The Scottish Parliament
Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Tuesday 4 December 2012

Session 4

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HEALTH AND SPORT COMMITTEE
33rd Meeting 2012, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

Bob Doris (Glasgow) (SNP)

COMMITTEE MEMBERS

*Mark McDonald (North East Scotland) (SNP)
*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:

Dr Richard Casasola (NHS Tayside, University of Dundee and Scottish Cancer Research Network (East of Scotland))
Vicky Crichton (Cancer Research UK)
Dr Tim Crook (Scottish Melanoma Group)
Dr David Dunlop (Scottish Cancer Research Network (West of Scotland))
Professor Charlie Gourley (Scottish Cancer Research Network (South East Scotland))
Dr Stephen Harrow (Beatson West of Scotland Cancer Centre)
Alistair Haw (Prostate Cancer UK)
Eric Low (Myeloma UK)
Richard Lyle (Central Scotland) (SNP) (Committee Substitute)
Karen McNee (James Whale Fund for Kidney Cancer)
Dr Noelle O'Rourke (Beatson West of Scotland Cancer Centre)
Dr Russell Petty (Scottish Cancer Research Network (North))
Kate Seymour (Macmillan Cancer Support)
Leigh Smith (Melanoma Action and Support Scotland)

CLERK TO THE COMMITTEE

Eugene Windsor

LOCATION

Committee Room 1

Scottish Parliament

Health and Sport Committee

Tuesday 4 December 2012

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

Decision on Taking Business in Private

The Convener (Duncan McNeil): Good morning, and welcome to the 33rd meeting in 2012 of the Health and Sport Committee. As usual at this point, I ask those present to switch off any mobile phones, BlackBerrys or other devices as they can interfere with the sound system.

The first item on our agenda today is to decide to take in private at next week's meeting consideration of our approach to our agreed work on post-traumatic stress disorder. We normally take approach papers in private, so can I have members' agreement that we should do so with this item?

Members *indicated agreement.*

New Medicines (Access)

The Convener: Item 2 is the committee's work on access to new medicines. This morning we have two round-table sessions: the first is made up of cancer clinicians; and the second is made up of patient representatives and organisations.

Given the number of people at the table, it would be easier if people could introduce themselves before we move on to the discussion.

Dr Richard Casasola (NHS Tayside, University of Dundee and Scottish Cancer Research Network (East of Scotland)): I am a consultant clinical oncologist in Tayside.

David Torrance (Kirkcaldy) (SNP): I am the member of the Scottish Parliament for the Kirkcaldy constituency.

Dr David Dunlop (Scottish Cancer Research Network (West of Scotland)): I am clinical lead for the Scottish cancer research network in the west of Scotland and clinical director of the Beatson west of Scotland cancer centre.

Mark McDonald (North East Scotland) (SNP): I am an MSP for North East Scotland.

Aileen McLeod (South Scotland) (SNP): I am an MSP for South Scotland.

Gil Paterson (Clydebank and Milngavie) (SNP): I am the MSP for Clydebank and Milngavie.

Dr Russell Petty (Scottish Cancer Research Network (North)): I am clinical senior lecturer in medical oncology at the University of Aberdeen and consultant medical oncologist at NHS Grampian.

Drew Smith (Glasgow) (Lab): I am an MSP for Glasgow. I apologise for being a few minutes late, convener.

Professor Charlie Gourley (Scottish Cancer Research Network (South East Scotland)): I am a medical oncologist in Edinburgh and the south-east Scotland SCRN lead.

Nanette Milne (North East Scotland) (Con): I am an MSP for North East Scotland.

Dr Noelle O'Rourke (Beatson West of Scotland Cancer Centre): I am consultant clinical oncologist in Glasgow and chair of the Beatson west of Scotland cancer centre consultants committee.

Richard Lyle (Central Scotland) (SNP): I am an MSP for Central Scotland.

Dr Stephen Harrow (Beatson West of Scotland Cancer Centre): I am consultant clinical

oncologist at the Beatson west of Scotland cancer centre.

The Convener: I am the MSP for Greenock and Inverclyde and the convener of the Health and Sport Committee. I thank everyone for coming. Welcome.

As this is a round-table session, we will do our best to allow discussion between people on the panel, and members will try to do more genuine listening than talking.

I will kick off the discussion with a broad headline and ask for views on whether the current appraisal system is fit for purpose for orphan medicines generally and high-cost cancer medicines in particular.

Dr Casasola: The system in Scotland gives us a rapid assessment of new drugs. For very expensive drugs, that assessment often gives a negative response, which can make things difficult for clinicians who have to deal face to face with patients who are aware of a drug's availability and of the cancer drugs fund in England. There is an inevitable inequality of access to those new drugs.

I guess that there is a counter side. I am not sure that the process is wrong, but it is very difficult to justify the extreme costs of some of the newer drugs when measured against their efficacy and effects in relation to patient survival. With my clinical lead for Tayside hat on, I have worries about the affordability of some of the newer drugs.

Dr Dunlop: I agree with Richard Casasola. Individual patient treatment requests for drugs that are not approved by the Scottish Medicines Consortium are made within a framework that is described by chief executive letter 17 from 2010 and which was put in place by the Scottish Government. The SMC function was also put in place by the Scottish Government.

There is sometimes a perception that the panels can apply permissive discretion or compassionate flexibility in individual cases, but that is not the case, certainly in the west of Scotland. We work carefully and robustly within the framework that is described in the chief executive letter. There is no latitude other than to make the decision based on the extent to which the patient's circumstances make them more likely to benefit from the treatment.

Professor Gourley: I back up what Dr Dunlop has said. IPTRs are not synonymous with SMC approval. It is often said that patients who cannot get drugs because they are not approved by the SMC can access them through the IPTR process, but it is difficult to get cancer drugs through that process. The benefit of getting SMC approval is that funding for the drugs then comes to the department. If we want to access a drug that is not SMC approved and we put it to our committee in Edinburgh, it is careful not to set a precedent in saying that an individual can get the drug, because it would then have to find the money from its existing budget for all the individuals who were in a similar setting. That is why the situation is a problem. IPTRs and SMC approval are certainly not the same thing.

The issue for me is how we can put patients at the forefront and access the drugs for them. Although the drugs are expensive, they are being provided elsewhere in the developed world. It is a big issue for patients who cannot get the drugs, but other issues are connected with that as well. In Scotland, we are proud of our history of conducting good clinical trials and being at the forefront of medical research. Historically, we have been involved in proving that the new drugs are beneficial to cancer patients, but we are moving into an era in which we are not being allowed to give the drugs that we have proved are beneficial. That has a knock-on effect for the next generation of clinical trials because, when they come along, people will assume that we can access the drugs—as the standard of care—through our normal healthcare system.

All trials compare a new combination of drugs with the standard of care. New drugs are now considered to be the standard of care but, because we cannot access them, we are also denying the next generation of patients access to trials of the next line of drugs. We are moving to being a generation behind because of that. That is why I believe that we need to find a way in which patients can access these drugs.

Dr O'Rourke: I agree with Charlie Gourley, and I confirm what Dr Dunlop said. We are working within the process that has been set down, and where drugs have not been approved by the SMC on the basis of cost effectiveness, we do not have access to them. The problem that we have as clinicians is that there is a public perception or misunderstanding that, somehow, we can access the drugs by using the IPTR process. That is not the case.

The percentages that are quoted for successful IPTR applications look promising because so few IPTR applications are made, and the reason for that is that, as clinicians, we know from the outset that we will not have the drugs approved. If the SMC has turned them down on the ground of cost effectiveness, we will not be able to access them for patients through the IPTR process. The process of filling in an IPTR form, raising the patient's hopes, having the application rejected and taking the patient through an appeal process—which is unbelievably painful for both the patient and their clinicians—only to be turned down at the end is not something that many

consultants will do more than once, because they feel so upset and distressed by the process on behalf of their patients.

The committee needs to understand that IPTRs are not a way for us to access drugs. In England, the cancer drugs fund allows access to drugs that have not been approved by the National Institute for Health and Clinical Excellence. However, we have no equivalent in Scotland, and our patients cannot access drugs that have been turned down on the basis of cost effectiveness. We all understand the difficulties with and constraints on budgets, but we need to make it clear that SMC's judgments are made on the basis of cost effectiveness and that the reason why these drugs are not approved is not because they are ineffective but because they are expensive.

The bottom line is that these drugs have licences because they work, are effective and have proven benefits for patients. However, they are very costly and the SMC has judged that we will not have them, and we are stuck with that decision. The patients do not understand the process; they expect to be able to access those drugs but they—and we—cannot. We keep trying, but there is no system that will enable us to access drugs for those patients. Even when we try to select patients who have the most chance of benefiting on the basis of molecular markers, we are in many circumstances unable to check the molecular markers to identify those patients who might benefit.

Dr Petty: I concur entirely with and emphasise what has already been said about IPTRs.

On the convener's question, I do not think that it is fair to say that the SMC process is not fit for purpose. As far as independent health technology assessment appraisals of new drugs are concerned, it is fit for purpose; indeed, few people would question the value of that process in determining cost effectiveness. The important distinction that I would make in that regard is between a drug's cost and its value, particularly as it is perceived by society, and the fact that that might not equate in a linear fashion with cost is a key issue that needs to be addressed.

With regard to Professor Gourley's comments on clinical research, my view is that this is not a theoretical construct. The lack of access of innovative medicines will affect—and, indeed, is affecting—clinical research in Scotland, because it means that clinicians are not able to offer the standard of care for comparator arms of trials. As a result, we might not be able to offer those trials to patients, which means that they might not have access to the latest protocols. It is universally agreed that clinical trials not only benefit patients but have additional benefits for research infrastructure, economic benefits and benefits with regard to the retention of clinicians. We need to realise that the impact on research is not something that might happen but which is happening.

Dr Harrow: As a clinician who has not yet spoken, I have to say that I have unsuccessfully navigated the IPTR process on a few occasions. One unfortunate situation that can emerge is when the issue of the availability of biological agents just across the border is not discussed with patients. In one case, a patient spoke to a family member who happened to be a director of public health down south and, in a subsequent meeting that he asked for, challenged me on why I had not discussed those drugs with him and felt that I had done him a disservice by not explaining all the options that were available to him. Such situations put me in a very invidious position. I work in quite a deprived area in the west of Scotland and might be put in the position of having to tell patients that the number of drugs that they cannot access within the colorectal cancer portfolio is greater than the number that they can access.

Moreover, when the patient in question spoke to his MSP about the matter, the member put the responsibility squarely on me to apply for the drugs through the IPTR process. However, because they have been turned down by the SMC, I am unable to access those drugs through that process. As I said, I have never been successful with that approach. Indeed, given the way in which the legislation is written, I would never be able to access those particular drugs for that patient.

The other issue goes back to the research side of things. I have just taken up an NHS Research Scotland fellowship and I was at a meeting recently where the health minister gave a talk about wanting Scotland to be at the forefront of biotechnology developments. I sat in the audience, knowing full well that actually we are not using a fraction of the drugs that we could use. The drug companies very much see Scotland's health service as being quite inferior, as it cannot offer those drugs to our patients.

10:00

The Convener: Some of these problems will be familiar to committee members from the evidence that we have previously taken and our engagement with patients and patients groups about what they are being told. From that headline, we must accept that the SMC has a job to do that has been laid down and that there are cost pressures, as we have heard. How do we address many of the issues that have been identified both this morning and in previous evidence?

A review is taking place. What should we be saying to that review? There is an opportunity here. We have had some contact with the people who will be involved in the review and we will submit the evidence that we have taken to the review for consideration. I do not know whether any of it will be taken on board, but we have an opportunity to say how we could make some of this better.

Help me out here, Professor Gourley.

Professor Gourley: Everybody respects what the SMC does on working out cost effectiveness—it is obviously a difficult job. However, the SMC largely responds to requests from drug companies to assess a drug, and NICE responds to requests from ministers to review a technology or drug. It would be great if we could feel that the SMC was actually helping us access these medicines. We all know that they are expensive and we do not want to bankrupt the health service, but there are good reasons why Scotland should be able to provide at least the most effective of those drugs.

There are ways in which that could happen—for example, if the SMC was not so hamstrung by rules. Recently a drug came through that clinicians in Scotland wanted to use at half its licensed dose, which might well have made it cost effective. However, the SMC was not allowed to assess an unlicensed dose. Obviously, given that the proposed dose was half of the licensed dose, there were not really any safety concerns, but the SMC was hamstrung.

