OFFICIAL REPORT
AITHISG OIFIGEIL

Health and Sport Committee

Tuesday 13 March 2018

Session 5

The Scottish Parliament
Pàrlamaid na h-Alba

Tuesday 13 March 2018

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HEALTH AND SPORT COMMITTEE
9th Meeting 2018, Session 5

CONVENER

*Lewis Macdonald (North East Scotland) (Lab)

DEPUTY CONVENER

*Ash Denham (Edinburgh Eastern) (SNP)

COMMITTEE MEMBERS

*Miles Briggs (Lothian) (Con)
*Alex Cole-Hamilton (Edinburgh Western) (LD)
*Jenny Gilruth (Mid Fife and Glenrothes) (SNP)
*Emma Harper (South Scotland) (SNP)
*Alison Johnstone (Lothian) (Green)
*Ivan McKee (Glasgow Provan) (SNP)
*David Stewart (Highlands and Islands) (Lab)
*Sandra White (Glasgow Kelvin) (SNP)
*Brian Whittle (South Scotland) (Con)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Dr Cat Ball (Association of Medical Research Charities)
Matt Barclay (Community Pharmacy Scotland)
John Brown (Scottish Lifesciences Association)
Aileen Campbell (Minister for Public Health and Sport)
Michael Clancy (Law Society of Scotland)
Professor Dame Anna Dominiczak (Royal Society of Edinburgh)
Dr Mark Flear (Queen's University Belfast)
Mike Liddle (Scottish Government)
Ruth Lunny (Scottish Government)
Gregor McNie (Cancer Research UK)
Peter Stapleton (Scottish Government)

CLERK TO THE COMMITTEE

David Cullum

LOCATION

Committee Room 4

Scottish Parliament

Health and Sport Committee

Tuesday 13 March 2018

[The Convener opened the meeting at 10:00]

Leaving the European Union (Impacts on Health and Social Care)

The Convener (Lewis Macdonald): Good morning, and welcome to the Health and Sport Committee's ninth meeting in 2018. I ask everyone, please, to ensure that mobile phones are switched off or to silent. I ask that everyone respect the processes of Parliament and not record or film proceedings, which will be done by Parliament staff.

Agenda item 1 is to hear evidence on the impact of leaving the European Union on health and social care in Scotland. We start today with consideration of the impact on research and clinical trials.

I welcome our first panel of witnesses. Professor Dame Anna Dominiczak is vice-principal of the University of Glasgow and head of the college of medical, veterinary and life sciences, and she is here representing the Royal Society of Edinburgh. Gregor McNie is head of external affairs for the devolved nations at Cancer Research UK, Dr Cat Ball is policy manager for the Association of Medical Research Charities, and Dr Mark Flear is a senior lecturer in law at the school of law at Queen's University Belfast. I look forward to hearing from you all. We invited Universities Scotland for representation at the session, but it declined because it was unable to put forward an appropriate representative. Nevertheless, I am delighted that we have such a high-quality panel of representatives from elsewhere. We begin proceedings with a question from Ivan McKee.

Ivan McKee (Glasgow Provan) (SNP): Good morning panel, and thank you for coming to talk to us.

I want to ask first about common frameworks—an issue which is very much in the news. Everybody—including the Scottish Government and the Scottish Parliament—agrees that common frameworks are needed. In health and social care, a surprising number of areas, including regulation of tobacco, food and blood safety, are covered by reciprocal agreements, on which Brexit will potentially have an impact. There are clear differences between the way that we do—and wish to continue to do—things in Scotland and the way that things are done in the rest of the United Kingdom. I want to hear your thoughts on what mechanisms should be put in place to implement common frameworks, and on the importance of the Scottish Government and the Scottish Parliament having a say in what is in those frameworks.

The Convener: Who would like to start?

Professor Dame Anna Dominiczak (Royal Society of Edinburgh): I will start by speaking about research and clinical trials, in which common frameworks are extremely important for a variety of reasons that relate to patients, the national health service and our links with the pharmaceutical industry.

There were early suggestions that it might be good if Scotland were to be different, but such thinking is very dangerous. In clinical trials or trials of medical devices, we have to work with other EU countries. Our market alone is not big enough to justify the presence of big companies in this country, and we would therefore be making legislation on the basis of our experience in Scotland or the UK alone. It is very important that we speak up and say that we need to belong to the system of European regulation of drugs, devices and clinical trials. If we try to be a little different, we will pay for it very dearly on many levels, including in terms of patient benefit. We know that patients who participate in clinical trials for new drugs or devices do better; that has been proved in many pieces of evidence.

In addition, we want the pharmaceutical industry to come to Scotland. Scotland not only takes part in clinical trials: it is also famous for being the best at organising and co-ordinating them, and at coming up with ideas.

We need to ensure that, in all those areas, Scotland is part of the legislation that covers the rest of Europe.

Dr Mark Flear (Queen's University Belfast): I will underscore what the committee has just heard. If researchers in Scotland want to continue to collaborate with researchers elsewhere in the European Union, it will be really important that we have what is, legally speaking, a harmonised approach. As you know, we currently have such an approach. If we deviate from it, there will be risks, some of which we have just heard about.

My specific interest is in clinical trials. There are various areas of health research; my background is in researching and writing on the law in relation to clinical trials. I am sure that it would be in the interests of researchers not only in Scotland and the UK but across the European Union—given the importance of the UK, and Scotland within the UK, in research and clinical trials—to maintain a harmonised approach.

Ivan McKee: Thank you for that input, which is valuable, but I was hoping to move the discussion in the direction of common frameworks across the UK post-Brexit. There is a clear risk that the UK will diverge from the European Union, which we all think—as you said—would not be a wise direction in which to go. In that context, Scotland would potentially be tied into common frameworks with the rest of the UK. How would that play out, given that the picture could get extremely complicated on a number of levels?

Dr Flear: At the moment, we are not quite sure what the common frameworks will constitute. There is a lot that is unclear: that is one such aspect.

On the question to which you seek a response, there could be a negative impact on researchers in Scotland if there is UK-wide divergence that makes the UK a less attractive place in which to carry out clinical trials. That is the starting point. However, I suggest that we need to think about demanding that, if there is to be a common framework for clinical trials across the UK, there should be no significant divergence that would undermine the ability to perform such trials in the UK and in Scotland. An effort to demand that that is ensured is needed, but it might, of course, be difficult.

Ivan McKee: As I said, everyone agrees that there must be a common framework between Scotland and the rest of the UK. The debate is about whether the Scottish Government and the Scottish Parliament would only be consulted on the framework, or their consent on how it would work would be needed. We could end up in a situation in which the UK feels that it wants to diverge from Europe, and Scotland wants to have a say in the framework and to steer the approach back towards more harmonisation with Europe, which the rest of the UK might not want. That could be very interesting.

The Convener: Do the other witnesses have any comments on the specific issue of how the development of a UK framework should be informed by stakeholders in the UK and in Scotland in order to ensure that it looks the right way?

Gregor McNie (Cancer Research UK): Mark Flear's comment about the need for "a harmonised approach" is helpful language. There is currently a specific technical discussion on common frameworks, but we need to look at the outcomes of a harmonised approach and possible future scenarios. Ivan McKee described a situation in which Scotland might diverge from the UK's approach and look to join up with the EU. The status quo should be that collaboration—as Anna Dominiczak articulated—is absolutely vital for research excellence in Scotland, across the UK and throughout the EU. When we do big trials or pieces of research, we look first to partners in the rest of the UK; it would be extremely uncommon that Scottish research would link only with the EU—

Ivan McKee: I have said twice that it is very important that Scotland does not diverge from the rest of the UK. The question is about what the common frameworks should look like.

Gregor McNie: I am sorry if I misunderstood you. To answer your point, the committee, along with the Scottish Parliament and the Scottish Government, has a voice in championing a UK approach that involves harmonisation with the EU, and the stronger that voice is, the greater will be the benefits for patients. As Anna Dominiczak articulated, research being embedded in the NHS leads to excellent service and better patient outcomes. Trials and research are not just technical exercises: they are fundamental to the NHS, so anything that the committee can do to champion a harmonised approach would be extremely welcome.

The Convener: Does Dr Ball want to come in?

Dr Cat Ball (Association of Medical Research Charities): I would simply echo Gregor McNie's points.

The Convener: We move to research funding, and we start with a question from David Stewart.

David Stewart (Highlands and Islands) (Lab): Good morning. I am interested in research funding, which—as we all know—has been a success story for the UK, because it has been a net beneficiary. Scotland receives more research funding per head than anywhere else in the EU; I highlight the importance of the horizon 2020 programme in that regard. What is your assessment of Brexit in relation to research funding?

Dr Ball: I am from the Association of Medical Research Charities—I will explain briefly what that is because my remarks will be more useful in context. We represent all the leading health and medical research charities in the UK, one of which is Cancer Research UK, which Gregor McNie represents. We have 140 members, 55 per cent of whom fund research in Scotland. Our members fund more research per head of population in Scotland than they fund in any other part of the UK, so the medical research landscape here is really important for them.

In addition to funding from charities, a key element is EU funding, which comes largely from the horizon 2020 programme. It is very important that we maintain our involvement with horizon 2020. Last week, the UK Government published a paper, "UK Participation in Horizon 2020: UK

government overview with Q&A", which states categorically that after the conclusion of the phase 1 agreement negotiations in December, the UK will be able to participate for the remainder of horizon 2020. If that agreement falls through, there is a commitment to underwrite research funding, so UK and Scottish researchers can rest assured that they will still be able to participate in horizon 2020.

What is now important is the need to ensure our association with the subsequent framework programme 9. The European Commission consulted on what that programme should look like, and a high-level group that was chaired by Pascal Lamy produced a key EU report, "LAB-FAB-APP—Investing in the European future we want: Report of the independent High Level Group on maximising the impact of EU Research & Innovation Programmes", to feed into the process. The report described the UK's continued involvement in the programme as a

"win-win for the UK and the EU."

The UK Government responded to the consultation as part of that process. It is clear that there is goodwill on both sides of the negotiating table with regard to a future partnership on scientific funding between the UK and the EU.

David Stewart: As panel members will be well aware, non-EU members cannot be full members of horizon 2020. The danger is that, even if the UK remains in the programme, it will be a real taker and not a real maker, which is fundamentally important.

Dr Ball: That is true—but there is scope for the UK to be an associated country. There is an understanding that the UK's participation as an associated country would not involve an off-the-shelf solution, and there is pragmatism on both sides around the idea that our relationship would look quite different from the EU's current relationships with other associated countries. As David Stewart said, the relationship will obviously not be the same as it is just now; the UK currently gets back significantly more from EU science programmes than it puts in. However, this is one area of Brexit in which I feel slightly optimistic that we might be able to have a future partnership with the EU that would ensure that collaboration can continue.

Professor Dominiczak: I agree with everything that has been said, but there are additional issues. It goes without saying that we need to remain an associated member of horizon 2020 whatever it costs, and not just for the grants and the activity but for the ability to form networks. We are now hearing from researchers and consumers of research, including the NHS, about how important those networks are. There are endless examples such as rare diseases, in which one country does not have enough people to build a framework or a proper network.

10:15

The UK has done very well in leading many of those networks and special interest groups, but we are already seeing a loss of leadership: since the Brexit vote, new groupings and networks that are being created are rarely chaired or co-ordinated by UK researchers. That should not be happening, but it is, because that is human nature. I am concerned about that. As David Stewart said, we would participate as consumers but we would not make the strategy happen. I might be too optimistic, but if there is any way we could pay a little more to take part in making and co-ordinating strategy, that would be extremely useful.

David Stewart: Panel members might like to answer a second question. If a private sector organisation was facing the loss of a customer such as Marks and Spencer, that would be on its risk register and it would analyse the issues. Is the potential loss of horizon 2020 and the associated negative impact highlighted on the risk registers of the University of Glasgow and the other institutions that are represented here? Is it likely that we will go from being a net beneficiary to a being a net contributor, as far as research is concerned?

Professor Dominiczak: Yes. Generally speaking, the issues are at the top of every risk register at every level in our universities, as are broader issues—consideration of which I hope will catch on—including our potential loss of researchers, talent and so on.

Dr Flear: I do not have access to my university's risk register, but I would be very surprised if the matter were not very high on the list.

