The Scottish Parliament
Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Tuesday 1 March 2016

Session 4

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HEALTH AND SPORT COMMITTEE
12th Meeting 2016, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

*Bob Doris (Glasgow) (SNP)

COMMITTEE MEMBERS

*Malcolm Chisholm (Edinburgh Northern and Leith) (Lab)
*Rhoda Grant (Highlands and Islands) (Lab)
*Colin Keir (Edinburgh Western) (SNP)
*Richard Lyle (Central Scotland) (SNP)
*Mike MacKenzie (Highlands and Islands) (SNP)
*Nanette Milne (North East Scotland) (Con)
Dennis Robertson (Aberdeenshire West) (SNP)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Maree Allison (Scottish Social Services Council)
Fiona Collie (Carers Scotland)
Angiolina Foster (Healthcare Improvement Scotland)
Professor Jonathan Fox (Scottish Medicines Consortium)
Beth Hall (Convention of Scottish Local Authorities)
Mike Liddle (Scottish Government)
Victoria MacDonald (Scottish Government)
Dr Rose Marie Parr (Scottish Government)
Paul McFadden (Scottish Public Services Ombudsman)
Shona Robison (Cabinet Secretary for Health, Wellbeing and Sport)
Iain Smith (Inclusion Scotland)

CLERK TO THE COMMITTEE

Jane Williams

LOCATION

The Robert Burns Room (CR1)

Scottish Parliament

Health and Sport Committee

Tuesday 1 March 2016

[The Convener opened the meeting at 09:33]

Interests

The Convener (Duncan McNeil): Good morning and welcome to the 12th meeting in 2016 of the Health and Sport Committee. As I normally do at this point, I ask everyone to switch off their mobile phones, as they can interfere with the sound system and the committee proceedings. I should, however, note that colleagues and clerks are using tablet devices instead of hard copies of the papers.

Agenda item 1 is declaration of interests. I welcome Bob Doris back to the committee but before I invite him to declare any relevant interests, I must put on record my—and, I am sure, the committee's—thanks to Fiona McLeod, who joined the committee for the period when Bob Doris was away and whom we have worked with in the past on the committee.

I invite Mr Doris to declare any relevant interests.

Bob Doris (Glasgow) (SNP): Thanks, convener. I, too, thank Fiona McLeod, who took over on the committee while I was on paternity leave.

Convener, I have no relevant interests outwith what is in my publicly available declaration of interests.

Deputy Convener

09:34

The Convener: Agenda item 2 is choice of deputy convener. The Parliament has agreed that only members of the Scottish National Party are eligible for nomination as deputy convener of the committee, and I therefore invite nominations for the position.

Richard Lyle (Central Scotland) (SNP): It is my pleasure to nominate Bob Doris.

Bob Doris was chosen as deputy convener.

Decision on Taking Business in Private

09:35

The Convener: Agenda item 3 is a decision on whether to take in private agenda item 5, which is consideration of the evidence on the social work complaints procedure. Are we agreed?

Members *indicated agreement.*

Access to New Medicines

09:35

The Convener: Agenda item 4 is an evidence-taking session on access to new medicines. I welcome to the meeting Shona Robison, Cabinet Secretary for Health, Wellbeing and Sport; Dr Rose Marie Parr, chief pharmaceutical officer for Scotland, Scottish Government; Angiolina Foster CBE, chief executive, Healthcare Improvement Scotland; and Professor Jonathan Fox, chairman, Scottish Medicines Consortium.

I invite the cabinet secretary to make a brief statement to the committee before we move to questions.

The Cabinet Secretary for Health, Wellbeing and Sport (Shona Robison): I am very pleased to be here this morning to talk to the committee about access to new medicines. As we enter the last few weeks of the parliamentary session, the committee should be very proud of its work in that area and the achievements that have been made in increasing access to new medicines in Scotland.

It is worth taking a moment to run through the main changes that have been made in the past two years—indeed, it is quite a list. The SMC now holds its meetings in public, and pharmaceutical company representatives are now part of those meetings; there is a new framework for considering ultra-orphan medicines; the patient and clinician engagement process has been introduced, together with additional opportunities for companies to put forward a patient access scheme; there has been an increase of around 40 per cent in the SMC's acceptance rate for end-of-life, orphan and ultra-orphan medicines; and there is a pilot on early dialogue with pharmaceutical companies. I have heard much deserved praise for the public and patient engagement programme that the SMC has put in place, and that work is being fostered through a pilot to share SMC decisions in confidence with patient groups ahead of publication.

We have replaced the rare conditions medicines fund with an expanded new medicines fund. The amount available has been doubled twice—in consecutive years—and this year stands at £90 million. That means that the financial support has been available to implement the increase in access to new medicines. Moreover, the flexibility that the committee called for in individual patient treatment requests has delivered a tenfold increase in access to end-of-life, orphan and ultra-orphan medicines, and there is an on-going pilot for the peer-approved clinical system.

The establishment of an area drug and therapeutics committee collaborative has achieved some early successes in bringing together representatives from across Scotland. It has led national work on optimising medicines use; it is supporting and strengthening public involvement; and it is developing and testing a new categorisation and communication policy for formulary decisions. The final development to note is the establishment of a formal programme of work for monitoring clinical effectiveness of cancer medicines in real-life settings. I should point out that many of the changes have been delivered by the SMC and HIS, and they should be commended for their dedication to making the changes that the Parliament and the Scottish Government asked for.

To take—and to answer—the convener's question, "Have we got more yeses?", I think that yes, without doubt we have. However, we are not complacent. We need to continue to build on what has been achieved, and more needs to be done on fairer pricing of drugs for the national health service and on ensuring that the patient voice is at the front and centre of decision making. A key next step is the independent new medicines review, led by Dr Brian Montgomery, which will launch officially on 21 March with a stakeholder event in Edinburgh. Dr Montgomery will take stock of progress and advise us on whether the systems that we have in place are fit for the future.

The Convener: Thank you, cabinet secretary. Our first questions will be from Nanette Milne.

Nanette Milne (North East Scotland) (Con): Cabinet secretary, I share your enthusiasm about progress so far and agree with you that more can be made.

On the distribution of spending from the new medicines fund, I was under the impression that the fund was held centrally and that applications could be made to it. However, I have since been told that it is actually distributed to national health service boards according to the NHS Scotland resource allocation committee—or NRAC—formula. Which of those views is correct?

Shona Robison: As the new medicines fund ensures that boards can deliver the policy intentions of the Scottish Government and the Scottish Parliament, it is the boards that receive the resources. In 2014-15, NHS boards required £1.1 million to support SMC decisions and £20.5 million to support individual and group patient treatment requests from the new medicines fund. Any funding that was not required by NHS boards for that purpose in 2014-15 remains available in 2015-16 on top of the new allocation that was made for 2015-16. We work closely with boards on monitoring the use of the funding to ensure that it is adequate to meet a board area's needs, and we will continue to do that.

Nanette Milne: Witnesses at last week's round-table discussion seemed unclear about which boards were using all their funds. NHS Greater Glasgow and Clyde said that it was using all of its funds and perhaps needed more. Are other boards using all of their funds, or are there are still more funds floating around that are not being used?

Shona Robison: We have asked boards to inform us immediately if they have any concerns about their funding allocation, mainly on the basis of its being sufficient to meet anticipated expenditure, and no board has raised that issue with us. We make it clear that boards are expected to use their funds for the stated purpose over the lifetime of the fund. That means that they might not spend the funding in a particular financial year, but we would expect them to spend it over the lifetime of the fund.

There should be more transparency in the use of the new medicines fund. We had planned to publish details of the number of patients being treated and the relevant drugs but, as the committee might be aware, there is an on-going freedom of information request that asks us to provide details of the spend on the top 10 drugs. That has been an on-going complicating factor, as releasing patient numbers and spend on drugs poses a risk to commercially confidential information on pricing. Once that process has been concluded, we will publish the information that we were planning to publish, and I hope that that will provide a bit more information about how the money in the fund is being spent.

Nanette Milne: That would be welcome. In our discussion, we heard that people did not know how many patients were being treated, what therapies were being provided and so on.

Do you think that the fund will continue to be funded centrally? I know that at the moment it is funded through the pharmaceutical price regulation scheme. Is that likely to continue?

Shona Robison: What happens beyond the current PPRS agreement is an important issue. As the committee will be aware, the scheme is negotiated between the United Kingdom Government and the Association of the British Pharmaceutical Industry. The Scottish Government and the other devolved Administrations had asked for inclusion in the previous negotiations but, unfortunately, that was refused. However, the Scottish Government has had greater involvement in the operation of the current PPRS and, post-Smith commission, there are on-going discussions about how Scotland can be included in future negotiations and decisions, whatever form they might take. Therefore, if the

UK Government wants to negotiate changes to the arrangements, we want very much to be involved in that, and I am sure that Wales and Northern Ireland feel similarly. We also have the support of groups such as the Scottish cancer coalition in that regard. It is important that we have a voice in discussions around any replacement of PPRS.

The Convener: I am looking for some clarity on the information that this and a future health committee will get and in what timeframe with regard to a breakdown of the spend on new drugs that are recommended by the National Institute for Health and Care Excellence and the SMC as well as those that are not recommended by the SMC. Can we get all of that information broken down?

09:45

Shona Robison: We want to furnish you with as much information as possible. As I have said, things have been complicated by an FOI request that has delayed our putting out that information.

One issue is information that strays into the commercial in confidence domain, where there are negotiations with pharmaceutical companies around price. Obviously there are sensitivities in that respect, but we want to provide the fullest information that we possibly can and to be as transparent as possible in that. Do you want to say a little bit about that, Rose Marie?

Dr Rose Marie Parr (Scottish Government): Transparency is an important issue. We definitely want to give information on that matter where we can; indeed, it is important that we do so.

With the new medicines fund, we have wanted to ensure an increase in access. That positive step has allowed NHS boards to deliver on the policy intentions of the Scottish Government and the Parliament with regard to increased access to new medicines. That is an important area. We want to be very involved before 18 December, which is when the fund might change, and in how the fund might be used in the future.

The Convener: The cabinet secretary might be intending to publish all that information, but I presume that information about, say, total spend on drugs that have not been recommended by NICE or the SMC will not get round the confidentiality issue, any business case or whatever.

Shona Robison: We would want to publish as much information as possible. I suppose that where we get into difficult territory is where an association can be made between individual patient numbers with regard to a specific drug and the cost of that drug, because you can then work out the price. There are also commercially sensitive issues around the pricing negotiations that pharmaceutical companies might have. Angiolina Foster might wish to say a little bit about that.

Angiolina Foster (Healthcare Improvement Scotland): I simply endorse the comments that have been made. With regard to our fundamental desire for maximum transparency, the trade-off is the commercial in confidence issue. We just need to be careful not to create any unintended difficulties there.

The Convener: The committee is trying to judge what would have been available anyway and what is now available that was not previously available, because that is what will tell us whether we have got more yeses. I should say that the evidence that we have received in written and oral form reflects the view of the committee and the cabinet secretary that we are making good progress here, so we are not trying to be negative in that sense.

The new medicines fund is funded by the rebate agreed through the PPRS. Last week, we heard evidence from, I think, NHS Greater Glasgow and Clyde that this year there was a funding issue—I do not know whether it can be accurately described as a funding shortfall. Is that a result of the reduction in the rebate? Does that present us with challenges in the shorter term? What do we expect the rebate to be able to fund in the existing scheme? I should say that, during this evidence session, we will probably discuss what the future will look like and how it will be funded.

