PUBLIC PETITIONS COMMITTEE

Tuesday 29 April 2008

Session 3

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PUBLIC PETITIONS COMMITTEE
7th Meeting 2008, Session 3

CONVENER

*Mr Frank McAveety (Glasgow Shettleston) (Lab)

DEPUTY CONVENER

*John Farquhar Munro (Ross, Skye and Inverness West) (LD)

COMMITTEE MEMBERS

*Bashir Ahmad (Glasgow) (SNP)
*Claire Baker (Mid Scotland and Fife) (Lab)
*Angela Constance (Livingston) (SNP)
*Nigel Don (North East Scotland) (SNP)
*Rhoda Grant (Highlands and Islands) (Lab)
*Robin Harper (Lothians) (Green)
*Nanette Milne (North East Scotland) (Con)

COMMITTEE SUBSTITUTES

Jim Hume (South of Scotland) (LD)
Marilyn Livingstone (Kirkcaldy) (Lab)
John Scott (Ayr) (Con)
John Wilson (Central Scotland) (SNP)

*attended

THE FOLLOWING GAVE EVIDENCE:

Scott Bryson (NHS Greater Glasgow and Clyde)
Dr Roelf Dijkhuizen (NHS Grampian)
Andrew Dillon (National Institute for Health and Clinical Excellence)
Dr Frances Elliot (NHS Fife)
Professor Peter Johnson (Cancer Research UK)
Dr Harpreet Kohli (NHS Quality Improvement Scotland)
Ewan Morrison (South East Scotland Cancer Network)
Dr Marianne Nicholson (NHS Grampian)
Dr Ken Paterson (Scottish Medicines Consortium)
Professor Alan Rodger (NHS Greater Glasgow and Clyde)
Dr Jean Turner (Scotland Patients Association)
Dr Andrew Walker (Scottish Medicines Consortium)

CLERK TO THE COMMITTEE

Fergus Cochrane

ASSISTANT CLERKS

Franck David
Zoé Tough

LOCATION

Committee Room 2

Scottish Parliament

Public Petitions Committee

Tuesday 29 April 2008

[THE CONVENER *opened the meeting at 14:09*]

Cancer Treatment Drugs Inquiry

The Convener (Mr Frank McAveety): I thank members of the public and the witnesses giving evidence to this important inquiry for their patience and welcome everyone to the seventh meeting this year of the Public Petitions Committee.

Most of this afternoon's meeting will be taken up with our inquiry into the issues raised in PE1108, which is from Tina McGeever and her husband Michael Gray. The inquiry is taking place at a particularly poignant time, given the very distressing news that Michael passed away two or three weeks ago. There have been some fantastic eulogies not only from friends but from those who worked with him in his different roles, and I put on record the Public Petitions Committee's appreciation of the exceptionally brave contribution made by Michael and his family. I know that he was very proud that the Parliament had decided to investigate the issues that he raised in his petition.

Perhaps in future people might not have to deal with some of the incredibly difficult financial and emotional issues that Michael Gray and his family had to face as a result of his serious illness. The cynical view of politicians is that they have no emotions. However, as we made clear when we previously discussed the petition, the committee was deeply moved by and very much concerned about the experience of Michael and his family.

We now need to examine the detail behind the issues raised in the petition to assist our consideration of the matter. As a result, we will take evidence from a number of witnesses, whom I welcome to the meeting. In particular, I welcome back a face that will be familiar to many around the table—certainly to those of us who are getting older and wiser. Jean Turner has served as an MSP and is now working on behalf of the Scotland Patients Association. She is joined by Professor Peter Johnson, chief clinician of Cancer Research UK, who has provided us with very good background material.

I realise that this experience can be quite nerve-wracking for witnesses, although it might be different for Jean Turner, who has, after all, been on our side of the table. Perhaps she will have a little bit more sympathy for those sitting on her side of the table this afternoon. Do you wish to make some opening remarks, or would you prefer to go straight to members' questions?

Dr Jean Turner (Scotland Patients Association): I think that we would both like to make a few opening remarks.

The committee has been very sympathetic in its approach to the petition, and I think that Mike Gray very much appreciated that. Mike asked me to become involved when his clinician applied for cetuximab under exceptional clinical circumstances. I had no problem with agreeing to his request, because I felt that the clinician should be supported. As a result, I got in touch with the Scottish Executive and was guided to a Health Department letter entitled "Patients Receiving Concurrent Treatment from NHS and Private Providers", which states:

> "This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer."

Most patients think that in such circumstances they can depend on their clinician. However, if the clinician wants to prescribe a drug that the health board does not want to pay for, the clinician simply has to back down and the patient has to pay for it privately.

14:15

Professor Peter Johnson (Cancer Research UK): It might be helpful if I give a little bit of background about Cancer Research UK's view of and role in all of this. First of all, however, I offer my condolences to Mr Gray's family and friends, for whom we feel very keenly.

Cancer Research UK is supported, through donations, by around 10 per cent of the United Kingdom population. It is the largest independent funder of cancer research in the world. We spend about £300 million a year in the UK, of which around £31 million is spent in Scotland. Our remit is primarily to undertake research and we support a large amount of basic research. The Beatson Institute for Cancer Research in Glasgow is one of our flagship core-funded institutions.

We also spend a lot of time on clinical trials, to bring direct benefit to patients. Around 16,000 patients per year take part in trials funded by Cancer Research UK. In addition, we try to provide an authoritative information service for cancer patients and we work on policy, to try to inform processes such as this about the best evidence and the approaches that are likely in future. We have a strong background in such issues.

We are very much aware that the outpouring of knowledge in recent years has led to a

progressive increase in the number of drugs coming through for the treatment of cancer. We are aware that the high cost of developing such drugs produces an ever-increasing burden on health services. Around £730 million per year is spent on cancer drugs in the UK.

In general, we are strongly behind the review processes that have been put in place in Scotland and more widely in the UK, which have served patients' interests well and dispassionately. The Scottish medicines consortium has done an exemplary job in producing authoritative and rapid reviews of the evidence base for new drugs. To some extent the SMC is the envy of clinicians who work in England, where until recently the processes were rather slower and less well informed by clinical input. As a general rule, we have regarded Scotland as a model of good practice in that respect.

There are concerns about the heterogeneity of implementation of the SMC's judgments and appraisals. If we consider Scotland as a whole it is apparent that spend on novel cancer drugs varies substantially from area to area. That might need to be thought about.

The Convener: I thank the witnesses for their helpful introductions.

Nanette Milne (North East Scotland) (Con): Professor Johnson, you said that in general the appraisal system is effective. That has probably come through in most of the written evidence that we received in response to our questions about the relative roles of bodies who are involved in the system. Can the appraisal process and relationships between bodies be improved?

Professor Johnson: The appraisal process is probably as good as it can be if it is to serve the different constituencies and ensure that appraisals are objective and authoritative. As I said, there appears to be some opacity around the implementation of judgments and appraisals. In particular, area drug and therapeutics committees, which are responsible for implementing guidance, appear to vary in their approach. I have no way of knowing to what extent that is the case, but a case can be made for a good deal more transparency in the process, because patients who try to negotiate their way through the system often find that arriving at where decisions are made is a rather opaque and Byzantine process.

Dr Turner: I agree that there should be more transparency, probably at local area drug and therapeutics committee level. Everything is on the web for people to see, but perhaps we do not know everything that goes on between advice being given to health boards and decisions being taken at area committee level, which is probably where inequalities in the system emerge.

Patients do not know anything about the SMC, the National Institute for Health and Clinical Excellence or area drug and therapeutics committees. They are stunned to be told that they have cancer and they expect to receive all the information up front when they start their treatment. They expect the best treatment. We do not live in a third-world country; we expect the best and we expect information up front.

The tragedy is that patients find it difficult to get that information. They sometimes feel that the gold standard that they are told they are getting is not necessarily what they would see as gold standard but is the gold standard that is cost effective for the health board. That is what I have gathered from speaking to patients' relatives.

Nanette Milne: I appreciate that. Given that there is acceptance that the SMC does a good job of assessing drugs early and letting health boards know about them, is there any need for area drug and therapeutics committees, which are another layer between the SMC and the patient? You say that the process is not transparent enough. Does it need to be changed?

Professor Johnson: Without knowing the detail of the different bodies' responsibilities, I would say that there is probably a good case to be made for a uniform national system of implementation. If such bodies are to exist locally, it would be extremely helpful for a standard approach to be taken. I understand that the SMC's rulings are not statutory, but it would be helpful for the Government in Scotland to take a view about the uniform implementation of such guidance.

Nanette Milne: Do you think that the SMC's rulings should be statutory, in the same way as NICE's rulings are statutory south of the border?

Professor Johnson: The approach south of the border has been helpful.

The Convener: Why are the SMC's rulings not statutory?

Professor Johnson: I cannot answer that question.

The Convener: When you speak to colleagues about how policy is arrived at and so on, do you get the sense that we have not adopted the statutory approach because we are trying to recognise the principle of responsibilities being devolved to different levels? Is that the history behind our process?

Professor Johnson: I honestly cannot say why the non-statutory route was taken when the system was set up.

Dr Turner: The SMC's rulings are set out as guidance, and a health board does not need to follow that guidance if it does not want to pay for

the treatment. I do not think that the local committees add much; the SMC does a good job on the whole. When the SMC gives advice, I do not see why the decisions should be made by another layer, because that means that the process takes longer and health boards might not take the advice. Either it is good advice or it is not. If it is good advice, why would a health board not take it? Does it come down to the funds available to each health board? We end up with a postcode lottery, which means that a patient in the north might not get medication that a patient in the south gets, and vice versa.

Nanette Milne: I have read so many documents that my memory might be failing, but am I right in thinking that the area committees are represented on the SMC?

Dr Turner: Someone who is appearing before the committee later can probably answer that question, but I think that people can sit on both.

Professor Johnson: As part of the cancer reform strategy, the cancer team in England will undertake a recurrent audit of the implementation of guidance from NICE, which is the statutory body. My understanding is that such an audit has not yet happened in Scotland. It may be worth having a systematic review of the level of implementation of the guidance that has come out. There is evidence of heterogeneity, but we do not know the underlying reasons for that. There may be something to be said for systematically reviewing implementation.

Nigel Don (North East Scotland) (SNP): On localised decision making, I read in the committee papers about managed clinical networks, which seem to be yet another area of, I presume, clinical decision making. Can either of you throw any light on whether MCNs make things more consistent?

Professor Johnson: The organisation and funding of health care is continuously evolving. There has been a series of initiatives, and MCNs provide another means to streamline, if you like, the process of cost control and provision of care.

To some extent, the MCN approach is close to what already exists in Scotland, in as much as a single body is responsible for health care—the board—but MCNs take a much stricter view about the implementation of clinical guidelines and the cost benefit analysis of that. Therefore, the approach is not unfamiliar, although it is a slightly more formal and overt method of regulation.

Nigel Don: Am I right in thinking that a managed clinical network operates within a health board area, rather than across health boards? That is my point.

Professor Johnson: Generally speaking, yes.

Nigel Don: Throughout this process, I have been interested in the idea of exceptional prescribing circumstances. I have to be careful about what I say because I am not a doctor and do not really know what they do—I guess that I will never find out—but on what basis is a doctor able to say in principle that a patient really should have product X when the rest of the world says that that would not be appropriate? How can an individual doctor build up a sufficient body of knowledge about that product to want to prescribe it when the rest of the world says that it is not a good idea? I am certainly not being critical of anybody; I simply wonder whether you can throw any light on how that happens and how we might accommodate it.

Dr Turner: In Mike Gray's instance, it was a last resort. It depends on when patients are diagnosed, because many do not know that they have the symptoms of cancer. It is important that they go along to their general practitioner and get all the tests done to diagnose what their problem is but, sometimes, they go for some considerable time with rather vague symptoms and do not really know what is wrong. Therefore, we end up with patients arriving to see a consultant at different stages. As it is the doctor's duty to do the best by the patient and pull out all the stops, they might prescribe a drug that they would not use in the normal course of events. A doctor might think about what else they can give a patient who is not lying in their death bed but walking about and trying to keep going to work. Given their knowledge, an oncologist should be able to say that a certain drug is the only way forward and should therefore be able to ask for special circumstances to apply. No two patients are alike.

