendment 20, in clause 6, page 5, line 46, at end insert "(subject to subsection (4))".

This amendment is linked to amendments 1 to 16, 19 and 21 to 35. It flags the provision made by amendment 29.

Amendment 21, in clause 6, page 6, line 4, leave out "or (4)" and insert

"(a) to (c), (l) or (m)".

This amendment is linked to amendments 1 to 16, 19, 20 and 22 to 35. It is consequential on amendments 3 and 4.

Amendment 22, in clause 6, page 6, line 8, leave out "or (4)" and insert

"(a) to (c), (l) or (m)".

This amendment is linked to amendments 1 to 16, 19 to 21 and 23 to 35. It is consequential on amendments 3 and 4.

Amendment 23, in clause 6, page 6, line 11, leave out "to (g)".

This amendment is linked to amendments 1 to 16, 19 to 22 and 24 to 35. It is consequential on amendments 25 and 26.

Amendment 24, in clause 6, page 6, line 12, leave out "either of the matters specified in section 264A(4)"

and insert

"any of the matters specified in section 264A(2)(d) to (f), (l) or (m)".

This amendment is linked to amendments 1 to 16, 19 to 23 and 25 to 35. It is consequential on amendments 3 and 4.

Amendment 25, in clause 6, page 6, line 13, at end insert—

"(ca) in relation to a person falling within subsection (1)(f) or (fa), the purpose is that of exercising functions connected with any of the matters specified in section 264A(2)(g) to (i), (l) or (m);".

This amendment is linked to amendments 1 to 17, 19 to 24 and 26 to 35. It is consequential on amendments 3, 4 and 17.

Amendment 26, in clause 6, page 6, line 13, at end insert—

"(cb) in relation to a person falling within subsection (1)(g) or (ga), the purpose is that of exercising functions connected with any of the matters specified in section 264A(2)(j) to (m);".

This amendment is linked to amendments 1 to 16, 18 to 25 and 27 to 35. It is consequential on amendments 3, 4 and 18.

Amendment 27, in clause 6, page 6, line 17, leave out "(c)" and insert "(cb)".

This amendment is linked to amendments 1 to 16, 19 to 26 and 28 to 35. It is mainly consequential on amendments 25 and 26.

Amendment 28, in clause 6, page 6, line 20, leave out "or (4)".

This amendment is linked to amendments 1 to 16, 19 to 27 and 29 to 35. It is consequential on amendments 3 and 4.

Amendment 29, in clause 6, page 6, line 20, at end insert—

"(4) The Welsh Ministers may disclose any confidential or commercially sensitive information disclosed to them under subsection (1) to any of the following persons—

(a) a Local Health Board or other person appointed under section 88(3)(b) of the National Health Service (Wales) Act 2006 to exercise the functions of a determining authority under Part 7 of that Act;

(b) a National Health Service trust established under section 18 of the National Health Service (Wales) Act 2006;

(c) any person who provides services to the Welsh Ministers or to any person falling within paragraph (a) or (b).

(5) A person to whom any confidential or commercially sensitive information is disclosed under subsection (4) may not—

(a) use the information for any purpose other than the purpose of exercising functions connected with any of the matters specified in section 264A(2)(d) to (f), (l) or (m), or

(b) disclose the information to another person.".

This amendment is linked to amendments 1 to 16, 19 to 28 and 30 to 35. It allows the Welsh Ministers to disclose information to other persons including Local Health Boards, National Health Service trusts and persons providing services to those persons.

Amendment 30, in clause 6, page 6, line 24, leave out "English producers or other".—*(Mr Dunne.)*

This amendment is linked to amendments 1 to 16, 19 to 29 and 31 to 35. It is a consequential amendment. A reference to English producers is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Question proposed, That the clause, as amended, stand part of the Bill.

Mr Dunne: Before I go into the clause as a whole, I would like to respond in further detail to the hon. Member for Central Ayrshire about excepted persons. Clause 6 will add a new section to the National Health Service Act 2006. It brings together information collection practices, both statutory and voluntary. The Secretary of State collects information from a sample group in England from time to time, but not from GPs and pharmacies in the devolved Administrations. Therefore, the definition of "excepted persons" covers those persons whom the Secretary of State does not intend to collect information from directly, because he would be relying on the devolved Administrations to do so. The terminology used in proposed new section 264B is new; it is not based on the 2006 Act, which the hon. Lady has read so diligently. I thank her for bringing the matter to the Committee's attention and I hope that that explanation meets her concern.

Dr Whitford: To clarify, is there a rational reason for the positioning of the section as between English health service products and the other health service products? I am sorry if, as a novice, I am creating extra work.

Mr Dunne: I think that is to do with parliamentary drafting on which I stand to become an expert; I look forward to seeing whether there is a clear explanation for that, which I can give to the hon. Lady as we debate the clause.

The clause enables the Secretary of State to make regulations that require any person who manufactures, distributes or supplies health service products, which includes health service medicines, medical supplies and other related products, to keep, record and provide on request information on prices and costs.

The clause brings together and consolidates existing information requirements related to controlling the costs of health service medicines, as well as medical supplies, in one place in the Act, as we discussed this morning. It also allows the information to be used for the purposes set out in the clause.

The clause also expands and strengthens our information collection. It enables the Government to make regulations to put current voluntary information provision arrangements on a statutory footing. For example, we collect information from manufacturers and wholesalers of unbranded generic medicines and specials to inform reimbursement arrangements for community pharmacies. The Bill will enable us to make regulations to get information on more products and from more companies. That is necessary to ensure that reimbursement prices for pharmacies reflect market prices of the whole market, rather than just of those companies that currently supply data to us. As in any industry, there are new market entrants and participants leave the market; this is a dynamic market and we need the flexibility to bring in new products from new companies.

The clause will also enable the Government to collect information to assure us that adequate supplies of health service products are available, and that the terms on which they are available represent value for money. If we were to have concerns about the supply chain or parts of it, or about specific products, we could obtain information from companies in the supply chain to assure us that the products, or the supply chain, provided value for money to the NHS and the taxpayer. Although the Government are generally not the purchaser of health service products, they do pay for them and therefore transparency and value for money of the supply chain are important. For example, if we were to consider limiting the price of a high-priced generic, the power to obtain information would be crucial to determine whether excess profits were being made. We could obtain information from a manufacturer, which would help us to determine whether the price it was charging the NHS was unreasonably high. That information would also inform our decision on what the right price should be.

The purposes for which the Government can collect information are limited and involve three areas: cost and pricing schemes, reimbursement of pharmacies and GPs, and assessing value for money. The clause provides the Secretary of State with the power to request any information for the purposes set out in the Bill. It also provides an indicative list of the type of information that the Secretary of State may request. Most of the types of information listed are already collected by the Government under statutory or voluntary arrangements.

The clause will also enable the Government to share information with a range of bodies, including Ministers in the devolved Administrations, the NHS, other Departments and persons providing services to those prescribed bodies.

Rob Marris: In the Minister's helpful letter to the hon. Member for Vale of Clwyd, sent yesterday, he said:

"At this moment the Government does not foresee any routine collections for those involved in the manufacture, distribution or supply of medical supplies".