Shona Robison: As PPRS receipts are expected to be lower across the whole of the UK, not just across Scotland, this is an issue across the board. The funding is based on an estimate of what we would expect to receive. We will have to manage that, and we will work closely with boards to ensure that we manage the budget. At the end of the day, the most important thing is that patients receive the support that they require and that the fund is used in the most appropriate way. As I have said, boards have the ability to manage the fund over a number of years to ensure that that kind of pressure does not arise in one financial year, and we will work with boards to ensure that that happens.

I guess that we will want to discuss around table any schemes to replace PPRS. Under the current system, you make an estimate and build your fund on the basis of that estimate, and issues can arise if those things are not in sync. We have had a bit of that this year. Last year, that was not the case—it was different. We do not know what will happen in future years. Perhaps as part of a review of PPRS we might want to look at whether we can better match the anticipated receipts and the funding that would come in when we set the budget for our new medicines fund. I am not sure

how we would do that, but it would be good if we could.

The Convener: So this year's shortfall, as described in last week's evidence by NHS Greater Glasgow and Clyde representatives, will not impact on patients or patient access to new medicines.

Shona Robison: No. We will work with boards to manage that and ensure that there is no detriment to patients.

The Convener: Does that mean that the Scottish Government will make up that shortfall this year?

Shona Robison: As I have said, we have asked boards whether they anticipate any problems with the resources and the demand that they have. At the moment, they have told us that they do not, but we are keeping a close eye on the situation. Boards are not saying that they will be unable to manage patient demand with the resources that they have, but if resources are required then obviously—

The Convener: As a matter of interest, would that include NHS Greater Glasgow and Clyde, which told us last week about a shortfall?

Shona Robison: Yes.

Dr Parr: It absolutely would.

The Convener: Is it the case, then, that this will not impact on patients and that it can be overcome either by health boards or by the Scottish Government?

Shona Robison: Yes.

The Convener: Is there any way of forecasting whether this year will be just a blip or whether there be an impact over the next session of Parliament?

Dr Parr: That is a good point, because horizon scanning in this area is quite difficult. However, although it is difficult to predict future spend, the Scottish Government works with HIS and the boards themselves on horizon scanning for new medicines fund expenditure. We work quite closely on that with boards, and it is a continuous process; that is how we draw up our horizon scans for boards as part of their financial planning. Some financially sensitive information is included, and the process with estimates is an on-going one. We want to continue to do that and to improve our horizon scanning as much as possible.

The Convener: Does that mean that there will be increasing pressure on the money for funding this scheme?

Dr Parr: There will probably be increasing pressure on the new medicines fund money, but it is definitely not at risk just now. I think that it is reasonable.

The Convener: Does the issue need to be looked at in the review?

Dr Parr: We certainly want the independent review to take stock of all progress to date. Indeed, it would be a really positive thing for Dr Montgomery to do. The other key area that we want to look at is commercial negotiation on price to ensure that we can do better under our current system by getting a better price. We want to look at improvements in that respect, too.

The new medicines fund is important. It has allowed boards to increase access to new medicines; indeed, there has been an increase of around 40 per cent in SMC acceptance with regard to medicines for end-of-life, orphan and ultra-orphan conditions, but we definitely want to negotiate better on price to ensure that Scotland gets better value for the money in the new medicines fund.

The Convener: I am sure that we will come back to that issue.

Malcolm Chisholm (Edinburgh Northern and Leith) (Lab): Two of the issues that have been prominent in the oral evidence, which you may have read, and in the written evidence are PACE and the IPTR. People really appreciated the extent of patient and clinician involvement, but two questions arose from our evidence on PACE. First, it is good to have pre-meetings, but there is concern that there is no possibility of questioning patients or clinicians at the final SMC meeting. Quite a few submissions and comments that were made in evidence last week suggested that that would be beneficial.

The second issue is evaluation of decision making by the SMC—in particular, the impact of PACE on it. I do not know whether we have any information on that or whether there are any proposals to evaluate it.

I would say that those are the two main issues that came up in relation to PACE, although the evidence is positive about what PACE has achieved so far.

Shona Robison: As Malcolm Chisholm said, we have received pretty positive feedback from patient groups about how their views are being taken on board and into account through PACE. One of the specific areas that I have asked Dr Montgomery to look at is whether more needs to be done around that. Malcolm Chisholm also mentioned the end point of decision-making. We have made huge progress but we know that more can be done and that further improvements can be made. Dr Montgomery will look at that—I am sure

that he will make recommendations that he thinks could further improve the system.

Malcolm Chisholm: I will kick off the questions about the IPTR, although I am sure that colleagues will want to follow up on it. The key issues are consistency and transparency—people have made various comments about how those might be addressed. Although the extent to which the IPTR had delivered more positive results for patients was welcomed, concerns were expressed about consistency among boards, about their decision-making processes and about the transparency of those processes. Are there any proposals to deal with that? To what extent will PACS address those issues when it is rolled out?

Shona Robison: As you have recognised, the extension of flexibility that the committee called for has led to the tenfold increase, from the time of the committee's inquiry. We can think about specific examples of where the IPTR has worked, and I know that the committee has heard direct evidence from people who have benefited. From the outset, we have been clear that there should be a reduction in reliance on PACS to access medicines, as a result of changes that have been made at the SMC. Dr Montgomery's forthcoming review will test how that has worked.

If the system had been rolled out in May 2014, it would have been ahead of a body of decisions that were being made by the SMC under its new process. The extension of flexibility has allowed 500 patients in 2014 to access orphan or ultra-orphan drugs that were not recommended by SMC at the time. The rolling out of PACS has coloured our view of how it should be done—that is why we went to the pilot. We recognised that the process was working quite well, so we did not want to jeopardise it by moving to a new system too quickly. That is why we are having the pilot in NHS Greater Glasgow and Clyde.

It is also fair to say that boards have adapted their decision making. They have applied the flexibility and we have seen the evidence of that in the numbers. The new medicines fund has supported the change of approach; that support has been important.

However, there are always going to be individual decisions and circumstances. No system can get away from that altogether, including the IPTR or PACS. Guidance to boards states that they should share best practice. We have encouraged that and are keeping a close eye on decisions that are made either way.

We are in a better place and we are moving forward with caution through the pilot and the move to the new system. We want to make sure that we continue with improvements, although difficult and unpopular decisions will still have to be made under the IPTR or PACS. No system will ever address that perfectly, but we are in a much better place than we were previously.

10:00

Malcolm Chisholm: I have a final question. What are the main ways in which PACS is different from the IPTR? It is being piloted. Is it about the detail or are you still exploring some fundamental questions about PACS?

Shona Robison: The changes that are being tested in the pilot are focus on capturing measurable clinical benefit and monitoring of outcomes and adverse events, which is key, prescribing clinicians seeking peer support on an individual-patient basis, the use of a panel of clinicians to oversee cases, and the consistency that it delivers. The focus of PACS is on the clinician being very much at the centre of the process but with oversight of it. So far, nothing in the pilot causes us any alarm. Perhaps Rose Marie Parr can say a bit more about it.

We think that some good information will come out of the pilot—not least through its trying to capture more information and to measure clinical benefit. We are less good at seeing what happens when a drug is out there with a patient—whether it is delivering what it was supposed to deliver or whether it is delivering more or less. How can we capture that information and feed it back in to the SMC for future reference? It is about trying to complete the circle of real-time information.

Dr Parr: That is right. I think that we are being cautious in the PACS pilot, which is the right approach. The outcomes of the pilot will be very important. We will also involve individual clinicians more.

We hope that, in the longer term, there will be less reliance on systems such as the IPTR and PACS, with the SMC's decisions being the ones that we stick with nationally. We will look at what happens with the pilot and roll-out through the independent review and we are open to making further changes, if necessary. As the cabinet secretary said, it is an interesting and difficult area for some people, so it is helpful that we are proceeding with caution.

We want to see the main route for access to pharmaceutical companies being in putting a good case through a good-quality submission, with a fair price and offering at the SMC first time around. That is what we would like most, but we will take all the routes into account.

Angiolina Foster: I will offer a couple of comments on the first part of Malcolm Chisholm's question about PACE. You asked whether it would be desirable for patients and clinicians who have

been part of PACE also to be present at the SMC meeting. One of the organisational arrangements that we have deliberately put in place is the patient involvement network, which is a support and consultative mechanism whereby we look, in a spirit of continuous improvement, at how the current arrangements may evolve over time. My sense is that, from the point of view of our internally driven—so to speak—continuous improvement, the patient involvement network may be the place where such proposals may come from, be looked at and mature.

The second aspect of Malcolm Chisholm's question about PACE was on its impact. I genuinely believe that the figures speak for themselves on the outcomes of the SMC's decisions before and after the introduction of PACE. I am sure that Professor Fox will wish to speak for himself, but I know that he is always very clear with his committee members about the importance that they ought to place on output from PACE meetings as a crucial part of the deliberations of his committee.

The Convener: Rhoda Grant has a supplementary question on the same subject, and I invite similar questions on the process from other members.

Rhoda Grant (Highlands and Islands) (Lab): My question is about how the IPTR system currently operates. People still express concerns that some people get access to medicines that others do not. That discrepancy looks more stark when they are being treated by the same clinicians, but come from different health boards.

I imagine that the information would be the same if it is coming from the same clinician, so it cannot be about whether the treatment can make a difference. What are health boards basing their decisions about those requests on? How transparent is the process, and how will it change?

Shona Robison: The clinical decision might be that one patient may benefit from that treatment while another patient may not, or it might be that the side effects could be such that a patient could not tolerate the treatment. We do not know what discussions are had about the clinical needs of patients, so a clinician might make different decisions about the same drug for two patients. Two health boards might make different decisions about a drug and a patient: we do not know the circumstances of those patients, which may be quite different.

That said, we keep a very close eye on ensuring that if we consider that a process raises questions, we look at that process and ask pertinent questions about it. The fact is that we have seen a different approach across the health boards overall—the numbers speak for themselves and would not be such as they are if that was not the case.

Ultimately—as I said to Malcolm Chisholm—there will be occasions when difficult decisions are made. We expect those decisions to be based on clinical judgments, and we expect boards to use best practice and guidance to inform their approach, whether under the IPTR or—in the future—PACS. If members think that that has not been the case and are aware of stand-out cases that they want us to look at, let me know and we will do that.

Rhoda Grant: How much work have you carried out with clinicians? Do you speak to the Beatson west of Scotland cancer centre, for example, and listen to what it says about different health boards giving it the okay for different drugs? It is treating patients, so it would know what information patients are feeding back to the health boards, and whether patients have differing outcomes. I do not have a specific example but, anecdotally, it seems that health boards take slightly different approaches.

Shona Robison: Yes, we do. Rose Marie Parr will say a bit more about that.

Dr Parr: That is an interesting area. Patient numbers in such areas are small, so it is quite difficult to interrogate the data. The data that we have to date show no evidence that there is a postcode lottery, although people perhaps have that impression. Individual decisions are taken for individual patients. It is right and proper that those decisions differ.

Before the policy changes were made, about 50 patients were accessing ultra-orphan, orphan and end-of-life medicines through the IPTR. By 2014-15, that number had increased to over 500 patients. The numbers are quite small, but we can see increased access. We have only anecdotal evidence that there is a postcode lottery, and we do not think that the numbers back up those claims.

One thing that we can do, and which the Scottish Government would help with, is share information among boards. Last week, the committee heard from clinicians that for some very small areas it is really good for clinicians to share information, so we encourage that.

The Convener: You and others will be aware of the written evidence that we have received and the oral evidence that we received last week. Most people have made the point that we are talking about evolution and are not criticising the progress that has been made. It is worth putting that on the record again.