Professor Johnson: Cancer medicine's reliance on evidence is probably better than that of almost any other field of medicine: our evidence bases are put together very carefully and more trials are conducted in cancer medicine than in just about any other area. We are comfortable with our evidence base, but the difficulty is always to extrapolate from the general to the particular, because there will always be unusual cases and cancers that behave in a way that does not fit the norm.

Although the general appraisal of a particular treatment gives one a view across a large population, there will almost always be exceptions. A key part of the system's humanity is that it allows those cases to be made individually. It is a positive aspect of the system, but a transparent process is required so that people can understand the case that they need to make and the basis on which it is accepted or declined.

Nigel Don: I know that we are here because of Mike Gray's case. He was a brave man indeed and I am grateful that he got us here, but I do not want to get lost in his case. If I understand you

aright, you are suggesting that it is perfectly reasonable for a clinician to examine the total body of evidence that the SMC might have seen, form his or her own judgment that, in the particular case of the patient whom he or she is treating, the evidence says that a certain drug might work and decide on the basis of that evidence to prescribe it.

Professor Johnson: Yes. I would not advocate unfettered autonomy, because that would risk creating a system that was difficult to manage. On the other hand, you could ask why we train doctors at vast public expense over a long time if we are simply going to tell them to follow a recipe. The exercise of individual judgment has to enter into the process, albeit within a clearly confined and constrained system.

14:30

Nigel Don: That is encouraging. Thank you.

Cancer Research UK's response to the committee's question 6 states:

"often ADTC decision-making is not transparent and it is difficult to know why certain decisions have been reached."

It also states:

"Where a Board decides not to make treatments available, they should make this explicit."

Will you expand on those comments?

Professor Johnson: I return to a point that I made a moment ago. Exceptional cases are often dealt with in a closed process and little information comes out about the basis on which decisions were made. As a general principle, it would be helpful for such proceedings to be as transparent, open and iterative as possible between the patient, their clinician and the body that makes the decision. That is the point that we were making in our submission.

Nigel Don: Fine. To extend that to the particular case that led to the committee's inquiry, I presume that you expect specialists to be able to argue for exceptional prescribing entirely on their own authority and based on their professional judgment. They would not need any back-up from the patient to make that happen.

Professor Johnson: I think that it is probably a combination of the two. The clinician draws principally on the body of evidence that is available and the particular circumstances of the patient, but I agree that, to a large extent, it is up to the clinician to make the case.

Nigel Don: Why would it be fair for a patient to have to be involved in the process, given that the vast majority of us do not know what the words mean and could not spell them?

Professor Johnson: We would not encourage a patient to become involved if they were unwilling. I do not know the circumstances of the particular case that you mentioned, but my experience of similar cases is that, often, the patient wishes to engage with the process. A large part of the problem of incurable illnesses and serious malignancies is that so little of what happens to the individual is within their grasp or their control. Many of the systems that we have set up seem almost deliberately to move the locus of control away from the sufferer. The greater their sense that they have an input to what happens to them, the more comfortable they feel. The process is often heavily driven by the patient themselves.

Dr Turner: I think that you would find that many patients do not want to be involved. If the system was a good one, they might not have to go through the torture of being involved in it. If we think beyond cancer treatment to other areas in the national health service, there is a tendency for patients to feel that they are coincidental to the running of the system. Professor Johnson alluded to that. Although doctors are taught to involve the patient, they come up and examine patients and speak to them without introducing themselves. Patients sometimes lose their personality and their control.

Some patients turn their head to the wall when they are told that they have cancer, which is a dreadful thing to be told, and argue that they want no treatment at all. Not everyone is as articulate as Mike Gray was, and not everyone wants to go through the process. Some patients do not know that all that information is out there and that they can be involved, because they do not get that information when they are diagnosed with cancer.

Relatives sometimes feel locked out as well. Recently, I spoke to a relative of someone who is going through chemotherapy and who had been told, "That's the diagnosis. This is what you're getting, and this is the process." The patient felt left out. Such treatment is a big event in somebody's life, but it is not just the patient who goes through the process. Relatives are on the sidelines, watching and worrying.

We could do better. Patients depend on the doctors providing sound information and giving the best treatment for their situations. If we have the information that patients need, they might not need to get involved in special prescribing.

Rhoda Grant (Highlands and Islands) (Lab): You said that certain drugs are sometimes used when all else fails. Is the patient given a proper chance of successful treatment if drugs are being used when there is almost no hope of anything really working? Is it fair to the patient that, because of the cost, the drug is not used until there is almost no chance of it being successful?

Given that drugs are approved for use on the basis of a cost benefit analysis, I guess that the question is: what are the benefits and the cost? Who makes that decision? An individual would consider a cost benefit analysis to be important to them and would pay a lot of money for a short-term benefit. It all seems to come down to that.

Dr Turner: Patients will take absolutely anything. They have said to me that, even if a treatment is experimental and has not been proved, they would take it if it gave them a chance of a few more weeks and months. However, on the whole, people get the right treatment for the right cancers. It is only as they go through their treatment that we see how they respond to it. As I understand it, not everybody responds in the same way to similar treatments. When you are running out of successful treatments, you will try those that have just been licensed or are sitting on the sidelines—although they might not be the first choice for that cancer, they might help with the symptoms. You are trying not to cure the cancer but to deal with the symptoms. That is what I meant.

The Convener: The petitioner and his family expressed concerns about self-funding. Cancer Research UK's response said that a wider debate needs to be opened up on a co-funding model. Will you expand on that? If I have picked it up correctly, the concern is that, because the individual had to pay for treatment, he could not get the other support and care that he would have expected from the health service.

Professor Johnson: At the moment, national health service patients can obtain free treatment under the framework about which we have talked. If treatments are approved, they receive them free, but treatments that do not meet the cost benefit criteria that are laid out are not provided.

Many people are puzzled by the system and do not understand why they cannot receive the basic care that the NHS would provide anyway and top it up with contributions from their own money. Cancer Research UK feels strongly that it does not wish to perpetuate a system that would drive inequalities in care, although, on the other hand, we see differences in the treatment that people can access. For example, in England it is possible to obtain private prescriptions for Viagra and flu vaccination from an NHS general practitioner if one does not meet the criteria that are laid down. Therefore, so-called top-up, or co-payment, already exists on a small scale.

The increasing introduction of private funding to the national health service—again, predominantly south of the border—has started a debate on co-funding. There are difficult questions and no obvious right answers. One wishes to avoid an overtly two-tier system.

At the moment, however, the only people who have access to certain treatments—which are admittedly of low benefit compared with the cost—are those who are extremely wealthy or who have private insurance. That is a small pool of people. If top-up payments were allowed, that pool of people would be considerably enlarged, because a much greater number of people would have the means to afford the drug if the rest of the care package was provided.

Clearly, one wishes to avoid detriment to the rest of the system and allowance would need to be made for the opportunity cost of providing the care, but I do not see why—at least in theory—such a system should not be devised. The question has not been widely aired and the system has not been considered in detail by the various health departments. It is something that people have difficulty understanding intuitively, so a wider debate and more honest exposition of the issues would be well worth having.

Dr Turner: I would certainly like a system whereby patients did not have to pay out of their own pockets. Private care has co-existed with the NHS for many years, since the inception of the health service. More and more people go for private health care and mix it with NHS care. They do not understand why, when they have cancer, they are suddenly up against a brick wall and have to pay for the drug and the NHS care. I do not see why there could not be central funding, in particular cases, for named patients that apply for it. That might be a way round the problem.

People put money into cancer research and into the health service, but many of them never call on the health service. People who have cancer find that they have to delve into their pockets, whereas those who have car accidents and suffer multiple injuries are treated. Those who suddenly find at the age of 30 that their kidneys do not work go on dialysis. If they did not get that treatment, they would die. It is difficult for the ordinary person in the street to understand why means cannot be devised to pay for cancer treatments. People do not have to pay for anything else.

Nanette Milne: I have the Health Department's letter of 5 February 2007, which essentially gives guidance on co-payment. To me, there are discrepancies. The first bullet point in the letter says that

"there is no legislation that allows NHS Boards to require the patient to pay for all aspects of their treatment if they opt to pay for a particular drug or other treatment not currently available from the NHS".

The final bullet point in the same paragraph says that

"NHS Consultants cannot treat a patient both as a private patient and as an NHS patient for the treatment of one condition during a single visit to an NHS organisation".

I have read and reread the letter and I suspect that those statements are contradictory. I would be interested to hear your views. I might also ask later witnesses for their views.

Professor Johnson: I agree that the subject is extremely confused and confusing. The question of private treatment is, perhaps, separate. It is clear that we should not mix private and NHS care within one episode because, for example, it is extremely difficult to understand how clinical responsibility could be maintained in such circumstances.

The legal basis for top-up payments in an NHS setting is unclear. Guidance from the health departments states that it is not allowed, but it is far from clear that that has a basis in law. We need clarity on that, because patients will continue to ask the question.

Dr Turner: When I first read the letter, I reread it and reread it. I thought that, if I was in that situation, I would not know what to do. The English is dreadful, and there are questions about its legality. It leaves people unsure about what they are supposed to do.

I can see the difficulties with mixing NHS and private care, which include difficulties with insurance and risk. If treatment takes place wholly within the NHS, the NHS carries all the risk. When treatment is part private, that is difficult.

14:45

Nigel Don: I return to your previous comment about the cost of rarely prescribed drugs. Simple economics suggests that if the drugs were prescribed more often, their price would come down. Then again, simple economics says that their price would come down only if there were a substantial change in their volume. I wonder whether the volume of a drug's sales in the UK would significantly affect its price internationally. If, say, instead of being prescribed in 1 in 1,000 cases a drug was prescribed in 1 in 100 cases, would that make any difference to the price or would there merely be a tenfold increase in the cost?

Professor Johnson: I am not sure that that would have much impact internationally, although quite a few parts of the world base their pharmaceutical pricing on what is determined in the UK.

The question of cancer drugs is particularly tricky under the pharmaceutical price regulation scheme, which is the non-statutory agreement between the Government and the pharmaceutical industry whereby the price of new drugs is determined. That is particularly to the disadvantage of cancer drugs and cancer patients because most of the process of introducing a new cancer drug involves patients for whom other treatment options have been exhausted and who then take part in clinical trials. Our evidence base therefore derives mainly from patients who are a long way down the line of treatment, who may have received several different types of treatment and for whom the benefits, almost by definition, will be marginal at the point at which the drug is introduced. They tend to be a rather small population of patients, as well. Therefore, the initial application for the licence often involves a small population of patients for whom the benefits are not great.

That pushes the pharmaceutical manufacturers to price the drug at the top of the permissible range under the scheme, because they know that the drugs will be prescribed in only a small number of cases. Because there is no history of drug prices being allowed to rise subsequent to licensing—there is always downward pressure on them—the manufacturer inevitably prices the drug initially at the highest level in order to recoup its research and development investment.

A different approach to pharmaceutical price regulation would probably be helpful. The Office of Fair Trading has come up with the idea of so-called value-based pricing, whereby the benefit to the patient—if one could quantify it in the way in which the quantifications are done in these systems—might be considered and the reasonable price that the manufacturer could expect the drug to be sold for in order for that benefit to be achieved would be the starting point, rather than a cap on the profits of the pharmaceutical company. That might artificially lower the price of some drugs at the point of licensing, but with the recognition that, as more use was made and as different indications showed greater benefit, the price would be allowed to rise in proportion.

The Government and the pharmaceutical industry are discussing the way forward and value-based pricing with the PPRS. It is an area in which we would welcome a great deal more transparency and open discussion.

Nigel Don: I cannot help wondering whether a drug's price should be based on a fixed return, whereby it would not matter how many pills were made because the cost would be entirely fixed. One could get a quantity to use in any way that one liked for a fixed cost per year. That would perhaps be pushing the boat out a bit too far.

Professor Johnson: There are different varieties of pricing, of which value-based pricing is one. The other possibility for mitigating the cost of expensive new medicines is the so-called cost-sharing arrangement that has been used for some new medicines, whereby the pharmaceutical

industry provides the new treatment either free or at a discounted rate for a certain period in order to determine whether there is a benefit in an individual patient. If there is a demonstrable benefit to that patient, the national health service might be expected subsequently to pick up the cost. Different pricing models are available, but until now we have been rather rigid in our thinking about how we set prices.

The Convener: We have had a fairly extensive series of questions. I will try to provide a wash-up of the core issues.