I would like to add to what the committee has heard so far rather than repeat what has been said, although I underline and agree with all the comments.

A specific concern that has not been highlighted thus far is the way in which Brexit impacts not only on leadership in research but on shaping the strategic direction of that research. We might, for example, focus our research on tackling disease by using high technology or simply through better prevention, and it is terribly important that we set a strategic direction. That is at risk because of Brexit. We have already heard that the UK is not withdrawing from networks, but is essentially facing a situation in which networks are forming outside the UK and marginalising our UK researchers. That is to do with actual research practice, but there are also legal issues in relation

to setting the strategic direction. Horizon 2020 is founded on a legal instrument, which determines not only how decisions are made on strategic direction but how they are implemented in policy. The UK is stepping out of that because of Brexit, which is a grave concern for research.

The Wellcome Trust and others have highlighted the importance—this underscores the points that have already been made—of trying to maintain networks and ensuring that, although Brexit means that the UK is withdrawing from the European Union, the UK develops some sort of associated-country status, especially in relation to the follow-up to horizon 2020. The Wellcome Trust has discussed that aspect and has made recommendations.

Of course, it is also for the EU to decide on the shape of the relationship—it is not the case that the UK will bark and the rest will follow. It is a negotiation. However, there is work to be done to explain, and to remind officials and researchers from the EU and the UK about, the importance of maintaining those networks and trying to develop something that facilitates a strong UK voice at EU level, as the Wellcome Trust has suggested.

Accountability is another issue. The Wellcome Trust has highlighted the importance of UK participation in FP9, which is the follow-up to horizon 2020. If the UK is not going to be involved in a more intense way than current associated members, there will be a problem with accountability. Essentially, the UK—including UK researchers and, ultimately, patients—will benefit from funded research programmes that the UK is not closely involved in shaping. That will be problematic.

Sandra White (Glasgow Kelvin) (SNP): The loss of research funding is very concerning. I am a Glasgow MSP—the University of Glasgow is in my constituency, and I know that the amount of funded research and collaboration that goes on there is fantastic. I have visited heart, kidney and arthritis research programmes, and I have met Anna Dominiczak. I really am quite concerned. It seems that the UK, and Scotland along with it, is being left out on a limb. We will be asking all the time for things from countries in the EU.

The risks around accountability and other aspects have been mentioned. Have we looked at ways in which we could maintain our position in research? David Stewart mentioned horizon 2020, the budget for which is £78 billion. Have we looked at how we can possibly get access to anything like that outwith the EU? We need that funding not just for the research, but to continue Scotland's reputation for attracting research grants. The horizon 2020 programme is fantastic, and we do not want to lose it. Have we looked at any contingency plans?

Gregor McNie: With regard to funding, the long-term risks have yet to be played out; the same is true for regulatory divergence. The immediate issue in the here and now is people, as Anna Dominiczak articulated. We are hearing anecdotally that, if someone graduates from a Paris university and has the choice to go anywhere in the world—researchers are very mobile individuals—they are less inclined to choose the UK post-Brexit. That is not because science has changed overnight or the quality of science has altered—it is about how people feel about things and see things, so messaging and symbolism are important at this stage.

On the domestic front, the UK Government and, to some extent, the Scottish Government should be up there in their commitment to science funding and research. They need to display an upward trend and a prioritisation of science and research funding to send out a global message that the UK is still very much a home for excellent science. If that wobbles at all, we will struggle to convince people to come here. That messaging can be actioned at both UK and Scotland levels.

Dr Ball: To echo Gregor McNie's point about the importance of people and collaboration, the actual funding for research is only one element—an important aspect is the work that the funding catalyses and enables, and how it allows UK and Scottish researchers to link into networks. I can give you some evidence to support the point about the current impact of uncertainty on people. Last summer, the British Heart Foundation—of which Anna Dominiczak is a trustee—surveyed its researchers in the UK and found that 80 per cent of the non-UK EU researchers whom it funds are considering moving their careers outside the UK. That figure is phenomenal. Uncertainty and the unknown nature of what is going on are having a real impact on our research workforce, and we have to be clear about that.

Professor Dominiczak: To return to the risks around funding, the UK Government pays a certain amount of money into EU networks every year. Yes, we currently get out more than we pay in, but your role as our representatives is to make sure that, at the very least, we continue to spend the amount that we currently pay to fund research in Scotland and the rest of the UK. I absolutely agree that, at this stage, any signals that we are weaker and less good will be lethal. There are already departures.

As the Royal Society of Edinburgh's submission to the committee states, Brexit is an opportunity for other countries to poach people, not only European citizens but people who are working in UK science across the board. We know that Australian, Irish and German universities are already doing that. I have anecdotal evidence that

German universities and research institutes are targeting our top researchers and inviting those who are German born to go back. We need to be extremely sensitive about our messages on finance, opportunities and the future and quality of our research, and about the welcome that we extend to everybody, and every talent, from all over the world.

The Convener: I bring in Jenny Gilruth—

Sandra White: I am sorry, convener—I would like to follow up on that.

The Convener: We have a quick supplementary from Sandra White.

Sandra White: I know that Jenny Gilruth is going to ask about collaboration, but I want to make the point that, although our research is high class, world renowned and so on, if we are not in the EU and in horizon 2020, we will have no voting rights and no say. Are there any contingency plans—apart from the suggestion that we should talk up the opportunities for researchers—for how we will get access to moneys? That is the point that I was trying to make. We will lose out on access to billions of pounds. Have we anything in place that could enable us to access that kind of money?

Professor Dominiczak: As colleagues have said, associate status is a must. Other countries benefit from associate status, but that is on the basis that they do not get back a penny more than they have paid in.

Dr Ball: Sandra White is right to highlight that associate countries have less of a say in how the programmes are steered. The UK has played a really important role thus far in shaping those European funding programmes. A key part of horizon 2020 is European Research Council grant money, which UK researchers are incredibly good at winning. The awards are prestigious, and the ability to win them is key for UK researchers, in particular early-career researchers. One could argue that the programme may, without the UK's influence in shaping it, become different and less excellence based. We should definitely aim for associate country status, but that is not without its challenges, and our position will not be what it is now.

Jenny Gilruth (Mid Fife and Glenrothes) (SNP): I want to drill down on the points that Sandra White made. Cat Ball alluded to workforce issues—it is all very well and good to get research funding, but we need the people to carry out the work.

Dr Ball: Absolutely.

Jenny Gilruth: Dr Ball, your submission points out that

"almost 70% of the Beatson's research scientists are non-UK citizens"

and that

"(28%) of academic staff in UK universities are non-UK nationals".

Gregor McNie's submission states:

"72% of UK-based researchers spent time at non-UK institutions between 1996 and 2012."

The number of EU nationals who are working in academia is disproportionately higher—5 per cent higher—in Scotland than in the rest of the UK. Do we have in Scotland a specific and different situation for which we need a different solution in planning our workforce for the future?

Gregor McNie: I am just double-checking the numbers in our submission. I do not think that the figures for the make-up of nationalities in, say, the Beatson institute for cancer research and the Francis Crick Institute in London constitute a significant difference. You point to the mobility of researchers, which is vital. A lot of researchers at the Beatson institute have spent time in other parts of the UK. We are not reading into the figures that there is a significant difference in the make-up of staff in Scotland—I do not think that we can say that.

Professor Dominiczak: I agree. The RSE's numbers show that Scotland is roughly the same as the rest of the UK in that respect, although there are differentials. The Beatson institute—which I know well, because it is associated with the University of Glasgow—is very international, but that is typical of excellent, top-quality places. The Francis Crick Institute, which Gregor McNie mentioned, is very similar. Those places act as a magnet for top talent, and we want them to do so.

The messaging that I have seen from the Scottish Government has been much more positive than the messaging from London—that is my impression. We need to maintain that positive messaging. Again, we request that you welcome, and give that message to, the top talent from all over the world.

10:30

Unfortunately, however, many colleagues who come from European countries as PhD students, young researchers and very senior researchers—they are the talent that we want—are uncertain about where they will be in a year or so. That is the risk that Jenny Gilruth was pointing out. Apart from being welcoming and so on, we should put in place other measures to make those colleagues as safe as possible. We must negotiate to ensure that their rights, and the rights of their families and children, are secure for the future. If we can do that, we will be winning.

Dr Ball: In the area of science and research, we think about immigration in terms of getting people in rather than keeping people out. For the UK to maintain its global standing, we need movement of people. Science relies on the flow of ideas and people, and on different ideas coming together—it cannot be done in isolation. The point about people is so important. Across the research community, it seems to be the most important point and it keeps coming up again and again.

Dr Flear: I am thinking about how to weave in my next point, which is related. If I may, I will relate a couple of anecdotes, or at least one. A colleague who was walking on campus—not at my university, but at a university in England—and speaking in her home language, which is not English, was subjected to verbal abuse by a passer-by. When you are on campus, you feel that you are at home, in a sense, and that you are safe, but that is not the only such example that I have heard. Colleagues who have been walking around the streets of London—an international, global city that voted to stay in the European Union—and speaking in their home language have also been subjected to verbal abuse.

Brexit is supposed to be happening but, however we feel about that, it is important that we try to remain as open and non-exclusionary as we can, if that is possible. MSPs in this Parliament, and Scotland, can send very clear signals in that regard. Scotland, and the Scottish Parliament and the Scottish Government, have been more successful at sending positive signals and being open than has been the case at a UK level. I think that it stems from the idea of some sort of civic pride, if I can use that term. That openness should be maintained and developed, because it is essential that we send signals to people out there that we treat everyone the same. Everyone should feel at home and welcome so that they can do their best possible work and, through research, benefit society at large.

Jenny Gilruth: I have a final question. Dr Ball, with regard to your point about immigration, your submission states:

"we remain concerned that that uncertainty about the UK's future migration system is damaging the UK's reputation and attractiveness as a place to do research."

Gregor McNie's submission states:

"The Scottish Government should call on the UK Government to design a future immigration system which enables us to attract, recruit and retain global scientific talent at all professional levels regardless of their nationality."

To pick up on Dr Flear's point, you might remember that, in October last year, the UK Government chief whip Chris Heaton-Harris MP got himself into a bit of bother over the Brexit letter that he sent to UK universities regarding the teaching of Brexit, in which he asked them to name lecturers. At the time, Lord Patten, the chancellor of Oxford University, described the letter as "offensive and idiotic Leninism". Are we in danger of losing our academic edge over Brexit because we cannot attract the talent that we need?

Professor Dominiczak: The answer is that we might, but we need to do everything in our power to ensure that that does not happen. That is why we are all here today—we want your help to ensure that it does not happen, because once it does, it will be very difficult to undo. There is a deeper understanding of the issues among politicians, academics and other colleagues, but we need to talk about them more broadly.

Dr Flear gave you one anecdote—I would like to give you another, because it is probably relevant to my point. I have lived in Glasgow since 1982, for 36 and a half years. I am a clinician scientist, and I used to enjoy it enormously when patients, taxi drivers and everybody else would ask, "Where are you from? You have such a nice accent." It was nice and friendly. However, a colleague in London, who was making a decision that was important for me, recently asked, as I was walking out of an important meeting, "Now that there is Brexit, Anna, do you plan to go home?" That was not nice.

We—lawmakers and others—need somehow to instil in the population the idea that researchers and people who work in the NHS, many of whom are academics who also work clinically, are people whom we want here. Times have changed, and the sort of questions that were really funny 10 years ago are now offensive and are pushing people away. However, I think that Scotland is better than the rest of the UK in that regard. I am a great believer in the idea that we are much more open and inviting, and that such unpleasant things happen much less often here. Nevertheless, we need to be very cautious, sensitive and proactive. I am currently on a barricade, and I say to people, including taxi drivers, "Please don't ask me where I come from—I am British, and I come from Bearsden."

Alison Johnstone (Lothian) (Green): In the past few months, my colleague Alex Cole-Hamilton and I visited Cancer Research UK's research facility at the Western general hospital and we were struck by the fact that almost every researcher whom we met was an EU national. We saw in practice the impact that could be felt if matters are not handled properly and sensitively. The Scottish Parliament information centre's research briefing for today's meeting tells us that

"Scotland employs proportionally more EU … and non-EU … staff"

than

"the UK as a whole",

and that that is clear throughout higher education, in which

"27% of research-only … staff … are EU nationals."