Bob Doris: I return to the subject of price. I have listened carefully; Rose Marie Parr said that

you want to negotiate better on price for the NHS, and the cabinet secretary said that you want to get the best deal for the NHS. Angiolina Foster's submission to the committee ahead of this evidence session says:

"Healthcare Improvement Scotland believes that the assessment process is best served by pharmaceutical companies offering a competitive price from the outset. The price considered in the assessment may involve"

a patient access scheme. Woven throughout all that, of course, is the fact of commercial confidentiality.

The theme again and again is that we could do better on price. That can mean only that pharmaceutical companies are charging more than we expect to pay for medicines. There is an obvious benchmark for me: are we getting as good a deal as England gets? I am keen to know whether we are negotiating as hard as we can on price and whether the pharmaceutical companies come to the table to make the best possible deal.

I spend much of my time working constructively with pharmaceutical companies as key stakeholders, but they are also private companies, so striking the balance between maximising shareholder profit and their corporate social responsibilities can be quite tricky. Prices have come up repeatedly in evidence this morning, so are we getting the best deal? What more can we do? How does the situation here compare with that elsewhere in the UK?

Shona Robison: Price has already been a really important area, and it will be very important as we go forward. We have monitored the issue very closely, not just in relation to medicines that fall within the SMC's new approach, but generally.

The short answer is that we do not always get to the company's best price first time round, or even at all, although I should be clear that not all the pharmaceutical industry behaves in the same way when it comes to pricing, and although companies are absolutely entitled to make commercial decisions on how they price their drugs, it is incumbent on all of us to ensure that the NHS has systems in place so that the best value is achieved and the need for time-consuming resubmissions to the SMC is avoided.

We take the view that there should be external commercial negotiations that are linked with the SMC process. The pharmaceutical industry could also do better on fairer pricing without unduly impacting on returns for its shareholders. If we get that to a better place, things such as the new medicines fund can go further and support more people. If a pharmaceutical company is able to offer a better price elsewhere, we would expect there to be no reason why it could not offer that better price to the NHS in Scotland, as well.

I have asked Brian Montgomery to look at how we can make those improvements. There are in the systems potential ways to have an earlier discussion to avoid reaching the position at the end of the process at which a better price is offered on resubmission that could have been offered in the first place, although sometimes months will have elapsed. There are definitely process issues that can be tackled to get to that better position.

As I said, we think that there should, linked with the SMC process, be external commercial negotiations that can drive a fairer price. We are very keen to pursue that.

Dr Parr: I absolutely agree. The only thing to add is that the Scottish Government can monitor price closely because we have access to commercially confidential information. That allows us to say that there could definitely be improvements in some areas, which would allow the new medicines fund, for example, to go further. We would like such improvements to come out of the review.

10:15

Bob Doris: Do either of the other witnesses want to add to that before I move on?

Professor Jonathan Fox (Scottish Medicines Consortium): I agree with everything that has been said. However, I note that the SMC does not negotiate on price, as that would conflict with its role in medicines assessment.

An additional point about getting the best deal is that the new processes and the PACE meetings allow companies to come back with a new or improved patient access scheme or confidential discount, which has helped on a number of occasions to improve the cost effectiveness of medicines. We have had about seven such occurrences, four of which resulted in eventual acceptance. That has helped with the ability to get medicines at the best price.

Bob Doris: That is helpful.

Convener, I should point out that I have met pharmaceutical companies frequently. I add for the record that I have never been paid to meet them and that it is done in a constructive, collegiate way—

The Convener: Too late. [*Laughter*.]

Bob Doris: —given my role on this committee.

The important point is that I have never yet met a company that has not said that it is in this for the best interests of the patients and the people it serves. I am therefore sure that, if better deals are being struck elsewhere in the UK, the companies will want to look at that carefully and work

constructively with the Scottish Government to ensure that Scotland gets a better deal than we are currently getting. I am sure that they were listening to the exchange that we have just had.

To move the debate on a bit, I note that we are also hoping to develop a Scottish model of value. The committee was keen to see that, having taken evidence on value-based pricing back when we were doing our initial inquiry on access to new medicines. I would be keen to hear any update that is available on that. In particular, my interest has always been in cases where the clinical evidence from trials is not as mature as it could be or does not have longevity. I apologise if my terminology lets me down; I suppose that I am referring to results-based reimbursement, for lack of a better description, and maybe even reimbursement in instalments. If someone can sustain employment for longer because of a medicine or if they have fewer social care needs because of a pharmaceutical intervention, that creates time-releasing savings in the health and social care sector, although there are up-front costs to the NHS for medicines.

It is in that context that I view any Scottish model of value. Pharmaceutical companies would be key stakeholders, working in partnership to develop that model. Is there any progress on that? Where are we with it? Can we hope to see something in the near future?

Shona Robison: We said from the outset that the new approach that the SMC adopted would be the first step in developing a Scottish model of value. The independent review under Dr Montgomery will consider whether the progress that has been made to date provides a solid base for developing the concept further. Some of the points that you make are very fair.

Dr Parr: I agree. There will be a lot of interest from both patient groups and the industry in seeing how we build on that model of value, and the new approach is part of that. Our new framework for end-of-life medicines and orphan and ultra-orphan drugs includes modifiers. That type of value can be taken forward as well, and patient and public involvement, the PACE process and the pilot PACS can all be added to the model. That represents solid movement on the way forward.

There are issues around trying to look at evidence and outcomes. I agree that sometimes the narrative is about not just access to new drugs but how they are used and what outcomes we get from them. We will definitely look at aspects of the context of new medicines and what evidence there is on what they will deliver both for the patient and for the NHS, and we certainly expect the review to look at the real-time health technology assessment that I think you were referring to. That definitely needs further consideration, for policy and practice in future. However, we would want to look at that as part of the wider group. We would also want to see what companies and countries are doing nationally and internationally in the area of health technology assessment. It would be very positive to go into that, too.

The Convener: Professor Fox, you said that the SMC does not negotiate the price, but an issue that has been raised by people who have tried to access new medicines is that, sometimes, even when the only thing that has really changed is the price, a new medicine has become available, which sort of sours the principle that price does not really matter. As we know from written evidence, and from oral evidence last week, the process is important to people.

There is also the issue of openness. The pharmaceutical companies have said that, whether the decision was right or wrong, if they knew more about the initial discussion and why a new drug was refused, they would be able to respond more quickly. The process itself has been criticised by all sides. The Government says that the process is not working for it from the point of view of price. The patient is denied access to a medicine or it takes longer to access it, and sometimes it is too late. Rightly or wrongly, a negotiation takes place, with people saying, “Let’s hear what you’ve got to say. We might able to offer you something.” To all intents and purposes, there is a negotiation, but the process has been highlighted as one of the things that are causing problems. Will such issues be addressed by the review, and if so, how?

Shona Robison: A key issue that Dr Montgomery’s review will consider is how we get the best price as early on in the process as possible in order to avoid the scenario that you describe. The review will look at how we can have an external process that, although linked to the SMC process, basically drives the discussion at an early stage, in which we say that what we want out of the process is the best, fairest price at the earliest possible stage. We want to avoid what you describe, which is a resubmission at the end of the process, with a different offer. We need to focus on getting the right set of procedures in place. Some of that, although no doubt external to the SMC, will have to feed into the SMC in the right way. A key ask of Dr Montgomery is to take that forward.

The Convener: Are we more likely to get a better price from pharmaceutical companies if we work with the UK Government or other European Governments, which are all competing? That is the market. How do we circumvent a market in which a company can sell a drug in Italy because Italy is prepared to pay twice the money for it?

Given our population size, and our demand and spend, how do we get a better price than our neighbours with populations of 60 million? We could seek a Scottish solution to taking on global companies, but are there opportunities here for Governments to work together to ensure better pricing?

Angiolina Foster: I sense that we are wrestling with three quite distinct concepts.

The first is the best pursuit of the best possible price for Scotland in a commercial context. The point that you are rightly flagging is that it is a global marketplace, so any improvement in the processes that Scotland deploys for commercial negotiations will need to recognise the global nature of that marketplace. That is concept one, if you will: the commercial issues.

Number two is the question of the overall affordability for Scotland's NHS of the drugs bill. That is quite distinct, and it is clearly a policy and value issue. The third concept is one of cost and clinical cost effectiveness. It is that third area—and only that third area—that is the business of the SMC's professional and public deliberations.

Those three things clearly interplay, but the mechanisms and possible maturing of each of them may take separate routes. Jonathan Fox may want to say more.

Professor Fox: Depending on what system is devised and developed for price negotiations, and depending on where in the process it comes in, the SMC's expertise can be very valuable in informing the system, without specifically taking part in its development. That is undeniable.

Having the SMC's health technology appraisal system has helped to get the best prices. Without it, the market would be far less controlled.

You talked about how price might still be a factor. Clearly, it is. Access to new medicines cannot come at any price. That has been stated many times, even by patient groups. We have, very deliberately, increased flexibility following the committee's advice and the cabinet secretary's instruction a few years ago, and there is no question but that that has increased access to these medicines. In addition, we have downgraded the importance of the cost-effectiveness information for ultra-orphan medicines. However, overall cost effectiveness—value for money—must still play some part in drug decision making.

The Convener: By the SMC?

Professor Fox: Yes.

The Convener: Is the current procedure for dealing with that—the quality-adjusted life year and all that—still the appropriate way to evaluate?

Professor Fox: It is an appropriate way to deal with the great majority of medicines. Remember that we deal with a lot of medicines that are not for the end of life or for very rare conditions.

The Convener: And at the current level of cap on cost per QALY?

Professor Fox: That is outside my personal domain, but there is an interesting argument. You heard evidence three years ago about what the QALY's true cost in the NHS might be. We have conventional ways of assessing these medicines: the thresholds are not strict, and various issues can be considered along with the cost per QALY. We have much increased the flexibility for some medicines. However, the current procedure is a proper way—or at least a way—of evaluating.

We have also offered people the opportunity to use other arguments, let us say, for very rare conditions—ultra orphans—but that is still at quite an early stage.

The Convener: Does that need to be developed?

Professor Fox: We are trying to develop it continually. Again, it is a question of our relationship with the pharmaceutical companies and getting an understanding of what may be acceptable in those unusual circumstances.

The Convener: Will the review deal with the cost per QALY and rare and orphan diseases, cabinet secretary?

Shona Robison: Yes.

Bob Doris: We have to be slightly careful on the cost per QALY. I apologise if I get the numbers wrong, but back when we did our initial inquiry, the rule of thumb for a bog-standard drug—although I know that there is no such thing as a bog-standard medicine—was £25,000 to £35,000, depending on the clinical evidence. That was what was affordable. A pharmaceutical company might have been prepared to settle for £20,000, but given that the crib sheet is so rigid, why would it not put in a bid at £35,000, at the top end, if it knew that the cost per QALY threshold was £35,000?

I know that Professor Fox does not deal with the pricing negotiations, but is there realpolitik in those discussions, in that you have to be slightly careful not to set out a rigid crib sheet on what the cost per QALY is? Why would a company not just go in at the top end of it and maximise its profit if it could do that? Does the cost-per-QALY chat come with a health warning?

10:30

Professor Fox: Yes. The fact is that, in the real world, competition helps. Remember that, after the SMC process, there is scope for tendering and

cost negotiations. Even after some medicines have been accepted at a certain cost—that can include the confidential discount; it is not necessarily the list price—there are opportunities for further negotiation at a national or a local level. I guess that there is a difference between what might be regarded as a price that allows cost effectiveness and the best price, which the cabinet secretary mentioned in her opening statement.

Bob Doris: Is that where the independent commercial discussions could take place, in tandem with but not as part of the SMC process?