I just understood the Minister to say—he will correct me if I misunderstood—that in certain non-routine circumstances in relation to medical supplies, the Government may wish to have information. I understand that, but I must say to him that that might create a problem for those medical suppliers that are not routinely supplying information, but feel that they still have to keep all the information as outlined in the clause just in case a little way down the road the Government decide that the circumstances are exceptional. Will he clarify that?

2.30 pm

Mr Dunne: I am grateful to the hon. Gentleman for raising some of the practical requirements of collecting and retaining data. Particularly in relation to medical

[Mr Dunne]

supplies, where we have this power already but have not exercised it, I can understand a potential anxiety that we may be changing the basis on which companies are requested to retain information. We will be consulting industry on the regulations, and a draft is available in the pack. Our intent is not to add to the burden, particularly on small companies, of retaining extra data that may never be called upon.

We will use the consultation to try to be as pragmatic as possible but, in the event of information becoming apparent to us within a reasonable period, we may wish to be able to go back and look at the data. The natural place to start the data gathering is the information that companies are obliged to retain for other Government purposes, such as HMRC requirements to retain information for six years. That will be our starting point in identifying the duration, the type of information and the manner of retention. We are not, in the first instance, looking to add an additional burden.

During the consultation, we may decide that there is some information that is routinely kept by companies that supply the NHS that it would be desirable for them to continue retaining for the same period but, as I stand here today, I do not have examples. I am sure an ingenious mind could come up with a devilishly clever example of information that would be useful, but I hope the hon. Gentleman will not be tempted by me to do so.

Maggie Throup (Erewash) (Con): The Minister says that he will continue to consult industry bodies, and there are some obvious bodies that I am sure he will have around the table. Can he reassure us that it will not just be the large bodies and that he will invite some of the smaller trade organisations to the consultation, too?

Mr Dunne: Yes. I am grateful to my hon. Friend for that intervention. We intend to consult the trade associations that we have already been consulting. As I said to the hon. Member for Wolverhampton South West, we do not intend to add unduly burdensome information requirements. One issue that we have agreed to consider in the consultation is the suggested size of business that should be capable of providing information. We have an SME definition in the regulations that is not precisely the same as other SME definitions elsewhere across Government, and we need to consider that carefully in the consultation so that we are not unduly burdening small companies.

Having said that, there are examples of pharmaceutical providers that may be large companies in other countries but are supplying through a UK subsidiary or a non-UK EU subsidiary that maintains a very small number of employees in this country, that therefore may fall within the more widely used SME definition but that nevertheless is a relatively large supplier of pharmaceutical products to the UK. There is a balance to be struck in ensuring that the universe of companies that we ask to retain data is big enough to capture reasonably large suppliers, even if technically those suppliers may fall within an SME definition.

The Chair: Order. The TV cameras are broadcasting this debate live, and I am sure the public want to see more of the Minister than our colleagues. It would be good if he faced inwards.

Mr Dunne: Mr Pritchard, your alertness to the media never leaves the forefront of your mind. I am grateful to you for drawing to my attention the fact that others are potentially listening to our proceedings.

It will be a public consultation, so companies that feel they have an interest will have every opportunity to participate. We have already engaged with a wide range of industry bodies in both medical supplies and medicines to draft the regulations.

Fortunately, inspiration has arrived to address the persistent comment from the hon. Member for Central Ayrshire about drafting. I hope that what I am about to say will satisfy her. She referred to amendment 11, which we have agreed. The Bill currently refers to purposes that are England-only and those that are reserved. The amendments refer to purposes that are England-only, Welsh-only, Scottish-only, Northern Irish-only and reserved. It is therefore necessary to make a distinction between products supplied to the health services in each of the different nations. If that leads to some disorder in how the measure has been written, I can but apologise to the hon. Lady. She has done a good service to the Committee in pointing that out, but that is as far as I am able to go on the matter today.

Clause 6 enables the Government to share information with representative bodies providing services, in addition to the bodies I have referred to. It restricts the use of information that is confidential or commercially sensitive to the defined purposes in the Bill. That is deliberate. It is important to provide commercial suppliers to the NHS with some confidence that any information they supply which may be commercially sensitive—of course, margin information is commercially sensitive—will not be capable of being disseminated beyond the prescribed bodies. The clause also enables the Government to prescribe in regulations representative bodies with which they may share information. In the illustrative regulations, we have prescribed a number of those bodies. There is also the possibility to prescribe other persons in regulations in due course, should suitable bodies emerge.

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.

The clause covers medical supplies and other related products, streamlines existing provisions for medical supplies and aligns them with those for medicines.

Medical supplies and other related products are wide-ranging, and there are tens of thousands of items. In regulations, the Government will prescribe for which medical supplies information is required to be kept, recorded and provided on request.

The illustrative regulations set out the type of products that may be affected. The Government will consult publicly on that. The Government have tabled amendments to the clause to reflect the instructions of the devolved Administrations in this area. The Department already collects a considerable amount of information from across the supply chain. The clause streamlines existing statutory requirements, puts existing voluntary arrangements on a statutory footing and strengthens the collections. It also enables the Department to use the information collected for multiple but defined purposes. If hon. Members are satisfied with my explanation, I ask the Committee to accept that clause 6 stand part of the Bill.

Question put and agreed to.

Clause 6, as amended, accordingly ordered to stand part of the Bill.

Clause 7

CONSEQUENTIAL AMENDMENTS

Amendments made: 31, in clause 7, page 6, line 32, at end insert—

"(A1) Omit the following provisions of the National Health Service (Scotland) Act 1978—

(a) section 49 (control of maximum prices for medical supplies other than health service medicines), and

(b) Schedule 10 (additional provisions as to control of maximum prices for medical supplies other than health service medicines)."

This amendment is linked to amendments 1 to 16, 19 to 30, 32 to 35 and 38. The provision made by section 49 of, and Schedule 10 to, the National Health Service (Scotland) Act 1978 is superseded by the provision made in the amendments.

Amendment 32, in clause 7, page 7, line 7, leave out "English producers and other".

This amendment is linked to amendments 1 to 16, 19 to 31 and 33 to 35. It is a consequential amendment. A reference to English producers is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Amendment 33, in clause 7, page 7, line 11, leave out "an English producer or other" and insert "a".

This amendment is linked to amendments 1 to 16, 19 to 32 and 34 and 35. It is a consequential amendment. A reference to an English producer is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Amendment 34, in clause 7, page 7, line 17, leave out "English producers or other".

This amendment is linked to amendments 1 to 16, 19 to 33 and 35. It is a consequential amendment. A reference to English producers is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Amendment 35, in clause 7, page 7, line 20, leave out ""English producer" and "other UK producer" are" and insert ""UK producer" is".—*(Mr Dunne.)*

This amendment is linked to amendments 1 to 16 and 19 to 34. It is a consequential amendment. A reference to an English producer is no longer needed as an English producer will fall within the definition of "UK producer" inserted by amendment 1.

Question proposed, That the clause, as amended, stand part of the Bill.

Mr Dunne: You will be pleased to hear, Mr Pritchard, that I have nothing to add in the clause 7 stand part debate, and I commend the clause to the Committee.

