OFFICIAL REPORT
AITHISG OIFIGEIL

Health and Sport Committee

Tuesday 21 January 2020

Session 5

The Scottish Parliament
Pàrlamaid na h-Alba

Tuesday 21 January 2020

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HEALTH AND SPORT COMMITTEE
1st Meeting 2020, Session 5

CONVENER

*Lewis Macdonald (North East Scotland) (Lab)

DEPUTY CONVENER

*Emma Harper (South Scotland) (SNP)

COMMITTEE MEMBERS

*George Adam (Paisley) (SNP)
*Miles Briggs (Lothian) (Con)
*Alex Cole-Hamilton (Edinburgh Western) (LD)
*David Stewart (Highlands and Islands) (Lab)
*David Torrance (Kirkcaldy) (SNP)
*Sandra White (Glasgow Kelvin) (SNP)
*Brian Whittle (South Scotland) (Con)

*attended

THE FOLLOWING ALSO PARTICIPATED:

Matt Barclay (Community Pharmacy Scotland)
Alison Culpan (Association of the British Pharmaceutical Industry)
Dr Alan MacDonald (Scottish Medicines Consortium)
Lindsay McClure (NHS National Services Scotland)
Jonathan Mogford (Medicines and Healthcare products Regulatory Agency)
Dr Brian Montgomery
Rose Marie Parr (Scottish Government)
Martin Sawer (Healthcare Distribution Association)
Warwick Smith (British Generic Manufacturers Association)
Elizabeth Woodeson (UK Government)

CLERK TO THE COMMITTEE

David Cullum

LOCATION

The James Clerk Maxwell Room (CR4)

Scottish Parliament

Health and Sport Committee

Tuesday 21 January 2020

[The Convener opened the meeting at 09:33]

Medicines (Supply and Demand)

The Convener (Lewis Macdonald): Good morning and welcome to the first meeting of the Health and Sport Committee in 2020. I take this opportunity to wish everyone a happy new year.

I ask everyone in the room please to ensure that their phones are switched off or to silent. It is acceptable to use mobile devices for social media purposes, but please do not take photographs or record proceedings.

Agenda item 1 is the committee's inquiry into medicines supply and demand. This is the first formal evidence-taking session of the inquiry, and we will hear from three panels this morning.

I welcome our first panel: Rose Marie Parr is the chief pharmaceutical officer in the Scottish Government; Elizabeth Woodeson is director of medicines and pharmacy in the United Kingdom Government Department of Health and Social Care; and Jonathan Mogford is director of policy at the Medicines and Healthcare products Regulatory Agency. Our first panel will help us to consider governmental perspectives on medicines supply and demand.

Our focus at this stage is on supply, purchasing, procurement and access to drugs. I will put a general question to all our witnesses. In view of the rate of growth in medicines expenditure, do you think that the price regulation schemes that are in place are serving the national health service well?

Elizabeth Woodeson (UK Government): You mentioned the rate of growth; it is interesting that the most recent figures show a flatlining—and even a slight reduction—in medicines spend. However, you are right about medicines spend having grown, historically, and sometimes having done so at a faster rate than that of the NHS budget.

As a result, we have the voluntary scheme that we have negotiated with industry. I think that it was in 1957 that we had the first pharmaceutical price regulation scheme, as it was known. The most recent version of the scheme came into effect a year ago and is known as the voluntary pricing and access scheme.

The VPAS scheme caps the rate of growth in spend on branded medicines at 2 per cent. Spend above that is reimbursed; payments are made by industry to the Department of Health and Social Care in England—and in Scotland, through the arrangements that we have to repay the devolved Administrations.

To come back to your question, we believe that VPAS is an effective mechanism for capping the rate of growth in branded medicine spend, which is, by far, the bulk of expenditure on medicines. We are grateful to industry for the way in which it works with us on the operation of the scheme. Certainly, ministers in England feel that the scheme is a success.

Rose Marie Parr (Scottish Government): I welcome the Health and Sport Committee's inquiry into medicines. It is good to have a conversation about supply and demand.

My Department of Health and Social Care colleague has talked about how we source medicines. Let me set that in context. Medicines are the most commonly used healthcare intervention and have been subject to scrutiny for a number of years, particularly since the thalidomide disaster in the 1960s.

We will hear about legislation and regulation, but we can think about the course of a medicine's progress, from research and development, innovation and the development of the active ingredient to regulation and licensing. We have the health technology assessment, through the Scottish Medicines Consortium and the National Institute for Health and Care Excellence, across the UK. There is also medicines governance across the health boards, with formularies, and there is individual prescribing guidance. That takes us to the patient and how they use the medicine for health gain.

Medicines have been well scrutinised and our systems in relation to cost and clinical effectiveness serve us well, but medicines cannot be seen in isolation from the pathway of care. We should consider not just their use but the health gain that is derived from them. Some of the conversations are about not just access to medicines but the outcomes of their use. I will be happy to expand on that later.

Jonathan Mogford (Medicines and Healthcare products Regulatory Agency): It might be helpful to explain that the key responsibilities of the MHRA, which is the regulator for the whole of the United Kingdom, relate to the safety, quality and efficacy of pharmaceuticals and devices that are used throughout the United Kingdom.

We work in close partnership with the Department of Health and Social Care—

particularly Liz Woodeson and her team—and NICE, which is the English body that is particularly set up to look at the cost effectiveness of products. It is a triangular partnership, if you like, in the context of the pricing discussion; we do not have a direct locus in any pricing discussion. There are close links between all three of us, although we have distinct and separate responsibilities.

Alex Cole-Hamilton (Edinburgh Western) (LD): Good morning. We have heard that the new price regulation scheme for branded drugs contains a commitment that pharmaceutical companies should offer the same price that exists for a drug in one UK country to all the other UK countries. However, Cancer Research UK says that it has heard anecdotally that there are discrepancies between the UK countries in prices for new medicines. Can you comment on that?

Elizabeth Woodeson: That is certainly the intention of the scheme. It is clearly laid out that there should be transparency of pricing in the different countries in the UK. Of course, that does not necessarily mean that each country is required to agree the same price. Pricing deals can cover not just the price, but other aspects as well. There can be different approaches such as outcome-based payment schemes—all sorts of different deals are available. Scotland or another country may choose to do a different pricing deal on an individual product, and that is allowed within the scheme.

Alex Cole-Hamilton: Has the new agreement had a demonstrable impact in reducing the discrepancies between the UK nations, notwithstanding the point, which I accept, that countries may choose to do things differently?

Elizabeth Woodeson: I really do not know. We do not track deals that are done in the other countries, so I could not tell you that.

Rose Marie Parr: It is early days for the scheme. We are working with our partners and the industry to get that transparency, and we have certainly had conversations on the subject with our colleagues in the Department of Health and Social Care and the other devolved Administrations. We are having those positive conversations and we are on the road to having a similar framework with similar pricing outcomes.

The Convener: Will you say a little more about how the pricing mechanisms are negotiated? For instance, we have heard that some of the money ultimately comes back to the devolved Administrations, but how does that work? How is it negotiated and how does it operate?

Rose Marie Parr: That is really important for Scotland. As you know, the licensing and pricing of medicines are reserved to the UK. The MHRA looks at the primary regulation for safe products as they come on to the market, and at pharmacovigilance afterwards. To me, there is something there about how we also use our levers within Scotland. We continue to have the policy of putting the money that is given back from the industry under what was the PPRS and is now the VPAS directly into the new medicines fund. That has been a really positive policy for Scotland. People can see the increase in medicines and the increase in medicines use, but they can also see that rebate being used transparently for the new medicines fund. Boards have gained over the past five years and they are due to gain up to £90 million or so in the current year. The rebate and how we use it is a very important aspect.

