HEALTH COMMITTEE

Tuesday 20 June 2006

Session 2

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HEALTH COMMITTEE
16th Meeting 2006, Session 2

CONVENER

*Roseanna Cunningham (Perth) (SNP)

DEPUTY CONVENER

*Janis Hughes (Glasgow Rutherglen) (Lab)

COMMITTEE MEMBERS

*Helen Eadie (Dunfermline East) (Lab)
*Kate Maclean (Dundee West) (Lab)
*Mr Duncan McNeil (Greenock and Inverclyde) (Lab)
*Mrs Nanette Milne (North East Scotland) (Con)
*Shona Robison (Dundee East) (SNP)
*Euan Robson (Roxburgh and Berwickshire) (LD)
*Dr Jean Turner (Strathkelvin and Bearsden) (Ind)

COMMITTEE SUBSTITUTES

Mr Kenneth Macintosh (Eastwood) (Lab)
Mr Stewart Maxwell (West of Scotland) (SNP)
Margaret Smith (Edinburgh West) (LD)

*attended

THE FOLLOWING ALSO ATTENDED:

Lewis Macdonald (Deputy Minister for Health and Community Care)

THE FOLLOWING GAVE EVIDENCE:

Dr Jennifer Bennison (Royal College of General Practitioners Scotland)
Jim Eadie (Association of the British Pharmaceutical Industry Scotland)
Mark Hazelwood (Multiple Sclerosis Society Scotland)
Dr Caroline Hind (Grampian NHS Board)
Clara Mackay (Breast Cancer Care Scotland)
Bill Scott (Scottish Executive Health Department)
Dr David Steel (NHS Quality Improvement Scotland)
Angela Timoney (Royal Pharmaceutical Society Scottish Department)
Dr Iain Wallace (Greater Glasgow and Clyde NHS Board)
Professor David Webb (Scottish Medicines Consortium)

CLERKS TO THE COMMITTEE

Lynn Tullis
Simon Watkins

SENIOR ASSISTANT CLERK

Graeme Elliott

ASSISTANT CLERK

David Simpson

LOCATION

Committee Room 1

Scottish Parliament

Health Committee

Tuesday 20 June 2006

[THE CONVENER *opened the meeting at 14:00*]

Items in Private

The Convener (Roseanna Cunningham): Good afternoon, everybody. We will deal with item 1 quickly. I ask the committee to agree to consider items 6, 7 and 8 in private. In the past, it has been our practice to take such items in private. Is the committee agreed?

Members *indicated agreement*.

The Convener: Thank you.

Subordinate Legislation

Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (draft)

14:01

The Convener: The committee is asked to consider an affirmative instrument: the draft Human Organ and Tissue Live Transplants (Scotland) Regulations 2006. I welcome the Deputy Minister for Health and Community Care and his officials; the minister is accompanied by Colin Cook from the Scottish Executive Health Department and Joanna Keating from the office of the solicitor to the Scottish Executive.

As stated in the committee papers, the Subordinate Legislation Committee considered the instrument and made no comment. Does any member wish to seek clarification of the instrument from the minister?

Members: No.

The Convener: Does any member wish to debate the instrument?

Members: No.

The Convener: I invite the minister to move motion S2M-4476.

Motion moved,

That the Health Committee recommends that the draft Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 be approved.—[*Lewis Macdonald*.]

Motion agreed to.

The Convener: Thank you. That was perhaps not your most onerous duty today, minister.

Regulation of Care (Applications and Provision of Advice) (Scotland) Amendment Order 2006 (SSI 2006/272)

Regulation of Care (Fees) (Scotland) Amendment Order 2006 (SSI 2006/273)

Regulation of Care (Requirements as to Care Services) (Scotland) Amendment Regulations 2006 (SSI 2006/274)

The Convener: Item 3 is consideration of three negative instruments. The Subordinate Legislation Committee drew our attention to aspects of the drafting of SSI 2006/272, but it does not believe that they affect the validity of the instrument. No issues were raised on SSI 2006/273 and SSI 2006/274. I have received no comments from members and no motions to annul have been lodged. Are we agreed that the committee does

not wish to make any recommendation in relation to the instruments?

Members *indicated agreement*.

The Convener: I suspend the meeting for a couple of minutes so that we can get the witnesses to the table for item 4.

14:02

Meeting suspended.

14:03

On resuming—

National Health Service Drugs Inquiry

The Convener: Item 4 is evidence taking on the licensing and prescribing of national health service drugs in Scotland. This is the third in a series of single-session inquiries that we are holding this year. Members have a briefing paper from the Scottish Parliament information centre.

We will take evidence in two parts. First, we have a panel session with those bodies that are involved in the licensing of new drugs in the NHS in Scotland, those who produce guidance on the use of new drugs, and those who implement that guidance. After half an hour, we will invite representatives of pharmaceutical bodies and patient groups to join the panel and participate in a round-table discussion on the issues that were raised in the first session and on a number of other issues, including the cost and availability of drugs, access to new drugs in Scotland, and the problems associated with guidance on the use of drugs in Scotland. At present, the guidance that is issued by the National Institute for Health and Clinical Excellence in England is then tailored by NHS Quality Improvement Scotland.

I welcome the participants who form the panel for the first session. They are Jim Eadie from the Association of the British Pharmaceutical Industry Scotland; Professor David Webb from the Scottish medicines consortium; Dr David Steel from NHS Quality Improvement Scotland; Dr Caroline Hind from Grampian NHS Board; and Dr Iain Wallace from Greater Glasgow and Clyde NHS Board.

My list also includes a Dr Jennifer Bennison from the Royal College of General Practitioners Scotland.

Dr Jennifer Bennison (Royal College of General Practitioners Scotland): I am here.

The Convener: I am sorry—the light is shining on your nameplate.

The Medicines and Healthcare products Regulatory Agency was invited to send a representative to the meeting but, unfortunately, was unable to do so. As I said, we will be joined by others for the round-table discussion.

The witnesses whom I have just named have been briefed to speak for a maximum of two minutes. Because time is tight, I hope that two minutes is the maximum that each of you will take.

Jim Eadie (Association of the British Pharmaceutical Industry Scotland): The Association of the British Pharmaceutical Industry represents 75 companies in the United Kingdom that research, manufacture and supply 80 per cent of the medicines that the national health service prescribes. However, before a medicine can be marketed in the UK, the pharmaceutical company has to submit a marketing authorisation application to the UK or European regulator. The Medicines and Healthcare products Regulatory Agency closely scrutinises all the evidence, including data on quality, safety and efficacy, that companies are obliged to place before it. The average submission for a new medicine consists of several hundred volumes of technical and scientific reports and data. During the process, the company will explain the data, provide clarifications and answer questions on the scientific evidence.

However, the granting of marketing approval for a medicine marks the beginning of a legal obligation on the applicant company to provide the MHRA with information both at regular intervals and on an ad hoc basis throughout the lifetime of the medicine. The benefit risk assessment of a medicine is a continuous process.

The pharmaceutical industry is committed to ensuring equitable access to clinical and cost-effective treatments and to achieving faster uptake of new innovative technologies through partnership and constructive engagement. The industry's contribution to the assessment process is vital to the production of robust, evidence-based guidance from the Scottish medicines consortium and NICE. Since its inception, the SMC has closely involved the pharmaceutical industry and the ABPI in its operation and development, and the ABPI welcomes such an important working relationship. However, under the SMC's robust process, other factors now affect the decision on whether a patient receives a new medicine, including the consideration of local issues by the area drug and therapeutics committees, which reserve the right to reject or accept SMC advice.

Dr Bennison: I speak on behalf of the Royal College of General Practitioners, which is the largest organisation for general practitioners in the UK. I consulted as many members as I could on this matter in the relatively short time that was available and the key point is that I could not find a single case of a GP who felt that he or she was unable to prescribe suitable and appropriate drugs to a patient.