Rob Marris: I hope the Minister does have a bit more to add. Clause 7 is very much the twin, or the other side of the coin, of clause 6. Clause 6 introduces big changes to the information supply regime, which we have just discussed. Clause 7 is getting rid of bits of the hitherto existing supply regime—not all of it, but bits. I want to probe him a little bit on that.

On page 7 of the Bill, clause 7(16) states:

"In Schedule 22 (provisions in relation to section 260) omit paragraphs 2 to 11."

Schedule 22, paragraphs 2 to 11, of the National Health Service Act 2006 is about enforcement. I am probing the Minister, given our discussion this morning when I said, in relation to some parts of the Bill and this area of human endeavour, that it was the only area I am aware of where a criminal penalty regime appeared to have been 100% successful and there had been no such prosecutions—intimating, although not proving, that that wrongdoing had been dissuaded by the legislation. We then come to clause 7, and the enforcement regulations and regime are altered. I want to be reassured by the Minister that the alterations do not weaken the enforcement regime. I am applying the Marris test to it; I cannot read absolutely every word of the 2006 Act, which I was involved in 10 years ago and runs to 258 pages—I will not do that—but what is being removed is a whole lot longer than what is being substituted in. That may be a welcome shortening, clarification and simplification of the law, or it may be a weakening of enforcement. I hope that the Minister can elucidate to the Committee, in broad terms, whether it is the former or the latter.

Mr Dunne: I am astonished that the hon. Gentleman does not have complete recall of everything that was involved in the 2006 Act, given the assiduous way in which he approaches legislative scrutiny. Accepting that uncharacteristic lapse in his memory, I should perhaps have said that the subsections in clause 7 merely bring forward the relevant consequential amendments, following on from the earlier clauses, to the National Health Service Act.

This morning, we discussed the one material change in enforcement that we are introducing through the Bill: reducing the criminal penalty currently available under the 2006 Act for bad practice uncovered in the supply of medical supplies, so that it is in line with the enforcement regime for medicines. To that extent, if the threat of criminal sanction were—as hinted at by the hon. Gentleman—the primary reason for the lack of convictions of a criminal nature for the supply of medical supplies, he might have a legitimate concern that we are watering down an enforcement regime that had worked so effectively that there had been no prosecutions. I would gently say to him that, as far as I am aware, not only have there been no convictions, but there have been few if any—I hesitate to say none, because I might not be able to prove that—prosecutions under those sections in the 2006 Act against suppliers of medical supplies. That is as much because it has not been brought to the attention of the Department that there is abusive pricing behaviour happening in the medical supplies marketplace. For that reason, there have been no prosecutions and, therefore,

[Mr Dunne]

no convictions. That is why we think it appropriate to remove the criminal sanction, so we may bring it into conformity with enforcement actions for medicines.

To put it in ideological terms, this is part of reducing the burden on business, because the power has proved to be one that is unnecessary for the Government to have—the power to introduce a criminal enforcement regime has not been used since its introduction by the hon. Gentleman in 2006.

2.45 pm

Rob Marris: I understand what the Minister is saying. I am not in any way suggesting that the overwhelming majority of medical suppliers are on the straight and narrow only because they know what the penalties would be for going off the straight and narrow. However, he needs to be a little careful about the direction of his argument, because—I think he would agree, but he can say if he does not—if crime in the United Kingdom fell to zero, I would not suggest getting rid of all police officers. I would say, "They are doing a fantastic job and it's great that we have all these law-abiding citizens. Let's just encourage them to carry on being law-abiding by making it clear that there are enforcement mechanisms and penalties for not being so." That is the philosophical, if not ideological, approach.

Mr Dunne: I agree with the hon. Gentleman. Neither he nor I is suggesting that there is cause and effect here in the element of the enforcement penalty element—

Rob Marris: I don't know.

Mr Dunne: Well, we do not believe so. What we do believe is that it is more important for us to have a consistent approach to enforcement when it comes to any future breaches or alleged breaches in respect of supply to the NHS. Frankly, it will be easier for the NHS to manage and easier for the industry supplying us to operate if they are all operating within the same enforcement regime. Therefore, I commend the clause to the Committee.

Question put and agreed to.

Clause 7, as amended, accordingly ordered to stand part of the Bill.

Clause 8

EXTENT

Amendments made: 36, in clause 8, page 7, line 29, at beginning insert "Subject as follows,".

This amendment is linked to amendments 37 and 38.

Amendment 37, in clause 8, page 7, line 29, at end insert—

"( ) Section (Provision of information to Welsh Ministers) extends to England and Wales only."

This amendment is linked to amendments 36 and NC1. Its effect is that the provision made by NC1 will extend to England and Wales only.

Amendment 38, in clause 8, page 7, line 29, at end insert—

"( ) Section 7(A1) extends to Scotland only."—*(Mr Dunne.)*

This amendment is linked to amendments 31 and 36. Its effect is that the provision made by amendment 31 will extend to Scotland only.

Question proposed, That the clause, as amended, stand part of the Bill.

Mr Dunne: This clause is the shortest in the Bill and it confirms the extent of the Bill as covering England and Wales, Scotland and Northern Ireland. I am sure we can all reach common accord in supporting the clause.

Question put and agreed to.

Clause 8, as amended, accordingly ordered to stand part of the Bill.

Clause 9

COMMENCEMENT

Amendments made: 39, in clause 9, page 7, line 32, at end insert—

"( ) Section (Provision of information to Welsh Ministers) comes into force on such day as the Welsh Ministers may by order appoint.".

This amendment is linked to amendments 40 to 42 and NC1. It makes provision for the Welsh Ministers to bring clause (Provision of information to Welsh Ministers) into force.

Amendment 40, in clause 9, page 7, line 35, at beginning insert "An order or".

This amendment is linked to amendments 39, 41, 42 and NC1.

Amendment 41, in clause 9, page 7, line 38, at beginning insert "An order or".

This amendment is linked to amendments 39, 40, 42 and NC1.

Amendment 42, in clause 9, page 7, line 38, after "section" insert "is or".—*(Mr Dunne.)*

This amendment is linked to amendments 39 to 41 and NC1.

Question proposed, That the clause, as amended, stand part of the Bill.

Mr Dunne: Briefly, clause 9 deals with the commencement of the Bill and ensures that clauses 1 to 8 come into force as determined by regulations. As I have indicated, there will be a public consultation on the regulations. It is the Government's intent that that consultation take place over the winter and it will conclude to enable the Bill to receive Royal Assent, following its passage through the House of Lords, by the end of the current Parliament.

Rob Marris: That is half of what I wanted to know—the Bill will have Royal Assent by then. Will the Minister say when it might come into force, pursuant to clause 9(2)?

Mr Dunne: The Department's intent is for it to come into force as soon as is practicable. The timetable for their lordships' House in determining legislation is way above my pay grade and, I would suggest, the hon. Gentleman's. We are therefore in the hands of the parliamentary authorities, but it is certainly our hope and expectation that, with effect from 1 April, the regulations— *[Interruption.]* I am seeking inspiration from the Department.

The Chair: I think the Committee will allow that.