We must realise that drug companies will not change their pricing structure for Scotland, because we are not a big enough nation and they have money to make on a global scale. The way that drugs are priced south of the border will change in 2014, with value-based pricing. Rather than a drug having a specific cost, its cost will depend on what value it will give. Oncology in Scotland has just moved towards an electronic prescribing system. Scotland is a small nation, so there is an opportunity for an organisation—be it the SMC or something else—to get involved in negotiating with drug companies, because drug companies come with patient access schemes that cut the cost of drugs.

It would be important for such discussions to be private. Scotland could perhaps get access to drugs without their costs becoming public to the outside world, because a lot of the rest of the world use the British price as the price that then applies.

For example, Herceptin, which is used to treat breast cancer, is much more cost effective if it is used just after patients have had an operation rather than when their cancer comes back. We could pay one price when we give it to patients after they have had their operation, but the drug company could discount it when we want to give it to patients when their cancer comes back. We have found from our discussions with drug companies that they are amenable to such situations. That approach could be applied in Scotland because we have electronic capture of online prescribing. We need an organisation to sit in the middle, if you see what I mean.

Dr Dunlop: I agree with Professor Gourley. There is an opportunity to negotiate with the pharmaceutical industry. There is a good example of that recently with a drug called abiraterone. On the second attempt, SMC approval was obtained with a more acceptable reduction in costs through a patient access scheme. However, it is unlikely that a lot of drugs will be made a lot less expensive. If we choose to revise the way in which the SMC process, or rather the post-SMC process—the individual patient treatment request access, or non-access, scheme—works to make it more permissive, we will have to pay for that either by not doing other things that we do in NHS Scotland or by having an equivalent to the cancer drugs fund, which clinicians south of the border say is far from perfect. In fact, that fund brings more postcode prescribing than existed previously, because each of the different strategic health authorities has a different shopping list that is influenced by its clinicians. That approach may therefore not be the answer, but whatever we come up with, if it is more permissive we will have to pay for it.

The Convener: Does anyone want to challenge that? I think that the SMC makes the point that if it were not tough, it would not go back to drugs and get the reductions. It said in its evidence that that is how it sees its role.

We welcome Dr Tim Crook. We are pleased to have you here.

Dr Tim Crook (Scottish Melanoma Group): Thank you.

The Convener: Does anyone else want to come into the discussion? I will bring Nanette Milne in afterwards.

Dr Petty: I will just briefly pick up on the issues around the SMC. On the value of medicines, as many people will know the SMC can apply modifiers to the cost-effectiveness analysis. That is important and should not be removed from the process. However, I am concerned that how the modifiers have been applied has not always been entirely transparent—at least, not to me as a clinician. For instance, it is possible to read SMC appraisals and see drugs that look similar in terms of their application to patients at the end of life, with similar clinical effectiveness and cost effectiveness. However, there are examples of

drugs that have been approved in that setting—the example of abiraterone for prostate cancer has already been raised—whereas drugs that have a similar clinical and cost-effectiveness profile have not been approved. Herceptin for use in treating gastric cancer is an example of that.

The modifiers are an important aspect, but the difficulty is that their application has not always been transparent. That undermines perceptions of the fairness of the process. Everybody understands the need to control costs, but the perception that that is done fairly is important. That relates to what was said earlier about the cost negotiations. They are clearly important, but I have slight concerns about the transparency of the process and how it might be perceived.

Dr Casasola: I reiterate Charlie Gourley's point about national negotiation with the drug companies to get them to look at reasonable pricing. To give a sense of the scale of the issue of the absolute costs of drugs, I did a back-of-the-envelope calculation and worked out that if I were to treat just 10 of my melanoma patients with ipilimumab at its current cost, I would have to ask my trust for an uplift of 30 per cent per year in my drugs budget. That is the magnitude of the costs that we are talking about.

Nanette Milne: Professor Gourley mentioned value-based pricing. That has been mentioned to us on several occasions, but there seems to be a lack of clarity about how it will work. Can any of the witnesses give any clarity on that? I have to say that I am slightly confused about what it means.

Dr Dunlop: I sit on the SMC. We have had presentations on value-based pricing from pharmacoeconomists from south of the border and have left the meeting completely baffled as to how it is going to be deployed if it is to deliver what it is supposed to deliver, which is the follow-on from the current cancer drugs fund arrangements.

Nanette Milne: I went to a meeting of the Association of the British Pharmaceutical Industry at which an economist from down south spoke about value-based pricing and I was utterly perplexed by it. To be honest, I did not have a clue.

Professor Gourley: We do not have to follow the English model. The great thing about some of the infrastructure and information technology systems that are in place in Scotland is the opportunity to set our own model. We could call it value-based pricing or just say that it is similar—a discount based on what we used a drug for. When we used it in the most cost-effective situation, we would pay the full price, and when we used it in a less cost-effective situation, the pharmaceutical company would cut the price—give us a discount—according to the efficacy that we would get.

There is no doubt that, at the end of the day, this has to be paid for somehow. I am sure that you have been quoted the figure of about £4 per person in Scotland per year to get equivalent access to what the cancer drugs fund achieves in England. That may not be the best example, because we all accept that the cancer drugs fund has limitations.

However, you should bear in mind the fact that we are talking not only about getting access to the best drugs for people in Scotland but about maintaining Scotland's position at the forefront of clinical research. Nowadays, a lot of science comes along with the clinical research because the drugs are all new biological agents. We are always saying how Scotland is such a good centre for life sciences and biotechnology. It will be difficult to maintain that if we are not at the forefront of medical research.

Dr Crook: I came to Scotland in the past six months, having been a medical oncologist in Essex for two and a half years. There, we had the cancer drugs fund and I could prescribe any melanoma drug that, in my clinical opinion, was in the patient's best interests.

As an Englishman looking after patients in Scotland, I think that there is an inequality that, to my mind as a simple doctor, is unacceptable, in that I cannot offer my Scottish patients the same medication with which I could treat my English patients. As a human being and a doctor, I do not see how that can be right.

The health economics are far too intellectual for a simple person such as me but, having come from outside Scotland, my perception is that the matter needs to be addressed urgently. The cancer drugs fund is full of imperfections, but patients who have received vemurafenib or ipilimumab, which Richard Casasola mentioned and which I am sure could be extrapolatable to any tumour site, are extremely grateful that the fund exists.

Dr Harrow: There is a colorectal cancer drug in the third-line setting that doubles overall survival rates compared with best supportive care. NICE turned it down on a multiple technology assessment. Apparently, that decision applies in Scotland.

Within the NICE documentation is a summary that states that it looked forward to further BRAF analysis, as perhaps it would be possible to drill down further and find people who would be more responsive to the drug. In spite of providing evidence of the benefit to the patient and of the BRAF and KRAS status, we were still denied the drug. This is a drug that doubles survival rates

from four or five months to nine months in a group of patients who have no other treatment options available to them. There was an IPTR and an appeal at which use of the drug was turned down despite every one of the 10 experts who deal with the drug across the border providing supporting statements and our own professor of translational medicine in oncology at the Beatson centre providing supporting documentation. The IPTR process does not allow us to access drugs that would double overall survival when patients have no other options.

10:15

The Convener: How would we create another system that would give doctors and patients a better chance of accessing new medicines and which would sustain the reputation for medical advancement and life sciences? What you have described is where we are now.

Dr Casasola: I do not think that the SMC process is wrong, but the quickest way would be to raise the bar that the SMC sets on the value for money of such drugs.

The Convener: Would that be a solution? It is my recollection that the bar—which is, I think, about £40,000—has not been raised since 2001.

Dr Casasola: The figure is about that.

The Convener: The figure has been increased to £50,000 south of the border. I do not know whether such things make significant material differences.

Dr Petty: That would be a solution, although I want to emphasise again that it is not the SMC process that is the problem. The route to doing that is to have—for want of a better word—a policy that would apply transparently and understandably the modifiers of the cost-effectiveness threshold. As I said before, I do not understand the current process and how the modifiers have been applied in different cases. What I have outlined may allow the cost-effectiveness threshold to be varied according to the value as assessed by a schema or policy that would be defined by particular modifiers. Obviously, end-of-life care would be one of those.

Dr Dunlop: I am the only oncologist on the SMC. Quite often at meetings, oncologists are surrounded by cardiologists and rheumatologists who treat other diseases and who find it very difficult to understand why we would want to use an expensive drug to allow a patient to live from 75 to 75 and a half years of age. We, however, find it very difficult not to understand that because we are sitting in front of the patient having that difficult conversation with them. Perhaps we need to help clinicians to have that difficult conversation more often and with more support. I reiterate that if we come up with a more permissive version of the post-SMC process, we will have to fund it, somehow.

The Convener: There is a difficult challenge in that. There is, of course, a wider point about what we do in the health service that may not be given a value if we apply some of the SMC principles—some of the other procedures would not survive if the SMC made the comparison that clinicians deal with every day of the week. There are also wider issues about how we help people in their life not only with drugs, but with care and support, and how we help them to make such decisions. I do not know whether any members of the panel want to respond to any of that.

Dr O'Rourke: We all understand the financial constraints and I think that none of us has a problem with the need for cost-effective analysis or with the fact that the SMC needs to exist.

I guess that the difficult thing for all of us—as clinicians working for patients—is inequity; patients' perceive that they can access drugs that patients in England and elsewhere in Europe can get, but that is not the case. If we are to maintain the SMC and the current financial constraints, the public need to be given the clear message that the Scottish Government has chosen not to spend money on certain drugs and that the status quo will prevail. The worst thing of all would be if patients were falsely to expect that they will get a standard of care or treatment that is as good as that elsewhere, when that is not the case.

Dr Harrow: In case people have the perception that we are somehow a group of hysterical consultants who want to prescribe lots of expensive drugs, I should say that I have submitted only two IPTR—individual patient treatment request—forms in the past year. I selected those patients rigorously and applied only on behalf of patients whom I really felt would benefit from the drug, and I work in a very big practice that covers the whole of the Clyde area, including Paisley, Inverclyde and the Vale of Leven. There is no indiscriminate asking for drugs for every single patient; I absolutely accept that we need to drill down and find out which patients would benefit most. However, if I provide on evidence an IPTR such as NICE has suggested it would look for and my request is still turned down, we are getting nowhere with providing the most needy patients with access to the drugs.

Dr Petty: On the earlier question about whether the same rigorous appraisals are applied to all new health interventions, I think that the answer is no. On whether that should happen, I think that the answer is probably yes. For example, it is recognised that new devices are not appraised to the same level as new drugs. That is an important

issue to address, particularly given finite resources.

The Convener: I am sorry. What do you mean by "new devices"?

Dr Petty: I mean new hip replacements, knee replacements or implants—that kind of thing.

The Convener: I am not sure whether the question that Gil Paterson wanted to ask is still relevant at this point.

Gil Paterson: I just wanted to make the point that as a matter of simple mathematics—I am sorry to put it in that way—raising the threshold from £40,000 to £50,000 would seem to me to involve an additional cost that we might not have resources for. The budget is the budget, and there is a limit to it. What do witnesses think about that?

Also, I understand that there has been talk of introducing value-based pricing down south. In effect, that would be overarching and would cover Scotland, given that drug approval decisions are made south of the border. How would we interact with that? Would our system disappear, or could it engage? I know that the matter is unclear, but does anyone have views on that?

Professor Gourley: There is certainly a lot of vagueness about how value-based pricing will work, and I do not think that anyone really knows. My understanding is that, once value-based pricing comes in, the situation here will still be different from the situation south of the border, although I might be wrong about that. David Dunlop might know better.

Under a recent agreement down south between the Department of Health and the ABPI, drugs that have been approved under the cancer drugs fund will be used to pilot a value-based pricing scheme. Obviously, those drugs are not currently accessible to us. My understanding is that once value-based pricing comes in, the cancer drugs fund will no longer exist, although I do not know whether that is true. There will be a grey area in that the drugs that have been approved by the cancer drugs fund will not be subject to value-based pricing. My understanding is that it has been agreed that value-based pricing will be piloted in England using those drugs; that could be replicated up here.

Gil Paterson: Do you mean that that would effectively bring them into the scheme?