Brian Whittle (South Scotland) (Con): Good morning. Some of the written submissions call for a different approach to pricing that would give rewards for the most effective medicines and incentivise the pharmaceutical industry to develop better medicines. Do you agree that we should move towards value-based pricing?

Rose Marie Parr: That is an important question. I will start with an overview. We have a lot of scrutiny of access to medicines and to new medicines, whether that involves people purchasing their own medicines from a community pharmacy or people getting a prescription from their healthcare professional. Access is important. People are also living longer, which is a good thing. However, we also need to turn the narrative to outcomes—the health gain that we get from medicines and how we will utilise it.

09:45

As members probably know, we have a lot of good data on prescribing in primary care. We can quite easily track the amount of drugs that are prescribed and who they are prescribed to on an individual patient basis. However, we do not have as good ways of tracking data in hospital and secondary care. We need to get prescribing decisions that are based on good data and good evidence and, in the longer term, we also need to think about outcomes or health gain in relation to those medicines.

Steps have been made towards that, but your question is important. In essence, we need to turn that narrative toward looking at health gain. The ability to prescribe in an evidence-based way is important for prescribers and for industry, so we can avoid waste and unnecessary prescribing and, most importantly, so that patients can get the best gain and reduced harm from their medicines.

The Convener: Do other witnesses want to add anything on that point?

Elizabeth Woodeson: It is important to remember the role of NICE in England and the

SMC in Scotland. They consider the value of medicines in the sense that, when they make their assessments, they look not just at the price but at the evidence of the benefit that a medicine delivers. When they approve a medicine, they look at cost effectiveness, which is about not just its price but its effectiveness. Value is taken into account in that sense, because the NICE assessment is a key factor in whether a medicine is available, and the pricing deals that are done take into account the NICE assessment of cost effectiveness.

Brian Whittle: I will pick up on a small point that Rose Marie Parr made about data collection in secondary care, after she said that we have good data from primary care. For good data collection in secondary care, a recording mechanism or platform would be required. Is one available, or does one need to be developed to enable that to happen?

Rose Marie Parr: We are at the start of that journey. A number of boards across Scotland have a hospital electronic prescribing and medicines administration—HEPMA—system, so they can electronically collect data on what is prescribed and some aspects of where it is used. As the patient is in front of them, they can also see whether a medicine works.

As part of our strategy for achieving excellence, we have a policy of moving HEPMA forward across the whole of Scotland. A number of boards, including the larger boards such as NHS Lothian and NHS Greater Glasgow and Clyde, are looking at implementing it.

We are getting to a better stage in relation to the collection of data in secondary care. That is really important, because we have information on aspects of how we dispense and purchase, but we definitely need data on how we can prescribe better. That is particularly so because some of the new medicines that will become more important will be personalised, such as gene therapies that are designed to treat people individually.

You will hear people talk about real-world data, and that is also important. You will see that some of our clinical trials are used in relation to our health care technology assessment. SMC and NICE look at early evidence on a population level to determine clinical effectiveness and cost effectiveness. However, some of the patients who take a medicine in, for example, NHS Greater Glasgow and Clyde, have co-morbidities. They might be very different from the clinical trial population, so real-world data on efficacy can be very different from clinical trial data.

The trajectory now is to try to get more of that real-world data. HEPMA will help to do that in secondary care, but we need to look at outcomes from medicines across the piece. There is a glimmer of hope in that, in the past number of years, the Government has sponsored a programme that looks at how drugs are used by the real-world population and what the outcomes are in that population. The cancer medicines outcome programme, which has been going for a number of years, has shown that drug effectiveness can be very different for people with multiple morbidities. We need to capture some of that and make it available around Scotland, so that we look at not just access but how medicines work for different population levels.

George Adam (Paisley) (SNP): I want to ask about value or outcomes-based pricing. If we go down that route, how will we manage the expectations of people who are living with long-term conditions? I will give you an example. My wife Stacey has multiple sclerosis, and every time that there is a story in the newspaper about a new wonder drug for MS, my mother-in-law gives us the newspaper cutting, which goes on the fridge.

That happens in the lives of lots of people. They hear companies saying that new drugs will do X, Y and Z. How can we manage expectations as we go down the route of outcomes-based pricing and ensure that the public appreciate and understand it? After all, drugs often do not make the big difference that people think that they will.

Rose Marie Parr: I agree with that. There are issues with how people across society look at medicines. For a number of years, our chief medical officer in Scotland has had a realistic medicines strategy, which includes lots about how we medicalise many things across society. Obviously, medicines are part of that. Perhaps it is how people value medicines that is important. We know that the old saying “A pill for every ill” is not correct. However, we want to encourage innovation with regard to long-term conditions and other conditions for which there is a direct need for medicines. MS is obviously one of those.

It is about trying to educate and inform patients about the value of medicines and when they do and do not work. That starts us on a journey. It is also about patients looking at self-care, which is a really important part of healthcare and health gain. Our 1,257 community pharmacies in Scotland are able to give advice on self-care. That might be about over-the-counter medicines or referral, or it might be health advice. Self-care is important.

Prescribing has to be effective and efficient, but we need to look at what the efficacy is. The SMC will do that for us at the population level and, at the individual level, prescribers and prescriber guidance will be guided by that.

Bits of the jigsaw are missing. Patients are actively looking for new medicines, and we need

better systems for medication review. Medication review is important and is needed so that people are not just started on a medicine and not looked at again. They might be harmed by their medicine and receive no benefit, so we need better medication review systems, as well as the capacity to review. In "Achieving excellence in pharmaceutical care: a strategy for Scotland", we say that community pharmacists could potentially look at long-term conditions and medication review for people in society who are worried or perhaps need a review of their medicines.

There is growth in the number of pharmacists and technicians in general practitioners' practices, and we need to look at systems of prescribing and at systems of deprescribing—that is equally important. That review is important, too.

We can educate people to not think that a prescription is the first thing. We have to look at not just self-care but aspects of talking therapies and social prescribing. That involves a mindset change for patients and the public, and a discussion about that needs to happen.

From what we have seen with antibiotic prescribing, there is a glimmer of hope that we can change patients' expectations. There is now a difficulty with antibiotic resistance and, in the five years from 2013, antibiotic prescribing was reduced by 8 per cent. Patients do not go to GPs expecting a prescription now, especially for viral illnesses. How can we utilise tactics to reduce expectations for prescriptions and perhaps reduce hope about outcomes?

Jonathan Mogford: We very much endorse the points that other members of the panel have made, particularly about the licensing process being part of the important interaction with companies that ensures that the claims that are made for products are backed by clear scientific evidence. As the safety, quality and efficacy regulator, we are very conscious of the importance of joined-up systems and the links with healthcare systems and organisations that are responsible for the cost effectiveness of products, and ensuring that patients and clinicians fully understand the nature of the products that are being used, because, ultimately, one of the key points of interaction is between the patient and the clinician.

Emma Harper (South Scotland) (SNP): I want to pick up on what Rose Marie Parr said about HEPMA. When I worked in a recovery room in NHS Dumfries and Galloway, HEPMA was starting to be rolled out, so I have experience of it. Where are we with the roll-out of HEPMA across Scotland? How are we able to better use data, particularly in relation to prescribing and secondary care?

Rose Marie Parr: Those are good questions. NHS Dumfries and Galloway and some of the smaller boards have fully implemented HEPMA, and NHS Ayrshire and Arran has used it in some of its hospitals for a long time, so we have the experience to allow us to roll it out a bit quicker. If I was being critical of HEPMA, I would say that its roll-out has not happened fast enough. However, in the past few months—certainly in the past year or so—we have had much more pace and traction.

