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Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Tuesday 14 May 2013

Session 4

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HEALTH AND SPORT COMMITTEE
15th Meeting 2013, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

*Bob Doris (Glasgow) (SNP)

COMMITTEE MEMBERS

*Aileen McLeod (South Scotland) (SNP)
*Nanette Milne (North East Scotland) (Con)
*Gil Paterson (Clydebank and Milngavie) (SNP)
*Dr Richard Simpson (Mid Scotland and Fife) (Lab)
*Drew Smith (Glasgow) (Lab)
*David Torrance (Kirkcaldy) (SNP)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Richard Lyle (Central Scotland) (SNP) (Committee Substitute)
Katy Peters (Department of Health, United Kingdom Government)

CLERK TO THE COMMITTEE

Eugene Windsor

LOCATION

Committee Room 6

Scottish Parliament

Health and Sport Committee

Tuesday 14 May 2013

[The Convener *opened the meeting at 09:45*]

Decision on Taking Business in Private

The Convener (Duncan McNeil): Good morning, and welcome to the 15th meeting in 2013 of the Health and Sport Committee. As usual, I remind everyone to switch off their mobile phones and BlackBerrys, which often interfere with our sound system. Witnesses and people in the public seats might notice that some members are using iPads instead of hard copies of committee papers.

Item 1 is a decision about whether to take another item in private. Do members agree to consider our draft report on the Victims and Witnesses (Scotland) Bill in private today and at future meetings?

Members *indicated agreement.*

Medicines (Value-based Pricing)

09:45

The Convener: We will take evidence on value-based pricing from Katy Peters, who is head of prescriptions, pricing and supply in the medicines, pharmacy and industry group in the United Kingdom Department of Health. Welcome. I invite you to make opening remarks before we move to questions.

Katy Peters (Department of Health, United Kingdom Government): Thank you, convener, and thank you for giving me the opportunity to make a short opening statement to set the scene. I hope that the committee will find it useful.

I am head of prescriptions, pricing and supply in the medicines, pharmacy and industry group at the Department of Health. That means that I have policy responsibility for prescription charging in England, medicines supply issues and, of course, the current pharmaceutical price regulation scheme—PPRS—and its successor arrangements, including value-based pricing.

I know that value-based pricing keeps cropping up in your inquiry into access to newly licensed medicines. I hope that I will be able to clarify the concept somewhat this morning.

What is value-based pricing? Put simply, it will be a pricing system for new branded medicines, whereby the price that the national health service pays will be more closely linked to a medicine's assessed value, taking account of improved outcomes for patients, wider societal benefits and factors such as the burden of illness.

In focusing on the value that a medicine brings to patients and society, we want to incentivise the development of more new, innovative and effective medicines, because manufacturers will be rewarded directly and comprehensively for the value that their innovations bring to patients and society.

As you have gathered from the evidence that has been presented to you so far, medicines pricing in Scotland is a reserved matter for the UK Government. Having a common branded-medicines pricing policy across the UK allows us to maximise our bargaining power and provides a useful degree of consistency and stability to the pharmaceutical industry.

It is of course recognised that the devolved Administrations largely determine their own health policies, including those that affect the use and availability of medicines within their health systems. What the Scottish Government and the Scottish Parliament spend their money on is

entirely a matter for them. That will not change under value-based pricing.

The current pricing system for branded medicines—the pharmaceutical price regulation scheme—has provided stability and predictability over time for industry and for the NHS. However, it was becoming increasingly clear that NHS patients were not always able to access medicines from which they could benefit, because there was an insufficient link between pricing and value. That is why the UK Government announced, in the 2010 coalition agreement, that it would move to a system of value-based pricing, so that patients can better access the drugs and treatments that their doctors think they need.

Since then, we have publicly consulted on our proposals. We have engaged with a wide range of stakeholders—patient groups, clinicians, industry and other interested parties—through a series of technical workshops and update events, and we are now in formal negotiations with the Association of the British Pharmaceutical Industry on aspects of the new pricing arrangements. The negotiations are confidential, and I hope that you will understand that that means that there might be things that I am unable to talk about in much detail today.

We still expect the new arrangements to be in place for January 2014. That is where we are.

The Convener: Thank you very much. I invite Richard Simpson to ask the first question.

Dr Richard Simpson (Mid Scotland and Fife) (Lab): My question arises from your very last comment. January 2014 is not very far away and this committee, and others like it, have no idea what is going to happen with value-based pricing. Will you explain to me the advantages of value-based pricing over a combination of the PPRS as revised—I think that it was revised in 2009—and patient access schemes, which seemed a rational and reasonable modification of the PPRS? That system has served us well for well over 50 years, and not only in terms of the supply of medicines. Until recently, innovative medicines were very expensive, which was the reason for PAS coming in. There is also a recognition that stability is necessary to maintain an industry that is one of the few that has a balance of payments surplus for the United Kingdom. This is a very important industry for the United Kingdom, so we must achieve a stable situation whereby its role in providing the economy with substantial benefits is maintained. My central question is this: what are the advantages of VBP over the PPRS, combined with PAS?

Katy Peters: I apologise for the acronyms. The PPRS has provided stability and predictability over time. However, it has not always provided access to medicines. The way that medicines are appraised in the English system occasionally means that not all aspects of their value are rewarded. For example, the current system does not always take systematic account of certain effects that we think should be reflected more systematically. We mentioned wider societal benefits in our consultation document. Currently, we do not systematically appraise medicines according to the impacts that they have on aspects such as employment, tax revenue and spending. Medicines can bring a set of benefits that are broader than health benefits, which we are not appraising consistently.

Some of the health benefits that medicines can bring might be more important and valued by society than others. We might be prepared to pay more for health benefits at the end of somebody's life than we are prepared to pay under the crude, quality-adjusted life year assessment of net health gain. Some types of health gain might be more important than others, which we would want to see reflected in what we describe as the burden of illness—the amount of health that someone has foregone.

With value-based pricing, we are considering paying more for the medicines that bring the health gains that society values; we are prepared to pay more for medicines that can treat people when they are severely ill.