Professor Gourley: Well—

Gil Paterson: My understanding is that what is being proposed in England will also cover Scotland, so we will need to decide to how interact with that in a different way, although I know that you would like things to be as they are now. My understanding is also that when it comes to approval of drugs, the system will be as it is just now, although it sounds to me as though when it comes to cost effectiveness of drugs, decisions will be United Kingdom led and will not be specific to south of the border. Perhaps someone knows different.

Professor Gourley: Unless the SMC disappears, cost effectiveness of drugs will still be assessed here. Historically we have been different. Cost effectiveness is assessed by NICE down south and by the SMC up here. My understanding is that if the SMC does not disappear, we are still going to have to establish cost effectiveness if we are to access the drugs, although I could be wrong. Everyone is very vague about what will happen in 2014.

The Convener: The system seems to have a lot of layers. If we cannot afford the drugs, why do we have all the layers including IPTRs and so on, especially if no one is going to get through them all? The barrier is the cost; it is not about outcomes because, as we have heard, outcomes can be very good. Why are we pretending otherwise?

Dr O'Rourke: You are exactly right.

Dr Harrow: Unfortunately, patients are being told that it is not down to cost but because of some other system. We need to be honest with patients and tell them that we are funding other things so they are not going to get those drugs. It is very difficult for clinicians to have those conversations with patients, especially if we do not discuss certain drugs and the patients find out about them and then come back to challenge the clinician to tell them why they did not discuss the drug with the patient and why they are not getting it.

Dr O'Rourke: On equity of access, my limited experience of going through the difficult process of IPTRs has seen patients going to appeal panels to try to get the drugs. The appeal panels were intended to be in the patients' interests, but one of the difficult things with them is that patients are allowed to attend. I do not think that people can begin to understand how stressful and traumatic that is for an ill person who is dying of cancer.

In the circumstances in which I was working, I sought to protect my patient from having to go to the appeal panel because I knew how difficult it would be. The patient was turned down for the drug. A similar application was made for the same drug and a younger, middle-class and articulate patient whose case was less good clinically went to the appeal panel and got the drug. That makes me think that the process is inequitable. A person who is able to go through the process and who is articulate, vocal and has the right background will have a better chance of getting the drug than a

more vulnerable patient. That is a difficult situation for us to be in.

Mark McDonald: The first thing to point out is that many us who are doing this inquiry will have been affected by cancer either through family or friends. It is worth getting on the record the fact that members are not immune to the issues that we are discussing.

Nonetheless, we have to look at the issues from a detached point of view and from all sorts of other angles at the same time. One of the angles from which I am looking is to do with the fact that a different panel of consultants from other backgrounds—whom we will have at next week's committee—will be advocates for their specialisms. How do we strike a balance in which we are not seen to be leaning too heavily in favour of one particular area of medicine?

10:30

Moreover, how would we then balance that against what is undoubtedly a finite budget resource? Can we strike a balance that would allow access to some of the medicines and which would allow other specialisms or other areas of healthcare to come forward and say, "Hang on. It's not just about cancer drugs. Other diseases need consideration"? Can we allow all that to happen within the available healthcare budget? I heard someone talk about raising the threshold; I am interested in exploring that suggestion further and finding out not only what it might mean for the wider availability of cancer and other drugs, but about potential cost increases and other areas in which costs might need to come down as a result.

Dr Harrow: There is a perception that we spend lots and lots of money on cancer drugs. I am sure that we do, but data that I have seen, and which I think have been presented to Parliament, suggest that across the country we spend about £10 million less on cancer drugs than we spend on statins. I do not know what the position is relative to the rest of the country, but it is being made out that cancer drugs are this big, bad, evil and very expensive thing.

Mark McDonald: I should perhaps clarify that I was not coming at this from—

The Convener: I will give you an opportunity to respond, Mr McDonald, but I do not want you to interrupt the witness.

Dr Harrow: That is fine. I had finished.

Mark McDonald: I was not saying that we spend too much on cancer drugs; I was simply asking about the likely impacts across the board if we were to make the changes that have been suggested, and about how we would balance that. I was not saying that we are spending too much and should not spend more; I just want to know about the impacts of changing the threshold.

Dr O'Rourke: I read all the evidence before coming to the meeting. One submission—these are not my figures but are, I have to admit, from the Association of the British Pharmaceutical Industry—highlights the relative costs of prescribing in Scotland across different areas of medicine and suggests that cancer drugs prescribing costs are 60 per cent of prescribing costs per capita elsewhere in Europe, while our cardiovascular drugs prescribing costs are at 90 per cent and mental health spending is at 100 per cent of the costs per capita elsewhere in Europe. Those are not my figures, but if they are correct they suggest that we are, as cancer drug prescribers—relative to the rest of Europe—underperforming, underprescribing and coming in cheaper than our cardiovascular and mental health colleagues.

Professor Gourley: There has been talk about raising the threshold, but to be honest I am not sure that that is necessarily the answer. It could be raised slightly, but I would prefer that the SMC was able to talk to clinicians and pharma, to be much more open and to be the vehicle for delivering the drugs. If we accept that a drug is good, our aim should be to find a way of getting under the top line to deliver it to patients. We should not have hard rules that prevent us from considering a particular dose of a drug; instead, we should be finding out how we can get it for people in Scotland. It might be better to think about changing the structure in that respect.

As for budget allocations, if all the money has to come from the health budget, we will have to start weighing the need for, for example, heart transplants and hip replacements against the need for cancer drugs. That, of course, will be very difficult, but at some point a decision will have to be made about the broader implications of not providing the drugs. We have already mentioned the effects on our life sciences and our place as world leaders. If we lose that place, the costs for Scotland will be much greater than simply the cost of the drugs, and it will have far greater global implications. We need to find some money from somewhere else.

Richard Lyle: I agree with Mark McDonald. I, too, have had several friends and close colleagues who have died from cancer. It is a touchy subject for us all.

I want to address the comments from Dr Tim Crook. You have worked in England and in Scotland. Is it the case that some drugs that we supply in Scotland are not supplied in England?

Dr Crook: There are very few such drugs in oncology.

Richard Lyle: Okay. My next question is for Dr Stephen Harrow, on the two IPTRs that you put in. What would you suggest that SMC do differently in order for them to have been passed?

Dr Harrow: There must be recognition of the fact that the way to get the drugs is not through the IPTR process. That is not what the IPTR process is written to allow me to do, as has become apparent to me.

How would we do it differently? As a clinician, I see hundreds of patients in a month—I select just a few patients, so my clinical skills should be valued when I submit a request. There should be a panel that would listen to what I have to say, because I am the one who has experience of the drug and the condition. The panel does not have that experience; its members may have a vague sense of the drug and the condition, but they do not see the patients or prescribe the drugs. I am the treating clinician who has been trained in the Scottish national health service.

If I were to make an IPTR every day, the panel might say, "This guy's clearly not playing by the rules. He's overexpecting on what we can deliver", but I am not doing that. I have selected patients whom I think would benefit from the drugs and I have evidence to say that they would benefit more than the population who were reviewed by the NICE multiple technology appraisal. Despite that, they have still been turned down and I am still going through the process, which has been going on for six months with delays on both sides of the fence. It is not a timely process and it is very distressing for the patient.

To pick up a point that Noelle O'Rourke made, it was the husband who came to the appeal and gave simple statements about his wife and their thanks for what they have had. However, afterwards he was in tears and I then had to break the news to his wife, who was also in tears. I can do that—I am a skilled clinician and a compassionate person—but I was anguished because I had thought that there was a process through which I would, if I put a good case, get the drug for the patient. There is not a process that allows me to do that—the process is stacked against me completely. It feels to me, as a clinician going through the system, that I am a lone consultant putting in an IPTR to a machine that is against me and which is trying to ensure that I do not get that drug. That is how it feels.

At the appeal that I sat through, there were representatives from pharmacy who had been reviewing things in the background so that they could put evidence together. I am on my own, doing a busy clinical job. I asked whether another consultant could come along to the IPTR appeal and was told that I was not allowed any other representation. However, the management are allowed additional support in arguing against my getting the drug. It was not a conversation about whether we could get the drug for the patient and whether they were the right patient to give the drug to; it was about trying to make sure that I did not get past that point.

Richard Lyle: I agree with the point about the bar being raised. You say that you have had only two such cases in a year. Should a clinician be allowed by the SMC to submit a certain number of requests that they would know would have a chance of being passed?

Dr Harrow: Such cases should go to an independent panel. With due respect, I do not think that the person who holds the budget should be the sole person to decide whether a patient gets access to a drug, because there is a conflict of interests there. That person should not both consider cases and be the person who is trying to keep costs down, which is a very difficult and invidious situation for them to be placed in. In my opinion, there should be an independent process.

Richard Lyle: Thank you.

Nanette Milne: Is the situation fairly uniform across the health boards or are there a variety of processes? Do IPTRs work in the same way throughout the country?

Dr Dunlop: I can speak only for the west of Scotland, where the process is completely confluent with CEL 17, which is the guidance. I convene panels—I chair and co-ordinate them—and I sympathise with the clinicians' position to a degree. However, we have to reflect on the fact that there must be scrutiny. Some common sense must be applied in relation to the drugs, because otherwise we would not need the SMC; we would just ask Dr Harrow who should get the drugs. That is not a situation that we can accept when we have the governance responsibility for delivering the health service. If we allowed new developments and technologies to be implemented and deployed without scrutiny of their clinical and cost effectiveness, the NHS in Scotland would soon be in even more financial trouble than it is in now.

There has to be scrutiny. What we have at present might not be perfect—I agree that it should be less complicated—but if we are to come up with a different version of that scrutiny that is less complicated, we must ensure that it is fit for purpose.

The Convener: I have listened to what we have heard over the past few months in our private and public meetings, and from a layperson's point of view, it seems to me that there is quite a lot of scrutiny. There are all sorts of layers; we have NICE, the European stuff, the SMC and the licensing process, there are all the boards to go

through and, at another level, we have the individual patient treatment requests. It looks like there is a lot of stuff in there.

Dr Dunlop: That might be the problem.

The Convener: That is the question that I am posing: is that the issue? To the layperson, it seems that there is a mountain of stuff to be gone through. Why does the process need to be so complicated? If everyone is doing a good job and we have confidence in NICE, the SMC, this process and that process, why do we continually question the same process again and again? From a layperson's point of view, it is confusing. As an elected representative, I represent people who have gone through the process and I know that it has been difficult and bureaucratic for them.

Professor Gourley: It is useful to hear about IPTRs and the stress that clinicians and patients are under, but I can simplify this a wee bit by saying that IPTRs are not the answer, because they are not a way in which to access the drugs. They are for exceptional cases, and it is extremely difficult for a clinician to demonstrate exceptionality.

The difficulty is at the SMC level. The convener said that it is difficult for a layperson to understand the difficulty. It arises because the cancer drugs are effective but very expensive. The value of SMC approval to the individual health board is that, if there is such approval, the cost of the drugs is paid. If there is no SMC approval, the health board has to find the money from elsewhere in its budget. We could make the issue a lot simpler by asking how we can allow the SMC to improve delivery. IPTRs are not the answer.

The Convener: Dr Dunlop's challenge is the cost, is it not? The drugs have to be paid for. Everybody agrees that this is a cost issue.

Dr Dunlop: Absolutely. If we come up with a system that is more permissive—if we raise the bar or come up with some other way of assessing the metrics before drugs are approved—we will have to find a way of funding that. The aim is for the right patients to get the right drugs at the right time. There is a lot of opinion and emotion in the room that is confirming that that is a difficult thing to do. A clinician might know that there is a good chance that a patient will benefit from a treatment, but the SMC might have determined that that benefit does not equate to its being cost effective. That is the difficulty. I agree that the post-SMC process is very complicated and very difficult to administer.

10:45

Aileen McLeod: My question is on a related point. We have been talking about the complexity and bureaucracy of the IPTR process, but are there problems with the transparency of the process and its consistency across the boards? If so, how do we get more transparency into the process and greater consistency across the health boards?

The Convener: Do I have any takers?

Professor Gourley: There is consistency: all the boards say no to the very expensive drugs. IPTRs are not really the answer.

Unfortunately, the situation is often that someone who has a certain cancer is told by their oncologist that a certain drug could help them but that it cannot be funded, and so that person writes to their MSP. We have heard that there is a process whereby patients can apply for access to such drugs, but for new, very effective drugs it is fair to say that the approval rate is a single digit percentage.