NHS Lothian has produced its final business case, and NHS Greater Glasgow and Clyde is quite close to doing that, too. It is really important to get the big health boards to utilise HEPMA. The north of Scotland takes a regional approach to HEPMA, and work on it will be done in quite a mannered way. I hope that the funding that has been given will mean that the roll-out can be done more quickly than has been the case in the past few years.

Once we have electronic prescribing, we will be in a much better position to get better data and outcomes. However, when we get to HEPMA stage 1, we will not have the complete answer. We will then need to look at a platform for how we utilise the data on a once-for-Scotland basis. Scotland is not that big a country. It has a population of 5 million or so, which is a good size to be able to look at outcomes, data and what might happen with some of our drugs in action.

The next stage will also include creating a national digital platform, and there are plans for that in our digital strategy. That will allow us to look at what happens in relation to not only prescribing but outcomes and data. Other countries across the world are able to look at their population and at the health gains from medicines and other healthcare interventions. I think that there will be quite a positive story in relation to HEPMA in the next few years.

Brian Whittle: You talked about being able to register data in relation to drug prescription in secondary care. In order to have an outcomes focus, a lot of prescription in a secondary care environment is taken outside secondary care into primary care. If we are to measure outcomes, there must be a link between secondary care and primary care, and I do not think that such a link exists at the moment. Is that the direction of travel that we are thinking of going in?

Rose Marie Parr: Yes. That is the direction of travel that we are going in, which is required. You make a good point about how we link up primary, secondary and social care, because that link is not there at present. How do we get electronic single patient records that are data driven? Our ambition is to get such records. We have really good connections with community pharmacy and general practice, and there has been the

electronic transfer of prescribing data for some time, but how do we make that seamless? That would bring an end to some of the issues relating to the fall-down in care between different areas of care. When people are discharged from hospital and go back into their community, some of the boundaries are not as seamless as they should be.

It is quite difficult to do medicines reconciliation when we are working on a paper system. How would we be able to reconcile medicines between primary and secondary care? If we had electronic data transfer, it would be much easier to do that. We want to look at new technologies that will allow us to do that.

As you know, we have to put energy behind the work. The number of people whom we treat in secondary care is increasing. We want to allow people in secondary care who are able to be stabilised on their medicines to come into primary care and to live more at home or in a homely setting, but we need the systems to be able to do that. We need the transfer of prescriptions to be safe and effective, and we need community pharmacies to allow us to get secondary care prescriptions that might be more complex than they have been used to and to use those medicines for long-term conditions that have adverse effects.

For me, the answer is the transfer of data that we understand and can have confidence in, medication review, and medication reconciliation across the piece.

10:00

David Torrance (Kirkcaldy) (SNP): Some of the biggest increases in prices in recent years have reportedly been in generic medicines. The Health Service Medical Supplies (Costs) Act 2017 gave ministers the power to intervene to control the price of generics when there is insufficient competition. Have those powers been used yet? If not, why not?

Elizabeth Woodeson: You are right that we have seen increases in the prices of some generic medicines, but there has been a relatively small number of what look like extremely steep and potentially unjustifiable increases. However, it is important to put that in context. Overall, the prices of generics in the UK compare very favourably with those in other countries, and we know from research and reports that we have pretty much the lowest prices among comparable Organisation for Economic Co-operation and Development countries. That has been confirmed by independent reports. Our system of competition in the generics market is broadly effective, and we get a good deal.

I wanted to set that general context, but you are right that we have been concerned about a handful of products that seem to fall outside the pattern. That usually happens when there is no effective competition—when the medicines are from a single supplier, and there are no other suppliers in the market. We looked at what we could do about that, and we took those price-setting powers.

Alongside those powers, we took the power to get information from the companies to explain the rationale behind the price increases. Of course, we hope that, through starting by requiring the information and having a dialogue with the company, it will not ultimately be necessary to use the price-setting power, because we would be able to come to an agreement with the company before reaching that point.

Obviously, price setting, or dictating the selling price of a product, would be a significant intervention in a marketplace. It is therefore very important that we consider carefully how to do that to ensure that we get it right and that we can win any challenge that a company might bring. We have been putting a lot of work into that and we have worked with our commercial directorate to check out whether we could use other approaches that would be equally effective and perhaps less interventionist and draconian. I assure the committee that a lot of active consideration is being done, and we expect to consult on the processes this year.

The Convener: Are those powers UK Government powers? There are no Scottish counterparts, so it would be for the Department of Health and Social Care ministers to make such orders across the UK. Is that correct?

Elizabeth Woodeson: To be honest, I am not 100 per cent sure, and I would rather not mislead the committee. Would you mind if let you know afterwards?

The Convener: Not at all.

Elizabeth Woodeson: Perhaps one of my colleagues remembers.

Rose Marie Parr: It is UK legislation. We have been involved in the discussions since the Health Service Medical Supplies (Costs) Act 2017 came in. It is important that we are joined up in that way.

If we think about that question from a Scottish perspective, the issues are around the Scottish drug tariff and how the Government and ministers determine the reimbursement to NHS contractors, and the Scottish drug tariff arrangements, which include generic and branded drugs. I agree that they are generally competitive across the UK.

Currently, 84 per cent of our prescribing is for generic drugs. That has been cost effective for the

NHS across the piece. The other way around cost effectiveness is to look at aspects of prescribing guidance. Across Scotland, millions of pounds have been saved by changing people not just to generics but to biosimilars, which are similar to the active ingredients that the patients used previously. There are areas in Scotland in which we can be nimble about getting the best price for the NHS.

Miles Briggs (Lothian) (Con): Good morning. I have a follow-up question on generics and competition.

Does the MHRA have any opportunity to encourage manufacturers to submit an application for a licence?

Jonathan Mogford: We do not. We operate in response to applications from companies for licences for generic and all other pharmaceuticals. We look to ensure that the processes that we run and the openness of the way in which the organisation operates are as appropriately supportive as they can be of companies that want to bring generic and all other pharmaceuticals to the UK market.

Miles Briggs: Is there anything that the MHRA could do to encourage greater competition and more companies to enter the UK market?

Jonathan Mogford: The fundamental point about licensing is that it has to be a response to an application from a company, organisation or body to put a product on the market. In the generic sector, that does not have to be a company in the traditional sense. The licensing process involves an agreement with the person, or entity, who is taking responsibility for a product and its use in the market. The nature of the interaction has to be that we respond to companies and organisations that wish to bring products to the market and which take responsibility for those products in the UK market.

Miles Briggs: Thank you.

The Convener: If the MHRA does not have the capacity or remit to encourage competition, is that done elsewhere in Government? If I understand you rightly, your role is to respond to applications, rather than to encourage applications.

Jonathan Mogford: Yes—it is that, and to ensure that the application process and the process of issuing licences for the UK run as smoothly and quickly as they can.

The Convener: I come back to Elizabeth Woodeson's points about considering other options apart from price intervention. If, as a primary choice, you seek not to intervene, can other levers enable competition to be stimulated in dealing with excessive price?

Elizabeth Woodeson: That is the question that we are considering and it is why we have not rushed to use the price-setting powers. We need to think about whether there are other ways of generating competition and encouraging new entrants to the market. We can all imagine what those ways might be. One might offer a higher price for new entrants to come in, fixed contracts or direct procurement or purchasing.

We are looking at all those different options to inform our consultation, and we are looking at them in the round, rather than simply asking whether we should impose a price. The risk of just imposing a price is that, if we get it wrong, there is a possibility that the company could choose to withdraw from the market altogether, which could be a disaster for patients who are dependent on that medicine. We feel that we need to tread very carefully—it is a balance. That is why it is taking a little time to develop the consultation. However, as I said, we have plans to get the consultation out this year.

The Convener: Thank you. You offered to get back to us on the working of the 2017 act in relation to the devolved Administrations. It would be helpful if you were to give us an update on the consultation at the same time.

Elizabeth Woodeson: Of course.