Shona Robison: Yes, although they would obviously have to relate to the SMC process and it would have to provide an input into them. We have asked Dr Montgomery to look at how that might work, what synergy there might be and the practicalities of how those discussions would sit alongside the SMC process—who would be involved and how it would work in practice. It is clear to me that getting the best price—which will be a fair price—for Scottish patients and taxpayers is very important, and we believe that there is room for improvement. We want to ensure that we get the best deal.

Rhoda Grant: Has the number of co-payments, where patients fund their own access to medicine, declined with the introduction of the new system? One of the main issues with the old system was that some patients could afford to make such payments to access new medicines, whereas others could not.

Dr Parr: There is some chief medical officer guidance from 2009, I think, that covers more than medicines but which was introduced to allow work on access to medicines in a previous parliamentary session. That guidance remains in place, although we are not aware that its provisions are being widely used—the Scottish Government does not hold that information centrally; it will be held by the boards.

We would be quite concerned if patients were paying significant amounts of money for treatments that did not provide a great deal of benefit. Going into and through the review, the CMO's work on realistic medicine and the whole area around how we want to speak to patients about shared decision making might provide an opportunity to discuss the matter further. Indeed, shared decision making between clinician and patient might provide an opportunity to look at some of those issues. Some of the drugs can be difficult to take and quite toxic, and that end-of-life discussion is very important.

Shona Robison: I think that, if the issue was widespread, I would know about it and people would be raising it with me regularly, but that has not been the case. It is something that we need to keep a close eye on but I am not aware, from issues being raised with me, that it is a common occurrence.

Rhoda Grant: I do not think that it is a common occurrence, but it occurs and we have taken evidence on it. When we looked at the system previously, there were issues around people paying for their own medicines and then, because they were already paying for their medicines, having to pay for treatments that they would have received free on the NHS, such as scans or blood tests.

My understanding is that that has now changed, in that they would pay for the drugs separately but would receive other treatment on the NHS. However, there is concern about delays around who pays for what. I am looking for some information on how the process could be speeded up to ensure that there are no delays in treatment. We were given the example of someone who got access to the drug treatment that they were looking for only weeks before their death, but had the co-payments been sorted out sooner they would have had treatment with that drug sooner.

Shona Robison: I am certainly happy to look into particular cases such as that one. You have said, quite rightly, that the CMO's guidance changed to ensure that the issues that you cited around aspects of treatment other than drug treatment were resolved. The number of cases is small, and we need to have relatives' permission to look into individual cases, but I am certainly happy to do that if there are still issues around timing. As I understand it, we are talking about a very small number of cases, and ultimately there still has to be a clinical judgment about whether someone could be harmed if they decide to go ahead with treatment when their clinician is of a different view. The clinical judgment in those matters is still important, but I will look into the circumstances in the case that you have raised.

Rhoda Grant: That would be useful. We would assume that, if the system was working right and the clinician thought that a drug treatment would be beneficial, there would surely be access to that drug so that people would not have to consider funding the treatment themselves. That was an issue historically, because those who could afford to fund it could access treatment and those who could not afford to fund it could not access it. It would be good to look at the issue in the round to see, first, whether it is happening—whether NHS treatment is being provided free and quickly—and, secondly, in what circumstances it is happening and whether the system is picking up on it.

Shona Robison: We will do that.

Richard Lyle: I have several questions. In these islands, in the context of the United

Kingdom, there are two distinct countries: Scotland and England. In England there is NICE and in Scotland there is the SMC. One of the comments that patients always make to me is that if NICE accepts a drug it is then brought to the SMC, which might not accept it. Why is that? Should we not be working together so that, if we have accepted a drug or the English body has accepted a drug, the work that has been done on that acceptance can be taken on board by the other organisation?

Shona Robison: It works both ways. There are drugs that are approved by NICE on which the SMC takes a different view; similarly, there are drugs that are approved by the SMC on which NICE takes a different view. I will hand over to Angiolina Foster in a second, but I should mention that a decision has just been made to bring the cancer drugs fund into NICE. Various views have been expressed about that, but our approach has been different, in that we believed that it was important to have a sustainable position. We had concerns that the cancer drugs fund would be pretty short term, and the question was, "Then what?" The answer is that the cancer drugs fund is now going into NICE and will essentially be absorbed through the NICE processes. Concerns are being raised because until that happened there was a different process. We have taken a more sustainable view of making the improvements incrementally and not putting all our eggs in one basket, with all the difficulties that have followed for the cancer drugs fund.

Angiolina Foster: It is a good challenge, Mr Lyle, but I ask Professor Fox to give you a more detailed explanation.

Professor Fox: The SMC started about 14 years ago, and its role was to assess all new medicines or significant new indications for medicines. We continue to do that. NICE has never had quite that remit, so there have been differences from the beginning. NICE selects medicines to appraise. Given the philosophy that Scotland should have a system that appraises all new medicines, I guess that that is one of the reasons.

The next reason relates to the notion of the circumstances of the population in Scotland being different from the circumstances of the population in the whole of the United Kingdom. In addition, increasingly, there is the fact that the NHS in Scotland is rather different from the NHS in England. I am giving you a number of reasons why I believe that the SMC should continue to exist. I would say that, of course, but I think that those factors are relevant.

Do we co-operate with NICE? We certainly do. Incidentally, NICE produces excellent output—there is no question about that—but its processing has traditionally been very much slower than ours. We have tried to make our decisions quickly so that we can shape future practice instead of having to change established practice. As well as being comprehensive, we have been rapid—and we still are rather rapid, even with the small increase in timescales that is related to the PACE process.

As far as co-operation with NICE is concerned, we talk to each other and read each other's output, but we co-operate on more levels than that. In particular, there is a thing called the multiple technology appraisal, whereby NICE is able to compare many existing medicines or other treatments within a specific disease area. We do not do that, but it can be very useful. The process often does not involve brand new medicines but looks at a therapeutic area in which there are several medicines. We usually adopt those via Healthcare Improvement Scotland—we have a mechanism for accepting them for use in Scotland. If we do that, that supersedes previous SMC advice. Therefore, we work closely in that respect.

Richard Lyle: I am not suggesting that the SMC should be done away with and taken over by NICE—quite the reverse is the case. The point that I am making is that people ask me why people can get a drug in England but not in Scotland. I know that we are taking steps to address that.

In a way, you let the cat out of the bag earlier when you suggested that the eventual acceptance of a drug is based on price. Last week, several witnesses suggested that we should have a hard negotiator who would negotiate the price. Is a drug eventually accepted in Scotland if the drug company comes back and says, "We made a mistake" or, "We can negotiate" or whatever? Is that a rule?

Professor Fox: I think that we should distinguish between the bulk of medicines that we deal with and those that are in the end-of-life category or the very-rare-condition category. In those cases, although we do not state a specific threshold, it is clear that the cost per QALY—not the list price, but the cost that the medicine represents to the NHS in Scotland compared with the benefits that it brings—is a major factor.

I want to correct an impression that was given at last week's meeting of its being just about the cost; it is not. It is not just the price or the cost of the medicine that we consider; we take into account all the healthcare-related costs in the conventional process for the new medicine compared with those for the comparator medicine—the previous medicine. By no means do we take into account just the price of the medicine; we look at all the costs, including any costs of not using the new medicine. That is all taken into account.

As I have said, we have a lot more flexibility in the new process, which has been shown by the increased acceptance rates that we have had. Indeed, for the ultra-orphan medicines—the medicines that affect very few people in Scotland, such as fewer than 100 people or thereabouts—price is even less important. However, it is difficult to sustain the argument that access to medicines can come at any price given the enormous price of some of the new medicines that are coming to market.

10:45

Richard Lyle: Like Bob Doris, I have had meetings with certain companies and the first thing that I have said to them is that their medicines are too dear. As you said, let us live in the real world, which is that we want the best for people in Scotland but we also want it at the best price. I agree with you.

Let us move on to something about which I do not know much and about which you might wish to enlighten us. Comments have been made about the membership of the SMC and about whether there are patient representatives on it. I am not asking you to name the SMC members individually, but how are they appointed?

It has also been commented that, although the SMC allows the public into its meetings and although more meetings have been held and the SMC has become more transparent, the votes that it takes are not made public. Will you explain that?

Professor Fox: From the beginning, the SMC has led the way in involving public partners and the industry as full voting members of the committee. It includes three public partners and three representatives of the pharmaceutical industry, who are nominated by the appropriate groups, as well as managers, finance officers, chief executives and a range of clinicians—doctors, pharmacists and nurses. It is a very diverse group containing all the appropriate stakeholders.

The other factor that we take into account is that we want representation from all the health boards in Scotland. We try hard to ensure, whenever possible, that the SMC covers the whole of Scotland in terms of the territorial health boards. We try to balance it in that way.

The SMC is a consortium of area drug and therapeutics committees, and the clinical representatives are nominated by them. We do not go out and pick people; we ask for nominations and then choose the nominees who best fit the necessary mix of skills and geographical representation.

Your second point was about voting. I have looked through all the written submissions, and the same point has been raised by a few of the pharmaceutical companies and the ABPI. I have some understanding of why.

When we moved to meeting in public, we changed to a system of paper ballots for the vote. That decision was made by a committee that included representatives of the pharmaceutical industry. We were told clearly that we could not reveal the result on the day because of possible effects on the share price locally and internationally as well as other commercial and, maybe, other considerations. Therefore, we could not use the previous method of an obvious consensus or a show of hands.

We have moved to paper ballots, which is the most appropriate method on practical grounds and on the grounds of transparency because we can assure the public that they have seen every bit of the discussion of the medicine. We have the entire discussion to the end and then ask for a vote. The votes are then taken away, they are counted and the results are announced to the committee in a short private session afterwards. We do not discuss the medicine again because that would not be in the spirit of full transparency.

The only exception to that practice has been that, in a very few cases—in the cases of, I think, seven out of the first 125 submissions—we have had to have a short private session to discuss commercially confidential information. In order to allow the whole discussion to take place in public, we have handled that by referring members to the paperwork instead of reading out the figures.

I could go on about why it would be difficult to change the process, but I suspect that you do not want me to.

Richard Lyle: There is one point that you have not answered. I know that it is hard to ensure this, given all the different organisations and patient representative groups that are out there, but is there a patient representative on the SMC or is it intended that there should be one?

Professor Fox: There are three public partners who, as it happens, have extensive personal experience in the healthcare context.

I think that you may be referring to whether we should have patients presenting the PACE statement. That was not recommended by the task and finish group, whose recommendations were the basis of our new process, but I think that the matter will be considered in the review.

The Convener: Malcolm Chisholm has a question on the same theme.

Malcolm Chisholm: It was useful to be reminded of the SMC's origins and how it was set

up to be different from NICE. However, in the past, there were problems in ensuring that boards implemented the SMC's decisions. Does that problem no longer exist or is that still a problem? Do you audit the extent to which boards follow and implement the SMC's decisions?

Shona Robison: I am not aware of any systemic problem with boards' implementation of the SMC's decisions. The figures would not be as they are if that were the case, and we are not seeing any stand-outs that are running counter to the direction of travel of other boards. I am certainly not aware of any issue.

Dr Parr: In many ways, having boards speak to each other has been one of the success stories. Indeed, there is a new collaborative, with boards speaking to each other through the area drug and therapeutics committees. HIS hosts those committees, so it may want to comment on the matter. There has been success there in the sharing of best practice.

The timeframe in which the Government expects boards to take decisions on SMC advice is still within 60 days of its publication and boards are meeting that deadline, which is also important.

The wider issue around collaboration is that there should be more consistent communication of boards' decisions across Scotland. That will be important going forward. We definitely want to see collaboration continue between boards' area drug and therapeutics committees, as that collaboration has been one of the new framework's success stories.