In Scotland, a range of advice sources is available to deal with difficult prescribing decisions, although the number of such sources varies depending on the area. Some practices have their own pharmacist; some have access to a locality-based pharmacist; and others use health board-based prescribing advisers. However, in general, GPs in Scotland are happy with the advice that is available.

Good local arrangements are usually in place for on-going prescriptions of costly drugs, which must be initiated by hospital colleagues, and GPs welcome those shared care protocols. Case mix is also a very important factor in prescribing, and nearly all the variation in GP drug spending can be accounted for—and, indeed, is justified by—differing populations. I should also point out that there are special arrangements to exclude from a practice's budget any unusually expensive drugs that, if prescribed, might adversely affect or skew it. In Lothian, we have local arrangements to evaluate and give GPs advice on unlicensed and off-label prescribing, which is more frequent than most people realise.

We welcome the expanding role of pharmacists, who now deal with minor ailments, and instalment and repeat dispensing. The college sees pharmacists as a well-educated and valuable resource, but there are limitations to do with information technology, the lack of a single record and the fact that most pharmacies lack private consulting rooms.

There are incentives for good, evidence-based prescribing, but no real costs for practices for prescribing that is less than ideal. Community health partnerships in Lothian are actively to manage prescribing budgets this year with incentives that will bring resource benefits to CHPs and practitioners.

Professor David Webb (Scottish Medicines Consortium): I speak on behalf of the Scottish medicines consortium, which is a group brought together by the NHS board area drug and therapeutics committees, to which we are responsible. We aim to provide a single source of timely advice for NHS boards on new drugs, using decisions that have been made in Scotland by Scottish health professionals.

The aim is to provide advice to the health service about all new medicines, all new formulations of existing medicines and any major new indications for existing medicines as soon as possible after a drug is launched, when it gets an approval and licence from the MHRA. Doing that at around the time that a drug is launched means that all the information about the drug is with the pharmaceutical industry. We receive submissions from the pharmaceutical industry, many of which are ABPI companies. We assess the drug to see whether it is clinically effective and cost effective, which means whether it provides value for money for the NHS in Scotland.

We do not consider safety; the MHRA does that, as well as considering efficacy in clinical trials. Once the MHRA has decided that a drug is safe enough, given its efficacy in relation to a particular condition, it will give it a licence. We would let the NHS in Scotland know as soon as possible after that whether the drug is appropriate for use in Scotland.

The members of the SMC include physicians, pharmacists and health economists who have an interest in and knowledge of new drugs. They also include ABPI members, as we have heard, trust finance officers and chief executives of the boards, including Tom Divers from NHS Greater Glasgow and James Barbour from NHS Lothian. We believe that we have strong support from doctors and other prescribers as well as from the NHS boards. We know from our website that we have received a lot of interest from overseas. Recently, NICE has changed its process to start to look at drugs early after launch, which mirrors the process that we have been following in Scotland for the past four years.

Dr David Steel (NHS Quality Improvement Scotland): NHS QIS exists to improve the quality of care and treatment delivered by the health service so as to promote better outcomes for patients and a better experience for patients and carers. To do that, we have five key functions. We issue advice and guidance on effective clinical practice by issuing guidelines, health technology assessments, evidence notes and best practice statements. We set standards so that the public know what they should expect from the health services. We review and monitor the performance of NHS services, support NHS staff in improving services and promote patient safety and clinical governance.

All our work is concerned with clinical practice and it frequently covers the use of drugs in NHS Scotland, which is the focus of the meeting. We do not have a role in the licensing of drugs. All our work is evidence based and is concerned with the clinical effectiveness of drugs or treatments—their effect on the people who receive them—and, in most cases, their cost effectiveness, which means whether they represent good value for money.

When we look at medicines, we generally assess classes of drug, rather than specific products. Having assessed their clinical effectiveness and, where appropriate, their cost effectiveness, we make recommendations to NHS boards and to the Scottish Executive. Responsibility for implementation of our recommendations remains with the boards and the Scottish Executive.

We are also responsible, as other witnesses have said, for commenting on the implications of one of NICE's products—its multiple technology appraisals—which is a new title that has recently been developed for the reasons that Professor Webb outlined, many of which refer to specific products.

We do not re-examine the evidence. NICE appraisals have a stringent evidence base. Their methodology has been internationally validated and the science does not change just because it has moved north of the border, although its application might be different. Our role is to consider factors such as the epidemiology of the condition concerned, the principles and values of NHS Scotland, the structure and provision of services in Scotland and other implications such as rural issues and predicted uptake.

Recently, that work, our dissemination of NICE appraisals and the work of SMC, to which Professor Webb referred, have had a major impact in taking the heat out of the controversy about postcode prescribing. In that and other ways, the work has led to significant improvements in the services that NHS Scotland provides. However, it is only a beginning. We are committed to building on those foundations, for the benefit of patients in Scotland.

14:15

Dr Caroline Hind (Grampian NHS Board): I speak on behalf of NHS Grampian. In NHS Grampian, we have a formulary group that meets on a monthly basis to consider prescribing issues and the introduction of new drugs. However, the group awaits SMC guidance before considering whether a medicine or formulation should be added to the Grampian joint formulary. We have a joint formulary for medicines because we want to have a list of drugs that is compiled and refined over many years by local specialists, generalists and pharmacists. It is intended to promote familiarity with a smaller number of drugs and, in doing so, to encourage better understanding of prescribing and to reduce the chance of error.

When the SMC has approved a new drug for use in Scotland, we write to clinicians who have an interest in using the drug to see whether they wish to add it to the Grampian joint formulary. If they respond positively, we process the matter through the formulary group and consider issues of funding and prioritisation and where the drug sits in relation to other drugs on the formulary—whether it is a first or second-line choice. Sometimes we have to draw up local protocols for use, depending on whether monitoring and shared protocols are required and whether we must take into account referral processes for GPs.

We consider that the medicines that are listed in the Grampian joint formulary should be sufficient to provide appropriate care for the majority of

patients, but we realise that there are exceptional circumstances and that items in the formulary may not be suitable for all patients. Mechanisms are in place to ensure that in the hospital system there is a one-off request process that allows clinicians to request, if they are required, medicines that are not on the formulary and which may not be kept in stock by the pharmacy. If general practitioners believe that a medicine is appropriate for a patient on the basis of clinical need, they are free to prescribe that medicine on a GP prescription, provided that the drug is licensed for use by NHS Scotland and is not a blacklisted item.

Dr Iain Wallace (Greater Glasgow and Clyde NHS Board): What we do reflects what happens in Grampian. Prescribing expenditure in Glasgow is £225 million a year, which is about 20 per cent of our overall health care budget. Although cost is important, quality of care is critical in the consideration of what drugs are prescribed.

The NHS board does not have any direct involvement in the licensing of new drugs, but pre-licence research trials are carried out on NHS patients in the NHS Greater Glasgow and Clyde area. I will outline the process that takes place in Glasgow once a drug is licensed. The NHS board receives professional advice from an area drug and therapeutics committee, which involves a wide range of clinicians and oversees the development of a board-wide formulary. The aim of that is to promote cost-effective prescribing practice. Drugs are included in the formulary after the SMC has evaluated and approved them, but only subject to local need. If the SMC designates a drug as unique, it goes straight on to the formulary. The SMC's ability to provide a timely response is extremely helpful to the health board in guiding local formulary management. I am sure that the evaluation process enjoys wide support, certainly among clinicians in Glasgow and Clyde.

When we have a NICE multiple technology appraisal, our ADTC reviews the local implications and determines whether any change to the formulary is needed. That involves engagement with groups such as managed clinical networks. After licensing but before SMC approval of a new drug such as Herceptin, the drug can be made available to patients through the board's non-formulary prescribing policy, which is similar to that in Grampian. In Glasgow we have also established a prescribing management group, which follows a single-system approach to managing prescribing expenditure by the board. We horizon-scan annually and look at the cost of new products coming on to the market, as well as cost volume changes for existing medicines. That consideration feeds into the board's budgetary exercise, so that we should have money for all available drugs that year. The group also oversees programmes to maximise cost-effective prescribing. That means that we are making best use of the money that is available, as well as allowing new products to be introduced.