Emma Harper: I want to pick up on issues around the Scottish drugs tariff. The NHS pays community pharmacists, as subcontractors, for the cost of a medicine as set out in the Scottish drugs tariff. That is negotiated between the Scottish Government and Community Pharmacy Scotland. Some issues have been raised around commonly used drugs, such as paracetamol. There have been stories in the media about the prescribing of paracetamol. I know that people can buy paracetamol for 20p in high street shops and supermarkets, but the NHS will pay community pharmacists substantially more—we are looking at £4.05 or £1.81 for 100 paracetamol, depending on whether they are capsules or tablets. Why is there such a difference in pricing and why does the NHS pay so much more for drugs such as paracetamol?

Rose Marie Parr: That is a good point. It is about how we utilise and reimburse pharmacists across the piece, and the Scottish drug tariff is part and parcel of that. It is down to part 7, which deals with generic medicines. You raise the point about generic medicines that can also be bought over the counter, for want of a better phrase. To go back to the issue of self-care, pharmacists would always want to talk about self-care in the first instance, whether in relation to analgesics or anything else.

We should also be mindful of the fact that a prescriber will issue a prescription for a long-term condition because it is needed, and there may be many people who need drugs such as ibuprofen or paracetamol for long-term pain control. Going to a community pharmacist or another outlet to buy a small amount of paracetamol would probably not be cost effective for them. When analgesics are used for long-term conditions, it is relatively cost effective.

We have to think about what the Scottish drug tariff is there for. It reimburses our community pharmacists for the drugs that they have already bought—they have taken the risk of buying them—but it also pays for aspects of the community pharmacy service. We have a contract agreement with Scottish pharmacy contractors around acute prescribing—everyone will see that when they take a prescription to a pharmacist—and around the pharmacy first service, which will be rolled out in April 2020. Pharmacists will be able not just to focus on self-care, but to look at pharmacy first treatment, which will include antibiotics for urinary tract infections and some skin problems. The point is to avoid having to go to a prescriber—a GP or someone in accident and emergency—and to allow community pharmacy to take on some of that burden. The issue for me is less about what drugs are within the tariff and more about how they are used and reviewed.

In the longer term, we want to consider how pharmacists in primary care or in community pharmacy can help to reduce polypharmacy and help people with long-term conditions who are taking way too many medicines that have not been reviewed over an appropriate timescale. If generic medicines are being prescribed, it is generally because people require them for a long-term condition. Those prescriptions should be reviewed. Buying over the counter is appropriate when someone needs small amounts of drugs or medicines, but it could cause difficulties for a patient with a long-term condition.

10:15

Emma Harper: It is important to highlight that people who have a long-term condition are often on paracetamol so that they can reduce their use of morphine-based and opiate-based medications, which are more expensive than paracetamol. There is a difference between the short-term use of paracetamol for a cold or the flu and its long-term use for pain management.

Rose Marie Parr: That is a good point. We have tested what would happen if paracetamol was not prescribed but was just made available to patients elsewhere, and we think that that would result in the increased prescribing of opiate-based analgesics, which might cause more harm.

Miles Briggs: One of the solutions to the issues that we are discussing concerns information technology systems and access to patient data. I co-chair the cross-party group on cancer, and a lot of our discussions hark back to what was being suggested 15 years ago. Why are our current IT systems so far behind what we see in other European countries?

Rose Marie Parr: In essence, the HEPMA framework seems easy to implement, but it is really difficult to roll out. Electronic prescribing is different from what goes on otherwise. In secondary care, we have had a paper-based Kardex system for more than 50 years. Our practitioners are used to it, but it is not fit for purpose for the future. You are right to say that there is a bit of impatience about why we are not yet where we need to be.

In relation to cancer, we can point to some good examples around ChemoCare, which has good data around prescribing and patients. Because we had that data, or intelligence, we decided to try to use it around our cancer medicines outcome programme. If we had such data for all other medicines, we would have huge amount of evidence to use with regard to how we prescribe in the future.

There is frustration, but we know that we can do what is required—ChemoCare is an example of that. HEPMA and the systems that come through our national digital platform will revolutionise what we do. Although we are focused on our medicines, our tariff and what we have just now, it is important that we go in that direction.

The SMC, which is world beating, is looking at health in terms of population, cost and clinical effectiveness. The times are changing for medicines. Some of our cancer therapies look not to some of the cytotoxics—the quite toxic drugs that we had previously—but to immunotherapy. We are looking forward to using some of the advanced therapeutic medicinal therapies, which sometimes do not look like medicines at all. We need to think about how our health service and our data systems will cope with all of that. For a small number of patients, it might be easy. However, on a population basis, that will present a challenge for the future.

We need to think about how our system deals with stratified medicine and personalised medicine. In that regard, we will not be looking at waste; instead, we will be looking at individual prescriptions for individuals. We absolutely need the appropriate IT and data if we are to cope with that.

Sandra White (Glasgow Kelvin) (SNP): Good morning. I thank the witnesses for their evidence so far, which has been interesting.

On the issue of Home Office licences for controlled drugs, the submission that we received from the University of Edinburgh said that care homes are not permitted to hold a licence to keep controlled drugs in stock but that hospices outwith the NHS are given such licences. The submission claimed that that has led to care homes increasingly using just-in-time boxes to get around the need for a licence. However, that, in turn, leads to many medicines being returned to pharmacies unused.

Perhaps Elizabeth Woodeson, as the UK representative—or anyone else—could explain why the law does not require a hospice to have a Home Office licence to hold those drugs but requires a care home to have one? Is there any movement towards changing the situation?

Rose Marie Parr: You raise a good point. People who go into care homes might be there for 15 or 18 months, so, in many cases, we are talking about palliative care. There is therefore an issue, which I think that we get round just now.

As part of our achieving excellence strategy, we are looking at how medication is used in care homes. A clinical fellow, who is an expert in palliative care, is considering how we can improve not just access to medication but the use of medication in care homes and thinking about how we can move forward on the issue, which is not necessarily to do with the legislation.

We have a network of community pharmacists who are experts in palliative care and hold medication for the purpose of adult palliative care, but we need to make inroads into paediatric palliative care. Children's Hospices Across Scotland, which, as members will know, is the association that runs children's hospices, has a pilot programme in NHS Forth Valley to do with pharmacists and the special, complex needs that children in palliative care have.

There are workarounds just now, which help, but in the longer term it will be important to change our approach in care homes.

Sandra White: The point that I was trying to get across is that the Home Office licenses controlled drugs. People in care homes can be there for longer than 18 months, but care homes are not licensed in the same way as hospices are licensed. You mentioned the trial that is happening just now. Is there any reason why care homes are not licensed? Are the people who run them not professional enough to administer controlled drugs? Is there movement on that? You mentioned community pharmacists, who can go in and do certain things, but why are care homes not licensed?

Rose Marie Parr: I think that it is a legal issue and that legislation would have to be changed to allow care homes to prescribe controlled drugs. I also think that there is enough expertise out there among professionals in care homes to allow them to do that; potentially, the issue is capacity, not competence, so we need to consider how such prescribing can be done safely and in a way that is based on guidelines and evidence. Some of the work that is going on in care homes will be quite helpful in that regard and we look forward to receiving the results, when we will be happy to give you more information.

Sandra White: Thank you for that clarification. If we want care homes to be licensed, do we need to approach the UK Government? It is the UK Government that issues the licences, not the Scottish Government.

The Convener: For clarification, I think that Sandra White is asking whether the legislation that governs the issue is UK legislation and therefore it is for the UK Parliament, not the Scottish Parliament, to address it.

Rose Marie Parr: That is absolutely correct. Controlled drugs are a matter for UK legislation.