Mr Dunne: I have had some extremely expert inspiration. In the event that their lordships choose to amend the Bill during its passage, it would be inappropriate to consult on the regulations finally until the Bill emerged from the other place. The consultation will therefore start as soon as we have Royal Assent, and the implementation of the proposals is therefore expected in the autumn.

Question put and agreed to.

Clause 9, as amended, accordingly ordered to stand part of the Bill.

Clause 10 ordered to stand part of the Bill.

New Clause 1

PROVISION OF INFORMATION TO WELSH MINISTERS

"After section 201 of the National Health Service (Wales) Act 2006 insert—

"Provision of information about medical supplies etc

201A Provision of information by persons providing primary medical services or pharmaceutical services

(1) Regulations may make provision requiring any Part 4 provider or Part 7 provider to—

(a) record and keep information, or information of a description, specified in the regulations, and

(b) provide that information to the Welsh Ministers.

(2) Information, or a description of information, may not be specified in the regulations by virtue of subsection (1) unless the Welsh Ministers consider that the information may be required for the purpose of enabling or facilitating any of the following—

(a) the determination of the payments to be made to any Part 4 providers;

(b) the determination of the remuneration to be paid to any Part 7 providers;

(c) the consideration by the Welsh Ministers of whether—

(i) adequate supplies of health service products are available, and

(ii) the terms on which those products are available represent value for money.

(3) The information which the Welsh Ministers may require from a Part 4 provider or Part 7 provider by virtue of this section includes the following—

(a) the price charged or paid by the provider for health service products;

(b) the price paid by the provider for delivery or other services in connection with health service products;

(c) the discounts or rebates or other payments given or received by the provider in connection with the supply of health service products;

(d) the revenue or profits accrued to the provider in connection with the supply of health service products;

(e) such information about medicinal products, other medical supplies or other related products as is necessary to verify whether or not they are health service products.

(4) Regulations under this section may require information to be provided in such form and manner, and at such time or within such period, as may be prescribed.

(5) Regulations under this section may provide for a person who contravenes any provision of the regulations to be liable to pay a penalty to the Welsh Ministers.

(6) If regulations under this section make provision by virtue of subsection (5) they must include provision conferring on Part 4 providers and Part 7 providers a right of appeal against a decision of the Welsh Ministers to impose a penalty.

(7) The provision of information by virtue of this section does not breach—

(a) any obligation of confidence owed by the person providing it, or

(b) any other restriction on the provision of information (however imposed).

(8) In this section—

"health service products" means any medicinal products used to any extent for the purposes of the health service continued under section 1(1) and any other medical supplies, or other related products, required for the purposes of that health service;

"medical supplies" includes surgical, dental and optical materials and equipment;

"medicinal product" has the meaning given by section 130 of the Medicines Act 1968;

"Part 4 provider" means a person who provides primary medical services under Part 4;

"Part 7 provider" means a person who provides pharmaceutical services under Part 7.

201B Disclosure of information

(1) Information provided by virtue of section 201A may be disclosed by the Welsh Ministers to any prescribed person or person of a prescribed description.

(2) A person to whom any confidential or commercially sensitive information is disclosed under subsection (1) may not—

(a) use the information for a purpose other than a purpose specified in section 201A(2), or

(b) disclose the information to another person.

201C Sections 201A and 201B: supplementary

(1) Before making regulations under section 201A or 201B the Welsh Ministers must consult any body which appears to the Welsh Ministers appropriate to represent Part 4 providers or Part 7 providers.

(2) Nothing in section 201A or 201B requires information to be provided, or authorises information to be disclosed or used, in contravention of the Data Protection Act 1998.

(3) Nothing in section 201A or 201B affects any duties, obligations or powers to require or authorise information to be provided, disclosed or used which exist apart from that section."".—*(Mr Dunne.)*

This new clause is linked to amendments 36, 37 and 39 to 42. Inserted after clause 6, the new clause allows Welsh Ministers to require the provision of information by providers of primary medical or pharmaceutical services under Part 4 or 7 of the National Health Service (Wales) Act 2006.

Brought up, read the First and Second time, and added to the Bill.

New Clause 2

REPORTING REQUIREMENTS OF THE SECRETARY OF STATE

"(1) Within 12 months of this Act coming into force, the Secretary of State must prepare and publish a report on the use of the Secretary of State's powers under this Act and must lay a copy of the report before Parliament.

(2) The report under subsection (1) shall include an assessment of the impact of the use of the Secretary of State's powers on—

(a) the availability and cost of medicines and other medical supplies to the health service and the terms upon which they are made available;

(b) research and development;

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

(3) Subsequent to the publication of the report in subsection (1), as soon as is reasonably practicable after the end of each financial year the Secretary of State must prepare and publish a report on the use of the Secretary of State's powers under this Act during the preceding financial year and the impact of the use of those powers on the matters under subsection (2), and must lay a copy of the report before Parliament.".—*(Justin Madders.)*

This new clause would place a duty upon the Secretary of State to place a report before Parliament on an annual basis on the impact of the Act on the pricing and availability of medicines and other medical supplies, research and development and the NHS's legal duty to promote innovation.

Brought up, and read the First time.

Justin Madders: I beg to move, That the clause be read a Second time.

[Justin Madders]

As is explained in the explanatory note, the new clause would put a duty on the Secretary of State to place before Parliament an annual report on the impact of the Act and, in particular, on the pricing and availability of medicines and other medical supplies, research and development, and the NHS's legal duty to promote innovation. I think we all agree that there are examples of unreasonable behaviour, but there may be occasions when there is a difference of opinion as to what amounts to unreasonable pricing practices, not least between the producers and the NHS.

We would be more assured if the consultation on the regulations had been completed by this stage. We are obviously not going to be in a position to know what that consultation has to say for some considerable time, so we believe the implementation of such a requirement would allow Parliament to scrutinise the impact of the legislation.

There has been some unease in the sector about the impact of the legislation and there is a certain amount of uncertainty, particularly around the future of the European Medicines Agency and the medium-term implications of Brexit not only for that agency, but for the research and development sector and the pharmaceutical industry as a whole.

We are one of the foremost countries in the world for drugs development, and our share of sales of the top 100 prescription medicines is 14%. The UK pharma industry employs 73,000 people, with very high-quality jobs in academia and science, but we cannot be complacent about the state of UK pharma, particularly as investment decisions are often made by parent companies in other parts of the world. That concern is compounded by the small volume of sales in the UK compared with other countries. We face increasing competition from emerging economies for R and D investment, with rapid growth in areas such as Brazil and China. That is not a new problem.

A report for the Secretary of State for Health by Professor Sir Mike Richards in 2010 on the extent and causes of international variations in drug usage explored levels of medicines uptake for 14 categories of drug in 14 high-income countries during 2008-09. The study showed that the UK ranked eighth out of the 14 countries. A follow-up study by the Office of Health Economics updated the quantitative analyses and ranked the UK ninth across all the medicines studied.

Apart from disadvantaging patients, the relatively low take-up of new medicines may put at threat R and D investment in the UK. We need some assurance on that and an ability to monitor and engage with the Government on it. We know many other countries are queuing up to take the European Medicines Agency off our hands, and there are real concerns about the knock-on impact of that.