We hear about some cases because they get into the papers, but the problem is not at that level—it is bigger.

Dr Petty: I agree with what has been said—the consistency is unfortunately negative.

The issue comes down to cost—we seem to have consensus on that—or, rather, it comes down to value. We appreciate that there are difficulties with value-based pricing, but value for money is the key issue. My perception as an oncologist comes from speaking to patients about this issue, and we have heard lots of personal experiences today. There is a discord perhaps between what patients see as value for money and what the rules of the SMC allow it to say is value for money. That is why there is a case for raising the threshold, or perhaps having a tariff of thresholds for different clinical indications. Such a system might be complicated, but the discord between value according to the rules of the SMC and value as perceived by cancer patients is at the heart of the matter.

Gil Paterson: We all find this a very difficult subject because we all have experience in some way. To be honest, I would not like to be in the shoes of the folk around this table. It must be very difficult.

If I were to hear that someone can get a drug in one place but not another, and that the models in those places were not the same, I would need to know exactly what was being done in preference to spending on drugs. How much money is being spent in place A as against place B? Is more money being put into preventative medicine or trying to stop cancer—or any other illness—very early on?

Although this inquiry is about drugs, I find it difficult to come to a solution with one part of the

equation. I would need to know what the whole journey is for an individual. Unfortunately, we find ourselves in a very difficult situation because we are dealing with people.

I have a simple question that I would like to get my head round, because I would like to solve the problem. If I decide to vote to say yes to very expensive drugs, I must accept that they would be for a limited number of people and that money would be taken away from other areas. How many people would be affected by taking money away from those other areas? Those people may well be cancer sufferers, too.

For me, that part of the equation is missing. We have experts here talking about one element of the treatment—the drugs element. I would like to hear about the things that happen before we get to that stage.

The Convener: There are no takers for that one.

Gil Paterson: It is a challenge, isn't it?

The Convener: It is a challenge for the Parliament. We agreed to free prescriptions but we did not make the calculation then. I suppose that we are at that starting point: do we hang tough on these issues and what is available at one point, which makes things easier at other points? Gil Paterson is right to say that our discussion is not just about one issue. The issue for the NHS in Scotland is about what we are doing and whether we are measuring the outcomes and value of all that we are doing. That might help us reach better decisions—but it is a big challenge.

Dr Crook: I want to reiterate what Charlie Gourley said earlier. If these drugs are not available in Scotland, there is a danger that our status as a premier league biomedical research country will be compromised and undermined.

In my first year in Dundee, I have formed the impression that the town absolutely relies on biomedical research. Edinburgh, Glasgow and Dundee do world-class biomedical research and have world-class clinicians and premier league scientists. We have not seen it yet, but it will come that, if such drugs are not made available, we will lose our cutting edge and our status. That will be a tragedy. It has taken a long time to build up our status, and Scotland is rightly regarded as world class in research, especially in cancer research.

Dr Harrow: I am under the impression that the First Minister has written to ask a number of pharmaceutical companies to invest in biotechnology in Scotland. As I said at the NRS meeting a few weeks ago, the health minister said that Scotland should be at the forefront of the developing market; that is where the money is and we need to get into it.

We are not yet providing the backbone or the basic control arm against which all the new drugs could be trialled. That is now known across the border. I did a fellowship at Vancouver in Canada, and the Canadians know that we are not providing the basic drugs that other centres are deciding are their controls before they start looking at new technologies and drugs. We are going to lose out on being at the forefront.

The Convener: Earlier someone suggested that that is happening now, and you are saying that that will happen in the future. What are the timelines for that? Who are we going to lose out to? Is there consensus around the table on that?

Dr Crook: There is a very good trial on melanoma coming up next year. I will not go into the technicalities of it, but I will echo Dr Harrow's point. The control arm includes ipilimumab, the drug that Dr Casasola referred to. It is ludicrously expensive, but nonetheless a MEK kinase inhibitor study, which is the next generation of melanoma drugs, requires it as part of the control arm. If a hospital cannot provide ipilimumab, it cannot have the trial. That could deprive Scottish patients of the next generation of MEK kinase inhibitor, which is a third-generation targeted therapy melanoma. It is an awesome drug, but we will not be able to offer trials in it.

That is an example of what Dr Harrow just said.

Dr Petty: It was me who said that the process is happening now. My practice is in oesophageal and gastric cancer. The standard of care in many countries would be considered to be the addition of the drug Herceptin or trastuzumab to chemotherapy. That is not reimbursed in NHS Scotland, so there are trials that I have not been able to participate in or to offer to my patients.

To pick up on another point, we must realise that, once the research expertise is gone, it will be really hard to get back. It is like a self-fulfilling prophecy: trials will go ahead without us and their control arms will be the standard of care, so it will be difficult to go to the SMC because the evidence that a trial will provide will be based on a standard of care that is not the standard of care in Scotland.

How can we assess comparative cost effectiveness under that system? That is just one example—there are many others that we could talk about—of where the effects of falling back will simply perpetuate themselves as negative impacts on clinical research, life sciences, the country's economy and so on.

Professor Gourley: I treat ovarian cancer. Because the SMC recently turned down bevacizumab, which is given to first-line patients in most of the developed world, we will not be able to participate in the new trials that are arriving on my desk that have that drug as the standard arm.

In an NHS structure in which cost is important, it is also worth remembering that trials sometimes deliver cost savings because the companies that offer the new drugs will provide some of them. Because we cannot provide the control arm and because, as a result, we will lose our reputation for running clinical trials, we will lose the opportunity to save not only through the trials that are cost saving in themselves but through other trials, too—some trials can be expensive because the control arm contains the standard of care available elsewhere. In any case, the overall net loss will be loss of access to new drugs on which, historically, patients in clinical trials have done a lot better.

Dr Harrow: We will also get no net influx of experienced consultants who want to progress healthcare in Scottish hospitals. People just across the border and in London who already have access to these drugs know that that will not be the case if they come up to Scotland. If I were a young researcher and the situation were to continue, I would see myself moving to another site to gain more experience. For example, I have had no experience of using bevacizumab, even though it is the standard of care not only across the border but in Europe and abroad, and I have limited experience of using cetuximab, not to mention the other drugs out there that we have not even mentioned yet.

The Convener: Given that these things are pressing and are happening, what dialogue have you had with the Scottish Government on your serious concerns? Indeed, does everyone accept that there are concerns in this respect, or does anyone have a contrary view? If not and if there is a consensus over this real and pressing issue, what dialogue has there been with a Government that is, after all, not remote?

Dr Harrow: I do not know the answer to that, but I can say that this is the first time that I have been invited to such a discussion. As an oncologist working at the coalface, I find it refreshing to be able to put across my views and I thank the committee very much for the opportunity. Nevertheless, I suspect that, instead of those who are actually at the coalface, the same people are going to meetings to talk about the same things. The further up someone is, the fewer patients they see and the less involved they are with things at the coalface.

Dr Casasola: All the cancer centres in Scotland are at least one consultant clinical oncologist short of being quorate. When we recently interviewed candidates in both Edinburgh and Glasgow, we made no appointments in Edinburgh and appointed only one person for the two jobs that had been advertised. As things stand, we are struggling with recruiting numbers in Scotland. If this issue makes the situation worse, we are going to be in trouble.

The Convener: Are you saying that you cannot recruit because of this issue?

Dr Casasola: It is not just this issue—I think that there are a lot of other factors involved.

The Convener: But you cannot recruit anyone.

Dr Casasola: That is right. We cannot.

The Convener: Okay.

Drew Smith: As I was going to ask a number of questions about that issue, those comments have been useful.

I want to return to a principle that Dr Dunlop and Dr Harrow have already touched on. When you make a case for a particular drug, do the people to whom you are making the case understand what you are doing? Do we need a system that deals not only with generalities but with specialities? In other words, should we as a principle be moving towards a system in which oncologists make the case for oncology drugs to other oncologists? Is that possible, desirable or what?

11:00

Dr Dunlop: There must be an objective arbitration or review of how we use limited funds in the NHS in Scotland. If we just accept that the individuals with passion and enthusiasm for the new drugs and health technologies make the funding decisions on using them, we will face serious challenges. That is not to say that the right patients, with their diagnosis of cancer, should not have access at the right time. However, it means that the big decisions on funding for expensive drugs must be part of a discussion involving a wider and informed medical community.

Dr Harrow: I accept what Dr Dunlop has said. However, I submitted late evidence for patients with colorectal cancer to an appeal panel, which felt that it could not understand the complexity of the argument; it did not understand the mutation discussion that I was trying to have with it. The appeal was sent back to directorate level and there was a request for independent specialists to advise.

The CEL document and Greater Glasgow and Clyde NHS Board's individual patient treatment request processes are peppered with phrases such as "typically should include a specialist in the field". I do not know what "typically" means in that regard, because any IPTR process that I have been involved in has not included a specialist in colorectal cancer. It is possible to get round that requirement by referring to the fact that the document says only "typically should include".

In the case in question, we spent a lot of time dealing with complex issues, which I found difficult to digest, assimilate and present in a coherent fashion, and then we went to an appeal at which people did not understand the issues. It was very galling to have the appeal go back to the directorate level, despite there being expert documentation that the studies were robust and well conducted and that they supported the premise of my argument, and then have the appeal turned down.

The appeal panel were perhaps not experts in all the issues, but I had documentation from 10 specialists around the country who all agreed that the principles set out in the guidance that the panel endorsed were met—that those in the studies should do better than and be different from the population already studied. The specialists concurred with my argument, but that still carried no weight. I am at a loss as to how else I can navigate through the system.

Drew Smith: I suppose that I am asking whether we should spend our time on examining whether improvements can be made to the system. For example, it might be that at the strategic level it is stated that specialists should typically be involved but in practice specialists are not involved. That suggests that changes could be made to the system to make it fairer, or make the practice more like what we say it should be, but would that change anything in reality?

The bottom line is cost: regardless of who we get around the table, we will get the same answer in that regard. The explanation or rationale for certain cost decisions might be that the argument was not understood or no specialists were involved. However, it seems that it would not matter whether specialists are involved, because the driver of the agenda is keeping costs down. You are saying to us that politicians making decisions about the process need to take responsibility for the costs.

Dr Harrow: Absolutely.

Mark McDonald: I guess that the moment has passed, but I want to address the fact that one could get the impression from this discussion that the SMC does not approve any new medicines. I do not think that that is the case. What is the ratio of approval at SMC level? I want to get that on the record because, given the way in which the discussion has gone, one could be forgiven for assuming that the SMC is approving no new medicines.

Dr Dunlop: Professor Timoney, who has already given evidence to the committee, would be best placed to answer that question for you.

On a point of information, my understanding is that Professor Charles Swainson will shortly start a review of the IPTR process. I understand that there is an appreciation of the fact that the process is not perfect and it is subject to review to try to make it fit for purpose.

The Convener: That is correct. I think that I mentioned that review at the start of the committee meeting, and that is why it is opportune that we are able to feed in some of the experience on the ground.

Of course, there is a difference between the SMC approval process and the individual patient treatment request process. Although we have had some evidence about how successful the IPTR process can be, we have also heard this morning that the figures may undersell the problem, in that any process that screens out people is not an automatic process. Only a minority of those seeking access to new medicines are successful in getting treatment, so I think that the evidence that we have suggests that there is a deeper problem.

I will allow a final question from Richard Lyle before I will bring the session to a close.

Richard Lyle: I just want to clear up, for myself and for other committee members, what Dr Stephen Harrow said about not having access to certain drugs. How many people need to be physically involved in the research on taking a new drug in order for Scotland to remain at the top of the league for cancer research? I take it that the number involved does not need to be hundreds, but is it five, 10, 20 or 30? How many need to be involved?

Dr Harrow: Are you asking about what needs to happen for us to be perceived internationally and nationally as being able to offer patients the standard of care?

Richard Lyle: You said that you have not had access to two particular drugs—I cannot remember which two drugs you mentioned—and that that means that you cannot keep up your standard of care and your research. How many people would need to be involved in taking those drugs?

Dr Harrow: I think that I would have offered the majority of patients whom I treated the standard of care that is offered across the border in Newcastle and Carlisle. Adding in biological agents along with the standard of care is the best care that they can have. That covers a lot of patients.

Richard Lyle: How many, roughly?

Dr Harrow: I see 30 chemotherapy patients at a Wednesday afternoon clinic, so it might be half of them per week. That is my practice, but there are other consultants—

Richard Lyle: Is that roughly 750 people a year?