Sandra White: That was the point that I was making. Maybe I did not explain it right when I mentioned Home Office licences. I do not know whether Elizabeth Woodeson wants to say anything about the issue.

Elizabeth Woodeson: It is indeed a matter for the Home Office. The lawful possession, supply, production, manufacture or cultivation of controlled drugs requires a licence from the Home Office.

I am not aware that there is a blanket restriction on care homes' ability to have such a licence. It would be interesting to explore the matter further. Clearly, it would depend on the staff; if a care home had a registered professional or doctor on site, I would have thought that that person could have a licence. I somehow doubt that there is a blanket restriction that says that no care home can ever have a licence to hold controlled drugs, but that is something that would need to be explored with the Home Office.

Sandra White: We can pick that up.

The Convener: It would be helpful to have clarity on that.

David Stewart (Highlands and Islands) (Lab): I am interested in what the panel has to say about the post-Brexit strategy. Let me start with Jonathan Mogford, because I am particularly interested in the approval of new drugs. As I understand it—and in simplistic terms—there are two main routes to approval: one is through the European Medicines Agency; the other is through the MHRA.

Obviously, we are reaching the point at which Brexit will happen. I think that you have just evicted the EMA, which is going to Amsterdam. What relationship will you have with it? Again, in simplistic terms, two agencies have been approving new drugs and that will go down to one. From an outside perspective, I would have thought that that will put a lot of strain on your organisation in relation to approval. Clearly, there will still be a relationship with the EMA. Will you describe what will happen? Is there the prospect of delay? Frankly, are you looking for new funds to expand your organisation, because that will be needed from the start of next month?

Jonathan Mogford: You are right—this is a big, complex area that is still evolving as the positions for the next round of the European negotiations are clarified. The situation is broadly as you have outlined. Pretty much all medicines regulation and, indeed, devices regulation is done in Europe-based networks at the moment. For pharmaceuticals, there are two broad types of market entry regulation. The European Medicines Agency co-ordinates the process for a relatively small number of the most innovative products. The main route for most of the rest of the products is a bundled set of national licences that operate under a decentralised process. That, too, is one in which the member states essentially work together, to arrive at a common licence for the whole of the European Union, including the UK. There are also significant links on pharmacovigilance, inspection and the like, in relation to which we all work together.

The European Medicines Agency has moved to Amsterdam already. We did not evict the agency; it moved. That has been part of a bigger process that has been going on over the past two and a half years since the referendum, in which, particularly on the pharmaceutical side, the EU27 countries have increasingly been preparing themselves to operate as a group of 27. Clearly, that brings with it the whole question of what the UK's relationship with Europe and, indeed, the rest of the world, will be after Brexit. It is important to bear in mind that, although we have spent a lot of time in the past few years focusing on the really important aspect of linkages across Europe, product development, particularly in pharmaceuticals but also in medical devices, is global, which means that a lot of the standards are global and there is close working across the regulators globally.

David Stewart: I am sorry to rush you, but I am conscious that I am asking complicated questions with only a few minutes left. Will you clarify a matter for us? Obviously, there is still a lot of discussion to be had between the UK Government and the European Union about the details of the transition period. What is your understanding of the EMA's role from 1 February? Has that been clarified by the discussions between the UK Government and the EU27? Will its current role continue? Will it completely stop? Will there be a halfway-house arrangement, which is the case with most things?

Jonathan Mogford: From 1 February, the systems will essentially remain operating at an EU27-plus-the-UK level. The big difference is that the UK, during the implementation period, will not be leading scientific assessment and scientific work in the system. However, the centrally authorised products will continue to be licensed for the EU27 plus the UK, and the decentralised products—the generic products—will similarly be licensed and valid for the UK.

In practical terms, there is absolutely no regulatory cliff edge at the end of January, and those systems will continue to operate. Work that is still going on in relation to the negotiations for the longer term and what will happen on that in the political declaration. Both sides undertook to explore possibilities for co-operation, which could take on a whole range of different meanings including mutual recognition agreements or exchanges of information and the like. There is still work being done on that.

10:30

David Stewart: In a nutshell—I am sorry to pressure you on time—is there any prospect of delay in the approval of new drugs, and will there be greater strain on your organisation because of the changes?

Jonathan Mogford: The systems will continue to operate as they are currently do after the end of this month, so there is no reason for delay in the regulation of new products. We are considering, and will need to further consider in the light of what is decided for the longer term, what that will mean for the agency's work.

David Stewart: My final question to the panel—more of a statement than a question, really—is on US-UK trade negotiations, which is quite a complex area. You will know from general commentaries that the US sees itself as subsidising the cost of medicines across the world. You might or might not have a particular view on that, but we had a quick look at the price of the top 20 drugs in the US compared to their price in the UK and found that—as you will know—they are roughly five times more expensive in the US than they are here. The argument that, if it waddles and it quacks, it is a duck is probably a relevant point there. Could our trade negotiations with the US impact on drug prices in the UK?

Elizabeth Woodeson: We are well aware that prices are typically higher in the United States.

There is clearly a risk of what you suggest, and we have been aware of it for a long time. We were pleased to hear strong statements from our Government on that, and the Conservative Party manifesto was clear on that point. It said:

"When we are negotiating trade deals, the NHS will not be on the table. The price the NHS pays for drugs will not be on the table. The services the NHS provides will not be on the table."

Our ministers are well aware of the risk you describe, and both the Secretary of State for Health and Social Care, Matt Hancock, and the Prime Minister have made strong statements on the pricing of medicines not being any part of those trade negotiations with the United States.

David Stewart: The convener will not allow me to make any political points, but I merely make the point that trade with the US is obviously vital, particularly now that we are leaving the European Union. There are obviously concerns about what it said at the macro level and what happens in reality—any trade deal involves negotiation on both sides and something has to give. For example, you will know that Scotch whisky now has a tariff of 25 per cent, which it did not have just a few weeks ago.

I hope that the situation that Elizabeth Woodeson reassures us will happen proves to be the case. If it does not, perhaps we can have UK ministers back here in a year or two. I should probably leave it at that before I get into trouble.

The Convener: Thank you. Raising political issues is one thing; raising Scotch whisky in a discussion on medicines is another altogether.

I come back to some of the issues around the MRHA. The Royal College of General Practitioners was critical of licence approvals from the EMA in relation to certain cancer drugs. It said that some of those approvals are not based on any evidence of benefit in terms of survival or quality of life.

I understand that safety and efficacy is your focus rather than value, but I would be interested in what the standard of evidence is in the licensing process—whether there is a requirement for peer review of claims that are made for particular drugs and whether you are satisfied with the quality of research that goes on behind drug licence applications.

Jonathan Mogford: The processes are peer reviewed and most cancer products certainly fall into the category of centrally authorised products in Europe, so they are overseen by the EMA. That brings together regulators from across the EU27 in peer-reviewed processes for the assessment and peer review of clinical trial evidence, and that forms the fundamental basis of the decisions.

The MHRA's focus on safety, quality and efficacy in its decision on whether a product is suitable to get on to the market and meets the claims that are made for it is one part of that more complex and bigger set of questions, which involves work that colleagues in NICE do on the cost effectiveness of the product. The MHRA has confidence in the rigor of the scientific understanding that sits behind those judgments, but it is the case that different products have different levels of benefits.

The Convener: Would you as a regulator welcome real-world data as a means of checking and affirming those conclusions?

Jonathan Mogford: That is an increasing and interesting debate that we are very enthusiastic about. We are conscious of the fact that, as entirely legitimate and understandable pressure to agree early use of products increases, products will be used at stages at which evidence of the effectiveness might usefully be supplemented with further real-world evidence. We are particularly interested in what could be done with greater use of real-world evidence in market-entry decisions.

Those are very active discussions and, as IT and data systems improve in health systems, we clearly expect that that will be an area of great development over the coming years.