Expert advice is provided to each directorate or community health partnership in the board, through our pharmacy and prescribing support unit. As others have mentioned, pharmacists are key to managing our prescribing budget.

Mrs Nanette Milne (North East Scotland) (Con): I am sure that you are all aware that the Minister for Health and Community Care has stated:

"NHSScotland should take account of the advice and evidence from the SMC and ensure that recommended medicines are made available to meet clinical need"

throughout the country. Is that happening in practice or does a postcode lottery still exist in Scotland? If the implementation of guidance is variable, can you put your finger on why that is the case?

The Convener: If members want to direct a question to a specific individual, they should name that individual. I do not want all six members of the panel trying to answer every question; if they did so, we would be here until midnight.

Mrs Milne: I am not sure who should answer my questions.

The Convener: The panel can decide who the most appropriate person is to answer them.

Dr Wallace: I will start by putting things in context. The SMC approved around 60 of the perhaps 90 to 100 new products that appeared on the market in 2005. Nine of those products were not put on our formulary in Glasgow. That does not mean that they were not prescribed—it simply means that they would not be expected to be used in 95 per cent of cases. A drug might not appear on our formulary because our clinicians, following consideration by the area drug and therapeutics committees, do not see any benefits that it would have over existing products in the formulary, but it can still be made available.

Professor Webb: We believe that the press's coverage of the postcode issue has reduced substantially since the establishment of the SMC. I think that there is much less postcode prescribing now, but there is confusion about it because there may be alternatives out there to drugs that we have approved as cost-effective and useful agents. If clinicians in a board area are happy with the alternative that they have, the failure to provide a drug would not necessarily mean that there is a postcode lottery. Patients would still have access to equivalent and appropriately effective drugs.

Mrs Milne: So ultimately, there is not a problem with clinicians wanting to prescribe drugs that have been approved.

The Convener: People may remember that there was a big controversy surrounding the prescribing of interferon some years ago. Some health boards prescribed it, but others did not. That was a big issue and there were many campaigns. Are members of the panel saying that that would probably not happen now?

Professor Webb: Herceptin is a good recent example to consider. Herceptin is a very expensive drug—it will probably cost the NHS in Scotland around £8 million a year—but we reviewed it very soon after it was launched and found that, although it is very expensive and that it would be costly for the NHS, it would be cost effective. Its use, which has been approved, is now being rolled out across Scotland. The SMC does not shy away from costly drugs—it is concerned about cost effectiveness and value for money.

Helen Eadie (Dunfermline East) (Lab): I would like Professor Webb, Dr Steel and Bill Scott in particular to answer my questions, which are on joint formularies and the area drug and therapeutics committees. According to an Audit Scotland report, eight out of 12 mainland health boards in Scotland have a joint formulary. Given that we now have the SMC, do we need area drug and therapeutics committees in Scotland? Is not there a case for having one body in Scotland to respond?

Professor Webb: I am not sure whether I can fully answer your questions. I would like to think that every board would have an area drug and therapeutics committee because there are still local issues to do with the provision and safe use of drugs in hospitals. Local ownership of decisions and local discussion of decisions on the use of drugs are still terribly important, and it is important that doctors, pharmacists and nurses have a way of getting together to discuss how they can safely and effectively use new medicines. They can avoid doing much of the work that they used to do in evaluating new drugs because that is done by the SMC, but that frees them up to do other important work on drug safety and drug efficacy.

Dr Steel: I can only endorse what Professor Webb has said. An important thing to bear in mind is that the SMC is a consortium. As such, it needs area drug and therapeutics committees that can come together to pool those things that it is appropriate to do once for Scotland. The area committees are also needed to apply locally the advice that comes from the SMC and to do other things.

The Convener: Bill Scott will need to wait until the round-table discussion, because he is not a member of the panel. I am sure that the round-table discussion will include consideration of similar aspects. Does Helen Eadie have a follow-up question on that issue just now?

Helen Eadie: No, not really.

Shona Robison (Dundee East) (SNP): Can the health board representatives say how much the financial health or otherwise of a health board comes into play when decisions are being made by local area drug and therapeutics committees? It stands to reason that, if a health board has a deficit, financial issues might end up being more of an issue in local committees' decisions than they otherwise would. Also, can Dr Wallace and Dr Hind confirm what percentage of prescribing is off formulary in their respective health board areas?

Dr Wallace: Let me start with the question about off-formulary prescribing. About 95 per cent of prescribing is within the formulary, so 5 per cent is outwith the formulary.

Sorry, I have forgotten the first question.

Shona Robison: How does the financial health of a health board have an influence?

Dr Wallace: As area drug and therapeutics committees are made up of clinicians, they do not have much of a financial element. People from finance do not attend the committee. Clearly, the cost-effectiveness of products is an important factor but, at the end of the day, decisions are not driven by cost. The area drug and therapeutics committee gives professional advice on what drugs should go into the formulary. It is then up to people like me to manage the prescribing budget to allow products to be made available.

Shona Robison: Why, then, do committees differ in their clinical conclusions if the areas that health boards serve do not have particular conditions that would merit a particular drug's being in, or excluded from, the formulary? I am struggling to get a sense of what the key differences are between health board areas.

Dr Wallace: Where quite a number of products have a similar efficacy and even cost profile—we call them me-too products—different health boards will go for different drugs. That might be for historical reasons, such as that people were involved in research. For those drugs, we simply need to choose three or four drugs out of a whole category of similar products.

Shona Robison: Presumably, the side effects of some of those drugs might differ.

Dr Wallace: We would have three, four or five such products in the formulary. Our formulary contains 900 products, so it is not a narrow

formulary. I cannot remember how many products are listed in the British national formulary—it might be 5,000 products—and the local formulary is a refinement of that. Our formulary covers 95 per cent of the drugs that are prescribed in our area. If patients require a drug outwith the formulary, an application is made under the non-formulary policy and the drug is usually prescribed.

The Convener: Before Shona Robison responds, I will let Dr Hind contribute.

Dr Hind: Many drugs do not make it into the formulary because we have similar chemical equivalents that do the same thing, have the same profile and are used for the same conditions. Newer drugs can be more expensive because they are issued under licence, whereas generic drugs that have lost their patent might do the same thing and be cheaper. To secure value for money for the NHS, we would probably say, "We have three of these already, so why do we need a fourth one that will be more expensive?" That is not necessarily to say that we would not include a me-too drug if there was an indication that we had not had the product before. We would consider the case on an individual basis, but we tend to look at such drugs as a group. If a drug is reasonably specific and does not have an equivalent, it is almost certain that it will be included in the formulary.

In Grampian, we have an element of management in our formulary group, in that the formulary group has a budget. For the big blockbusters—not for the reasonably priced drugs for primary care settings but perhaps for the big ones for, say, cancer chemotherapy—we have money to start the funding process within the financial year. A new drug might come on stream in the last quarter of a financial year whose budget was set 18 months previously, so we have money to fund it in the financial year and we are allowed some leeway so that we can build in the cost in the budget-setting process for the following year. Usually that happens with the big, expensive items that often hit the acute sector, rather than with drugs in the primary care sector. Our formulary group has finance available. We work out our expected costs for the year and for the following year.

14:30

Mr Duncan McNeil (Greenock and Inverclyde) (Lab): I want to return to one of Helen Eadie's points. We have heard today about the various systems in NHS QIS, the SMC, NICE, the Scottish intercollegiate guidelines network—SIGN—and the area drug and therapeutics committees. The defence of the process that we have heard is that it keeps people involved—I imagine that it would do. That may not have financial implications, but it will certainly have productivity implications. Cannot a case be made for simplifying the procedure and doing away with some of the duplication, while keeping people involved? The real question is whether the process is a cost-effective use of NHS resources.