The loss of that talented workforce, who not only bring us their work but contribute socially and culturally, would be significant.

We have discussed the need for positive messages. On the whole, Scotland is culturally very welcoming, which we want to emphasise. However, we need to take practical steps to ensure that Scotland does not lose out on talent. Do you believe that the significant contribution that EU researchers make to Scotland's health and research workforce, for example, indicates the need for Scottish control over immigration? Would it be a helpful practical aid if that policy were to be devolved?

Professor Dominiczak: I think that that is a legal question.

Dr Flear: That is a big question and, to be honest, I am not sure that I have an appropriate answer. I will give you a legal response. I understand the reasons why one might argue for devolution of immigration policy. There are some good arguments; Alison Johnstone outlined one argument in respect of research staff. However, the practicalities are an issue, and there are countervailing reasons that others would put forward, which would have to be challenged and responded to. I am not sure that I can really say much more on immigration. Related aspects, such as drawing people in, are less politically charged and may meet with less of a fierce response from others. I imagine that some of those things are already within the powers of this Parliament.

Sometimes it is important to focus on what can be achieved using the tools that are already available. There seems to be a need to go after control of other tools, and it is possible to work towards that, but we need to focus on what can be done right now, because Brexit is happening right now. The key points to consider are what we have now, what we are going to lose or are at high risk of losing, and how we maintain those things. I suppose the question is, how does Scotland maintain those things? With regard to immigration, how does Scotland ensure that it continues to attract the best people from around the world, including the European Union? That is probably not exactly what you wanted me to say.

Dr Ball: Science is inherently global and collaborative, and we need as few barriers as possible across the UK and Europe and around the world. Scotland and the UK are on the global stage, and we need to have no barriers to the movement of scientists and research talent.

Gregor McNie: That said, there are specific actions that the Scottish Government can take, which brings us back to messaging rather than more regulatory approaches. Just after the EU referendum, the Scottish Government ran an excellent campaign—I think that it was called, "Welcome to Scotland" or "You're welcome in Scotland"—that it put out swiftly and directly following the vote in order to say to an international audience that Scotland still welcomes them. It would be good if that campaign was redeployed at an appropriate moment. On that platform, given all the evidence that the committee has heard this morning, I would hope that Scotland would have a good bit of leverage within the UK to set an example and to lead on openness to immigration and the movement of researchers.

Professor Dominiczak: I do not know what I can add to that—I agree with everything. Research, in particular biomedical research that helps patients and changes the way in which we practise medicine, is so important that we could perhaps make an exception and say that free movement of talent, wherever people come from and whether they are younger or older, should be maintained. I know that important bodies such as the Wellcome Trust and the Russell group of universities have been discussing whether there can be exceptions to the rule.

Dr Ball: It is important to emphasise that the UK Government should not open up the system that is currently used for non-European Economic Area nationals to include EU nationals. For science and research in particular, that would be a bit of a disaster.

Professor Dominiczak: Yes.

Miles Briggs (Lothian) (Con): What Dr Ball just said has almost answered my question. With regard to future frameworks, we have discussed global research networks. How does the system currently work for non-EU international researchers who come to the UK? Where can it be improved? I hear what you say about not necessarily opening up that system to include EU citizens. Are there currently issues with people who come from outside the EU to carry out research in the UK?

Dr Ball: Absolutely—there are definitely issues with non-EEA nationals who come to do research in the UK. For example, there is a cap on the number of tier 2 visas—the skilled visa route—and it has been breached twice in recent months. Research talent from outside the EEA is not getting to the UK because the cap has been hit and the UK is saying, "No more." Recently, the Association of Medical Research Charities and

Cancer Research UK were signatories to a letter to the Prime Minister from the Campaign for Science and Engineering that highlighted that very point. It said that the system simply does not work for science and research—it needs to be changed, and the arbitrary cap needs to be removed.

Professor Dominiczak: If we add to that the issue of clinically qualified researchers, things become even more complicated because, apart from immigration rules, there is the issue of registration to practise. I am sure that the committee has spoken, or will speak, to the General Medical Council about that. For EU nationals, the current process is quick and easy. For people from all over the world outside the European area, it is a long process in which they require hundreds of pages of evidence to say that they are fit to practise in the UK. Although that is important for safety, it would be a big obstacle if it took us a year to get a top researcher into the UK.

The Convener: Emma Harper has a question on the impact of Brexit on research and innovation.

Emma Harper (South Scotland) (SNP): I am sure that the answers that you give me will be similar to your previous ones, but I am interested in the impact of Brexit on innovation. Cancer Research UK's submission refers to

"a thriving pharmaceutical and biotechnology sector"

that has developed a number

"of new therapies and medical technologies".

It goes on to state:

"25% of the world's top 100 prescription medicines were discovered and developed in the UK."

10:45

Quintiles IMS, in its submission to the House of Commons Health and Social Care Committee's inquiry into Brexit, said:

"Analysis … suggests that the implications of Brexit could prompt business decisions that will decelerate UK pharmaceutical market sales growth over next three years."

I am curious about innovation and research. I am aware that people all over the world collaborate to develop research processes and innovation, and I would like to hear your thoughts on those comments.

Dr Ball: That question speaks to Anna Dominiczak's point about Scotland being part of a wider market and having a larger global share of the pharmaceutical market as part of the EU. The European Medicines Agency, which is the EU body that regulates medicines across EU member states, collectively makes up 25 per cent of the global sales market, whereas the figure for the UK in isolation is 3 per cent. Those figures speak for themselves with regard to the value of collaboration and joining together, and the impact that that has on the UK's ability to attract investment from industry, which has a knock-on effect on innovation.

Gregor McNie: In the immediate term, the fall-out from the vote has created a large degree of uncertainty. The global industries are very mobile, and because of that uncertainty, even before Brexit has happened, some of them are withdrawing and relocating to other parts of the world. Uncertainty is an issue, and it is important that we get more certainty and clarity from the UK Government on its intent with regard to joining the EMA. Again, I go back to the point about messaging, which is the most vital aspect right now. If the UK Government could be very clear about its intent to stay in the EMA framework, and about how that would happen and the timescale that would be required, it would help to deal with a lot of the immediate issues.

To go back to how that plays out in Scotland, I highlight the example of lung cancer, which is Scotland's cancer of greatest incidence. I am aware of three lung cancer drugs in the pipeline, for which the patient populations in Scotland are of the order of 50, 20 and 10 respectively, in the context of a cancer that affects thousands of people every year. The patient populations for a lot of innovative medicines are tiny, and we need to be on the European stage in that regard. As I said, the uncertainty around the EMA is proving to be harmful in the immediate term.

Dr Ball: The impact of that uncertainty plays out in another way. The major pharmaceutical companies that are based in the UK are having to undertake a lot of planning and draw up risk mitigation scenarios. The money for that tends to come from research and development budgets, which are by definition the most flexible. When a company suddenly needs to source funds for planning in response to the current uncertainty, the money comes from its R and D budget. That obviously has a knock-on effect on the development of medicines and on patients.

On the point about the importance of collaboration, I highlight the issue of patients who have rare and less common diseases. By definition, there are fewer patients with rare diseases, so we need a multinational, joint EU approach just to source enough patients for trials so that medicines can be licensed to come to market. That is an important angle.

Professor Dominiczak: Precision medicine is another area in which Scotland has a huge chance to lead the world, but again we need collaboration, and we need industry to be present and joined up. I spoke about that from Glasgow this morning on Radio 4. Precision medicine requires health data

and early diagnostics so that it can be applied in the NHS. We have in Scotland all the ingredients that enable us to be the best in that area, but we need industry. Precision medicine is not about research in an ivory tower, but about implementing a new way of practising medicine in the NHS. That can happen only if companies—big and small—want to be in Scotland.

As we just heard, the risk is that uncertainty about the future means that companies might not want to invest. In order to prevent that, we have the industrial strategy challenge fund, the life sciences sector deal and so on, but Scotland needs to fight to be at the forefront in that area, and we need to bring the companies with us. Gregor McNie is absolutely right: we need to mitigate the risk now, because there is no time. We have a chance to lead the world in precision medicine, but others are following suit.

Brian Whittle (South Scotland) (Con): Good morning, panel. I want to go back and explore our current, well-established collaborative relationships with the EU. Are you seeing an impact on those relationships and collaborative patterns pre-Brexit?

Gregor McNie: Yes, in short. We know that that is the case anecdotally, and we have reached out to our research community with regard to the impacts. There is a sense that, if someone is putting together an EU partnership, they may wonder whether to talk to the British arm when they know that there is uncertainty around the future and that collaboration might be a bit more difficult. Although nothing has changed in a sense, we are hearing anecdotally that a lot of people are simply opting not to do the difficult job of involving the UK. That also plays out in the decisions that people make on where to conduct their research, or where to go after graduation or further on in their career. We are hearing anecdotal evidence on that front about not only recruitment but retention. People who are currently here and are thinking about the next step in their career might be that bit more incentivised to go elsewhere if they think that it will be less easy for them to practice in the UK. Anecdotally, all those issues are playing out, at least in our community.

Brian Whittle: Is that a perception or a reality, or do both those elements play a part?

Gregor McNie: It is a reality, because it is happening. As I said, the science has not changed, although the bigger risk is that the excellence of our science will start to diminish as a result of those other issues. The immediate challenge concerns the human behaviours that are occurring because of the current environment, and we need to look quick smart at how we address that.

Professor Dominiczak: The evidence is already more than anecdotal. For example, the number of PhD applications to the Russell group universities, two of which—Glasgow and Edinburgh—are in Scotland, has reduced by 9 per cent. We already know, therefore, that PhD students—our talent for the future—are not coming to Scotland. As we discussed earlier, we are no longer leading and co-ordinating, and we also know that even the amounts of money that are coming in are smaller this year than they were in the period before Brexit was announced. Although nothing has happened yet, and we still have the same rights, there are fewer applications coming in, and there is less money coming back to the UK and to Scotland.

Dr Ball: What the science community needs now is certainty. As I said at the beginning of our discussion, there is scope for a good outcome and some positivity around whether that could happen. However, unless we get some knowledge of the outcome soon, there is a risk that the damage will already be done, and it could be too late. I appreciate that that sounds alarmist, but there is real damage going on as a result of the current uncertainty.

Brian Whittle: That leads me on to my next question. In the current negotiations and the way in which they are dealt with, are there opportunities to foster new relationships and build stronger collaborations in the future? I am thinking in particular—to go back in time a little bit—about the academic health science networks that were established down south. They were looking to push not only into Europe but into a more global space, especially in the treatment of rare diseases. We have been talking about the need to recruit patients for rare-disease studies from Europe—and rightly so, because we are discussing Brexit. However, the reality is that the recruitment of patients for such studies must be global, so it involves more than just Europe in that sense.

How does the language from the Scottish Government and the Scottish Parliament play into that? How do we provide opportunities to strengthen that global collaboration? I have always thought that there are no real boundaries in health, and rare-disease research seems to be an area in which we could make a big push to maintain collaborative partnerships.

Professor Dominiczak: You are absolutely right—there should be no boundaries or borders. It has been suggested—this was published in *Times Higher Education*—that there should be a global network instead of a European network. However, it is clear that cost and complexity would be an issue. It could not happen overnight—it would require many years of negotiation and a

willingness from countries to pay in and come together.

In a sense, the networks across Europe are very convenient for research because the systems are similar in some ways, as are the patients and the ways in which health and research are practised. We have the World Health Organization, of course, and it would be possible to build a global network for health research and implementation—that is a wonderful idea—but, as you can imagine, it would take years of planning and it would be very expensive to bring everything together. The EU is already there, and it works. Fantastic networks and collaborations have been created across Europe in all areas, including disease and public health, and people have learned how to work together. It would be very difficult to replace that with something global. We can dream, and I am with you on the idea that there should be no borders, but I cannot see that a global network would easily replace what we have just now.

Dr Ball: Absolutely. Any exploration on that front would need to start with getting the movement of people right. The mobility of researchers underpins the whole area.

Alex Cole-Hamilton (Edinburgh Western) (LD): Good morning, panel, and thank you for coming to see us today.