Dr Harrow: The patients are usually on a course of drugs, so there would not be a new person getting the drug every week. However, I have no experience of using the drugs, as I did not train with them. I had some experience when I did my fellowship in Canada, but what is the standard of care there is not the standard of care here. My fellowship was in 2008, so the problem is not new.

Dr Dunlop: Let me make a couple of points. First, you might leave here with the impression that these drugs are available in every strategic health authority south of the border, but that is not true. Some strategic health authorities have made the decision that drug X or drug Y is not on their list of drugs that is funded by the cancer drugs fund.

Secondly, the phrase "standard of care in the developed world" has been used a lot during this meeting. The standard of care in the developed world is partly driven by reimbursement. In many countries that do not have a public health system, reimbursement determines the standard of care. The committee has to appreciate that point.

Dr Harrow: I do not know what percentage of health boards south of the border offer what I would consider as the standard of care, but I do not think that, because they are not offering it, we should not be offering it in Scotland. If we think that something is the best treatment and we can afford it, we should aspire to offer it.

Dr Casasola: I want to return to the earlier point that we are looking at only one part of the equation. Most of us round the table would accept that we lack radiotherapy capacity in Scotland. To give the committee a measure between the two aspects, for the cost of treating 20 patients with ipilimumab I could buy a new linear accelerator. Therefore, 20 patients could get chemo or I could have a linear accelerator that could treat 40 patients a day for 10 years. We are focusing on drugs, but there is an opportunity cost if we fund more in the way of drugs. That cost could be our inability to optimise our capacity in radiotherapy.

The Convener: I think that most committee members get that wider point. Today, and in our inquiry, we are considering new medicines, but the committee is also considering the health service. We have just finished work on the health service budget, so we are pretty aware of some of the pressures and strains and the competition for finite resources.

Dr Petty: I want to pick up on several points that have been made and to return to the issue of value for money, particularly in wider health service provision.

I know that the committee has taken evidence from patients and patients groups and that it will take more evidence from them. It is important that we determine what patients with cancer believe is value for money. That is the key issue. Although it is difficult to speak to patients about the issues face to face, it is possible. It is not possible in all cases because of the complexities of some clinical situations, but we all speak to patients in our clinical practice every day. We should not underestimate the ability of cancer patients to appreciate value for money and to make trade-offs involving issues such as linear accelerators versus drugs. We need to ensure that, as part of the process, we get an idea of what that view is, or how to determine it.

The Convener: That is a nice cue, because our next panel will have a patient focus.

We have covered a lot of issues, but I say to the witnesses that if you feel that any areas have not been covered and you have not put important points on the record that you wish to put on record, I give you an opportunity to do so now. We also have your written evidence.

As no one has any further points, it simply remains for me to thank you all very much for your time and participation and for the evidence that you have provided in written form and orally.

11:13

Meeting suspended.

11:19

On resuming—

The Convener: We have been joined by our second panel of witnesses for this agenda item. As we did with the first panel, we will go round the table and introduce ourselves before we move on to the discussion.

David Torrance: I am the MSP for the Kirkcaldy constituency.

Eric Low (Myeloma UK): I am the chief executive of Myeloma UK.

Mark McDonald: I am an MSP for North East Scotland.

Karen McNee (James Whale Fund for Kidney Cancer): I work in communities development for the James Whale Fund Scotland.

Aileen McLeod: I am an MSP for South Scotland.

Gil Paterson: I am the MSP for Clydebank and Milngavie.

Kate Seymour (Macmillan Cancer Support): I am the external affairs manager for Macmillan Cancer Support.

Drew Smith: I am a member for Glasgow.

Alistair Haw (Prostate Cancer UK): I am from Prostate Cancer UK.

Nanette Milne: I am an MSP for North East Scotland.

Vicky Crichton (Cancer Research UK): I am public affairs manager for Cancer Research UK.

Richard Lyle: I am an MSP for Central Scotland.

Leigh Smith (Melanoma Action and Support Scotland): I am from Melanoma Action and Support Scotland.

The Convener: I am Duncan McNeil, MSP for Greenock and Inverclyde and convener of the Health and Sport Committee.

I welcome all the witnesses, who may have been present for the earlier evidence-taking session, which we opened by asking, on the basis of the Scottish Parliament information centre briefing, whether the current appraisal system—the SMC—is fit for purpose in general, for orphan medicines or for high-cost cancer medicines. We hope that the witnesses will be able to discuss that question among one another. We will give them precedence and will do our best to listen more than we talk, although I am not always successful at that.

Does anyone want to pick up the general question about whether the current system is fit for purpose?

Alistair Haw: I am happy to start off on that.

One of the most recent and high-profile cases with which Prostate Cancer UK has dealt is that of abiraterone. Much of our experience of the system is based on that.

Our general feeling about the SMC system is that it does not take sufficient interest in what patients feel about a drug. It really is not as open as the NICE system south of the border. It does not give individual patients the opportunity to feed into the process. It does not give people the opportunity to give direct evidence on behalf of a charity or patient interest group. In Scotland, we can merely give written evidence to the SMC and it is dealt with in a quite different and inadequate way.

If something is coming up at NICE that relates to us, we are contacted, informed about it and given advance warning. In Scotland, we have to check the SMC website and keep an eye out for it. In that sense, the SMC does not seem as open as the system south of the border. We would be keen to develop and improve on that.

There is a strong feeling of unfairness among patients. For abiraterone, that sense of injustice was added to by the fact that the drug was approved in England and Wales before it was approved in Scotland. Northern Ireland was next in line. Throughout the process, men in Scotland who were dying of incurable prostate cancer and were in considerable pain could see that the drug was widely available south of the border through the cancer drugs fund.

I and my charity would not argue for the cancer drugs fund to be implemented throughout the UK because we understand and accept that it is a short-term, England-only solution. However, one of the other problems that arose during the approval process for abiraterone was that when patients expressed disappointment about the inability to access the drug through the NHS although it was widely available in England—we have figures that show that, during that period, 97 per cent of the people who applied for it via the cancer drugs fund got access to it—Government ministers and politicians would often point to the individual patient treatment request as some sort of cancer drugs fund with a kilt. They would say that somebody could just apply for abiraterone and would be able to get it, but that is not how it worked at all.

That raised many false expectations. It led to individual patients going to their doctors and requesting abiraterone. We have anecdotal evidence of doctors saying to patients that they would go through the motions and apply for the drug but they would not get it.

The system in Scotland needs to be more accessible to patients. It needs to give the impression that it is listening to them and that it gives feedback on the information that charities and patient interest groups provide for the drug approval process.

Eric Low: We need to be cautious about what we have heard this morning, particularly about comparisons. We are not comparing apples with apples, as the NICE system is very different from the SMC system. I am not sure whether constantly comparing the two processes necessarily gives MSPs the right message.

We must concentrate on what the problem in Scotland is—can we define it exactly and the reasons for it? I do not know whether anybody knows NICE's budget and the number of staff that it employs compared with the SMC's budget and the number of staff that it employs, but the fight is not fair—the SMC employs 14 people. Given its workload and what it does, the SMC does a spectacular job. If we really want to help, we must

sit down with the SMC and understand the job that it wants to do but simply cannot do.

The committee is right to ask for all this patient input, but the SMC does not have the remit, the process or the budget to get anywhere close to the level of patient involvement that NICE has. Evidence is needed to show the difference that patient involvement makes. If NICE were asked for evidence about the point in the appraisal process at which patient input makes a difference, what would it say?

The Convener: Do you want us to shout out answers?

Eric Low: No. NICE would say that such input hardly ever makes a difference. Evidence from Canada, which has an evolved HTA process that is based on a combination of what the SMC and NICE do, is that the more patient involvement there is, the more likely a negative outcome is. The point is not that patients do not have an important role to play, but that we are talking about cost effectiveness; if a drug is not cost effective, what we as patient advocates can do to make a truly massive difference is limited, unless something is on the margin of the quality-adjusted life year.

The committee has talked about thresholds this morning. The threshold in Scotland is exactly the same as that in England—it is £30,000, not £40,000 or £50,000. Evidence has just been published in England about reducing, not increasing, the threshold. Patient input makes a massive difference only when we are on the threshold.

Making comparisons with Europe is difficult. We need to have not comparisons but a thorough interrogation of Scotland's position. What are the issues and barriers in Scotland that are causing our problems? The first issue is that the IPTR process is not fit for purpose. If we get nothing else out of this morning, we must can that. We must stop putting patients through that awful process, which is not, never has been and never will be fit for purpose. The problem is deciding what we do next.

We need to look at the SMC and think about the reasons why it says no. That has not come up this morning. The issue is not just cost effectiveness. When we have asked the SMC about that—other people around the table have been there—it has said that, often, it says no because the drug company's submission is not good enough and there is uncertainty about the data that has been presented.

If the inputs into the system are not great, what comes out of the system will not be great. We need to concentrate on the problem, which is that drug companies do not necessarily have the scope—and the SMC does not have the process—to do the early engagement that NICE can do in England.

We must look at the SMC. It does a fantastic job, but it needs more resources and a more flexible and pragmatic remit that allows it to engage with industry early, so that it can understand ahead of time the potential issues and have enough time to work on finding solutions. That would ensure that the evidence and data that the SMC has, on which it bases its very difficult decisions, are fit for purpose for Scotland. That is not the case currently.

I agree with the comments this morning about the need for a bit more transparency about decision making when appraisal decisions—decisions about what to say yes or no to—are being made, and we need to understand a bit more how the SMC applies its decision-modifying criteria. Possibly, we need to give the SMC a remit in discussing price a bit more directly with the industry. As we have heard, that is a big issue in England, where NICE is saying yes more often now because it has the ability to discuss price. It can do a commercial-in-confidence discount. All the drugs that are being approved in England come with a sizeable discount—that is why they are being approved—but the SMC does not have the remit to have the same type of discussions with the industry.

There should not be a knee-jerk reaction; we should be calm and work with the SMC and the industry to see how we can improve the system we have in order to deal with some of the issues that come out of the other end.

11:30

Alistair Haw: I would like to pick up on that, in case some of the points that I made at the outset have been misinterpreted. I was not making an attack on the staff of the SMC. I fully accept Eric Low's point that the people who work there work extremely hard and to the best of their ability, given the resources that they have, but I feel that some of what he said gave the impression that, because he felt that the patient voice did not have much of an impact, there was almost a case for asking why we should bother consulting the patient. I do not know that I would agree with that. As a result of the publication in *The Herald* of a letter from our chief executive, Owen Sharp, we had an exchange of letters with the SMC, in which it made it clear that there have been a number of cases in which the input of patients has led to a different decision being made. Therefore, I do not think that it is quite accurate to say that patient input does not make a difference.

However, at the same time, it is extremely important to point out that patients in Scotland who want to get abiraterone on the national health service—we are talking about men who are terminally ill and who, in many cases, are in extreme pain—can see that the use of abiraterone on the health service has been accepted elsewhere in the UK. Men in England have been able to access it for months, but patients in Scotland cannot do so. The fact that there was a high-profile example of an individual who was widely assumed to be on abiraterone who had his life extended made it extremely difficult for the men concerned.

As that was happening, those same men, who were very keen to have their voices heard and to make people in the SMC know how they felt about the issue and how much of an impact having abiraterone would have on their lives, were told that they could not even make any representations to the SMC. That situation must be addressed. Such patients can make representations to us or to other cancer charities, and we can feed that in, but I feel that it is completely untenable for individuals to have no voice at all, which is currently the case.

The Convener: Others are anxious to get in.

Vicky Crichton: The first thing that I want to say is that the SMC does an extremely important job in very difficult circumstances. We would probably all agree that that is the case.

What is important for a system that works is that it is evidence based, equitable and transparent. I think that the present SMC system is evidence based, although some improvements could certainly be made, which I will perhaps come back to.

There are some real challenges in respect of whether decision making at local level is equitable. I am talking about the post-SMC stage, when health boards implement SMC guidance, and the IPTR system.

There are real issues to do with transparency, as well. It is particularly important that the SMC can be more transparent about its decision-making processes. Transparency is also necessary at local level.