Angiolina Foster: A mechanism that Healthcare Improvement Scotland has—again, very deliberately—put in place to support that is the collaborative, which is designed to address any perceived inconsistencies or differences in timeframes for implementation on the ground of the SMC's decisions. We sense that a number of the perceived differences are to do with inconsistencies of language, right down to issues of vocabulary and how the process is being described locally. Although, on one level, it may sound a little mundane or trivial, we are finding that the material that we provided to the collaborative and shaped with its members around the consistent use of words and the description of activity on the ground is beginning to dispel any perception of inconsistency or failure to implement. Over time, that greater consistency will help the situation enormously.

Bob Doris: I am glad to hear that there is now a collaborative. There are 14 area drug and therapeutics committees, which is a heck of a lot of committees for a nation of about 5.3 million people. Will the review look at how they can work more closely together to integrate a lot more of what they do? My understanding of managed clinical networks is that a lot of that integration is starting to take place.

Shona Robison: Yes. We have been encouraging more regional working and regional planning of services generally, including in that area. That work is under way.

Dr Parr: It is, and boards are exploring how more regional structures might operate in practice. We see that already in clinical practice in some areas, and that helps the communication. The collaborative that was mentioned by Angiolina Foster will help that and will ensure consistency of information.

The Convener: I have a couple of brief follow-up questions. Richard Lyle covered the issue of voting, and we have a good response on record that balances what we heard before.

Beyond the issue of pharmaceuticals, a discussion has taken place with practitioners and patient groups about the need for greater clarity. They go to meetings and, in some cases, get a good hearing, but they are then mystified as to why they are turned down. They ask themselves whether they are being listened to. There has been a call for greater clarity about the decisions that are taken following those discussions—a call for an explanation. Does the SMC accept that? Will that issue of clarity be addressed in the review? Indeed, will it be addressed at all?

Professor Fox: Yes, we accept that we should look into that to see whether we can provide better explanations. However, it is sometimes hard to provide a full explanation because of the amount of material that is declared to be commercially confidential, particularly in relation to cost. Therefore, there is a problem with giving a full explanation. Nevertheless, that is only part of it and we will try harder to address the issue in the review process. That is probably all that I should say on that point. It is something that we will look into.

The Convener: We are trying to reflect the written and oral evidence that we have received and demonstrate that we are listening.

Professor Fox: The PACE statements are always presented very powerfully to the SMC committee. I have always reminded the committee of the powerful influence that the statements should have on decision making, which Angiolina Foster mentioned. However, for all the reasons that we have discussed, even if a powerful PACE statement is accepted, that does not mean that the SMC committee will accept the medicine. There is no question about the power of the statement.

The Convener: The call was for greater clarity around those decisions.

In our previous work, we recognised not just that some of the work of the SMC is at the forefront in the United Kingdom but that the SMC is an exemplar to similar organisations that are struggling with the issues that it has been struggling with. Bob Doris mentioned that we have medicines that are given breakthrough status by regulators. We need to get some clarity on that, because we are hearing evidence about whether the whole process is fit for the future. If the SMC is to continue to be at the forefront of the work, what will we do to address the issue, which we heard about from an oncologist, that the evidence for breakthrough medicines is not as good as we would expect it to be for other medicines and new drugs? How can we ensure that, in relation to breakthrough medicines, the SMC is fit for the future?

Professor Fox: That is a very good point. That is one of the major challenges that the SMC will face in the coming years. It is also something that we have discussed with similar groups around the world, all of which face the same kind of issue.

It is something that we are working on. In the future, we will have to come up with a mechanism to deal with the relative immaturity of the data that you referred to, because medicines are getting their approvals earlier and are coming on to the market earlier.

This may not be applicable to all those medicines, but the SMC may have to consider, as a one-off process albeit with the possibility of fairly early resubmission, some kind of conditional acceptance, with the opportunity for a review, that would be based on the real-world data—which we have been talking about—that needs to be collected about the benefits of those medicines when they are used in NHS Scotland.

The answer is yes: we are seriously considering the issue.

The Convener: Will it be covered by the review?

11:00

Dr Parr: I think that it will be covered. At present, it is difficult to use patient data from real-life situations in a systematic way to make health economic assumptions. The Scottish Government is therefore providing investment to NHS Greater Glasgow and Clyde to enable it to work with the Farr institute of health informatics research and others to look at the clinical effectiveness of cancer medicines in real-life settings, considering not just issues of access but how the medicines are used. That will give us information on medicines that have been accepted by the SMC and perhaps pointers for the future. The concept of investing in new medicines on the basis of little evidence means that giving people earlier access to medicines is definitely going to be a major decision for us going forward, as it will be for other HTA organisations. We expect that such suggestions will be put forward by the independent review, and we will want to see both national and international evidence for them.

The Convener: I thank the cabinet secretary and her colleagues for their evidence and time this morning.

Last week, the patients groups and other stakeholders showed their appreciation of the progress that has been made through the Scottish Government and the committee. We should take some satisfaction from the fact that the committee, working with the Scottish Government and others, has made some progress. The word “evolution” was used, and the cabinet secretary reaffirmed its appropriateness today. There is more to be done, but progress has been made.

I suspend the meeting briefly to allow a changeover of witnesses.

11:01

Meeting suspended.

11:07

On resuming—

Subordinate Legislation

Public Services Reform (Social Work Complaints Procedure) (Scotland) Order 2016 [Draft]

The Convener: Agenda item 5 is consideration of an affirmative instrument. As usual with affirmative instruments, we will be taking evidence later on from the Cabinet Secretary for Health, Wellbeing and Sport and her officials. Once we have asked all our questions, there will be a formal debate on the motion.

Before I introduce the panel on the record, I want to acknowledge the milestone that the committee has reached today: at this meeting, we will welcome to the committee our 1,000th witness of the current parliamentary session. I am sure that members will agree that witnesses play a vital role in the committee's work. Committees might be the gateway to the Parliament, but we are nothing without those who are prepared to engage with us by giving us the oral and written evidence that informs all our work. We are proud of the level of engagement and anything that we have achieved as a result of our reports is to the credit of those who have engaged with the Scottish Parliament's committee system.

Our 1,000th witness is therefore Fiona Collie, the policy and public affairs manager of Carers Scotland—I am not going to go on and say who is the 1,001st, 1,002nd and so on. I also welcome to the meeting Beth Hall, policy manager, health and social care team, the Convention of Scottish Local Authorities; Paul McFadden, head of complaints standards, complaints standards authority of the Scottish Public Services Ombudsman; Iain Smith, policy and parliamentary officer, Inclusion Scotland; and Maree Allison, director of fitness to practise, Scottish Social Services Council.

Given the time, we will go directly to questions.

Malcolm Chisholm: I thank all the witnesses for their very interesting submissions.

I will start with a general question. As I understand it, the Scottish Public Services Ombudsman's paper explains that the order will align the social work complaints procedure with the health procedure, which the SPSO already deals with. Perhaps the SPSO representative can confirm that. Will the two processes now be identical? After all, that seems to make sense in this era of integration.

Those who have concerns will also be interested in knowing whether the ombudsman process will lose anything. Will the range of issues that the complaints review committees currently consider still be considered? Will a more centralised procedure result in any loss as a result of the loss of the locality dimension to the current situation?

Paul McFadden (Scottish Public Services Ombudsman): I can give you some general background information. For a number of years, since the Sinclair report, we have been raising concerns about complaints in the areas of social work and social care more generally where there have been multiple, complex routes for complaining and different statutory processes in place. With the approach of integration, there was a feeling that an opportunity might be missed to align the processes.

Again, over a number of years, we have been aligning complaints-handling processes in the public sector to produce a standard model procedure that has two stages with timescales and standard requirements with regard to governance and the handling of complaints. The exceptions to that have been in the areas of social work and health, as separate statutory schemes were in place under the Patient Rights (Scotland) Act 2011, the Social Work (Scotland) Act 1968 and various directions.

As a result of a commission by the Scottish Government, we have been working on the back of a Scottish health council report to bring the NHS complaints process into line with what is now standard practice across the rest of the public sector. That process is well under way, and the procedure will be in place for the NHS from April 2017. Complexity is therefore one element that we have raised.

The other area is, of course, the complaints-handling process in social work. The processes will align and become the same process, with the same standards. Crucially, from a complainant's point of view, there will be a single process point of entry and one joined-up response. Those key requirements ensure that complainants do not have to engage with different agencies on a complaint spanning different services. We feel that that will ensure a very clear, simple and consistent process for people who are complaining about services in that area.

The second part of the order also dates back to 2008, when the Sinclair report recommended that the SPSO take on the role of the existing complaints review committees. From what we can see, it is almost universally accepted that the complaints review committees system has not operated effectively, and the proposal is to give the ombudsman a professional judgment role on top of the wider maladministration role that we have as part of our standard role. That is the role

that the complaints review committees currently play, and it would mean that, in what is clearly an extension of our current remit, we would have the same role as the complaints review committees in that regard. The benefit of giving the ombudsman the professional judgment role is that it will align with the role that we have had for a number of years with regard to health complaints, which we investigate on the basis of clinical judgment.

Currently, we see complaints that cross over both areas. Such decisions are made by joint agencies, but we can look at judgments only in relation to their health board elements; we cannot look at the local authority elements. The proposals as outlined will mean that we can take a holistic look at those types of complaint and will allow a clear alignment with the integration agenda.

The Convener: Do the other witnesses concur or take a slightly different view? I see that Iain Smith is anxious to come in.

Iain Smith (Inclusion Scotland): The question was about whether the process might lead to a loss of locality issues from CRCs. I think that the general view of users is that the CRC system just did not work and did not deliver for service users, who wanted a review. Over the past few years, we have seen—and the committee has been heavily involved in this work—a number of pieces of social care legislation that provide a background of rights defined on a national basis. It therefore makes more sense for these issues to be addressed through a national complaints system to ensure consistency in how complaints are dealt with.

Such issues arise with the Social Care (Self-directed Support) (Scotland) Act 2013, the Public Bodies (Joint Working) (Scotland) Act 2014 and the Carers (Scotland) Bill, which has just been passed. All of them set out certain principles and guidance about the level of service that people should expect based on the rights and dignity of service users, giving them choice and control over participation in public life, and they all provide national guidance that is to be delivered locally. However, where that guidance fails to be delivered and where people's choices or dignity are not properly respected, there should be a national complaints procedure to look at that and to ensure that the national principles that have been agreed by the Parliament and the committee are delivered to individuals.

11:15

Fiona Collie (Carers Scotland): I agree whole-heartedly with what Iain Smith has just said. If the SPSO's role was taken in isolation, I do not think that the process would be clear. However, bringing in the two-part model complaints-handling procedure to make an aligned system will make it clear to carers and people who use services how they should make a complaint; how their complaint can be resolved and the timescales for that; and that they should follow exactly the same route in making a complaint about health, about social care or about an integrated service. That significant step forward will reduce confusion and enhance clarity for people who make complaints.

Beth Hall (Convention of Scottish Local Authorities): Our members were broadly supportive of the recommendations of the short-life working group that originally looked at the issue and which made its recommendations in January 2014. However, the statutory instrument before us does not go into the detail of how the new system will work, and our members have a couple of concerns about the proposed changes, principally around the alignment with the model complaints-handling procedure that operates in other areas of local government services.