Rose Marie Parr: I agree with that. As we give more flexibility to SMC, which makes assessments of health technology for clinical and cost effectiveness, we see medicines coming forward with less of an evidence base and we see earlier access to some medicines. We have that flexibility to look at what an in-term acceptance might be. I know that you will talk to SMC colleagues later. There is an issue around changes in the maturity of evidence. We are seeing medicines at an earlier stage of their development, so it is even more important that we have checks and balances around harm and benefit as we use them.

The Convener: I thank all our witnesses. Your evidence is much appreciated, and I know that there are a number of items on which you intend to come back to us.

Rose Marie Parr: I can give you the achieving excellence strategy document, which I have spoken about a number of times. It is all about medicines and pharmacy.

The Convener: Thank you very much.

10:38

Meeting suspended.

10:42

On resuming—

The Convener: Our second evidence panel on medicines supply and demand comprises industry representatives. I am pleased to welcome Alison Culpan, who is Scotland director of the Association of the British Pharmaceutical Industry; Warwick Smith, who is director general of the British Generic Manufacturers Association; and Martin Sawer, who is executive director of the Healthcare Distribution Association.

As with the previous panel, we will ask a range of questions for about an hour. If we are unable to address in that time any issues that you think that we ought to know about, please feel free to supplement your evidence after the meeting.

I start with the same question that I asked at the start of the first panel session. From an industry point of view, how well do the current price regulation schemes work?

Alison Culpan (Association of the British Pharmaceutical Industry): I thank you for inviting the ABPI to give evidence. We think that the schemes work very well in Scotland. The Scottish Medicines Consortium works out the clinical benefit and cost effectiveness of a medicine for patients in Scotland, and NHS National Procurement does a very good job in trying to make sure that our members give it the best deal possible. From that perspective, the system is working well.

On top of that, as Elizabeth Woodeson spoke about in the first panel session, there is the arrangement between industry and the UK Government—in which the Scottish Government plays a large role—which puts a 2 per cent cap on the growth of NHS expenditure on branded medicines. For new medicines, anything over and above that percentage goes back into the NHS. We are fortunate that in Scotland, it goes into the new drugs fund, which we believe is a good use of it. In 2019-20, Scotland will get £70 million back through that fund. We are happy with that arrangement as it provides surety for the NHS in Scotland, and it is one of the reasons that spending on medicines is a flat line. It is also important to remember that the percentage cost of what we spend on medicines in 2020 is only 1 per cent more than what was spent on medicines in 1948.

10:45

As a percentage of NHS spend, we are spending the same amount on medicines, and yet we have made great advances in this area over the past 40 years. For example, survival rates for cancer have doubled, and there is in Scotland an ambitious scheme to eradicate hepatitis C through medicines—I could go on. Since 1948, a plethora of advances have made a huge difference to the lives, and to the quality of life, of people across the UK, including in Scotland.

The Convener: You make a strong point about the stability of the percentage that is spent on medicines. It is clear that the volume of spend on medicines has increased because the volume of health spend overall has increased.

Alison Culpan: Yes, indeed.

The Convener: Is the containment of the medicines share of the budget across the piece the consequence of a series of effective control mechanisms in the NHS? Is the system evolving in a way that the industry can live with and support?

Alison Culpan: It comes from a combination of good stewardship from Scottish Government officials and the industry playing its part in trying to make sure that the use of medicines in the NHS is sustainable. We expect that the current schemes will continue. As Elizabeth Woodeson said, they have been in place for over 60 years, since 1957, and we do not expect them to stop. The schemes tend to reflect what is going on in the environment at the time, and we think that we can look forward to working in partnership with the Government of the day to ensure that patients can access our innovative medicines.

Warwick Smith (British Generic Manufacturers Association): I will answer the convener's question in terms of both price and the attractiveness of the market that has been created for companies to launch generics in the UK. I say the UK rather than Scotland, because volume plays a big part with generics. If we get on to Brexit, as I suspect we may, I will raise the volume issue in that regard. The bigger the market and the higher the volume, the lower we can keep our prices and the more secure we can keep supply.

Liz Woodeson mentioned some comparative data from other countries. Just over a year ago, we commissioned an economics consultancy firm, Oxera Consulting, to look at how the market works in the UK and to compare it with other European countries. We asked Liz Woodeson's team to name the countries with which they would like us to compare the UK so that we did not simply cherry-pick a basket of countries for comparison.

The results of that work show that the price of generic drugs in the UK is the lowest among comparable countries in Europe and in comparison with the United States, as David Stewart mentioned earlier. Prices range from being 25 per cent higher in other European

countries with the lowest prices to 700 per cent higher in other comparable countries. I am sure that we will talk about specific products but, overall, prices controlled by competition produce a better outcome for the payer than the more interventionist Government-led systems that we see in the rest of Europe.

On the attractiveness, availability and accessibility of medicines for patients, we can then pose a question: if prices are so low in the four home nations, why is the UK an attractive market? It is because there are low levels of Government intervention. Once we have a licence from the MHRA, we can launch the product. In other European countries, there are different stages of approval, be it for reimbursement or equivalence, which takes time and money. To be frank, the UK is also attractive because we are an EU member state and therefore do not have to go through two separate procedures for the four home nations and for the EU27.

In terms of both overall price—individual products notwithstanding; we can come back to that point—and making the market attractive in spite of the price, the current system for unbranded generics works very well indeed. We would like some shifts around the edges between branded and unbranded generics, but the position overall is positive.

That is not about praising the industry—I am praising regulators and successive Governments for understanding that message and setting up the market to work effectively.

Martin Sawer (Healthcare Distribution Association): Good morning—I thank the committee for inviting us. As you know, the HDA represents the larger wholesalers and distributors across all four countries of the UK. We do not have a statutory role in price negotiations, but we are the recipients of how price regulation works or does not work. I echo the earlier comments that the flexibility of the pricing regulation schemes, both branded and generic, has provided a lot of resilience in the supply chain—unlike in some other European countries, as members may be surprised to hear, where tendering and fixed pricing has resulted in worse shortages than we have seen in the UK.

We support the flexibility that has been created to enable generic prices to rise. It allows for a bit more resilience, because new manufacturers will enter the market, and it creates incentives to purchase in the supply chain. As wholesalers, we try to get the best deal from manufacturers because we own most of the products that we distribute. Likewise, pharmacies use wholesaler competition to try to buy and purchase in the most attractive way, based on the reimbursement prices that they will get. We certainly think that incentives in the supply chain provide a lot of competition across the UK, and that volume is important to keep supply going. We therefore support the current schemes.

The Convener: We heard in the previous evidence session about some issues with particular generic medicines and the possibility for intervention in that regard. It is clear from what you have said that you would have some issues with that. However, in general, it seems that the current system does what manufacturers and wholesalers want it to do as well as working from an NHS point of view.

Warwick Smith: The current system delivers not only for the NHS but for patients. With regard to the high prices for specific products that have been mentioned, I believe that there are currently up to nine competition law investigations, although I think that the Competition and Markets Authority has withdrawn from two or three of them. The BGMA would be the first organisation to criticise manufacturers if it turned out that there was any form of malfeasance behind those prices. However, it is wrong to assume that any significant price rise is unjustified. It may in fact be justified—if the committee wishes, we can go into some of the reasons for that.

It is right that Government has powers to get the data to investigate those high prices, and we welcome the UK Government's new enhanced powers in that regard. It would not be in the interests of the BGMA's members if it looked as though there was something wrong with the occasional product and there was no way to deal with that.

Brian Whittle: The new price regulation scheme for branded drugs contains a commitment that pharmaceutical companies will offer the same price for a product across the whole of the UK. However, Cancer Research UK has heard anecdotal evidence to suggest that that is not the case, and that there are certain discrepancies in the prices for new drugs. Do you recognise that issue?