Dr Simpson: That is very helpful indeed. We are having a review of the Scottish Medicines Consortium, part of which is about greater public involvement and looking at issues such as the effect on carers, for example. I entirely agree with what you are saying: the social and societal elements need to be considered.

However, I am concerned that we are getting rid of the PPRS at the same time. I gather that there is a successor PPRS—although not for new active substances. Will that include the sort of limitations on profit, advertising and so on that are contained in the PPRS, which help provide the stability that the industry needs?

Katy Peters: As we set out in the consultation document, the system that we are looking to introduce has value-based pricing for new medicines and a successor to the PPRS for existing medicines. In August last year, we published a joint statement with the ABPI, in which we set out that the new PPRS would evolve from, but would be similar to, the current PPRS. One of the reasons why we put out the joint statement was to create greater stability with regard to what was likely to be included in the future arrangements.

The exact detail of what the successor PPRS looks like forms part of the current negotiations. I

apologise, as I suspect that I might say this a few times but, because those negotiations are confidential, I cannot go into the ins and outs of what may or may not be raised by different sides. However, the joint statement that we published in August might be helpful if people want further information on what the successor PPRS arrangements are likely to look like.

Dr Simpson: That is very helpful.

I have a final, quick question. Is it the intention to have a new structure, in addition to the National Institute for Health and Care Excellence and the Scottish Medicines Consortium, to look at value-based pricing? I am interested to know that, because the SMC system is different from the NICE system—the SMC will look at all medicines that the industry refers to it, whereas NICE only takes referrals from the Department of Health and the UK minister. There are two different systems in existence, and I am not at all clear about how the new VBP system will fit together with the relative roles of NICE and the SMC.

Katy Peters: The role and remit of the SMC are determined by the Scottish Government.

When it comes to how we expect value-based pricing to operate, in some ways there will be a health technology assessment component and a pricing component. We have announced that NICE will do the bulk of the HTA process for England. We have always said—we said it in the consultation document—that NICE would do the basic pharmacoeconomic assessment. In the recent announcement, we said that it would assess all components of the value-based system, including the issues that I mentioned earlier, such as wider societal benefits, the burden of illness, and therapeutic improvement and innovation, and how those will all fit together. We have announced that NICE will pull together all those assessments for England.

In some ways, I suspect that the system will not look that different from the current system, whereby NICE makes an assessment of the clinical effectiveness and the cost effectiveness of a medicine and—on occasion—takes account of some additional factors. I suspect that the new system will involve an HTA process that is even more rigorous and which takes account of a broader range of factors, such as those that I have mentioned.

Dr Simpson: There will not be a separate VBP structure. That will be part of NICE—NICE will take that on board.

Katy Peters: Yes, we have announced that NICE will be—

Dr Simpson: That gives me a problem, because the SMC is faster than NICE is. It is highly regarded around the world. Speed is of great importance to us up here. If we will have to wait for a VBP assessment from NICE, even with the new requirements that the minister in England has placed on NICE, that will still be a much slower process than the current one in Scotland, as far as I can judge. I have significant concerns about that.

What discussions have you had with officials in Scotland about the perceived interaction between the SMC and the new system?

Katy Peters: I will address the point about the speed in Scotland, in so far as it is my place to do so.

One of the things that we said in the joint statement in August is that we expect medicines to have freedom of price at launch. Our expectation is that a company will be able to propose the price, as it does at present, under the structures of the PPRS, so there will be freedom to make an assessment on the basis of that price. That price will be available quite quickly, as it is under the current system, so that bit of the system will not change, according to what we said in the joint statement. Therefore, we will not have to wait for NICE to complete the HTA process before a price becomes available throughout the UK. As I said, much of the system might not look that different from the current system. That deals with the issue of pricing and speed in Scotland. Obviously, it is for the Scottish Government to determine how it wants the SMC to respond to any such price.

We have had—and have always had—substantial discussions with Scottish Government officials on a wide range of issues, not just those relating to pricing. In my opening statement, I mentioned the series of technical workshops to which we invited officials from the Scottish Government and the SMC and we also have a large number of bilateral discussions on a wide range of issues. Those discussions include but are not constrained to the negotiations and value-based pricing.

Dr Simpson: Thank you.

10:00

Bob Doris (Glasgow) (SNP): The ministerial foreword to the English Department of Health's consultation document on value-based pricing says that

"There must be a much closer link between the price the NHS pays and the value that a medicine delivers",

and one of the objectives mentioned in the document is to

"ensure value for money and best use of NHS resources."

No one will disagree with that, but I think that a particular gap needs to be addressed. The issue is not just the "use of NHS resources" but the use of local authority resources with regard to the assessment of social care needs on the basis of whether or not a drug is available. What discussions have you had with local authorities to ensure that they make an input on how value-based pricing could save them money in future, and what modelling work has been done in that respect?

Katy Peters: We have done a lot of modelling on VBP in which we have covered a much broader range of values. Indeed, at the very heart of value-based pricing is the idea that we need to take account of a broader set of effects. I have already mentioned employment effects but we should also take into account the effect not only on the social care system but on carers and the amount of informal care that is provided. When a medicine can affect the amount of informal or social care in the system, that should be reflected in the price.

At our technical workshops, we described how that might happen and views on the issue were also expressed in the public consultation. That is one way in which we have engaged with local authorities, but I repeat that what lies at the core of value-based pricing is the idea that we take account of all components of a medicine's benefits, which will cover privately and publicly funded social care and informal care.

Bob Doris: Have you solicited the views of the Convention of Scottish Local Authorities on value-based pricing?

Katy Peters: I am not explicitly aware that COSLA is one of the organisations that we have had discussions with. However, the website contains a list of all the organisations that expressed a view on value-based pricing in the consultation.

Bob Doris: Given that COSLA is the umbrella organisation for Scotland's 32 local authorities, I would hope that it would be a statutory consultee so that you could get an accurate picture of how value-based pricing fits with the Scottish policy context. It might be useful if you could tell me whether the Department of Health in England has contacted COSLA directly on this matter. You will have to forgive me—I do not know the name of the umbrella group for local authorities in England—but have you directly discussed value-based pricing with that organisation? I feel that, if we are to get this right, it is essential that you have those discussions.

