The Scottish Parliament
Pàrlamaid na h-Alba

Official Report

HEALTH AND SPORT COMMITTEE

Tuesday 23 February 2016

Session 4

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HEALTH AND SPORT COMMITTEE
11th Meeting 2016, Session 4

CONVENER

*Duncan McNeil (Greenock and Inverclyde) (Lab)

DEPUTY CONVENER

*Fiona McLeod (Strathkelvin and Bearsden) (SNP)

COMMITTEE MEMBERS

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

*attended

THE FOLLOWING ALSO PARTICIPATED:

Sandra Auld (Association of the British Pharmaceutical Industry)
Dr Sara Davies (Scottish Government)
Natalie Frankish (Genetic Alliance UK)
Professor Rob Jones (Beatson West of Scotland Cancer Centre)
Lesley Loeliger (PNH Scotland)
Alpana Mair (Scottish Government)
Dr Catriona McMahon (Association of the British Pharmaceutical Industry)
Aileen Muir (NHS Greater Glasgow and Clyde)
Leigh Smith (Health and Social Care Alliance Scotland)
Maureen Watt (Minister for Public Health)
Mark White (NHS Greater Glasgow and Clyde)

CLERK TO THE COMMITTEE

Jane Williams

LOCATION

The Sir Alexander Fleming Room (CR3)

Scottish Parliament

Health and Sport Committee

Tuesday 23 February 2016

[The Convener opened the meeting at 09:30]

Decision on Taking Business in Private

The Convener (Duncan McNeil): Good morning and welcome to the 11th meeting in 2016 of the Health and Sport Committee. I ask everyone to switch off their mobile phones because they can interfere with the sound system as well as with the committee's proceedings. However, my colleagues may use tablet devices instead of hard copies of the committee papers.

I have received an apology from Rhoda Grant. Malcolm Chisholm is still at the Devolution (Further Powers) Committee and will join us shortly.

The first item on the agenda is a decision on whether to consider in private item 10, which is consideration of the main themes arising from today's evidence session. We would normally take such discussions in private. Does the committee agree to take item 10 in private?

Members *indicated agreement.*

Subordinate Legislation

Public Bodies (Joint Working) (Scotland) Act 2014 (Consequential Modifications) Order 2016 [Draft]

09:31

The Convener: The second item on the agenda is an instrument that is subject to affirmative procedure. We will hear, as usual, evidence on the instrument from the Minister for Public Health and her officials. Once we have asked our questions we will move to the formal debate on the motion.

The instrument that we are considering is the draft Public Bodies (Joint Working) (Scotland) Act 2014 (Consequential Modifications) Order 2016. I welcome the Minister for Public Health, Maureen Watt. The minister is accompanied by Brian Nisbet, who is a senior policy officer in the health and social care integration directorate; Clare McKinlay, who is a solicitor from the Scottish Government; and James Laing, who is a policy officer at Disclosure Scotland. I invite the minister to make a brief opening statement.

The Minister for Public Health (Maureen Watt): I would like to say a few words about the draft order, which has been produced as a consequence of the establishment of integration joint boards under the Public Bodies (Joint Working) (Scotland) Act 2014. The purpose of the order is to amend the Protection of Vulnerable Groups (Scotland) Act 2007 and the Protection of Vulnerable Groups (Scotland) Act 2007 (Prescribed Services) (Protected Adults) Regulations 2010.

The amendments are technical and are necessary to ensure that the PVG scheme continues to apply to its full extent once integrated health and social care arrangements are in place. The amendments make it clear that staff who deliver to vulnerable people health and care services that are provided or secured under the integration arrangements remain within the scope of the PVG legislation.

The practical impact on health boards and councils will be minimal because staff who provide such services for those organisations are already doing regulated work and so are able to join the PVG scheme. The amendments should not to lead to more staff having to join the PVG scheme. The changes will ensure that the integration arrangements do not have the unintended effect of removing the possibility of health boards and councils carrying out PVG scheme checks in appropriate cases.

Committee members will wish to note that the order does not introduce new policy, but is needed

simply as a result of wider legislative changes that provide for integration of health and social care. I am happy to take questions.

The Convener: If there are no questions for the minister we will move to the formal debate on the affirmative Scottish statutory instrument on which we have just heard evidence. I remind the committee and others that, during the formal debate, members should not put questions to the minister and officials may not speak. I invite the minister to move motion S4M-15463.

Motion moved,

That the Health and Sport Committee recommends that the Public Bodies (Joint Working) (Scotland) Act 2014 (Consequential Modifications) Order 2016 [draft] be approved.—[*Maureen Watt.*]

Motion agreed to.

09:35

Meeting suspended.

09:36

On resuming—

Pharmacy (Premises Standards, Information Obligations, etc) Order 2016 [Draft]

The Convener: Item 4 on our agenda is another affirmative instrument. The instrument that we are now considering is the draft Pharmacy (Premises Standards, Information Obligations, etc) Order 2016. Again, we welcome the Minister for Public Health, who has been joined by Alpana Mair, who is deputy chief pharmaceutical officer in the healthcare quality and strategy directorate.

I invite the minister to make a brief statement.

Maureen Watt: Thank you, convener. The statement on this instrument is slightly longer than the previous one.

The Scottish Government and the health departments in the three other nations are committed to legislative change in healthcare regulation to enhance public protection. That is why changes are being made to the General Pharmaceutical Council's legislation through the order, which is made under the Health Act 1999. The change is to ensure optimal design to provide safety for users of pharmacy services, while facilitating and reducing the barriers to responsible development of practice, innovation and a systematic approach to quality in pharmacy.

The General Pharmaceutical Council was established in 2010 with the approval of both the Scottish and United Kingdom Parliaments. The order will make seven key amendments to the legislation governing the GPhC's processes. The first is to remove the requirement for the GPhC standards for registered pharmacy premises to be set in rules. Those will now be set in a more proportionate and flexible way, without requiring the use of rules that must be formalised in legislation. As a consequence of moving the premises standards out of the rules, they will no longer be included in a statutory instrument that is subject to Privy Council approval and laid before both the UK and Scottish Parliaments. Standards for individual registrants are not subject to such procedures. However, the order does include an explicit and important requirement for the GPhC to consult Scottish ministers, as well as English and Welsh ministers, on changes to pharmacy premises standards.

Secondly, the proposals will enable the GPhC to apply the standards to associated premises that are integral to provision of pharmaceutical services as well as to registered premises. That reflects the fact that, in some respects, the traditional model of pharmacy premises being entirely self-contained operations at which all aspects of the retail pharmacy business are carried on is outdated. For some businesses, integral parts of their business operations, such as electronic data storage, may be elsewhere.

The third amendment sets out the registration sanctions that the GPhC may use where pharmacy owners breach the standards. The General Pharmaceutical Council already has powers to issue improvement notices where a pharmacy owner breaches the standards for pharmacy premises. The order will mean that breaches of premises standards will be dealt with as a disciplinary matter by the GPhC's fitness-to-practise committee.

Fourthly, the order will introduce the use of interim suspension orders by the GPhC when that is in the public interest, prior to a disqualification decision or a removal decision taking effect after a full hearing of a fitness-to-practise case. Those changes reflect the move to align better the disciplinary provisions for pharmacy owners in respect of breaches of pharmacy premises standards with those for individual registrants.

As well as the changes to premises standards, the order makes some adjustments to the GPhC's powers to set rules around information-gathering obligations. Should the GPhC exercise its amended powers to make rules on information obligations, those changes will be subject to further parliamentary scrutiny. The order provides for a new criminal offence to support enforcement of the rules on information obligations. That provides a backstop should a pharmacy business fail to comply with an improvement notice from the GPhC. The Crown Office and Procurator Fiscal

Service has been consulted and has indicated that it is content with that.

Fifthly, the order makes changes to the GPhC's powers to gather information from pharmacy owners so that the regulator will be able to allocate resources proportionately by assessing the risk in a pharmacy. The order also clarifies when the GPhC can require pharmacy owners to provide such information through its rules, and the type of information that is covered.

The sixth amendment clarifies what information the GPhC may publish in reports of pharmacy premises inspections and makes it clear that if a report includes personal data it is assumed, for the purposes of data protection requirements, that such information can be published.

Finally, the order will make a correction to terminology used in the General Pharmaceutical Council's procedure on the notification of the death of a pharmacist or pharmacy technician in Scotland. The legislation is changed to refer to a district registrar, rather than the Registrar General, as is currently the case.

The Scottish Government considers that the best way to improve consistency, create greater efficiency and simplify professional healthcare regulation would be to introduce a single UK bill covering all professional groups, which would build on the work of the Law Commissions. I understand that the Department of Health has now confirmed that there will not be such a bill in the near future. Instead, the department has proposed a consultation leading to a policy paper on future regulatory policy. The Scottish Government is disappointed at the lack of a bill, but is currently working with the Department of Health to understand the nature and extent of the new proposals.

The order will make important changes to allow for optimal design to provide safety for users of pharmacy services, while facilitating and reducing the barriers to the responsible development of practice, innovation and a systematic approach to quality in pharmacy.

I am happy to take any questions that members have on the draft order.

Richard Lyle (Central Scotland) (SNP): I seek some clarification on pharmacy premises standards. We have stand-alone pharmacies, pharmacies that are joined to doctors' surgeries, pharmacies within stores such as Boots and so on. Would the instrument allow a pharmacy to be established in a grocery shop or a wee corner shop? There are a lot of areas where there is no pharmacy near certain parts of the population. Would the order change that situation or am I going down the wrong path?

Maureen Watt: I will ask Alpana Mair to answer that question.

Alpana Mair (Scottish Government): The standards apply to registered pharmacy premises. In order for a pharmacy to be established it would still have to go through the normal procedures—the order does not amend those or change the control-of-entry requirements that currently exist.

Richard Lyle: Will a pharmacy apply to be established within a locality under the same regulations as before?

Alpana Mair: Yes.

Richard Lyle: Thank you.