To pick up on the discussion about patient involvement, one of the SMC's massive strengths is the speed with which it undertakes its appraisals—they happen incredibly quickly. From a patient perspective, the fact that those decisions are made swiftly is very welcome. The process that NICE goes through in England is a much more deliberative process and involves much more input from patients and much more discussion with clinicians. Those things are incredibly welcome, but they come with a time burden. We might need to look at how we balance those two aspects, so that we can have more input from patients and patient groups and ensure that clinicians feel that they have been listened to sufficiently throughout the SMC process, while ensuring that we do not add significantly to the length of time that the SMC's decision-making processes take, because that would be a loss.

Kate Seymour: I reiterate what has been said about the IPTR process, which used to be called exceptional funding or exceptional prescribing. It is about exceptional cases and it is for individuals. We need to focus on where the SMC is not working at the moment. I agree that it does a very good job on the whole, but there are groups of patients—particularly patients at the end of their lives and patients with rarer cancers—for whom the system does not currently work.

I have great sympathy for the committee. When I started to work on the issue, trying to understand how things worked was like wading through treacle. I can only imagine what it must be like for patients. We need to focus down on where the system is not working so that we can consider how that can be fixed. Whether there can be a perfect system remains to be seen, but we can certainly do better for some groups of patients, particularly patients at the end of their lives and patients with rarer cancers.

The issue of transparency is hugely important. It is important that patients are able to understand what is happening to them and why decisions have been made, although that might not change the decisions. I think that that has an impact on the outcomes of decisions, particularly around the use of modifiers, which were mentioned this morning. In England, modifiers specifically relating to the end of life did not work perfectly either, but at least it was very clear that they were aimed at end-of-life patients. If the SMC and all the other bodies involved could be more transparent about how and why decisions are made, even if that did not necessarily change those decisions, that would change how the system works.

I agree that it is primarily about budgets. I know that we are talking about access to medicines but, earlier this week, there was stuff in the media about radiotherapy capacity and staffing issues. If we are talking about cancer treatment, we must consider the budget as a whole. Obviously, we would not want to be taking money from radiotherapy capacity or palliative care, for instance. The cancer service is expensive and very important, and we need to look at it as a whole.

We need to be careful that patient involvement remains equitable. There are good, strong charities and support groups for some groups—those with prostate cancer, for instance—but a

person with a particular cancer may be the only person in Scotland or in a very small group in the UK with it, and it is much more difficult for them to advocate on their own behalf. We need to consider the weakest point of any system that we are looking to put in place and how we can mitigate the issues.

Leigh Smith: I want to take up the points about the size of charities and their capacity to represent patients. We are a very small charity that represents patients with early disease and late disease. We mainly try to reassure patients with early disease and give them psychological support to live with going back to clinics regularly. We appreciate that things for those at the other end who attend oncology units are exceedingly tough. Over the period of almost 10 years in which our group has met, we have seen so many young people die that we have stopped having group meetings. We offer support on a one-to-one basis and have meetings in which speakers talk only about genetics, aromatherapy or things of that sort, because it simply became too trying for people to watch young folk around them going downhill and dying. We have had more than one case in which the patient has not come back to meetings in the early days because they had bad news and were told that there was not anything else for them.

First, I am not crawling, but I am so impressed with the *Official Report* of 18 September. I really think that our MSPs do an absolutely fantastic job in wading through this treacle and getting a handle on it. I am just so impressed.

Secondly, I think that the SMC is almost to be pitied. It is being pilloried—it is not the first time that I have cursed it—but it has an exceedingly difficult job and does its best. It has an alerts system and if we register with it, it will e-mail us when a drug in our area comes up. It does try to help us. It has also appointed a public involvement officer, Linda McGlynn, who has been a tremendous help, particularly to those of us who are learning our way. Linda might be able to help you on the informal feedback that we get.

We know that, where there is almost a 50:50 split in the committee, what the patients have said can swing the difference. Unfortunately, we have not been able to swing the difference. We have had two new drugs—the first since the 1970s—which have improved the chances of people surviving the most common cancer in 15 to 34-year-olds, which kills more people under the retirement age than over it. I am biased because I was one of the few people who responded to DTIC. I was treated in 1983 and I am still alive and well today. Nobody would have given a fiver for my survival for a year, never mind five years, but I know three of us who have come through it and come out the other end. Until patients get the chance to try a drug, we really do not know what the outcome will be.

Statistics give only guidance, and the individual patient is not a statistic. That is where the great heartbreak comes in. The SMC cannot look at a family and say, "This woman has an 18-month-old child"—as I had—"and elderly parents. We can expect her to bring up her child at no cost to the state, be back at work being a taxpayer"—which I was, on a good salary, until I was 62—"and look after her parents," which I did until they died. None of that is taken into the equation. I wonder whether we need to be very strong and say that until someone is 70, they can have the more expensive drugs but then, once they get to 70, they have had their threescore years and ten. I will be 70 at my next birthday, but I think that we must let young people have the money that we have.

The Convener: Thank you. You got a wee bit extra time for your nice comments. We are, however, under time restrictions and I want people to be able to get back in. Does anyone else want to respond to the general question? We have heard some positive points for the SMC about swift action and the benefits of patient access. From Mr Low, we heard some ideas—which lead us to the next question—about how the SMC could be improved in terms of raising the threshold, the flexible remit, the discount, the quality and the cost. I do not know whether we can go into some of that.

Do you want to come in at this point, Mark?

Mark McDonald: If you are opening up the discussion.

The Convener: I was opening it up for our panellists, but go on.

Mark McDonald: I have some questions that flow on from what has been said so far. I was interested in what Mr Low said about some of the reasons why medicines are rejected. I wonder whether there is an element of spin out there that focuses purely on the cost, whereas we are hearing that, sometimes, the technical clinical data that lies behind the submissions is the reason for rejection. We perhaps do not hear enough to that effect. Is that part of the transparency issue? Should the SMC look at how it can better report the reasons why it rejects medicines, so that people do not perceive that every rejection is on the basis of cost?

I am a big fan of Ben Goldacre's "Bad Science" column in *The Guardian*, in which he often talks about the difficulties in getting accurate reporting of, say, clinical trials and the clinical data that lies behind medicines. We often see reports of this or that wonder drug and, even though the data on which the claim is based might not be the most

robust, that perception of the drug has already been put in the minds of the public. Do we need to look at that issue with regard to the wider transparency agenda and examine how the SMC can better report its reasons for rejecting new medicines?

11:45

Vicky Crichton: Obviously industry can play an incredibly important role in ensuring that its submissions to the SMC are responsible with regard to the prices for which it is offering the drug in question and that its data and evidence are sufficient to allow the SMC to make a decision. I have become a bit of an expert in deciphering SMC decisions. Its language is not particularly accessible—indeed, it is incredibly opaque—but once you start to learn the code, you can see when it is saying, "This is simply too expensive" and when it is saying, "The data isn't strong enough". Nevertheless, it would be incredibly helpful if it could be clearer and more direct about why it is saying no. I think that the perception is that there can be only one reason, but that is not always the case.

Eric Low: The previous two speakers have made great points. Indeed, I point out that NICE has to deal with the same issue about uncertainty of data. In the previous evidence session, you discussed the complexity of the system, what with the American, European, NICE, SMC and IPTR processes, but the fact is that they all do different things. The European Medicines Agency and the Food and Drug Administration in the States, for example, focus on safety and efficacy and are not interested in price or value for money. It is just not their job. As a result, when drug companies carry out their global registration studies to bring a drug to market, they might have to make some commercial decisions about the trial design but the FDA and the EMA have a big say in what that study looks like. At that point, these things are miles away from Scotland and the SMC; these are global studies on safety and efficacy and are influenced—perfectly legitimately—by whatever the commercial agenda might be, the FDA and the EMA. When NICE and the SMC get the data, it does not fit neatly into their remit, which is to make good decisions on how we spend a finite budget in either Scotland or the UK. The question they are grappling with is the value of the drug to Scotland based on the evidence in front of them.

It is not just Ben Goldacre who is raising these questions. The ABPI, the Ethical Medicines Industry Group, the BioIndustry Association and everyone else understands that the data that we are asking NICE and the SMC to assess has huge limitations. As I said, if the inputs into the system are suboptimal, what we get at the other end might also be suboptimal. The big challenge for us all is to think about how we can come together and ensure that the evidence on which we are basing these very difficult decisions is of a higher standard and more relevant to the locality in which decisions about investment and how we spend our money are being made. We struggle with that in Scotland and the UK.

The Convener: But with the QALY, the SMC is clearly basing its judgment on cost.

Eric Low: Absolutely—and when you introduce uncertainty into the situation the QALY goes up. As a result, even for relatively cheap drugs, the QALY can be really high. As Vicky Crichton has made clear, it comes down to the relationship between the evidence and the costs of the drug and, in some of its judgments, the SMC has deemed there to be not enough evidence to spend that amount of money for that amount of benefit.

The Convener: But that does not apply here. The reason that the prostate cancer drug was not available here as opposed to Northern Ireland, the rest of the UK and the rest of Europe was cost.

Eric Low: Obviously, I am sympathetic to the abiraterone issue. As was said this morning, the majority of drugs get through but some fall foul of the system and we need to understand why and what we can do to fix it quickly.

As everyone know—it came up earlier this morning—price-setting is a UK-wide responsibility but making judgments about value is devolved. We sometimes get discrepancies in access when NICE has different criteria and a different remit under which to judge what it deems to be valuable in England than Ireland and Scotland have. Some of us patient groups think that it is bizarre to have three HTA systems in the UK that throw up different and often conflicting results.

The Convener: Our challenge is dealing with the Scottish Government's review. How can the system be made better? Is it worth a candle?

Vicky Crichton: I have some practical examples of things that could be done within the review. A few people have mentioned end-of-life modifiers or decision making. Most of the treatments that are available through the cancer drugs fund in England that are not available as standard on the NHS in Scotland are for patients who are at the end of their lives. They offer additional quantity and quality of life. The SMC modifiers do specifically say that if a treatment is for a patient who is at the end of their life, that is taken into account and there is more flexibility. It is not clear what scope those modifiers give and what additional give they allow. Someone mentioned earlier that NICE's end-of-life criteria are very clearly defined and say how much additional give the system has for certain

categories. If the SMC was to be advised that we believe that patients particularly value treatments at that stage in life and that it should allow a higher amount of flexibility, that would be a particularly helpful development.

The Convener: The committee is considering whether the system can be made better and how it can be made better.

Alistair Haw: I want to go back to Mark McDonald's point and agree that what he said is a very important aspect of the situation.

Some around the table have suggested that they have had feedback on their submissions from the SMC but from my experience of working on abiraterone twice and cabazitaxel, that was not the case for my organisation. However, if improvements have been made, I am pleased to hear it and I look forward to things changing for my organisation in the future.

It is important to be clear about what the decisions are based upon. As Vicky Crichton said, sometimes decisions are not as clear as they ought to be. If a bit more clarity was provided, particularly about the input from patient interest groups, such as Prostate Cancer UK, it would help people to know how to make their submissions better in future, and to be better advocates on behalf of patients. It might also mean that we could have a better understanding of the impact of the information that we provide to the SMC on behalf of patients, perhaps on the back of a survey that we have undertaken, and whether it could have had more of an impact, and so on. I feel that we are still in the dark about such things at present.

On the patient involvement point, others have pointed out that it can be difficult for patients to make direct representations, especially if they have a very rare cancer or other rare disease. The other side of the coin is that some small charities or patient interest groups do not have the capacity to respond in such cases either. If that is the case, there might be no input from the public at all, whether direct or indirect. The SMC has acknowledged that sometimes, even in cases in which it has sought direct advice from a patient interest group, it gets nothing. If individuals could respond to the SMC, it would get some direct feedback from patients even if it did not get it indirectly. That is an important point.

Leigh Smith: The SMC public involvement officer who helps small—and perhaps even large—charities to put in a submission has been a great benefit.

I worked in the NHS for the first half of my working life and the pharmaceutical industry for the second half, so my experience is not limited to being a patient. I cannot understand why the new drugs committee, which has about dozen people, and the full SMC, which has about 19 people, meet at regular intervals to assess medicines when we know that a big part of their remit is to ensure value for money. We have health economists—there are some on the SMC—and we must direct the drug companies first to the health economist, so that their submissions are scrutinised before they are put in. By doing that we would avoid spending money on meetings and people's time unless the submission had a chance of succeeding. That scrutiny could be done one-to-one with the health economist, who would help the company to make the best argument and to understand the QALYs and what the limitations are. There would be a cost saving there and it would perhaps mean that things got done a lot faster. I appreciate that the SMC works quickly, but if the drug companies were made to pay for guidance through, for example, Andrew Walker at Glasgow University, we would get much better submissions and we might get more access to drugs.