Katy Peters: We have engaged with many colleagues in social care in the UK on this issue. When I am back in London, I will check the details of the public organisations we have consulted, but I point out that, in England, the UK Government's Department of Health deals with social care and that is where we have been channelling those discussions. Organisations had an opportunity to raise those issues in the consultation and the modelling work has definitely covered those matters. We have also discussed value-based pricing with NICE, whose remit now covers social care.

Bob Doris: I thank you for that answer but, with genuine respect, I get the feeling that you are missing out the Scottish policy framework and the vital role played by Scottish local authorities. I would have expected the Department of Health to have made direct representations to the authorities and it could be a fundamental flaw in trying to get value-based pricing and its impact on Scotland right. Nevertheless, I am sure that the committee would welcome more information on that matter.

You mentioned modelling work. As you are aware, the committee is conducting an inquiry into access to new medicines and there has been a Scottish Government review of that as well. As you would expect, pharmaceutical companies speak to MSPs and the committee and give their views on that. When I have spoken to pharmaceutical companies, I have consistently asked about value-based pricing. I have asked them whether, when they put their evidence to NICE or the SMC under the current system, they do any health modelling work about what the social care benefits would be, in pounds and pence. To date, none of them has done that—if I have got that wrong, I am willing to hear from any of the pharmaceutical companies that I have met.

Can you explain in a bit more detail the modelling work that has been done to elicit what the social care savings could be for certain drugs? I am unclear how that modelling work can be done without speaking to local authorities.

Katy Peters: The modelling work that we have done has been discussed at various technical workshops that the ABPI and member companies were invited to and attended. They have seen that work.

We set out a framework for wider societal benefits of a medicine: the benefits to the individual and other people in society, such as friends and family, and the impact on all aspects of Government revenues, including employment and tax, and on different types of spending, such as social care bills. That impact is then subdivided into impacts on informal carers, public funding and private funding. A framework can be provided that allows the assessment of how a medicine could impact on different aspects of social care. We then do, in essence, a literature review on what

evidence there is out there on how big those effects are.

How such a system will operate in practice will critically depend on the medicines that are brought forward by companies. Whether in 2014, 2015 or 2016 medicines are demonstrating social contributions to reducing the burden on social care will critically depend on those medicines and will in part depend on the evidence that is produced by companies. However, the framework that we set out in the technical workshops allows for a much more detailed calculation of social care and its different aspects.

Bob Doris: I genuinely appreciate that, but I am trying to understand how you can feed the numbers on the social care bill in Scotland into any modelling that you have unless you speak to Scotland's local authorities and ask them what their social care bills are. I am not trying to be awkward; I am just trying to make sure that you are taking specific account of the Scottish public policy situation. For example, we have a national carer strategy, free personal care for the elderly and a change fund for older people. All across the board there is a different policy framework in Scotland. I want to make sure that, when you look at the on costs—or on savings—of social care and feed those numbers in, you speak to Scotland's local authorities and use numbers in a Scottish context. I am unsure how you are able to achieve that.

Katy Peters: I am happy to discuss—partly through my colleagues in the Scottish Government—what the appropriate forum is for such a dialogue. It will continue to be for Scotland to decide how it funds and what arrangements it makes for social care. However, we are happy to discuss with Scottish colleagues in the Government the appropriate way for such a dialogue to take place.

Bob Doris: I may come back in later with some more questions. I have a feeling that my colleagues will want to ask some.

Aileen McLeod (South Scotland) (SNP): In some of the evidence that the committee has taken in our inquiry into access to new medicines, there have been concerns about the implications of the value-based pricing system for the SMC's appraisal system. What discussions have you had with the SMC and what contribution has it made? I understand that, when Professor Angela Timoney of the SMC spoke at a recent meeting, she closed with a slide of the Loch Ness monster, which she claimed she might find before she found value-based pricing.

Katy Peters: As I said, there have been on-going discussions about value-based pricing with colleagues from Scotland and the SMC. We have had a series of meetings, at which different organisations have been present, and we have had a series of workshops on things such as how the research that underlies the assessment of some of the components, such as burden of illness and therapeutic innovation and improvement, could be measured. There have been invites to the SMC on those issues, it has attended a lot of the technical workshops, and follow-up material has been presented to it.

The SMC is a hugely respected organisation, and as such we value its views and thoughts about how value-based pricing could operate. Because we have now announced that NICE will take forward the bulk of the HTA process and it is very good at consulting a wide range of stakeholders, there will be plenty of opportunity for it to engage with the SMC as appropriate. Indeed, there is already dialogue between the SMC and NICE about a huge range of HTA issues, so there have been—and there will continue to be—plenty of opportunities to engage.

However, this is not a simple area, so it is right that we ensure that there is time and that there are opportunities for different organisations to engage and understand how their roles are affected.

Aileen McLeod: There has been consultation with the NHS in England, but what role has the NHS in Scotland had in the consultation so far? How has its involvement been working in terms of the discussion?

Katy Peters: We have routed the discussion through Scottish Government officials. We have had a lot of discussions about the issues around how value-based pricing will be taken forward and also the negotiations on price—both about the value-based pricing aspects of the negotiation and about the successor to the PPRS. There has been a lot of dialogue and discussion and it has primarily been routed through Scottish Government officials.

Aileen McLeod: One of Professor Routledge's review recommendations was that citizens juries and citizens panels should be set up. Which of the patient groups in Scotland have you been consulting?

Katy Peters: We have had a large engagement with patient groups. Some of them present themselves as UK groups. An example is Myeloma UK, although it is based in Edinburgh. We have had a huge amount of engagement with patient organisations. First, there were a large number of consultation responses from them. We have also had individual meetings with individual organisations. We have met some of the broader alliances. One of the workshops that we set up was specifically to engage with patient organisations. We also had a workshop

specifically on inequalities issues, on which we thought that it was particularly important to engage with patient organisations. They have been helpful in making us understand the impact of the policy and the questions that we need to debate.

Aileen McLeod: Thank you.