Nanette Milne (North East Scotland) (Con): I apologise if I missed this point, but does the order bring Scotland more into line with the rest of the UK and Northern Ireland?

09:45

Maureen Watt: As I said in my opening remarks, we would like to see a more level playing field. That will not come in the near future, but we are working closely to ensure that standards are more aligned.

Nanette Milne: I just wondered what the situation is south of the border.

Alpana Mair: Draft pharmacy standards are in place across the four countries. The legislation will make the standards, which will apply across the four countries, enforceable.

The Convener: It was mentioned that there would be a consultation on any future proposals in this area. Who would carry out the consultation, how would Scottish pharmacy play into it and who will evaluate its results?

Alpana Mair: There are two aspects to that. Are you referring to the pharmacy standards that are in place?

The Convener: Yes.

Alpana Mair: The General Pharmaceutical Council—the GPhC—recently conducted a consultation, which was undertaken by an independent body. Community Pharmacy Scotland and other pharmacy contractors in Scotland would have been able to contribute to that. The GPhC has considered those comments, and it has revised and amended how it undertakes the inspections.

The Convener: According to the committee's notes, there were concerns about how any set of patient standards would be acted on or enforced. Would further consultation be wise at this stage?

Alpana Mair: As I said, the consultation has taken place recently. The response to it was

positively in favour of how the GPhC was progressing the changes that it had made.

The Convener: There were concerns and a lack of clarity about how any breaches in the standards would be dealt with.

Alpana Mair: Concerns can be fed back to the GPhC. When the GPhC formerly sets its standards, the process is open to people feeding back to it.

Maureen Watt: Any concerns would not be brought as breaches of premises standards; rather, they would be dealt with as a disciplinary matter under fitness-to-practise standards.

The Convener: We have exhausted questions, so we move on to agenda item 5, which is the formal debate on the affirmative SSI on which we have just taken evidence. As is usual at this point, I remind members that they cannot put questions to the minister and officials may not speak in the debate.

Motion moved,

That the Health and Sport Committee recommends that the Pharmacy (Premises Standards, Information Obligations etc.) Order 2016 [draft] be approved.—[*Maureen Watt.*]

Motion agreed to.

The Convener: We suspend to allow a changeover of witnesses.

09:48

Meeting suspended.

09:49

On resuming—

National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016 [Draft]

Healthcare Improvement Scotland (Fees) Regulations 2016 (SSI 2016/26)

Protection of Vulnerable Groups (Scotland) Act 2007 (Prescribed Purposes for Consideration of Suitability) Regulations 2016 (SSI 2016/27)

Public Services Reform (Scotland) Act 2010 (Commencement No 7) Order 2016 (SSI 2016/22)

The Convener: Agenda item 6 is an evidence-taking session on four Scottish statutory instruments that, taken together, provide for the regulation of independent healthcare clinics. I welcome—again—Maureen Watt, Minister for Public Health. The minister is joined from the Scottish Government by Dr Sara Davies, public health consultant, and Ailsa Garland, solicitor. Minister, do you want to make any opening remarks?

Maureen Watt: Yes, please, convener.

Thank you for providing me with the opportunity to explain the rationale behind the National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016, which, along with a commencement order laid at the same time as that SSI, expands the regulation by Healthcare Improvement Scotland of independent healthcare provision to include clinics in or from which services are provided by doctors, dentists, nurses, midwives and dental care professionals.

The Scottish Government commissioned an expert group, which included a range of service providers, members of the public and industry regulators, to develop the strategy on which the policy is based. The outcome of the expert group's work, which the Cabinet Secretary for Health, Wellbeing and Sport accepted in July last year, has been developed, with stakeholder engagement, in the policy to extend the regulation of independent healthcare to specific clinics in order to continue our programme of improving public safety and standards of care wherever services are accessed.

The policy has been welcomed by many regulatory bodies, including the British Association of Cosmetic Nurses and the General Medical Council, which will be issuing new guidance in spring for doctors who carry out cosmetic procedures. Significantly, many of the service providers have indicated their support for the policy. Although I recognise that service providers incur costs for the purposes of registration and inspection of premises, I consider that to be a necessary burden to ensure the safety of both users and providers in the industry.

The affirmative order that is before the committee—the National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016—amends the definition of an independent clinic in the National Health Service (Scotland) Act 1978 by including the additional health professions of registered nurses, registered midwives and dental care professionals. The rationale for the addition of those three groups is that, due to the changing nature of the independent healthcare market, those professionals can now offer services that include the provision of cosmetic procedures. The proposed change in the definition is supported by the chief medical officer, the chief nursing officer and the chief dental officer, as well as external stakeholders.

The order also adds specific exemptions to the definition of an independent clinic. That reflects the policy intention that the purpose of regulation is not to regulate services that are ancillary to the purpose of an organisation, which is why health clinics in schools, colleges and universities or occupational health services that are provided solely for employees by the employer are exempted. The purpose is also not to regulate services that are inspected by NHS Scotland—jointly NHS, independent general practitioner and primary dental services—and not to put a disproportionate regulatory burden on first-aid clinics, for example at sporting events, or talking therapy clinics.

The related order, the Public Services Reform (Scotland) Act 2010 (Commencement No 7) Order 2016, commences provisions in the 1978 act so that regulation of independent clinics will go live on 1 April 2016, with a delay, until 1 April 2017, in the introduction of the offence of not registering a clinic. That year's grace will allow clinics that are new to the area of regulation to work with HIS to understand the requirements of registration and ensure that their systems, policies and care are in place for the process and the following years' inspections and reports.

The Healthcare Improvement Scotland (Fees) Regulations 2016 set the maximum fees that can be charged by HIS on matters such as applications for registration of independent healthcare services. That is a ceiling and, as required by the enabling powers, has been consulted on together with the fees that HIS plans to charge for the year 2016-17. The regulations set maximum fees in relation to independent hospitals as well as clinics and revoke and replace existing fees regulations from 2011. I am aware that the fee structure has generated some interest but, as HIS is providing the service on a cost recovery basis, it is intended to be self-funding.

The Protection of Vulnerable Groups (Scotland) Act 2007 (Prescribed Purposes for Consideration of Suitability) Regulations 2016 will allow HIS to check the suitability of a provider or manager of an independent healthcare service that is registered with it.

In summary, the Scottish Government considers that the best way to improve patient safety in the independent healthcare clinic setting is to introduce regulation of clinics through the legislation described. I am happy to answer any questions that committee members have.

The Convener: Thanks, minister. The first question is from Fiona McLeod.

Fiona McLeod (Strathkelvin and Bearsden) (SNP): The instruments are very much about phase 1 of a three-phase approach towards the regulation of the industry. Can you give us any idea of a timetable for the different phases?

Also, one of the issues that arose from the round-table discussion that we had last week was that, over the three phases, we will end up with a situation in which some clinics have to register or some people will be regulated. How will the different ways of looking at that over the three phases all come together?

Maureen Watt: Phase 1 commenced in 2014 and we are obviously at the end of that stage now. Phase 2 will commence in April 2016, on the completion of phase 1, and we expect that to last until the end of this year. Phase 3 will start thereafter and will probably take another year, I think.

Dr Sara Davies (Scottish Government): Yes. For phase 2, there have been preliminary discussions through the expert group, but the proper work for phase 2 will need to be scoped and provided to the minister with recommendations.

On Fiona McLeod's question about whether some providers and clinics will be regulated, at the moment the aim is that the clinics will be regulated, because healthcare professionals are regulated under other circumstances. For phase 2, the idea is to find a way of making sure that the non-surgical cosmetic procedures that are carried out by other healthcare practitioners such as beauticians or hairdressers, which are a limited stock of non-surgical cosmetic procedures such as dermal fillers, are also captured. Whether that will be through work with the environmental health officers who license skin piercing and tattoo parlours has to be scoped and options have to be provided.

Phase 3 will be for people such as the very few healthcare scientists who provide laser services. Again, whether they are clinics and would be regulated as in phase 1 has to be scoped out.

Fiona McLeod: It helps to get that explanation. Thank you.

Malcolm Chisholm (Edinburgh Northern and Leith) (Lab): So to an extent, the distinction between phase 1 and phase 2 is that, in phase 1, the responsibility for inspection and regulation will be that of Healthcare Improvement Scotland and, in phase 2, that will be somebody else's responsibility. Is that partly what the distinction is based on?

Maureen Watt: We would need to see exactly what the outcome will be after consultation. Local authorities may well have a bigger role in the second phase than they do in the first phase.

Malcolm Chisholm: Is what is proposed fundamentally what was proposed a long time ago

in the Regulation of Care (Scotland) Act 2001 in relation to the inspection of independent clinics by the care commission—as it was being set up then—but with that now the role of Healthcare Improvement Scotland?

Maureen Watt: Yes. I was not around then, obviously, but I do not think that that was taken forward to regulation. It was then superseded by the Christie commission and the change to public services. Sara Davies can give a better explanation.

Dr Davies: Not at all. As the minister said, there was the work from 2002. Then there was the Scottish Medical and Scientific Advisory Committee—SMASAC—report, after which the CMO had a specialist advisory group looking at cosmetic surgery in 2005-06. That recommended moving forward with the regulation of independent clinics, but then there was a change, as the minister said, with the move to Healthcare Improvement Scotland.

The Scottish Government then had a consultation on what should be done. The block has always been that doctors' and dentists' clinics had to be regulated, because it was right to do so at that time. What we have now brought forward is a result of all the consultation and the need to cover a wider group of healthcare professionals.

10:00

Malcolm Chisholm: Some concerns were raised in evidence. The British Association of Aesthetic Plastic Surgeons was concerned about

"some situations where non health care practitioners are working within independent clinics and providing cosmetic interventions."

I do not know how that will work and whether that will be part of phase 2.

The British Dental Association was concerned that

"the definition of 'independent clinic'"

was based

"on the healthcare professional providing the service"

rather than

"on a specific procedure".

The BDA gave the example of

"beauticians working in beauty salons who carry out teeth whitening ... without any regulation or formal training".

