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Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Tuesday 27 March 2012

Session 4

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CONTENTS

HEALTH AND SPORT COMMITTEE
12th Meeting 2012, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

*Bob Doris (Glasgow) (SNP)

COMMITTEE MEMBERS

*Jackson Carlaw (West Scotland) (Con)
*Jim Eadie (Edinburgh Southern) (SNP)
*Richard Lyle (Central Scotland) (SNP)
*Fiona McLeod (Strathkelvin and Bearsden) (SNP)
*Gil Paterson (Clydebank and Milngavie) (SNP)
*Dr Richard Simpson (Mid Scotland and Fife) (Lab)
*Drew Smith (Glasgow) (Lab)

COMMITTEE SUBSTITUTES

Rhoda Grant (Highlands and Islands) (Lab)
Adam Ingram (Carrick, Cumnock and Doon Valley) (SNP)
Nanette Milne (North East Scotland) (Con)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Chad Dawtry (Scottish Public Pensions Agency)
Joan Fletcher (Association for Glycogen Storage Disease UK)
Eleanor Guthrie (Scottish Public Pensions Agency)
Lesley Loeliger (PNH Scotland)
Stephen Nutt (Rare Disease UK)
Nicola Sturgeon (Deputy First Minister and Cabinet Secretary for Health, Wellbeing and Cities Strategy)

CLERK TO THE COMMITTEE

Douglas Wands

LOCATION

Committee Room 2

Scottish Parliament

Health and Sport Committee

Tuesday 27 March 2012

[The Convener *opened the meeting at 10:08*]

Decision on Taking Business in Private

The Convener (Duncan McNeil): Good morning and welcome to the 12th meeting in 2012 of the Health and Sport Committee. I remind all who are present that mobile phones and BlackBerrys should be turned off because they interfere with the sound system.

Agenda item 1 is to decide whether to take in private items 6 and 7. Item 6 is consideration of the committee's approach to future scrutiny of issues raised relating to the petitions that we will consider today. Item 7 is consideration of our work programme. Do members agree to take those items in private?

Members *indicated agreement.*

Dr Richard Simpson (Mid Scotland and Fife) (Lab): Are we taking item 8 in private, too?

The Convener: Yes—we agreed at a previous meeting to take item 8 in private.

Petitions (Witness Expenses)

10:09

The Convener: Agenda item 2 is to invite the committee to delegate to the convener responsibility for arranging for the Scottish Parliamentary Corporate Body to pay, under standing orders rule 12.4.3, expenses of witnesses who attend to give evidence on the petitions. Do members agree to delegate that responsibility to me?

Members *indicated agreement.*

Subordinate Legislation

National Health Service (Superannuation Scheme and Pension Scheme) (Scotland) Amendment Regulations 2012 (SSI 2012/69)

10:09

The Convener: Agenda item 3 is evidence on the National Health Service (Superannuation Scheme and Pension Scheme) (Scotland) Amendment Regulations 2012. The item follows a request from the committee for oral evidence from the Scottish Government on the negative Scottish statutory instrument. I welcome the Cabinet Secretary for Health, Wellbeing and Cities Strategy, Nicola Sturgeon; Chad Dawtry, who is director of policy, strategy and development in the Scottish Public Pensions Agency; and Eleanor Guthrie, who is a senior policy manager with the Scottish Public Pensions Agency. I invite the cabinet secretary to make brief opening remarks.

The Deputy First Minister and Cabinet Secretary for Health, Wellbeing and Cities Strategy (Nicola Sturgeon): I take no pleasure whatever in speaking to the regulations. I recognise—from the number of people in the public gallery—the strength of feeling on the issue and I understand the reasons for it. As members will be aware, the Scottish Government has repeatedly made clear our opposition to increasing employee contributions at this time and in this way, and we have called repeatedly on the United Kingdom Government to rethink its policy. At a time of pay freezes, increases in national insurance contributions, higher VAT and rising inflation and fuel costs, we believe that it is wrong to require public servants to increase their pension contributions. Indeed, we go further than that and consider that pensions should be within the remit and decision-making power of this Parliament—not the UK Parliament.

As members will be aware, the UK Government has refused to change its policy. On 5 September last year, the Chief Secretary to the Treasury wrote to the Cabinet Secretary for Finance, Employment and Sustainable Growth to make it clear that the Scottish Government budget would be cut to the tune of £8.4 million for each month beyond April this year in which the increases were not implemented in the national health service, teachers', police and firefighters' schemes. That would reduce the Scottish budget by about £100 million in 2012-13, more than half of which would come from the NHS budget, which would have a serious impact on front-line services.

It was therefore with considerable—I stress "considerable"—reluctance and regret that the Scottish Government decided that the increases to the four schemes would have to be implemented from April this year in order to avoid passing on to our public services and communities the £100 million reduction in the Scottish budget that we would otherwise face.

We have put in place protection for the lowest-paid people. For example, nobody in the NHS scheme in Scotland who earns below £26,557 per annum full time will pay a single penny more. To put that in context, that means that 47 per cent of the NHS workforce will not face increased contributions in 2012-13.

I stress that the regulations apply to 2012-13 and that we have not yet taken decisions for 2013-14 and 2014-15. The position for those years will be considered in the context of negotiations with scheme stakeholders on the terms for a reformed NHS pension scheme in Scotland, which we expect to be in place in April 2015. In fact, those discussions will kick off tomorrow at a meeting of the Scottish terms and conditions committee, which I will attend.

That is all I want to say by way of introduction. We are going down this road with considerable reluctance, and the situation that we are in stems from the fact that pensions are, substantially, a reserved matter. That, as well as its practical implications, are things that the Government regrets.

Dr Simpson: Am I correct that the NHS pension scheme is currently in surplus? If so, what is the surplus? Underlying that is a question about whether the proposed additional contributions are to maintain the balance of the scheme or are part of a deficit reduction contribution that is being levied specifically on public sector workers.

10:15

Nicola Sturgeon: The answer to your first question is yes: the NHS pension scheme is in surplus. In this year, 2011-12, £887 million is going into the scheme and £810 million is coming out. The projected figures for 2012-13 are £879 million and £883 million.

As I and my fellow ministers have said previously, the UK Government's policy of increased pension contributions is not about the sustainability of pensions but about deficit reduction. It is wrong to seek to reduce the deficit at the expense of public sector workers in that way.

However, the position that we are in is as I narrated it in my opening remarks: if we do not implement the increases from April, the NHS budget alone will take a hit of £4.6 million every month. On other occasions and in different contexts, we have discussed around this table the pressure that the NHS budget is under. In all conscience, I cannot allow the NHS budget to take such a hit, because that would hit front-line public services.

I made the point in my opening comments that only NHS staff who earn more than £26,500 per annum will pay increased pension contributions in 2012-13, so the 47 per cent of the NHS workforce who earn less than that figure will pay no increased contributions in the year ahead.

Dr Simpson: That point leads into my next question. I am advised that the pension rate will be levied on the basis of the pro rata full-time salary. Many staff—particularly women—are part time. If someone has a pro rata full-time salary of £30,000 but earns only half that, because they work only half time, their percentage will be that for £30,000 and not the lower rate. You were careful with your words in saying that nobody who earns less than £26,500 full time will pay an increased contribution, but if I am correct the effect on many part-time women workers in the health service will be punitive. I would like confirmation of whether there is an anomaly that will be particularly punitive for part-time women workers.

Nicola Sturgeon: I was not being "careful" with my words; I was being honest with the committee.

Dr Simpson: I was suggesting nothing else.

Nicola Sturgeon: I referred deliberately to full-time salaries. The premise of Dr Simpson's question is correct: it is standard practice in public sector pension schemes to levy the pension rate on full-time salaries.

It is important for me to be clear: I am not defending the pension contribution increases. I really wish that we in the Parliament were in a different position and that we had control over our resources and our pensions policy, so that we could take different decisions. Believe me—it gives me no pleasure to find myself in the current position, but it is the reality in which we live right now.

As I said, tomorrow we will with NHS stakeholders kick off scheme-specific discussions for the longer term, for the same reason why we are having today's discussion, which is that we are required to work within a financial envelope. However, we have made it clear that we are open to negotiations on how we can do things differently in Scotland, if there is the will to do that. I hope that the discussions will be constructive and will allow us to get to a different position.

Dr Simpson: I fully appreciate the Scottish Government's position and I understand that you

do not wish to cut the NHS budget by about £50 million. Nevertheless, that choice is open to the Scottish Government. You say that you are unhappy about the situation—I appreciate and understand that—and that the UK Government has put you in a particularly difficult position, but the choice is still for the Scottish Government to make. If the scheme is in surplus by £77 million this year, which is more than the loss that the NHS budget would experience, is that surplus accessible to you? Why cannot you decide to postpone the increases for a year because the scheme is in surplus?