Dr Steel: The process is complex, which is why we all welcome the opportunity to explain to the committee how it works. I argue strongly that the system is fit for purpose and that there are good reasons why we do things in the way that we do. I am happy to explore particular examples. I have already touched on why the work of the SMC is distinct from but closely related to the work of my organisation—we have two complementary organisations, rather than have all the work wrapped up in one organisation. Without doubt, having national organisations that do the work that is best done nationally provides considerable benefits for the NHS. There is a lot of evidence, not only in this area but in others, that we have the balance broadly right in Scotland between the work that is done at the centre and the work that is left to the NHS boards because they are close to the staff who deliver the care and, importantly, to patients.

We examine the process continually. Indeed, the SMC and my organisation have recently commissioned work to assess the effectiveness of what we are doing and the impact that we are having on the quality of patient care. We will learn from the assessment and apply the results.

Professor Webb: If the question was about the role of area drug and therapeutics committees, there are—

The Convener: To be fair, the question was about the entire network of overlapping and connected processes.

Mr McNeil: I was asking whether it is cost-effective, whether it could be simplified and whether duplication arises. Are you saying that all the processes are completely separate?

Professor Webb: At this stage the SMC is a fairly unique entity. NICE is about to start doing what the SMC does for a selected number of drugs, but we are the only group in the UK to consider drugs at the point of launch and to give early advice to the health service soon after that. NICE's multiple technology appraisal approach, which considers a group of drugs often 18 months to two years after the launch, is entirely complementary, because the evidence base is much bigger at that point. NICE's funding allows it to do modelling using clinical trials data to define specific populations that may benefit. Our early judgment and the later judgment from NICE are entirely complementary. Our service for all drugs costs less than £1 million a year. I think that NICE

has a budget of about £30 million a year. The approach in Scotland is cost effective. We benefit from NICE's MTA approach.

The Convener: Can we have a GP's perspective from Dr Bennison? You are looking from street level up the way. Duncan McNeil's question was about whether anything could be done more effectively, more cost-effectively, quicker or more efficiently. Are there any processes for which you wonder whether we really need to do it that way?

Dr Bennison: Most GPs on the ground are probably not terribly familiar with the precise arrangements relating to all the big organisations, but we have local people to whom we can speak for advice. Except in specific cases, most GPs would not go back to examine the detail of the SMC guidance on a particular drug. We would rely on our local prescribing advisers or whoever we happened to have locally to give us the relevant information.

As GPs, we feel quite proud that the rapid assessment of new drugs that is carried out in Scotland allows us to know quickly whether we ought to be prescribing a particular drug, but there might be a role for a national organisation that concentrates on policy issues rather than clinical issues. One of my colleagues suggested that a Scottish drug utilisation research unit—it would need a snappier title—could be set up to investigate the practical aspects of prescribing throughout Scotland. There is a huge opportunity to use the massive amounts of data that are available through ISD Scotland. The use of community health index numbers is unique to Scotland. The fact that every patient has a unique number means that we could find out all sorts of useful things by linking hospital morbidity data with prescribing data.

The Convener: I am not sure that Duncan McNeil was looking for suggestions for yet another organisation; that was not quite the intention of his original question. I want to move the discussion on so that we can start the round-table discussion. I will allow one more question for this panel.

Dr Jean Turner (Strathkelvin and Bearsden) (Ind): My question is about licensing and non-licensed products. The case of Herceptin has already been mentioned. Patients nowadays are very well informed and know when a drug that comes online can be used. For example, they would know that Herceptin could be used for some but not all people who are in the very early stages of breast cancer. How do the health boards and other people help GPs and consultants to prescribe drugs that are off licence?

The other case that comes to mind is that of Sativex, which I found out about through a constituent. The Home Office lifted the requirement for an import licence so that Sativex could be prescribed to named patients, but GPs and consultants are reluctant to prescribe the drug because it does not have a licence yet. Some patients could benefit from using drugs that are not yet on licence. I know that the system in Scotland is speedy—Herceptin is a good example of that—but how could that issue be tackled in the future?

The Convener: Who would you like to answer that?

Dr Turner: Iain Wallace and the GP representative.

Dr Wallace: I will give you an example. In children's services, quite a number of the drugs that are used are off licence, but it is clear that the clinicians feel comfortable prescribing them. People are often more reluctant to prescribe a very new product that no one has had much experience of using.

Herceptin is a good example of a product that was being prescribed in Scotland, even though it had not been licensed for a new indication in early-stage breast cancer. Professor Alan Rodger from the Beatson oncology centre worked with regional cancer networks to agree a way forward, which I think gave clinicians the confidence to prescribe Herceptin pre-licence in certain circumstances. When clinicians have confidence in a product, we find that they will prescribe it pre-licence.

Dr Bennison: It is unusual for GPs to initiate the use of a new drug such as Herceptin. Such decisions are usually made in conjunction with specialist colleagues. I know that in Lothian there is a policy on the use of unlicensed and off-label medicines. There is a traffic light system for the use of new products: green is for unrestricted general use, amber is for general use with restrictions and red is for specialist use only. A new drug will be assessed quite rapidly in Lothian and I imagine that similar systems are in place elsewhere. There are people to whom we can turn for advice on particular drugs. We feel quite well supported by that system.

The Convener: Will you be quick, Jean, because we need to move on to the round-table discussion?

Dr Turner: If a drug that is not on licence is prescribed to a named patient, would both consultant and GP have to be willing, from a legal point of view?

Dr Wallace: At the moment, the prescriber takes responsibility. If something goes wrong with a particular medication, there is a raft of support for

employees within health boards, but it is still up to the prescriber to make the ultimate decision.

The Convener: I ask the panel members to stay where they are. The other individuals who are involved today are already in their seats. They are: Bill Scott, the chief pharmacist; Angela Timoney from the Royal Pharmaceutical Society, who we know from previous sessions; Clara Mackay from Breast Cancer Care Scotland; and Mark Hazelwood from the Multiple Sclerosis Society Scotland. You have heard an overview of how the system works according to those who work it, and we now want to open up the discussion. I would like Mark Hazelwood and Clara Mackay to begin the discussion, from the point of view of those with the end-user certificate, if you like—this is like arms sales. Will you briefly say something about your perspective, including what you consider to be people's real experience?

Clara Mackay (Breast Cancer Care Scotland): I welcome the opportunity to be here and to speak about the experience of breast cancer patients. Breast Cancer Care is a United Kingdom-wide organisation and we know that throughout the UK anxiety about access to treatments and drugs is probably the most serious issue for breast cancer patients. It has been interesting to listen to the evidence. Looking across the board at the queries to our helpline and through our one-to-one services, I can say with great confidence that breast cancer patients in Scotland share the same level of anxiety as breast cancer patients throughout the UK. However, as an organisation that is able to look across the UK, it is clear to us that Scotland has a much more effective, efficient and—I would say—patient-responsive and friendly approach to making treatments available. As has already been flagged up today, Herceptin is a good case study of that.

I want to make two points on the patient experience and from the patient point of view. First, from what we hear from people with breast cancer, we have a real concern about an increasing undermining of the trust and confidence between patients and those that treat them. People are often suspicious that they are not being given access to treatments that they would benefit from. That is one of the most unattractive issues to arise from the debate about access to medicines.

Secondly, we share a concern with the people we serve that—perhaps because of the way in which the media manages stories about treatments—there is an increasing tendency to pit patient group against patient group. Breast cancer patients who access Herceptin are sometimes portrayed as taking treatments away from other patient groups. That is an incredibly unfair and difficult burden to place on patients. It highlights the need to review the systems that we have and to ensure that they are fair, equitable and transparent. We should ensure that individual patients do not have to fight or work their way through systems and that they do not find themselves, in some instances, demonised for trying to access treatments that are known to be effective and from which they would benefit clinically.