Would those two situations be captured by phase 2? How would they be dealt with?

Dr Davies: I will answer the first question. If a beautician is working in an independent clinic providing certain services, it may well be that there is a nurse there. If the beautician is doing certain types of non-surgical cosmetic procedures, they will need a prescriber. If a clinic is providing certain prescribed medicines such as botulinum toxin in all its varieties, there will need to be a prescriber, so that clinic will be regulated. The person who is delegated to give the treatment will have to be under the supervision of one of those professionals.

On the example from the British Dental Association, as I think was heard in evidence, at a certain percentage of the chemicals, teeth whitening has to be done by a dentist. One of the other aspects of the work may well be that there is greater awareness of who should be doing what.

Richard Lyle: I want to ask about that very subject, because I was quite shocked on hearing the evidence about teeth whitening. When I was driving one day, I noticed an advert at a tan shop saying, "Get your teeth whitened here." That shocked me. What would happen regarding those premises? They would have to take that out, surely.

Dr Davies: The legislation is clear that teeth whitening is a role for dentists. That has possibly always escaped people's awareness. Teeth whitening has to be done by a dentist, at a certain percentage of the chemicals. At other percentages, it can be done by different groups of people. I believe that, in some situations, people used to be able to buy kits in certain shops to do it at home. The level of teeth whitening that is done by dentists must only be done by dentists. I am not answering your question, but the answer is that, if teeth whitening that should be done by dentists is being done by people who are not dentists, that should be reported.

Richard Lyle: There are adverts on the television inviting people to send away for such kits.

Anyway, I will leave that to one side and I will come on to my main question. Regarding fees, I am all for regulation and picking up people who are outside the system. We must ensure that, for instance, people's teeth do not fall out after they have been somewhere that is not regulated to get their teeth whitened. However, I am concerned about the level of the fees. In some instances, they can be nearly £2,000. There are independent midwives, and I see that there was strong resistance to having a flat registration fee. Why is that approach being proposed?

I was shocked to find that those who apply but do not meet the criteria and are refused do not get their fee back—HIS keeps the fee. I was given the assurance that HIS would work with the person concerned to ensure that they met the criteria, but there are still such cases. Independent nurses and midwives and other people who may be working

and making a living outside the health service—I say that with the greatest respect—could be faced with a fee of nearly £2,000 in order to set up. Will that encourage people? Why do we not have a sliding scale? Why do we not say that, if people do not meet the criteria, they get a proportion of the fee back? I would certainly not like to hand over £2,000 only to be told that I do not meet the criteria and I will not get my £2,000 back.

Maureen Watt: I take your point but, as I said in my opening statement, HIS is working on full cost recovery, and the same work must be done regardless of the person making the application. That was discussed by the HIS board, and it was judged that a flat fee would be the fairest approach for the first year.

We need to put it in context. There are probably only about three independent midwives in Scotland. All providers, including midwives, will have a full calendar year to register and discuss the process with HIS.

Dr Davies: As you heard from HIS at your previous meeting and as we have heard from HIS previously in relation to people putting in applications, the registration process is quite discursive. It is not a case of people providing the money and it not being returned. A lot of consultation goes on. HIS provides as much as it can by way of templates for the type of policies that people are meant to have. There is quite a long process to work through before there is a definite handing over of a cheque that cannot be returned.

Richard Lyle: If someone applies, can they sit down with HIS, prior to handing over their money, and talk through what they want to do? That might allow them to conclude that they will not meet the criteria, so they can do something else.

Dr Davies: Yes.

The Convener: I take the point. The evidence that we have received confirms that there are few independent midwives, but they are there and they are doing a job, and they will be affected by the measures. There is quite a difference between Optical Express, for example, and an independent midwife, but they will have to pay the same flat fee.

The other point that has been raised with us is about what aspects of independent midwives' work would be inspected. They do not operate on the high street; they operate in people's homes. As well as the challenge of the fees that would be levied upon them, there is a question of how to effect the objectives of the measures.

Dr Davies: As I think we heard from HIS previously, the idea of the regulation is to review current practices in a range of areas. That is about clinical governance as well as business matters.

For a midwife, for instance, HIS would want to check her record keeping, the decontamination of objects and how she manages her complaints system, in the same way as it would do for independent nurses with a small clinic providing services in a range of places. That is about the governance, the clinical governance and the financial viability of the service. That is the sort of thing that HIS would want to consider in the place that the midwife decrees is her office. There would be a report on the work that she does in people's homes. HIS would therefore not inspect individual homes where she provides her services, but it would want to ensure that her service is a viable entity and meets the standards that are required for it.

The Convener: But she is already complying with standards and is, I presume, paying a registration fee as a nurse or midwife. She is regulated by all of that, which assures some of the quality issues. Nurses and midwives will have to pay a fee of thousands of pounds to be registered, but how will that mean that someone who purchases additional services will get a better quality or safer outcome when those nurses and midwives are already regulated?

Maureen Watt: There is a big difference between operating in a hospital, a dentist's premises or an independent hospital and working in a person's home. As Sara Davies said, there are issues around decontamination and ensuring that the equipment that is used is clean and up to standard. At the end of the day, it is about the protection of consumers. In this case, people are not working in a regulated environment, and it is important that standards are high.

The Convener: At last week's committee meeting, there were questions about how dentists are currently inspected and there was a request that any inspections that are carried out on private dentists be carried out by dentists. People asked why dentists, who are contracted to deliver services as part of the national health service, have a different inspection regime from other parts of the health service, and there was a suggestion that we now have an opportunity to ensure that dentistry as a whole is regulated and inspected by HIS. Why do dentists stand separate from other practitioners?

Maureen Watt: At your evidence-taking session before the recess—

The Convener: Right enough, the meeting was two weeks ago. The recess flew by.

Maureen Watt: I think that people were surprised to hear that private dentists are not regulated at all, even though people who go to

private dentists can pay a lot of money to do so. Consumers will be pleased that private dentists who operate completely outwith the NHS system will now be regulated.

The Convener: Yes, but that regulation will be different. There was an opportunity to ensure that all dentists were regulated in the same way.

Maureen Watt: They will be regulated according to the same sort of inspection as independent hospitals. It is not quite the same approach as is taken with the NHS facilities, where public money is involved.

The Convener: So you agree with the principle that dentists should inspect themselves. The suggestion is that the inspection of a dental practice in the NHS should stand separately from the new regime, and that qualified dentists should carry out those inspections. Dentists are happy with that situation, of course. The only plea that they made to the committee was that, if we are going to inspect the private dentists, it should be dentists who carry out that inspection.

Dr Davies: As you probably heard during your evidence gathering, health boards inspect the dental practices that are under the NHS. The work that HIS is doing with the GDC and other dental groups is designed to ensure that the inspections of purely private dentists that HIS will now start doing meet what HIS wants to do with regard to independent healthcare regulation but also tie into what the health boards are getting from other NHS dental inspections.

The plastic surgeon at your last meeting said that HIS will need experts to conduct examinations of different types of clinics. Getting independent dentists to inspect other dental practices is what happens at the moment in relation to the NHS.

The Convener: It is like saying that only doctors can inspect doctors and only nurses can inspect nurses, is it not?

Dr Davies: Absolutely.

The Convener: HIS is not staffed in that way. The inspectors that HIS uses have a speciality in inspecting—you mentioned book keeping and record keeping. I think that there is an inconsistency here that has been highlighted by the new measures. There is a big argument that HIS is not independent enough from health boards. We have health boards inspecting dentists and dentists carrying out inspections. That does not seem a reassuring model for managing risk and the hierarchy of hazards.

10:15

Maureen Watt: We would expect the inspection procedures to be drawn up with healthcare professionals in the mix, whether they are doctors or dentists. Those professionals might not necessarily carry out the inspection, but would at least have had an input into the inspection procedures.

The Convener: They would be inspected against standards. We must have more dentists than we did 10 years ago if they are running about carrying out inspections.

Nanette Milne: You have an uncanny knack of answering the question that I was going to ask, convener.

I was quite surprised to see the independent midwives included, because I understand that they are already pretty heavily regulated by the Nursery and Midwifery Council. What can HIS do that is better than the current regulators? It seems odd that independent midwives are included.

Dr Davies: The reason that the independent midwives are included is to cover the two areas: the midwifery practice and where a midwife takes additional training and is involved in cosmetic procedures. The expert group advised that there are some midwives who also carry out cosmetic procedures—outwith their midwifery practice. We wanted to make sure that there were no gaps in covering the healthcare professionals who were providing such services.

Independent midwives are well regulated in relation to midwifery services. Whether the clinic or organisation, in the sense of the total services that they provide, is looked at is not clear, because they are regulated for part of the services that they provide, but not the totality.

Nanette Milne: That is helpful. I had not picked up the point about the cosmetic side.

HIS seems to be involved in many areas of health inspection these days. Are you confident that HIS will be able to get the appropriate people to carry out the work?

Maureen Watt: HIS has been provided with extra resources to deal with the extra work.

The Convener: If there are no other questions I will pick up on Richard Lyle's earlier question about professionals offering services online or on television and so on in Scotland, whose businesses are registered outwith Scotland or have no fixed premises or just a PO box. Will such companies be required to register?

Dr Davies: Where services are provided from a base in England they will be regulated by the Care Quality Commission. Where services are provided in Scotland, where at all possible they will be dealt with under the regulation.

Where a business has only a PO box or website it is quite difficult. HIS is already looking into how it

can track down the business to ensure that there is some type of regulation.

The Convener: That could become a loophole for teeth whitening.

Dr Davies: It is more a question of how practical it is for HIS to regulate such services. HIS will say to people with websites that if they provide services to Scotland they must be regulated.

The Convener: That will be the basic requirement. Whether they will and how we make them will be the challenge.

Dr Davies: Exactly. However, HIS will be saying that services to people in Scotland must be registered through HIS.