The impact assessment for the Bill says there will be a reduction in revenue for the pharma sector, unsurprisingly. It also says:

> "Reduced pharmaceutical company revenues are also expected to lead to a reduction in investment in research and development… and consequent losses of spill-over benefits for the UK economy, valued at £1.0m pa."

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.

Dr Whitford: I rise to echo some of the points raised. We have discussed a lot of issues around the decision to leave the EU, including the loss of the EMA. As well as possibly losing international and multinational pharmaceutical companies—particularly those from the London area, which have based themselves here because of the EMA—it is clear that drugs may end up going through a licensing process for the UK later than is currently the case. They are likely to go through the American market and then the EU market, which will still have 450 million people, and we are likely to slide down to be more like Canada and some other countries. This is a very unstable time for research, because of the loss of Horizon 2020 and the EMA, and for our pharmaceutical industry, which is a major player in the UK. It is incumbent upon Government to ensure that the Bill has no unintended consequences that exacerbate that.

3 pm

Mr Dunne: I thank the hon. Member for Ellesmere Port and Neston for raising the issue of reporting requirements, which is very important. I will come on to explain what is currently proposed through regulation. The hon. Gentleman and the hon. Member for Central Ayrshire mentioned the risks to investment in this country for our critical life sciences and pharma industries, which is a legitimate concern that the Government share. Irrespective of the manner in which Brexit takes place, it is important that we maintain the UK as a vibrant centre for such investment. We are aware of concerns from industry about the wider landscape, including Brexit, but the Bill is about getting value for money for the NHS and the taxpayer. It is just one element of the action that the Government are taking in the field of medicine and life sciences. Key industry stakeholders have indicated their support for many of the provisions in the Bill, as we heard in last week's oral evidence session, and for the broad principles of aligning the voluntary and statutory schemes and taking action against those companies that have made unjustified price hikes.

Separate from the Bill, the Government are taking action to secure the UK's future as an attractive place for the life sciences sector. We are clear in our commitment to life sciences, and to building a long-term partnership with industry. As an example, I draw Members' attention to the accelerated access review, which made recommendations on reforms to accelerate access to innovative medicines and medical technologies for NHS patients. The Government and our partners are considering those recommendations, and we will respond in due course. We want to make the UK the best place in the world to design, develop and deploy life sciences products. We do not believe that the Bill will have any material

impact on that effort, other than the minor impact noted in the impact assessment, which was referred to by the hon. Gentleman.

I point Committee members to the illustrative regulations for both the statutory scheme and the information provisions. First, the final regulation—regulation 32 on page 16 of the draft regulations—refers to the publishing of an annual report on the impact of the regulations. I think that is what the new clause is calling for, but it is already intended in the regulations. Secondly, the final regulation of the information provisions—regulation 14 on page 8—refers to the publication of a review of the information requirements we are proposing.

I accept that reporting is an important principle, but we believe that setting out the requirement to do so in primary legislation is too restrictive. It is expected that, over time, both the statutory scheme and the information requirements will be amended through their respective regulations to reflect changing circumstances. It is essential that the review and reporting arrangements can be similarly flexible so that they remain appropriate to the schemes in operation. Were the new clause introduced as the hon. Gentleman proposes, there would be a lot of prescription in primary legislation. Given the pressures on legislative time, we do not believe that that is the right way to do it.

I reassure Opposition Members that our illustrative regulations require an annual review to set out the scheme's objectives, and to assess the extent to which our objectives have been achieved and whether they remain appropriate. Those requirements will be tested through the consultation on the regulations. We will of course take account of the views expressed. Much of the information provided to the Secretary of State will be commercially confidential. I am sure that suppliers have every confidence that the Government will maintain that confidentiality in anything they publish, but I want to take this opportunity to reinforce that principle.

Rob Marris: If the draft regulations are to pass into legislation as currently drafted, I congratulate the Government on the annual review in draft regulation 32 and its Doppelgänger in draft regulation 14. They are excellent, because they actually talk about assessing the effectiveness, or otherwise, of a particular piece of legislation. That is often sorely lacking in this place, so I offer my congratulations.

Mr Dunne: Rare praise indeed from the hon. Gentleman. That is definitely going to go down in the annals of the *Wolverhampton Echo*, which I am sure will attribute an appropriate front page to that praise for the Government from the Member of Parliament.

To revert to where I had got to, I am sure hon. Members appreciate that there is clearly a limit to the level of detail we are able to publish, and I am sure that hon. Members appreciate that. Any information that we publish will be at a consolidated level, protecting suppliers' confidentiality, which I have touched on several times, but will allow the Secretary of State to be clear on the basis of the conclusions to his review. We will, of course, be able to use supporting information to evidence our conclusions.

Turning for a moment to the detail of the proposed new clause, while the requirements set out in it reflect the duties placed on the Secretary of State in the Bill, I must be clear that the content of such a report should not be restricted. It must be able to address key issues arising during the course of the year, in the case of the annual report, and during the seven-year duration of the information regulations, in the event that such implications might have an impact on the operation of the schemes. Flexibility is at the heart of our proposals to address the issue through regulations. It would not be appropriate for such a report to address matters relating to the NHS duty to promote innovation. That is the one point of more substantive difference that we have with the drafting proposed by the hon. Member for Ellesmere Port and Neston.

We have already discussed the Government's position on innovation. We are very clear that we are for it, as is the hon. Gentleman. However, we do not think it is appropriate to link measures in the Bill to that issue, which is a wholly different and much more wide-ranging issue than the narrower one of pricing and the cost of the medicines and medical supplies.

Julie Cooper (Burnley) (Lab): Does the Minister agree that there is a direct connection between control of the price of medicines and innovation, and that, if we do not achieve the correct balance, pharmaceutical companies will lack the motivation to invest in the extensive research and development that we all want to see?

Mr Dunne: I do not actually agree that there is a direct link. There is no question but that, in order to stimulate continued investment in R and D, it is appropriate for the industry to see a stable marketplace in a country as significant and important as the UK, and throughout the nations of the UK, for medicines and medical supplies. We are a large market. We spend more than £15 billion a year on pharmaceutical products, and we are also acknowledged by those companies to be a reference market for many other countries that do not have such a large or well-organised supply chain as we do. I accept that, in principle, it might be rather different if this were an emergent market.

Individual drugs are emerging through R and D programmes, but I do not think that is the same as the measures we are introducing, which are primarily designed to limit excessive abuses of pricing position, in which a company may be a monopoly supplier, in the case of the unbranded generics. For the branded products, we have a long-established procedure for recognising the recovery of R and D costs through the pricing mechanisms, and while we may not like paying for some of those branded products at the rate that we have to, we recognise that it is a competitive marketplace and, because of the cost of innovation—the cost of conducting clinical trials and so on—it is necessary to stimulate that innovation to ensure that those companies make a reasonable profit.

Promoting innovation is a high priority, not only for the Government and the NHS but for many other stakeholders in the industry. In our view, it would not be possible to quantify the contribution of the schemes in the Bill to that endeavour, for the reasons I have discussed. Trying to assess the impact on innovation is a much wider endeavour that does not just rely on price. For those reasons, I urge members of the Committee to reject the new clause.