Nicola Sturgeon: The figures are cash-flow figures and relate not to pensions paid out, but to future pensions commitment—

Dr Simpson: I understand that, but there is still a surplus in the pension scheme.

The Convener: Richard—let the cabinet secretary finish.

Nicola Sturgeon: Sure, there is a surplus—but the solution is not quite as simple as offsetting in the way that you suggest.

As regards the premise of your question about choices, a choice to take £50 million out of the health budget is not—given its implications—one that I consider to be possible in the context of the financial environment that we live in. I am sure that if I were reducing the health budget by £50 million, I would be getting fairly severe criticism from members who hold the point of view that Richard Simpson is putting forward. It is understandable that he is doing so; that is not a criticism.

The situation is not of the Scottish Government's making. As I have said, I wish that we had control over our own resources and our own pensions policy; perhaps the Parliament will get those powers in the not-too-distant future. I do not take any pleasure in being put in this position by the UK Government, but for as long as the UK Government controls such matters, that will be the reality of the world that we live in.

Richard Lyle (Central Scotland) (SNP): Good morning, cabinet secretary. I agree totally with the comment that you have just made. People can make choices when they control their own affairs, their own money and what they can do with that money. The Scottish Government is being forced to make cuts by the UK Government because it is trying to reduce the deficit. I totally disagree with the way in which it is forcing us to do that.

I understand that, in a submission to the Scottish Government, Unison has suggested that the efficiency savings of more than £175 million that have been made in health could be used to not implement the increases in pension contributions, but you have said that the money from the efficiency savings needs to be invested in front-line services. That is my first point.

I turn to the local government pension scheme, which we are refusing to—

The Convener: I am sorry, Richard. That is not a matter for this committee.

Richard Lyle: Okay.

No one who earns less than £15,000 a year will face an increase in their contribution. Can you confirm that no one who earns between £15,000 and £21,000 will have to pay more than half the average increase in contributions?

Nicola Sturgeon: I will come back to that point.

Your first point was about efficiency savings. Efficiency savings that are made by NHS boards are reinvested in front-line services. If some of the efficiency savings money were to be used to plug a gap in pensions, that amount of money would not be available in the future for front-line services, so the hit on front-line services would be the same, regardless of how it came about.

I have no criticism whatever to make of Unison or any other union that is campaigning against pension contribution increases. I fully understand their position. However, the choice that I face is—to use Richard Simpson's terminology—Hobson's choice. If I were to take the other route, I would cut £50 million a year from the health budget. As well as having understandable concerns about pension contributions, unions including Unison rightly make representations on the size of the NHS workforce and the other implications of the efficiency savings that the health service makes, and I would simply be increasing that burden. I do not consider that we have much of a choice: we have been backed into a corner by the UK Government. I do not like that and I desperately hope that we can get into a different position for the future, whereby the Scottish Parliament and the Scottish Government are the decision makers not just in name, but in reality and in substance.

Richard Lyle's second point goes back to the point that Richard Simpson made. I think that the figures that you quoted are for policy across all schemes. The figure that I gave in response to Richard Simpson's question is specific to the NHS. The £26,500 figure that I quoted, below which there will be no increase, is a whole-time, full-time figure.

Richard Lyle: I appreciate that you are not involved in the banking side, but I return to the question that Richard Simpson posed about the fact that the NHS pension scheme is in surplus. I note that most pension schemes rely on the value of shares, and the share market is volatile at present, given the problems that the UK has faced in the past number of years. Do you agree that the

fact that a pension scheme is in surplus now does not necessarily mean that it will be in surplus in the future?

Nicola Sturgeon: I ask Chad Dawtry to comment from the Scottish Public Pensions Agency perspective and to give a wee bit more explanation of the point about the surplus and accounting in relation to pension schemes.

Chad Dawtry (Scottish Public Pensions Agency): It is probably a good thing to recognise that the NHS scheme is what is known as an unfunded scheme, or a pay-as-you-go scheme, so it does not have any investment funds backing it up. It relies on the Government of the day to stand behind the pensions promises that have, in effect, been bought with previous contributions.

As far as the surplus is concerned, it rather depends on the demographics of the scheme. In recent years, we have seen a number of schemes, such as the teachers' scheme, change from a position in which there was a cash-flow surplus of income over expenditure on pensions. As Richard Lyle rightly suggested, that will change over time as the pensions promises that have been built up over many years fall due.

Richard Lyle: Thank you.

Bob Doris (Glasgow) (SNP): I have great sympathy with health service staff, Unison and their campaign. I will summarise where we are. I note that the UK Government knows that the health scheme is in surplus. Unison states in its submission to us that it seeks a Scottish solution to the issues of the long-term sustainability of pensions, but the Barnett formula is being used as a gun to the head of the Scottish Government, and is getting in the way of that to the tune of £550 million over the spending review period.

It seems that you're damned if you do and damned if you don't: either you take money away from front-line services, or you place an increasing burden on NHS staff. Neither is a choice that you wish to make, but you must choose one. I agree with you that protecting front-line services should take priority—it is with a heavy heart that I say this—over avoiding increasing the cost burden on NHS staff.

I mention the Scottish solution for which Unison is calling because you mentioned that you hope to have had by 2015 negotiations with health sector trade unions on a new Scottish scheme. Is the Barnett formula a barrier to long-term sustainable health service pensions? Whatever discussions you have with Unison about how to structure pensions, you have to look over your shoulder to a UK Government that is saying, "If you do it this way, we'll take £50 million from you, and if you do it that way, we'll take £150 million from you." Is the Barnett formula tying your hands and preventing you from finding a Scottish solution in respect of sustainable public sector pensions?

Nicola Sturgeon: Let us just say that the Barnett formula does not make it easy. Today, we are talking only about the contribution increases for 2012-13; we are not talking about anything beyond that. As I said in my opening remarks, we have deliberately taken no decisions for years 2 and 3 of the scenario. For as long as we, as a Parliament, are funded as we are, if we go outside the financial envelope of the UK Government in terms of pension contributions or the overall cost of a pension scheme, that money will be docked from our budget. If we have a pension scheme that is in any way more costly than the UK Government's, we have to pay for it, and the money has to come from elsewhere in our budget, with the associated impact on front-line services.

I mentioned the STAC committee meeting that will take place tomorrow, and we have said that we are keen to negotiate on the longer term, but as I said, for as long as we are funded in the current way, we need to keep our eye closely on the financial envelope. However, we are keen in those discussions to maximise the range of issues that we are able to consider in negotiations—including, for example, the issue of normal pension age and state pension age—and to look at second and third-year contribution increases to see whether there are different ways of doing things. I do not want to say any more about that just now, because to do so would be to pre-empt the result of negotiations that are under way, but the Government is willing to try to get a better package put together, if that is at all possible. That said, we need to stay within a financial envelope: if we do not, the impact on front-line services will happen further down the line

10:30

Bob Doris: Does the fact that this is a one-year pension increase mean that you are hopeful of, or optimistic about, finding another way to ensure future long-term sustainability? More important, will that involve the UK Government reconsidering its position on the issue and our continuing to make representations on the matter?

Nicola Sturgeon: We would not be going into negotiations if we did not want to find a different way. Because negotiations have not started, I cannot say whether that will be possible, but the Government—I know that I speak for my ministerial colleagues with regard to the schemes that they are involved in—is willing to seek common ground and to find a different way.

We continue to make representations to the UK Government. Although I do not think that there is any immediate prospect of the UK Government

changing its policy on this—there is certainly no sign of that on the horizon—that does not mean that we will not continue to make our views, which reflect the views of the public sector in Scotland, abundantly clear to it.

Bob Doris: Has anyone suggested where the £50 million might come from, should the regulations not be imposed?

Nicola Sturgeon: There has to my knowledge been no such suggestion. My experience is that there are never too many people who want to make those kinds of suggestions—understandably so. That is not a criticism; no one likes to consider where the impact of any cut might be felt. Over the lifetime of the Government, we will be increasing the health budget in what are very difficult circumstances. However, taking £50 million out of the budgets that we have set in the comprehensive spending review would be a difficult challenge and, indeed, it is the reason why I am sitting here this morning having this discussion.

Bob Doris: This is not a question; I simply note that evidence that has been taken by the committee consistently shows that efficiency savings in the NHS must be reinvested in the service in order to deal with sharply increasing demands that result from demography or health sector inflation.