Nanette Milne (North East Scotland) (Con): Ahead of today's meeting, we received a briefing paper from Prostate Cancer UK. To summarise, it says that the Department of Health at Westminster has not consulted patient organisations meaningfully on the proposed changes. It states that few details are available about how VBP will work in practice and how the proposed weights for wider societal benefits, burden of illness and therapeutic innovation will be combined, which continues to prevent meaningful engagement.

Will you comment on that? Prostate Cancer UK clearly has views about prioritising end-of-life drugs and significant concerns about the impact of proposals to prioritise drugs that would help people to return to work. They feel that the patient voice is still not strong enough in appraisals of new medicines.

10:15

Katy Peters: Several issues are important in understanding the role of the patient, even with the current system of value-based pricing. One thing that we have said about value-based pricing is that we will use the quality-adjusted life year in assessing a medicine. The QALY is drawn from the assessment of patients across a broad range of diseases. A great thing about the QALY is that it allows us to compare the impact on health across many different diseases. It is therefore absolutely at the heart of what we expect to be delivered through value-based pricing. That is a core role for engaging a broad range of patients and ensuring that the impact that a medicine has on patients is reflected in the future system.

We have had debates with various different patient organisations—as I said, we have discussed the issue with many of them—and we have invited them to a lot of the workshops. Given that the workshops are highly technical and that spaces have been slightly limited, we have been unable to invite everyone. There has been a lot of dissemination of information from those workshops to the patient organisations. The issue of treatment at the end of life was raised with us. In England, NICE currently has an explicit end-of-life adjustment that can be applied. On the concept of burden of illness, we are looking at how end-of-life treatment is appropriately reflected in the burden of illness. There are lots of mechanisms, therefore, to ensure that we pick up the issues that are affecting people with prostate cancer through the consultation process and through the mechanics of calculating a value-based price.

Nanette Milne: During our conversation, it struck me that I should ask you whether the results that you are hoping to achieve with value-based pricing could not be achieved by altering, for instance, the modifiers or the criteria that the SMC uses when judging new medicines, without having to change the complete system?

Katy Peters: Much of the way in which value-based pricing is likely to be implemented is through the HTA process. We are discussing with NICE what is appropriate for England. As I said earlier, in many ways, the system may not look that different from the current system, so much of this will be taken forward—certainly in the English context and in terms of how NICE plays its part—through changing the details of the HTA process. Whether the Scottish Government wishes the SMC to adopt a similar approach in making decisions about the use of and access to medicines in Scotland is a question for the Scottish Parliament and the Scottish Government.

The Convener: I have a question about the confidentiality of the negotiations. I presume that the appropriate minister in the UK Government has been kept up to date about all the negotiations, including what stage they have reached, what progress has been made, what barriers there are and so on. Has there been any engagement between the UK Government minister and the Scottish and Welsh equivalents to bring them up to date, minister to minister?

Katy Peters: That is a difficult question, because we are now getting into debates about confidential letters that are exchanged between ministers.

The Convener: I am asking not about the detail, but about whether, given that the UK minister has the information, it has been seen as appropriate to share that, minister to minister, between the UK department and the equivalent ministers in Wales and Scotland.

Katy Peters: There has certainly been an exchange of letters about medicines pricing.

The Convener: Which—

Katy Peters: Which discusses the issues that we are discussing here—yes, absolutely.

The Convener: How recent was that exchange?

Katy Peters: I do not have the data of the latest letters with me. As I said, there have also been discussions with officials in the Scottish Government. To some extent, it is for them to make decisions—

The Convener: Within the past month?

Katy Peters: Certainly not within the past month, as far as I am aware.

The Convener: Within the past two months?

Katy Peters: Are we planning to run an auction here? Certainly not within the past two months. There is—

The Convener: Recently?

Katy Peters: I would need to check what is appropriate for me to share with the committee with regard to internal communications with Scottish Government ministers. I understand that a meeting with your cabinet secretary has been set up for July.

The Convener: Who requested that meeting?

Katy Peters: My impression is that, as such things are arranged in correspondence between offices, a request for that specific meeting came from your cabinet secretary's office.

The Convener: Has the SMC raised any concerns or criticisms in the various workshops or in communications—given that it has concerns about Loch Ness monsters and whether the negotiations are going too fast or too slowly—about the delay and its lack of involvement in the process?

Katy Peters: I would not say that the SMC has raised criticisms. It has raised a set of entirely sensible questions, which are about the process, the issues and the impact on Scotland rather than about the general principles and the impact that they might have on the Scottish system.

The Convener: But no questions have been raised about the delay or the lack of information.

Katy Peters: No, I am not aware of any.

The Convener: Thank you.

Thinking about the impact that value-based pricing would have on the Scottish system from a layperson's point of view, what benefit would there be for those people who are seeking access to new drugs and medicines? How would value-based pricing ensure greater or better access?

Katy Peters: The core of value-based pricing is the ability to pay higher prices for medicines that deliver value for patients. Explicitly adjusting for factors such as the wider societal benefits and the impact on the care system provides the scope for higher prices, which may encourage medicines to be made available in the UK that deliver high value, and which would not have been available under the current system.

The Convener: NICE would operate that south of the border. Would you envisage the SMC taking the results of the work that you have done over the piece—such as the conclusions from the studies and the workshops—and using it in Scotland, or not?

Katy Peters: We would be more than happy to share with the SMC—as I think we have done—the details of the technical work that we have done on developing a possible value-based pricing model. If the SMC did that with the Scottish Government's support and the Scottish Government wanted to reflect that in its HTA process, we would have no objections whatsoever. As I said, that is a question for the Scottish Government and the Scottish Parliament.

The Convener: Could the SMC take that work now, draw on the results and make progress itself if it wished to do so?

Katy Peters: Yes. The SMC has attended a series of technical workshops and, if it wanted to use that information to develop its own system, we would have no difficulty with that.

The Convener: So, if the SMC was concerned that you were not going to meet your date of January 2014, could it take matters into its own hands?

Katy Peters: The January 2014 date relates not simply to the HTA aspects of value-based pricing but to broader issues, such as the negotiations on the successor arrangements for the PPRS.