Justin Madders: I hear the Minister, but I have to say that I respectfully disagree with some of what he said. I think there is a direct connection between the effects of

[Justin Madders]

the Bill and the impact on research and innovation. That is what the impact assessment clearly states. I feel that having draft regulations that have not yet been consulted on is not an adequate substitute for the assurances that we are seeking.

Mr Dunne: I am grateful to the hon. Gentleman for letting me intervene. We are not saying ourselves that there is no such direct relationship between innovation and the cost of drugs; we are taking evidence from a report on "Key Factors in Attracting Internationally Mobile Investments by the Research-Based Pharmaceutical Industry", which was undertaken by NERA Economic Consulting, and from a publication specifically on the voluntary scheme by the Office of Fair Trading. Both those documents date from 2007, when the hon. Gentleman's party was in office. The impact assessment, as he pointed out, refers to an impact of £1 million, which needs to be set against the benefit of close to £90 million that the high-value generic clauses impact. We therefore think, relatively speaking, that it is not significant.

Justin Madders: We will have to see whether those figures and estimates become reality, in particular in the light of the fact that the industry has not yet seen the regulations proposed. The approach is a wider one, based not only on the impact on research and development but on the continued duty of the NHS to promote innovation and the way in which the powers will affect the availability and cost of medicines and medical supplies. I will press this to a vote.

Question put, That the clause be read a Second time.

The Committee divided: Ayes 5, Noes 9.

Division No. 2]

AYES

Cooper, Julie	Madders, Justin
Cummins, Judith	
Kendall, Liz	Marris, Rob

NOES

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

Question accordingly negatived.

New Clause 3

REVIEW OF POWERS TO CONTROL PRICES OF UNLICENSED MEDICINAL PRODUCTS FOR HUMAN USE

"(1) Within six months of the passing of this Act, the Secretary of State shall commission a review of the adequacy of existing powers to control prices of unlicensed medicinal products for human use, including the enactment and enforcement of those powers, and shall lay the report of the review before the House of Commons."—*(Dr Whitford.)*

This new clause seeks to explore whether existing powers provided under the NHS Act 2006 regarding price control of "specials" are adequate.

Brought up, and read the First time.

Dr Whitford: I beg to move, That the clause be read a Second time.

The point of the new clause is to explore a particular problem with what the Minister referred to earlier as "specials". They are unlicensed preparations, often topical medicines, often used for severe skin conditions such as hard-to-control psoriasis. The British Association of Dermatologists reports that patients in England, Wales and Northern Ireland are struggling to get them prescribed, because the costs have spiralled out of control.

In Scotland, until last September, three quotes had to be obtained and one of them had to be from an NHS manufacturer. That has been streamlined, and a single quote, provided it is from an NHS manufacturer, is now acceptable. The British Association of Dermatologists looked at the 12 top specials that its members prescribe and estimated that if an NHS manufacturer had been used, instead of £845,000, the cost would have been £162,000. The association also reported that several private manufacturers are keeping two price lists—one for Scotland and one for England—and some of the dermatology items in England are eight times the price in Scotland.

That is literally holding people to ransom, and the result, because CCGs are hard pressed for cash, is that they are not comfortable funding specials and GPs are not allowed to prescribe them. Anyone who has ever had a dermatological condition of any kind, or knows someone who has, knows how unpleasant and utterly dominating of one's life it can be. It is awful that patients, in particular in England, are not able to access such medicines. The new clause is looking at whether specials will be covered and whether enough attention is to be paid to them. The number of patients is small—hence the top 12 still come to less than £1 million—but for those patients this is a major issue.

3.15 pm

Mr Dunne: Again, I am grateful to the hon. Lady for drawing the Committee's attention to the issue. I confirm, for the benefit of the Committee, what the specials are—she has characterised them well.

From our perspective, unlicensed medicines or specials can be manufactured or imported to meet a patient's individual needs when no licensed product is available. By their nature, specials are bespoke, and costs need to be balanced against the availability of treatment for an individual. I am aware of concerns that some specials, especially those not listed in the drug tariff, are not being prescribed because of their cost—the hon. Lady highlighted those for dermatological treatment. It must be recognised, however, that with specials, because of their bespoke nature, there are few if any economies of scale and they can be expensive to manufacture.

Under section 262 of the 2006 Act, the Government have the power to limit the price of any health service medicine, as long as the manufacturer is not in the voluntary scheme. Manufacturers or importers of specials are generally not in the voluntary scheme. Specials are health service medicines and we can therefore limit their prices. At the moment, the Government do not use their power to control the prices of specials. The hon. Lady gave an example, without naming the product, of a significant price differential between Scotland and England; if she is willing to write me a note after the Committee, I

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

Dr Whitford: While there are not major economies of scale, if national health manufacturers are used, it is possible at least on a regional basis to pool some together. As things are at the moment, a pharmacy can simply approach its sister or mother company and ask for a price, which creates a vested interest in making the price high. I think that things can be done, which seem to be working in Scotland, so they are worth trying.

Mr Dunne: Again, I am grateful to the hon. Lady—

The Chair: Order. We have a Division in the House, so I will suspend the sitting. If there is one vote, may I ask Members not to take longer than 15 minutes to return and, for every subsequent vote, no more than 10 minutes? The Committee will sit after 15 minutes.

3.17 pm

Sitting suspended for a Division in the House.

3.31 pm

On resuming—

Mr Dunne: As we broke—literally, I was saved by the bell—I was describing how setting prices as suggested by the new clause could have unintended consequences. We are concerned that it may lead to manufacturers stopping the production of some specials if they are no longer profitable and patients facing adverse consequences.

By setting reimbursement prices in the drug tariff in primary care, the Government encourage pharmacy contractors to source specials as cheaply as possibly, which in turn creates competition in the market and, as a result, reimbursement prices decrease. For those specials not listed in the drug tariff, pharmacy contractors have no incentive to lower the list price. Currently, less than 1% of the total expenditure on medicines in primary care is on specials. Nevertheless, I believe those products, like all other products destined for the health service, should provide value for money to the NHS and the taxpayer. The information power in the Bill will help the Government to determine whether the products provide value for money and the illustrative regulations include an obligation to review those provisions.

The new clause would require the Secretary of State to commission a review of the adequacy of existing powers to control prices of specials, including the enactment and enforcement of those powers. The Government keep their power to control prices under review all the time; it was a review of those powers that led to the Bill in the first place. The Government believe that we have sufficient powers to limit the prices of specials if need be. The hon. Member for Central Ayrshire appears to have evidence of specials being priced to Scotland materially more advantageously than to England. If she would be willing to make that information available to us, we would be delighted to consider it.

Dr Whitford: I wonder whether the Government have given any consideration to having NHS manufacturers provide these products or to including some of the topical specials in the drug tariff, so that the price is kept down. Otherwise, despite the Bill, these drugs will be left outside its provisions. They are going to be too expensive and patients will suffer from that.

Mr Dunne: For the reasons that I have said, we have the power to look at the pricing of the specials already and we have not had evidence that the pricing has been abusive. We already have that power. We will keep prices and specific drugs under review. The best way to take that forward is to leave the powers as they are and not to proceed with the new clause, but to invite hon. Members to highlight specific examples that they are aware of.