Jackson Carlaw (West Scotland) (Con): Good morning, cabinet secretary. For the committee's benefit, can you provide illustrative examples of the kind of pension that NHS employees currently receive and the pension that they would receive in the future?

Nicola Sturgeon: I can provide the committee with as much detail on the matter as it wants. According to figures for 2010-11, the average NHS pension is £7,057.

Jackson Carlaw: What would be the projected future pension under the changed arrangements?

Chad Dawtry: In terms of the actual negotiations—

Jackson Carlaw: I understand that the figures are available from the UK Government, so I assume that you have them.

Chad Dawtry: The UK Government will certainly have figures for the reforms that it has concluded—

Jackson Carlaw: Yes.

Nicola Sturgeon: We, however, have not concluded those discussions, so we do not have the figures for Scotland.

Jackson Carlaw: Do you expect the figure to be greater than £7,057?

Nicola Sturgeon: That will depend on the conclusion of the negotiations, which will—as I have said—kick off tomorrow.

Jackson Carlaw: Do you expect the figure to be greater than £7,057?

Chad Dawtry: That really is a matter for negotiation.

Jackson Carlaw: Would you expect it to be lower than £7,057?

Nicola Sturgeon: I am not going to sit here and give you a purely speculative figure—which it would be, given that we have not concluded the negotiations.

Jackson Carlaw: Thank you.

The Convener: Gil—do you have a question?

Gil Paterson (Clydebank and Milngavie) (SNP): Yes—sorry, convener; I was intrigued by that line of questioning.

It seems to me that the surplus offers a short-term solution, and I have two questions on its possible use. First, would there be punitive measures from the UK Government if the surplus were used in Scotland, or could it be used in Scotland without any effect? Secondly, if the surplus were used in the short term, would that have an impact on the long-term viability of the scheme?

Nicola Sturgeon: I will ask Chad Dawtry to come in on the accounting point.

Chad Dawtry: In effect, the surplus is not owned by the Scottish Government. The financing arrangements mean that the UK Government handles the money so, in effect, we pass it through to the UK Government on an accounting basis.

Nicola Sturgeon: The letter to the finance secretary from the Chief Secretary to the Treasury, which I think has been published and everybody has seen, was very clear. It said that if the increases were not applied, the Scottish Government budget would undergo deductions to the tune of £8 million a month. There was no dubiety or room for misunderstanding on that point.

Gil Paterson: Are you saying that, even if it were practically possible to use the surplus, punitive measures would kick in?

Nicola Sturgeon: Yes.

Gil Paterson: So Scotland should be in line with England. Is that what the policy is driving at?

Nicola Sturgeon: If we do not implement the increased contributions from 1 April this year, our budget will be cut by the corresponding amount. If

we do not implement them in all schemes, the deduction will be £8 million-plus; if we do not implement them just in the NHS scheme, the deduction will be £4.6 million a month.

Gil Paterson: Thank you.

Drew Smith (Glasgow) (Lab): I will return briefly to Richard Lyle's point about the viability of the scheme and the projections on the surplus. Mr Dawtry said that, although the teachers' scheme has been in surplus in the past, the surplus has declined over the years. I just want to be clear that you do not expect that to happen in the NHS scheme, because presumably the surplus could increase.

Chad Dawtry: On the basis of scheme demographics—obviously, tens of thousands of people have built up pensions promises over time and will be retiring over the next few years—that is exactly what will happen.

Drew Smith: Are those projections that you have published or that you can share?

Chad Dawtry: We can clarify the projections that we have for the committee, although I cannot give you them just now.

Drew Smith: That would be useful. I wanted to ask the cabinet secretary about the opt-out, which is clearly a big concern for a lot of us. If people's contributions are increasing, they might be more likely not to bother paying in as that extra money is simply too much for them. Do you have any sense of the likely scale of the problem? Has the Government modelled that at particular rates, for example if 30 per cent or half of the workforce opted out?

Nicola Sturgeon: I will let Chad Dawtry come in in a second on that. The opt-out concern is legitimate and it was one of the concerns that we expressed to the UK Government. The reason for trying to deliver protection for those at the lower-paid end of the scale is to try to minimise the potential for opt-out. I have already quoted the figures, and I will not repeat myself, but that is the reason. I will let Chad answer the point about the modelling.

Chad Dawtry: The threshold that has been set reflects lower-paid staff. We already know from some of the information that we have on the scheme that, generally speaking, lower-paid staff have lower participation levels in the scheme. That is a matter of concern. It also recognises a particular point in the pay spine at which newly qualified staff join the NHS, as we have a fair amount of anecdotal evidence that, if people do not join the scheme on day one, it is harder to get them to think about it again in the future. There has been a deliberate policy to try to resolve that issue.

Drew Smith: Finally, has the Government considered at this stage—perhaps it will be part of the negotiations you spoke about for future years—whether something can be done about your pay policy? If my maths is correct, the figures that Richard Simpson identified suggest that—we will leave aside whether they work full-time or half-time hours—someone who is paid a total of £14,000 could pay a higher contribution rate than someone who is paid £15,000 or higher. Surely that could be ameliorated through an adjustment to the pay policy that would offset that increased contribution.

Nicola Sturgeon: Obviously, the bulk of NHS staff are paid within the UK agenda for change system. Up until now, we have had UK pay arrangements in that respect. We can perhaps look at these things in the negotiations that are about to start, so I am happy to consider your point.

Drew Smith: Looking at this from the union's perspective, I am worried. What confidence can the workforce have about the negotiations on years 2 and 3? I know that you genuinely want to get the right solution. If we have not been able to get there in year 1, surely there will be a level of cynicism and a belief that, once you agree it for one year, it will just roll on into years 2 and 3.

Nicola Sturgeon: I see this from the union's perspective as well. It is not my policy that I am sitting here talking about. It is a policy that we are bound into because of the way in which this Parliament is funded and because of the devolved-reserved split in responsibilities. We go into these negotiations for the longer term with an open mind, a willingness and a desire to find common ground and a meeting of minds. However, if members of the committee have reservations about the ability to do that within the cost envelope, I look forward to those members who are expressing understandable concerns joining me in arguing for the Parliament to have genuine choices for the future when it comes to pensions. That would demand not just pensions policy being devolved but the Parliament having a funding system in which we have control of our own resources. I simply ask those who are expressing understandable reservations about and hostility to the position that we find ourselves in to think that through to the logical conclusion.

The Convener: There are some other questions before we bring people in for second questions.

On the demographics and the financial viability of the pension scheme, is it a particularly Scottish focus or a UK focus?

Chad Dawtry: It is a general focus. The committee will probably be aware that Lord Hutton conducted a review on behalf of the UK

Government, and there is quite a lot of information in his interim report and in his final report that sets out that detail.

The Convener: But when we talk about the NHS scheme, is it a UK scheme that we are talking about and not a Scottish one?

Chad Dawtry: The demographic implications are the same in Scotland as in the rest of the UK.

The Convener: Yes. The cabinet secretary has led us to a point that the committee may consider, which is how we could expand the choices, whether through greater devolution or—this is the cabinet secretary's position—something further than that. Has there been any risk assessment or evaluation of members' benefits if the majority of the members of the scheme went somewhere else and there was a smaller scheme? Would that be a good outcome or a bad outcome?

Chad Dawtry: I am not quite sure how best to answer that. At the moment, the negotiations are predicated on taking forward something that is based, at least loosely, on the UK Government's scheme.

The Convener: Yes, but the cabinet secretary has invited us to look at something for the future, which I presume would be the majority of NHS pension members going somewhere else. What would the impact of that be?

Chad Dawtry: I am not convinced that that is—

Nicola Sturgeon: I am not sure that I understand your question.

The Convener: Maybe I have misunderstood the cabinet secretary. I thought that she was saying that we could have a stand-alone Scottish pension scheme for the NHS that would be better able to avoid these circumstances and better able to provide and maintain the pension at a cheaper rate. Is that not what I heard?

Nicola Sturgeon: Are you referring to the negotiations that we are about to embark on, or are you talking about the scenario of a Scottish Government having independent powers over pensions and the resource decisions that come with that?

The Convener: I have not heard a description of how things would be better with a smaller number of people in the pension scheme, with all the liability that would be involved.

Chad Dawtry: I may not have explained that properly: there is already a separate NHS scheme in Scotland, if that is your point. I apologise for not making that clearer.

10:45

The Convener: Just to get some clarity on the full-time equivalent and part-time equivalent situation, could you say whether someone who is on £14,000 and working part time would be subject to the 8 per cent contribution rate that is laid out in part 2 of the scheme?