I want to move the discussion on to the issue of clinical trials, which touches on some topics that we have already addressed. It is fair to say that the EU's 2001 clinical trials directive has had its critics, and it is slightly cumbersome in some ways, but it is set to be superseded at the end of this year by a new directive, which everyone agrees is largely an improvement. However, Brexit will remove us from the scope of the clinical trials directive. The witnesses who gave evidence on the subject to the House of Commons Science and Technology Committee expressed concern about a lack of regulatory alignment and said that we should continue with regulatory alignment even after we leave the scope of the directive, so that trials would not be changing regulation midstream. That touches on Emma Harper's point about problems that may affect patients who have ultra-orphan conditions, and who might benefit from life-saving therapies only as part of a pan-European trial. What steps do we need to take to ensure that regulatory alignment allows us to buy into those trials? Alternatively, do we need a new bilateral agreement with the European Union when we leave?

Dr Flear: I can come in on that, because it is a legal question. The clinical trials directive will be replaced by the clinical trials regulation, but that will not happen until after March 2019, which will be post-Brexit. There is a problem—I am wondering how much to say on this. The CTR is a regulation—if it were introduced before Brexit, it would be directly applicable and would be written into UK law, so it would apply to researchers. However, the point at which it would become applicable falls after Brexit, which raises the question whether the text of the regulation will be brought wholesale into UK law. I believe that I have read that that is one idea that has been discussed. To respond directly to Alex Cole-Hamilton's query, I think that continued alignment would be very wise, especially in light of the evidence from other panel members today.

Dr Ball: Mark Flear can correct me on this, but I think that continued alignment with the clinical trials regulation would involve more than a simple legislative fix. It would not be as easy as simply bringing it into UK law. The CTR is underpinned by infrastructure, which includes a clinical trials portal and a database. The aim of the regulation is to align the trials process further and make trials easier to carry out, and those two underpinning features will enable that to happen. It is not clear how a country that is outside the EU, as the UK will be, would participate in that system. The question of how the UK can participate in those two key bits of infrastructure needs to be included in negotiations.

11:00

Dr Flear: To build on what Dr Ball said, the portal and the database, which the CTR brings in, will be key to the functioning of clinical trials. There is another important point. Article 7 of the European Commission's draft withdrawal agreement states clearly that, upon Brexit, after the end of the transition period, the UK is not to access—or even attempt to access—any EU database, including the clinical trials portal and database. To go back to Alex Cole-Hamilton's question, even if the UK were to adopt wholesale the text of the clinical trials regulation, as it is free to do, there remains a question—which is worth underscoring—around continued access to the portal and the database, which will provide important information for researchers that ultimately ensures patient safety down the line. That access would have to be included in the agreement between the EU and UK on future arrangements.

Alex Cole-Hamilton: So you believe that, as part of the negotiations on trade, criminal justice and everything else, we should seek a new bilateral agreement that keeps us seamlessly within the pan-European clinical trials apparatus?

Dr Flear: That needs to happen, whether it is as part of some sort of comprehensive agreement or in the form of a specific agreement on the clinical trials sector.

Professor Dominiczak: It is absolutely essential that we ensure that that happens, because otherwise everybody—the NHS, patients and researchers—will lose out. I cannot even imagine how, as my colleagues have discussed, Scottish patients could be excluded from on-going or new trials; that would almost be a criminal offence.

The Convener: Emma Harper has a final question on clinical trials.

Emma Harper: I recently read Health-EU newsletter 183, which focused on "Organ donation and transplant in the EU". It mentioned that the on-going clinical trials mainly involve children. As a former liver transplant nurse, I know that it is really difficult to get hearts and livers for five-year-olds. The article says that, so far, 23 transplants have taken place across many borders in the EU. It is clear that we will face a real challenge if we do not have access to the regulations, requirements and common frameworks, given that our weans may need livers from other areas. It would be quite a challenge to set up transplantation regulations, would it not?

Professor Dominiczak: Yes—we can only agree with you. The impact would be similar in other areas, but that would be the case specifically for children with rare conditions, as you mentioned. There are not many donors and few organs, and an open-borders policy has helped many people, so we should do everything that we can to ensure that we do not lose our membership of, and cease to belong to, those organisations.

Dr Ball: Mark Flear used the word "harmonisation" earlier. It is a legal term, but the science community has adopted it, and we are very much calling for continued harmonisation with the EU in a lot of the frameworks that work for medical research and for patients.

Emma Harper: I have a wee supplementary. If we have to pay for access to the EMA and to all the other regulatory bodies and agencies, that will have financial implications, will it not?

Dr Flear: Yes, absolutely.

Gregor McNie: Yes.

Dr Ball: Yes.

Professor Dominiczak: Yes, but every penny would be well spent.

Dr Ball: Absolutely—I very much agree.

Gregor McNie: It would have service implications as well. As I said, where NHS excellence happens, research is a core ingredient. If we start pulling it out, we will lose the talent and the best people who want to teach and practice in our hospitals, which will have an impact on patients and outcomes. Research is never separate from the NHS and the delivery of healthcare in Scotland.

The Convener: I thank all our witnesses for today's session, which has been informative and extremely helpful. I suspend the meeting for a few minutes to allow for a change of witnesses.

11:04

Meeting suspended.

11:10

On resuming—

The Convener: I welcome to the committee our second panel of witnesses—old friends and new: John Brown, director of policy at the Scottish Lifesciences Association; Matt Barclay, director of operations at Community Pharmacy Scotland; and Michael Clancy, director of law reform at the Law Society of Scotland. As you know, our focus this morning is on the regulation of medicine and medical devices. Emma Harper and Alex Cole-Hamilton both have questions on the sharing of data.

Emma Harper: I am happy for Alex Cole-Hamilton to go first, because he is the data person.

Alex Cole-Hamilton: My question follows on quite well from the line of questioning on clinical trials regulation that I put to the first panel of witnesses. They talked sensibly about our access to databases, not least for clinical trials, when we crash out of the EU. They were all of a mind that we need some kind of bilateral agreement that involves more than just regulatory alignment, so that Scottish patients, especially those who have ultra-orphan conditions, might continue to enjoy the advantages that they currently have as a result of our access to databases and pan-European clinical trials. That will not happen if we leave the European Union without a deal in this area. Can you give us an idea of what type of deal we would need? What are the barriers to that, and what would be the implications if we had no access to European databases?

Matt Barclay (Community Pharmacy Scotland): I am happy to kick off on that. With regard to the supply chain and the safety of medicines that are supplied to patients, the whole EU set-up is designed to allow pharmacovigilance throughout the 28 member states. Adverse events in relation to medicines in Scotland are generally reported through the yellow card scheme, and the information is passed on to Public Health England, which passes it on to a European database. That type of intelligence allows for data to be co-ordinated and subsequently communicated throughout the 28 member states. In addition,

antimicrobial resistance can be mapped across Europe, which allows pharmacists—even those in community pharmacies—to obtain information about prescribing patterns and what should happen in Scotland in a European context. From the perspective of ensuring the safety of medicines, we cannot lose access to that level of data. I would like to think that we would continue to be part of that data sharing, because the UK, among the 28 member states, has a substantial population feeding in information that benefits Europeans as well as patients in Scotland.

The Europe-wide general data protection regulation is due to come into force in May this year. For a number of years, the Information Commissioner's Office has been lobbying to update data protection laws. That is now happening Europe-wide, and we would like our access to that system to be maintained. It provides safeguards and offers the potential for professionals to exchange and transfer patient information and data safely, not only across the EU but within the UK—for example, between a community pharmacy and a general practitioner. We would like to maintain our access in that area.

Emma Harper: When the committee took evidence last week, I asked questions about the European Centre for Disease Control. A lot of information is currently shared, not only on antimicrobials but on antivirals such as the flu vaccine, and on potential flu pandemics. Data sharing is obviously really important, not just Europe-wide but worldwide, in enabling us to protect people from the flu virus. I suppose that Matt Barclay's comments on that will be similar to the answer that he has just given.

11:15

Matt Barclay: Yes—that area is hugely important, and we need to remain part of that set-up. Flu vaccines are global; they are developed in Australia in response to the flu viruses that emerge there, and companies then develop vaccines for use across the UK and Europe in the upcoming season. I am sure that that level of information will be shared; I would like to see that access maintained.

The Convener: I ask Ash Denham to open the questioning on the wider issue of medicines regulation, which I know will be of interest to all the panel members.

Ash Denham (Edinburgh Eastern) (SNP): Good morning, panel. I turn to the European Medicines Agency, which is, as we know, unique in the world. We do not currently have any clarity from the UK Government on whether we will retain membership of the EMA. From the submissions that the committee has received, that seems to be a very serious issue. We have seen evidence that it could destabilise the medicine supply chain. One submission highlighted comments in *The Lancet* that suggest that it will be very costly to taxpayers and that there will be increased costs and delays. Can you explain exactly what you see as the potential consequences if the UK was outside the EMA?

John Brown (Scottish Lifesciences Association): First, the Prime Minister said last week that the UK Government would seek to attain associate membership of the EMA after Brexit. She did so in the context of referring to a number of regulatory areas, including aviation safety, on which she said that the UK would seek to remain within the European Aviation Safety Agency, as Switzerland currently is. In a way, we can take Switzerland as an example of the UK's position after Brexit. Swiss airlines do not need to ask someone else within the EU border to carry out tests, because they have an agreement with the aviation safety regulator. It is basically a mutual recognition agreement—I will come back to that phrase several times in response to questions. To reiterate, Switzerland has a mutual recognition agreement with Europe on aviation safety.

The UK Government's current position, as the Prime Minister explained last week, is that it will seek associate membership of the EMA. However, the industry view—I represent businesses in the life sciences sector that make medicines—is that the UK should have a mutual recognition agreement on health regulation. There are many such agreements throughout the world, and an agreement between the UK and the EU on medicines would avoid the need for double testing, as in the aviation example that I highlighted, in which people do not need to do all the tests and checks twice. It is vital that the UK gets a mutual recognition agreement with the EU on medicines, and we and other industry bodies are pressing the UK Government on that issue.

The Convener: Would you like to explain the critical differences between mutual recognition and associate membership in that context?

John Brown: Associate membership of the EMA would give companies access to the expertise that the agency currently holds. In fact, a large part of the EMA's expertise is British. It has been in London since its inception, and moving it while retaining the expertise will be an extremely difficult task.

If one looks at the amount of regulatory and technical expertise in medicines and medical products across Europe, it is evident that a large proportion—more than pro rata—comes from British experts. That is one reason why the EMA was located in London. There will be a lot of

issues for the EU in moving the agency, but the UK's ability to have associate membership of the EMA will allow companies that are thinking of new medicines to talk to the agency as members rather than as third parties.

Mutual recognition is global. At present, if a medicine comes from America, it will be tested in America to Food and Drug Administration standards and, when it comes to the EU, it will be tested again to ensure that it accords with European regulations. That is what we call double testing. A mutual recognition agreement means that the recipient state accepts the efficacy of the testing in the originating state. In fact, the EU and the US are currently negotiating a mutual recognition agreement, which is due to come into force next year. A mutual recognition agreement is about recognising each other's testing quality and not needing to check everything twice.

The Convener: That is understood. Does Ash Denham want to come back in?

Ash Denham: I think that Matt Barclay wants to come in.

Matt Barclay: I agree with everything that John Brown said. From a supply point of view, Community Pharmacy Scotland is probably the largest stakeholder in terms of daily transactions with and advice to patients. I would like to think that, for patients, the process of accessing medicines and receiving advice from pharmacists on a daily basis is essentially seamless. However, the whole supply chain is extremely complex. When the products leave the manufacturer, they often cross many borders in the EU and—as John Brown explained—globally to reach the wholesalers, which distribute medicines to the pharmacies. The UK currently imports 90 per cent of its medicines, and about 50 per cent of those are imported from the EU. Mutual recognition would be very beneficial in order to allow for frictionless trade, so that I and my pharmacy can obtain medicines with no additional barriers and supply them to patients. It would ensure that the process in which a GP writes a prescription and I receive it and provide medication to patients is as seamless as possible.