Mark Hazelwood (Multiple Sclerosis Society Scotland): Thank you for giving the Multiple Sclerosis Society Scotland the chance to input to the discussion. I acknowledge the progress on this area of public policy. For about eight years, the MS Society was involved in addressing postcode prescribing of disease-modifying drugs. On reflection, there has been a great deal of improvement north and south of the border—but particularly north of the border—in the speed of the process, transparency, engagement with patient groups and the arrangements that are in place. That progress should be recognised.

A few other points came out of the long experience of people with MS in relation to that issue. First, people do not always see access to drugs in isolation; rather, they see it as part of a mix of services that they need. It is sometimes difficult for people to be told that certain drugs do not represent the best use of health care resources when they are aware that other health care resources that could make a big difference to them are not available where they live. I understand that there are drug-focused institutions, but we must try to see drugs as part of a range of interventions that can help people.

14:45

Secondly, MS presents some challenges that are also presented by other conditions. There are long-term conditions, fluctuating conditions and variable and unpredictably progressive conditions that throw up enormous technical challenges for institutions such as the SMC and the pharmaceutical industry. Industry trials may be quite short if companies want to rush things through and get a patent, so reaching a view on the benefits of interventions for lifelong conditions such as MS can be difficult.

Today's discussion has very much concentrated on costs to the health service, but trying to capture the benefits of interventions is a challenge. Health service costs are quite easy to capture if we are talking about the amounts of money that are paid, but the impact on and costs to society of untreated diseases—particularly long-term, chronic conditions—are more difficult to determine.

I will finish by giving some thoughts on things that might be taken on board in the future. We

would like the SMC's horizon scanning to be shared with patient groups so that we are also privy to what is coming down the product pipeline. That would help us to be alert to making submissions to the SMC when there are new drugs. The process can be tricky. For example, a drug that was flagged up as being for strokes, I think, resulted in a recommendation that showed that it also had implications for people with MS.

We would like there to be opportunities for patient groups to have a richer input to the SMC process, perhaps by people presenting themselves in person. The regulatory authorities could send signals to the industry that the outcome measures that are used in trials should focus on what is important to the people with the conditions and not just on things that are easier to measure. That was certainly an issue with beta interferon. With that drug, people talked about mobility outcomes, for example, which are relatively easy to measure, but people who had access to it also talked about its impact on their fatigue and pain and on a range of symptoms that were not well captured in the trials methodology. That is another area in which we can ensure that the process captures benefits for people at the end of the line.

The Convener: A few issues have been raised. I wonder whether Jim Eadie wants to say something about the comments that have been made about the start of the process and the speed with which companies want patents. Professor Webb can then say something about the comments that have been made about the SMC.

Jim Eadie: The process of researching and developing medicines is complex and time consuming for companies. Researching and developing a medicine takes in the region of 10 to 12 years and the costs that are involved can be as much as £500 million per medicine. Therefore, the companies involved have an important role to play.

On ensuring that we have medicines for patients, I was struck by what Mark Hazelwood said about not looking at drugs in isolation. We will lose something critical if we always consider the costs of new medicines without considering the broader impact of their benefits and the spending that is saved elsewhere in health budgets and in the system. Perhaps an example will best illustrate what I mean. Members should consider the medicines that have been developed to treat Alzheimer's disease. Such medicines might cost £2.50 a day, which is not an insignificant amount over a year—we are talking about a cost of just under £1,000—but if the medicine prevents someone from having to receive residential nursing care, which would mean a significantly higher cost of perhaps £30,000 to the national health service, there will be a saving. The NHS and the social care system need to be aware of that.

The Convener: The problem with that is that the cost of residential care does not come out of the NHS budget; it comes out of a completely different budget.

Jim Eadie: That is the issue. We are looking at costs in isolation—we are considering silos of expenditure.

The Convener: Absolutely. You are saying that we should consider the benefits that new medicines could have right through the system.

I invite Professor Webb to pick up on some of the comments that Mark Hazelwood and Clara Mackay made about the SMC.

Professor Webb: I was pleased by Clara Mackay's initial comments and much of what was said thereafter resonated with some of our concerns. We are particularly anxious to get the right outcome measure for the patient. We often consider outcome measures that are not those that we would think would be of most direct interest to the patient group. We would like to look more broadly at societal costs, which we use as a modifier in our process. If companies are prepared to identify and highlight those issues, that obviously improves their case for getting the drug approved for use in Scotland. We certainly do not ignore those issues. The more clearly they are flagged up, the easier it is for us to give them consideration. We like to think about such matters.

There are non-drug treatments that work just as well as drugs—for example, cognitive behavioural therapy is used to treat depression—but when it comes to interventions that require a different sort of assessment, we just do not have the data that we have for drugs. We have much clearer cost-effectiveness data for drug treatments.

The final point was about horizon scanning. I can see where Mark Hazelwood was coming from on that. We have a problem with horizon scanning in that we receive confidential information from drug companies at an early stage and I am sure that they would be distressed if we were to share that widely. Nevertheless, I am sure that we could ensure that the Multiple Sclerosis Society and other societies that have an interest in a particular condition always have their chance to comment before a drug comes into our process. We certainly do not want to lose the opportunity to hear the voices of such organisations on every occasion.

The Convener: There is a question hanging over for Bill Scott, which Helen Eadie asked earlier. If he took a note of it, he can deal with it now. I invite other panellists to indicate whether

they want to participate in this part of the discussion.

Bill Scott (Scottish Executive Health Department): I understood the question to be about whether there was a need for all the area drug and therapeutics committees. Drug and therapeutics committees do not consider only new medicines or formularies; they play a vital role in ensuring that there are safe systems of work and of administering drugs in hospitals and in the health boards more widely. In addition, they are a feeding ground for the larger groups in which people can hone their expertise and skills without experiencing the fear of having to pitch themselves against national experts. DTCs are a good ground for education. That is why I support local committees.

I believe that the SMC and NHS QIS play complementary roles and that the expertise and skills that are required for the SMC could not be readily transferred over to NHS QIS because they are different parts of the equation. I still favour having our national committees, but I think that they should work together in partnership—which they do. Incidentally, we have a drug utilisation group at NHS National Services Scotland.

The Convener: Duncan McNeil will be so pleased to hear that.

Helen Eadie might like to respond, but I want Bill Scott to take a minute to explain his role as chief pharmacist in the whole set-up.

Helen Eadie: Let us analyse the answer that Bill Scott has just given about the role of the drug and therapeutics committees. You have told us that they consider safety and the way in which hospital systems work. I guess that my concern is the same as Duncan McNeil's, if I picked him up right. It has been said that the operation of the DTCs does not cost anything, but I would argue that any time that is taken from a patient's interaction with a consultant or a doctor represents a cost to that patient. That is what drives my concern. Audit Scotland's concern was that the eight committees across Scotland are, in effect, all doing the same thing. In spite of what our esteemed friends have said, Audit Scotland and others continue to share some concerns, so I remain to be convinced.

Bill Scott: If committee members just sat around and talked, I would agree with you. However, we must consider capacity planning. We cannot secure expertise for the future unless staff are trained in such groups. There is also peer review of how people work, which is valuable. The approach contributes to patient care because it builds understanding about the safety of medicines. It is also about investing in staff and ensuring that they feel they contribute to the goals and operation of the NHS.

The Convener: Will you comment briefly on your role as chief pharmacist, before I bring in Angela Timoney and Duncan McNeil?

Mr McNeil: May I first briefly follow up Mr Scott's comments?

The Convener: Okay.

Mr McNeil: If we reduced the number of health boards, would we also reduce the number of ADTCs?

Bill Scott: Committees might amalgamate, but we would still need local people who had ownership and felt that their contribution was valued.

Mr McNeil: How many such committees serve the larger population in England?

Bill Scott: How many committees do we have in Scotland? Committees are a way—

Mr McNeil: Is there a committee in every health board?

Helen Eadie: There are 8 ADTCs and 12 mainland boards.