Eleanor Guthrie (Scottish Public Pensions Agency): They would be subject to the contribution rate that is relevant to their whole-time equivalent pay. Someone on £14,000 might be working two thirds time, half time or whatever, so they would pay the whole-time equivalent rate.

The Convener: It is clear that the rate of 8 per cent will have a serious impact on those low-paid workers. Is that being considered in the negotiations?

Chad Dawtry: Yes. It is worth pointing out that there is tax relief on that contribution, so those workers would not pay the full 8 per cent.

The Convener: But is that issue being seriously considered by the Scottish terms and conditions committee?

Chad Dawtry: Absolutely.

The Convener: Cabinet secretary, you referred to making representations to the UK Government on flexibility and on the choices that would be available to us to make without incurring any penalty. What was the nature of those representations? Have you met the Secretary of State for Health?

Nicola Sturgeon: I met Andrew Lansley a few weeks ago, and pensions was one of the issues that we discussed. Most of the Scottish Government's representations on pensions have—as you would expect—come through the Cabinet Secretary for Finance, Employment and Sustainable Growth in the form of representations to the Chief Secretary to the Treasury. The chief secretary's letter, to which I have already referred, came out of that dialogue.

The Convener: I understand.

Jim Eadie (Edinburgh Southern) (SNP): Cabinet secretary, you said that you believe that the motivation behind the UK Government's planned changes is more to do with deficit reduction—what might be termed a naked cash grab—than the sustainability of public sector pensions.

I note your and the Scottish Government's commitment to ameliorating the impact of those changes on low-paid workers who are employed in the NHS. Can you confirm that the full impact of the changes in the period to 2014-15 could result in a cumulative reduction of more than £0.5 billion in the Scottish Government's budget over the

spending review period if it does not pass on those increases to public sector workers?

Nicola Sturgeon: To be clear, the UK Government intends to make savings of £2.8 billion across UK-wide public sector schemes from April 2014. It is doing that through increasing employee contribution rates by an average of 3.2 per cent in three annual increments—40 per cent, 40 per cent and 20 per cent—starting in April this year. That saving is already built into the cost envelope.

If we did not apply the increases for future years, and did not make any corresponding offsetting savings, our budget would be reduced by the same order of magnitude that I have said would apply if we did not increase contributions this year. What that would amount to over the spending review period is in the realms that you have just mentioned.

Jim Eadie: Is the better package that you hope may arise from negotiations with the health service unions based on flexibility from the UK Government, or are you assuming that there will be no such flexibility?

Nicola Sturgeon: There is no flexibility from the UK Government with regard to the overall cost. If we arrive at a package that costs more—to use simplified language—than the package that the UK Government has negotiated, that extra cost will come out of our budget in the same way as the cost of not applying the increases in 2012-13 would do.

I am deliberately not getting into the realms of what might or might not be possible through negotiation, because the negotiations have not commenced yet. It is clear from my comments about cost envelopes, and who bears the burden of going outside those cost envelopes, that the Government is willing to try to find flexibilities, but those are flexibilities that will come from our negotiations with the unions, not flexibilities that are being offered to us by the UK Government.

Jim Eadie: That is clear. Thank you.

Dr Simpson: I should have said earlier that I am a member of the NHS pension scheme. Fortunately, I am at the stage at which I do not have to make contributions, as I am a retired member of the scheme.

Within the envelope of the regulations, would the Scottish Government be allowed to amend the contributions in any of the sections? For example, 3,000 staff in the NHS are employed at a rate above £100,000 a year, and some are on considerably more, if we include the pensionable distinction awards. I think that *Scottish Review* said that one doctor was earning £260,000. Would it be practical to say immediately that distinction awards were non-pensionable as a measure to provide a pot of money to support part-time, less well-off workers? Is that within your powers?

Nicola Sturgeon: The simple answer to your overarching question is yes. However, in our consultation document on the pension increases, we said clearly that we did not want an outcome in which anyone in any of these pension schemes had to pay more than their counterparts down south. To reduce contributions in some groups, in order to stay within the cost envelope, would increase contributions in other groups. We said that we did not want to do that. If there is willingness on the part of stakeholders, that is an issue that can be discussed as we go forward.

I do not say this to make it sound as if it is all okay, but it is worth pointing out that, of all of the schemes, the NHS scheme is the one that has the highest level of protection, in terms of the thresholds that we spoke about earlier.

Dr Simpson: Sorry, I do not understand the last point. Protection from what?

Nicola Sturgeon: I referred to a salary figure of £26,500; that is the highest level at which protection applies in any of the schemes.

Richard Lyle: As Dr Simpson has made that declaration, I had better declare that I, too, am a member of the NHS pension scheme.

Bob Doris: I do not know whether we all need to do that now. I am in the teachers' pension scheme. My wife is a practising nurse, so she is in the NHS pension scheme. It goes to show that the issue is not a distant concept to MSPs and that we have friends and relatives who are directly affected by it. That is important, particularly for Unison members in the public gallery, who are following proceedings.

Nicola Sturgeon: I do not know whether I have to declare that my sister is a member—

The Convener: Please do not. If no one else does, I will not mention all of my family.

Nicola Sturgeon: Bob Doris's point is important. There is probably no one around the table—

The Convener: I think we got the point.

Drew Smith: I am not a member of the NHS pension scheme—I do not think that we all need to declare that either.

It is not a flippant point, so I hope that the cabinet secretary will not take it as one, but has the Government modelled the cost of the likely industrial action arising from the changes? We are saying that if we take one choice, there will be a cost, but it is likely that the alternative will not be cost free either.

Nicola Sturgeon: I do not take that as a flippant remark—indeed, I do not take any of this flippantly at all—but all your question does is to underline the Hobson's choice faced by the Scottish Government as a result of the constraints on our decision-making powers. I do not want industrial action in any part of the NHS, because I do not think that such a move is in the interests of those who work in or rely on the health service. However, the reality is that, if I were not sitting here proposing these regulations—reluctantly and with great regret—I would probably be sitting before you being questioned on how the NHS was going to absorb a £50 million reduction in its budget. That is the situation that we are in. I do not like it, but it flows from the governance of the Parliament, of its resources and of pensions.

The Convener: If the NHS cannot take a £50 million reduction, what sort of cost would it be able to absorb?

Nicola Sturgeon: We are about to embark on negotiations; as I have said, they kick off tomorrow. I have been very up front about saying that, if we do not want to place a cost on the NHS, we will have to stay within the cost envelope. However, I am not going to constrain those discussions or start to speculate about such territory before I have even sat down with stakeholders—as I will tomorrow—to set out how we will proceed with the negotiations.

The Convener: So the committee should accept that there will be a cost.

Nicola Sturgeon: I have said that our starting point is the need to keep within the cost envelope and to see whether we can do things differently within it. Beyond that comment, however, I will say no more. I am not going to constrain the discussions before they get under way, because it would be wrong of me to do so.

The Convener: I am sure that we all look forward to a successful outcome to the negotiations and hope that we avoid industrial action. I thank the cabinet secretary and her colleagues for their attendance and for answering our questions.

Community Care (Joint Working etc) (Scotland) Amendment Regulations 2012 (SSI 2012/65)

Community Care and Health (Scotland) Act 2002 (Incidental Provision) (Adult Support and Protection) Order 2012 (SSI 2012/66)

National Assistance (Sums for Personal Requirements) (Scotland) Regulations 2012 (SSI 2012/67)

National Assistance (Assessment of Resources) Amendment (Scotland) Regulations 2012 (SSI 2012/68)

National Health Service (Optical Charges and Payments) (Scotland) Amendment Regulations 2012 (SSI 2012/73)

National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Scotland) Amendment Regulations 2012 (SSI 2012/74)

Food Hygiene (Scotland) Amendment Regulations 2012 (SSI 2012/75)

Personal Injuries (NHS Charges) (Amounts) (Scotland) Amendment Regulations 2012 (SSI 2012/76)

The Convener: The next item is formal consideration of SSI 2012/69 and eight other negative instruments. Members will have received a cover note setting out the purpose of the instruments.

The Subordinate Legislation Committee has drawn only SSI 2012/75 to our attention on reporting grounds as it raises a devolution issue. Do members have any comments on the nine SSIs, particularly SSI 2012/75?

Dr Simpson: Convener, I wonder whether you can clarify the process. If we do not give notice of lodging a motion to annul now, do we still have time to do so?

The Convener: Yes. As we discussed at the pre-meeting briefing, we are simply noting the position. The issue remains live and any MSP who wishes to lodge a motion to annul the pensions regulations—SSI 2012/69—can do so between now and 17 April.

Dr Simpson: That is very clear, convener.