Alison Culpan: The new VPAS, which is the voluntary arrangement that Elizabeth Woodeson described, contains a clause about transparency across the four nations. The ABPI encourages its members to give each of the four nations the same arrangement, and the new VPAS makes that clear.

Within those arrangements, however, there may be a few different wheels turning at the same time. Price is a major element, but there is also the collection-of-data element. In addition, there is one element that we do not have in Scotland—NHS National Procurement cannot do anything about it, but it is important, and the committee may want to

consider recommending it. In the system in England, uptake has forged one of the major planks of the voluntary arrangement. That arrangement is about not just access to medicines—which in Scotland means that medicines have got through the SMC—but seeking to understand, support, and promote the use of new, innovative medicines. That is one example of how companies may have different packages in different countries.

In general, we encourage ABPI members to give the same arrangements to all four countries, but they have to take into account that each country still wants to keep its own sovereignty over what it does for medicines and how they are accessed within that country. Those tensions exist but, in general, NHS National Procurement does a very good job in getting ABPI members to give it the best price possible, even if the arrangement does not cover the other aspects that I mentioned.

Brian Whittle: I guess that in order to understand whether that process is working, a monitoring system needs to be in place to measure it. How is the process currently monitored?

Alison Culpan: The different procurement departments in the UK will share that information; the ABPI does not keep such information. We encourage our members to promote a level playing field, but it will depend on the arrangement that each company comes to with the particular nation that it is dealing with.

Miles Briggs: My question comes on the back of Brian Whittle's question about VPAS, looking towards outcomes—payment for results, basically. What should that look like? That would start to answer some of the questions that Brian Whittle raised about how you monitor the outcomes that you are trying to achieve.

Alison Culpan: Absolutely. I know that you chair the cross-party group on cancer, Mr Briggs; we have been asking for many years in that forum for the data on cancer to be improved. As Deming the statistician said, "In God we trust; everybody else must bring data."

We desperately need data. We have moved into a whole new world of data where patients have data on their wrists and keep all sorts of information about their health. We want to tap into that to look at the outcomes.

I get worried when we get too tied up in thinking only about price rather than value. Let us say that Mrs McCarragher has a £1 inhaler, which keeps her asthma or chronic obstructive pulmonary disease at a certain level. If she was to get the new inhaler, she could climb stairs and stop getting blue-lighted into hospital, which brings into play another value in respect of that medicine. However, because data is not collected and shared between primary and secondary care, those in the secondary care setting do not know which inhaler she is on or what interventions have taken place, so they would not understand why she was no longer being blue-lighted.

We need to be able to collect the data so that we know what the outcomes are. We would like the Government to really get behind that and to implement what came out of the data-scoping task force, which looked at indications and outcomes. We would then be able to see whether our medicines are doing what we say they will do and whether the right patients are getting them.

With regard to the future of medicines pricing, we can consider the whole area of gene therapy; we can read in this morning's *Scotsman* about exciting new research into chimeric antigen receptor T-cell therapies. However, we need the data to identify patients and to know that we are getting the right outcomes and value for money from what is spent on medicines.

Brian Whittle: For a number of years, the committee has talked about, and heard a lot of evidence on, the need to collect data and to have a platform that allows patient data to be not only collected but seamlessly shared. We hear all the time that that is what is required, so there is frustration in the committee that it is not happening. Where are we with that? Why is it not happening?

11:00

Alison Culpan: I have been working on that for more than 20 years—I was working on geographically mapping disease 25 years ago. I find it frustrating that we have had the community health index number for so long and yet we have not really made the most of it. We ask the committee to look at whether the Government should be putting more resource and commitment into making everything come to fruition in this area. We do not have time to wait for it to come forward. There are new therapies for which we need the data so that we know where to find the patients who will get the best use out of the medicine. We are as frustrated as the committee is—we absolutely need the Government to prioritise this area, just as it prioritises other areas.

To go back to Andrew Morris's data-scoping task force, its report contained a line that crystallised the situation. It said that, with data, we save time, money and lives. That is why it is so important that the Scottish Government puts more resources into and focuses its attention on this area, as it would with any other significant priority.

I should clarify that, from an industry perspective, we are not seeking the data so that

we can drill into it on a named-patient basis—we are looking for aggregated anonymised data. We need the NHS to have that data so that it knows that it is getting the right medicine for the right patient at the right time.

Sandra White: Alison Culpan mentioned the industry perspective, which is important. However, evidence to the committee has also highlighted the importance of changing the culture among GPs. It is not as simple as saying that the Scottish Government should put resources in or do whatever, regardless of anything else. Patients and the public tell us that the data should belong to them. It is an oversimplification to say that the Government should simply put resources in. The pharmacists want to work along those lines, but there are stumbling blocks. We need the GPs to come on board. Do you agree?

Alison Culpan: Absolutely. In Catherine Calderwood's first annual report, "Realistic Medicine", she said that it takes a whole generation for Scotland to adopt innovation. That is just not fast enough. When we look at the fantastic stuff that is happening now, we want the uptake to be driven faster.

You are right—the culture in Scotland is one of people saying, "We'll just wait and see". Another cultural issue is that people are scared. I found it interesting when I talked to people in health boards that they did not know about the arrangement with industry, and the submissions to the committee's inquiry from health boards mention the arrangement very few times, if at all. They are worried that they are spending vast amounts of money, but they do not seem to appreciate that a 2 per cent cap is in place and they will get the money back.

I do not know whether we need to work on getting people to appreciate that they should not demonise progress. We have to get moving, otherwise Scotland will lose out, not least from the perspective of innovation. We need to be an innovative nation that can attract investment as we move forward. Right now, there is huge investment—£2.5 billion—and thousands of jobs in Scotland from the pharmaceutical industry, and we need to keep ourselves in that position.

I absolutely agree with you on the cultural aspect. I am not sure what we can do to help you in that respect, but if there is anything that we can do, we are all ears.

The Convener: There is clearly a wider conversation to be had on that topic, but that is a useful start.

Emma Harper: Good morning. I am interested in drug shortages—but not Brexit-related shortages, on which my colleagues will ask questions later. There have previously been medicines shortages for various reasons. The medicines have included antidepressants and painkillers, and I am aware that a fire in a factory in India led to a shortage of the antibiotic clarithromycin. Shortages hike up prices.

There are also issues to do with community pharmacists having to source medicines or alternatives. That increases prices, too, and mechanisms are needed to reimburse them. Will you explain why we have shortages? What can we do to solve problems that might be created?

Warwick Smith: That is a complex issue, but I will try to keep my explanation as brief as possible. We track our members' performance in meeting orders from their customers, which is one way of gauging the market as a whole. At the moment, we are broadly in the mid-range of supply. We measure timing for deliveries. When it is bad, it is in the mid-70s; when it is good, it is in the low-90s. We are currently in the mid-80s, which we think is in the broad range of normal.

As someone in the supply chain told me, every shortage has its own story. However, some factors apply at the moment that have probably not applied previously and they will be affecting some products. For example, the Chinese Government is moving manufacturers of chemical plants, including manufacturers of active pharmaceutical ingredients, from urban areas to rural areas for environmental reasons. That is not being done in a phased way, which means that there is a time gap between a factory being closed and another one being built.

The introduction of the European Union falsified medicines directive means that every pack must have a unique serialised number. That has slowed production lines by about 10 per cent, which has taken capacity out of the manufacturing chain.

In addition, due to downward pressure on price, manufacturing—particularly of active pharmaceutical ingredients, which are the chemicals that make the drug work—has shifted from the traditional areas of Spain and Italy to India, and now to China. There is more manufacturing in India—Emma Harper mentioned a fire in India—and we have seen shortages having been caused by Mumbai dockers striking.