Rob Marris: The Minister says that the Government have the power. He may well be right, but for us lay people these are quite complex issues. The power to which he adverted is section 262 of the 2006 Act, which, as far as I can see, is not amended by clause 7 of the Bill. As I understand it, section 262 continues unamended. Section 262(2) says:

> "The powers conferred by this section are not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies."

This may well be my ignorance when it comes to topical medicines, specials and so on. Perhaps all specials are produced by manufacturers or suppliers that are not in the voluntary scheme. I can see the possibility. If the Minister can confirm that, I will see that section 262 does not apply.

Mr Dunne: The hon. Gentleman has again surprised me by apparently not being as attentive as usual to the comments that I made earlier. I said while introducing the new clause that manufacturers or importers of specials are generally not in the voluntary scheme. There may be some exceptions, but by and large, they are not. Therefore, we are in a position to limit the price of specials, but as a rule we have not adopted that power.

Rob Marris: That is helpful of the Minister, but it still confuses me a bit, and I hope that he can help to elucidate. He said that manufacturers and suppliers are not generally in the scheme; that is the adverb that he used a moment ago. That suggests to me that some of them might be, and would therefore not be subject to the section 262 price controls, which he prays in aid when he says, as I understood him to say to the hon. Member for Central Ayrshire, "Nice try, but no cigar. We're not going to accept this." One reason that he gave—not the only reason—was that we already have the power. The adverb "generally" suggests to me that in relation to some companies, we do not.

Mr Dunne: But this applies to all companies in the voluntary scheme. There is no particular difference between a special and a non-special. If a company is supplying products in the voluntary scheme, it is in the voluntary scheme. Therefore, it is at the negotiating table when it comes to considering the circumstances in which it supplies those products. If the company is in the scheme, that includes the specials.

Rob Marris: I thank the Minister; that is helpful. He is on top of his brief, as ever, and needed no inspiration to tell me that. It is helpful. The power does exist. I

[Rob Marris]

would like to ask the hon. Member for Central Ayrshire, because she has considerable expertise in the field. My expertise, such as it is, is as a lawyer. I see in her new clause the words

" unlicensed medicinal products for human use".

She may be able to tell me, because it is her new clause and she may have been looking at this issue. Where in the 2006 Act, or indeed in the Bill, although I think not, can we find what that phrase means? It may well be understood by medics—the topicals, the specials and so on—but it may not be understood by judges, for example. Can she help me on that when she winds up this debate? Otherwise, it seems to me as a layperson that the phrase

" unlicensed medicinal products for human use"

could cover homeopathic so-called remedies. I do not think that the Secretary of State should be reviewing the pricing of homeopathic remedies.

To make my position clear, I think that homeopathy is bad science and a load of nonsense except for the placebo effect, but I use it as an example of unlicensed products that claim to be medicinal. I suspect that the hon. Member for Central Ayrshire would agree with my broad characterisation of homeopathic so-called medicines, apart from the placebo effect. What does that phrase in her new clause mean, and is it defined anywhere in law, or is it so obvious to medics that they and everybody in the pharmaceuticals business know what it means?

Dr Whitford: The phrase is the standard definition of specials. I cannot remember off the top of my head where exactly it comes from, but it is the recognised definition. It would not usually mean things such as homeopathic medicines. It is often things that are quite old and that have been around a long time that are not worth licensing, because they are not new and nobody will make any money out of them. We have a lot of products like that, but they are recognised within the practice of medicine. They are particularly common within dermatology, because of different topicals and the need to make different strengths of topical depending on the condition being treated.

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

Clause, by leave, withdrawn.

New Clause 4

Review of extending provisions to repurposed off-patent drugs

'(1) Within six months of the passing of this Act, the Secretary of State shall commission a review on whether the provisions of this Act shall extend to the regulation of the prices of repurposed off-patent drugs and shall lay the report of the review before the House of Commons.'—*(Dr Whitford.)*

Brought up, and read the First time.

Dr Whitford: I beg to move, That the clause be read a Second time.

The new clause seeks to explore one of the other anomalies that was challenged through a private Member's Bill last November but unfortunately was talked out by the Minister at that time: repurposed off-patent drugs. Those are drugs designed for a particular use that, often during their use for that condition, contribute in relation to another condition.

Today, we have had considerable talk about the need to support pharmaceutical industries and encourage research and development, but the finding of a new purpose for a drug rarely comes from the pharmaceutical industry; it is usually done at a clinical or academic level through noticing patterns in clinical practice and following those up with trials. It is therefore not really something for which the pharmaceutical industry should receive a major award financially, although naturally if more of a company's drugs sell and it is still producing them, it will see a benefit, which is totally fair enough.

One of the concerns is that, for a medic under the General Medical Council, there is a hierarchy of what we can prescribe, and at the top of that is licensed drugs for the purpose of the licence. Below that come repurposed drugs, which are therefore not licensed for that purpose. It is specifically stated that "they do the same" is not a sufficient excuse for using an off-patent generic drug.

With some of the drugs we have, new purposes are being discovered. Some statins can reduce brain atrophy in progressive multiple sclerosis. We have, as was referred to earlier, the use of bisphosphonates to prevent metastatic breast cancer and the use of tamoxifen to try to prevent breast cancer. That Bill was partly about trying to promote the use of those drugs, because they are off-patent and cheap, but one of the concerns among the medical profession is about a drug company buying a drug, tweaking it ever so slightly and then suddenly re-releasing it as a drug for multiple sclerosis at 10 grand a day instead of sixpence. What I do not see in this Bill is a recognition of the ability of people to come back and license a drug and totally change the price or to manufacture that drug simply as a generic with a massive price.

There was a case with the drug Lyrica, which is also known as pregabalin. The commonest use of that is for neuropathic pain: people who have had nerve damage from surgery or trauma and have difficult-to-control pain. The drug was originally designed for epilepsy, and Pfizer, which makes it, managed to get a court order saying that the patent on its use for neuropathic pain would continue to 2017 and that it would sue general practitioners who prescribed it as generic. That case has run for quite a long time, and I am proud to say that GPs basically ignored that order and have used the generic, but the advice of NHS England, which still sits on the website, says that GPs must prescribe Lyrica as Lyrica, which is obviously much more expensive. Therefore, over the last year GPs have had to be sitting out there exposed, open to the threat of litigation.

That is a real concern with repurposed drugs. That profit has been earned not by pharma's research but by the research of other people usually in the public sphere: academics and in the NHS. Again, the new clause is to raise an issue that is not covered in the Bill and to see whether it has been considered at all by the Government.

3.45 pm

Mr Dunne: I am grateful to the hon. Lady for raising this issue by tabling her new clause, because it gives us an opportunity to discuss an issue of considerable interest across the House. I am delighted to be able to inform the Committee that we do not believe we need to review whether the Bill's provisions should be extended to repurposed off-patent drugs, because they will apply to those drugs whether they are licensed branded medicines or generic medicines. The new clause is therefore not necessary, because those drugs are already included.