The pricing aspect would be covered by the negotiations, and I do not think that the SMC could take that into its own hands, because pricing is a reserved matter. It is, of course, for the SMC to take any material that we provide to it and use that as it thinks appropriate, which I presume would be in line with its agreement with the Scottish Government and the Scottish Parliament.

The Convener: This is probably a daft question. The procurement process—the buying of drugs—is a matter for the health service, is it not?

Katy Peters: The decision about whether to buy a medicine at a given price is a decision for Scotland, yes.

The Convener: Thank you. If committee members who have not yet spoken do not want to come in, I will bring Richard Simpson back in.

Dr Simpson: One of the difficulties that I have is to do with the difference between the proposed approach and the modifiers that are developing in Scotland, which take account of issues that Katy Peters has talked about, although there has perhaps not been the same emphasis on employability and tax take, which are interesting—I am thinking particularly about employability, in relation to the expensive new biological drugs for rheumatoid arthritis.

It seems to me that, at the end of the day, people will make value judgments on the weighting that is given to the societal aspects. In your modelling, what weightings will be given to different aspects? How will weightings be determined, and by whom? Is the modelling publicly available?

Katy Peters: As I said, pricing negotiations take place between the industry and Government, but issues to do with core societal judgments about what matters and what we should be prepared to pay for—critical questions, such as whether we are prepared to pay more for people towards the end of their life—have been addressed, in part through the technical workshops and through broad engagement. We commissioned research into society's views on the issues from the University of Sheffield.

We have always said that such research will inform and not determine any pricing scheme. It is clear that a pricing scheme must be affordable. We have had quite a lot of engagement in terms of the evidence base, and we have now said that NICE will be responsible for the overall framework. NICE will develop the overall framework for the HTA process in England and will consult as appropriate, according to its normal patterns.

Dr Simpson: In a sense, we have been here before. A similar approach was taken in Oregon, where the public were asked for their views. One of the interesting responses was that HIV drugs should not be purchased, because of what was almost a moral judgment that money should not be spent on a particular group.

If new drugs to treat drug addiction come along, as they might well do, such as expensive vaccinations, and if the judgments of the public as a whole are to be given significant weighting, we could end up with such a moral, judgmental approach. I am concerned about the balance that we will strike.

Katy Peters: The role of the patient is key, I think, in the context of the quality-adjusted life year. That is why the QALY is so useful; it is a systematic way of assessing what a broad range of patients want to see reflected.

We have engaged with the literature and, through the University of Sheffield, in original research on public preferences. As I said, such work will inform but not dictate or determine pricing. There will still be a filter, through the HTA process, whereby a large number of people will look at possible weighting, to ensure that we do not produce anything counterintuitive, to ensure that the approach is explicable and to absorb some of the moral questions that you raised.

10:30

Dr Simpson: Have you tried out a citizens jury system, or equivalent, involving the participation of the public?

Katy Peters: We have not taken a citizens jury approach. We did a large survey of the public to get a take on their views on such issues as burden of illness and therapeutic improvement and innovation.

Dr Simpson: The advantage of a citizens jury approach is that the juries are properly briefed. A proper analysis and an evidential basis are presented to the jury before it makes its decision. Is that system being considered, or not?

Katy Peters: It is not one that we are actively considering. The research that we commissioned endeavoured to set out quite a lot of information for the people participating in the survey, through the type of questions that we asked. There was an attempt to brief the people who participated in the survey. We wanted quite a large sample, and that is why we went for the survey methodology.

Dr Simpson: I would say that a combination of those is probably the way to go.

Katy Peters: I would not rule that out for the future, but it is not something that we have done so far.

Gil Paterson (Clydebank and Milngavie) (SNP): Returning to the point about consultation, have you had face-to-face meetings with representatives of institutions in England that are interested in the issue?

Katy Peters: Yes.

Gil Paterson: Can you tell us about the organisations with which you have been involved?

Katy Peters: There are a lot of organisations involved.

Gil Paterson: One or two would be fine.

Katy Peters: We have engaged with pharmaceutical firms and with patient organisations—both representative bodies and individual interest patient organisations. We have engaged extensively with the NHS. We have engaged with and discussed the issue with NICE. I have been up to Edinburgh previously to discuss the matter with the Scottish Government and get its views on how the arrangements might operate.

Gil Paterson: To be frank, when it comes to consultation with the same interested parties in Scotland, I find your answers a bit sketchy. Perhaps I am wrong. Could you inform us about exactly when and with whom you have engaged in Scotland? Did you do so to the same degree here? This is a reserved matter. In many ways, we are very much in Westminster's hands. My

expectation and the committee's expectation is that you would duly consult to the same degree here, but it is not coming over that way, to be honest.

Katy Peters: A lot of the patient organisations with which we discuss the issue are UK organisations. One point that comes up a lot in relation to the consultation is how the system works in the different devolved Administrations. We have regularly discussed with the UK reps how it might operate. We have explained the system as being one in which pricing is a reserved question, whereas the aspects relating to how Scotland spends Scottish money are, of course, for the Scottish Government and Scottish Parliament to determine.

Industry has shown a lot of enthusiasm for engaging with us on the issue, but we have tried to engage with a much broader range of organisations. One reason why we did the workshops was to ensure that a large number of organisations that are interested in the issue had an opportunity to express their views. That is why we ran a full public consultation, with more than 180 organisations expressing their views.

Gil Paterson: Which do they include? You have talked about UK institutions. This is the UK, in that regard. I am asking about people with whom you have engaged, specific to Scotland, pro rata. I recollect that you said in your introductory remarks that you have many meetings with officials in Scotland involving the matters that we are discussing.

My question relates to meetings on those matters specifically, not to the general meetings that happen all the time between devolved Governments and the London Government and its departments. Specifically on the issue that we are discussing, what meetings have taken place between the Scottish Government and Westminster officials in the Department of Health?

Katy Peters: There have been a large number of meetings between officials from the UK Government and the Scottish Government specifically on pricing. At those meetings, a lot of time has been spent discussing value-based pricing, the impact on Scotland and the successor arrangements for the PPRS, although other issues have been discussed, such as the security of supply of medicines. I would say that the vast majority of the time in the meetings so far has been spent on the issues of value-based pricing and the successor arrangements for the PPRS.