The Convener: If there are no further questions we will move to the formal debate on the affirmative SSI on which we have just taken evidence. Again, I remind the committee that members should not put questions to the minister during the formal debate and that her officials may not speak in the debate. I invite the minister to move motion S4M-15452.

Motion moved,

That the Health and Sport Committee recommends that the National Health Service (Scotland) Act 1978 (Independent Clinic) Amendment Order 2016 [draft] be approved.—[*Maureen Watt.*]

The Convener: Richard Lyle wishes to contribute to the debate.

Richard Lyle: I agree to the order, which will tighten up the situation. As I said earlier, I was quite concerned two weeks ago when we were told that tooth whitening could be done anywhere, and I saw it on a notice outside a shop.

The only concern that I have is the cost, if someone applies and does not get their fee back. However, I have sought assurance on that, and we have been given the assurance that people will be allowed to sit down and discuss the matter with HIS to ensure that they are not paying fees, only for HIS to come back a couple of weeks later and say, “Sorry, you do not meet the criteria.”

The Convener: No other member wishes to speak and the minister has nothing to add in summing up. The question is, that motion S4M-15452 be agreed to.

Motion agreed to.

10:20

Meeting suspended.

10:24

On resuming—

The Convener: Under agenda item 8, which is more subordinate legislation, we have two negative instruments before us, both of which were discussed as part of the evidence that we took on regulating independent clinics.

The first instrument is the Healthcare Improvement Scotland (Fees) Regulations 2016. There has been no motion to annul and the Delegated Powers and Law Reform Committee has not made any comments on the instrument.

As members have no comments, do we agree to make no recommendations on the instrument?

Members *indicated agreement.*

The Convener: The second instrument is the Protection of Vulnerable Groups (Scotland) Act 2007 (Prescribed Purposes for Consideration of Suitability) Regulations 2016. There has been no motion to annul and the Delegated Powers and Law Reform Committee has not made any comments on the instrument.

As members have no comments, do we agree to make no recommendations on the instrument?

Members *indicated agreement.*

The Convener: Thank you. I will suspend the meeting until our next witnesses arrive.

10:25

Meeting suspended.

10:34

On resuming—

Access to New Medicines

The Convener: Item 9 on our agenda is an evidence-taking session in which we will have a progress update on access to new medicines. It is a round-table session, so we will all introduce ourselves—although, looking around the table, I see that many of us have been here before.

I am the MSP for Greenock and Inverclyde, and I am the convener of the Health and Sport Committee.

Lesley Loeliger (PNH Scotland): I am the chair of PNH Scotland.

Dennis Robertson (Aberdeenshire West) (SNP): I am the SNP member for Aberdeenshire West.

Malcolm Chisholm: I am the MSP for Edinburgh Northern and Leith.

Leigh Smith (Health and Social Care Alliance Scotland): I am from Melanoma Action and Support Scotland, but I am here representing the Health and Social Care Alliance Scotland.

Mike MacKenzie (Highlands and Islands) (SNP): I represent the Highlands and Islands.

Natalie Frankish (Genetic Alliance UK): I am the development officer for Scotland for Genetic Alliance UK and Rare Disease UK.

Colin Keir (Edinburgh Western) (SNP): I am the MSP for Edinburgh Western.

Mark White (NHS Greater Glasgow and Clyde): I am the director of finance in NHS Greater Glasgow and Clyde.

Richard Lyle: I am an MSP for Central Scotland.

Aileen Muir (NHS Greater Glasgow and Clyde): I am the lead pharmacist for governance in NHS Greater Glasgow and Clyde.

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

Professor Rob Jones (Beatson West of Scotland Cancer Centre): I am a medical oncologist at the Beatson in Glasgow.

Fiona McLeod: I am the MSP for Strathkelvin and Bearsden, and I am the deputy convener of the committee.

Sandra Auld (Association of the British Pharmaceutical Industry): I am the director of the Association of the British Pharmaceutical Industry in Scotland.

Dr Catriona McMahon (Association of the British Pharmaceutical Industry): I am the lead Scottish Medicines Consortium member for industry, working with the ABPI and companies. I am also an Edinburgh-trained physician.

The Convener: We will go directly to questions from the committee.

Nanette Milne: I am interested in hearing how things are progressing with access to new medicines. As you know, the committee has done a lot of work on the issue over the years.

How has access to new medicines improved since our investigations began? Have any changes been successful in improving access to the drugs? Where does progress still need to be made? I am particularly interested in the uptake of the new medicines fund.

The Convener: That sets the scene. We have received written evidence, but everyone has a chance to place issues on the record today.

Lesley Loeliger: Two weeks ago, I was fortunate to take part in the patient and clinician engagement meetings that have been taking place in the SMC. As a patient, I had an amazing opportunity to speak about my condition and the costs that exist, other than the basic costs of the drug, and to have clinicians who are experts on my condition and my drug speak on behalf of the drug. Before the PACE meeting, I was given amazing help and support by the SMC. The one-to-one help with my preparation for the meeting was second to none.

You asked what could be improved—obviously, some things could be improved. My drug is used for another condition, which is called atypical haemolytic uraemic syndrome. People with that condition had a PACE meeting in December that, by all accounts, went well, but they have been turned down for the drug. It makes perfect sense to me that not every drug can be accepted—that is not what we were looking for in the process—but the wording of the rejection concerned me, as it seemed to imply that we are looking at the bottom-line expense of drugs. I completely understand that, but I think that what is slightly lacking is an understanding of the overall cost and the difference that such decisions make to people's lives as well as the extra things that need to be in place, such as dialysis. There must be a bit more clarity about how the decisions are made.

Furthermore, if there is a rejection on the ground that a drug is far too expensive—which I completely understand—I would like there to be some clarity about what negotiations will go on after that stage, at which a drug company can be brought to task. Those things might happen but, if patients could have sight of that process, we would have more faith in the system and a bit of

hope that we had a path of care still available to us.

Professor Jones: I will try to represent the views of my colleagues at the Beatson. We have noticed a significant lowering of the threshold for the acceptance of drugs by the SMC. That is the bottom line.

By and large, my colleagues who have taken part in the PACE scheme—I have taken part in it myself—are very enthusiastic about it because it provides an opportunity to give information over and above what can come out in a written submission. There is a bit of perplexity, however. We accept that, even when a PACE group warmly supports the use of a drug, it will not always be accepted, but we would like a clearer explanation from the SMC—particularly when the PACE group has given resounding support to a drug that is then rejected—as to specifically why the group's recommendations have been rejected. The SMC has, nonetheless, made tangible improvements.

The other aspect of access to medicines is the individual patient treatment request. There have been some concerns among colleagues that that has led to different thresholds being set in different regions of Scotland for acceptance of the same medicine in the same clinical circumstances, which is something that none of us is keen to support. None of us has seen any evidence of the peer-approved clinical system—PACS—in action yet, but it represents an opportunity to try to level out the interregional variability regarding individual patient treatment requests. Nevertheless, we are keen that, even with an overarching agreement on access to medicines when the SMC has not accepted their use, an individual patient treatment pathway should still be retained no matter what process is put in place with PACS.

The Convener: I am trying to encourage the MSPs around the table, but they are not putting their hands up to speak. We have a panel here, however, and we are going to give it a voice.

Leigh Smith: I hope that everyone has read Dr Andrew Walker's submission. Andrew is an academic and a poacher turned gamekeeper, one might say, or perhaps a gamekeeper turned poacher—it is hard to say from his record. In his submission, he has clearly laid out exactly how many drugs have been accepted, and there has been a definite improvement.

Nevertheless, I echo what Professor Jones just said. I have been to four PACE meetings that had a really strong staff that was well supported by the SMC. On each occasion, when the plea for a drug to be accepted was made by us, by the patient and by the consultant dealing with melanoma patients at the Beatson, we came away from the meeting feeling that we had done our best, that the request had been accepted and that all would be well. However, when we went along to the full meeting to see the result, it came across very strongly—it is part of the transparency—and we could see very clearly that the place for the clinician would have been at the full meeting, where they would have been able to answer any questions that were still unanswered. That would have allowed the committee to make a properly informed decision.

I was dreadfully disappointed to find that, although one of the drugs that we had pleaded for had been accepted for first-line use, we had lost out on second-line use because of unanswered questions in the final meeting. We have a whole batch of patients who have done well on a first-line immunotherapy treatment but who will, in time, start to fail on that or will not respond to it, so they desperately need the second-line therapy. However, that means having to go to a resubmission, which takes even more time, and clinicians' time is desperately important. We are very short of clinician time for melanoma patients and we cannot afford to give up any more of it to bureaucracy.

10:45

Natalie Frankish: I agree with what Leigh Smith says. One of the real strengths of the new system is the way in which patients and questions are involved in the PACE process, which has certainly been an excellent step forward. In particular, the patient involvement team at the SMC does an absolutely fantastic job of raising awareness about what the SMC does and how patients can be involved in it.

However, there is a glaring omission at the final decision meeting in that there is no patient or clinician around the table to answer those questions. Sometimes, things are lost or tangents are taken, and the discussion would benefit from the ability of a clinician or a patient to clarify a point. That is a necessary next step to take. There is certainly room for the pharmaceutical industry to sit around the table and answer questions, and the same courtesy should be extended to patients and clinicians.

Sandra Auld: The ABPI commends the SMC for the substantial process changes that it has gone through. It has worked very hard to pull through those changes. If the intention was to have more acceptances, that has happened—and quite dramatically. However, the system needs to continue to evolve to deal with the new and different types of medicines that are coming through and will continue to be presented to the SMC. If the SMC wants to stay at the forefront and continue to be the world-recognised organisation that it is, there must be a continued evolution.

Dr Jones mentioned IPTRs and the PAC system. It has become clear that there must be a safety net for medicines that are not recommended. We are waiting to see what the IPTR replacement will be. I know that there has been discussion of a pilot in Glasgow, but I am not clear about the detail of that.

The Convener: From the written evidence and from what the panel have said, it appears that genuine progress has been made. The committee was looking for more yeses in the system and there clearly have been. The fact that people appreciate the engagement, the involvement and the opportunity to give greater detail has come out in the written evidence, too.