Any licensed branded medicines that are developed may be included in either the voluntary or statutory scheme and be subject to all the provisions of those schemes. Unbranded generic medicines are subject to competition in the market, which keeps prices competitive and secures value for money. As we know, and have already debated today, there are examples of unscrupulous companies making unjustified price hikes for unbranded generic medicines when there is no competition in the market. As we have said, both today and on Second Reading, the Bill provides the Secretary of State with powers to intervene in such cases, in addition to the powers that the Competition and Markets Authority can exercise.

Having once again explained the specifics of how repurposed medicines will be affected by the Bill's provisions, it might be helpful if I outline for the Committee some of the progress that has recently been made in supporting repurposing. For the reasons the hon. Lady identified, repurposing has benefits for patients in allowing drugs to be introduced as quickly as possible to provide alternative treatments to those originally intended by their manufacturers, where there is robust clinical evidence for new uses of existing medicines. 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.

I hope that with that explanation, hon. Members will agree not only that repurposed medicines are included within the Bill's provisions, but that robust action is being taken by the Department and across the medical establishment to support repurposing for the benefit of patients. I ask the hon. Lady to withdraw her new clause.

Dr Whitford: I welcome the Minister's explanation of what has been happening behind the scenes since the Off-patent Drugs Bill last year. The Bill Committee, of which I was a member, had a lot of discussion about the need to have a system for recognising the drugs, giving doctors and other prescribers the reassurance they needed to use them, and using the "British National Formulary" as a tool. We have heard nothing for a long time, so I really welcome the update that the issue is being taken forward. Prescribers are not all doctors now, and it is important that everyone who prescribes has the reassurance of knowing that they can safely prescribe and not be open either to making an error or to litigation. I beg to ask leave to withdraw the motion.

Clause, by leave, withdrawn.

New Clause 5

EXTENDING PRICE CONTROL TO OTHER MEDICAL SUPPLIES

'In section 260(5) of the National Health Service Act 2006, after first "includes" insert ", but is not limited to, investigative,"'—*(Rob Marris.)*

This new clause is to ensure that the Bill's provisions on price control apply to other capital equipment such as MRI scanners by including such items within the definition of "medical supplies".

Brought up, and read the First time.

Rob Marris: I beg to move, That the clause be read a Second time.

I am glad that the Committee has generously left me sufficient time to deal with the new clause, which involves a tweak in the wording of the Bill. Clause 6 inserts section 264A into the 2006 Act, and section 264A(9) states:

"'Medical supplies' is to be read in accordance with section 260(5)"

of that Act. There is a synopsis of the subsection in paragraph 66 on page 14 of the explanatory notes, which hon. Members may have in front of them.

Page 162 of the 2006 Act states, in section 260(5):

"In this section and Schedule 22—

[Rob Marris]

'medical supplies' includes surgical, dental and optical materials and equipment…and 'equipment' includes any machinery, apparatus or appliance whether fixed or not, and any vehicle."

That definition is fairly clear but not sufficiently wide, hence my new clause, which would clarify it. Regarding medical supplies, there are, to my mind, three adjectives there qualifying two nouns, the three adjectives being "surgical", "dental" and "optical", and the two nouns being "materials" and "equipment". There is considerable NHS expenditure on equipment—and materials, but particularly on equipment—that is not, as I understand it, surgical, dental or optical. A particularly expensive form of such equipment, as I outline in the explanatory note, which is helpfully on the amendment paper, is MRI scanners. They vary, obviously, but in round terms they cost about £2 million a throw and the NHS, understandably, has an awful lot of them—they are a magnificent diagnostic tool. There may well be other pieces of equipment that are perhaps not quite as expensive but which would not come under the rubric of surgical, dental or optical.

It seems, therefore, that there is a gap in the 2006 Act, and the new clause, which I am sure the Government will accept, is intended to plug that gap by indicating that those three adjectives are descriptive of the two nouns, but other adjectives could also be applied. For example, "investigative" is included in the new clause. The new clause would therefore simply ensure that there is no misunderstanding of the intent of section 260(5) of the 2006 Act. It is a helpful clarification to the Government.

Mr Dunne: I am sure that you share, Mr Pritchard, my pleasure that the Committee has had the benefit of the hon. Gentleman's forensic scrutiny and his particular facility for not only the English language but its parliamentary use. If we had not had a new clause tabled by him we would have all gone away deeply disappointed. I am grateful to him for taking such trouble to table the new clause and to explain its intent.

I can assure the hon. Gentleman and the Committee that MRI scanners, by way of example, and all other investigative medical supplies are covered by the current definition of "medical supplies" in the 2006 Act. When looking at the definitions in the first draft of the Bill, I had a concern that we were describing products too widely. My concern was not that we would exclude specialist medical equipment but that we might include other materials used in the construction of buildings used by the health service—for example, bricks—as an object for price control, which clearly is not the intent. We looked carefully at the definitions, which is why I can say with some confidence that the hon. Gentleman's new clause is unnecessary.

I will explain that more specifically. Section 260 of the 2006 Act makes it clear that "medical supplies" should be read in the context of medical supplies required for the purposes of the health service. That excludes all medical supplies not destined for the health service. MRI scanners clearly are destined for and used in the health service. Secondly, section 260 provides examples of products that would be included by the term "medical supplies" and does not limit it to those products.

The Government consider that the current definition of "medical supplies" already includes the examples given by the hon. Gentleman and other investigative products and that there is no need to make the proposed amendment. We are concerned that by including further examples and trying to provide a definition that meets the hon. Gentleman's intent, we might inadvertently find ourselves excluding other things that are in fact included within the more general description of medical supplies. The current definition is sufficiently broad to cover all medical supplies required for the purpose of the health service. Notwithstanding the hon. Gentleman's enthusiasm, I encourage him to withdraw the new clause.

Rob Marris: I beg to ask leave to withdraw the clause.

Clause, by leave, withdrawn.

Question proposed, That the Chair do report the Bill, as amended, to the House.

Mr Dunne: We are now at the conclusion of our deliberations. Thank you very much indeed, Mr Pritchard, for using your new-found experience in chairing Bill Committees to such good effect. You have conducted our affairs in a characteristically skilful way, and I am grateful to you, the Clerks and the Doorkeepers for managing the Divisions. I am grateful to the Front-Bench spokesmen from both the official Opposition and the SNP, as well as to all Back Benchers who have contributed to our deliberations. We have given this short Bill adequate and appropriate scrutiny, and I hope it will proceed to consideration on Report, where it will get continued consensual support across the House, which is, frankly, a joy to participate in.

Justin Madders: I echo the Minister's words of thanks, including to you, Mr Pritchard, for the sensitive way you have handled our discussions. We have made good time today, while enabling everyone to contribute who wished to. I am grateful to the Minister for his clarification on a number of points. There are issues we will have to continue to discuss, but in the main he has been able to put our mind at rest on a number of issues. I also thank the SNP Members for their contributions, as well as all Back Benchers.

The Chair: I thank the Clerks, officials, Doorkeepers, the Minister of State, shadow Ministers and all colleagues.

Question put and agreed to.

Bill, as amended, accordingly to be reported.

3.59 pm

Committee rose.

Written evidence reported to the House

HSMSB 05 British Healthcare Trades Association

HSMSB 06 RFW Associates

HSMSB 07 British Association of Dermatologists