Mr McFadden has just said that further work is being carried out to bring the complaints procedure in the health service closer to that procedure. Although we would welcome that as providing the consistency that Fiona Collie has just referred to, we are concerned because, whereas the current social work complaints procedure allows 15 days for the initial front-line resolution stage, the model complaints-handling procedure allows only five. We would like the 15-day timescale retained for that stage for the following reasons. First of all, in comparison with other local authorities service areas, social work is by its very nature more complex, in that it focuses on relationships that have begun to go wrong by the time things have reached the complaints stage. Secondly, the cases that lead to a complaint are often the more complex ones. We are therefore looking for assurances that the timescale of 15 days will be retained.

Our members are broadly supportive of the extension of the SPSO's role to enable it to consider not just maladministration but professional judgment, but they have some queries or concerns about what professional expertise will be drawn on to fulfil that role and how the interface with the SSSC, which currently looks at professional judgment and malpractice, will work. We seek clarification on those points.

On the issue of a local versus national focus, I am aware that the Sinclair report highlighted the need for providers to be able to resolve complaints more, not less, locally. We would therefore like some clear thinking about what complaints resolution will look like on the ground, especially for more vulnerable groups, if we have a centralised procedure. Will people have the opportunity for a face-to-face hearing, perhaps with the support of advocacy services, or is it

proposed that it all be done as a paper exercise? If there is to be a centralised face-to-face approach, what support will be available to enable people to participate in that?

Those are just a couple of thoughts on the issues that have come up so far.

Maree Allison (Scottish Social Services Council): As the professional regulator of the social services workforce, we consider any issues in relation to social workers' professional judgment. Although we broadly welcome the simplification and streamlining of complaints procedures, we believe it important to work closely with the SPSO to try to avoid duplication or any unnecessary lengthening of investigation times for both the person who brings the complaint and the worker whose professional judgment might have been called into question.

The Convener: The length of investigations has been mentioned a couple of times. Are there any statistics on that? How many cases are resolved within 15 days?

Beth Hall: We do not have that information to hand today.

The Convener: Okay. Malcolm, do you want to follow up?

Malcolm Chisholm: That was all useful and interesting. Let me summarise what has been said. On the one hand, Paul McFadden has said that we have to bring the health complaints process into line with the other processes and that, basically, professional judgment is the issue that distinguishes social work and health from everything else. Is my understanding right, or are there other differences?

Paul McFadden: In terms of the ombudsman's role, that is the key difference. As far as the local process is concerned, however, there are a number of differences.

Malcolm Chisholm: I have to say that I was surprised by what Iain Smith said; he seemed more positive than he is in his written submission, in which he expresses concern that the SPSO's decisions are not binding. In a way, Mr Smith, you would like it to go further.

Iain Smith: Yes, we would. I was just answering the question that you asked rather than necessarily speaking to what is in our submission. Our view is that, for certain aspects of the decision making, the SPSO should have the right to overturn the local authority's decision—

Malcolm Chisholm: But that goes beyond any powers that the ombudsman—

Iain Smith: But with the powers that the ombudsman will have over the Scottish welfare fund, they will be able to change a decision and impose an alternative one. Our concern is about what will happen with regard to many of the issues that we have highlighted, such as social work packages, if the ombudsman's investigation determines that the social workers decided that X was required but the local authority decided that it only had the resources to provide Y. If the ombudsman says, "You should provide X," and the case goes back to the local authority, which says, "No, we can only afford Y," the service user will be no better off. We believe that, in certain circumstances, the ombudsman should have the right to say, "No, you must deliver service X, otherwise you will not meet the national criteria that have been established."

On social care charges, for example, if a local authority is not taking account of disability-related expenditure in determining the contribution that a person has to make towards social care charges, and the ombudsman disagrees with what is happening, how will things change if the local authority decides not to accept the ombudsman's recommendation? There is no right of appeal, so we do not believe that the approach is compliant with the European convention on human rights.

There are many other areas where that is the case, including self-directed support packages and portability. When someone moves from one local authority area to another, they might find it difficult to get a package transferred. There is a range of areas where we believe that the proposed powers do not go far enough.

Malcolm Chisholm: The point about the ECHR is interesting, because presumably—

The Convener: I do not want to interrupt what is a pretty interesting conversation, but Beth Hall has been trying to get in for a wee while, and she might add to our understanding.

Beth Hall: Is that okay, convener?

The Convener: Yes. I said that it was okay. [*Laughter*.]

Beth Hall: I just want to pick up on three things. A colleague mentioned the welfare fund and the fact that the ombudsman can overturn decisions in that context, but I should highlight that the welfare fund is a very different thing. It is a national fund that local government simply administers. We do not set the budget—the money is ring fenced—and we have to follow national guidelines, including those on eligibility. With social work services, local government sets the budget, it is accountable to communities for how services are then managed and decisions are subject to local eligibility criteria. As you can imagine, we see any ability for the ombudsman to overturn those decisions as interfering with councils' local democratic accountability.

Someone suggested that that equates to there being no appeal, but people are able to appeal decisions—for example, around SDS resource allocation. That is an internal process, but with regard to the wider complaints process, judicial review is, as I understand it, still available to people as the last resort. I do not have any legal advice on whether the judicial review element is compliant with the ECHR, but I imagine that Scottish Government colleagues will be able to advise on that.

Fiona Collie: I am a little bit concerned about that, given that we are trying to put in place something that allows us to seek a resolution for people who have made a complaint about, say, the allocation of a budget, a service that is not working effectively or someone's professional judgment. We do not want people to have to go to judicial review. Not only is it expensive, but it adds an additional layer of stress to carers and people who use services. Whatever direction we go in, we must focus completely on seeking resolution at the earliest possible stage to ensure that when it gets to the point that the SPSO becomes involved we seek a resolution that is appropriate to everybody, even if that requires a compromise.

Paul McFadden: The most important thing is that we have in place processes that allow someone to take their dissatisfaction with a decision to an independent body for a review of whether that decision was reasonable. Since 2008, there have been various consultations on and discussions about how to fix a broken complaints system. If Government and Parliament wanted to look at an appeals system, we would need to have a whole different discussion.

We have said before that, if in taking on this role—which we think will give people an administrative justice route to challenge decisions that have been made on their social care assessments—we started to see that there was a need for something more, we would identify that need and report as such to Government and to Parliament. However, we are not aware of anything that would suggest that there is such a need at the moment. Clearly, it is not for the ombudsman to decide whether we should be taking about an appeal or a complaints route, but we feel that the proposals as outlined will maintain people's administrative justice rights and give them a right to approach an independent body to assess whether its decisions were reasonable.

With the Scottish welfare fund, which is a very different scheme, we are essentially talking about an appeals route. The role that we have replaces a previous role played by the independent review service at the Department for Work and Pensions. As my colleague has highlighted, this is a national scheme to which clear national guidance is applied, and one difference, therefore, is that there is clarity at national level that might not exist in relation to existing social work services.

Iain Smith: On Beth Hall's point about local discretion, we understand that social work departments have discretion and that it is more difficult to have an appeal route around discretionary decisions. However, I must stress that a national framework has been created that puts behind social work legislation certain rights and principles that social work authorities have to abide by. It is in those cases where there is a failure to abide by those principles that people should have a right to review and appeal. If a person's right to dignity has not been delivered because a local authority has decided that it cannot afford to provide overnight care for them, they should be able to challenge that without having to go through judicial review, which is cumbersome and expensive and requires a high level of failure for an appeal to be successful. A review through the ombudsman—or whatever body does it—would allow it to say that a local authority had got something wrong in a particular case and that it must change its decision. That is what we are seeking—it is not necessarily a judicial review process.

The Convener: I suppose that the question then is: how would such an approach square with what Beth Hall has said about policies being set locally and about local democracy? There is not an imaginary decision somewhere else that will overturn that democracy. I suppose that that is what we are wrestling with.

Iain Smith: Yes, but the issue is that legislation on health and social care, self-directed support and carers—the national care standards are coming through—sets principles that give service users the right to dignity, choice control, public participation and so on. Service users ought to have a system that ensures that those rights are respected by the local authorities that are providing the services.

11:30

Mike MacKenzie (Highlands and Islands) (SNP): This is quite an interesting and important area. If I understood the ombudsman's written evidence correctly, it was suggested that you would not take up a local policy issue unless it related directly to the complaint of the person affected and that person specifically associated their individual problem with the policy area. I wonder how realistic it is for the individual making the complaint to be aware of local policy and understand the connection between the policy and their complaint.

If you were to notice multiple complaints arising in a certain area because of particular policy decisions, would you, as the ombudsman, reserve the right to challenge that policy position, or can such a challenge be triggered only if a member of the public makes the connection and draws it to your attention?

Paul McFadden: We look at complaints from the point of view of the impact on the individual of how their care needs have been assessed within the framework that Iain Smith talked about, which is legislation, national and local policy, and entitlement. Essentially, we are looking at whether the individual is getting access to their rights and whether the judgments that have been made in assessing their needs have taken account of those rights.

The element in our evidence on the wider resource decisions was designed to answer the question that the committee has raised—or that has been raised in evidence—which was whether we would be able to comment on larger resource decisions by a council. An example would be where a decision has been taken to close a day centre. Elements of professional judgment may have contributed to that decision, and the way in which the order is drafted would allow us to look at that. However, such decisions are made in the context of a wider range of factors, including user input, and local discretion, democracy and resource concerns.

In the submission we were trying to highlight that, if a person demonstrated that they had been impacted or that there had been an injustice or a potential injustice against them, it is probably unlikely—our experience in relation to clinical judgment in health is that it is unlikely—that we could look at specific judgments that had been made in such cases and comment on them.

Mike MacKenzie: With the greatest respect, you have almost repeated my question back to me. What I am suggesting, in general terms, is that it is fairly unrealistic that the person making the complaint would make such a suggestion. If I were to do a straw poll and ask people in the street about local authority policies, for instance, many of them would not be able to give a coherent account of local policy. I suggest that it is a bit of a stretch to assume that such complaints will be made so coherently—in an ideal world, perhaps.

We heard from Mr Smith that certain rights are pretty well described and inalienable. If, for instance, you were to receive a number of complaints in a particular locality that led you to believe that there was a policy problem, would you be able to analyse the overall situation and make recommendations with regard to that policy?

Paul McFadden: When a person brings a complaint to us, that individual usually brings a general description of the circumstances and the way in which they have been affected. They do not necessarily identify a particular policy that has had an impact on them. We go through a full process, in which we speak to the person to understand their complaint. We do that as a matter of course, and we try to unpick the underlying reasons. We look at the information given by the local authority in relation to the case, and we try to unpick whether there are issues in relation to it.

On the wider issue about a range of complaints in one locality or about one policy, we could certainly see any issues in the intelligence that we were getting or the learning that we were identifying, and if we did we would feed that back to the particular authority. As the legislation is laid out, we are an ombudsman that looks at the impact on individuals—that is the role of the ombudsman—and recommendations on an individual case will relate to the case. We could make recommendations that are related to the wider policy, but they would have to respect local decision making and discretion.

Beth Hall: It is useful to be clear that the purpose of the social work complaints procedure is exactly that. It is about how individuals and their families experience the services and it ensures that, when it does not go as everyone would like it to, they have some kind of redress.

The procedure is not about examining local government's policy and budgetary decisions at the macro level. The local authority is there to scrutinise the budget and its implementation through the members who have been democratically elected. That scrutiny is subject to further scrutiny through bodies such as Audit Scotland, and it can be escalated all the way up to the Accounts Commission, which has significant powers through the penalties that it can levy on local authorities if the implementation is not going as it should.

We must remember that the complaints process needs to be responsive to individuals. I accept that, if patterns emerge in those individual complaints, there needs to be further discussion and connections need to be made. However, as my colleague from the SPSO outlined, there is the ability to do that.