Other questions are whether the SMC listens and whether a decision will always be down to cost. I am looking at Mark White because he is the man with the balance sheet and his submission mentions the costs, the diversion of resources, the limits that we have and so on.

Mark White: There is not much more to add. The new medicines fund has been excellent in allowing us to allocate resources to rare and orphan drugs without having to divert resources from other areas of our healthcare provision. We are supportive of the fund, and we hope that it will continue.

The Convener: What level of funding is given to the likes of NHS Greater Glasgow and Clyde?

Mark White: In 2015-16, the total pot of the new medicines fund was £90 million. NHS Greater Glasgow and Clyde's share from the national resource allocation committee equates to about £22 million or £23 million. The initial figures for 2016-17 are down on that amount, but we are still finalising those figures with our Scottish Government colleagues. That is the level of funding for a board of that size.

The Convener: The 2016-17 figures are down, so there will be a gap.

Mark White: It is likely that there will be, but we are still finalising the numbers.

The Convener: Have you been spending your allocation?

Mark White: Absolutely. We are spending more than our allocation.

The Convener: You are spending more than your allocation.

Mark White: The new medicines fund contributes—it is helpful—but it is still not enough. We have to find funding from other sources in order to fund fully what is needed.

The Convener: No boards other than NHS Greater Glasgow and Clyde are represented here, but does anyone else want to pick up on the regional application of the medicines? Professor Jones has mentioned that progress is not as great in some areas as it is in others. Indeed, the written submission from the Beatson west of Scotland cancer centre uses the term "postcode prescribing".

Sandra Auld: The committee asked whether the changes have improved access to new medicines. The approval rate has certainly improved, but we are not clear whether that has translated into patients being able to access the new medicines. It would be helpful to have, for example, Healthcare Improvement Scotland identified as an organisation that would monitor the implementation of SMC decisions as we moved forward. That would make clear throughout the health boards what was happening where.

The Convener: You might want to come back and give us a full explanation of that point, because my simple mind questions how, with more money and more patients overall, there can be a contradiction between patient access and approval rate. Leslie Loeliger wants to speak—please help me.

Lesley Loeliger: I was going to say that we were trying to get rid of the IPTR system—that was one of the things that were meant to happen. We were going to move to PACS, which has been mentioned, but that has not happened.

In the interim, we still have a situation in which each health board is following its own IPTR protocol. I printed out most of the IPTR protocols that I could find from the different regions. They still ask for a patient's clinical circumstances to be significantly different from those of other patients and for there to be a significant difference in the way that a drug would affect them. There are 15 people with my condition on the drug in Scotland, and it is very hard to be different in a cohort of 15 people. The issue that we have is that the practice is to use an IPTR form that still requests exceptionality—a clinical difference. We need to see the PAC system in place.

Professor Jones: I am the person who is guilty of using the term "postcode prescribing", although I qualified it with the phrase "low level". That issue concerns both clinicians and patients.

When there is an SMC acceptance, we have no tangible concerns about differences in implementation. I am not saying that there are none, but I have no evidence of them.

The issue is with non-accepted IPTRs. They may be so only prior to an SMC review, of course, and they might ultimately be accepted by the SMC. Prior to July 2013, there were reasonably clear definitions of when IPTRs should be accepted and, by and large, those definitions

meant that they would not be accepted. Clearly, we have seen a dramatic lowering of the threshold. However, the problem now is that there are no clear criteria for when an IPTR should be accepted. Therefore, if a patient submits the same request in different parts of Scotland, they may get different answers.

A nationally agreed system would be good, but I reiterate that we are very keen to retain the process by which individual patients' needs can still be met. Notably, in England there is now virtually no process by which an individual patient's needs can be assessed. That causes a lot of problems for patients there, and I do not think that we want to see that happening in Scotland.

The Convener: I see that Richard Lyle wants to come in. You are at the bottom of a long list, Richard. Dennis Robertson is next.

Dennis Robertson: Thank you, convener. I want to continue the discussion on the IPTR system. Lesley Loeliger said that she wanted to abolish it. In her evidence, the cabinet secretary suggested that there has been a substantial increase in medicines because the IPTR system has been reviewed. Do you agree with that submission from the cabinet secretary?

Lesley Loeliger: I am sorry—are you asking whether there has been an increase in access to medicines?

Dennis Robertson: Yes, a substantive increase.

Lesley Loeliger: It is not that I wanted to get rid of the IPTR system. In the access to new medicines inquiry, one of the things that were discussed was an overhaul of the IPTR system.

I would say that the new medicines fund has increased access to medicines considerably. I know that all the patients who have my condition have the drug. Without a doubt, something is working.

The point is to try to make sure that we fill in those gaps that still need to be filled. In my patient group, when a new patient comes in, I still find myself asking them which area they come from, and I do not want to have to keep asking that. I want access to be fair throughout the country.

The Convener: Sandra, do you want to respond to Dennis Robertson's question?

Sandra Auld: We understand that there has been a specific issue with IPTRs once a medicine has not been recommended by the SMC. If IPTRs had been approved but the medicine is then not recommended by the SMC, there might be a gap before a resubmission is made. There has been a sharp decline in, and maybe a complete cessation of, the approval of IPTRs. Those are patients who are no longer able to access a medicine, and that is a real concern for us.

Natalie Frankish: I will give you a patient organisation's perspective. We have had much less criticism of the IPTR system from our member groups and fewer people are coming to us with tangible problems that are not down to communication issues with clinicians.

There is a little bit of a difficulty, because although we can say for sure that there has been an increase in the number of people who access medicines through the IPTR route, we do not really know why that is. It comes down to the lack of guidance that is available. The interim guidance for the IPTR system says that there is no exceptionality, whereas the forms suggest that there still is. The message on what is happening on the ground is a little bit inconsistent.

We are really supportive of the PAC system and our patient groups are keen to see it moving forward. Understandably, there must be a pilot: we need to know that the transition will be smooth for patients and that they will not end up lost in the system. The lack of communication on that has been slightly disappointing; it would be good to know and to be able to tell patients what is happening and when it will happen, and to have an understanding of the system before it is in place.

Leigh Smith: We have not had anyone apply through an IPTR to have a drug for melanoma accepted. Because of the changes in the system and companies perhaps seeing an opportunity to be reheard by the SMC, it appears that the SMC's workload has increased substantially. The time gap between a drug being licensed and the case being heard by the SMC appears to be growing; perhaps there is not enough time or staff to process things. We have patients who are in desperate need of new drugs that are licensed and accepted in England, but which they are unable to get because they have not been accepted in Scotland because they have not been tried, or because they are not available for second-line use or for an IPTR.

A lot has improved. I was delighted to read the NHS Greater Glasgow and Clyde submission, which says that patients with cystic fibrosis and renal disease have benefited from the new medicines fund. However, it is very disconcerting to read that the Beatson people have not seen any of the money. They have not benefited at all, despite the fact that the Beatson is in Glasgow, where the pilot scheme is. I hope that I have not misunderstood that.

Professor Jones: I can clarify that. None of the consultants at the Beatson centre is aware of

having benefited, and the assumption is that the funding takes place behind the scenes. That was one of the specific questions that were asked. We have seen no evidence of having benefited, but I do not think that there is a suggestion that that is not happening.

Aileen Muir: That is absolutely correct. Behind the scenes, we look at what medicines have been prescribed by consultants, then we submit the list to the Scottish Government in order to access the new medicines fund. It is not unexpected that consultants themselves would not have anything to do with that. It is data that comes out of the system. The fund has been accessed widely for the appropriate medicines.

Dennis Robertson: Lesley Loeliger mentioned different protocols in different areas. Professor Jones, you said that perhaps national guidance would be more effective, although you still want there to be an element of individuality. Who would write the national guidance? Would it be you?

Professor Jones: I am not sure that guidance is necessarily the way forward, because it is difficult to formulate. We want to see greater consistency across the country and there are a variety of mechanisms by which we can generate that. One of my concerns about PACS is that although we want to move away from exceptionality, we need to know what we want to move to. Clearly, it cannot be blanket acceptance, because that is the SMC's job.

The issue is very difficult. However, there may well be systems through which clinicians can get together to at least find processes to minimise inequalities of access.

11:00

Dennis Robertson: Do you have proposals in mind?

Professor Jones: This may not be the place to put those forward. There are a couple of potential ways in which that could be done, one of which could be to have groups of specialists. I treat prostate cancer, and only about a dozen of us in Scotland will prescribe drugs to treat that. We meet regularly and all know one another. We could at least get together to define what our wishes are—we have tried to do that—but even that is quite difficult.

A second approach would be a process by which IPTRs, or whatever replaces them, are reviewed on a national basis. I do not actually know what happens to an IPTR in Lothian. I know what happens to IPTRs in the four member health boards in the west of Scotland. There are a number of ways in which that could be done.

Dennis Robertson: That is very helpful.

The Convener: Does anyone else have a solution to some of those problems or wish to make a comment?

Lesley Loeliger: We have come back to the point that I raised when we first started talking about this, which is that, for very rare conditions, there are very few specialists. There is one recognised expert in my condition in Scotland. We need a centre of excellence for different conditions, although I know that that would not necessarily be possible for every condition.

I am very grateful that I have my recognised expert close by, but that is not the same for every patient throughout the country. All patients deserve the same expertise when their drug regime is being considered.

The Convener: The other issue, which I think was mentioned by Leigh Smith, is that of the unintended consequences and delays that are involved in potential negotiations. Some of the written evidence suggested that we were creating a system in which the pharmaceutical companies put in a bid to provide drugs and medicines and expect to be sent back to revise it, which distorts the system. That was mentioned in NHS Greater Glasgow and Clyde's evidence.

I am looking for delays in the system. In much of this area, we are talking about small numbers of individuals whom you are all trying to help. If that process becomes burdensome for the administrators of the system and the negotiation process is time-consuming, that has a disproportionate effect, given that the people involved are at the end of life.