Richard Lyle: On SSI 2012/75, given that Michael Matheson's letter explains the situation, I

do not think that we need necessarily agree with the Subordinate Legislation Committee. I am quite happy to agree to the instrument.

The Convener: Taking into account Richard Lyle's comments, does the committee agree that we do not wish to make any recommendations on the instruments at this stage?

Members *indicated agreement.*

10:59

Meeting suspended.

11:00

On resuming—

Petitions

Orphan Diseases (Access to Therapy) (PE1398)

Pompe Disease (Access to Therapy) (PE1399)

Paroxysmal Nocturnal Haemoglobinuria (Access to Therapy) (PE1401)

The Convener: Agenda item 5 is oral evidence on three petitions, which relate to access to medicines for orphan diseases and individual patient treatment requests. I welcome the people who are here to represent the petitions: Stephen Nutt is executive officer at Rare Disease UK; Joan Fletcher is family support officer at the Association for Glycogen Storage Disease UK; and Lesley Loeliger is founder and chair of PNH Scotland. I will give each of you the opportunity to make brief opening remarks before we move on to questions.

Stephen Nutt (Rare Disease UK): First, please accept my apologies on behalf of the chair of Rare Disease UK, Alastair Kent, who had a prior commitment and was unable to make today's meeting. Secondly, I thank the Health and Sport Committee for the opportunity to give evidence on an issue that is vital for many patients who live with a rare disease in Scotland.

There are more than 6,000 rare diseases, affecting one in 17 people at some point in their lives—that amounts to 300,000 people in Scotland. Rare diseases are a significant health and social care issue, which is why Rare Disease UK has been calling for a strategic plan to facilitate research and improve access to treatment, care and support for patients with rare diseases. We are pleased that the Scottish Government is currently consulting jointly with the other UK health departments on such a plan.

Access to medicines for patients who are affected by rare diseases is and will continue to be a growing issue, but the issue must be viewed in context. For the vast majority of rare diseases, no effective treatments are available, and the best intervention for which most patients can hope is the effective palliation of symptoms.

In the minority of rare diseases for which a treatment has been approved that has the potential to improve the quality or increase the quantity of a person's life, patients and their family members are understandably eager to have fair access to the treatment. For the reasons that are

laid out in PE1398, we do not think that patients in Scotland currently have fair access to treatment.

We are keen to stress that we are looking for decisions to be made equitably, not preferentially. Patients who are affected by rare diseases want to be sure that they will be given a fair hearing. However, decision-making frameworks that were designed for common conditions generally cannot capture the unique characteristics of rare diseases.

That is why we are calling for a revision of the IPTR process for rare diseases, to ensure that patients with rare diseases in Scotland have equal and fair access to potentially life-altering treatments, when such treatments exist.

My final plea is that the committee does not forget our concerns about the Scottish Medicines Consortium appraisal process, which are also set out in our petition.

I thank the committee for its attention and will be happy to answer questions.

Joan Fletcher (Association for Glycogen Storage Disease UK): Good morning. I am a clinical nurse specialist and I work as the family support officer for the Association for Glycogen Storage Disease UK.

Pompe disease is a progressive muscle-wasting disease, which affects mobility and breathing and, in children, the heart muscle. When treatment is delayed or withheld, patients become extremely disabled and premature death occurs.

Pompe disease is a very rare condition, which affects very few people. When PE1399 was brought to the Parliament, 11 patients had been diagnosed with Pompe disease in Scotland. Three patients—two children and one adult—are currently receiving treatment; others have been rejected, despite going through the lengthy individual patient treatment request process. Two patients have been refused treatment and their subsequent appeals have been declined; in another case a decision is pending. Three patients are not eligible for treatment at present and two patients have moved to England and are now receiving treatment.

The situation that I described highlights the inequalities that exist in the healthcare system in Scotland. Patients in Scotland are being subjected to a postcode lottery for a treatment that is readily available in England, despite recommendations from clinical experts. All patients who meet the criteria in the clinical guidelines in England are eligible for treatment immediately. Early treatment is essential to halt the destruction of muscle. Infants who get no treatment decline rapidly and die within the first 12 months of life.

The quality ambitions in "The Healthcare Quality Strategy for NHS Scotland" are not being met for patients who suffer from Pompe disease. According to the ambitions:

> "The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, and wasteful or harmful variation will be eradicated",

and

> "There will be no avoidable injury or harm to people from healthcare they receive".

The IPTR process is not working for patients in all NHS boards in Scotland. Some patients are being denied treatment simply because of where they live, as a result of their local health board's interpretation of IPTR policy. We urgently require a change to the policy or the introduction of an alternative process for commissioning orphan drugs.

I thank members of the committee for your time and attention.

Lesley Loeliger (PNH Scotland): I am here to represent the charity PNH Scotland and the PNH Alliance. Paroxysmal nocturnal haemoglobinuria is an ultra-rare bone-marrow disease. There are approximately 22 PNH patients in Scotland.

I was diagnosed with PNH five years ago. At the time, I was told that the median survival rate was 10 years. I am extremely fortunate to be on the drug Eculizumab, which allows me to have a normal life expectancy again.

The setting up and running of the patient support group, PNH Scotland, has enabled me to meet almost all the PNH patients in Scotland and to learn about their vastly different experiences of diagnosis, care and treatment. In my health board area, five patients have been recommended for Eculizumab. Of the five, I have been granted funding but the other four have not been so fortunate. One gentleman was refused funding several times. When I spoke to him, he told me that all he wanted was a life. Sadly, he died the next day. One patient for whom the drug was recommended was turned down for funding despite several appeals. She was given the drug only when she had a near-fatal blood clot on her kidney. The other two patients have also been turned down.

There are only a handful of PNH experts in the whole of Europe, but we are in an extremely privileged position, in that we have a national PNH centre of excellence in Scotland, at Monklands hospital. The centre can give expert PNH opinion for patients in Scotland nationally, but funding decisions are still made regionally, and regional boards do not always accept or acknowledge the expertise that is available to them at Monklands.

There is inequity of funding between health board areas in Scotland and within the UK as a whole, because Scotland is the only country in the UK that is not funding Eculizumab.

The PNH centre of excellence at Monklands has the expertise to recommend treatment but not the authority to grant funding. This is what needs to change.

Thank you.

The Convener: I thank you all.

Fiona McLeod (Strathkelvin and Bearsden) (SNP): I thank the witnesses for their interesting and informative introductory statements. I am conscious that, on 13 February 2012, the Scottish Government issued new guidance for all health boards on the SMC and IPTRs. Will the witnesses comment on that guidance? Does it ensure, as it set out to, that we have safe and effective use of new medicines? Will the witnesses also comment on the additional measures to improve NHS board consideration of IPTRs?

Lesley Loeliger: We are very grateful that changes were made quickly after we asked for help. Unfortunately, PNH Scotland feels that the wording of the guidance needs to be made more robust. The guidance states that an expert in the field must be present on the appeal panel. Depending on the health board region that the patient was in, that could be a local haematologist rather than a PNH expert.

Many haematologists with 20 or 25 years' experience may never have had the chance to meet a PNH patient, and the condition is specific. We have a centre of excellence at Monklands. As I said, there are few experts on the condition in Europe but most of them are in the UK and we even have one in Scotland. I recommend that the wording be made slightly more robust so that what is meant by "expert" is understood.

Stephen Nutt: The new guidance does nothing to change the situation on rare diseases. Rare diseases have specific characteristics and the frameworks that are designed to deal with common conditions cannot capture those.

Fiona McLeod: I thank Ms Loeliger for her useful comment. The committee wants to understand how robust the guidance is. We may want to further tease out the use of experts.

With my ex-health librarian hat on, I wonder about rare diseases and what Mr Nutt said. Where I worked, we dealt with long-term, chronic illness, often involving orphan diseases. Is Mr Nutt saying that we need separate guidelines for rare and orphan diseases? If we do that, how robust could they be? Would we end up having to have guidelines for each individual rare or orphan disease? Is that practical? With, perhaps, a dozen sets of guidelines, how would we be able to track across them to ensure equity of application? That is what worries me from an evidential point of view.

Stephen Nutt: I accept that point, but the guidance that was issued in February did not change the situation. Although the word "exceptional" is not explicitly used any more, there is still a general assumption that one needs to prove that a patient is exceptional from the general category of patients. With rare diseases, that is almost impossible to do. We are dealing with a small cohort of patients as it is, so it is almost impossible to demonstrate that one patient is exceptional compared to another.

Apart from having a small quantity of patients, much less is known about a rare disease or about the prognosis of a rare disease. That can make satisfying evidential burdens quite difficult.