Bob Doris: Beth Hall's contribution was helpful because it was almost as if we were discussing two different things—a complaints process and an appeals process for resource allocation at the local level. My understanding is that the SPSO will step in to take on the powers and responsibilities that local authorities had previously and make sure that, within the resource allocation that is set at the local level and within the structures

established for care at the local level, individual complainants will have their cases handled appropriately through the process.

I guess that some of our witnesses wish the SPSO to go further than that; some of the submissions make that argument. However, today we are scrutinising the handling of the complaints process. A good example of the crossover for the SPSO would be in the complaints that I have had about service delivery issues with Cordia in Glasgow. I hope that that is improving as a work in progress—to be kind to those involved. If a number of service failures occurred and vulnerable constituents were complaining to the SPSO, the process and structure of that service might be an issue for the SPSO, but would the Care Inspectorate be the partner agency to see whether the quality of service was fit for purpose more generally?

I do not have any concerns about the process passing to the SPSO. It has to happen under health and social care integration, and it would be crazy to look at the SPSO for only one part of the picture and go elsewhere for the other part. This just has to happen. My question is about the links with the quality of service more generally across the local authority or an integration board area. What do you see the links being in the future with the Care Inspectorate and the more general level of care? It would have a democratic responsibility to hold local authorities to account if they are in breach of the level of care that they should be providing.

Paul McFadden: In social work, we look at the broad-term assessment of care needs. Complaints about registered care providers and the delivery of care would go to the Care Inspectorate. It is the national body responsible, and it will continue to be so.

On linking up learning or looking at the assessment of what we see and how it links with what the Care Inspectorate sees in delivery, the order also contains provisions to allow us to share information with the Care Inspectorate and the SSSC, which will help us in providing information. Our role is to work with regulators but there are restrictions on the information that we can share about individual cases. The provisions in the instrument will make information sharing a lot easier. From an early stage, we have been keen that it should be as easy possible for us to feed back into the national regulator.

Bob Doris: Are there other bodies that you should be sharing with? We have the SSSC and the Care Inspectorate. Who else might have an interest in having such information? I understand the fact that local authorities are democratically accountable, but there are checks and balances in the system. We mentioned two organisations that are part of those checks and balances, but should we add any other organisations? Do we have the right balance?

Fiona Collie: The Mental Welfare Commission for Scotland certainly looks at individual issues and how the two bodies will link together. Given that the Care Inspectorate is involved, too, it can be quite confusing for carers and users of services to know who to complain to or get support from if things are going wrong. I think that some clarity around the role of the Mental Welfare Commission in relation to that of the SPSO would be useful.

The Convener: As no one else wants to respond, we will move on to Rhoda Grant.

Rhoda Grant: I would like to get some clarity on professional judgment, which has been the subject of previous questions. I assume that it is the local authority's collective professional judgment that will be reviewed, because if it is an individual's professional judgment that is the issue, that will be picked up earlier in the complaints process. I assume that, if somebody's professional judgment is way off, that will be an issue for the SSSC rather than the SPSO. Is that correct?

Paul McFadden: In general, the way that we work is that we look at the judgment and the actions of the organisations, and we report our decisions against the organisations. It is clear that we look at individuals' judgments, but we are keen to emphasise that our focus is on the collective judgment of the organisation.

We have already committed to exploring further our interaction with the SSSC—we intend to develop the existing memorandum of understanding and so forth. We want to understand exactly when we might want to cross-refer when the higher threshold has been met in relation to the actions of an individual.

We have experience of working with regulators in other areas—the General Medical Council and the General Dental Council are obvious examples. Those arrangements have worked very well since we have had the powers in relation to health. We will work closely with our partners to make sure that we get things right.

Maree Allison: We would certainly hope and expect that employers would make a referral to us at an early stage if any issues with the professional judgment of individual social workers were identified in the complaints process at an early stage. However, we anticipate that there might be cases in which the ombudsman identifies issues at a later stage. If that is the case, we hope and expect that there will be close working between the two bodies to ensure that those issues are dealt with as effectively as possible.

Rhoda Grant: I would like to ask about hearings. I know that, with the SPSO, some of the process is a paper-based exercise that does not involve hearings, but if hearings took place, where would they be held? I know that constituents have expressed concerns to the SSSC about having to travel quite a distance to access hearings. If we are talking about people who require care services and who are therefore quite vulnerable having to travel to access a hearing, surely that would put pressure on them to withdraw their complaint, because they might not be able to get to the hearing. What support would be available to them to attend?

Paul McFadden: We will not hold hearings as a matter of course, as we do not think that that is necessary in relation to the complaints that we are talking about. However, we are quite clear that we have the power to undertake hearings—indeed, we have the power to go as far as to put people under oath, although we have never had to use it. We will hold a hearing when we think that that is necessary to understand the circumstances of the case and in the interests of fairness.

We will have to speak to Iain Smith's organisation and other third sector organisations and users about how we will conduct those hearings. We have had some discussions on the issue in relation to the role of the Scottish welfare fund, which will come in on 1 April. We have had some helpful feedback from Inclusion Scotland members and users on that system, which will transfer over in relation to the process we are discussing.

If we assume that the order goes ahead, there will be a process of discussion on how it should be put in place, taking account of the needs—and respecting the dignity—of individuals in that context.

The Convener: It appears that committee members have no other questions, so I will give Iain Smith a moment to cover any issues that were not mentioned in his organisation's submission, and I will offer the other witnesses the same opportunity. We have time for a brief round-up, as we have just sent for the cabinet secretary, from whom we will take evidence next.

Iain Smith: To follow up the point that Paul McFadden has just made, it is important that local authorities and the Government recognise that advocacy support will have to be available to service users who wish to raise complaints. I am not sure that it has been recognised in the financial memorandum for the order, but there will be costs associated with having an effective complaints system for both health and social care. That is important.

11:45

One other point to make is that we are aware from anecdotal evidence that many service users do not wish to make a complaint about the assessments that they have received for social care packages. They are frightened that, if they do so, their packages might be cut further. It is important to bear in mind that they need advocacy support to give them the confidence to challenge decisions that they think are wrong. As I said, there is anecdotal evidence that people are concerned that SDS assessments, for example, are resulting in cuts in their packages and that, if they challenge them, they may be cut further.

The Convener: Does any other witness want to put anything on the record on that point or any other?

Fiona Collie: I want to re-emphasise the point about advocacy and say that there is a real need for advocacy for carers. There has been a reduction in services across Scotland, and guidance is due to come out about developing new services. Advocacy for carers and for people who use services is vital, and we need to look at how to build a network across Scotland both to support the making of complaints and to resolve issues in the first instance.

Beth Hall: I have two points. First, we want to see further work done to look at what the costs of the new system might be. In part, that will depend on the choices that the SPSO makes on physical hearings and where they would take place.

Secondly, we want the guidance on the new system to be co-produced with organisations such as Inclusion Scotland, carers organisations, the SPSO and COSLA. That would provide the opportunity to pick up issues that we have been discussing such as advocacy and how vulnerable people can be supported.

The Convener: Have you done any work on the costs associated with reducing the 15-day time limit to five days?

Beth Hall: No, we have not. As the time limit is currently 15 days for social work complaints procedures, we are looking for it to be maintained at that level when the new system comes in. The costs I was referring to were more around stage 3, which is the part that is changing significantly. We have talked today about there being a more centralised approach.

The Convener: I was trying to get a weighting of the benefit to the person making the complaint against the impact of reducing from 15 to five days. Would there be a resource implication or additional costs? I assume that the five-day period was chosen because it is part of the model for how

we expect public services to respond in the first instance.

Paul McFadden: Yes. Scotland is unique in that it has a standard process across the public sector. The aim of the five days is to empower staff to resolve things quickly, close to the point of service. We have achieved that in services: 80 per cent of local authority complaints are resolved at that stage.

We have flexibility, as we recognise that some judgments take a bit longer. We need to enable people to make judgments without having to escalate the issue unnecessarily. That flexibility exists already in relation to the community health partnerships. There have been minor suggestions from the working group, which we fully understand in the context of vulnerable social work users, that we will take account of.

On cost, it is important that the independent service is resourced so that it can be effective. One of the key things will be the recruitment of advisers, which we have in relation to health. If we are to make decisions on other people's judgments, it is important, as Beth Hall said earlier, that we have access to solid, professional advice, and that would be part of the cost. That is something that we will work closely with the Government and others on.

The Convener: I thank you all for your attendance today and your written and oral evidence.

I suspend the meeting to allow the witnesses to change over.

11:50

Meeting suspended.

11:51

On resuming—

The Convener: We welcome, for the second time today, the Cabinet Secretary for Health, Wellbeing and Sport, Shona Robison, and her Scottish Government officials Mike Liddle, policy manager, integration and reshaping care division, and Victoria MacDonald, senior principal legal officer. We are expecting a brief opening statement from the cabinet secretary.

Shona Robison: Thank you for inviting me to give evidence to the committee on the draft Public Services Reform (Social Work Complaints Procedure) (Scotland) Order 2016. There is a long history of discussion around the current system for social work complaints going back to the Crerar review in 2007 and the Sinclair report in 2008, which called for the streamlining of the complaints system.

Our draft order is fully in line with the Sinclair report's recommendations. Our intention is that the changes that we will make will shorten the timescales that a service user faces when making a complaint and bring the procedure for making a complaint about social work into line with the procedures for health and other local authority complaints. In all those cases, the Scottish Public Services Ombudsman is the appropriate external body to investigate if necessary following internal consideration of the complaint. The order will extend the SPSO's ability to consider discretionary decisions taken in the exercise of social work staff's professional judgment.

During our consultation on the order, some respondents raised concerns that there may be an overlap of functions between the SPSO and the Scottish Social Services Council, which is the regulatory body for social work staff. The SPSO and the SSSC have a memorandum of understanding between the two organisations. That will be updated to ensure that there is a clear delineation of the roles of the two bodies. The order also allows the sharing of information between the SPSO and the Care Inspectorate and the SSSC where appropriate should something come to light in the handling of a complaint.

During the consultation and in responses to the committee's call for evidence, some respondents highlighted the need for the SPSO to ensure that it has appropriate independent social work advice in reaching decisions about professional judgment. I confirm that, in the same way that the SPSO receives professional medical advice in its investigation of complaints into health services, it will ensure that it has professional social work advice in its investigations into social work complaints.

If the order is approved by the Parliament, the SPSO will work with stakeholders, including service user representatives, to produce a model complaints-handling procedure, which will be published before the SPSO takes on the social work complaints function in April 2017.

The Convener: Thank you. Our first question is from Malcolm Chisholm.

Malcolm Chisholm: The draft order will bring the social work complaints procedure into line with health and other local authority—I cannot read my own writing—complaints procedures. Am I right to say that, specifically, it brings it into line with health because of the professional judgment factor?

Shona Robison: Yes.

Malcolm Chisholm: Most people would say that, in an era of integration, the draft order is a good idea. However, the concern was raised in oral evidence that it might not be ECHR compliant,

because the ombudsman would not be able to direct a local authority to follow the decision at which he or she arrives. Have you considered that dimension? Would you agree with that view? I presume that you would not.

Shona Robison: On the first part of your question, we recognise the importance of ensuring that the complaints procedure is joined up from the perspective of the complainants. Health boards and local authorities must agree and set out in their integration schemes their arrangements for managing complaints relating to the delivery of services that are in the scope of integration. I hope that that gives some reassurance that there will be synergy and coherence.

You raised an ECHR issue. It is important to remember that the SPSO is fully independent of local authorities, so the criticisms that have been made about the links between complaints review committees and local authorities are being dealt with in these reforms. Ultimately, in the same way as for judgments on health, it is for the public body to implement, in a very public way, the recommendations. That is how it works for health and other services, and that is how it will work for social work. It would be unusual to say the least if a public organisation was to say, "Well, we know that that is the recommendation, but we will ignore it anyway." That does not happen in reality.