Aileen Muir: In our submission, we said that we would prefer the pharmaceutical industry to come forward with its best price right at the beginning of the process, rather than us having to go back to it or wait for a patient access scheme in the middle of the SMC process. That would be a much more efficient way forward than expecting to have some price reduction in the middle. We would prefer that to happen, in the interests of efficiency and the best use of everyone's time.

Mark White: I have nothing more to add except to reiterate that some of the discounts that we subsequently get are sizeable and can be very beneficial but happen after the event. Such a level of negotiation earlier in the process would be more helpful.

The Convener: How do you know whether a figure is the best price?

Mark White: I could not comment.

Leigh Smith: A great deal of expertise is used at the various meetings. The best person to negotiate a price with a pharmaceutical company may be someone who is a skilled negotiator, as

they will certainly have to deal with a skilled negotiator from the pharma industry.

In the past, it would fall to the principal pharmacist to work out a deal on drugs and the price that would be paid. The people involved were in very close contact with one another, and if someone got a penny more off a pack than someone else, the pharma people got to know about it very quickly.

The place of the SMC might be to ignore the price and the negotiation side of things, to decide whether we need a particular drug and how much of it we will need, and to feed that information to a negotiator to get them to screw down the pharmaceutical company and get the very best price. That is repeated by Andrew Walker in his submission.

Sandra Auld: I would like the committee to focus on the value of medicines rather than the price and to consider how the system that we have in place can be adapted to deal with the newer medicines that will come through for very small patient populations so that patients in Scotland can access them. Because of the way in which our NHS and academic centres are designed, there is a real opportunity that Scotland can lead the way on that. We need to make the most of that opportunity.

The Convener: We are just trying to establish whether there is an issue. The committee is looking to make recommendations about the evolution of the process, so we need to know whether it is an issue.

Aileen Muir: There could be a more efficient way of doing things. In Scotland, we have NHS National Procurement, which is the body that negotiates on prices. However, when a new medicine comes to the market, that is often not the time that that happens. It is up to the pharmaceutical industry to produce a patient access scheme at that point—as the system stands, the onus is on the industry at that point.

The Convener: I think that Malcolm Chisholm has a question.

Malcolm Chisholm: The discussion has moved on since I thought of coming in. I am interested in finding out where there is agreement so that we can know what change to push for. I was struck at the beginning by the emphasis on the PACE process, because Genetic Alliance UK and the Beatson seemed to be saying much the same thing, and I have been supporting a campaign by Breast Cancer Now, which is also asking why patients and clinicians are not available at SMC meetings. There seems to be agreement on that.

I am interested in hearing a bit more on the IPTR process. For example, Breast Cancer Now would welcome consideration of a national decision-making system. Should we be trying to bring about some improvement to the IPTR system now, whether that proposal or something else, or should we introduce the PAC system as soon as possible, although it seems clear from what Professor Jones said that that will not necessarily solve all the problems? I do not have a sense of any consensus about what we should do for situations that the IPTR system currently covers.

Natalie Frankish: It will be quite difficult to answer that question until we know the outcome of the pilot that is happening in Glasgow. Although we are unsure what it will look like, it is important to remember that PACS was developed through a real multistakeholder consultation on what should be the best system. We would hope that that would have some positive impact but, until the pilot has communicated on what has happened, it is hard to know what the system will look like in practice.

For me and the patient organisations with which we consult, there is a frustration that PACS has not come into place yet. We are keen for it to develop quickly now that there is a pilot. However, until we know the results of the pilot, it is hard to know exactly how it will work in practice.

Dr McMahon: There is a natural tension in the system between the desire to be able to identify the best treatment for the individual patient who is in front of us on a given day as a consequence of their clinical need and the national perspective of a proposal that would manage the majority of requests that might come through.

As Professor Jones says, individuality is important and it is the SMC's job to give the blanket position on a medicine when it is possible to do so. As Natalie Frankish says, it is very much about consultation, working through the pros and cons and testing the system to identify where the best answer sits. My feeling is that it would be difficult to put in place a solution that would be national and would cover all disease processes. In fact, as a best-case scenario, we would probably end up with an individual solution for each disease process so that every patient group has its own system, because needs vary according to the patient's presenting issues.

I would love to be able to say that there was one answer, but there is a natural tension in the system that makes that difficult.

Malcolm Chisholm: There could be national criteria for individual diseases. I think that that is what Professor Jones was saying about prostate cancer.

Professor Jones: I am trying not to speak specifically about prostate cancer.

There are opportunities for saying that a particular group of patients—defined by X, Y and Z—should be able to access a certain drug that is not accepted by the SMC. The problem is that that will be disease indication-specific, which I suspect will not deal with the majority of situations in which a patient's individual needs are for a drug that is not accepted by the SMC. That cannot deal with the whole problem.

Dr McMahon: This is where there is an opportunity in the process, rather than specific guidance or a specific decision. We must ensure that the processes that we put in place reduce the confusion and complexity, rather than having definitive decisions.

Leigh Smith: Like Professor Jones, I do not want to concentrate too much on my own disease area. However, for melanoma, only four or five clinicians in Scotland—if that—are likely to use the sort of drugs that we are discussing. Scotland is a small country. We have roughly 1,200 new cases of melanoma each year, from which 200 people at most will go on to need this sort of drug.

Following up what happens to patients when they are given a new drug over a certain threshold would provide much more evidence or post-marketing surveillance. What really happens when such drugs are used in Jock Tamson's bairns instead of patients who have been carefully selected for drug trials for a variety of reasons?

If we fed back to the pharmaceutical industry the results of the real-life, everyday usage of its drugs, we might well be able to negotiate an even better price for the information that we could sell it, which would then be used throughout the rest of the world. We are an ideal size for such research and we are in dire need of knowing exactly how much benefit we get from our huge spend on these very expensive drugs.

It is not impossible that computer programs are available that can take patient input about everyday side effects, for example. Every time someone has a side effect, that means an intervention such as a hospital visit or another drug, which all adds to the cost. We really need to see the global cost of treating diseases and not just the price of the drug.

Natalie Frankish: I completely agree with that statement. The wider view of the value needs to continue to be taken up and discussed with the SMC.

Although we have seen an increase in acceptances across the board since the changes have been made, it is difficult to know why those changes have happened. Is it because of PACE, the patient access scheme or cost? What is the contributory decision and factor? A process is needed for constant evaluation of decisions so that we can pinpoint where in the process they are being made. That will give us scope for making the process sustainable for the future.

11:15

Dr McMahon: We are talking in similar terms. In the future, we will need to look at significant changes in the regulatory structures. Medicines are now being approved on more immature evidence than healthcare systems have to date been used to. When we look at rare diseases or ultra-rare diseases, we are looking at an evidence base that is not at all aligned with the gold standard that clinicians are used to using when making evidence-based decisions.

The industry is interested in looking at earlier health technology assessment approvals—that is, earlier agreements for medicines that can be used conditionally in the Scottish healthcare system. Is there an opportunity to do exactly what Leigh Smith talked about, which is collecting the evidence as the medicines are used actively with patients—who experience the condition, the medicines and the consequences, both good and bad—and playing that back into an evaluation of the medicines?

When we talk about patient access schemes, we mean simple discounts at the moment. However, there are many ways to look at the true value of a medicine other than by modifying the price.

Some medicines that will come through in the next few years will still have a cost per quality-adjusted life year that is above £50,000 to £60,000, even if they are made free. That is purely a consequence of the way in which the medicines might be introduced. The cost of the medicine per se is not the only aspect that we should look at, and the industry is interested, as patient groups are, in working out how we could look at that.

The Convener: Are there any other views on that point? When it is put in that way, it plays into other evaluations of the justification of spending by health boards and the best treatment for patients. Access to a specific drug is not always the best treatment; the chief medical officer has commented recently on overmedication.

What is best for the patient? What is going on to evaluate the benefits and justify the costs? Are any bodies or groups coming together to do the work that Leigh Smith suggested?

Professor Jones: I can speak only with limited knowledge. There has been a large exercise to ensure that all cancer drugs are prescribed by a computerised system, which uses the same database throughout Scotland. That will give the opportunity to draw together information on every

patient who is prescribed those drugs in the NHS in Scotland.

Aileen Muir might have more information. There is on-going work to harmonise the systems so that we can deliver more data. It is really important to manage expectations, because it is difficult to quantify the benefit that a drug gives an individual patient. I am not saying that we should not do such work, as it is important, but I would not want to raise expectations that we will be able to say that a drug delivered a gain of so many quality-of-life years.

The Convener: There is a downside to that as well.

Professor Jones: Yes.

The Convener: How difficult would it be to get an exercise off the ground? What level of work has taken place?

Aileen Muir: I agree with Rob Jones that work is going on to bring together reporting mechanisms from the prescribing system. Sometimes, the challenge is that we have an information technology system that has been established for one reason and we try to use it for another. That inevitably makes the task more difficult. We are using a prescribing system that might be used slightly differently by different boards to get out similar data.

In NHS Greater Glasgow and Clyde, we do small-scale work on individual medicines and how patients respond in a real-life situation. At the moment, that requires a long and laborious methodology, because it has to be done by people in a long-hand way. Once work has moved forward on reporting mechanisms from the prescribing system, we will be in a better position to do that. We may be able to do small-scale work at the moment, but to have a large-scale post-marketing exercise seems out of reach.

Sandra Auld would be able to tell us how much a robust clinical trial costs. Post-marketing work to get robust data would also have a cost attached, which I imagine would be quite large.

Sandra Auld: What came to mind as Aileen Muir was speaking is that the industry would be willing to collaborate on such work. It should be a collaborative venture, and we would be willing to work with the NHS to put systems in place.

Leigh Smith: A system has been presented and accepted by the IT systems people in the Scottish Government. It is defined so that a patient with an iPhone can input their own data on a side effect, for example, as it happens. The system has been used in some disease areas, some health boards are interested in it and we hope that it will evolve and be available for all of us.