We fully support the need for frameworks and guidance. We are not saying that every drug for a rare disease should be given to every patient without consideration, with no framework and with no requirement for evidence to be submitted. However, frameworks and guidance must deal with rare diseases appropriately, given the specific nature of such diseases. If frameworks that were designed for common conditions are used, that is an extra burden for a patient with a rare disease to satisfy on top of all the other difficulties that are associated with having a rare disease.

11:15

Fiona McLeod: I will tease that out a wee bit further. Are you saying that although the guidelines are a big step forward, we need to ask for a wee bit more evidence—perhaps from the cabinet secretary—on some issues? I am still not sure what you think we need for rare and orphan diseases.

Stephen Nutt: The current criterion for a successful IPTR is to show that

"The patient's clinical circumstances ... are significantly different from either ... the general population of patients covered by the medicine's licence; or ... the population of patients included in the clinical trials for the medicine's licensed indication as appraised."

A clinical trial that relates to a rare disease will be based on the patients who have the greatest need, because a very small cohort of patients will be able to participate. Satisfying the criterion for a successful IPTR is almost impossible. The criterion is okay for common conditions, but it does not work for rare diseases.

The problem has two sides. The Scottish Medicines Consortium appraisal process is inappropriate for rare diseases and leads to many orphan drugs being rejected, so the only hope for

patients with rare diseases to access their treatment is through the IPTR process, which provides an inappropriate framework. The issues are difficult to divorce from each other.

I come back to the point that the Scottish Medicines Consortium criteria are not fair for rare diseases. That creates a knock-on effect, which is seen a lot more in the IPTR process.

Fiona McLeod: I am a bit confused. You say that clinical trials for medicines for rare diseases will involve those with the greatest need, but surely such clinical trials take in a wider spectrum of needs, given the small cohort of people with rare and orphan diseases who can be examined.

Stephen Nutt: I cannot quite answer that question in detail. You would need to ask it of someone with a research background, who could explain the position better than I can.

A related issue is that getting the numbers for clinical trials is difficult, which means that treatments and their effect are a lot less certain and which affects the study of conditions. Trying to prove that a patient is different when not so much evidence is known is difficult, if not impossible.

Fiona McLeod: I think that I should stop as I am getting technical.

The Convener: I will test what has been said. There is another side to the story. In its submission, the Scottish Medicines Consortium accepts some of the argument that has been made. I am trying to get at whether you agree with that, given your experience. The SMC says that it

"recognises that efficacy data are ... often limited"

and adjusts its models to take that into account. It also applies different criteria to cost per quality-adjusted life year. The SMC says that it accepts your argument and has taken it into account in models that it applies.

The committee wants to hear your response to that. Perhaps we can start with that and work back. If witnesses feel that they do not need to say anything because someone else has said it, that is fine—they can sit out a question—but I want to spread the questions among the panel.

Lesley Loeliger: I come at this from a patient perspective and therefore tend to have more to do with individual patient treatment requests rather than the SMC approval side of things, but my feeling was that the SMC was still looking at these matters on the basis of what it calls the QALY, or quality-adjusted life year—in other words, the quality of the years that are expected to come—which is difficult to establish.

As for your worry that we might end up with 100 different rare disease charters, one thing that I have learned on my slightly steep learning curve is that although there are many rare diseases the treatment issues are all very similar. We have already had a meeting with Rare Disease UK about working on a steering committee to consider the commonality rather than the differences between rare diseases. The issue seems to come down to the QALY cap on the money available.

Aside from that, the SMC deals with IPTRs on the basis of expert advice and if the board were able to take the opinion of an expert who understood the system it would make all the difference. The SMC might say that it has consulted an expert, but it will not be the correct one. Even though the process might follow the wording that you have referred to, that particular expert might not actually be able to give us the information.

The Convener: I suppose that the challenge lies in getting pharmaceutical companies to invest in research. It is clear that the issue has a European dimension, a Scottish dimension, a National Institute of Health and Clinical Excellence dimension and a new drug approval dimension. The fact is that much of the procedure is dominated by all those issues, even before we get to IPTRs.

Stephen Nutt: The SMC can use certain modifiers for orphan medicines. That could be a positive move, but in our view, since their introduction in 2007, modifiers have made no difference to the proportion of medicines that are recommended. The problem lies in both the fact that the model is based on the QALY, which cannot capture the characteristics of rare diseases, and the fact that we are not entirely sure how and when the modifiers have been used. If they have been used, that information will be specified in the detailed advice document, but it remains unclear whether in practice they make any difference to the process and the decisions that are made. Instead of having a QALY-based model and using modifiers in a not entirely transparent way, we think that it would make a lot more sense to have an appraisal process that captures the nature of rare diseases and can appraise them effectively in the first instance.

Bob Doris: To be honest, I am finding it difficult to get my head round this issue. I hope I am recapturing Mr Nutt's comments, because I want to get them clear in my mind, but I think that he said that he did not expect every IPTR to be successful for every condition. Obviously, all committee members will be saying, "If this was me or my family, I would want this treatment, irrespective of how good or wonderful the guidelines might be". Speaking for myself, I think that, if my request were processed under the guidelines but was refused, I would still be dissatisfied. As a result, I found Mr Nutt's

comment that he did not expect every request to be successful to be helpful, because it allows us to focus on how we might improve the guidance.

Do you think it reasonable that we look at how health boards manage the guidance that has just been published? We might well decide to monitor that—we will discuss how we take forward our work later. Do you think that we should follow the matter closely?

Joan Fletcher: Because of the small number of Pompe sufferers, a Pompe patient will struggle to show that they are significantly different from other Pompe sufferers, which is required for an individual patient treatment request to be successful. Because of the small numbers, because the disease is so widespread and because the patient is so affected, it is difficult to prove that one patient is significantly different from the rest of the population.

There is evidence that Myozyme is an effective treatment for Pompe patients and can halt the progress of the disease. We therefore ask why someone has to be significantly different from the rest of the population if it has been proven that other patients respond to the treatment. Why do we need to prove that a patient is significantly different for them to access treatment?

Bob Doris: I was making a more general point—it was not specific to Pompe or PNH. There are new guidelines, so it seems reasonable to monitor how those are applied across health boards. I will come back to those particular conditions but, in general, is it reasonable to want to monitor the impact for those with rare and orphan diseases?

Stephen Nutt: Joan Fletcher's answer illustrates how the new guidelines will not actually change the situation. That situation still applies and the new guidelines do not do anything that will necessarily alter it. There are positives in the new guidelines in relation to monitoring and the attempts to enhance the effectiveness and standardisation of IPTRs, but the crux of the problem remains, and the guidelines will not necessarily do anything to change that.

Bob Doris: One strand is that we can get more information and clarity on the use of expert opinion in appeals. You have asked for more clarity on that, and we could seek to monitor that situation.

You make a strong point about how we gauge a patient to be exceptional. That takes me on to my next question. I understand that at the UK level there is a further consultation on the management of rare diseases across the UK and that the Scottish Government is participating in that. Is that an appropriate vehicle to tease out the question of how we get criteria that can deal with the exceptionality issue? We do not want to take evidence on the issue and then let it gather dust. We want to find out what the appropriate mechanism is for analysing the issue further. Would that be an appropriate vehicle?

Joan Fletcher: Are you referring to the guidelines of the advisory group for national specialised services?

Bob Doris: I will read out what I am referring to. I am sorry, as I do not know which of you submitted PE1398, but it states:

"We would also like to notify the Committee that a public consultation on a UK plan for rare diseases as referred to previously has been launched by the Scottish Government jointly with the other UK health departments. We have submitted this consultation document."

Could that be a vehicle for further teasing out how we get fair and equitable criteria for deciding on individual patient treatment requests?

Stephen Nutt: All three organisations that are represented here will highlight the issue in our responses to that consultation. For your information, I think that you are referring to the UK plan for rare diseases, which is out for consultation until 25 May. The four UK health departments have worked together collaboratively to produce that consultation document. We think that there are many weaknesses in it and we were disappointed with its contents—or rather, the lack of content. However, we will use the consultation as an opportunity to highlight our concerns, as we are doing today.

11:30

Bob Doris: We can contact the Scottish Government and look at the consultation, but I am trying to tease out the best way forward. I have not another question but an observation on how difficult I find the matter as an MSP. I wondered what treatments are available in Scotland that are not available in England. The process throws up all different kinds of conflicts. Leukaemia is not an orphan disease, but in May last year a lot of media attention was given to about 1,000 leukaemia sufferers in England who were not getting access to a treatment that they would get had they been resident in Scotland.