If the kind of mutual recognition agreement to which John Brown referred—the term "alignment of regulations" is often used—is not in place, there is potential for increased costs across the piece. Manufacturers have to make money from medicines, and wholesalers make money on the margins in the distribution of those medicines. As part of our financial package, my members in Scotland are allowed a degree of margin to enable them to meet their cost base. That forces—or encourages—them to purchase very efficiently and to keep prices extremely low for the NHS, which is the ultimate consumer of those medicines.

It is recognised that medicine costs in the UK are among the lowest in the world. In America, which John Brown mentioned, it is much more costly to provide medicines than it is in the UK. In order for the current system to be maintained and supported, it needs to be as aligned or—as John Brown said—as reciprocal as possible.

Michael Clancy (Law Society of Scotland): The Prime Minister said in her speech that she would want the UK to have associate membership of the EMA and other agencies, including the European Chemicals Agency and the European Aviation Safety Agency, to which John Brown referred. However, she went on to say:

"We would, of course, accept that this would mean abiding by the rules of those agencies and making an appropriate financial contribution."

The Prime Minister then said:

"associate membership of these agencies is the only way to meet our objective of ensuring that these products only need to undergo one series of approvals, in one country",

which sets out an important objective.

She also said that she would want to

"negotiate"

so that the UK

"could continue to provide … technical expertise."

Finally, she said that that would

"permit UK firms to resolve certain challenges related to the agencies through UK courts rather than the ECJ",

for which the more modern term is the Court of Justice of the EU.

It is fine that the Prime Minister wants that to happen. However, it is quite clear from the draft guidelines for the negotiations that the European Council published on 7 March that it takes a different view. At paragraph 6, it states:

"The European Council further reiterates that the Union will preserve its autonomy as regards its decision-making, which excludes participation of the United Kingdom as a third-country to EU Institutions, agencies or bodies."

In the negotiation flow, it may be a case of, "Back to you, Prime Minister", but it certainly seems that the upcoming negotiations will be difficult if the UK is to persuade the EU to relax its approach, or if the EU asks the Prime Minister to think again.

I turn to Switzerland. The Law Society of Scotland, in its submission to the committee, refers to the confidentiality agreement that the Swiss have with the EMA and the EU's directorate-general for health and food safety. That agreement, which includes the Swiss Agency

for Therapeutic Products—or Swissmedic—and the Swiss Federal Department of Home Affairs, contains no automatic recognition of marketing authorisations that are granted by the EU. Therefore, the Prime Minister's aspiration for one series of checks may not be the way that we end up going, if a Swiss-type agreement—which is different from associate membership—is where we finally arrive.

Ash Denham: That is the point that I was going to raise on the back of John Brown's comments. Canada and Switzerland each have a separate approval system, but medicines typically reach the market in those countries about six months later than they reach the EU market. Is there a risk that, if the UK Government is not able to get the type of agreement with the EU for which we all might wish, there might be a delay in new cancer medicines, for example, reaching the UK? Do you see that as a risk?

John Brown: Yes, I do. Around 82 million packs of drugs cross the EU-UK boundary every month—that is a lot of drugs. The process is currently frictionless, to use the popular term. If it becomes encumbered by the need for double testing and for what is referred to as double batch-release sign-off, that will slow down the supply of drugs to patients. The pharmaceutical industry in the UK is pressing the Government on the potential patient safety issues In that regard.

I will quickly expand on what I have said. Medical devices are tested only once: when they are designed and their manufacture begins. I know that the scope of the committee's consideration includes medical devices. However, medical device manufacturers—of which there are a large number in Scotland; we have far more medical device and medical technology companies here than pharmaceutical companies—do not, from an economic point of view, see Brexit having a big impact on their industry. Once a device has been tested and accredited, it can be sold. There is some regulatory overview of its use—for instance, if something explodes, there is a process that is equivalent to the pharmacovigilance process, and a report is made. However, by and large, once a device is approved, it is available for sale anywhere. With medicines, even after initial clinical studies have been done, every batch of medicines is tested—or rather, medicines undergo continuous safety testing in laboratories. Under EU regulations, that testing must take place within EU borders for a drug to be supplied in the EU. For drugs manufacturers in Britain, it would mean double safety testing if we did not get some sort of mutual recognition.

11:30

Every batch of drugs that is released to patients has to be signed off in a regulated process by a qualified person, which is a term of regulatory art, and that must be done within EU borders. Without an MRA, it is probable that medicines that are made in the UK will have to be tested in the UK, and then tested again, and each batch that is released will have to be tested in the UK before someone in Europe does the same again. That becomes a patient safety issue, for the reason that—as Ash Denham mentioned—it will slow things down.

Brian Whittle: Good morning, panel. As John Brown mentioned, the Prime Minister is seeking an associate relationship with the EMA, which is what we would all hope for. However, as Michael Clancy pointed out, that is not necessarily the EU negotiators' current position. I suppose that it boils down to what is likely to happen and the likelihood of such a relationship being agreed.

That spins us back to the current relationship between the MHRA and the EMA, and the potential impact on the EMA if the MHRA were not part of an associate relationship. It is my understanding that the MHRA has a significant input into the EMA. What, therefore, is the likelihood of the two parties coming closer together as we get closer to the need for an agreement? Would it be correct to say that, in reality, the EMA would want the MHRA to maintain its part in the whole process?

John Brown: I have been working with the pharmaceutical industry for seven years, and I believe that, after the FDA in America, the MHRA is the best-regarded medical regulatory agency in the world. It is certainly up there with the FDA in the quality of its work and its expertise. The MHRA is a huge contributor to the work of the EMA, and that will not stop. It will still be a very well-respected regulator.

Brian Whittle: If we cut through all the rhetoric that seems to be following the EU negotiations, the reality is that both sides would prefer to maintain some sort of close relationship.

John Brown: Yes. I have to choose my words carefully, but the pharmaceutical industry is quite a powerful lobby—it is well funded and is very good at lobbying national Governments, not only in Britain—and it is very alive to the threat of double testing and double everything. It would be foolish to say what is going to happen, but there is still a degree of optimism that the European Council's response is just part of the negotiation. The Prime Minister says that she would like to do something, and Europe says, "That is cherry picking, and we are not going to allow cherry picking." I am not going to say how it will end.

Brian Whittle: I am with you.

Matt Barclay: I have heard, in some quarters, that there is possibly a small opportunity here, although I do not know how likely it is. Under the Swiss, Canadian and Australian models, those countries get their new medicines between six and 12 months later than countries in the EU. However, if we were to align so closely to the EU that it would sign off the marketing authorisation at an EU level, there would potentially be a role for the MHRA in speeding up the process within the UK to allow new medicines to come in potentially even more quickly than they would come in within the EU. I am not sure how likely that is, but I have heard from and spoken to people in the industry who say that, although it is unlikely, it is a potential positive.

The Convener: As John Brown said, we cannot predict the outcome of the negotiations.

Michael Clancy: We will know more, shortly. The European Council is meeting at the end of this month, and we will then have a better vista of the approach that it will take. I take John Brown's point that what we have discussed is negotiation talk, but negotiation talk lasts a long time, and it is only 381 days from today until 29 March 2019—I checked my Brexit countdown calendar this morning. Time is running out for us, as we are getting to the stage at which the positioning must give way to actual agreement.

The Convener: Sandra White has a brief supplementary question.

Sandra White: I am glad that Michael Clancy is counting down the days—I could not do that. I can talk about cherry picking, though, because that is what the negotiations are about. I am interested in how Brexit will affect the patients—the people—at the end of the day. For a start, things will be more expensive, but I also worry about counterfeit drugs getting into the system. How will we prevent that from happening if we are not a member of the EMA?

Matt Barclay: At the minute, there is a good system among the 28 countries in the EU. Marketing authorisation covers all the countries, and we operate wholesale dealer licences in the same way through the wholesale chain. There is already a strong guarantee that medicines are authentic, but a new piece of legislation—the falsified medicines directive—is due to come in in February 2019, which is, ironically, the month before Brexit is due to happen. It involves a significant undertaking by every single EU country to build an electronic database and use electronic mapping. Come next March, community pharmacies should have special scanners that will allow them to scan medicines for patients. If a drug is signalled as a counterfeit medicine, that will come through on the scanner.

The amount of counterfeit medicines in the UK supply chain has been relatively small over the past 20 years or so. The risk would be if we were to reverse the current position and not take on board the falsified medicines directive. To be fair, there is no sign of that—the UK Government and Community Pharmacy Scotland have both been involved in the UK falsified medicines directive working group for community pharmacy, and there is no indication that we will not be part of that system. However, if we were to fall out at any point in the future, the UK could potentially become a dumping ground for counterfeit medicines, because we would not have the safeguards that the other EU member states would have. That is a potential risk.

The impact on the whole system raises a patient safety issue. When I am supplying medicines in the pharmacies in which I work as a locum clinician, I know that, in general, they are safe. As I said, the falsified medicines directive is a new addition to the system that is seen as being very important.

Michael Clancy: We currently have in place legislation that protects us against fraudulent drugs. The important point to remember is that, as the new directive comes into effect, in March next year, the European Union (Withdrawal) Bill is designed to transpose it from EU law into UK law. Therefore, we will carry forward that legislation, subject to agreement on the reciprocal elements that are involved in the database arrangements. I have no doubt that that is exactly the kind of area in which the United Kingdom Government will want to negotiate access to the information in the database, if not to the database itself, in the same way as currently happens in the area of criminal justice with databases such as ECRIS—the European criminal records information system—and Eurodac.

We ought not to be fearful that we will be flooded with counterfeit drugs all over the place. There will be mechanisms in place—albeit that they will not run as smoothly as we might expect them to—to protect people from that kind of criminal activity.

The Convener: We will move on to questions on medical isotopes and Euratom, starting with a question from David Stewart.

David Stewart: Good morning, panel. I have been very interested in looking at medical isotopes over the past few months. One of the little-known aspects of Brexit is our withdrawal from Euratom, which I suspect is not the most popular or well-known body in the UK. As the panel will know, Euratom monitors the supply of medical isotopes,

which—again, as you will know—we do not produce in the UK. What is your assessment of that?

As you will all know, medical isotopes are used in gamma cameras and PET scans and for therapeutic purposes, and they are very important in the treatment of cancer. What assessment have you made of the impact of the UK's withdrawal from Euratom on the supply of medical isotopes—in particular, for those who are suffering from cancer?

Michael Clancy: I should declare an aged interest here, as I was a member of the Scottish Government's working party on positron emission tomography—PET—scanning from 2003 until about 2011.

David Stewart: I am glad that you did not ask me what PET stood for.

Michael Clancy: Well, just you wait—what is an isotope, Mr Stewart? [*Laughter.*] No—we will not play that game.

I have a personal and professional interest in medical isotopes. We should roll back to the beginning of this particular aspect of leaving the EU. When the Prime Minister gave notification to the European Commission and the European Council, almost a year ago, that the UK was withdrawing from the EU, it included our withdrawal from Euratom—that is the European Atomic Energy Community; I want to make sure that we are all on the same page. No real rationale was given for that. The explanatory notes to the European Union (Notification of Withdrawal) Bill simply said that it would be a consequence of what was happening.

If one wishes to identify why the UK Government has withdrawn from that particular treaty, one has to look, for example, at the fact that Euratom as a community is subject to the CJEU and that it brings with it some movement of people, such as research experts, across the EU. One can therefore see why the Government might have taken that view. Membership of—or being subject to—the CJEU is one of the Government's red lines, and the free movement of people is another.

If one were to look at the agreement of December last year between the UK and EU, one would see that, on citizens' rights, the CJEU has been given the opportunity to take referrals from UK courts for a further eight years from the leaving date. One would have to press the Government on the particular point about how that red line is capable of being massaged a little in relation to citizens' rights, yet it still holds good for Euratom.

David Stewart: I will make two other points while I still have the facts in my head.

The scale of the isotope issue is phenomenal. I looked up the UK figures and found that 700,000 medical isotope procedures were used in the UK last year, of which approximately 70,000 were in Scotland. On the supply side, in a non-technical sense, the raw ingredient for medical isotopes is molybdenum 99, and six countries have 90 per cent of the world's supply. Four of them happen to be in the EU, so we can do the maths. We know that the demand is great and that, basically, the EU has a massive supply base—if not quite a monopoly—of new radioactive isotopes. In theory, Hinkley Point will be capable of producing that material, but it will come on stream in 2027, so that is an argument for another day. I am very concerned about the future supply of medical isotopes for cancer treatment.