However, we also have the problem that medicine is evolving at such a rate, and stratified medicine is coming along. The system will have to constantly evolve. There may be a situation in which there are three patients in the whole of Scotland who need a particular stratified drug.

The Convener: Health boards might want to use such an evaluation system for all sorts of procedures. A good argument has been made for looking at outcomes, and not just in relation to cancer drugs, as we are talking about drugs for rare diseases.

Richard Lyle: I totally agree with Lesley Loeliger's earlier point that keeping people in their own homes may save on costs and lengthen people's lives. As far as I am concerned as a politician, the cost should not come into it, although I know that it does for Mark White.

We have been given evidence that

"cross-border differences are fewer now than in early 2013—indeed there are some drugs which are accepted for use in NHS Scotland which are not accessible in NHS England".

Why is that? My concern is that there are drugs that are accepted in England that the SMC does not accept in Scotland. Why can the National Institute for Health and Care Excellence and the SMC not work together? Maybe Professor Rob Jones will answer this question: if one of those agencies accepts a drug, why does the other not accept its findings? Then we could ensure that such drugs were evaluated throughout the United Kingdom.

Someone can correct me if I am wrong, but I think that NICE decides the price and we have to follow. I love the idea that we could get a strong-arm person in to cut a few pence off some prices, but most of the drug companies say to me, "It costs us millions of pounds to develop these drugs, so we need to recoup our money." Maybe Professor Jones could inform me why we do not have acceptance on both sides of the border.

Professor Jones: I raised the point about cross-border differences simply because it causes patients a lot of anxiety if they perceive that they cannot access a drug that they know that they could access if they had an English postcode. The NHS in Scotland and the NHS in England are very different, and we have to have our own processes. It is not for me to decide how things differ across the English border, but it is difficult to see how we could have an independent healthcare system if we had to follow decisions that were made entirely by another country.

Richard Lyle: I would hope that the NHS in England followed our decisions.

Professor Jones: Often the Scottish decision comes before the NICE decision. We should remember that England has had the cancer drugs fund, which has enabled more rapid access prior to a NICE decision. We debated that approach, but I could detect no appetite from anybody in Scotland for an English-style cancer drugs fund in Scotland. When we see where that fund is going, I think that we were right.

Dr McMahon: With regard to Mr Lyle's question about the differentiation, some of that sits with the definitions that we use in Scotland. For example, our definition of end of life is three years or fewer, whereas in England, the definition is two years or fewer. In Scotland, we do not set a threshold per se.

As an SMC committee member, I know that we have thoughts on the cost per QALY and the implications of that, but there are no set numbers that define our decisions. In NICE, much more definition sits behind the process. Those are the major differentiators and are why we get medicines through in Scotland that might not necessarily get through in England.

On the other point, NICE does not set a price. NICE is an HTA body, which is similar to what we have in Scotland, but it uses a different process. Its job is to determine the value of a medicine in terms of its cost effectiveness. The price is set in collaboration with the UK Government, as that is a defined responsibility of the UK Government, and the companies then offer discounts. The price is set—it has international implications—and it is discounted from that point onwards. NICE does the same thing as the SMC does in determining cost effectiveness.

Richard Lyle: Concerns have been strongly expressed about the number of submission deferrals that companies are experiencing and about what appears to be a limiting factor on throughput—the limit of three PACE submissions per month. Given that SMC processes evolve, does it have the right resources and skills in the right places? Does the SMC have the support that it requires to adhere to the decisions that we are making?

Dr McMahon: One of the pleasures of my role is that I get to see things from the perspective of the industry and of the SMC. From the industry perspective, my answer is that we have in the past 12 to 18 months seen a significant number of new medicines coming through as a consequence of company pipelines starting to deliver. Companies have become much more efficient and effective in developing their medicines. As a consequence, more medicines are getting licensed and coming through to health technology bodies such as the SMC.

The SMC has an embrace-all-medicines strategy, which means that it has to consider virtually all new medicines. My feeling is that the pipeline of medicines, the number of medicines and, critically, the complexity of those medicines are continuing to grow, with an SMC structure that is fully cognisant of the transitions that are happening. Conversations that I have had with the SMC indicate that it knows that that is happening, but the resources are behind the pipeline delivery. The SMC will need more resources and we will see more complex medicines, probably more PACE medicines and more complex decisions having to be made by the infrastructure of the SMC in the committees.

Sandra Auld: The PACE process also has resource implications for health board representatives, patient groups and charities. This is not just about SMC resources; PACE puts resource requirements on other organisations in attending and contributing to meetings.

The Convener: How does that impact on the wider costs of processes and the involvement of a health board?

Mark White: It contributes to the bottom line that we have to manage internally. It is as simple as that.

The Convener: So there is a cost, but it has not been defined.

Mark White: In effect, yes. We have to work back to establish what the cost will be and build that into our budget, so that we manage it in the best way that we can.

11:30

Natalie Frankish: There can be an impact on patient organisations—particularly those for very small disease areas, when just one person might head a UK-wide organisation. That person might provide peer support to other patients and might not get involved in such processes.

There is a capacity issue that affects a lot of patient groups' ability to get involved. The patient and public involvement team at the SMC has been excellent and has provided as much support and advice as it can to help smaller groups through the process. However, there are times when patient groups are not there, and we need to recognise how to adapt in those situations.

Sandra Auld: I do not know whether Dr Jones wants to say anything about the clinical input to PACE and the demands that it puts on the system in relation to clinic time and patient-facing time.

Professor Jones: Clinicians certainly have a number of calls on their time. I would like to think that clinicians would prioritise such activity,

because we put a high value on it; that point was clear when I discussed this with my colleagues. We in Glasgow are maybe a bit luckier, because the meetings are held in Glasgow. I know that there are difficulties in getting people in from other areas.

Aileen Muir: I suggest that it is true that it can be difficult to physically attend a meeting, but I know that a lot of clinicians from other health board areas try to teleconference or videoconference. They certainly make efforts to take part in the process. As Dr Jones said, they seem to value that extra dialogue.

Lesley Loeliger: As somebody who runs a charity on her own, I know that there is a financial impact from going to the meetings, but attending the PACE meeting was incredibly important and valuable. For my clinician, it involved time out of a busy work schedule, but she also said how amazingly valuable it was to attend the meeting.

I always come back to the fact that, from the start of the process, my whole wish was that we would have a clearer understanding of exactly what has been described—the overall cost of a drug and not just the bottom-line cost. As Richard Lyle kindly brought up again, if we had some kind of mechanism—even a price for each thing that can happen to a patient over and above the cost of the drug in question, which would allow us to say, "Look, this is the cost for a person with this ultra-orphan condition if they do not have the drug"—that would make the PACE system a lot better.

Leigh Smith: I am sorry to repeat this, but the PACE system is brilliant. We are well supported to use that system, but I am concerned about the clinicians' time. We have one part-time clinician in the west of Scotland who looks after melanoma patients. One of the advantages of the new drugs has been that the clinics have grown. The number of people who go along to clinics regularly has multiplied because people are surviving longer, so that part-time clinician's workload has grown enormously, and she has to take time out to go to PACE meetings. We have had four of those meetings since the PACE system started.

I feel that the clinician's place needs to be at the final SMC meeting. That would be a better use of time, because there is an impact on patients. If people have to wait longer because of clinic timing—their visit might be due one day but put back for two weeks because there is no one to see them—there is a constant add-on to the system and to the bureaucracy. We have to use a clinician wherever they can be of most value, which means bringing them in not at the PACE meeting but at the new drugs committee, which is when the first decisions are made, or at the final stage.

We have to make sure that there is a clear division between the new drugs committee deciding that a drug is too expensive and the matter going to PACE, because that is when the patient access scheme comes into play. If the final decision is made on the basis of the drug discount, it is such a waste of time—not just for small charities but for clinicians—to go along to a PACE meeting. That will have taken up everyone's time, but the difference will really have been made by the fact that the cost has been dropped. I am sure that everybody who has any experience of that would agree with me. We need those aspects to be separated.

The Convener: Looking at some of the evidence, I suppose that the on-going issue is that the funding for the new medicines fund is based on the share of a rebate. Andy Walker has pointed out that a new agreement is due in 2018. Is the rebate going to be as generous? If not, how will the fund be sustained? Will the boards be able to sustain it? Indeed, the question within the question in my briefing is whether more cost-effective treatments are being used elsewhere that could play into some of this.

Does anyone want to respond to that? I think that Mark White started to answer the question when he talked about being in a good position now because, as a result of the system that the Scottish Government has put in place, money is flowing to the boards to deal with these matters. Is that the best way of using the money or are there other cost-effective treatments that could give us similar results?

Mark White: I have no doubt that it would be worth taking more of a look at the area. As I said, the new medicines fund is a welcome source of funding and it has enabled boards at the front line to devote resources to exactly the kinds of drugs that we have talked about today.

As for the renegotiation, I am not sighted on that at the moment and have no idea how it will pan out. These things are determined as much at a UK level as at a Scottish Government level, but I hope that it will result in funding sources that are similar to those that we have seen over the past two to three years. As I said, though, I am not sure how that will pan out.

On your last question, our pharmacists are continually looking at and reviewing other cost-effective methods. It is a challenging area and we need their expertise at the table.

The Convener: Does anyone else have insights into this? I know that it is a bit early but, given that we are talking about a scheme with a £90 million budget, £23 million of which goes to Glasgow, and given that there will be a renegotiation in 2018, we should be starting to get some appreciation of

what is going to happen. The question might be more appropriate for the cabinet secretary, but does anyone have any insights on the matter?

Sandra Auld: From a pharmaceutical industry point of view, no. I am unable to shed any light on that.

That said, I continue to applaud the Scottish Government's stance on the payback from the pharmaceutical price regulation scheme, which has left Scotland being the envy of other nations. As we move forward, however, I wonder whether it would be reasonable for other interventions to be afforded the same scrutiny as medicines to ensure that medicines are not looked at in the singular way that they are at the moment. That might be something to consider.