Bill Scott: The committees help to manage a complex organisation. The NHS is Scotland's biggest employer.

The Convener: I am still not quite clear about Bill Scott's role, but I invite Angela Timoney to comment before I come back to you. The committee has heard from the chief medical officer in the past and we want to hear about the chief pharmacist's role in the context that we are discussing.

Angela Timoney (Royal Pharmaceutical Society Scottish Department): I am here on behalf of the Royal Pharmaceutical Society, but I am also the vice-chairman of the Scottish medicines consortium and I am involved in NHS Tayside's area drug and therapeutics committee, so perhaps I can explain the role that pharmacists play and why it is necessary for each health board to have an ADTC.

Much of the work that our ADTC used to do on evaluating new drugs has passed to the national Scottish medicines consortium. However, new drugs account for a small part of the overall volume and cost of drugs that are used in the NHS. Audit Scotland said that new drugs account for approximately 5 per cent of the total NHS drug budget for general practitioner prescribing and our work on acute prescribing in Tayside demonstrated that new oncology drugs account for about 2.5 per cent in the year after their launch. Therefore, ADTCs need to consider how the other 95 per cent of medicines are used throughout the NHS. We have been freed up and we have been able to change how we work, so that we can

consider quality assurance processes and review the prescribing of existing drugs. We need to do that in consultation with local prescribers if we are to make meaningful changes—that is what ADTCs do.

The Convener: I am determined to get my minute's-worth of information out of Bill Scott.

Bill Scott: I am the chief pharmaceutical adviser to Scottish Executive ministers. I also give advice to colleagues in the NHS and administer the pharmacy division in the Health Department, which is the point of contact for the MHRA for the enforcement of the Medicines Act 1968 and any other drug-related matters.

The Convener: Thank you.

Euan Robson (Roxburgh and Berwickshire) (LD): I think that Angela Timoney made this point, but I presume that the bulk of the work of ADTCs is consideration of not just new drugs but the effectiveness of existing medicines.

How does the work of ADTCs link with that of NHS QIS or the SMC on the effectiveness of existing approved medicines? In layman's terms, how would a medicine be taken off the list, if that needed to happen?

For example, I understand that there were concerns about Zyban, which is a drug for helping people to give up smoking. I am not clear about what happened to it, but where did it fall into the process? Did people begin to prescribe it in Scotland and then problems were found with it? How do people go back through the system and take things off the list or warn against using them in certain ways as a result of experience?

15:00

Angela Timoney: There are two answers to your questions. First, the SMC is a consortium of ADTCs, and a standing item on our agendas is feedback from the ADTCs on the information and guidance that we give them. Therefore, a process is in place.

Secondly, Zyban was out before the SMC existed. There are systems and processes for complaints about the adverse effects of drugs. The yellow-card system, for example, is open to doctors, pharmacists, nurses and others. A local role of an ADTC is to ensure that appropriate reporting takes place and that information goes to the Committee on Safety of Medicines Scotland and the United Kingdom system so that the adverse effects of drugs are notified.

Professor Webb: I am still worried that people do not recognise the value of ADTCs. I will give two or three examples of their value. First, shared care protocols are developed, which usually involves a local specialist and a local general practitioner. Local dialogue between the two people who must bear responsibility for an activity is important. Developing shared care protocols nationally is difficult because that approach does not identify the two people who are participating in the activity.

Another example is critical incident reporting. We must ensure that people safely receive the right dose of the right drug at the right time. If somebody makes a mistake and the process goes wrong, handling that becomes a sensitive issue. Such things are much better handled through an ADTC than nationally. Reporting would be much less effective if a national body considered close shaves.

A third example is yellow-card reporting, or reporting the adverse effects of drugs. We know that local systems can be used to increase yellow-card reporting, and different regions will find that there are different benefits from using different processes to improve yellow-card reporting. Local systems can be used to get the best out of the health service. There are differences in the provision of health care in the Highlands and Islands, for example, and its provision in big cities such as Glasgow and Edinburgh. There are also differences in how people manage medicines policy, which needs to be dealt with on a regional basis.

Shona Robison: I am curious about what happened to the Health Technology Board for Scotland. Why was it brought into being in the first place? Why was it thought that dissolving it was necessary? Duncan McNeil mentioned the plethora of organisations. I never quite understood the HTBS's role.

Dr Steel: I think that attempting to answer that question falls to me.

The answer to the simple part of the question is that the work of the Health Technology Board for Scotland has been incorporated into the work of NHS Quality Improvement Scotland as part of the evolution of the landscape. The aim was to achieve greater rationalisation and co-ordination of related activities, and there is evidence to suggest that that has happened. When an issue is raised with us, we can decide on the most appropriate response and then intervene. A recent example relates to screening for MRSA. The most appropriate response in that context was a health technology assessment, and we were able to make that response.

I am not sure whether it is for me to say why the Health Technology Board for Scotland was created and to answer for ministers' decisions back in 1999, which is when it was established, I think. However, you have touched on another

example in which a balance has to be struck between not unnecessarily duplicating work and doing things locally—in this case at a Scotland level—where that is appropriate, which we have discussed in relation to arrangements in Scotland. That is why we do not redo all the NICE multiple technology appraisals; if we did, that would clearly not be a good use of public resources.

There has been a distinctive Scottish slant to all the health technology assessments that have been undertaken by the HTBS and NHS QIS. A key element is the provision of services in Scotland, which members will know differs in important respects from provision in England. However, in developing our programme, we considered carefully what happens in England, particularly work from which we can learn. We hope that the reverse applies, so that colleagues south of the border can use our work. Indeed, there is evidence to suggest that they do just that. We share things rather than unnecessarily duplicate what we do.

This is an evolutionary field and, with regard to our current arrangements, one must remember where we have come from. A few years ago, each ADTC did the work that we now do. We have established the SMC, but that is not the end point; the process is constantly evolving. We seek always to ascertain whether we are doing things in the most effective way that we can.

Shona Robison: The work of NICE would be the equivalent of the work of the SMC and NHS QIS. What is NHS QIS's current budget?

Dr Steel: The mainstream budget for its work is about £13 million. In addition, there is the money that comes to us from the Scottish health council, which takes the budget up to a total of about £15 million.

The Convener: Two committee members are waiting to ask questions, but a round-table discussion is not meant to be confined to just politicians asking questions of those who have been invited along. We hope to encourage individuals to ask questions of one another, if a question occurs to them. I am conscious that, with the exception of Angela Timoney, only committee members' hands are going up. Strictly speaking, we try to discourage too much domination by committee members of a round-table discussion. I put that out there for one or two of the other folk.

Dr Turner: I want to draw in what Clara Mackay and Mark Hazelwood said about how treating patients with the best drugs affects them and their families because I believe that there is a big cost that is never estimated. I do not know who could best feed back all the information on this—it could come from people in general practice and primary care. As I have said previously, drug treatment of asthma is costly, but for many years such treatment has saved patients from being admitted to hospital. Similarly, if a patient with Alzheimer's disease is treated correctly, that means that the family and the patient are happy and that there are fewer primary care interventions. I wonder whether any of the organisations represented around the table would like to take up the issue of patient involvement and perhaps do research into how drug treatments affect patients and families. I think that such information would provide important feedback.

I remember from my general practice days that there was a hard-and-fast view that drug treatment of Alzheimer's was probably not cost effective. However, it seemed to be cost effective to the families of Alzheimer's patients. If a drug makes such a patient easier to manage within the family, with fewer medical or primary care interventions, and allows family members to have their own lives, that is a saving that has never been measured. Similarly, surely we must be able to measure the fantastic savings from asthma treatment over the past 20 or 25 years in preventing patients from having to go into hospital as emergency cases. However, I do not know whether that work has been done.

The Convener: Is there an example anywhere of an attempt to quantify benefits in the way that Jean Turner has described?