You have both said, in response to different questions, that the process could be much more transparent and open, with shared discussion and negotiation with the medical experts, the patients and their families, and so on. You also mentioned the need for a review of the national system of implementation. There is a range of issues.

We all understand how Byzantine our health provision can be and how big a task it is to bring about dramatic change. What process should a patient in Scotland experience who, in five years' time, faces what the petitioner faced? Will either of you give a sense of that, forby the points that I have mentioned from the comments that you have made so far?

Dr Turner: I want a considerably shortened process. In Mike Gray's case, it took weeks for the clinician to ask for permission to prescribe. We forget that if we are not actually involved in the process. Patients do not have an awful lot of time. All of us are born to die, but a person who is diagnosed with cancer knows fine well that the clock is ticking and does not have time to wait for somebody to make a decision about their treatment. The doctors may debate the merits but, for the patient, we must make the process simpler and speedier. I would like the committee to take that up with the Cabinet Secretary for Health and Wellbeing and perhaps get the Health and Sport Committee to review the process and whether there really is a need to have area drug committees.

Professor Johnson: I agree. I hope to see a more streamlined and transparent process for implementation of the guidance. Different models of pharmaceutical pricing and, possibly, a more liberal regime to allow people to help themselves in such circumstances would also be positive steps forward.

The Convener: I thank you both for your contributions this afternoon. They have been extremely helpful in developing our awareness of the issues.

We will have a short suspension for the switchover, so members can have a quick comfort break.

14:52

Meeting suspended.

14:55

On resuming—

The Convener: I welcome our second panel of witnesses. They have seen the format, so I hope that this will not be too intimidating for them—some experienced faces are looking at me, so I do not expect that to be the case. Dr Ken Paterson is the chairman of the Scottish medicines consortium and Dr Andrew Walker is its health economic assessor. Dr Kohli is the medical advisor of NHS Quality Improvement Scotland and Andrew Dillon is chief executive of probably the best-named organisation in Scotland, if not the UK: the National Institute for Health and Clinical Excellence, which is sometimes known as NICE.

We have a series of questions. Some will be similar to previous questions, so the witnesses will have picked up the tone of the inquiry. Would any of you like to make opening remarks that would help the committee or would you like to go straight to questions?

Dr Ken Paterson (Scottish Medicines Consortium): It would make sense just to go to questions.

The Convener: Okay. You have heard what has been said so far.

Nanette Milne: I will pick up—as I did before—on the various bodies' roles and functions. The written evidence suggests that they work fine. Is there any need for improvement to the system? Is there anything that would streamline it more? Is there a need for the area drug and therapeutics committees? How would you envisage any reform of the present system?

Dr Paterson: I guess that I should answer that first, wearing my SMC hat. We do not believe that there is any need for significant reform of the current structures. We believe that each of the organisations that are involved—the SMC, the area drug and therapeutics committees, NHS QIS—and our interaction with NICE are clearly defined. We each have particular roles and responsibilities and the SMC would not wish its responsibilities to be expanded beyond their current levels because doing what we do is enough work for us.

There is a structure that allows appropriate interaction, and significant change to it would not be appropriate. The SMC was formed as a consortium of local area drug and therapeutics committees precisely to avoid duplication of effort in Scotland. Prior to the advent of the SMC in 2002, each individual area made its own decision about new drugs. It was realised that that was

inefficient—the SMC came out of that realisation. We would be keen for that system to continue and we are grateful for the endorsement that many people have given to our processes and outputs.

Area drug and therapeutics committees still have a role, although their role in respect of cancer medicines is perhaps open to inquiry. SMC acceptance of a drug for use in Scotland is not necessarily a recommendation to use it. Many of the drugs that we consider are treatments in busy therapeutic areas in which multiple therapeutic options are available. We decide whether a drug is cost effective and may be used in Scotland. When we have done so, it is then for clinicians within individual areas to add it to their local formulary and use it, although it is equally open to them to say that they do not see a place for the new therapy because other equally effective options exist. There is a two-stage process: the SMC says that clinicians may use the drug and then a local area drug and therapeutics committee decides whether it will use the drug locally.

It can be argued that cancer medicines are a little different because many of the agents have no equivalents. The SMC expects that the great majority of the cancer drugs that it accepts for use in Scotland will find use within the NHS here. However, we accept that there may be variability according to local circumstances. For example, we recently considered a drug for management of lung cancer: it is no better than many other drugs in management of lung cancer and it is more expensive than some, but it is an oral therapy as opposed to an intravenous therapy. We recognised that that advantage might be of particular relevance in rural areas, so we might expect it to be used more in the Highlands or the Western Isles, whereas for patients who live in a conurbation such as Glasgow or Edinburgh, the intravenous alternative might continue to be the front-line therapy.

Those are the kinds of decisions that area drug and therapeutics committees can make with an eye to local circumstances, and which the three west of Scotland cancer networks can make within their organisations. We are not looking for major changes: we think that area drug and therapeutics committees still have a role to play in cancer medicine and, more important, beyond cancer medicine, which represents a minority in the drugs that we consider.

15:00

Dr Harpreet Kohli (NHS Quality Improvement Scotland): I would echo what Dr Paterson has said. The word “Byzantine” was used earlier. Perhaps to the outsider—someone who is not in the system—our structures and processes look complex, but those of us in the system are very sure that each organisation knows its remit and what it has to do. We have very good working relationships across the different organisations. We have mechanisms for communicating with each other: if issues arise, we deal with them.

The written evidence included an example of the consistency of advice between the Scottish intercollegiate guidelines network’s clinical guidelines and SMC advice. There are mechanisms in place to deal with problems that arise—they can, and do.

Nanette Milne: Should the English route be followed and SMC advice put in statute?

Dr Paterson: Technically, the SMC does not exist. It is an informal coming together of area drug and therapeutic committees. Making our informal organisation produce statutory advice would be going some distance.

Our advice is advisory, but there is agreement among NHS chief executives that, by being part of the consortium, they have—in large measure—signed up to that advice. They accept that an area that does not act on the advice must justify that. I believe that health board chief executives accept that they cannot simply pick and choose SMC advice. As I said, by being part of the consortium—as they all are—they have signed up to taking on board that advice.

The current SMC structure makes it difficult to put the advice into statute. It already carries strong force, so I am not sure about the necessity of going down that route.

The Convener: From earlier contributions, I appreciate the need for consistency, and the contribution that your organisations make.

I say to Dr Kohli that my use of the word “Byzantine” was more of a generic reference to the health service as the big “HMS Health Service” and not to the interrelationships between your organisations. That having been conceded, the question remains: Why are there so many differences in such a small country? I understand that one treatment might be thought to be more applicable in one part of the country than in another. For example, services for clients in rural Scotland may need to be implemented differently to those for people in urban areas because of the difficulties in accessing support structures in rural areas. Everyone might concede that point, but the concern that underpins the petition is the lack of clarity and consistency in decision making across the country, particularly in a specialist area as obvious as cancer care.

Dr Paterson: Given that I am not an oncologist, I feel slightly unable to answer the question in detail. Later this afternoon, the committee will take evidence from expert oncologists. They will give

members a better idea. Our advice prevails in Scotland, but it is up to local clinicians how to treat patients.

In terms of cancer care and chemotherapy, I am not going beyond my remit in saying that the differences between therapeutic regimes are often relatively small and relate more to adverse events than to benefits. Different clinicians take different views of the balance between the benefits and side effects of different cancer treatment regimes. Variation in treatment does not necessarily reflect lack of access to treatment in an area; it means that clinicians in one part of Scotland take a different view to those in other parts of the country. We are talking about judgments, not black-and-white situations. Clinicians take different views of the benefits and side effects of individual therapies.

My reading of the submissions from the cancer networks did not leave me with the impression that clinicians in those networks feel that they are unable to use the drugs that they wish to use because of issues at their local level.

Dr Kohli: The SMC, NHS QIS and NICE provide advice to health boards and organisations. Each organisation states that health care professionals need to take account of the circumstances of their patients. Each organisation also recognises the advice that we provide to the health service. However, individual health professionals, together with their patients and the patients' carers, continue to have issues to consider.

Dr Andrew Walker (Scottish Medicines Consortium): When I read the papers of the written evidence to the committee, I was struck by how little good evidence the committee was presented with. There was a lot of opinion but very little data. You will gather that one of the deficiencies in the health service at the moment is a lack of good quality data on hospital prescribing. There is a real gap and that has been the case for years. I wish to correct one point. You have figures, for instance in the written evidence from the Association of the British Pharmaceutical Industry (Scotland), but they are sales figures based on cancer networks that cut across health boards. We know about the figures on an aggregated level—we know how much of a particular medicine was used in the west of Scotland—but we cannot get down to health board level. I am not sure that there is evidence for heterogeneity in prescribing, although I could not prove that homogeneity exists either. There is a real lack of data.

On exceptional case prescribing, we have one very sad case that has quite rightly been brought to public attention, but we do not know how many more there are, and there are no central data on anything to do with that issue. I do not know how helpful a comment that is; but one thing that really struck me was how little the committee has to go on. We are really giving you our opinions rather than giving you data.

The Convener: Can you provide me with any data?

Dr Walker: No. I suppose the data exists in individual hospitals, or individual clinicians know what they prescribe for patients, but we do not have—and never have had—a national system that collects the data centrally and which would allow us to say how many patients are getting one drug and how many patients are getting another drug. Earlier witnesses were asked what they would like to change in five years. I would pick our having a national system that would enable us to flick a switch and produce tables and charts to show you how many patients were or were not getting a drug in each area.

Dr Paterson: In fairness, the cancer networks are further down the route of having that data than almost any other part of secondary care in the NHS in Scotland. They may be able to give you rather more data than those in some other areas of care.

The Convener: That is helpful. Would you even hazard a guess as to whether we are within reasonable striking distance of being able to gather information that would allow the likes of Dr Walker and others to carry out a more systemic analysis, or are we a substantial distance away from it?

Dr Walker: That question is probably better directed to the witnesses who come after us, as they are closer to the grass roots and will know better than us. I would not hazard a guess about any NHS information technology system.

Dr Paterson: A process is under way to try to procure an electronic prescribing system for Scotland. We are at the point of trying to see whether we can get a system. If we can, it will have to be bought and installed, which will take a minimum of five years.

The Convener: That is why we all love the NHS so much. Getting the data is one issue and how the data are gathered is another. I concede the point that because of national strategies, more progress is being made on cancer data. It would be helpful to get some pointers in the right direction. We will inquire of the subsequent witnesses in that respect. A number of questions have probably cropped up in the meantime.

Angela Constance (Livingston) (SNP): I accept Dr Paterson's point that just because the SMC approves a drug and enables it to be used does not necessarily mean that the drug should be used. He referred to local circumstances. Can Dr

Paterson give an example of why a drug that the SMC has approved for use should not be used?

Dr Paterson: The obvious example I can think of is outside the area of cancer. We approved the seventh drug in a class called triptans for the treatment of migraine. It was yet another drug in the therapeutic class and six other drugs were already on the market. It was the same price—to be honest it was slightly cheaper than and not quite as good as some of the others—and we said that it was an acceptable drug for use in Scotland. It has sold virtually nil since then. That is probably as it should be, because there are six other drugs on the market that are of equivalent benefit and equivalent price. The last drug to arrive in the marketplace is always going to struggle. There are many other examples of that within therapeutic areas. Such drugs tend not to have widespread uptake because by the time we get to the third, fourth or fifth drug—what are known as "me too" drugs—the therapeutic area is mature and well established.

I cannot give you an example of that from within the field of cancer not just because I cannot think of one quickly, but because, as Angela Constance mentioned, we at the SMC have much less data on the use of drugs in secondary care—at which stage most cancer chemotherapy is given—than we do on primary care. The long-established principle of SMC advice is to be permissive, saying "You may use this drug," rather than instructive, saying "You must use this drug," and that has been effective in other therapeutic areas.

Angela Constance: I listened with interest to your comments about the lack of data, and the opinions—I note what you said about them being only opinions—in the written submissions. I noted with interest that Dr Kohli said that he felt that the system actually worked well. I do not mean to put any of you gentlemen on the spot, but I am interested to hear whether you can convince us that the postcode lottery does not apply in Scotland.

Dr Paterson: No one else seems to be rising to the challenge.