Kate Seymour: As Eric Low said earlier, we need to build more negotiation into the system so that the process is not a drug company putting in a submission, the SMC saying no, and then the company resubmitting an application if it has more evidence. There is not enough negotiation and flexibility in how the system works. The process can be prolonged, and drug companies can be put off resubmitting applications. If we increase the communication between the SMC and the drug companies and involve patients and other groups, that should improve outcomes because we should be able to look at what the blockage is. There may be some drugs that are just too expensive. We have a finite budget. It is for people here to look at the health budget and the amount of money that we want to put into cancer services. We must look at whether we can do better within the budget that we have. Part of that must come through discussions between the different parties at an early stage.

The Convener: It comes back to the resources that were mentioned earlier. If we do all that you describe, do we sacrifice what Vicky Crichton identified as good about the SMC process: it is swift when it works? We heard that 14 people work for the SMC and we are looking for engagement and for meetings before applications go in. Is it reasonable to ask for all that?

Kate Seymour: We have also talked about where we think that there may be too many layers. Have we got our resources right? We do not want to talk about just the SMC; let us look at the whole system. Parts of the system could be refocused to provide better outcomes.

Eric Low: Those are key points. If you think about the cost of two new high-cost cancer drugs compared with the cost of adding two or three staff to the SMC, the return of investment would be phenomenal. If we fixed the individual patient treatment request and took investment out of that area and reapplied it to the SMC, that would be money well spent.

A point was made about end of life, which is obviously a key area. NICE did not introduce end-of-life criteria because patients who had cancer would value an end-of-life intervention—of course, most of them would—it felt that that was what society wanted it to do. An important part of how MSPs organise the health budget is society's preference for how money is spent. NICE felt that society was saying that it valued end of life, so NICE made some allowances with the end-of-life criteria.

12:00

An interesting point is that the threshold for end-of-life interventions—the patient must live for at least two years and benefit from the drug over at least three months—is completely arbitrary and is not based on any empirical evidence whatsoever. When the SMC looked at that, it asked whether that is really what we want to do, given that we do not have strong evidence for what society's preference is or for what the threshold for end-of-life interventions should be. The SMC deemed that its QALY decision modifiers accounted for end-of-life situations, but we do not really know, because we do not really understand what they do. However, a whole body of evidence on societal preferences for health investment is now being produced. It would be worth getting access to that evidence, because it is very enlightening about what society values in terms of quality of life and length of life at the end of life.

Vicky Crichton: I will pick up on some of the issues with local decision making that were raised in the earlier session. We have talked a little about issues with SMC decisions, but we also have a concern that decisions on whether drugs are included in local formularies are not very transparent. We do not know whether there is variation in access to treatments across Scotland because it is not possible to read that from the information available. This may or may not be the case, but certainly the perception is that when the SMC makes a decision it is not always clear whether those drugs are available. The Scottish Government guidance says that local health boards should then make the drug or its equivalent available. It should be the case that, if a health board says that it will make an equivalent available, it should specify that.

Secondly, there has been a lot of discussion on whether we should have IPTRs. IPTRs do a very specific job for a very small number of patients and for those individual patients they will be very important, but they are not an answer to population access to treatments. If we are going to have IPTRs, the comments made by the clinicians this morning suggest that the guidelines on their use need to be clear and transparent. Clinicians need to know what information and evidence they need to present to make a case that a particular patient should have access to a drug and they need to know what parameters will be used to judge that. Clearly, that is not the case at the moment, and that does not suggest a system that is equitable. By definition, those are individual decisions. The outcome might not be the same—a patient in one area might get the drug and a patient elsewhere might not because those patients are clinically different, and that is fine—but the decision making and the process that has been gone through must be equitable.

Alistair Haw: I will pick up on the point that Vicky Crichton made. After abiraterone was approved by the SMC, we took the opportunity to write to each health board in Scotland to ask if and when the drug would be available. There was wide variation in the responses: some health boards said, "It is available as of now"; other boards said that they were waiting for their local meeting to take place to decide whether to make it available; and other boards did not respond.

I keep coming back to the example of abiraterone because that is a recent experience. Abiraterone is for men who do not have time to waste; they do not have lots of time on their hands. The drug has already been put through a process that has made it available elsewhere in the UK. People have said that the SMC system is quicker—the evidence seems to suggest that that is generally the case—but abiraterone is a clear example where the SMC process took longer despite having very limited patient involvement.

After the drug was put through that entire process and was finally approved, people thought, "Great, I can now get access to abiraterone," but that was not necessarily so. Some boards were very quick, whereas others thought, "It is very good that the SMC has said that, but we will need to decide what we think." To use a cliché, there appears to have been a postcode lottery in the follow-up to the decision to approve the drug. There is a general perception that a drug that has been approved by the SMC will be available very swiftly to people who require it, but in our experience that is not always the case.

Richard Lyle: Mr Low commented on NICE. Per head of population, what is its budget? How

many staff does NICE have, compared to the SMC?

Eric Low: The budget has been reduced, but I think that it is something like £80 million and that there are 300 or 400 staff.

Richard Lyle: That is 300 or 400 staff, compared to 14 for the SMC.

Eric Low: Yes.

Richard Lyle: You said that the IPTR system is not fit for purpose and should be done away with. What would you put in its place?

Eric Low: IPTRs should stay for the purpose for which they were invented, but they should not be used to arbitrate on drugs that fall foul of the SMC. It is not exactly clear what should be put in place. The issue that we have discussed is that we need to improve the SMC process to get more approvals. We cannot start by providing a solution to a problem that we are not sure exists. We need to look at the SMC process and get early engagement, as Kate Seymour rightly said. We need to consider how to modify the SMC process in applying decision-making modifiers and allow it to negotiate more with the industry on price. We can then see what happens. Even we, as strong patient advocates, need to accept that, inevitably, there will be a cohort of drugs that are deemed to be just too expensive and not worth the money.

Part of the issue is that there is often a discrepancy between the data that the SMC uses to make its decisions and what doctors want to do in clinical practice. The data is based on a phase 3 randomised study, which was probably designed 10 years ago, of a self-selected group of patients who have matched some entry criteria. I have sympathy with some of what the doctors said earlier. They are highly skilled doctors who need to make good clinical decisions about the patient who is sitting in front of them. Patients are not all the same, and their cancer is not all the same. Even with prostate cancer and melanoma, there is a lot of heterogeneity.

We must give doctors a bit of informed decision-making capability so that they can make good clinical decisions for their patients. We do not do that in either England or Scotland, because of the strictness and robustness of the guidance from NICE and the SMC. We know that there are huge limitations in that process, so perhaps part of the solution is to create an infrastructure that allows us to give doctors a proportion of the ability to make decisions to invest wisely on behalf of their patients, alongside SMC guidance.

Richard Lyle: By my counting, Dr Stephen Harrow sees on average 750 patients a year, but he said that he submitted only two IPTRs in a year. Should doctors be allowed to submit a certain number or a certain percentage of IPTRs? Dr Harrow said that he submitted only two requests out of 750 people. Should those requests not have been granted?

Eric Low: Ultimately, there might have to be a number, because we have to budget for the decisions, but we can predict how many decisions might be made in any budget year. We need to give doctors flexibility in making investment decisions, but that needs to be done within a framework. As David Dunlop said, we cannot advocate that the really enthusiastic doctors should make all the funding decisions. Therefore, there needs to be a framework within which we empower doctors to an extent to make good clinical decisions alongside or in addition to SMC guidance.

Kate Seymour: The IPTR system is not the answer to the issue. It does what it is supposed to do, which is to deal with individuals who are different from the rest of the patient population. However, we have an issue with groups of patients—sometimes very small groups and sometimes bigger ones—whose drugs have been turned down by the SMC. The IPTR is not the appropriate process for that. We need a process in the SMC that deals with that issue.

IPTRs are for individuals. Perhaps we need something that looks at specific groups. Also, what Dr Harrow said about having specialists as part of the decision-making process is extremely important. It is a great concern that people are being asked to make decisions when they do not understand the intricacies of the progression of a disease or what a medicine might do.

The Convener: Should there be wider criteria for the SMC? In its evidence to us, it conceded that it looks at a particular budget and the decisions that it makes at that point can impact on other budgets, such as those for community care. It seemed from that evidence that the SMC could have broader criteria.

We heard this morning that, in relation to cancer services, there is a general problem with recruitment. That must concern you. There is a wider issue about the health economy and how we can maintain a leading edge in Scotland. Access to medicines and new drugs does not benefit only the patients, however many of them there are. It also benefits the wider health of the services that we provide, the skills that we have as a country and our ability to maintain a leading edge.

Eric Low: Again, I urge the committee to have some caution around the notion that inward investment is linked to SMC decisions. NICE gets the same story. We have done a lot of work with MPs down south, the Department for Business, Innovation and Skills and the trade and industry

associations, and the extent to which the pricing of a drug in a country relates to inward investment is a controversial area.

There are two types of research. One is the science that is done in laboratories, universities and academic institutions and the other is the clinical development, which is the clinical trials. Those are two very different levels of investment.

The Convener: Mr Low, you were here during our first round-table session this morning. It included David Dunlop, who is clinical lead for the Scottish cancer research network west and is involved in the SMC, and Dr Russell Petty, who is a clinical senior lecturer. I could go on, as we had eight senior cancer consultants here. You have just contradicted them, in that none of them, when asked, said that they disagreed with the remarks that have been made round the table that this is having an impact. Why should the committee accept what you are saying in your evidence today?

Eric Low: I have huge respect for those doctors, but I have met as many doctors who disagree. I think that there is some self-interest there because they are doing the studies.

If we look at all the reasons that the Government has to get inward investment, a decision by the SMC is only one of them. There are a huge number of other factors that the drug companies consider when they make decisions on investment in research and development. I do not disagree that the SMC has an impact, but we need to be proportionate and balanced; we should not get too carried away.

The Convener: I accept your clarification. I was just admiring your bravery in going against the view of all those people, given that they are clinicians and some of them, such as Dr Dunlop, are involved in the SMC.

Drew Smith: I think that most of the witnesses were here for the earlier session. A different view is coming through in the current session about what the issues are.

I hear what people are saying about whether we have the technical data, how the SMC is taking decisions and how we can improve that. I suppose that I want to go back to the basics of the issue. Mr Low said that the objective is to make those improvements so that more drugs can be approved, but is that our objective? If it is, why is it? Do we have a situation in Scotland in which not enough drugs are getting through the system and we have a problem that we need to deal with, or is that not the case?

Eric Low: That is a very good point. As David Dunlop said, we are not trying to advocate a yes to every drug; rather it is an issue of value and cost. If we can get a better relationship in the system between the perceived value of the drug and the cost that we want to pay, we might get more yeses—as we do in England. The issue is that the price of the drug and the magnitude of the benefit are not deemed to be equitable. If we could have some discussion of cost as proportionate to potential benefit, we might get more yeses.

12:15

Vicky Crichton: Some drugs that have been turned down by the SMC show some clinical benefit—most of those drugs will be in the end-of-life category—which we know to be incredibly valuable to patients, but they are not being made available, because of high cost or problems with data. We would very much like to see some of those drugs being made available. We need to look at what is stopping SMC from saying yes and see whether we can improve the system. As Eric Low said, it is not about everything being available; it is about the possibility of the SMC making available the treatments that add additional benefit—a number of which have come in over recent years.

Leigh Smith: There has been a lot of discussion about budgets and the rest of it. I wonder whether health boards count up the value of drugs that are given freely for the treatment of patients on trials. Trials are important, as they are used not just to expand knowledge but to treat patients. The drugs are given for free by drug companies and often the comparator drugs, too, are given for free. In itself, not having access to trials will put up the cost for a health board, and I wonder whether that is ever taken into account.

Where investment is made into equipment, staff and the rest of it, drug companies pay for patient investigations, so more value is gained from the investment that has been made. That is something else that I do not think is taken into account.

I feel for the doctors who daily have to turn down otherwise fit patients with a cancer.

Kate Seymour: We have quite a passive system. Perhaps we need to build into the system a more proactive approach to—as I think someone said this morning—looking at how to get a drug approved and whether the issues are to do with data or cost. That might just come about because of the SMC's lack of capacity. We can work more proactively on how we solve some of the issues with particular drugs.