Mark White: It is a fair challenge. Looking at the whole healthcare system and the patient journey, I do not think that many other areas are scrutinised as much as medicines are, and we have already debated the wider costs with regard to added value, knock-on effects and wider implications. It is true that the same rigour is not applied to many other parts of the system. Perhaps a debate for another time is whether that should be a further development of the process.

Dr McMahon: Again, this is not unique to the Scottish healthcare system, but it is very much about adding new things to the system while not decommissioning the old. There might be some opportunity in that respect, and that aligns with what Mark White has just said. It is all about identifying the old that can be stripped out in order to find potential funding.

The Convener: Another issue is the threshold of £30,000 per QALY. Is that too high? Could it be harming people? After all, drugs are not made available above that threshold.

Dr McMahon: From my understanding of the system and from working in it, there is no actual threshold. The new drugs committee works to a tight process and it applies a threshold—my understanding is that it is £20,000. If you are under that, you will get an approval through the NDC as long as other parameters are defined. If you are over that, you get an automatic rejection from the NDC because it works within a tight process of ensuring that the analysis and assessments are high quality and rigorous.

It is thereafter, at the SMC, that modifiers can be applied and, as a consequence, people can draw their own conclusions about the value of a medicine. At the SMC, there is no defined threshold per se for what is and is not approvable. That is reflected in the range of costs per QALY and the incremental cost-effectiveness ratios—the ICERs—that come through the system.

We could talk about whether £30,000 is enough or not enough and too low or too high but, in fact, it is not applied to any massive degree in the system.

The Convener: There is a threshold that can trigger that bureaucratic process. If it was set at a different level, might that reduce some of the burden?

Dr McMahon: One of the conversations that we are having in the industry is about whether it is possible for decisions to be fast-tracked as a consequence of the threshold that is being achieved. However, we are in the early stages of talking about those opportunities.

I am sorry to say this, but that approach deals with medicines that are not much of a problem to us. The medicines that we are talking about in our conversation today are probably not the ones that would fall into those easier decision frameworks. The approach is about being able to meet future needs by giving capacity, rather than assisting with decisions on the medicines that we are talking about round the table.

Natalie Frankish: Absolutely. There is no defined threshold within the SMC, but that does not mean that one does not exist. Some statistics in one of the submissions that I read suggest that a medicine at the £60,000 to £70,000 threshold is unlikely to get through the system. There is no defined threshold, but that does not mean that the system cannot be prohibitive.

We have to step back and look at how we can futureproof the process, because there is no doubt that more complex medicines will come through that will command a higher price, and it is important to make sure that the process is robust enough to assess those medicines. Whether we do that by using QALYs plus something else or we have no QALYs at all, that has to be the next thing that we look at.

Nanette Milne: Dr McMahon talked about looking at things other than drugs and perhaps decommissioning things that are not cost effective. The committee agonised over that a bit in our inquiry, and it might be something that a future committee could be encouraged to look at and take some evidence on.

I wonder about the uptake of the new medicines fund. We spoke about what might happen in the future, and we know what NHS Greater Glasgow and Clyde is getting from the fund. Do we know whether other health boards are using up their allocations from it? Is any money going spare? If so, should there be a fairer way of sorting it out?

The Convener: I do not think that anyone here can give us those figures, but we can request them.

Nanette Milne: It would be quite useful to know.

Richard Lyle: I thank everyone who has attended this session. I know that you are all committed to helping people, and at the end of the day, as Lesley Loeliger said, our first priority is to save patients.

We have been reminded that there is a need for increases in the number and type of patient voices on all the SMC's decision-making panels. Do all the witnesses support that view? It is impossible to have every person who is interested in a particular disease on the relevant panel, but should we have more patients on panels pushing for what is best for patients?

11:45

Natalie Frankish: The short answer is absolutely—that should happen. It is important to have a patient perspective on every panel or decision-making body, regardless of whether they have a personal interest. The patient can give a unique perspective, and they can lend it to the discussions. Along with discussions with other patients, that perspective can provide an aspect that may be missing at the moment.

Sandra Auld: The SMC user group forum has produced work in which companies have made information available to explain to patient organisations what they can contribute in their patient group submission. The industry, along with the SMC, is working hard to try to help the quality of information improve so that, ultimately, the submissions are better.

Lesley Loeliger: Although each rare condition has its own set of issues, there is a lot of commonality between them, so having as many patient representatives as possible is an excellent approach.

Natalie Frankish: The patient involvement network, which is a sub-group set up by the SMC's public involvement team, has been a positive step, too. It has brought together representatives, mostly from umbrella organisations but also from patient groups that have been through the process. The network has been a good opportunity to feed back on what is working and where improvements could be made on things such as the guidance for patient groups that are going through the process. I hope—as I suppose the SMC does—that that will continue to grow.

The Convener: In 2009, the Scottish Government issued guidance to NHS boards that clarified that patients could privately fund part of their treatment while still being treated by the NHS—for example, if they wanted to pay to access a drug that had not been recommended for use by the SMC. Do you keep track of patients who use that route?

Aileen Muir: The advice is extant, so patients can utilise that route. It is a rare occurrence, but it happens occasionally.

The Convener: Is use of that route rarer now? How many NHS Greater Glasgow and Clyde patients take advantage of that mechanism?

Aileen Muir: I cannot tell you the figure for that over a certain period, but it has been used only very occasionally.

The Convener: We do not keep track of the numbers involved or the progress—

Aileen Muir: We do keep track of it. I just cannot tell you the figures for the past year.

The Convener: Maybe you could share that if it is in the public domain.

Aileen Muir: We will be able to share information on that.

The Convener: That is fine.

Leigh Smith: We had one patient who paid £90,000 for her treatment because it was not available through IPTR or in any other way. The process took about three months. The first price that was given was £75,000, but we then discovered that the cost was that amount plus VAT. It was a long, arduous process for the patient and her family and they had to give up a great deal to achieve it. At the end of the day, it did not make a blind bit of difference. By the time she got the drug, she had had a brain secondary and she died within weeks of starting the treatment.

By all means, people should be allowed to make up their own minds about how they want to spend the money that they have earned and, no doubt, paid tax on, but the process must be much faster. For example, cancer grows all the time and, if the process is not faster, people are just going to be throwing away their money. It is beholden on drug companies at least to offer patients who go down that route the best price that they have made available to the SMC rather than charging them the full cost plus VAT.

The Convener: I want to establish whether the mechanism has been effective, whether it is being used and whether its use is in decline. We will take whatever information is available, because that is one of today's key issues.

Members have no further questions, but we do not want you to say on your way home, "I should have said that." Now is your chance to speak, and I am happy to go round the table. Is there one thing that you want to leave with the committee, albeit that it will be more for our legacy paper considerations?

I see that Lesley wants to come in. I knew that she would have one or two things to say.

Lesley Loeliger: The changes that have been made are remarkable. The SMC has picked up the most amazing amount of work. I would just ask for increased transparency at every level. My clinician does not always know what is happening and cannot always give patients a response, which can be hard. Transparency is the big thing for me.

Leigh Smith: I reiterate NHS Greater Glasgow and Clyde's point that there is no encouragement for the industry to quote its best price up front, which delays access and requires more NHS time to revisit cost efficiency mid-process.

Like Lesley Loeliger, I thank the SMC staff who have been involved in this evolving process. The PACE process has been of great assistance and we especially value the kindness that the staff have shown when patients attend. I thank the clinicians who have given evidence and therefore have to catch up with their clinical work at some other stage, which probably means going home late to their families night after night, and I thank the Health and Sport Committee for all the work that it has put in. The work must have been onerous and we really appreciate it. Thank you.

The Convener: I think that we should stop there. [*Laughter*.]

Natalie Frankish: I am going to say nice things, too. I definitely commend the committee on its work on the issue. It has been a long piece of work, but the fact that we are now really drilling down into the bedrock of the issues is a testament to the committee's commitment. I commend the SMC for taking forward the changes so positively and for its level of engagement with patient organisations.

For me, there are two key points that will influence how we move forward. The first is that we should evaluate how decisions are being made at the SMC and the real impact of PACE. Secondly, transparency around the IPTR and PACS transition is incredibly important as well.

Sandra Auld: I echo the thanks to the committee for undertaking this and previous evidence sessions.

An area of continuing concern for the industry, which was also raised in a couple of submissions to the committee from other organisations, is the voting process in the SMC committee. There is some feeling that voting does not provide the transparency that is aimed for. On occasions, the decision reached has not necessarily mirrored the discussion beforehand, and on a couple of occasions the knock-on effect has been that companies have gone back to the SMC, having had a "not recommended" or "not accepted", to look for guidance on how they might tailor a new submission. Because it is not known how individuals voted, the information that the SMC has given those companies has been based on a personal view rather than on the view of the committee. That does not help companies to move forward.

I do not know whether Catriona McMahon wants to add anything on that.

Dr McMahon: In order to ensure that the first resubmission does not transition to a second or third, it is really important that companies clearly get the message about the basis of a non-recommended position. At the moment, that does not happen. That issue fits into the overarching call for greater transparency across different areas.

Another aspect of the committee's inquiry was the Scottish model of value. We have improvements in the SMC process, but I am not necessarily seeing the Scottish model of value being as tightly defined or shaped as it could be to assist patients, patient groups, industry and the SMC to establish what we need to be doing. We talk about the QALY threshold, price and other things, but the essence is value. I do not think that we have defined what we value and therefore what should fit into the value equations.

The Convener: I see a lot of nodding. That might be an omission on our part.

Thank you all for coming and giving your precious time, and for your kind comments on the committee's work. It was not the committee that did it, but the people who participated in committee hearings and provided evidence and written submissions. It is heartening to learn that some progress has been made. We have had evidence this morning that a good model is in place. Of course it can be improved, and I hope that we can work together to ensure that it is future proofed and that we not only maintain what is good in the system but improve it.

11:56

Meeting continued in private until 12:11.

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