11:45

Michael Clancy: You are absolutely correct in saying that there is no UK producer of those isotopes. Only three countries in Europe—Belgium, the Netherlands and France—have reactors that can produce molybdenum 99, and the supply chain, which is quite complex, therefore needs to be maintained. The fire in the channel tunnel in 2008 interrupted the supply chain for those isotopes, which meant that procedures were postponed for some time until things got back on an even keel. It is essential, for both diagnostic and therapeutic application, that we have a consistent supply of medical isotopes.

If you trawl the evidence that has been given to the UK Parliament's Health and Social Care Committee, you will see a memorandum from the Department of Health and Social Care that talks about the extent to which the Euratom treaty restricts export. According to the department, the treaty does not restrict export; the important aspect is the security of supply that it provides. Because the isotopes are not fissile material, the EU allows them to pass through borders. We—not the Law Society, but we as citizens—want that supply to be secure so that, on the occasions when one of us or someone whom we know and love requires that kind of treatment, the material is there to provide it.

Matt Barclay: You may not be surprised to hear that Community Pharmacy Scotland does not deal with radioisotopes, but we cited that issue in our evidence with regard to the potential big impact on patients. I will build briefly on Michael Clancy's point. Without the frictionless efficient movement of those products, an element of decay can occur. We could buy 100 per cent and have 100 per cent available for use among patients in the UK and Scotland, but, if there was any delay at customs under any future arrangement, there could be an

element of decay, which would mean increased costs and less availability for use in patients.

John Brown: I will make a linked point that is not about medical isotopes but about their shelf life, as it were. Modern medicine is moving towards cell and gene therapies. Those are, by their nature, not the same as long-life tablets such as aspirin, which still work even if they are kept in a cupboard for three years before they are taken. The move towards cell and gene therapies is slow because they are very expensive, but it is fair to say that many medical experts regard those medicines—at least in part—as the future.

One of the issues that we have spotted is nothing to do with medical regulation; rather, it is to do with terms of trade and customs arrangements. If we have customs arrangements that do not allow such products to pass quickly from one country to another, they will degrade and may, in fact, become useless. Some cell therapies must be used within hours of manufacture, and a whole network of suppliers exists to ensure that that is possible. A new UK-EU customs arrangement that slows down the transfer of material across customs borders could have an impact on patient safety where those new therapies are used. That parallels the issue of isotopes losing their efficacy.

The Convener: I will bring in Jenny Gilruth.

Jenny Gilruth: David Stewart has covered my points.

The Convener: We will move on to talk about the regulation of medical devices. First, however, I think that Michael Clancy has a supplementary point to make.

Michael Clancy: It is just a small point. The idea of projecting information about this matter is quite important if the UK Government wants to use the CJEU as a reason for coming out of Euratom and even for having special arrangements through associate membership of the EMA. We must remember that, during the whole time that the Euratom treaty has been in place, only eight of the 48 cases on Euratom matters that have gone to the CJEU have related to the United Kingdom, and only two of those were found in the European Commission's favour. The United Kingdom has a good record of compliance with the treaty, and we must be alive to the fact that the anxiety about the CJEU is not as forthright and real as it might be.

The Convener: We have already heard about the importance of medical devices in the Scottish sector, but Alison Johnstone wants to come in.

Alison Johnstone: Good morning, panel. As you will know, medical devices are regulated EU wide, and we have concerns that medical technology companies in the UK may be incentivised to relocate. We would want to avoid that, because apparently 94,000 people are employed in the sector and it has a turnover of £17 billion, so any loss could have a large impact on the UK economy. In leaving the EU, the UK will lose influence in shaping policy, legislation, procedures and so on. I am interested to hear your views on the risks associated with the UK losing full membership of CEN—the European Committee for Standardization—and CENELEC, which is the European Committee for Electrotechnical Standardization, and on how those risks might be mitigated, if they can be.

John Brown: For obvious reasons, the regulation of medicines has always been extremely rigorous. Until a few years ago, medical devices were not so heavily regulated because the definition of a medical device is that it does not go inside the body or, if it does, it does not interfere with the body's physiology. It might be a hip joint, for example—it is not a medicine. However, in the wake of the PIP implants scandal, the European medical regulators, including the MHRA, have done a lot of work, over the past five years, to raise the standard of regulation of medical devices considerably.

I will not make comparisons, but medical devices are now regulated much more stringently than they were. New regulations are coming into force, and—as we have heard with regard to the falsified medicines directive—they will be transposed from EU law into UK law by the UK Parliament. Life science companies in every sector—including medicines, medical devices and diagnostic tests—very much want UK regulation to stay completely consistent with EU regulation for the foreseeable future, otherwise they will lose markets. The UK regulatory arrangements for medical devices are currently consistent with the EU regulations, and I believe that they will stay that way.

Given that the standards have just been greatly upgraded in their rigour, we are now in a good place, as it were. Nearly half the Scottish life sciences sector is composed of companies in the areas of medical technology and diagnostic testing, and I have not heard from a single one of those companies that it is even thinking of relocating. Once a company gets a product tested and can show that it conforms to the regulations, it can sell it anywhere in the world; it does not need to keep testing it. Our members are not currently concerned about the potential threat that Alison Johnstone has highlighted.

Alison Johnstone: Do the other witnesses share that view?

Michael Clancy: I have no view on that.

Matt Barclay: I probably agree with John Brown, as he is much closer to the issue than I am.

Going back to a point that he made earlier, the MHRA has taken a huge role in the area of regulation—up to 50 per cent of tests and regulatory processes occur through the MHRA. Again, that benefits the EU as well as the UK. The MHRA is an internationally recognised partner in global health, which is very helpful with regard to what we are discussing.

Brian Whittle: The committee has done quite a lot of work around digital health and the adoption of digital technology in the health service. What stage is the health service currently at with regard to the adoption of digital health technology, and what impact will Brexit have on that?

John Brown: As a trade body, the Scottish Lifesciences Association has many members in the area of digital health who are seeking to do business with the NHS. Leaving aside economic and health issues—those were covered in the committee's previous inquiry, which looked at the adoption of new technology by the NHS—we see no impact as a result of Brexit. The ability to trade in software is pretty much free of boundaries. For example, Craneware, which is one of our member companies in Edinburgh, supplies a quarter of US hospitals with its billing software without reference to borders.

I will touch on one issue that comes back to regulation. A lot of medical software is currently not regulated, which poses a risk to patient safety. More and more medical people are using apps on their phones, but how do they know that the programme or the phone does not have a bug in it that could kill a patient? Digital health companies are slowly moving towards thinking about the need to have their software regulated, which would mean meeting standards of efficacy. That is a huge issue for software companies. How can they prove that a massive piece of software has no mistakes in it that could kill a patient? Those issues are only just emerging.

The MHRA has not published any regulations on that issue, but it recently introduced draft guidelines, which is a small first step towards the regulation of medical software in the UK. At present, the area is pretty much unregulated, which is an issue for health. However, we do not currently see there being any impact at all in that area as a result of Brexit.

Brian Whittle: I am aware that Craneware is an Edinburgh company that supplies a huge amount of technology to the US, although it does not supply technology within Scotland.

John Brown: Hospitals in Scotland do not bill their patients. Craneware has gone for a US market that exists only in the US, and it has been very successful.

The Convener: You say that the story of the regulation of medical software is just beginning. Does that mean that, because of the timing, three separate strands of regulation will be developed in the UK, the EU and the US?

John Brown: Such regulation is in its very early stages in Europe. However, the MHRA is starting down that track by issuing draft guidelines. Drawing on my earlier comment about the respect that the MHRA is accorded globally because of its regulatory clout, those guidelines will be studied by other regulators, and I would not be surprised if they fall in line, because the issues are the same everywhere.

The Convener: I ask Ivan McKee to come in, because I know that he has questions on a number of areas.

Ivan McKee: Good morning, panel—it is still morning at one minute to 12; it has been a long morning. I would like to ask about common frameworks and, on the back of that, about trade agreements. We have talked extensively about the relationship between the UK and EU that might or might not be in place in the future, and the way in which the UK as a whole operates in that environment is also a topic for discussion.

12:00

Everyone agrees that there should be common frameworks in a number of areas where they are relevant. Around 100 areas have been listed, several of which are in the health arena. Given that Scotland's health service is different in many respects, to what extent should your organisations—as Scottish organisations—have some input through the Scottish Parliament and the Scottish Government to influence the direction of the UK's common frameworks? If those frameworks threaten to diverge from EU standards, could Scotland, if it had a significant say in their generation, have an influence in that area and keep the standards more closely aligned with EU standards in future?

Michael Clancy: The issue arises from clause 11 of the European Union (Withdrawal) Bill, which seeks effectively to withdraw from the Scottish Parliament competence in connection with EU law. Yesterday, as it happens, the Government minister, Lord Callanan, tabled amendments to the bill. They were published this morning. I have not yet had the chance to analyse them, but, from what David Lidington said last week, we can assume that they completely change the orientation of clause 11 in many respects. We can come back to that later.

On Friday, the UK published the document, "Frameworks analysis: breakdown of areas of EU law that intersect with devolved competence in Scotland, Wales and Northern Ireland", which is quite interesting. It breaks down areas of EU law that intersect with devolved law, and it includes a couple of areas of interest to the committee, such as social security co-ordination and cross-border healthcare rights, on which the UK Government says that "no further action" is to be taken. A few areas, such as blood safety and quality, the regulation of tobacco, organs, public health cross-border issues, and tissues and cells, are subject to non-legislative common frameworks. There are 24 policy areas in which the UK Government believes that it has competence, including reciprocal healthcare and nutritional health claims. The final area of interest to the committee—which the UK Government believes to be reserved in any event—concerns medical devices, which we have just been talking about.

I searched schedule 5 to the Scotland Act 1998, which lists all the reservations, quite closely, and I could not see medical devices mentioned. However, I believe that they fall within the context of consumer protection, which is a reserved matter, along with some other aspects of medicines and medical products. I could not find the precise phrase in the 1998 act—maybe someone who has read the act more closely will be able to identify it for me. The issue is that those proposed frameworks are the subject of negotiation between the UK Government and the Scottish Government. We have to find out now what the Scottish Government will say about that and about the amendments that have just been lodged, which will come up for debate at the House of Lords committee next week. If there is a fast-moving area in legislation, this is it, and the committee might want to revisit the matter when things are a bit clearer.

Ivan McKee: Yes, but if things are happening now, we should surely be trying to influence the direction of travel.

Michael Clancy: Indeed, but it is difficult for me to say anything until I have had the chance to look at the amendments.

Ivan McKee: I understand. Do the other two panel members have any comments on what influence you believe that you should have on how the common frameworks shape up?

Matt Barclay: Michael Clancy has answered the question quite comprehensively. Community Pharmacy Scotland's submission mentions areas such as reciprocal healthcare and public health. Given that health is devolved, as you say, we believe that we should be allowed to maintain an element of divergence from the UK. Essentially, we would like the current approach to be maintained. For example, the community pharmacy contract in Scotland is very different to the contract south of the border, and that has happened since devolution. If any common frameworks impacted on our ability to continue with that, we would be worried.

Ivan McKee: I understand. Let us move on to the issue of trade agreements, which intersects with various areas that the committee has considered; it came up at committee last week. You mentioned public health. It is clear that areas such as tobacco regulation, minimum pricing and food standards in the context of tackling obesity could potentially be pulled in by the UK Government as a bargaining chip in negotiating trade agreements with third parties post-Brexit. Have you given any thought to that area?

John Brown: No.

Matt Barclay: Not on a large scale, I have to say.

Ivan McKee: Do you see any risks if that situation were to arise?

John Brown: It is not an issue for businesses.

Michael Clancy: The transatlantic trade and investment partnership negotiations between the EU and the US raised certain anxieties about healthcare providers being allowed to operate in the EU to the perceived detriment of EU citizens. However, that treaty did not proceed, so we do not know what would have happened. If it was suggested that, as a result of trade negotiations, there would be detrimental effects in a range of areas, people would want to know. However, I fear that the same confidentiality restrictions that applied to the TTIP negotiations would apply to the negotiations on any trade agreements between the UK and any third countries. The difficulty will lie in whether we are able to find out.