I cannot answer that, because we have very limited data on it; certainly, we have virtually no data for secondary care and oncology. The representatives of the cancer networks who will speak to the committee later might well have some data on it.

We have looked back at how some of the SMC's early decisions were enacted throughout Scotland. It is difficult for the third or fourth drug in a class, because there is significant variation throughout Scotland, but we are not really bothered about that, because there are equivalent therapeutic options for patients. If Grampian decides to use a new drug and Lothian does not, there are equivalent drugs out there that Lothian will use. Therefore, technically there is postcode variation in the use of such drugs, but no patient has been denied appropriate therapy as a result.

When we examined the use of new classes of drugs we did not, in general, find dramatic variations between different health boards in Scotland. That evaluation of our work is on-going, so I do not have the final details, but in general the prescribing of brand new drugs in primary care is fairly even throughout Scotland. The prescribing of "me too" drugs in Scotland is quite variable between different areas, but we do not think that that is something to be particularly concerned about. Patients will not receive one particular migraine drug because they are receiving one of the others; and since the drugs are all much of a muchness, that is not something to get terribly excited about.

Angela Constance: Given the lack of data and all those on-going evaluations, can you give examples or more specific evidence of why the system is, in your view, working well?

Dr Paterson: We have now carried out more than 400 assessments and we have put out more than 400 pieces of advice. As part of our primary care review, we found that when we have recommended drugs for usage, there has been usage—although there are exceptions. When we have said that drugs are not recommended for use in the NHS in Scotland, there has been a very low level of usage, although not zero usage, because an individual patient's circumstances might mean that a particular SMC decision does not apply in that case. In general terms, the outcome of the evaluation so far is that SMC advice seems in large measure to be followed.

Dr Kohli: The processes and the structures that are in place allow for that consistency of advice to be given to the health service in Scotland. The issue of data has been noted, and increasingly in future we will have access to such data. In all the organisations—NHS QIS and SMC—the feedback on the consistency of the advice provided and the understanding of the different forms of advice is positive.

15:15

Dr Paterson: In the field of cancer, from what we hear from colleagues down south, we believe that where we have assessed a cancer drug and have recommended its use, the uptake here has been more rapid than it has been in the NHS in England, because of positive SMC advice. Obviously, that is good, because we are not just about preventing non-cost-effective treatments from being used; we are about ensuring that cost-

effective treatments are used and are available to patients in Scotland.

Dr Walker: There is also an issue around what you mean by talking about a postcode lottery. At the end of the previous century—the previous millennium—we were still talking about a situation in which Glasgow could say yes to a medicine and Edinburgh could say no. The choice was that stark. Patients living 50 miles apart with the same condition would or would not get the treatment.

Now, the issue is more about the level of implementation. Despite the fact that we do not have data, we feel that all of our decisions are implemented, but are they implemented consistently across the country? The definition of postcode prescribing has mutated a little bit from a yes/no and black/white type of question to one about the level and speed of implementation. I do not think that anyone says no when we say yes, except in the circumstances that Ken Paterson has described.

We are trying to get into the fine points and the data do not really let us do that, so we cannot quite answer the question at the moment. However, at least we have moved the debate on from the situation in 1997 or 1998, when one health board saying yes and one saying no gave the newspapers an easy headline about undermining public confidence in the NHS.

The Convener: In a sense, the case that we are talking about took that journey. The patient perhaps sensed that it was a yes/no decision and moved into a discussion with the health board to make it decide yes, but was concerned about how they came to be in that situation and was faced with the lack of data and clear information that you have talked about.

Dr Walker: I agree. The situation has changed because there is now one consistent source of advice in Scotland. Now, the question is whether there are any exceptional cases in which one might step away from centralised advice in a particular set of circumstances, rather than whether two health boards are looking at the same evidence and coming to fundamentally different conclusions.

The Convener: What is the relationship between the roles of SMC and NICE and the advice and guidance that they each give?

Andrew Dillon (National Institute for Health and Clinical Excellence): The relationship is very constructive. NICE does what Scotland wants it to do. If there is a need in Scotland that is not immediately covered by the SMC's work or by other activities sponsored by NHS QIS, NICE guidance, where it exists, is available for use.

The relationship has changed over time. Since NICE started and the SMC was established, the need to use NICE guidance in Scotland has reduced and its use is now largely limited to what are called multiple technology appraisals, which compare groups of drugs rather than assessing single new treatments as they are introduced. That seems to work well and I entirely understand the basis on which NICE guidance is being used.

The roles are framed differently. Ken Paterson has described the way in which the SMC frames its guidance. There is a recommendation to area boards in Scotland about what they should list or not. In England and Wales, NICE guidance is more directive; there is a clear recommendation to use something in specific circumstances or, more rarely, not to use a treatment, but in practice that is a minority of our recommendations.

You asked about postcode prescribing, and there is no doubt that variations continue to exist in England. The extent of compliance with NICE recommendations varies from one product to another, from one appraisal to another, and across the different types of NICE guidance.

We have a programme to capture, as far as we can, all the publicly and—where we can access them—privately available sources of data to track the impact of NICE guidance in England and Wales. We are not doing that for Scotland because, clearly, that is a matter for the Scottish agencies. The picture is by no means complete, but it indicates what is happening. The nature of the response to our guidance will and does vary, even in a field such as cancer in which one might expect a positive NICE recommendation to be taken up quickly. Even then, local barriers to the implementation of national recommendations still exist. Sometimes those relate to funding—the cost impact of a positive recommendation can be considerable and can put substantial stress on local budgets. However, that is not always the case. There is a significant issue around clinical leadership, and you might wish to question the next panel of witnesses about the circumstances in which that applies. In England, there are well-organised cancer networks with similar responsibilities and a similar brief, yet there are still significant variations in the uptake of recommended treatments for patients with particular cancers.

The current arrangements in England, Wales and Scotland are better than what we had prior to 1999. For all the flaws and criticisms that people might lay at the doors of those who do the work, and for all the improvements that one might identify as being required in how we go about it, it is better to have national guidance and a clear statement, and for the struggle to be about making that guidance consistent working practice for all patients, than to use the arrangements that existed before. We have a national health care

system to administer, albeit one that is split among the four countries of the UK. People expect the N in NHS to mean something, and the right place to start is to have a clear national position.

The Convener: That is a helpful contribution.

Rhoda Grant: I want to ask about criteria for approval. I can easily understand the criterion of benefit versus side effects. I also understand that clinicians may build an exceptional case on that basis. They might say that a particular patient is in generally good health and could withstand the impact of any side effects, or they could point to the lesser side effects of some drugs. I can understand how exceptional cases could be made.

Approvals that are based on cost benefit analysis are more difficult. It comes down to benefits versus costs, and what I might see as the benefits and costs will be quite different from what you might see as the benefits and costs. I suspect that every clinician will have a different outlook on the cost benefit ratio, which I can imagine might lead to postcode-based prescribing. If a certain board was willing to pay a higher cost for a given benefit, and its budget, unlike that of other health boards, allowed that, the various arguments that we have been discussing would come into play.

Should we be considering cost and benefit at all? Should it be left to health boards? How can the system be made more open to patients? If it was my life, or even months of my life, at stake, I would pay as much money as I could get my hands on to get the benefit. If somebody told me that the drug would not be of benefit to me, that would be difficult. I would be interested to hear your comments on that.

Dr Walker: I totally understand what you are saying. You are talking about the difference between the patient perspective and the population perspective. Groups such as NICE and the SMC will always come to such issues from the population perspective, and they will talk about the typical patient and their quality of life. There is an immediate issue there, in that the exceptional case will always be seen from the point of view of the individual patient and their particular circumstance. We never have that luxury. We might be dealing with a drug that could affect, say, 400 or 4,000 patients. We cannot conceivably take every single case into consideration.

You should not forget—and Ken Paterson alluded to this—that cancer medicines comprise only 10 to 15 per cent of what we do, and we want to achieve consistency not just across cancer medicines, but across medicines for epilepsy, diabetes and so on. We are trying to make definitions and to pin down how much longer patients will live and what their health status—if I may use that rather grandiose term—will be. I am really talking about patients' quality of life: their level of symptoms; how much pain they are in; how much mobility they have; how much mental suffering they are enduring; and so on. We try to capture that in a measure called a quality-adjusted life year, or QALY. We basically assume that, whatever we do for patients, whether they have advanced-stage cancer, early-stage cancer, epilepsy, diabetes, chronic pain or whatever it happens to be, we can capture the benefit using a QALY.

I can go through that system in a bit more detail if members wish. It is the lingua franca of the health technology assessment world. It is what we use; it is what NICE will use; and it is what our counterparts in Sweden, the Netherlands, Australia and Canada will use.

That measure seeks to capture the additional health benefit to the patient of having a medicine. We try to wrap up a reduction of symptoms, an avoidance of worse symptoms and an increased length of life in the QALY, which is a measure of the health benefit. That deals with one part of your question. The pharmaceutical companies that make submissions to us to convince us that a medicine should be used are well aware that that is the measure that we use, and are used to converting their clinical trial data into those terms when they make a pitch.

As you rightly say, the second thing that we have to do is weigh that against the additional costs that are involved. In addition to considering the additional cost of a medicine, as Ken Paterson said, we take into account whether it will be given in pill form or whether it will be provided intravenously, through a drip. We also take into account any side effects and the costs of treating advanced-stage disease. Those factors are all included in our calculations. The cost of the drug is not the only issue—we consider the patient's whole experience.

If there are any additional costs—in almost all cases, there are—we must weigh them against the additional health benefits that are captured in the QALY framework. The issue then becomes, "What are we willing to pay for a QALY?" As you rightly say, a patient might be prepared to pay an infinite amount of money, but if we were to spend such large sums, other patients in the health service who did not need drug treatment—for example, patients who needed radiotherapy or a completely different type of service—would lose out.

The issue that we face is that patients would like us to approve many medicines. We know that with the budget that is available we cannot approve all of them, so we try to find a balance. NICE and the SMC have arrived at a level that we think roughly balances those two pressures. It is almost certainly acceptable to spend up to £20,000 to

provide a year of good-quality life, and it is probably acceptable to spend between £20,000 and £30,000. We would not say that a QALY that cost more than £30,000 was unaffordable, but we would have to examine the circumstances. That is the cost effectiveness part of the calculation.

The SMC's committee also considers all the other factors. The treatment might be for a rare condition or it might be a breakthrough treatment for a cancer that affects children, for example, in which case consideration would have to be given to whether cost effectiveness was the only relevant factor.

I realise that I have talked for quite some time. We build up the QALY based on quality of life and once we have weighed that against the cost, the committee considers everything else that we need to take into account. I hope that I have explained roughly what we do.

Rhoda Grant: We would be grateful if you could provide a written submission on that—we do not want you to go on for too long.

Dr Walker: Sure.

The Convener: Perhaps you could make your written submission a wee bit shorter than the explanation that you have just given.

Dr Walker: Okay; I will try.

Rhoda Grant: My second point goes back to the lack of data. Surely the role of the SMC is to evaluate the situation following approval or non-approval of a drug. If such data were available, they would be extremely important in informing decisions about whether to update advice and guidance. For example, if people were using drugs that had not been approved, they could feed back data that would add to the available information and would enable you to update your advice. Data could also be provided on drugs that had been approved, but which were not being used because they were not that great. Would that not be a benefit?

Dr Paterson: It could be a benefit, but it would involve a huge amount of work. We put through seven or eight new drugs a month, which is a daunting undertaking. If we began to revisit previous decisions by pulling together and reanalysing data, we would create a huge amount of work for ourselves. There are other agencies within the information services division that are beginning to collect such data. I do not believe that the SMC, as it is presently constituted, has the resource to monitor decisions that it made a year or two ago or to gather its own evidence on them. That would require a huge investment, as it goes well beyond the scope of the data collection that we talked about earlier.

When we say yes to a drug and it is used, that is fine. If it subsequently falls out of favour with clinicians, that is fine, too, because something else will replace it. If we reject a drug, it is open to the manufacturer to come back to us at any time with new information or new analysis to try to persuade us that we made a wrong decision. At that stage in a drug's life cycle, it is nearly always still the sponsor company that is undertaking the trials and collecting data. If new data come to light, the company can come back to us any number of times to invite us to agree that the drug represents a cost-effective treatment. If we say no to a drug, the safeguard is that we can always consider it again. If new information comes to light, we are very open to changing our mind. At least half of resubmissions lead to a change of decision because of new data, new information and new analysis.