A serious issue for politicians to grapple with is how to ensure that there are fair, equitable and transparent procedures and guidelines for making such decisions. I leave that issue sitting there. I genuinely hope that the committee can tease out a way forward that gives you fairer and more equitable treatment.

Stephen Nutt: I will pick up on the earlier point. It is inevitable that some patients will be disappointed. We realise that we do not live in a world of unlimited health budgets, but we ask that fair and equitable processes are put in place for

rare diseases. All the appraisals are currently done by both the SMC and the IPTR process under guidelines and frameworks that were designed for common conditions and which therefore do not capture the characteristics of rare diseases.

Jim Eadie: I have a couple of interests to declare. First, in a previous life I was a member of the SMC. Secondly, prior to being elected I provided some consultancy services to a public affairs company in London, which was looking specifically at the funding of medicines for an orphan condition. None of that makes the issue any easier for me to understand than it is for my colleagues. I am struggling to get my head round some of this.

On the arrangements for national risk sharing in Scotland as distinct from AGNSS, which was mentioned, when I last looked at the national risk-sharing scheme in Scotland in about 2009, there was a budget of £30 million. Most of the budget—£23 million—was for recombinant treatment for haemophilia. In principle, money is available for conditions that affect a small number of people but have a very large price tag attached to them.

The national risk-sharing scheme was devised largely so that health boards that were facing a financially significant cost and so which were at financial risk would not be exposed and could pool their funding arrangements through the scheme. It is interesting that none of the witnesses have referred to the scheme. Will you say a little bit about the national risk-sharing scheme and whether the medicines for the conditions that most concern you were considered for inclusion in that scheme?

Stephen Nutt: I shall answer the broad question and Joan Fletcher can refer to specific issues.

AGNSS is a separate process.

Jim Eadie: Sorry, can I clarify that AGNSS is a formal process that exists in England but not in Scotland?

Stephen Nutt: Yes. AGNSS makes recommendations to ministers in England for the commissioning of treatments or services for diseases that affect fewer than 500 patients in England. It has developed a decision-making framework to appraise drugs for very rare conditions. In Scotland, health boards can apply to fund treatment through the orphan drug risk-sharing scheme when medicines have been accepted by the SMC or, I believe, in the case of certain successful IPTR requests. The scheme is essentially designed to ensure that no one health board bears too much of the burden if there happens to be a cluster of rare disease patients in one health board area. In general, localism in relation to health is seen as a good thing, but one can see that that does not necessarily apply to rare diseases. It would be quite costly for one health board to bear the entire brunt of the cost.

Jim Eadie: I am trying to understand your experience of the scheme in Scotland. I understand that part of the eligibility criteria is that there must have been approval by the SMC. Has that been the burden? I also understand that there is a precedent for medicines that have not been approved by the SMC to go on to be included in the national risk-sharing schemes. Can you tell us your experience?

Joan Fletcher: Yes. From my experience, Myozyme, which is a treatment for Pompe disease, is not recommended by the SMC but is included in the risk-sharing scheme. To get that, we need a successful IPTR from the local NHS board.

Jim Eadie: So, the barrier is the IPTR process.

Joan Fletcher: Yes. It is included in the risk share, but first someone must be successful in that process.

Jim Eadie: And that is why it is available in some health boards but not in others.

Joan Fletcher: That is the question that we are asking: why the inequality? We do not know why there are inequalities between different health boards.

The Convener: To be fair, it comes back to the individual criteria. As we heard earlier, something can be available not just in one health board and not in another but to one person in one health board area and not to another.

Joan Fletcher: Yes.

Stephen Nutt: That goes back to the dual problem that I was speaking about earlier. Almost half of all orphan medicines will not be recommended by the SMC, so in the absence of such a recommendation, patients will have to go through the IPTR process, which leads to a postcode lottery.

Jim Eadie: Can we just be clear about this? When a medicine is approved by the SMC, it is automatically included in the national risk-sharing scheme and will then be made available to all patients with that condition in Scotland.

Stephen Nutt: Yes.

Jim Eadie: But when it is not approved, the evidence base is made available to the national risk-sharing scheme and it can be included, but it is up to individual consultants or clinicians to apply through the IPTR scheme.

Stephen Nutt: Yes, that is right.

Lesley Loeliger: As far as I know, Eculizumab, the drug that I am on, is not part of the sharing scheme. I will look into that, because I was not aware of it as a patient. It is quite new to me. I imagine that my drug would fall under the same criteria as the Pompe drug.

Jim Eadie: I do not want to pursue this line further, but it would appear from what the other witnesses have said that there is no reason why the medicine that you mentioned would not be included in the risk-sharing scheme, particularly since there is still a further barrier that consultants and patients have to go through. Perhaps that is something on which the committee could seek clarification.

Lesley Loeliger: Yes.

Dr Simpson: I like to try to look at these things as logically as I can. Let me lay out the issues and see whether you agree. First, there are rare conditions and you would submit that at the moment the SMC general approval system, with its QALY levels, even with the modifiers, is not adequate to take them into account. That is your first point. We do not know whether the modifiers listed in the SPICe briefing are effective, adequate or whatever; you just feel that the system is not appropriate.

At a second level, there is the question of what NICE terms ultra-rare conditions. The Scottish Government does not recognise that term and neither does the SMC and it could cover the very small numbers—for example, the tiny numbers of people who have the Pompe condition—that mean it is impractical to operate the system at a Scottish level. It might even be difficult at a UK level, but it is certainly impossible to produce the proof at a Scottish level of a Scottish cohort.

Therefore, there is a separate problem in that the term “ultra orphan drugs” is not recognised and the mechanism for approval by the SMC is, in your view, not appropriate. Am I correct about where things stand at that level of approval?

Lesley Loeliger: Yes.

Joan Fletcher: Yes.

Stephen Nutt: I certainly agree with that. You have captured the issue, which is that, in the first instance, there is the problem with the SMC, which causes the knock-on effect in the IPTR process. The term “ultra orphan” is generally accepted among the rare disease community, but there is no formal mechanism for recognising an ultra orphan disease in Scotland.

Dr Simpson: Is “ultra orphan” a European term as well? Is it recognised anywhere in European licensing conditions or is it defined anywhere?

Stephen Nutt: It is generally accepted that such diseases affect fewer than one in 50,000 people in the general population.

Dr Simpson: That is helpful.

Stephen Nutt: That definition is used in Wales as well.

Dr Simpson: We do not have an advisory group for national specialised services and we do not use the English service for conditions that affect few patients—50 would be the rough equivalent in Scotland. Is the fact that there is no equivalent mechanism through a separate organisation in Scotland part of the problem? Is part of the problem that the SMC deals with everything and does not have the ability, as NICE does, to pass something to another organisation that has the specific task of considering it?

Joan Fletcher: Yes.

Lesley Loeliger: That captures the issue in a nutshell.

Dr Simpson: Have your groups suggested to the Scottish Government that we should use AGNSS as a mechanism for looking at approval rather than set up a separate mechanism for very small groups? Have your groups suggested that we should simply buy into the AGNSS system? Would that mechanism be helpful?

Joan Fletcher: It certainly would. AGNSS does not just fund the treatment; it funds the services, and it constantly monitors them and reviews the service agreements with the healthcare providers that it uses. It constantly monitors what drugs it has approved to be used and when they should be used. It is not simply given an open blanket of money, and it does not simply say, “We will approve all these drugs.” It continually monitors which drugs should be used, whether they should continue to be used, when they should be used, and when their use should be stopped.

Dr Simpson: So if they are ineffective—

Joan Fletcher: There are guidelines to stop treatment if they are ineffective.

Dr Simpson: We might try to find out about that.

In Scotland, we have the national services division as part of NHS National Services Scotland, which runs national services. Are the treatment systems for Pompe disease and PNH managed by the national services division or another mechanism?

Joan Fletcher: Pompe disease is managed by—

Dr Simpson: The NSD.

Joan Fletcher: Yes.

Lesley Loeliger: I am afraid that I do not know the answer to that question. I am sorry.

Dr Simpson: If something is not approved by the SMC, we will be into IPTRs of course. I understand you to be saying that because the numbers involved are so small, it is impossible to determine that an individual patient is different from the general population. The criteria that would apply to IPTRs for the latest prostate cancer drug, for example, for which there might be significant numbers of applications given the hundreds of individuals involved, would make it possible to demonstrate a difference in that group, but it is not possible to demonstrate a difference where the numbers are so small.

Joan Fletcher: Yes.

Stephen Nutt: Yes.