Ivan McKee: The issue would therefore be not only that the Scottish Government would be unable to prevent the UK Government from trading access to the Scottish NHS, but that we would not even know that it was happening.

Michael Clancy: I could not go that far, because I do not know what the parameters of the negotiation would be.

Ivan McKee: But it is a possibility.

Michael Clancy: You may say that.

Ivan McKee: I think that it is what you just said previously. You said that we would not know what was happening.

Michael Clancy: I said that we would not know what was happening—that is true.

Ivan McKee: I have one final question. We have talked quite a bit about the problems with Brexit. It will make things more expensive and more difficult in areas such as the supply chain, access to skilled labour and access to research, among several other areas that we have discussed. Do you see any advantages to it?

John Brown: Yes. If double testing is needed—I hope that it is not—there will be a business opportunity for companies in the UK that can do the testing that is currently done elsewhere. In addition, some of our members have put forward the view that, in the context of the value of a batch of medicine, which can be extremely high, the cost of double testing will not be large. If double testing and double batch-release sign-off were imposed because we could not reach a mutual agreement, there would be an impact on the cost of medicines, but it might not be as large as some people fear. I am not in a position to say how large it might be, or to give you the proportion in cost terms, but some businesses are quite relaxed about the situation.

One example is IQVIA, which used to be called Quintiles Scotland. It is based at Livingstone and employs 1,000 people, and every morning it brings in through Edinburgh airport a plane load of samples to be analysed before the results are sent back. As a global business, IQVIA treats Brexit as simply one of the business risks that it takes wherever it is in the world. Charles River, which operates out of Tranent, is another such company. It does a lot of work in clinical studies, and it is used to operating across boundaries because it is a big global company. In fact, one of Scotland's greatest strengths in life sciences is in contract research for clinical studies, and those big companies are doing a lot of business. Over the past five years, they have each increased their staffing levels by about 25 per cent, and they are bringing in work to Scotland from all over the world. They are doing so in the knowledge of what might happen, but they just see it as a business risk that they have to manage.

Ivan McKee: I fully understand that, but you are giving examples of companies that, while they might not find things to be worse, would no longer have an advantage. In addition, those examples show that it is possible to generate business with third countries even when we are part of the EU, which means that there is no advantage to Brexit in that sense. You gave the example, if I understood you correctly, that some companies might be able to profit from the fact that everyone else is having to pay more for their medicine because of double testing.

John Brown: They might profit from the fact that there is new business.

Ivan McKee: Yes, but the costs still have to be paid by the health service and the public purse.

John Brown: Indeed. A big global company that operates in the area of medicines testing has recently made an inward investment in Scotland. I cannot say why it has moved in, but it is interesting that it has done so just now—the investment happened only in the past few months. It is a testing company.

The Convener: That is a fascinating aspect on which to end our session. I thank all our witnesses for their useful evidence. I suspend the committee briefly to allow for a change of witnesses.

12:11

Meeting suspended.

12:16

On resuming—

“Sport for Everyone” (Government Response)

The Convener: In a moment we will move to agenda item 2, on the draft Community Care (Personal Care and Nursing Care) (Scotland) Amendment Regulations 2018.

Before the commencement of the meeting, we had a discussion on our “Sport for Everyone” report, which we completed on 28 November 2017. I know that the matter has been drawn to the minister’s attention this morning. We were expecting a response from the Government in January. The minister will recall that I wrote to her in February to ask her about that response, and I wonder if she would like to take the opportunity this morning to tell us when we should expect it.

The Minister for Public Health and Sport (Aileen Campbell): Thank you, convener. I understand and appreciate the timescales that you are setting out. We would expect you to have it very soon. It is with me before we issue it to you, which we will do imminently. There was a lot within the requirement of the letter. It required us to engage with many different departments and agencies, and we want to furnish the committee with the right level of detail and do justice to the work that you have put in.

It will be with you shortly. I apologise for the delay, but it is in order to give you the best response that we can, given the importance of the topic. It is indeed topical, given members’ continuing interest around diet and obesity strategy and the whole host of other public health developments that are happening.

I can only apologise for the delay, but it is because of the attempt to get you the right information, and engagement has had to take place across many different parts of the Government. I hope that that meets with your understanding, although I understand the requirement to get you the response as soon as we can. As I say, it will be with you imminently.

The Convener: I am grateful, minister—that is helpful. Having sat at a ministerial desk—

Aileen Campbell: On the other side of the table.

The Convener: —I know that, once something is on the desk and you have taken that responsibility, it is now over to you.

Aileen Campbell: It is over to me—absolutely. I am a poacher turned gamekeeper, Mr Macdonald.

The Convener: We look forward to hearing more very soon.

Subordinate Legislation

Community Care (Personal Care and Nursing Care) (Scotland) Amendment Regulations 2018 [Draft]

12:18

The Convener: As with all instruments that are subject to affirmative procedure, we will now have an evidence-taking session with the minister and her officials on the draft regulations. During the evidence session, there will be an opportunity for committee members to ask the minister and her officials any questions that they may have on the draft regulations.

In addition to the Minister for Public Health and Sport, Aileen Campbell, I welcome Mike Liddle, from adult social care policy, and Emma Stevenson, from the Government solicitors. Thank you for coming. I invite the minister to make a brief opening statement.

Aileen Campbell: Thank you, convener. As you say, I am joined today by Emma Stevenson and Mike Liddle.

The draft regulations reflect our continued intention to increase free personal and nursing care payments in line with inflation. If they are approved, the regulations will continue to benefit vulnerable people aged 65 and over. The rates are calculated using the gross domestic product deflator, which is an inflation prediction tool. The regulations will increase the personal and nursing care payments for self-funding residents in care homes in line with inflation, which this year gives an increase of 1.56 per cent. The weekly payment for personal care will rise from £171 to £174 per week. The nursing care component of the payment will rise by £1, going up to £79 per week.

It is estimated that the rise will cost approximately £2.1 million. Funding of £66 million was allocated to local authorities for social care in the 2018-19 budget, taking this proposed increase into account.

The free personal and nursing care policy continues to command strong support and, as you will be aware, by April next year we will have extended free personal care to people under the age of 65.

I am happy to take questions on the draft regulations.

The Convener: Alex Cole-Hamilton has the first question.

Alex Cole-Hamilton: Thank you, convener. I welcome the minister and her officials. Thank you for joining us today.

To some degree of fanfare at the most recent budget, the Government announced a 3 per cent pay increase across the board for public sector workers. I am interested as to why the payments for personal and nursing care have gone up by only 1.56 per cent. Obviously, many care and nursing professionals will be public sector employees. Who is expected to meet the shortfall between the 1.56 per cent increase and the public sector pay increase of 3 per cent?

Aileen Campbell: Using the GDP inflator to ensure that the level of payment is increased is not unusual; it is the approach that has been taken over a number of years. Regarding council budgets, I point to the fact that the amount going to local authorities has increased to £66 million to reflect wider social care needs. Aside from that, the wider local government settlement takes into account some of the broader pressures around staffing.

Alex Cole-Hamilton: So, although it is not reflected in the payments that we are discussing, the workers who will be delivering the care will all be receiving a 3 per cent pay increase, which is to be funded entirely through an increase or uplift in the local government settlement.

Aileen Campbell: The draft regulations concern the free personal care element. The measures are not unusual. This is the approach that we have taken over a number of years, and the increase is a regular thing that happens, which we have presented to the committee. Within other parts of government there has been a reflection of the wider social care needs that have been met within the Government's budget.

Alex Cole-Hamilton: I accept that the Government has used this model for uplifting these payments before, but I imagine that the majority of the payments—at £174 for personal care and £79 for nursing care—are largely staff costs and go to pay staff salaries. Obviously there are overheads included in those figures, but if we have come to a national decision that public sector workers require a 3 per cent pay increase and if, by extension, we want to ensure that the private sector social care workforce is keeping pace with that level—if that is the value that we are putting on staff costs—why is the uplift only 1.56 per cent?

Aileen Campbell: That is due to the measure being about free personal care and the commitment to ensure that it increases by inflation. This is my regular appearance before the committee because of the way in which we have

increased free personal care, using the GDP deflator model, which is not—

Alex Cole-Hamilton: You do not think that there is a case for changing that.

Aileen Campbell: If you would like to engage on that issue, that would be absolutely fair. However, we were also committed to extending free personal care to under-65s. I am happy to have a conversation with you and the committee if that is something that you want to revisit, but the instrument concerns the regular increase through the GDP deflator model to ensure that free personal care increases in line with inflation.

Mike Liddle (Scottish Government): The payment rate shown is going to the self-funders within residential care, so it is providing an uplift to the people who are funding their own care and to the amount of public money that is paid towards their care. Additional money has been put into the budget over the past couple of years to enable payments of the living wage for social care staff.

Alex Cole-Hamilton: I am not trying to be difficult, and I accept that the rate is for self-funders. However, if the cost of their care is going to increase by more than the amount of the payment that we are offering, is that not a problem?

Aileen Campbell: Again, the draft regulations are about the simple matter of increasing free personal care for over-65s, which had not been increased until 2007, when we came into power. There had been no increase until then. We came into power and we decided that the right thing to do was to ensure that the payment increased by at least the rate of inflation. If there are other things that you want us to do to alter how we approach the matter, I am happy to have that discussion, but, on the draft regulations before you, I say that these measures are a fairly regular thing that we do to ensure that the rate is keeping pace with inflation.

The Government is taking a wider look at a number of different policy areas across the piece to ensure that adult social care is keeping pace with the change of need. We can consider the matter, if you or the committee so desire.

Mike Liddle: There has also been agreement between the Convention of Scottish Local Authorities and the care providers on an uplift to the national care home contract for this year. That will find its way through to putting extra money into the pockets of those care workers, too.

Miles Briggs: Good morning to the panel. In your opening statement you mentioned what is known as Frank's law. Will you give us and update on Frank's law and the regulations that will extend free personal care? Do you envisage those being brought to the committee in April? Any update that you have on that would be useful.

Aileen Campbell: That was the timescale that we publicly set out. April will be the deadline for that, and work is on-going. The group that is considering the matter has met twice, and it will meet again next week—Amanda Kopel is due to present at that meeting. Engagement work is on-going to keep up the pace to ensure that we make good on that commitment.

Miles Briggs: So you expect local authorities to deliver that provision from April next year.

Aileen Campbell: Yes.

The Convener: As there are no further questions from members of the committee, we will move to the next item on the agenda, which is the formal debate on the affirmative Scottish statutory instrument on which we have just taken evidence. I remind committee members that there is no opportunity at this stage for further questions. You may of course offer debating points, but there will be no questions as such, and we will then move to a conclusion.

Motion moved,

That the Health and Sport Committee recommends that the Community Care (Personal Care and Nursing Care) (Scotland) Amendment Regulations [draft] be approved.—[*Aileen Campbell*.]

Motion agreed to.

12:27

Meeting suspended.

12:28

On resuming—

Carers (Scotland) Act 2016 (Adult Carers and Young Carers: Identification of Outcomes and Needs for Support) Regulations 2018 [Draft]

Self-directed Support (Direct Payments) (Scotland) Amendment Regulations 2018 (SSI 2018/29)

Carers (Waiving of Charges for Support) (Scotland) Amendment Regulations 2018 (SSI 2018/31)

Carers (Scotland) Act 2016 (Short Breaks Services Statements) Regulations 2018 (SSI 2018/32)

Carers (Scotland) Act 2016 (Review of Adult Carer Support Plan and Young Carer Statement) Regulations 2018 (SSI 2018/33)

Carers (Scotland) Act 2016 (Transitional Provisions) Regulations 2018 (SSI 2018/34)

The Convener: Agenda item 4 is a further session on subordinate legislation. I welcome Peter Stapleton, from carers policy, and Ruth Lunny, from the Scottish Government's solicitors department, who are supporting the minister for this item. We again welcome Aileen Campbell. This set of SSIs includes one instrument that is subject to affirmative procedure in draft, and five instruments that are subject to negative procedure.

Once again, I invite the minister to make a brief opening statement in relation to the affirmative instrument and the five other sets of regulations.