We make eight decisions every month, so to follow up the 100 decisions that we might make in a year would represent an enormous amount of work.

15:30

Dr Kohli: I want to come back to the use of QALYs. As a representative of NHS Quality Improvement Scotland on the SMC, I know that we are kept right by the health economists on some of the heavy-duty health economics. I think that Andrew Walker emphasised that point. The QALY should be seen in the context of the other information that is before the SMC. As a mere public health physician, I would be worried if any assessment considered only the cost per QALY, but it does not; all the other information is taken into account. The QALY is not a technical answer but is a tool that helps us to assess and evaluate. In this case, it helps us to evaluate cancer drugs.

Nanette Milne: Have there been instances of SMC guidance being superseded by or changed following a NICE appraisal?

Dr Paterson: Andrew Walker is our data guru, so I shall let him answer. He will know the number.

Dr Walker: Our data guru is actually behind me in the public gallery—my research assistant, Corinne. However, I think that there have been five instances in which an initial SMC no has been overturned by a subsequent NICE yes. As Andrew Dillon has already said, NICE guidance supersedes SMC guidance only when NICE has done one of the slightly longer, multiple technology appraisal processes. Some of the guidance that NICE is producing now, based on single technology appraisal processes, does not supersede what we do at SMC.

As I say, there have been five instances. One was a cancer drug—docetaxel, which is for prostate cancer.

Nanette Milne: So that is five out of a total of about 400, did you say?

Dr Paterson: The total for cases that we and NICE have considered is not 400; it would be five out of about 90 or 100, I think.

Dr Kohli: No, it is 55.

Dr Paterson: I am sorry; it is 55.

We are not unhappy with the situation. The NICE multiple technology appraisal process normally takes place two to three years into the life of a drug. Again, it is not just one drug that is being assessed but a whole therapeutic area. By the time of the assessment, new and additional information will often have come to light. We regard our rapid process at the time of licensing a drug as being complemented by NICE's reconsidering of the situation two to three years down the line. We are entirely comfortable with the possibility of there being changes in advice. You can make a decision only on the information that you have at the time; if appropriate, new information should lead to a change of decision.

Nigel Don: I want to return to the issue of price. So far, price has been spoken about as if somehow it were handed down on tablets of stone. Perhaps you feel that it is.

I acknowledge that good-quality synthetic chemistry costs money, but nonetheless the cost comes with far fewer noughts on the end than does the cost of the development process for a drug. I do not think that anybody will dispute that. The basic point is that the development cost is a fixed cost and is a substantial cost that will be written off whether you like it or not. If I had come in with the sixth "me too" drug, I would not be putting it in at the same price—although I used to in other businesses—as the ones that I was trying to follow. I would want to sell something; even if I sold it at a discount, I would still want the income, would I not?

Can you give me an idea of where the price comes from and of how negotiable it is? We know that a QALY has to be under £30,000, so an accountant somewhere in those big businesses must be trying to work out how to make money.

Dr Paterson: You are now taking me well outside my area of expertise and are asking me to change sides, over to the pharmaceutical industry.

The price that the SMC is offered, and the price that the NHS is offered in the United Kingdom, is the price that the pharmaceutical company offers. We have no ability to negotiate that price. The mechanism for controlling pharmaceutical company profits is the PPRS scheme that Professor Johnson spoke about, which controls the overall profits of a company but does not do anything about the price of an individual drug. There are no mechanisms by which we can enter into any negotiations on that price. The price is the price is the price.

It will not surprise you to learn that a number of the health economic cases that we consider have a cost per QALY that is suspiciously close to £30,000, and you cannot help but wonder whether the company has worked back from the cost-per-QALY figure to get the price. Professor Johnson also mentioned the OFT's suggestion of a value-based pricing approach, which would involve the company telling us what the drug does and us telling it what the price should be. However, we are a substantial way away from that at present.

Nigel Don: I recognise that I am asking you to change sides, in a sense, which is, perhaps, not fair, but am I right in thinking that an awful lot of the cost effectiveness of what you are doing is entirely dependent on people who have nothing to do with you sorting out the cost and price models of the drugs and what the NHS is prepared to pay for them? Their decisions could make a huge difference to the decisions that you come to without you changing your clinical assessment.

Dr Paterson: Perhaps. The worry about a value-based pricing approach is that companies will all set the price at £30,000, and that you might end up paying more for some drugs than you might have paid otherwise, because it is recognised that you are willing to pay that much. However, I suspect that the knowledge that the drug will be subject to an assessment process by the SMC is factored into the pricing of some drugs and results in the price of some drugs being lower than the companies would like them to be because they realise that, otherwise, it is unlikely that the £30,000 threshold will be met. Of course, it is possible that some companies might realise that they can get away with charging a bit more and still come in under the threshold. The difficulty is that the NHS has no involvement in that process at all.

Nigel Don: Thank you. I think we know where to point the guns.

The Convener: A number of you talked about the progress that is being made nationally on cancer. The petition dealt specifically with cancer, but is there any evidence that other illnesses have less resources? If someone was in a similar situation to Mike Gray, but suffered from a different illness, would they be able to secure the same sort of intervention from the SMC and others?

Dr Paterson: Absolutely. The SMC is not about cancer, cardiac disease, respiratory disease or mental illness; we are about getting the right drugs to the right patients. Therefore, we have exactly the same assessment process and criteria for

drugs for any illness. As Andrew Walker said, part of the difficulty that we have is that, often, we find ourselves comparing apples and oranges—and, sometimes, things that are much more differentiated than two sorts of fruit. However, our aim is to make the same sort of decisions, regardless of what the therapeutic area is. In other words, we should try to get the maximum benefit for the NHS's drug expenditure without being influenced by the sort of illness that someone is suffering from. People suffer symptoms of and have their lives shortened by all sorts of illness, and we should be trying to deal with the issues, irrespective of the underlying diagnosis.

The Convener: I asked this question of our previous panel, so I will ask it of you as well. What changes need to occur over the next four or five years for the situation to become better or more effective?

Dr Paterson: I hope that in four or five years' time the SMC is doing exactly what it is doing at the moment, unless we move to a value-based pricing structure, which would then automatically ensure that every drug was cost effective, because the price would be set in way that would ensure that it was possible to prove its cost effectiveness.

The case of the individual with whom the petition was concerned is in the realm of local decision making. The SMC is about making decisions for a population; the management of an individual is the responsibility of that individual's local health board. I would like there to be an improvement in the speed and transparency of those local processes, as was alluded to earlier. That would ensure that if there were exceptional circumstances that meant that SMC advice should not apply in that case, that decision would be made timeously and with as little stress to the patient as possible.

Dr Kohli: The point about data has been made. I would also want to keep the organisations and bodies that are involved in the area under constant review, so that if any streamlining is necessary, we can argue for that. We will keep a watchful eye on that.

Dr Walker: If I were in the patient's position, I would want consistency. No matter how good or bad I thought that the decision was, I would not want to feel that the health board area that I lived in was what mattered. Speed and transparency are fine, but I would like consistency on top of that, so that I would know that the same factors were being considered.

Andrew Dillon: I hope that, in five years' time, science has advanced sufficiently so that the new treatments that we are looking at will generate sufficiently substantial additional benefits for patients over current treatments that we do not have to have these arguments at all, and that any evaluation of the additional benefit that a new treatment brings is so significant that, based on a reasonable price being charged to the health system, it makes sense to use it.

The Convener: I think that we have asked the questions that we wanted to ask, so I thank the members of the panel for their participation.

We will have a five-minute comfort break.

15:41

Meeting suspended.

15:47

On resuming—

The Convener: I welcome our final panel of witnesses this afternoon. With us are Dr Marianne Nicholson, who is a consultant in clinical oncology with NHS Grampian; Dr Roelf Dijkhuizen, who is the medical director of NHS Grampian; Professor Alan Rodger, who is medical director of the Beatson oncology centre; Scott Bryson, who is a specialist in pharmaceutical public health with NHS Greater Glasgow and Clyde; Dr Frances Elliot, who is the medical director of NHS Fife; and Ewan Morrison, who is lead pharmacist at the south east Scotland cancer network.

We have a formidable panel. There are almost as many witnesses as members, so we can have an even battle. You heard some of the clear directions of travel in our discussions with the two previous panels, so we do not need to think too hard about where we will go with our questions. If you wish to raise any compelling issues now, feel free to do so. Otherwise, we will move straight to questions.

Nanette Milne: I will be consistent and ask for your opinions on area drug and therapeutics committees. We probably accept that the system works between the SMC, NICE and NHS QIS. What are your opinions on the need for those local committees and their work? Coupled with that, are the cancer networks throughout Scotland working? It was suggested at a recent meeting of the Parliament's cross-party group on cancer that a review of the networks is required because they are not working consistently—they are not all working well.

Dr Roelf Dijkhuizen (NHS Grampian): Some discussion has taken place already about the role of the local committees. Advice comes down from the SMC to local boards. When the SMC has approved a medicine, whether it goes on the formulary—the local board's record—automatically depends on the nature of the medicine. It also depends a little bit on the points that we have

already heard about, for example there might be many similar drugs on the market at the same or a lower price, it might not be considered responsible to use the drug, or the drug might not be as good as other drugs. Under those circumstances, a local committee can decide not to put a drug on the local board's formulary.

When the advice from the SMC is to turn down a drug on the basis of cost effectiveness, the board tends to follow that advice—it is as simple as that. It is not the role of the board to consider cost effectiveness—that point has been made throughout the debate, right from the start, and it is still being made. The boards subject themselves to the judgment of an expert group—the SMC—that has been brought together to consider cost effectiveness and which includes clinicians, public and patient representatives, and health economics experts. It uses, for example, QALYs—which you have heard about—to judge whether a drug is cost effective or should be turned down because it is not. Boards cannot easily consider such matters, because they are all in different circumstances—they have different budgets—and they would come to different decisions.

The local committees consider local circumstances for drugs that are marginal or that have a special local importance, such as the example that has been given of an oral drug that is more appropriate for people who live in rural areas. In that case, however, the SMC has already indicated that the drug is appropriate for patients in rural areas.

Dr Marianne Nicholson (NHS Grampian): At the sharp end, I sat with the SMC in its early days and I now accept its decisions. There have been situations in which a drug for cancer has been accepted by the SMC and the local drug and therapeutics committee has asked me whether I need the drug and want it to be added to the armamentarium. My main oncological interest is lung cancer, and on at least one occasion, because of my personal experience of a drug and its side effects, and the fact that there was an active alternative with which I was more familiar and happier, I decided not to request that our local drug and therapeutics committee add the drug to the armamentarium. That saved the committee from going through the machinations of implementing the SMC's advice. That is how individual clinicians' decisions can play a role.

I sat on the SMC and now accept its decisions. It is a super committee. It is open, transparent and organised, and it provides an opportunity to learn how lots of different specialists around a table come to a decision that is in the best interests of the people of Scotland. It provides enormous value, and its way of working just now is very good.

Professor Alan Rodger (NHS Greater Glasgow and Clyde): I strongly support the SMC, but I also strongly support the current ADTC system, particularly because of my experience in NHS Greater Glasgow and Clyde. As far as I am aware, over the past four years, four cancer drugs have been approved by the SMC—not all of them chemotherapy drugs—that our ADTC, on the advice of the clinicians who treat cancer, has agreed not to add to the formulary. Two of those drugs deal with chemotherapy-induced vomiting, but we already have access to much cheaper and very effective drugs to reduce chemotherapy-induced vomiting. However, we allow the use of drugs that are not on the formulary through the exceptional case process, which, since its introduction four years ago, has proved to be very smooth and quick. The fact is that patients are not disadvantaged. A very small number of them with particular chemotherapy regimes might benefit from such drugs, and we can build that into protocols if required.

In the case of another chemotherapy drug, breast cancer specialists at the Beatson and across the west of Scotland felt that other, more effective breast cancer drugs were available, and they decided against putting it on the formulary. However, from time to time, after exhausting every other treatment for a given patient, they can ask to use that particular drug. If it is an exceptional case, their request will be granted.