Jim Eadie: The Association of the British Pharmaceutical Industry Scotland and the industry have been conscious for some time that we are not capturing the kind of life experience to which Dr Turner just referred, so we commissioned pharmaco-economic research from an organisation called NERA Economic Consulting, which considered two particular disease areas in Scotland—coronary heart disease and diabetes—and provided data on their increasing burden. The issue was the costs of providing medicines for those diseases and the savings that result elsewhere in health budgets and more widely in society. The research found that maintaining the level of expenditure on cholesterol lowering medicines—statins—over five years would save 4,000 lives in Scotland and save the NHS some £50 million. Therefore, pharmaco-economic data are available that demonstrate not only the cost of medicines but their value to patients.

It has been found that tighter management of type 2 diabetes significantly lowers the number of people who are admitted to hospital. The saving to the Scottish economy from getting back to work people who were not in mainstream employment is about £5 billion. Some work has been done on that.

The Convener: Do you have any executive summaries to send us?

Jim Eadie: Yes. We also have a breakdown of the data by health board, which shows the numbers of lives that would have been saved and of hospital admissions that would have been prevented.

The Convener: We would all appreciate seeing that, if that is possible.

Dr Steel: I assure Dr Turner that NHS QIS and the SMC have a commitment to do just what she mentioned. Hitherto, we have relied mainly on input from patient groups such as the two that are represented today. In all our work, we ensure that the relevant group is closely involved. However, we are going further. In several of our studies, we have used surveys of patients that were undertaken by the Picker Institute, for example, to find out what matters most to patients and what the impact of different options would be.

The task is difficult. Given that we must be an evidence-based organisation, all of whose recommendations are underpinned by evidence that will stand critical scrutiny, we must find patient evidence that is just as strong as the clinical and cost evidence that is in our equation already. We are up for doing that, but we need help to take it forward.

Dr Wallace: I will follow up Jim Eadie's comment. In Glasgow, we examined the cost of statin some years ago. We covered not just the high-level cost of managing the budget, but the benefits to patients of reduced bed occupancy, for example. We consider the whole health system, but we are not very good at looking into the benefits for social services and voluntary sector demand.

The Convener: I will raise an allied issue. Controversies arise frequently about the use and application of various drugs. The current controversy concerns drugs that many patients want to use in the early stage of Alzheimer's. I think that I am right in saying that the agreement is that those drugs should not be used until later. I do not want to walk through that process—I am not asking about that. I ask you to tell us who we should write to when we receive in our postbags concerns about such matters, as we all do. I think that we have all followed the practice of writing to people and receiving letters in return that say, "Not us—somebody else," or, "Nothing to do with us, mate." That follows on a little from what Duncan McNeil said—there is a wee bit of buck passing. What is our first port of call?

Dr Steel: I have to hold my hand up to that. The piece of work that you mention is a NICE multiple technology appraisal, so it falls to us, using the procedure to which I referred in my introduction, to decide whether it applies to Scotland. We are engaged on that task so that we can announce our recommendation at the same time as NICE announces its recommendation for England and Wales. I have received many letters about that, including some from committee members, and I am sure that I will receive more.

One of the drugs concerned has been subject to SMC examination—I do not know whether Professor Webb wants to add anything on that.

The Convener: I am saying that there is some confusion about who to approach. When constituents approach us, who do we approach? The situation is a little confusing—I do not know whether the representatives of the two patient organisations want to comment on that. Who we should approach is not always clear. Even now, you talk about going back to the SMC.

Dr Steel: I am sorry; I just wanted to draw attention to the fact that the SMC had considered one of the drugs concerned. The answer is that NHS QIS is the body that is responsible for dealing with those matters. When issues that are raised with us are issues for NICE, we pass them on to NICE. However, for Scotland, I should be regarded as the postbox.

The Convener: You are the first port of call.

Dr Steel: Yes.

The Convener: Thank you—that clarifies the matter. I do not know whether Clara Mackay or Mark Hazelwood wants to comment; Clara Mackay had her hand up. I have not forgotten Helen Eadie, who is on my list, but I want to bring in others.

15:15

Clara Mackay: It is fair to say that patients are incredibly confused about who is accountable and where the buck stops. I expect that Mark Hazelwood has had similar experience. Our experience in England with Herceptin was that there was a lot of buck passing, which can be unhelpful.

I will comment on data and the ability of patients and patients groups to influence the systems for determining which drugs should be made available and under what circumstances. At Breast Cancer Care, we put a huge amount of resources into trying to do exactly that by pulling together patient experiences, patients' data and individual patients to contribute to the process. We have a real dilemma about the extent to which we are able to do something meaningful and useful, which comes back to the criteria for hard evidence, what is acceptable and the weight that is given to evidence. We have never really been able to square that, but we feel a huge commitment to inputting and an obligation to continue to do it.

I am not sure whether the resource that is provided by the voluntary sector and the organisations that represent patients' interests has ever been totalled up, but I would say that it is huge and that there is a case to be made for ensuring that those resources are used as effectively as possible.

I will ask a slightly unrelated question about horizon scanning. At Breast Cancer Care, we have anxieties about the appropriateness of our current systems for reviewing drugs and their effectiveness and for taking into account resources issues in making drugs available. The Herceptin case underlined those anxieties. Drug development appears to be changing as new types of drugs are made available. Herceptin is a good case study in that it is a targeted treatment, is very expensive and benefits a very small group of patients. That feels different from what has happened with many of the drugs that have been made available in the past, and we are not entirely sure that the systems that we have in place for costing drugs—that is, the agreement that is made about how much a drug will cost when it is first made available—and the processes that such treatments go through are appropriate. Do other panel members, perhaps those from the industry and the regulatory bodies, have a sense of whether we will still use the SMC and medicines licensing processes in five or 10 years' time, or will we have to make significant changes to those systems to meet the new demands?

The Convener: That was a long question.

Jim Eadie: I will start with horizon scanning, which is not that easy, although the issue that Clara Mackay identified is important. As far as possible, the health service and society need to know what new medicines are coming through the pipeline and to be able to plan for the introduction of new treatments that have budgetary implications. The problem is that the price of the medicine is usually not set in the United Kingdom until close to the point at which it receives its licence. In many other European countries, the price is not set until some time later because of their systems of pricing and reimbursement. The price is a sensitive issue because of the competition that exists between companies and we therefore cannot know too far in advance what a medicine's price will be.

We are addressing that issue, although it is sensitive. The industry, in partnership with the SMC, is creating a system through which companies will share information as far in advance as possible but confidentially. The totality of that information will be shared with the decision makers within the health service who have to plan their budgets to make the funding available for new medicines.

The question of where the SMC, the licensing process and the assessment processes will be 10 years from now is probably best passed to one of my colleagues.

Professor Webb: If I may, I will go back a step. We receive excellent and informative evidence from a number of patient representative groups, Breast Cancer Care included. The evidence is not ignored; it is circulated to our members and presented at meetings. I can assure Clara Mackay that, on occasions, it tips the balance and helps us to make decisions. It can also provide an insight that we would not have had otherwise. I hope that groups such as Breast Cancer Care continue to provide that evidence.

I turn to the much harder questions that Clara Mackay asked. Clearly, in working towards budgeting for drugs, we need first to do the horizon-scanning work. Drug companies have changed the way in which they develop drugs. They now embed health economic studies in their research programmes. Nowadays, some of the answers to questions on cost effectiveness are more readily available than may have been the case in the past. Many issues still need to be addressed. There has been talk of the conditional licences and further post-marketing studies that may be needed—those are specific to specific drugs. We will always need to address cost effectiveness as well as safety and efficacy. However, I am not sure how we will do that.

The Convener: Does anyone else want to come in? Do you have a comment, Dr Steel?

Dr Steel: No.

The Convener: Helen Eadie has been waiting to get in and Nanette Milne and Duncan McNeil have also indicated that they want to say something. I am thinking of bringing the session to a close at around 3.30 pm.