The Convener: It might be helpful if the committee could have a summary of the meetings. The previous cabinet secretary expressed confidence that the engagement would happen. I do not know whether there has been a recent tapering off. We sometimes start off with good intentions and then there is a lot of engagement, but it tapers away. I do not know whether that is what has happened, but it would be helpful for the committee to have a summary of the meetings and the range of subjects that have been discussed, so that we can establish whether there has been consistency and commitment. That would be helpful.

Katy Peters: That would be fine.

The Convener: It would also be helpful if we could have a link to the survey that you mentioned, if we do not have it already. In evidence on access to medicines, we have heard about society's opinion, and that issue is in the recommendations that are before the committee. It would be interesting to have that, as well.

Katy Peters: Of course.

Bob Doris: We are talking about a consultation, and it is right that we should ask about the details of it. It might be useful if you could give the committee a list of not just the respondents to the consultation, but the statutory consultees that the Department of Health contacted directly, so that we can see whether there were any omissions. Perhaps we could have got that information before today, but we did not. We would find it helpful if you could provide it.

Understandably, NICE is working hand in glove with the Department of Health to roll out value-based pricing, but there is an unavoidable impression that the SMC is not as closely involved in the process as it could be and that it might have to wait until value-based pricing emerges and then respond to it. No doubt we will find out about that from the SMC in due course. Is it reasonable to suggest that there is perhaps a nervousness there?

Katy Peters: Clearly, the SMC is a hugely respected organisation. We respect its views and it has been involved in many of the events. We are more than happy to have additional conversations with it. It is a little tricky for me to come along from London and lecture the SMC on what it should and should not do, which is why I am slightly nervous. However, we are more than happy to engage with the SMC and we strongly encourage it to engage with NICE about the specific HTA issues.

Bob Doris: Maybe I did not clarify my question. It was not a substantive question; it was just based on an impression that I got when I made other comments. NICE is going to deliver value-based pricing in England and it is directly part of the process of developing value-based pricing. The SMC will deliver value-based pricing in Scotland, but it is not an integral part of the development of value-based pricing. Therefore, will the SMC be starting from behind in terms of preparation?

Could the SMC have been a more integral part of the process? I do not know the SMC's views on that—I am merely asking the question.

Katy Peters: It will always be possible to reflect afterwards on whether we could have done something different. That is true of any policy.

We were keen to engage with as many stakeholders as we could on the issue, which is why we ran so many workshops and were accused by certain organisations of inducing consultation fatigue. We are also keen for the SMC to be involved as it sees fit. We do not want to step on the toes of the Scottish Government and the Scottish Parliament, but if people want the SMC to engage, I am sure that that can be facilitated.

Bob Doris: I am sure that the Scottish Government would be up for partnership working if it were asked.

I will ask a few questions about what will happen when value-based pricing comes in. Dr Simpson made some comments on that and I want to ensure that I understood the situation properly. The point was made that the SMC makes decisions quickly, based on strong evidence, and is a world leader in approving medicines in that respect. You seemed to suggest that, if there is a longer process for setting the value-based price—whatever that may be—the SMC could, in the interim, continue to use the current system of QALYs with modifiers to decide whether to approve a drug, based on a price that has been suggested by a drugs company.

Katy Peters: Drugs companies will maintain freedom of pricing at launch within the constraints of the pricing agreement. The SMC will have the opportunity to make an assessment of that price based on the current Scottish system. I do not see why anything to do with value-based pricing would change that.

Bob Doris: Let us say that a drugs company launches a drug. The drug is available and safe to use and, if someone can pay for it, they can use it, but we would like it to be available on the NHS in the various nations and regions of the UK. What happens if the drugs company goes through a value-based pricing system, whatever the mechanisms are within it, but thinks that that could take six months whereas it could get a decision from the SMC in two months?

You discuss the system with drugs companies all the time. Have they said to you whether they would be likely to make an interim application to the SMC or just wait for the longer period that it would take to get a decision at UK level?

Katy Peters: The drugs companies have not raised that explicit issue about the SMC with us. However, we have said that there will still be freedom of pricing, as set out in the joint statement, so the system will not change that much. The SMC will be able to take that price and assess whether it represents good use of Scottish money to buy the medicine at that price.

Bob Doris: Yes—but that will be before the medicine has been through the modelling work of value-based pricing at UK level. I would be surprised if the matter did not come up in discussions with the industry. If a new drug is launched that people can get privately, but which we would like the NHS also to have, will the drugs company make a submission to the SMC and to the UK value-based pricing model at the same time, knowing that the SMC decision could be three, four or five months quicker and that, therefore, the drug could be made available across Scotland more speedily? Have drugs companies said that they are likely to do that?

Katy Peters: We have not had that sort of debate. We do not anticipate a UK value-based pricing authority—I think that you used that expression.

Bob Doris: I can only apologise if my terminology is wrong.

Katy Peters: There is no need; it is a complex issue, so the question is worth asking. We do not envisage an HTA being imposed on a UK basis. We envisage that, for England, NICE will undertake the full value-based pricing assessment. Therefore, the system will not look much different from the current system.

A drugs company will launch a price under freedom of pricing as set out in the joint statement. We have freedom of pricing to ensure that the UK is an early-launch market. The price will, therefore, exist. The SMC will make its assessment and NICE will make its assessment based on that price and information. The SMC uses the framework that is set for it, and NICE uses the framework that is set for the English system, so the speed with which the processes will happen may well be just as it currently is. We do not expect the NICE assessment process to take significantly longer under value-based pricing. There is no need for it to take any longer.

10:45

Bob Doris: I want to check whether I have misunderstood. The reference price of drugs is reserved to the UK and the value-based pricing model will be a UK model, which will go through NICE. An element of pricing will have to be determined through value-based pricing, as laid down by the Department of Health in conjunction with NICE.