The vast majority of drugs approved by the SMC for use in the NHS go through such a process—it is, in fact, the clinicians who advise the ADTC on these matters. For example, in one case, the SMC decided not to approve a bone-strengthening drug called zoledronate that is used in the treatment of prostate cancer. I discussed the matter with clinicians who treat prostate cancer and a proposal was put before our ADTC. As Mr Bryson knows—having brought the proposal to the ADTC on behalf of the drugs and oncology group in Glasgow—the discussion was difficult, but in the end the ADTC approved the limited use of zoledronate with a very clear protocol, and patients can now receive it without having to go through an application process.

I have found the ADTC to be extremely supportive. Another, more recent, case involved a chemotherapy drug that is used in the treatment of upper gastrointestinal cancer. This was not a "me too" drug; it was an oral preparation of a drug that we already give by injection. It was suggested that we should hesitate to put this extremely expensive form of the drug on the formulary, but when it was explained that the oral form would be used to treat the same patients—after all, oral chemotherapy can be as devastatingly toxic as intravenous chemotherapy—and that administering the drug orally and not intravenously would take a

considerable load off service delivery, the ADTC was perfectly happy to allow its use. One might have wondered whether it was a sort of "me too" drug and whether we actually needed it. In fact, we are using it in the treatment of breast cancer, upper GI cancer and colorectal cancer.

I should point out that the SMC also deals with drugs that are not submitted to it. However, although the pharmaceutical industry appears to support the SMC process in its submission, it seems to hold back from submitting certain drugs on time or when the evidence is available. In such cases, the SMC often decides not to approve the drug, which can cause us considerable problems. Some drugs are probably not being submitted because they are exceedingly expensive, but in any case the industry must be pressured into supporting the whole SMC system, not just the bits that suit it.

Dr Frances Elliot (NHS Fife): I chair NHS Fife's ADTC which, I should point out, has a number of other functions apart from receiving recommendations from the SMC. In the south east Scotland cancer network area, which my colleague Ewan Morrison can say more about, NHS Fife is not involved in any of the SMC decisions on cancer drugs. Such matters are dealt with by NHS Lothian on behalf of the network boards to ensure that any cross-border delays that might affect not only Fife but Dumfries and Galloway—which also plays into the cancer network—are avoided. The ADTC's other functions relate in particular to primary care prescribing. For example, we monitor clinician compliance with the board area formulary.

Scott Bryson (NHS Greater Glasgow and Clyde): We strongly support the SMC and welcome the specialist input from the regional networks.

The ADTC has a distinctive function. Instead of second-guessing the SMC's output, we take a more pragmatic approach. As Frances Elliot made clear, the SMC's emergence means that ADTCs have a relatively minor role in considering new medicines. As the advisory committee to the NHS board, we deal, I concede, with financial planning, any service redesign that is required in the management of medicines, communication and prescriber education. Mostly, however, it is about risk management—making Scotland the safest country in the world in which to take medicines. The ADTCs have a wide-ranging role around that remit.

I am, however, hearing concerns about the lack of transparency, which we need to take on board. All our activities are in the public domain—the minutes of our meetings, our formulary decisions and our protocols—but there is clearly an issue that we need to take away from discussions such as this, to consider how we can improve our links with patient interest groups, the ABPI, cancer research networks and so forth. We can take action on that following today's discussion.

16:00

Ewan Morrison (South East Scotland Cancer Network): I want to add to what Frances Elliot said and possibly answer part of Nanette Milne's question about the cancer networks. There are four health boards in the south east Scotland cancer network. The advice from the SMC comes to NHS Lothian—the largest health board with a cancer centre—and is then adopted by the four constituent boards. The advice is adopted quickly so that there is a consistent approach across the four health boards, which is particularly useful for clinicians. The process involves considering not just the cost of drugs but the local service costs to cancer centres, such as pharmacy, medical, nursing and pathology costs. We do not just rubber stamp the SMC's guidance; we add our local advice to it and then push it out to units for use at the sharp end.

Nanette Milne: Are the cancer networks working effectively across Scotland or are there regional variations that should be looked into?

Dr Nicholson: As you probably know, the networks are often tumour dependent. For example, for rare tumours, such as hepatobiliary cancer, there is a national network rather than a regional network. The north of Scotland network deals with lung cancer and cancer research.

I chair the lung cancer network, which meets only two or three times a year. We examine the audit data, which are vital in informing us how many patients there are, who is receiving treatment and—although it has been inordinately difficult to get the information—what the outcomes have been. It can be misleading to look at any piece of information in isolation, so whichever drugs we use and however many patients we treat, we need to know the outcomes, although they are difficult to measure. One of the difficulties for the networks is getting hold of adequate audit data in a timely fashion, as the audit staff are often working on other priorities.

Professor Rodger: I think that the networks work quite well. I read the minutes of the cross-party group on cancer and noted that the clinicians from Dundee had raised questions about the networks. The north of Scotland network has a particular problem, because it has three cancer centres within it that must function as a unit. There have been difficulties in the past, but the situation is improving. I am the chair of the Scottish radiotherapy advisory group, which has been proactive in trying to help parts of the northern

network's radiotherapy service. For instance, Inverness has only one machine, and it is quite old. What would happen if it stopped working? Using the good offices of the network up there, the radiotherapy community in Scotland as a whole has drawn up a process to deal with that crisis should it arise. A similar process has been drafted for the brachytherapy facilities on the east coast. That works.

You must remember that there are two types of network—the overall regional network and, within it, the individual tumour-related networks. In the west, there are sub-groups for pharmacy, palliative care and so on, but most of the networks are tumour related. They are working better than they were; it is coming together.

I return to the issue of new drugs. Herceptin was discussed at the meeting of the American Society of Clinical Oncology in May 2005, but it was not until November of that year that the first papers on it were published. We had that lead time in which to begin to see that something was different in breast cancer, particularly for the 20 to 30 per cent of patients who could benefit from being treated with the drug early rather than at an advanced stage, which is what was happening. We had good opportunities to discuss the issues with our horizon-scanning pharmacists, who could start to work with the clinicians in the networks. That was done on a Scottish basis by the three regional networks. We discussed how many patients were likely to need the drug, what the costs would be and what sort of patients would be involved, and we were able to move forward. Certainly, we were able to introduce the use of Herceptin from November 2005 on a non-formulary, non-licence, exceptional-case basis within a clear protocol that was very close to that of the clinical trial. In fact, the SMC did not give its approval decision until the following July or August, so we were actually treating patients a little bit earlier.

Another set of breast cancer drugs is the aromatase inhibitors. In Scotland, the three breast cancer networks got together and decided to draw up a protocol for their use, because the SMC was likely to make the decision for early use much quicker than NICE. I was part of the NICE process and it was due to start on the day on which the bombs went off in London, so we did not meet that day; we met a week later.

NICE did not hand down its decision until, I think, the following September—a year and a bit later—although it had predicted that timescale, because that was its process. The SMC came up with a much quicker decision, but by that time our network people had sat down together in one place in Scotland and drawn up a protocol for the use of those drugs, and they were used early on and the boards accepted their use. Having said that, the networks have met again to modify that guidance as more information has become available. There is therefore evidence that, in many ways, the networks are working for the benefit of patients in Scotland.

Rhoda Grant: The networks look at outcomes and how drugs are working. How is that information fed back to the SMC to be disseminated to other networks?

Dr Nicholson: It is not.

Rhoda Grant: Would that not be a good idea, so that other networks could benefit from the information?

Dr Nicholson: That is outwith the SMC's current remit. The SMC is tasked with considering new drugs or new indications for drugs and judging their acceptability for the NHS in Scotland. If there is an information gap that needs to be closed in terms of the penetration of drugs to patients, it would mean a new and separate remit for the SMC or for a different organisation entirely.

Nigel Don: I would like to move on to exceptional prescribing. I am conscious that exceptional prescribing has brought us here today, but I do not want to get too close to any particular case. Are exceptional prescribing systems now effective, speedy, and transparent? To what extent are they public?

Dr Elliot: In our submission is a copy of the NHS Fife request form. The system is fairly speedy. The forms come to every ADTC meeting where a clinician feels that they have a case to bring. Occasionally, if the request is very urgent, we will circulate it to ADTC members between committee meetings so that we get a rapid response. We do not deal with cancer drugs locally; as I said, they are dealt with at regional level. In light of our experience of using the request form, we plan to modify it.

Points were made earlier about openness and transparency. Information about decisions is made available in the minutes and on our public website. However, like many of my colleagues, I acknowledge that we do not have members of the public on our ADTC. Reflecting on today's discussion, we might like to take that back to our boards so that we can consider how to improve transparency for the public and involve people in the process.

I believe that the request form works well. You will see that it asks for quite detailed information. However, as I said, the NHS Fife internal process does not take cancer drugs into account.

Ewan Morrison: I will address the SCAN perspective on exceptional circumstances. Exceptional circumstances are handled through the Edinburgh cancer centre medicines

management committee, which meets every two weeks. Proposals can come from any part of the network—from Dumfries and Galloway right up to Fife. If something is needed very quickly, the chairman can put it through, which helps with the speed of the process.

To give you a flavour of the kind of cases that arise, we recently had a patient with dementia who was on an endocrine drug therapy, and a request was made to give them a non-SMC-approved drug intravenously. The circumstances were exceptional and the case was approved. You can see from that example that the committee works across the whole of SCAN.

Dr Dijkhuizen: You will have received the NHS Grampian procedure with our written submission. Our policies are transparent in principle; minutes and policies are on the website. It is optional, rather than compulsory, for patients to attend hearings. In NHS Grampian, the clinician who requests exemption from the SMC's decision because of exceptional circumstances presents the clinical data that support the request, but the patient or their representatives are invited to attend.

There is an issue in understanding when the exceptional treatment procedure kicks in. When treatment with a drug that has been turned down by the SMC is initially being considered, it is for the treating clinician to bring the procedure into play, if they are of the opinion that the patient is different from the group of patients to whom the SMC decision refers. At that point in the process, the clinician is in a vulnerable position, because they know that the board will not fund the drug because the SMC has turned it down, but they also know that there is a procedure for exceptional circumstances. That is a difficult moment, because the clinician has to discuss the situation with the patient. Another issue that comes into play is the option for the patient to go private and fund the treatment themselves, if their case is turned down as not being exceptional. There is a lot of pressure on everybody involved at that point in the system.

Nigel Don: I am concerned about speed. I come from an industrial background, as you may have appreciated. During my industrial career, if I had to make a decision in a hurry, my relationship with my boss enabled me to get his approval to do what I wanted to do, and it was done within hours. It was more to do with communication than the substance of the decision. Fundamentally, it was about whether he trusted my judgment.

We heard earlier that the individual consultant appraises the data. I have every respect for that; I am sure that we expect consultants to be able to examine data, because they are trained to do so. However, if that is the clinical judgment process, why does it take a significant period of time for the administrative system—whatever that may be—to decide whether that judgment can be implemented? Who has to reappraise what the consultant says, and why does that take any time? We are talking about cancer treatment, in which two weeks is a long time.

Dr Dijkhuizen: It is certainly incumbent on the organisation to limit, as far as possible, the amount of time that is involved, but the organisation must have a process to involve various people, including clinicians, in making judgments. That is part of the transparency that we have discussed. We are talking about providing equity of access to cancer treatments for patients in Scotland. If we leave such judgments purely to individuals, we have no guarantee whatsoever that there is equity of access to treatments. We need some kind of transparent process to confirm the assessment.

Others might confirm this point about the timeline. When a clinician sees a patient, the clinician knows—although they might not be sure—whether the patient is a candidate for exceptional treatment under the local guidelines. The clinician knows the patient well, so deciding whether the patient should apply for exceptional treatment is actually a very quick process.

After the initial decision, we do everything that we can to get a panel together within a week or two to consider the request. We strive to ensure that a week or two is the maximum time.

16:15

Nigel Don: Is it wholly unreasonable to suggest that two days is different from two weeks, and that two days would be better?

Dr Dijkhuizen: Two days would be better, but getting the data together for consideration at the meeting tends to take more than two days.

Nigel Don: I understand.

Scott Bryson: I would like to reassure the committee. I support my colleagues' comments about getting the balance right, but, at the risk of becoming anecdotal, I will describe a recent, very difficult case in Glasgow that was outwith the field of cancer. A small child was seriously ill with a rare disease and was treated with an orphan medicine. We were able to put the review case together and deal with it within 48 hours. If the circumstances dictate, NHS boards can be responsive. Different boards have different systems, but we all adopt the same principles. On this occasion, it worked in the patient's interest.