Helen Eadie: Thank you for remembering me, convener.

Whenever I listen to the news or hear different commentaries, I always feel a sense of pride that SMC is leading the way in a number of different ways. I wanted to put that on the record.

That said, I ask SMC and others to consider reviewing MSP postbags. The point that the convener made was an apposite one. MSPs have struggled on their constituents' behalf to get them the medication that they need. Many patients are clued up on the latest medicines that are out there. As gatekeepers, the ADTCs have made it really difficult for people to access the drugs that they need. I could cite a number of different cases, but I will not take up time in doing so. I will give only two examples: arthritis and osteoporosis—I do a lot of work on such cases. People know about anti-

tumour necrosis factor drugs, but in some cases they cannot access them locally.

I return to the point that Jim Eadie and others made very well today. We have to look at the cost benefit analysis of patients who have had their lives transformed by drugs such as anti-TNF drugs or the drug that treats ankolysing spondylitis. Those drugs make such a difference to patients' quality of life. However, people are being told that they cannot access them because the price is, let us say, £10,000 a year. We just tell people that they cannot access a drug treatment, even although it is there and will transform their life. It is easy to see why an element of suspicion can creep in. That is undoubtedly the reason why Audit Scotland picked up on the issue.

The Convener: I will bring in Nanette Milne and then Duncan McNeil before panel members pick up on what has been said.

Mrs Milne: How do the discussions that we have had, particularly on horizon scanning, tie in with, for example, the projected growth in drug budgets over the coming years? How does that sit with the £20 million efficiency target that is being dealt out at the moment?

Mr McNeil: I will also go back a couple of steps. Jim Eadie said that 4,000 lives had been saved by the use of statins. Of course, we also know that those who live the longest are living for even longer and that the gap between those who live long lives and those who live short lives is widening, not narrowing. What work have you done at the next stage to see how many more lives we could save if we prescribed more of those statins to people who really need them? It may be a cheap point to make, but I keep forgetting the different titles of all the organisations involved; there are so many of them. What work have NHS QIS and SMC done to ensure that we are picking up on Angela Timoney's point that, instead of focusing on the 5 per cent of drugs that are new on the market, we ensure that we are effective in using the medicines and drugs that are available to us now?

The Convener: I invite Jim Eadie to pick up that last question and then we will hear from others.

Jim Eadie: The piece of work that was referred to earlier looked specifically at the benefits to the health service in Scotland if we were to maintain the current level of prescribing of statins. The result was 4,000 lives saved; 3,000 fewer angioplasties; and 2,500 fewer heart bypass operations. It did not look at what further savings could be made. That is perhaps because the evidence base for the use of statins is now widely recognised so the gap is not as great in that particular disease area as in others where we are seeking to close the gap. Perhaps members have set us a challenge that we need to go away and think about. If there is work that needs to be done, I am sure that we will consider it.

The Convener: Do others want to respond to some of the points that have been raised?

Dr Bennison: In response to Duncan McNeil's question, work is going on that will produce a lot more data and probably provoke more prescribing of drugs such as statins. You might be aware of the work of the Scottish primary care collaborative, which is looking at access—the big subject that everyone is talking about. I am sure that members get letters about it in their postbags. The collaborative is also looking specifically at managing diabetes and coronary heart disease. That will produce a wealth of information and we hope that we will see distinct changes in admissions, bypass grafting and so on over the two years of each phase.

The 2010 initiative is about looking for people who do not come to see their doctor but who have high-risk factors. I am sure that lots of them will end up on statins.

Dr Wallace: The overview from boards is that we have a limited budget for health care so we have to get the greatest health gain for every pound spent. Sometimes that creates a bit of pressure between what an individual patient wants and what benefits the whole population of a health board area.

Using the example of statins, we might choose a cheaper statin that could treat far more people than a more expensive one. However, more expensive medicines can be used on selected patients who suffer from post-myocardial infarction or heart attack because they give a better pay-back. It is a constantly moveable feast and we have to try to target resources as best we can.

The Convener: Nanette Milne raised a point about expected efficiency savings and how they factor into the discussion. David Steel wanted to respond and I ask him to pick up on Nanette Milne's point.

Dr Steel: Certainly—Nanette Milne's and Mr McNeil's points are linked. The new drugs that are becoming available and the wider uses to which existing drugs can be put present challenges for the management of the health service budget, both in the Scottish Executive and in health boards.

I have two points to make. First, as was said before, we must remember the benefits to patients. There are good news stories and Herceptin is a good example of the improvement in the quality and length of life that such new drugs offer people.

The real challenge—generally and not just in this field—is disinvestment, at which we have not been very good. One of the challenges for my organisation is to address that issue as well as to look at new things that might be done when we find that what we are currently doing is less good than it might be and, in some cases, has very little beneficial effect. We must state that clearly and work with health boards to transfer money from existing uses into new uses. It is easy to say that in a room such as this and very much more difficult to do because of all the expectations and support.

One of the reasons why today's round-table session is so useful is that we need to share those concerns with as wide a group as possible. Committee members have a key task to explain to constituents the sort of challenges and opportunities that health service managers currently have.

On Ms Eadie's point about to whom we should address those questions initially, they should be put to the board responsible for taking the decision about the constituent who writes to her about their situation. If the answer is that the board acted in the way that it did because of national guidance produced by one of our organisations, it does not matter which of us you write to. We work from the same building and can therefore ensure that the right person responds to the query, whatever it is.

15:30

The Convener: I want to be sure that earlier statements on cost have not been picked up wrongly. I think that Bill Scott said that the SMC costs £1 million.

Professor Webb: I said that.

The Convener: Does it cost £1 million?

Professor Webb: About that.

The Convener: And NICE costs £30 million.

Professor Webb: About that.

The Convener: And NHS QIS costs £15 million.

Dr Steel: It does. That figure seems a lot higher than it should if we were just the equivalent of NICE, but there is also a read across to the National Patient Safety Agency and the Healthcare Commission, which are English bodies, and a few other bits as well.

The Convener: So, SMC plus NHS QIS do not just equal NICE; they equal NICE plus a lot of other things.

Dr Steel: Exactly.

The Convener: Otherwise the total would be £16 million, to set against the £30 million of NICE. But you are saying that you two together are a good deal more than NICE. [*Laughter.*]

Dr Steel: I cannot improve on that.

Angela Timoney: I want to make a final point about the growth in the drugs bill and about efficiency savings. From a health board perspective, tough decisions have to be made. In NHS Tayside, we use information from the SMC about horizon scanning to try to predict growth so that we can plan for it. However, we must also consider what changes we can make through our ADTC. We consider the guidance on changes in how drugs are used, and we consider what is available generically. We balance those considerations to try to get the best for patients.

Next year, we plan to come in on target with our efficiency savings and to meet the new challenges posed by new drugs coming through. Achieving such a balance is not easy; it requires a lot of debate and a lot of local collaboration to get people to agree and to stick to the tough decisions on the targets that they have to meet.

The Convener: I thank everybody who has participated this afternoon. Our discussion was fairly brief but nevertheless important, because it is obviously central to the way in which the whole system works. I am not sure whether the politicians are necessarily any clearer about the issues, but we may now have a much better steer on where to send all our letters.

15:32

Meeting suspended.

15:33

On resuming—

Petition

Hospital Parking (Charges) (PE967)

The Convener: I do not expect item 5 on our agenda to take terribly long. Petition PE967, by Louise MacLeod, is on charges for car parking at hospitals and has been formally submitted to the committee.

Following a decision taken at our evidence session on 6 June, we will discuss car parking charges in the private session that will shortly follow the public session of this meeting. I therefore propose—unless committee members want to comment now—that we should simply roll our consideration of the petition into that private discussion.

Members *indicated agreement*.

The Convener: We have agreed to consider PE967 as part of the committee's inquiry into car parking at Scottish hospitals, which we will discuss at item 6 on our agenda.

15:34

Meeting continued in private until 16:08.

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