Katy Peters: The issue is complicated. When I took up my role, I spent quite a lot of time thinking through the processes. The pricing aspect is reserved, by which I mean issues such as freedom of pricing and whether, under the PPRS, we have profit control or price profiles. The question of whether there is freedom of pricing at launch is a reserved matter.

Separate bits of the process then operate at devolved Administration and England level. The HTA aspect of the system operates at England level, so NICE makes assessments based on English patterns. The SMC makes assessments based on the remits that are set for it and, I presume, Scottish take-up, Scottish disease prevalence and so on. The HTA process and how the money is spent are devolved matters. We do not envisage that that will change under value-based pricing. The system might, as I said, look very similar to the current one.

Bob Doris: My lack of clarity might be the result of there having been a bit of an information gap during discussions about the process. I suspect that the committee will want to return to that. There seems to be a lack of information in the public domain. Your assurances sound good, but we cannot really touch, feel or smell that, because we do not know what will happen. I think that many members share my nervousness.

Katy Peters: We addressed the role of the devolved Administrations in the joint statement. We said, in essence, that we are not expecting much change. I will send you a copy of the joint statement, which you might find useful.

Nanette Milne: In England, patients have benefited from the cancer drugs fund, which we do not have in Scotland. How do you envisage value-based pricing affecting patients who would benefit from new drugs that would qualify under the cancer drugs fund? Will there be an impact on Scottish patients?

Katy Peters: England introduced the cancer drugs fund. The fund has proved to be popular and more than 28,000 patients in England have benefited from it. The fund is time limited and we have made no statement of what will happen beyond the three years of its operation. Discussions are going on about the fund's future.

It has become the responsibility of NHS England to manage the cancer drugs fund, so we will need to consider NHS England's views about the fund's future path. In the English context, we have said that individual patients who are benefiting from medicines through the cancer drugs fund will continue to receive those medicines. We see that very much as an English decision about the cancer drugs fund. I know that you have been considering access to new and innovative medicines and that there is discussion about different funds in Scotland.

We have found the cancer drugs fund useful and are undertaking certain types of evaluation of it. However, we see it very much as an English thing, although we would be happy to share experiences of the CDF. I would be very interested to hear your views on what impact it might have on Scottish patients. I understand that it is an issue that is debated in Scotland quite significantly.

Nanette Milne: That is interesting. I was not sure about patients currently benefiting from the cancer drugs, but you have clarified that role, as far as England is concerned. There is therefore the possibility that English patients could benefit while Scottish patients would not get those drugs, if we do not have a cancer drugs fund.

Katy Peters: We have said that we are keen to ensure that individuals who currently benefit from the medicines in England continue to do so; I think that we set that out in the consultation document as one of the possibilities. We have said that the primary focus of VBP will be new medicines, but there is a question about whether any medicines that are currently available through the CDF would be assessed with a VBP assessment.

Nanette Milne: That is helpful.

Dr Simpson: Your last comment—that it has not been decided yet whether VBP will apply only to new substances—is very interesting. There is still a huge amount of uncertainty, with which the committee is trying to grapple.

On your discussion with my colleague Nanette Milne, we have a rare conditions medicines fund and the individual patient treatment request system, which is one of the things that this committee is looking at in the light of the Routledge, Scott and Swinson reports. The system is different up here. At the moment, the Scottish Medicines Consortium approves some drugs that are not approved by the National Institute for Health and Care Excellence, while NICE approves some drugs that are not approved by the SMC. We therefore do not have a homogeneous situation across the United Kingdom; there are many significant differences.

I am still trying to understand what the new system will mean. I understand how a medicine's price will be declared under freedom of pricing. The medicine will then go through an HTA and a value-based pricing assessment, if we introduce that. However, if the SMC wanted to retain something that was related to the patient access scheme and which affected the pricing—in other words, the pricing would be dependent on outcomes—would it still be open to the SMC to do that? Would the pricing have to be part of the value-based pricing system?

Katy Peters: I clarify that we do not expect an HTA assessment and then a value-based pricing assessment; we expect that it will all be undertaken as one assessment, with additional weightings being put in.

The current PPRS sets out the provisions for patient access schemes in England and Wales, which have proved to be popular. Quite a large number of them are available in England and Wales, and they are basically an agreement between a company and the Department of Health, with input from NICE. However, we have not said whether such an arrangement will be included in the negotiations. As I said, the PAS issue is very much one of pricing, which is one of the issues for the negotiations. Scotland operates its own PAS system, and how that operates in the future will be a question for the Scottish Government and the Scottish Parliament.

Dr Simpson: So we would end up with an HTA, which Scotland does as well, and a VBP assessment by NICE, which we would have to wait for before we would be able to go into a PAS, if we wanted to.

Katy Peters: No.

Dr Simpson: I am sorry, but I am still not clear about this. The SMC operates at the moment within the PPRS, but we can modify it with the PAS. We will have a VBP assessment for new substances instead of the PPRS, but we will still be able to modify it with the PAS and will not have to wait for the VBP to be determined before we negotiate our PAS, if we want to do that. Is that the case?

Katy Peters: The medicine will be licensed and get its price, and the SMC can then undertake an assessment as it currently does. Any debates about patient access schemes that the Scottish Government wants to take through that route would be a question for Scotland. The NICE assessment, which is a traditional HTA but includes a wider set of factors, does not really affect that timeline because the price is set and the SMC has its own role. That is how I understand the system, although I am not an expert on the Scottish system. The SMC can make its assessment, and those arrangements can continue at the determination of the Scottish Government.

Dr Simpson: Okay.

Bob Doris: Thank you for increasing my confusion. Value-based pricing is apparently a reserved issue. We are looking at it and there seems to be an information gap, so we are delighted to have you here. Your last comment seemed to suggest that NICE will do its HTA and value-based pricing together, and will come out with an approval or otherwise for new drugs in England. Meanwhile, Scotland can just continue to do its own thing and completely ignore value-based pricing. Is that what you are saying?