This is a big problem, but it is focused on particular areas, medicines and patient groups. We should focus proactively on where problems are coming up and identify them before decisions are made, because it is quite clear which drugs will struggle to get approval. We should take all

the action that we can to try to solve a problem before it gets to an SMC decision, rather than passively waiting for a decision and then a resubmission. That could help us to at least say to patients that we have taken every possible action to get their drug approved within a finite budget.

Eric Low: That is an important point. I will give an example of what our organisation has done. We have sat down with drug companies, the SMC, NICE and the NHS and said, "Okay, we know the pipeline for myeloma"—that is clear very early on, because the clinical trial protocols were done five years ago. We have engaged with those companies and organisations and looked at the protocol and picked it apart at a very early stage. We predicted which areas would be problematic for NICE and the SMC when they make decisions, because the research is not based on a Scottish or UK comparator.

We have built a clinical trial network of eight institutions across the United Kingdom to set up an academic study that runs alongside the global commercial study and delivers UK and Scotland-centric data, which we put on the table before the SMC and NICE to plug the evidence gaps that lead to the uncertainty around the value of a drug.

One of the issues that we have is that we were unable to hook in a Scottish centre to the clinical trial network. That goes back to some of the issues that were raised this morning. We do not have the clinicians in place to enable us to commit the time that is necessary if we are to monitor clinical trials. We need to think about how we can incentivise a talent pool in Scotland. We heard this morning that there are issues around recruitment. We have tried to help to recruit doctors to positions in Scotland, but it is difficult to attract the talent, because of the research structure. Another issue, according to the feedback that I have received, is the merit award—doctors from Scotland who went to England to further their career cannot afford to come back because the salaries in Scotland are not competitive. I do not know the ins and outs of the matter, but there seem to be issues with attracting top doctors to Scotland.

Gil Paterson: Does anyone have any insight into how value-based pricing might affect Scotland?

Vicky Crichton: I am not sure whether my view entirely qualifies as insight. What you heard this morning is probably the case for all of us as well. In principle, value-based pricing is incredibly welcome. It brings into the discussions some other things to do with value that are important to patients, so it seems like a good proposal.

At the moment, there are two challenges. In general, at a UK level, there is not a lot of information about what value-based pricing will look like in practice. Given that we are talking about something that is to come in in 2014, that is starting to become quite concerning. We want that information to come forward and we want there to be engagement with patients and patient groups about what they value, so that that can be taken into account. It is incredibly important that that happens fairly swiftly.

The second challenge concerns the specifics of how value-based pricing will operate in Scotland. Because medicine pricing is reserved but decisions about availability on the NHS are devolved, we have a two-stage process in which the decision about the price is made at the UK level and then the SMC process kicks in. The suggestion seems to be that, under the value-based pricing system, those two processes will happen concurrently. Obviously, that leads to questions about the role that the SMC would have, if any, after VBP, and what discussions would take place in Scotland about access. It is incredibly important that the Scottish Government is engaging with colleagues in the UK Department of Health and is feeding in comments about how the system needs to operate so that it makes sense for the Scottish system. If the decision is made and the system does not work, it will be difficult to change it at that point. There has to be strong engagement in that regard.

The Convener: I think that the Scottish Government and the Cabinet Secretary for Health and Wellbeing have corresponded several times on the issue and officials are working closely on it. They are completely engaged with and involved in the process, and they are aware of what is going on. You can be assured that they are participating fully in the process.

Gil Paterson: I want to return to the issue that I raised earlier about how we as laypersons can make our decisions with regard to the overall budget. This inquiry is specifically about the purchase of drugs, but what are your views on preventative spend and the prospect of our recommendations cutting the feet from under other spending? Like our previous witnesses, everyone around the table is involved with cancer patients, but the point is that whatever we decide might result in money being taken away from things that happen at the early stages. What is your view on that? I realise, of course, that I am asking you for the wisdom of Solomon.

Eric Low: That is the issue that we are all grappling with: there is a finite amount of money and if you spend it in one place, you cannot spend it in another. Everyone will argue their own case for spending it on prevention, imaging, drugs or whatever, but I am not sure that we have enough

empirical evidence about what society feels we should be spending the money on.

Optimally, we want a health system that gives everyone the best possible treatment and care as discussed between the doctor and the patient, whatever that intervention might be and at a cost that is fair. However, if we are talking about a finite budget, we will also have to talk about disinvestment. As in England, we in Scotland do a lot of things that are not efficient and we need to disinvest strategically in certain areas and reinvest the money in the system in critical areas. All Governments are going to have to grapple with the question of how we strategically and fairly disinvest to create more money—under the curve, as it were—for investing in really critical areas that might be defined through some future multi-stakeholder process.

Vicky Crichton: Picking up on Kate Seymour's earlier comments, I think that the discussion about access to medicines has been incredibly high-profile and emotive—and understandably so, given that the process is horrendous and difficult for the patients and families involved. However, it is important to point out that, as far as the treatment of cancer is concerned, there have been incredible advances in surgery and there are incredible new radiotherapy techniques that, although incredibly expensive, are very effective and indeed cost effective. Those points should not be lost in the wider debate, but the fact is that they do not tend to appear in the media. After all, you do not hear people talking about getting a new form of radiotherapy in the same way that they talk about getting individual drugs, not to mention all the talk about the importance of early diagnosis or spending on preventative activities. Although this is a difficult and important debate, it should not be seen as wanting to take funding away from elsewhere in the system. Those things, too, are vital.

The Convener: In its submission, the ABPI mentions prescription charges and says that

"loss of exclusivity"—

mainstreaming, if you like—

"will

- Save NHSScotland an estimated £316m"

Have there been any discussions with the cancer charities about how such savings might be invested?

Eric Low: We speak to the ABPI all the time about finding solutions and think that it is important for everyone to be as collaborative as they can be and to get what they need out of the system.

It is very difficult for us to interpret some of the figures that are being bandied about and to know what they actually mean. One of the questions that have come up in the past when savings have been made is what happens to the savings. The NHS in Scotland has budget silos so, if I have a new diagnostic test that costs £50 versus the old one that costs £1, but I am the laboratory guy, I am not going to spend the money because I will not get the benefit. Even if it means that I could save three people from going to dialysis at a cost of £300,000, I will not get the benefit of that saving. There is therefore work to be done to identify where savings can be made and how best to reinvest them in the NHS to get maximum benefit for patients and the taxpayer. A job of work needs to be done on how we allocate and use the savings that can be made and how we can make budgets work together rather than independently so that such savings can be realised.

12:30

The Convener: The ABPI says that the NHS is going to make a £316 million saving on the prescribing budget. Perhaps where such savings go is a bigger question for the committee.

Leigh Smith: The question was about prevention and how to balance budgets. Of all the cancers, the most common by far in Scotland is skin cancer, whether it is basal cell or squamous cell cancer, and it all has to be treated. Basal cell and squamous cell cancers kill people less often, but it still costs money to treat them and at least 80 per cent of melanoma and non-melanoma cancer cases are caused by overexposure to the sun. We have children under our control right through from nursery age until they are in their 20s but nothing requires individual schools or education authorities to provide any sort of protection for children in the spring and summer months when they are in school. I am sad to say that children get sunburned on their school sports days.

CRUK brought out a lovely wee simple slogan a few years ago. One instance of severe sunburn in alternate years triples rates of skin cancer. We have it within our power to prevent so much skin cancer with so little spend; it must be worth it.

The Convener: Mark McDonald, did you have a point?

Mark McDonald: I will save you a bit of time, convener. Gil Paterson's question essentially wrapped up most of what I was going to ask so you can skip me.

The Convener: Thank you. Nanette Milne—I am sorry; I almost missed you.

Nanette Milne: I have a comment rather than a question. Mr Low's points about disinvestment and silo budgeting are very important, although they

might go beyond this inquiry. The health service is going to have to consider such issues. That point came out in our evidence session with the SMC when it said that other procedures and processes within the NHS are not scrutinised to the same degree as the availability of drugs. That should be flagged up as something for us to look at in future.

My other point is about the IPTR. I was a member of the Public Petitions Committee that discussed cetuximab and the difficulties that the exceptional prescribing procedure caused patients. It was on the back of that that the IPTR system was devised, to make life easier for these exceptional patients who were trying to get access to treatment. Clearly the system has not worked in the way in which it was intended and the public and health boards need a lot more clarity about exactly what the IPTR system means, to make sure that it is applied uniformly across the country if it continues to be applied. What we have heard today has flagged that up significantly.

The Convener: Does anyone wish to respond to that?

Alistair Haw: On IPTRs, evidence has been given orally and in written submissions about the way in which they have been misrepresented. That must stop happening, because it gives people false hope.

On the lack of clarity, there is also an issue with the fact that no statistics are currently compiled about the number of IPTRs that are submitted, the response rates and the number of patients who ask for an IPTR but are told that they are not going to get one because their doctor feels that it would be a waste of time and that the system is not appropriate for that patient. If steps were made to start to collate those statistics throughout the country, we would be able to build up a bigger picture. That is an important point, given the context of the way in which the IPTR has been built up as a solution for people who need drugs that have either not yet been assessed or been rejected by the SMC. I want to put that point on the record.

The Convener: Obviously, we have tried to cover a number of areas and we also have your written evidence, but if there is a pressing issue that has not been covered that you want to place on the record, please mention it now.

Vicky Crichton: Let me say something quickly about the review that has recently been announced. For obvious reasons, it is very welcome that we are continuing to grapple with the issue, and the pieces of work that will be undertaken will be incredibly useful in that regard. However, we have not yet seen—the committee may have this information or may wish to ask for it—further information about the broader scope of the review, its timescales and the stakeholder input. It is good to hear that the evidence that the committee has taken will be fed into the review, as it is important that stakeholder input is taken on board. As part of the review, we need to work towards a long-term sustainable solution that is evidence based, equitable and transparent, because tinkering around the edges is not going to help.

The Convener: Yes, that point is well made. As I mentioned earlier to committee members, we are pursuing the remit of the inquiry through the minister and his officials and we will speak further with the people who are setting its agenda. We have had verbal assurances that we will still have time to complete our inquiry and feed it into the process. We hope that our inquiry will at the very least be read with interest and inform their discussions.

Alistair Haw: Let me make a couple of final points. On value-based pricing, I want to put on record the fact that Prostate Cancer UK has recently published "Value-based pricing: Getting it right for people with cancer", which has been produced jointly with a number of other cancer charities, including those around the table today. I would be happy to pass that on to the committee if that would be of assistance. I could not possibly summarise the whole document here and now, but I can reassure the committee that it is not just in Scotland that we complain that the patient interest is sidelined. A key point is that the debate that is currently going on in Westminster about value-based pricing seems to be between the Government and the pharmaceutical industry, with the patients having been shut out. That is one point to take away from the document, which I would be happy to share with the committee.

Also, I referred earlier to the letters that we sent to health boards after the SMC approved abiraterone. I would be happy to share those with the committee if that would be beneficial.

Finally, although I hope that I have made plain how people felt about the experience with abiraterone, I feel that the context of that is incredibly important. Not only is prostate cancer the most common cancer in men and almost as common as breast cancer is in women, but by 2030 it will be the most common cancer overall. Despite that, in addition to that experience with abiraterone, the Scottish Government's detect cancer early programme, which was published in the last year or so, made no reference to prostate cancer and the quality performance indicators that were published for prostate cancer were pretty patchy, sporadic and incomplete, which did not seem to take much account of the evidence that we submitted. That is the context of all the

comments that we have made in our written and oral submissions.

The Convener: Thank you for that. We look forward to receiving those further submissions. The last word will go to Leigh Smith, as she was so nice earlier.

Leigh Smith: I must remember that for the future.

Regarding the Scottish intercollegiate guidelines network, we hope for a review of the SIGN guideline 72 on melanoma. I just cannot imagine that the SIGN committee will not decide that the new drugs have a place in preference to DTIC, or at least second after DTIC. I just wonder where that will place us. If SIGN says that that should be the standard of treatment and the drugs have not been approved by the SMC, I honestly do not know where that puts us.

The Convener: You have placed that on the record and it will be part of our considerations.

I thank you all for your attendance and participation and for helping the committee with your evidence.

12:40

Meeting continued in private until 12:59.

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