Dr Simpson: There is something that I do not understand, which I would value comment on. Why on earth do we use the IPTR system for orphan or ultra orphan conditions? I think that we have been told that there are only 11 cases of Pompe disease and 22 PNH cases. A system with 14 separate IPTR committees potentially considering matters is incredibly bureaucratic and wasteful. Have you proposed that we should have a national system of approval for IPTRs for orphan and ultra orphan drugs?

11:45

Lesley Loeliger: Although in Scotland there are 22 patients who have the condition that I have, only 12 of them are recommended for the drug. At the moment, there are three who are not funded. The experts are already aware of what makes a patient suitable for the drug—they already make that difficult decision. The number that we are talking about is even smaller. We are not saying that, because there are 22 patients, we are looking for 22 people to be on the drug. Only about half of the patients are suitable for the drug. There has to be a different method of handling such very small numbers.

I come back to the point that, with the IPTR system, if the appeal panel does not take the correct specialist information, it will be very hard for patients to get funding. When appeals have been turned down, families have told me that they were told that they were turned down "on good medical advice", but the medical advice came from a local haematologist who did not have expertise in PNH. That is where the wording of the guidance comes in. We can wait and see how such patients go, but we must remember that we are talking about people's lives. This is literally a matter of life and death. I do not mean to sound dramatic, but I am being honest when I say that I cannot wait to find out whether these patients can find a different way of getting on the drug. At the moment, I am talking about three patients who need to be on the drug and for whom waiting would not be acceptable.

Joan Fletcher: I echo what Lesley Loeliger said. We had 11 Pompe patients when we first submitted our petition. Three patients are already receiving treatment. We have another three patients, two of whom have gone through appeals and been refused treatment, despite the fact that independent clinical experts have recommended that they should receive it. Two people have moved to England. We are talking about a small figure. The number of people who need treatment at the moment is three. Three patients are not eligible for treatment under the guidelines. There are three patients in Scotland who are eligible for the treatment who are not receiving it.

Mention has been made of the clinical experts. We have had clinical experts give evidence to say that a patient is suitable for and would benefit from treatment, but they have still not been given it.

Dr Simpson: I understand that, in the case of PNH, there is an expert who is based at Monklands. In a number of cases, that national service has recommended treatment, but that recommendation has been rejected by a local board with an IPTR panel that has not had a clinical expert on it.

Lesley Loeliger: That is right.

Dr Simpson: In your view, the new guidance is not sufficiently tightly drawn to ensure that there will be a genuine expert on such panels.

Lesley Loeliger: A simple change could be made to the relevant sentence. A couple of words could be added to specify the level of expertise that is required. A panel that was dealing with my situation would have to have a PNH expert on it. That is all that I would want. Sometimes letters of support have gone in to appeal panels from our Scottish PNH expert and have not even been considered.

The point that I have always made is that we are not looking for blanket coverage for all patients. With some patients, the experts have already taken the very tough decision that they are not suitable for the drug. I hold a patient group that meets every three months at Monklands. Patients will come to me and say, "I am not suitable for the drug," because that determination has been made; it is not a case of someone who does not fully understand the condition saying that they do not think that they are suitable for the drug.

Dr Simpson: That is very helpful. My final question is a highly technical one. Am I right that the treatment for PNH to which you refer has a number needed to treat of 1, which means that, for

every patient who is treated, there has to be one success? If the number needed to treat is 5—that is, if we have to treat five patients who have the condition to get one success—that hugely alters the cost ratios and makes the decision-making process much more difficult. However, the other day, someone said to me, "Ah, but the treatment for PNH has a very specific number needed to treat, which is 1." In other words, if we treat a patient, the treatment will be successful, provided that the patient meets the criteria for the drug in the first place.

Lesley Loeliger: Yes. Eculizumab has proved to be one of the most efficacious drugs in the world. During the initial trial of the drug it proved so successful that people had to stop giving the placebo to patients in the control group, because it was not fair on them. It is an amazing drug.

It was originally thought that Eculizumab would give only a better quality of life. I am not daft; I understand why it might not be worth spending a huge amount of money just on that. However, it is now understood that Eculizumab returns a normal life expectancy. The most recent research, which was done by an expert down south and the results of which have been demonstrated worldwide, shows that the drug gives me my life back. It gives me a proper life expectancy again.

Dr Simpson: That is very helpful.

Jackson Carlaw: I thank all the witnesses for their approach to the matter and for sharing their detailed knowledge. I am also grateful to members of the committee who are better versed in the issues than I am.

As Bob Doris said, something that comes across in the papers on the petitions is the inequalities in the UK, when NICE approves a drug and the SMC does not—that is the pattern with which we are more familiar, but it must operate the other way round, too. When that happens, it must compound people's sense of injustice, because they might know or be in touch with people who have a similar condition, perhaps through a patient support group, who live on the other side of the border and have different access to treatment.

When a different conclusion is reached, although the interpretation is based on exactly the same evidence, is that explained in a way that is understood, at least, or does it generally just leave people bewildered?

Lesley Loeliger: Are you talking about when someone is turned down for funding in the appeal process?

Jackson Carlaw: I was thinking about situations in which the SMC and NICE take completely different positions.

Lesley Loeliger: Oh, sorry. I think that that is a question for Stephen Nutt.

Stephen Nutt: I should clarify that NICE generally does not appraise orphan drugs. NICE recognises that such drugs are not appropriate for appraisal through the cost-per-QALY method and I think that it has appraised only five of the 74 orphan drugs that are available. My co-petitioners' drugs are made available in England because they are commissioned on a national basis. There is a separate decision-making framework for such decisions. In essence, we are looking for a similar approach in Scotland.

That brings me back to what I said about how local decisions are not necessarily best in the context of rare diseases. A framework that enabled decisions in such cases to be made in Scotland would be highly beneficial.

Jackson Carlaw: Whatever the process is, is the determination expressed in a way that can be understood, or does it leave people bewildered?

Lesley Loeliger: I can speak from the patients' perspective. Patients come into the patient group and say, "I've been turned down and I've been told that it was on sound clinical grounds." That seems to be what they are told. They know that there is an amazing drug for their condition, because they know that when I was not on the drug I had to be carried upstairs and changed, because I physically could not do anything, and now they see me looking perfectly well, despite my having PNH. They know that Eculizumab is an exceptional drug, which would get them out of their depression about not being able to work or do anything. All that they are told is that the decision was based on sound clinical grounds, which makes no sense for patients who have seen the effects of a miracle drug. It is very depressing for them.

Jackson Carlaw: Right. In terms of what is at stake, we are talking about a life-and-death issue, but the decision is explained no better than a delay on a train journey is explained, when we are told that we are not moving for technical reasons.

Lesley Loeliger: Yes, there is a lack of information.

Bob Doris: I bow to members who have specific knowledge—I am playing catch-up with members such as Mr Eadie and Mr Simpson. I am looking for a wee bit of clarity. Did one of the witnesses talk about a case in which a patient was approved for treatment at Scotland level but the IPTR was turned down by the local health board?

Lesley Loeliger: I think that you are referring to cases in which the Scottish and UK PNH experts recommended a patient for the drug but the patient was turned down at regional level.

Bob Doris: That is the clarity that I was looking for. Was the Scottish expert's input part of the statutory process, or did they lend their support to an individual? If I or someone in my family had such a disease, I would want to go to that person for a letter of support. I am wondering whether the Scottish expert's input was part of the mechanism.

Lesley Loeliger: It was not part of the process—that is my wording, because as it turned out, in one appeal panel in the region that I have been talking about, the local haematologist who was considered to be the expert was aware that he was not an expert and, off his own bat, requested a letter of support from the Scottish expert, Dr Lindsay Mitchell, to say that the patient required the drug. The letter went in but was not considered.

The key point for me has always been that Dr Mitchell is the person in Scotland who has the knowledge—there are also experts down south, who come up every three months to see patients at Monklands hospital. Those are the people with the expert knowledge.

Bob Doris: Was the local individual who had asked for input from the national expert part of the statutory process? Did someone at local level say to them, "You are the local expert; give us your opinion"? I am trying to understand who was in the system and who was outwith it.

Lesley Loeliger: The local haematologist was on the appeal panel that was considering the funding.

Bob Doris: That is helpful—that is what I wanted to establish. I am sorry for being long-winded.

The Convener: If there are no further questions, I thank the witnesses for being with us. I would like to say that the meeting has clarified matters, but of course it has not done. However, it was very useful to hear your evidence, which is valued. The committee will discuss how we proceed with the petitions. I thank you again for coming and for your useful evidence.

Stephen Nutt: Thank you.

Joan Fletcher: Thank you.

Lesley Loeliger: Thank you.

The Convener: As we agreed previously, we now move into private session.

11:57

Meeting continued in private until 12:35.

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