Katy Peters: NICE undertakes the HTA aspects of the system for England, so it may well not be that big a change, as NICE's role relates very much to those aspects. Just as in the current system, there is freedom of pricing at launch in the context of PPRS, and the SMC makes a set of decisions and recommendations. The medicine may or may not be assessed by NICE, because we have a slightly different set of criteria to decide which medicines go to NICE. NICE then makes an assessment based on a wider set of factors in a more systematic fashion than it currently does.

Bob Doris: For the part of that process that includes value-based pricing, who decides the framework for value-based pricing in Scotland?

Katy Peters: If there is a pricing debate, the question whether there is freedom of pricing at launch is determined by the UK Government. It is for the Scottish authorities to make a decision on the bit of an HTA that relates to whether Scotland spends money on a particular medicine at a particular price.

Bob Doris: Yes—but that is not the answer to the question that I asked you. I asked who decides. We know that there is a reserved aspect of pricing—although I must admit that I do not fully understand how it works—and we know that value-based pricing is being taken forward by the UK Government and that that aspect is reserved.

At some point, someone has to decide—forgetting for a moment about approval or otherwise, or the question of whether to provide patient access or not—on the value-based pricing element of any new drug, and someone has to decide on the modelling work and the measures around that.

Does the SMC have complete freedom to run its own system of value-based pricing if it wishes and to decide what the outcome for a price will be, or is it bound by a decision that is made elsewhere? Right now you seem to be saying that the SMC can continue to do everything that it has always done and we should not worry about it. Those are not your words, but I am coming to that conclusion based on your comments so far. Which bit is reserved?

Katy Peters: The bit that I would say is classically reserved is the pricing element. The SMC cannot say, "No, you don't have freedom of pricing in Scotland."

Bob Doris: Right. Can the SMC say that value-based pricing in Scotland is completely unique to Scotland because we have our own health and social care system, prevalence of disease, life

expectancy and multimorbidity, and that we will therefore decide on value-based pricing all by ourselves or just ignore it completely? Can it do either of those two things?

Katy Peters: As I said, the PPRS document reflects the issues that are reserved. Scotland cannot say that there is no freedom of pricing, and that profit controls must be operated in a certain fashion and that there must be a certain profile for list prices. Those aspects of the system are reserved, and relate to the price.

However, given a particular price, the debate about whether that drug or medicine is a good use of Scottish money would be a question for the Scottish authorities, including the SMC.

11:00

Bob Doris: That bit is crystal clear. What is not crystal clear—although I do not think that we will get any further this morning—is that although we know about pricing controls and the reserved aspects of those, which you have listed, none of that has anything to do with value-based pricing, from what I can see. We are here to discuss the reserved aspect of value-based pricing and how that will impact on Scotland. I am singularly unable to identify any aspect of value-based pricing, as you have outlined it, which is reserved.

Katy Peters: There are debates about how we will price new medicines. The part of the debate that relates to the pricing framework for new medicines, and how that fits into the European Union transparency directive, is reserved. Because value-based pricing will be applied to new medicines, how they are priced will be affected. However, the HTA process is a debate for Scotland and reflects Scottish preferences and societal judgments. Debates about the pricing profile for drugs—such as whether there is a maximum price; whether, if the medicine is available at a price that is higher than the one that has been agreed at UK level, there is a blacklist; what its availability is—concern issues that are reserved.

Bob Doris: Right. You just mentioned a blacklist, if a price is agreed that is higher than the UK level. Can you explain what you mean by that?

Katy Peters: There are difficult questions around what exactly is the status of NICE's approval. In the EU there are debates about the definition of a blacklist, where countries say, "You cannot have that medicine." In England we have a system where NICE says, "You must have it", and for medicines where NICE does not say that, it is up to individual commissioning authorities to make decisions.

Bob Doris: I am grappling with this—I think that other committee members are, too. Thank you for your answers.

Gil Paterson: I am confused.com, as it were.

As I understand it, the UK Government is trying to achieve a situation in which provision of new medicines is considered over a period. In other words, the medicines may be expensive at the start, but if savings may be made because of the impact over a person's life, the medicine may be approved. Have I got that right?

Katy Peters: Yes, you have. The HTA looks at both the savings and the cost to the system over a person's life.

Gil Paterson: If I may check that I have got it right, a drug that costs £30,000, let us say, may be expensive now, but in the new system that £30,000 will be assessed over the piece in terms of savings to the health service and the impact on the individual and communities. Is all that part of the value-based pricing method?

Katy Peters: The value-based pricing method takes the current price and looks at the benefits over the course of an individual's life, and then makes an assessment of whether that price is worth it, given the broader set of issues.

Gil Paterson: This is the bit that I struggle with. The system is based on measurements of what happens in England, which has a different system; the problem is that here we do business entirely differently. For instance, we are endeavouring to spend money up front, in the way that you have described. Our system is different, as is the energy and money that we are putting in with preventative spend, but decisions on drugs will be based on an English model, into which we in Scotland have no input. How do you evaluate what happens here in Scotland specifically, compared with what happens under a different model? You could be talking about Hong Kong, and coming up with a model for that country. That may sound ridiculous, but a system could be modelled on somewhere else that does not fit our way of operating, and brought into the UK.

I am not talking about diseases; clearly, there are particular diseases in Scotland. We are very good at having bad health—I understand that. I am saying that although the systems and the impacts upon people are entirely different, that difference will not be measured, as you describe it, given that those aspects will be reserved.

Katy Peters: It comes down to the distinction between the pricing part of the system and the HTA aspect of the system. The HTA aspect is taken forward by NICE in England and will be, I presume, by the SMC in Scotland. Those bodies can therefore assess what is the appropriate

impact—how we value appropriately the price that has already been given by the company, based on the system with which they are dealing. If the Scottish Government wishes, the SMC can take account of the social care system in Scotland when it makes its assessment. That is a decision for the Scottish Government.

The Convener: We will reflect all your evidence in our final report. Value-based pricing has been mooted for a long time now as some sort of panacea that would cure all the ills in the system. We seem to be waiting for tablets from the mount. From the evidence that we have heard, there will be no easy decisions here about the question of access to medicines.

Thank you for being with us this morning. We look forward to final conclusions and to a greater understanding of how they will impact on the Scottish scene.

11:07

Meeting continued in private until 12:25.

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