Professor Rodger: When I took up my post in Glasgow about five years ago, I could see no formal process in the Beatson. I felt that being phoned in the corridor by someone asking for a

particular drug for patient X was not the best process. We therefore developed a process, which has continued to be developed and is now the regional process. I do not take decisions on the entire region—different processes exist across the region—but we use basically the same form.

We use our experience and ask, "What information do we require?" We try to move as fast as possible, which is why requests in the Beatson come to my desk in the first instance if a drug is non-licensed and is not on the formulary. Those are the two criteria—it does not matter whether the drug has been approved or not by the SMC. That applies to all drugs. If the situation is urgent, my BlackBerry goes off and the details come to me. If I am not around, other people are there as back-up.

We ask for certain information; obviously, it is clinical information. We encourage the clinicians to give as much information as they can about the patient, the disease and the evidence for the treatment. We ask about previous treatments and—very importantly—what treatment would be given if the product being requested were not available, and we ask what would be done if the product were declined. The clinician then gets an answer, yes or no. If it is no, they get an explanation so that they can explain the decision to the patient. The clinician also knows that there is an appeal process. To my knowledge, we have not had an appeal in the system, although people have asked questions and we have received a number of letters, from MSPs, MPs and all sorts of people. We try to be fair and to deal with cases as quickly as possible. If there were a need to go through the appeal process, it would happen as expeditiously as possible.

I am sometimes asked for drugs for patients in the bone marrow transplant unit when they are actually dying of the side effects of the transplant process. They might need an antifungal agent that is not licensed and may be toxic, and the clinician will get an answer within hours of their putting pen to paper or sending an e-mail. They will get a decision as soon as the request gets to my desk, or, if I am away, the request will be passed on.

We move quickly. The idea that every cancer decision has to be implemented within two weeks is not correct. For most patients who need chemotherapeutic changes for advanced cancer, one or two weeks is not usually critical, but if a patient is already in organ failure and might be plucked back by some drug, they will get it very promptly.

Ewan Morrison: The Edinburgh cancer centre medicines management committee is a committee of clinicians' peers. Although individual clinicians make decisions about exceptional circumstances, a committee of their peers decides whether those decisions are reasonable. After that committee has met, the process is the same as that which Alan Rodger described for emergency situations, and there is instantaneous feedback to the clinicians by both phone and electronic means. As Alan Rodger said, the timescale is very short.

Nigel Don: I am reassured by your comments. Maybe one of the issues is a lack of understanding in the media about appropriate timescales. That is not something that I choose to judge, but if we can improve the public's expectations and understanding it might help the whole process.

Dr Dijkhuizen: However, in a life-threatening situation in which a decision must be made in 30 minutes or a few hours, such a process cannot be followed. There will always be decisions that have to be made on the spot, responsibility for which goes up the medical line management structure. We have to make such decisions occasionally, as we cannot get people together and get data on the table in a matter of hours. When it is clinically indicated, decisions are often made on the basis of thin evidence and short communications between clinicians and their senior managers.

Dr Nicholson: It is always much easier and faster to say yes than it is to say no. That is why it is essential to have the documentation and the core quorate group to make the decision, which can take time to arrange.

Robin Harper (Lothians) (Green): I am trying to clarify in my mind what I have heard this afternoon. I understand what you have said about the work of the SMC, the regional groups and the boards. By the time you have finished your consideration of a drug and it comes down to clinicians' choice from the drugs that are available, cost effectiveness is no longer an issue because it has been dealt with at a higher level, but in exceptional circumstances there could be drugs the cost effectiveness of which has not been fully tested. Is that correct?

Dr Nicholson: Yes.

Dr Dijkhuizen: Yes.

Robin Harper: When you have a committee meeting under exceptional circumstances, would cost be a consideration, despite the recommendation of a clinician who is used to making decisions without having to consider costs?

Dr Nicholson: That is a very good question. At that point, if a clinician makes a submission as an exceptional circumstance, they will be convinced that it is more likely that the patient will gain benefit. The clinician will appreciate the fact that there is a cost implication but, because we are advocates for our patients, if we believe that there are extenuating circumstances—whether or not

they are identified from a particular feature of the patient's tumour on the biopsy—we will want to make that case strongly while acknowledging that the drug is likely to fail the cost-effectiveness evaluation.

Professor Rodger: Cost does not usually come into our consideration. In first-round applications for non-formulary, non-licensed drugs, I see the cost of the drug on the form less than 10 per cent of the time. Clinicians usually do not bother to ask the pharmacists, although they are encouraged to do so. The decision is driven not by the cost of the drug, but by the clinical judgment in a particular patient's situation.

There are some drugs—including one that we are considering carefully in Glasgow at the moment—for which the cost will be £250,000 per patient per year. Clearly, that needs a higher level of discussion, but for the vast majority of the drugs that I deal with in the Beatson, the issue is not the cost but the clinical effectiveness of a drug that is never going to be licensed, that has been refused a licence or that has not been approved by the SMC.

Robin Harper: Do you agree with the comment that the availability of data right across the board and the speed of decisions could be improved? I totally accept your reasons for spending longer on certain decisions, but you can take some quite swift decisions where it is sensible to do so.

Scott Bryson: I will certainly add my weight to the emerging consensus about the importance of data. Indeed, the current deficit has been recognised at the highest level, and NHS National Services Scotland information services division is working on the hospital medicines utilisation database, the initial focus of which will be cancer and antimicrobial medicines. I expect genuine progress to be made on this issue within this calendar year. That can only be to the advantage of the NHS, the specialist networks and individual patients.

Professor Rodger: I would welcome the ability to produce better data. For a start, it would allow us to avoid using data from the Association of the British Pharmaceutical Industry, which simply delves into what it has sold and tries to illustrate through demographics that one area is underutilising its products.

For example, the association maintained that there was a disparity in the use of Herceptin in Scotland. Indeed, it pointed the finger at the west of Scotland, which particularly aggrieved me, given that, with the full agreement of the four health boards in the area, we had introduced the drug to a larger group of patients earlier than any other part of the UK. The west of Scotland cancer network has completed a very careful audit of its use to find out whether the women who should have received the drug have done so; if not, why not; and whether women did not receive it because of other core morbidities. For example, its use is limited in patients with heart disease. The audit concluded that those who should and could be getting Herceptin as an adjuvant in early breast cancer have indeed been doing so, and it is important that that should continue.

As far as non-formulary drugs are concerned, we collect data on what has been applied for and what the results have been. We have wonderful people called pharmacists who act as our gatekeepers and police officers and tell us when unlicensed drugs might be in use. Although overworked, they, too, try to produce data, and we have tried to develop the practice of going back to them and asking what has happened to patients on drugs that we have either approved or not approved. Because there are not enough pharmacy staff, we have been unable to complete that part of the audit track, but that is what we want to do.

Ewan Morrison: At the moment, we use very broad information, but we want micro-level information that tells us, for example, which cancer niche prescribers are using the drugs for and lets us follow the process to see whether we are getting the full effect of the drug for the money that we are spending. It would be good if we were able to support the NHS in that manner.

Robin Harper: Can pressure from the pharmaceutical industry and, indeed, from your own system result in cancer drugs being wasted? Has anyone, for instance, suddenly become keen on a drug, which might have led to overbuying?

16:30

Professor Rodger: We do everything possible to save money. For instance, if possible, we run clinics that are purely for Herceptin, which means that if part, but not all, of a vial is used, the rest can be put into the next syringe for the next patient. That can be done with drugs that must be made up on the spot rather than bought in syringes, which is sometimes another way of saving money. However, that approach means that it may not be possible to deliver Herceptin in every local chemist shop, as some people think it is dead easy to do. We have saved an enormous amount of money by centralising some of our Herceptin clinics in Glasgow. We have also ensured that we have many clinics outside Glasgow. To start with, all the other health boards with which we work, apart from one, had difficulty delivering Herceptin, because they needed extra staff, but we now deliver it in each of those health boards, at least in one centre and sometimes in two. We try to save money.

When an oral chemotherapy drug came along that could replace an injectable form, the ADTC asked whether we were overusing drugs and might throw the new drug at patients who would not be suitable for treatment with the intravenous form. I can say without a shadow of a doubt that our clinicians would not offer that drug to patients who were not fit for the treatment. The patient's performance status or full clinical status is crucial. Clinicians would not say, "Oh, this is easy—take a tablet, dear." In fact, oral chemotherapy is a cause for concern in England at present but, fortunately, in Scotland we have a Health Department letter from 2005 that gives clear guidance on the safe delivery of chemotherapy. No such guidance exists in England. I do not know about my colleagues on other boards, but we found that guidance extremely useful in ensuring increased safety and efficacy. It requires clinical protocols to be in place and there must be justification. The process is very good. That letter is one of the better ones that have come from the department—another letter was alluded to earlier.

Dr Nicholson: Robin Harper is right, but I want to go beneath his question and talk about the relationship with pharmaceutical companies. In oncology, we do a lot of clinical trials because we generate an evidence base. Many of the trials are sponsored by pharmaceutical companies, so that we have access to new drugs, but I remain convinced that those companies do not have enough influence on individual clinicians to alter what they would normally do—we still have our patients' interests at the heart of what we do.

Rhoda Grant: I want to move on to top-up payments, or public and private payments. One issue that was behind petition PE1108 was that, when the drug concerned was not available on the NHS, the whole treatment became private. Is that not wrong? When we dug down into the figures, we realised that the cost of the drug was small compared with the cost of the full treatment. Surely a person could receive most of their treatment free and pay for the drug that is not funded, rather than for the whole treatment. That could make a big difference to the number of people who are able access such drugs.

Dr Dijkhuizen: I was fairly closely involved in the case to which you refer. I agree that the situation is uncomfortable. Ironically, it is evident that cost did not drive the issues, because the drug was not all that expensive. We would appreciate more clarity on mixing private and NHS treatment. We have tried to obtain clarity on that, but we are not getting it. We are left having to judge, case by case, whether the mix of private and public funding should apply. One particular problem is that we often cannot hand a patient over to the private sector because in many centres the private sector is not big enough to take them. NHS Grampian would want to keep everything under one hat for that purpose because it is not practically possible to make the separation in the way the health department letter suggests—we have difficulty with it because it places us in the uncomfortable position of having to make judgments on a case-by-case basis.

We hope to avoid the patient having to top up everything, and not just the drug, but there is the risk that our board's position of wanting to avoid such situations as much as possible is different from the position of another NHS board, which might take the view that if part of a treatment is the delivery of an unfunded drug, the whole treatment or whole delivery of the drug should be private. Everybody will have different opinions about that, so it would be helpful to have a national position on it from the health department.

Rhoda Grant: As Nanette Milne said to a different panel, we have all seen the Health Department letter that states that there is no legal status for withholding NHS funding for one part of a treatment, but it also states that you should not be able to access co-funding. That is confusing. Do you envisage any problems with co-funding? I suppose that an obvious one is that co-funding can still produce inequality because some people might not be able to afford the drug, far less the rest of the treatment. Can the panel see ways of getting round such problems?

Dr Dijkhuizen: Many matters will need to be thought through in detail, particularly where responsibility for the delivery of the various aspects of treatment lies. The question is who, in the end, is responsible for the treatment. Clarity on that point is needed. The governance aspect is important.

The principle of equity of access should be upheld as much as possible, given that we cannot achieve complete equity of access in the present circumstances. The simple reason for that is that, even in the exceptional circumstances debate, it is possible for someone to fund their own treatment up to a point. If you are the one in 100 or 1,000 who would respond to the treatment favourably, your clinician could ask for exceptional treatment, but someone can get to that position only through funding the treatment privately. I cannot envisage an easy solution for that inequity; not even the HDL can help us with that. However, the HDL can help us to consider carefully how, in the delivery of cancer treatment, we can combine the privately funded part with the NHS-funded part in a meaningful and fair way, ensuring that there is as much equity of access as possible in the circumstances.

Professor Rodger: The situation is a moral, ethical and logistical nightmare and minefield. For example, it is possible to argue that the health

service should provide the antibiotics for someone who is getting private treatment for, say, having their bunions removed, because they would get the antibiotics anyway. That is the silly side of the coin. Petition PE1108 is about a drug that is not particularly expensive, as has been said, but drugs that are not on the formulary because the SMC has said that they should not be used in NHS Scotland can be horrendously expensive—we are talking not about a few hundred pounds but about several thousand pounds. The question is what type of treatments we should consider.