I do not know whether Mike Liddle has anything to add.

Mike Liddle (Scottish Government): I have nothing to add to that.

Malcolm Chisholm: I understand your point, because in practice that is what happens. However, that concern was raised.

Your first point was interesting. The issue came up in another meeting that we had, and it is about what the ombudsman will do. I kind of assumed, when the integration joint boards were set up, that they would deal with complaints. Are complaints still going to be dealt with separately by local authorities and health? I think that you were touching on that in the first part of your answer.

Shona Robison: The integration scheme has to set out the process by which a service user or anyone complaining on their behalf may make a complaint. The arrangements set out in an integration scheme do not alter the underlying position, which is that complaints are to be dealt with under existing health and social work complaints procedures. However, the health board and local authority must ensure that the arrangements that they have agreed jointly are clearly explained, well publicised and accessible, and that they allow for timely recourse. Of course, they must also ensure that people are signposted to independent advocacy services.

At the end of the day, all that a service user will want to know is that their complaint will be dealt with. How that is dealt with behind the scenes needs to be consistent and joined up. Both bodies must work together when something spans the services of both organisations. You can envisage that, in the world of integration, that might include services that are delivered jointly by both organisations that involve going into someone's home. There must be synergy in the way in which complaints are dealt with, although legally they will be dealt with under the auspices of both organisations, as set out in legislation.

Bob Doris: I will pick up on some concerns that were raised by the previous panel. COSLA expressed concern that, whereas there is currently a 15-day window in place for complaints at the most local level, the period will now be five days in order to achieve consistency nationally. We were told that there could be discretion in relation to that. How can we make sure that appropriate discretion is shown in practice?

I will take this opportunity to roll together a couple of questions. Currently, people without social work expertise are making professional judgments on people who have that expertise. We heard from the SPSO that it would seek to recruit people with social work expertise, and I want to know what level of oversight the Government will have to make sure that that happens.

Those were two concerns of two groups that support the reform. I hope that we can get some reassurance from you in relation to that on the record.

12:00

Mike Liddle: In the working group that was chaired by the Rev Dr Graham Forbes in 2013, one of the issues raised was whether to have a five-day or a 15-day timescale at the front-line resolution stage, and we listened to that concern. We have committed to looking at that when the model complaints-handling procedure is being produced. That work will be carried out by the SPSO in collaboration with the service users and other organisations. That issue has been raised consistently, and we expect that it will be addressed in the model complaints-handling procedure.

Officials from the Scottish Government will work with the SPSO and those other organisations to make sure that, when it comes to producing a good complaints-handling procedure for social work, the guidance is appropriate for service users as well as for local authorities.

Bob Doris: Will relevant SPSO employees with substantial social work experience be involved in that process?

Mike Liddle: Absolutely. The resources that will be provided to the SPSO to enable it to carry out those functions will be sufficient for it to take on social work professionals to ensure that there is good professional oversight of any issues raised. There will be social work professionals working with the SPSO.

Bob Doris: My final question is a reiteration of one of the questions that I asked in the earlier session in relation—not for the first time—to the fact that, whenever there is a complaints process, the theme very quickly turns to appealing decisions that are made by local authorities. MSPs are lobbied on that in relation to other pieces of legislation.

Local authorities make financial decisions, which I may or may not always agree with, to direct their resource allocation towards providing services and addressing need. Rather than looking at the overall allocation, the complaints process will look at how people go through that system. However, if there is a service failure for individuals because not enough care is provided, the SSSC and the Care Inspectorate might have something to say about that. I am pleased that information-sharing arrangements are in place.

Fiona Collie suggested that the mental welfare foundation may also be a relevant body. Will you keep under review how we can share that information as much as possible, putting those important checks and balances in the system?

Shona Robison: Yes. One of the most important aspects of a complaint is how the organisation learns from that complaint and improves how it does things. You are right that it is very important that the dots are joined up between the SSSC, the Care Inspectorate and, indeed, the Mental Welfare Commission. If information comes to light during the process of a complaint that may have wider implications—whether for the conduct of individuals or the service more widely—it is very appropriate that those organisations can take that information forward.

In the health service, there are a number of routes to that learning. There is Patient Opinion, for example. If something were raised in Patient Opinion that could be of particular concern, we would expect that it would be looked into, particularly if there were issues of concern for individual welfare.

One of the most important aspects of this change is bringing the organisations together. I understand that, at the moment, they are not allowed to share any information except in certain circumstances. Victoria MacDonald can explain that further.

Victoria MacDonald (Scottish Government): At present, a threshold must be met before the ombudsman can provide information to other organisations such as the SSSC or the Care Inspectorate. The purpose of the amendment in this order, and the amendment to the schedule, is to allow it to do so in a wider range of circumstances that it thinks are relevant to those bodies' functions.

Bob Doris: It is the Mental Welfare Commission, not the mental welfare foundation, of course—I got that wrong. You may take a view about whether that is an organisation with which information should be shared to a greater degree, as appropriate.

Shona Robison: It is not explicitly listed in the provisions, but it is something to which we should give consideration.

Victoria MacDonald: I do not think that that came up in any of the consultation responses in the quite extensive work that was done. I am talking off the top of my head, but I suspect that it has to do with the nature of exactly what role the Mental Welfare Commission has in individual cases, as compared with the role of the Care Inspectorate and the SSSC. There is nothing to prevent that from being done in a subsequent order, if appropriate, but I am not aware that it has come up in any of the consultation to date.

Bob Doris: That is pretty much my final question. I just wanted to ensure that you keep a weather eye on such things as guidance and regulations and that you update things as appropriate. It is not job done, but it is transition made, and that will have to be followed through on an on-going basis.

Shona Robison: We will definitely continue to monitor that.

The Convener: I have a couple of detailed points, but first I have a strategic one, about the national care standards. How important are they in providing points of reference for how a service is delivering? It was in 2011-12 that the committee recommended the review of national care standards. When will they be in place? Will they be in place before 2017, when the order is in operation, and how important will they be to what people can expect in terms of delivery on the ground?

Shona Robison: Yes, they are very important, and it is my understanding that they will be in place in that timeframe. There is synergy there, as I recollect, but I will confirm that. That backdrop of the standards that are expected will be an important reference point for service users and the SPSO. I will get a note to the committee to confirm the timeframe on that.

The Convener: I appreciate that.

I have a question on the detail about allowing five or 15 days for complaint handling. We are focusing on timely resolution, and the five-day limit meets that requirement. As MSPs, we know that that can be very important indeed to ensure that something does not become a full-blown complaint and that requirements are satisfied. That is an important element. At the next stage, what can meaningfully be done to ensure that, in that five days, advocacy can be put in place so that the individual is fully aware of their rights and of the local council policy relating to the complaint, and can be supported in their complaint? Is it realistic to expect all that to be put in place in five days and that the complaint can be handled and dispatched efficiently, or will that become a problem in itself? If we are setting an unrealistic five-day target, we will get breaches and people will complain that they have not been heard within five days. I am thinking about the detail and the practicalities there.

I have one final question, which I might as well ask now. If a complaint concerns a social worker's professional opinion, how do we ensure that we can get the appropriate person involved at that very early stage—someone with the skills to review the professional opinion that has given cause for complaint?

Shona Robison: On the final point, there is good experience of doing that in the health service. When there is a health service complaint, the ombudsman is now well experienced in bringing in the right expertise to provide the level of advice that is needed. Essentially, this will be the same. It might take a little bit of time to build up those contacts, but I imagine that there is a good template that can be applied to social work services, where there is a big range, from services for children to services for older people and people with learning disabilities. The expertise that is required to give advice on those services will be a bit different. I assume that the ombudsman will have that bank of expertise to draw from.

I understand your concern, but I think that five days may be a challenge for someone with additional support needs who may need intensive advocacy input to take a complaint forward. Five days should still be the aim, but the process should be done properly, making sure that the person's concerns are fully expressed. There is a balance between trying to deliver it in five days and giving the person the opportunity to express their complaint properly.

Mike Liddle: It is important to be clear that the five-day period is for the front-line resolution. At the following stage, a senior manager would look at the complaint. The focus is on getting that right so that the change can be made at the very first stage. I know that it is more a matter for local authorities, but we will provide the SPSO with sufficient funding to ensure that it has advocacy support for people who come to it.

Shona Robison: Advocacy support, and the expertise.

The Convener: So, to meet the requirement of five days in the legislation, we just need to acknowledge the complaint and say that it is being investigated. Are you saying that that would meet the requirement?

Mike Liddle: No, we would try to resolve the complaint at the first stage wherever possible. We would aim to resolve a complaint in five days to start with, but there would be the possibility of extending that to 15 days if the local authority or the complainant need additional time.

Shona Robison: In circumstances where the complaint involves somebody with profound additional support needs, it may be more appropriate to take that extra time. Ultimately, it is a matter of judgment.

Rhoda Grant: I pick up from you that people with additional support needs would get advocacy. It may be that people who put in a complaint are quite vulnerable. People who receive support services would probably also require advocacy. Is it built in that the complainant would have access to advocacy throughout the process—from the appeals process to the process with the SPSO?

Shona Robison: My understanding is that advocacy is available for anybody who requires it. I do not think it is for defined cases.

Mike Liddle: No, not that I am aware of.

Shona Robison: My understanding is that it is self-selecting.

Victoria MacDonald: That is my understanding.

Shona Robison: If somebody feels that they need support when making a complaint, and they ask for advocacy, they do not have to fit into a particular definition. By and large, they determine themselves whether they require that advocacy. We have to monitor the process to make sure that it is adequate. I am sure that the SPSO will keep us fully informed as to whether it feels that the resources meet the demand. We will have to monitor that as we go along, but my understanding is that it is self-selecting.

Rhoda Grant: If hearings are required, more resources might be needed to get the hearings to go out to people, rather than to have people travel to the hearings. It can be quite distressing for people to go a long way from home and stay overnight, as well as going through the complaint process.

Shona Robison: Again, I am sure that the SPSO will judge those things on the basis of the needs of the individual. For example, if somebody has limited mobility, it may be absolutely right that it would go to the service user, rather than the service user being expected to go to a central point such as the SPSO office. That is my understanding of the situation.

The Convener: As there are no other questions, we move to the formal debate on the affirmative Scottish statutory instrument on which we have just taken evidence. I remind members and others that members can discuss issues with the cabinet secretary but should not put direct questions to her during the formal debate, and officials may not speak in the debate. I invite the minister to move motion S4M-15465.

Motion moved,

That the Health and Sport Committee recommends that the Public Services Reform (Social Work Complaints Procedure) (Scotland) Order 2016 [draft] be approved.—[*Shona Robison.*]

Motion agreed to.

12:16

Meeting suspended.

12:18

On resuming—

National Health Service (General Dental Services) (Scotland) Amendment Regulations (SSI 2016/53)

The Convener: Under item 7, we will deal with two negative instruments.

There has been no motion to annul the regulations. Members will be aware that the Delegated Powers and Law Reform Committee has commented on drafting errors in the instrument, and the Scottish Government has confirmed that it intends to lay a correcting instrument early in the new session.

As members have no comments, do we agree to make no recommendation?

Members *indicated agreement.*

Personal Injuries (NHS Charges) (Amounts) (Scotland) Amendment Regulations 2016 (SSI 2016/59)

The Convener: There has been no motion to annul the regulations, and the Delegated Powers and Law Reform Committee has not made any comments on the instrument.

As members have no comments, do we agree to make no recommendation?

Members *indicated agreement.*

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

12:18

Meeting continued in private until 12:25.

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