12:30

Aileen Campbell: I do not think that I will be as brief as I was for the previous item, as there are a number of sets of regulations to refer to. As you have mentioned, I am joined by Peter Stapleton and Ruth Lunny.

It is just over two years since the Parliament passed the Carers (Scotland) Act 2016 with unanimous support, putting in place an important new approach to supporting carers. The 2018-19 budget includes an additional £66 million to support additional expenditure by local government on social care, including the implementation of the 2016 act. We expect the full amount to be transferred to integration joint boards for those purposes, in line with their delegated responsibilities.

This batch of six statutory instruments are the final ones required to enable implementation from the start of April, and I will say a few words about our approach to each set of regulations.

The transitional regulations provide for carers who receive support under the existing system to move to the new system under the Carers (Scotland) Act 2016. They require local authorities to continue providing support to existing carers and to continue to waive charges, until the carers move to the new system or cease to need carer support. Local authorities must keep that support under review until the carers move to the new system.

The regulations allow the transition to the new system to be phased in within three years, or within a year for young carers. Those carers must be offered an adult carer support plan or young carer statement sooner where there is a change that has a material impact on the care that they provide. They have a right to request an adult carer support plan or a young carer statement at any stage.

Those transitional arrangements are designed with three principles in mind: to provide continuity of support during the transition process for carers already receiving support; to allow a managed transition, so that existing carers move into support under the 2016 act on a phased basis and over a reasonable timescale; and to be responsive to the circumstances of individual carers.

The short breaks services statements regulations add further requirements to the 2016 act's duty for local authorities to prepare statements of the short breaks services available in Scotland. In particular, they require local authorities to consider the views of carers and carer representatives when preparing the short breaks services statement, and to provide contact details for the responsible department regarding publication. That will help to ensure that statements are appropriate to the needs of local carers, and that they know who to contact for further information. Following last year's consultation, the regulations also require the first statements to be published by the end of December, so as to allow adequate time for the information to be assembled and for local discussion to ensure that the statements are as useful as possible.

The two sets of amendment regulations on the waiving of charges and on direct payments update legal references in 2014 regulations so that they refer to carer support under the Carers (Scotland) Act 2016. When the new duty to support carers

takes effect from 1 April, the amendment regulations will maintain the existing requirements for local authorities to waive charges in relation to carer support and not to means test carer support delivered via a direct payment.

The review regulations set out circumstances in which young carer statements and adult carer support plans must be reviewed—in particular when the carer or cared-for person moves, or if there is another change that the authority decides has or could have a material impact on the care provided by the carer. Examples of such circumstances will be discussed and outlined in guidance.

Finally, the draft regulations on the identification of carers' needs and personal outcomes, which the committee is considering under the affirmative procedure, set out requirements that align those responsibilities with those for the preparation of young carer statements and adult carer support plans. As discussed in the policy note, the draft regulations are essential to the definitions of "identified personal outcomes" and "identified needs" under the 2016 act, so that the key duties in relation to adult carer support plans, young carer statements and carer support can work as intended.

In summary, supporting the proposed changes will enable the Carers (Scotland) Act 2016 to be implemented from the start of April and will put in place important new rights for carers as part of the structured, personalised approach to carer support envisaged under the act.

I am happy to take questions on this suite of regulations.

The Convener: Thank you. I remind colleagues that we are again in a two-stage process. There is now an opportunity for questions to the minister and her officials. When we move to the formal debate, there will be no such opportunity. If there are questions, this is the time to ask to them.

Emma Harper: I have had a number of constituents call me about carer assessments and the requirements for those assessments. I am interested to know whether the instruments actually lay out how an assessment should be undertaken. Is that part of the process?

Aileen Campbell: A lot of local work will be happening to ensure that design and local circumstances are reflected in how the assessments take place. Perhaps Peter Stapleton would like to offer Ms Harper some ideas on how that is happening in a practical sense.

Peter Stapleton (Scottish Government): There is quite a lot in the 2016 act on the content of adult carer support plans and young carer statements. There is a lot of detail on what they need to cover: emergency planning, identifying needs, personal outcomes and so on. We have supplemented that in the guidance, which is due to be issued very shortly. It has been out in draft for a while for local areas.

We are taking a conversational approach with carers so as to understand their needs, what is important to them and the personal outcomes that should be focused on in the adult carer support plans and young carer statements. That is not outlined in the instruments before you, but there is quite a lot in the act and the supporting guidance, both on the content and on the approach to developing the plans.

Aileen Campbell: There is a lot of attention on the young carer element to ensure that those provisions are implemented in an age-appropriate way and are understandable for the young people who are in need of that support. I have seen a lot of engagement, with different local authorities doing different things to ensure that that engagement is happening and that it is inclusive and as facilitative as it can possibly be, depending on the age of the young carer.

Alison Johnstone: I invite the minister to respond to concerns that she, too, will have received from carers organisations and the Convention of Scottish Local Authorities, for example, on overall funding for implementation of the 2016 act. It is fair to say that there is a view on the part of those involved in the provision of care that the act has not been adequately resourced. Some people believe that there will be a potential shortfall of tens of millions of pounds by the end of year 5. Will the minister address those concerns? I appreciate that she said that local authorities have a duty to provide support, but I would like to hear her views on what the Scottish Government could be doing to help and to allay those concerns around the financing of the act.

Aileen Campbell: The 2018-19 budget includes an additional £66 million to support that expenditure by local government on social care, which takes into account the pressures around implementation of the 2016 act. It is important to note that that will take the overall package of additional direct investment in health and social care integration to more than £550 million in 2018-19.

There is on-going dialogue around the financial implications of the 2016 act. That is why we have the carers act finance group, which is led by ourselves in Government and includes COSLA, local government services and national carer organisations. It includes the suite of people who have an interest in ensuring that implementation happens in as good a way as it possibly can.

There is also a bit of work around the uncertainty of future demand. Part of that work will involve assessing the true impact of the act as it is implemented. Preparatory work is happening so as to get a much more accurate baseline of support, and work is on-going so that we can gain a much more detailed level of understanding about the impact. That will allow the carers act finance group to look into that and to understand what the financial impact might be—if it is higher or lower than set out in the financial memorandum, or right on the money. It is important to recognise that it was understood that in years 1 to 5 there would be an increased need as a result of the implementation of the act.

There is money in the system, and there is a recognition that we need to continue to monitor things. Work is being done to ensure that our understanding is adequate. We have set out the anticipated costs within the financial memorandum, which take into account additional requirements.

The Convener: It is worth highlighting COSLA's specific concern about the waiver of charges and short-term and replacement care. You have made no allocation for those directly, in the sense that you have assumed that they will be picked up by local government through flexibilities. If that proves not to be the case, will you revisit that matter before next year's regulations are brought to the committee?

Aileen Campbell: That is why there is benefit in having the carers act finance group, which brings together COSLA and NCOs, which have also expressed some concerns. There is also the monitoring that we have put in place to get a better understanding of the impact of the bill. That will include the waiving element—it covers the act in its totality. We can consider those matters.

However, it is important to say that the waiving was not part of the 2016 act; it was already in place before the Carers (Scotland) Act 2016 came into being. Local authorities are already spending about £200 million on that aspect—on respite and on the waiving.

We can continue to consider that, and we can continue to have a dialogue on it. The finance group offers us an opportunity to have that on-going dialogue.

The Convener: My other question is more technical in nature, but it is still important. A drafting error in the Carers (Scotland) Act 2016 (Review of Adult Carer Support Plan and Young Carer Statement) Regulations 2018 (SSI 2018/33) has been drawn to the attention of the Government by the Delegated Powers and Law Reform Committee, and I understand that the Government has no plan to make a further instrument to correct that error. I wonder if either the minister or her officials could explain their reasoning for not offering an immediate amendment regulation, as we have seen in response to other drafting errors in recent weeks.

Aileen Campbell: Do you want to understand why we have used a correction slip, as opposed to revoking the SSI?

The Convener: Sadly, we had another drafting error in a set of regulations that came before us recently, and the Government issued a second instrument to cover the same territory, which immediately replaced the first one.

Aileen Campbell: Corrections slips are appropriate to use when the necessary change is deemed to be a minor one. There has been discussion between the Government and the Queen's printer, which did not take any issue with us using that approach. From our perspective, that approach would seem to be appropriate and proportionate to the correction that needed to be made, which was essentially a bullet point number change. The mistake did not change anything fundamental within the legislation; it was a simple typo. We think that we made the change in a proportionate way—particularly given the pressing deadline of 1 April for implementing the 2016 act.

I do not know whether Ruth Lunny wishes to add anything, but we certainly think that that was a proportionate response to the error that was made.

It was a matter of timing. If they are passed—granted, we need to have your agreement—the regs will enable us to implement the act, as agreed in 2016.

Ruth Lunny (Scottish Government): I echo the minister's comments on that. It was regarded as a minor error that did not affect the ability to interpret the instrument as it is meant to be interpreted. There has been no issue taken with the printers on progressing in that way. In fact, I believe that that is in progress at the moment.

The Convener: I appreciate the explanation. It is important for the committee and for Parliament to have correctly drafted instruments coming before us, and that every measure should be taken to ensure that errors of that kind do not happen. We have now had three such errors in the past few weeks, and we would be keen to have that issue addressed.

Aileen Campbell: I will certainly take that point on board. Nobody wants there to be mistakes in legislation, regardless of whether it is a simple typo or something more fundamental. We will ensure that the wider Government understands that that needs to be examined.

The Convener: I am grateful.

We move to agenda item 5, which is the debate on the instruments. As before, this is an opportunity for members to take part in a debate, but no further questions will be permitted.

Motion moved,

That the Health and Sport Committee recommends that the Carers (Scotland) Act 2016 (Adult Carers and Young Carers: Identification of Outcomes and Needs for Support) Regulations 2018 [draft] be approved.—[*Aileen Campbell*.]

The Convener: I invite contributions from members to the debate on the motion, and on the negative instruments associated with the draft regulations. There being none, I therefore put the question to the committee—

Alex Cole-Hamilton: Convener.

The Convener: My apologies.

Alex Cole-Hamilton: I am sorry, but just to clarify: are we debating the affirmative instrument as well?

The Convener: The affirmative instrument is the matter on our agenda.

Alex Cole-Hamilton: I would like to make a brief comment, if I may.

The Convener: Absolutely.

Alex Cole-Hamilton: I will not vote against the passage of these instruments, should it to come to a vote, because I would not wish unnecessarily to hold up the uplift of payments, but I want to put a marker down. Although I accept that there is a standard model for increasing the payments in line with inflation, which I think is a good thing, when there is an exceptional shift—

12:45

Aileen Campbell: Excuse me. Sorry, but are your comments about the deflator?

Alex Cole-Hamilton: That is what I am asking about.

Aileen Campbell: That was the previous instrument.

Alex Cole-Hamilton: Yes, but we—

The Convener: We have debated that one.

Aileen Campbell: We have done that one.

Alex Cole-Hamilton: Oh—I have missed the boat on that. My apologies.

The Convener: I am grateful for your vigilance, minister. I had failed to notice that the member was repeating a previous matter.

Aileen Campbell: That is fine.

The Convener: On this item, to be clear, the motion that the minister has just moved relates to approval of the draft Carers (Scotland) Act 2016 (Adult Carers and Young Carers: Identification of Outcomes and Needs for Support) Regulations 2018.

Motion agreed to,

That the Health and Sport Committee recommends that the Carers (Scotland) Act 2016 (Adult Carers and Young Carers: Identification of Outcomes and Needs for Support) Regulations 2018 [draft] be approved.

The Convener: We now turn to the negative instruments. The minister made comment on them but, as they are negative instruments, I simply need to seek the committee's approval. There has been no motion to annul any of the instruments and, in the case of four of the five instruments, there has been no comment from the Delegated Powers and Law Reform Committee, the exception being SSI 2018/33, as I mentioned in my final question to the minister—and you have heard the minister's response to the comments made on that.

I invite any comments from committee members. As there are no further comments, do we therefore agree that the committee should make no recommendations on any of the instruments?

Members *indicated agreement.*

The Convener: That concludes the agenda item. I thank the minister and her officials for their attendance.

We now move into private session—we have two brief items to discuss.

12:46

Meeting continued in private until 13:00.

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