Should someone who can afford medical insurance be able to get certain treatments privately and the rest from the NHS? Someone who has no insurance or private resources would never be able to access that treatment in the same circumstances. I know of a case in which someone's insurance company was prepared to pay for quite an expensive drug that the SMC said is not recommended for use in NHS Scotland, but the company paid for the drug for only one year, so the request at the end of the year was that we consider it as a non-formulary, exceptional case—the exception being that, through their insurance, the person could afford to pay for the drug for a year. The issue is why the insurance company would not continue to pay for the drug. This is a huge and difficult issue, and there needs to be clarity on it. Unfortunately, the CMO's letter is not only not clear on that point, it is utterly confusing. A number of us have raised the issue. In Glasgow, three of us sat down together to try to thrash it out and assess what it means practically.

Then there is the clinical governance issue. Someone might get three drugs through the NHS and one through the private sector. They might all have to go in through an intravenous line. That costs money. The NHS would put in the line. If it got infected, would it be the NHS's responsibility or the private sector's responsibility? If the patient became severely ill as a result of the combination of drugs, would they go into the private sector because it was the expensive, non-approved drug that caused the trouble? It might not have been the expensive drug that caused the trouble. How do you work that out? I can tell you that, in such circumstances, the patient would come straight back into the NHS under "unscheduled care". There might be two clinicians: one in the private sector delivering one drug, the other in the NHS delivering three drugs. That is not good clinical care. It is a recipe for disaster. All that has to be worked through carefully. There has to be a degree more clarity than we got in the letter from the department.

The Convener: That is fairly candid. Are there any examples of people co-funding elsewhere in Europe? Does it work?

Professor Rodger: I do not know of any examples in Europe. In Australia, they have a peculiar mixed health-care system where the federal Government underpins private care and the state Governments pay for public care. There is a fair bit of moving back and forward between the two. The average Australian spends 800 Australian dollars, which is about £400, each year on health care, through private insurance or prescription charges—their charges even for subsidised drugs are slightly higher. There is a rather mixed economy. We are about to see changes in England, where people are being paid not by results but by what they do in cancer, such as delivering x-ray treatments and chemotherapy. Of course, there is then more pressure to utilise the private sector. It will be interesting to see what happens there, as we have heard from the representatives of CR UK.

Dr Nicholson: I have frequently talked to patients who are facing their mortality and are therefore desperate for something to be done. They ask me whether it would be different if they were paying for treatment. I can tell them hand on heart that it would make no difference at all if they were paying, because no treatment is guaranteed to work and no treatment would not have side effects. I would therefore say that the clinical judgment is that it is better to go for quality of life without any specific anti-cancer treatment than to pull something from the cupboard so that I can feel like a god in a white coat.

Communication between the clinician and the patient needs to be carefully managed, without being muddied by the joint approach between public and private funding. Although it is essential that the debate starts and we have guidance, we have to keep in mind that these people are desperate and will do everything they can to access a drug, even if it has a very small chance of providing any clinical benefit.

Rhoda Grant: In Michael Gray's case, it appears to me that the clinician said that there would be a benefit in using the drug. A clinician might say that there would be a benefit in using a drug, but the health board might not fund it. It does not always seem to come down to the clinician's decision about what is in the best interests of their patient—others seem to be making the decisions. The process does not appear to be open and transparent. If it is your life and you cannot understand why someone is withholding the treatment, that makes a bad situation much worse.

Dr Dijkhuizen: I played with the idea of bringing the clinician who was involved in this patient pathway to the committee to answer your question, but I understood that the issues are wider and that we did not want to talk only about Michael Gray's case. The clinician is aware of the

funding situation and that he and his peers are involved in the SMC decision-making process. The SMC's turning the drug down was not a controversial issue with the clinician who treated the patient. The clinician was completely aware of and in agreement with the SMC decision. The clinician was also of the opinion that no exceptional circumstances allowed the patient's case to be brought to the board. That has never come out in discussion afterwards, but that was the situation.

I have said before that clinicians are in a very difficult situation with patients who are keen to have treatment because of the predicament that they are in. Handling such conversations is not easy. We have had confusion on the pathway because when the clinician said that although he knew that NHS Scotland did not fund the treatment he would write to ask for the position to be confirmed, we went a bit off the rails—in fact, more than a bit, because what happened had quite an effect on the patient, given his circumstances. We did not respond swiftly, in writing, to that written request; we sent a local pharmacist to ask the clinician why the letter had been sent and the clinician said that it was because he wanted confirmation. At that point, we thought that the conversation between the pharmacist and the clinician would provide the confirmation, but the expectation was still that a letter would follow. We made quite an awful communication error—we did not keep the patient in the loop of what was going on. We failed on that and we discussed that with the patient. We said that we were sorry about that.

The process was never that the clinician thought that something needed to be done but that the health board said, "No, you can't do that." I have now described the situation in too much detail, but that was what happened.

16:45

Rhoda Grant: You are saying that if the clinician had said, "This is the best treatment for my patient," the health board would have approved it.

Dr Dijkhuizen: If the clinician had said that the patient's circumstances were different from those in the SMC decision-making process, we would have started the exceptional treatment process and tried to keep it to one or two weeks, but the clinician did not hold that opinion.

Rhoda Grant: We come back to somebody funding treatment privately to prove the case for it—to prove the benefit and that they are an exception—because that is the only way they can do it in some circumstances.

Dr Dijkhuizen: That is the dilemma that has arisen from the situation.

The Convener: Much of what you have said is in the written evidence and the letters between you and the committee, so that has been confirmed, in a sense. The issue is difficult and sensitive. Our inquiry was precipitated by a particular case, your role in which has been contested gently today, that might highlight a general issue.

There are three issues on which I would benefit from having clarity. Have national guidelines been issued on the staffing and health board framework for the structures for the exceptional circumstances process? If not, should they be, to ensure transparency?

I have a more philosophical point. I understand the position that Professor Rodger, other witnesses today and previous witnesses have taken. We had a perverse situation. The individual who came to the committee believed in the collectivist provision of the health service. I do not know his politics, but I presume that he believed in the idea of taxation to pay for the public health service. He was concerned that, because of his circumstances, he had to use his own money to get a private element of treatment, which then militated against other treatment from the public health service. As he said twice at the committee and through submissions, he would have been happy to have the NHS; he wanted it to meet his need in his darkest moments.

I am trying to get a sense of what you do when you have a CMO letter that lacks clarity on how to address that dilemma. It would be helpful if you would tell me about the exceptional circumstances structure. Is there a national framework for it? How do we deal with that individual's concern? It was not that he had a bit of cash about him and felt that he was entitled to buy his way through the medical process, which is the normal assumption about private money and inequity in the health service.

Dr Dijkhuizen: There is a guideline that boards need to have an exceptional circumstances route in place but, as far as I am aware, there is no diktat on how exceptional circumstances boards should be configured—on who should be members of such a board or the timescale in which it should come to its decisions—so we put our own system together by going through the literature and seeing how other health care systems had handled similar situations. That is how we configured ours in NHS Grampian, but perhaps other witnesses have further information on how they constituted their boards to consider exceptional treatment requests.

Scott Bryson: I support the observation that there is no national directive. I understand the background to the question. Thinking about the logistics of it and the scale of variation across

individual NHS boards from NHS Greater Glasgow and Clyde, which serves the needs of a quarter of the population, through to some of the island boards, I wonder whether a one-size-fits-all approach would be appropriate for exceptional circumstances. Reflecting on earlier comments about the need for individual boards to show responsiveness and act promptly in exceptional circumstances, I do not see immediately how a single structure could suit every eventuality.

Ewan Morrison: That is certainly the case within SCAN as well. The purpose of our committee is to support the SCAN network. It provides expertise and a speedy turnaround of the advice for that group. I am not aware of any documentation or legislation that covers who is on it, but it provides a peer-reviewed group that examines the clinician's submission.

Angela Constance: I have a broad question for the clinicians on the panel. Will they say something about their experience over the years of patients having, for whatever reason, opted to fund their medicine privately? Is it rare? Is it exceptional? Is it becoming more common? Has the patient opted to do it or have they felt compelled to do it?

Dr Nicholson: I have been a consultant in Aberdeen for 14 years. It is the oil capital of Europe and we have many people who are privately insured. When they come to me to ask whether they can go private, I usually tell them that they will have the same treatment from the same clinician in the same team without any inordinate delays in accessing it and that the only benefit to them of going private may be that we will try to get them a single room if they come in for chemotherapy, but it is not guaranteed, and that the hospital will be refunded for the cost of their drugs. Most of them then decide to stick with the NHS.

I trained in London, where many more patients were privately insured. It was a different ball park there—drugs that were not available on the NHS could be accessed privately—but we have caught up. As a result of the work of bodies such as the SMC in Scotland, we are fortunate in having access to the majority of drugs that we need to deliver the best evidence-based care.

Professor Rodger: There is really no private practice in the Beatson. There are private hospitals that deliver chemotherapy and consultations, but the people who use those services are insured and want to make use of their insurance. They will see a particular consultant. Only a very small number of people do private practice. It is possible for someone to be treated for breast cancer, for example, in the private sector but not by one of the breast team at the Beatson. The same applies to other diseases. There is quite a small amount of private practice.

Patients have certainly asked me about private treatment. I have had similar discussions in Edinburgh, where I worked for many years. I had a private practice in Edinburgh. The majority of patients were quite content with the health service, as they would have got no additional benefit from being a private patient—they could not queue jump or anything like that. They got the same treatment and saw the same people. However, some people prefer to go to a private hospital to have their chemotherapy, because they feel that such hospitals are more comfortable. That said, there is not a huge private practice.

The Convener: Members have no other questions. We have gone over the core areas that we needed to address.

I genuinely thank our witnesses. I hope that the session, which has been lengthy, has been of benefit to us all. I recognise the difficult circumstances surrounding the meeting and thank NHS Grampian for being willing to confront some of the issues. Let us hope that we can make progress on the issues that have been raised.

I wish our witnesses a safe journey.

New Petitions (Notification)

16:57

The Convener: Agenda item 2 is notification of new petitions. Do members have any comments to make? Should we simply note the new petitions?

John Farquhar Munro (Ross, Skye and Inverness West) (LD): We should.

The Convener: Okay. Thank you.

Mainstreaming Equal Opportunities

16:57

The Convener: Agenda item 3 is consideration of a paper from the clerk on mainstreaming equalities in the work of the Scottish Parliament.

We have received a letter from the convener of the Standards, Procedures and Public Appointments Committee that asks for our views on formally reporting on mainstreaming equalities. Do members have any comments to make?

Nanette Milne: I think that the current system has worked satisfactorily.

The Convener: I do not have any problems with the recommendation in the paper. Are members content to continue with the existing arrangement of publishing an annual equalities report? I think that that would be expected of all the Parliament's committees. Should the production and publication of that report be formalised through a rule change in the standing orders?

Nanette Milne: Is that necessary?

The Convener: That is for the committee to determine. Do members have any strong views on the matter one way or t'other?

Rhoda Grant: We discussed what approach should be taken in the Health and Sport Committee and decided that committees should be asked to publish a report. If they did not comply with that request, perhaps a formal rule change could be considered, but we thought that that should not be done immediately. Rather, we thought that committees should be given the chance to comply voluntarily.

The Convener: Okay. So there should be autonomy for the committees. We do not wish the production of equalities reports to be formalised, but we will produce them as a matter of practice. I will prepare an appropriate letter to the convener of the Standards, Procedures and Public Appointments Committee.

Commonwealth Games 2014 (Consultation)

16:59

The Convener: Agenda item 4 is consideration of a paper from the clerk on the Scottish Government's consultation on the 2014 Commonwealth games.

Stage 3 consideration of the Glasgow Commonwealth Games Bill will take place in the Parliament tomorrow, but the Government is consulting on a lasting legacy for Scotland from the games. Members have a copy of a draft response to the letter from the Cabinet Secretary for Health and Wellbeing that we could send. I think that she sent a letter to all the committees. Policy committees will have a much clearer perspective on the matter.

This week's Audit Scotland report affirms the existence of issues that petitions have raised to do with the infrastructure challenges that Scotland faces and the broader problem of community-based sports development and participation. The two big issues are infrastructure investment and participation. I think that our draft letter is an appropriate response.

I now close the meeting.

Meeting closed at 17:00.

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