Therefore, we have had a series of issues whereby the supply chains have got longer, thinner and probably less resilient than they were in the past.

A price increase here, though, often means success and not failure, because it allows the manufacturer to bear additional costs, remain in the market and get the medicine to patients.

Where there are fixed prices in Europe and manufacturers cannot make increases, they tend

to withdraw from the market. At the moment, the DHSC's shortages list has about 78 products on it, but the Swiss list has, I think, 600 on it. That inherent flexibility, albeit at the cost of a short-term increase in price, can keep medicines flowing to patients.

I have mentioned the work by Oxera Consulting. That showed that, when there is a spike in prices to cope with a shock to supply, 75 per cent of those products are typically back to the normal price within 12 months. Again, as we get back to normal, competition kicks in and the price comes down. However, my overall message is that a price increase can be the market working to ensure the supply of medicines to patients.

Emma Harper: Does the UK Government bear the brunt of price increases because it supports the community pharmacists to mitigate them?

Warwick Smith: It does. The UK Government and community pharmacy have done a lot of work. Indeed, the wholesalers, represented here by Martin Sawer, have done a lot of work to make that system more efficient. We welcome the fact that, for example, the UK Government has taken powers to require the actual prices to be given to it within 48 hours. Frankly, in the past, it was just our members who did that work on a voluntary basis. That information is therefore available and the UK Government has looked at different ways of using that data so that community pharmacy is properly reimbursed for the charges that it faces.

Martin Sawer: We agree that any patient having to wait for a medicine is one patient too many. However, despite the headlines, we are in a better place than we were perhaps 10 years ago in the UK, when shortages began to impact. A lot of that, as Warwick Smith said, has been down to better communication with the NHS. We provide a lot more data now to the NHS.

It is ironic that Brexit planning has helped over the past two years, because the Government has a much better understanding of the supply chain and where products are. The NHS is now better armed to communicate internally; for example, every month it lists products that are in short supply and when they might come back into supply.

The sector has had to deal with the symptoms of being unable to get enough medicines to supply to pharmacies, hospitals and dispensing doctors. Our IT systems and management controls are now much better, we stock take every 24 hours and we can ship product around the country overnight to where it is needed.

I think that the convener has been supplied with an infographic that we are giving to every pharmacist to try to explain the reasons for a shortage. As Warwick Smith said, every medicine shortage has a story, and a shortage in one product is not necessarily the reason for a shortage in another.

Communication and a bit more transparency will help, as we are starting to see. We are also working with pharmacy patient medication record providers to develop a much better system for the coding that tells them why they have not got a product and when they might be able it get it back in stock. A lot of the problem is that the poor pharmacist with a patient does not know when the medicine will come or why it is not there, and it can be some time before that information is communicated. We are trying to make sure that that happens a bit quicker.

Emma Harper: Are there particular groups or types of drugs that are more prone to shortage? I listened to a BBC Radio 4 programme about a shortage of hormone replacement therapy meds and antipsychotic drugs. Is there a drug shortages' predictor, with red lights flashing for those drugs that we must keep an eye on?

Warwick Smith: Frankly, it is difficult for us to get to the root cause. We are working with industry colleagues and the UK Government to improve the situation. We believe that HRT shortages are due to the Chinese API issue that I have mentioned in which two suppliers of oestrogens have been closed down and not yet recommenced supply.

It is difficult to pinpoint specific issues. For example, the regulators have recently found a potential impurity in the manufacturing process for two products, and one has been withdrawn from the market because there are alternatives. Sometimes, a shortage can be caused by a safety issue, and we cannot predict where those will come from.

Martin Sawer: Having managed the symptoms for some time, we have started to exhaust the different levers that we have. The BGMA has mentioned the need for a more strategic review of the origination of APIs. There is a more strategic review at a European level about whether consolidation in manufacturing may have gone too far and that we need a bit more resilience, which might mean reshoring some manufacturers back to Europe.

Warwick Smith: I think that Martin Sawer's point is critical. We can deal with the symptoms, but we need to focus on and resolve the causes. Clearly, moving manufacturing of the finished form product out of the UK and the move of API manufacturers to the far east weakens the resilience of the supply chain. If there is a glimmer of hope in a post-Brexit world—if you will excuse a political comment—it is that there could be industrial strategy that looks at the off-patent sector. That aspect could potentially become

increasingly difficult in a post-Brexit world, and we are encouraging the UK Government to look at that. I think that there is some sympathy there in that regard.

The Convener: Thank you—that was very interesting.

Miles Briggs: I have questions about the wholesale market, and Martin Sawer has already outlined the complexities of the supply chain. Some of the written submissions from community pharmacists mentioned the increasing amount of time that they are spending to source medicines. Are there ways to make the system more efficient? In England and Wales, there is more monitoring of where medicines are. What could that approach look like in Scotland?

11:15

Martin Sawer: I am not aware of any monitoring in England and Wales that is different to that in Scotland.

Because of the Brexit work, we have a much better understanding of how much stock is around. The difficulty is in knowing whether it is in the right place at the right time. That is the next challenge.

As I mentioned previously, we are working with pharmacy bodies across the UK in order to communicate better to them. Some of that is about amending the PMR coding systems, because each system has its own different coding. Depending on the IT system that a pharmacy uses, they sometimes get a different code. We are trying to make it simpler. We are collaborating with manufacturers to make sure that the information that we give pharmacies is correct, and we are reducing the codes from around 150 to around 12, to make it simpler; that is the plan. That is a concrete example of what we are trying to do. This is about communication and information for the pharmacist.

Miles Briggs: Is there a role for the central medicines intelligence unit in relation to where medicines and stocks are for primary and secondary care?

Martin Sawer: Speaking personally, and for the sector, I am not convinced that that type of more interventionist supply management would work. Historically, we have had issues with pandemic planning, which one could say was more interventionist, and that has been expensive for the public purse. A much better way is to work with the private sector, as has happened with supply ever since the NHS was invented. The private sector will find the gaps and will usually fill those holes much more quickly, because it is incentivised to do so.

Miles Briggs: The direct to pharmacy initiative has restrictions or quotas. Is that right?

Martin Sawer: "Direct to pharmacy", unfortunately, is a bit of a misnomer. There are only five direct to pharmacy schemes, for the largest branded manufacturers. In fact, one of them has pulled back in the past 12 months to traditional wholesale. Wholesaling is where we buy the product. In the large majority of cases, that happens by volume.

There are four manufacturers now who do DTP schemes—the wholesalers won all the contracts—in which we get paid a fee for distribution—and the pharmacist buys the product directly from the manufacturer. Those are subject to quotas, as are a lot of other products that we own for which we impose quotas on the pharmacy.

Part of the reason for that is that there are too many wholesale dealers' licences. We have 2 per cent of wholesale dealers' licences and our members distribute 90 per cent of NHS medicines. Small businesses may not have wholesaling as their main business, but they can wholesale. Sometimes, that means that we do not know where product is. However, the situation provides competition, because if there is a shortage of a product in a local area, a small wholesaler may be able to provide product.

There are a lot of unknowns in the supply chain. We consider that greater transparency would help. We do not always know who we are selling to. We might sell to one business, thinking that it is a dispenser, when it is actually being used to wholesale. That is one of the reasons why we implement quotas. We impose a lot of quotas on businesses that have a wholesale licence.

The Convener: Who grants wholesale licences?

Martin Sawer: They are granted by the MHRA, but under an EU regulation. That might give us, or the MHRA, greater flexibility from 2021 onwards.

The Convener: It will still be an MHRA responsibility, but the context in which it provides the licence will change.

Martin Sawer: That is correct.

David Stewart: Good morning, panel. You will have heard my questions about Brexit to the previous panellists. How confident are you in the security of supply of medicines post-Brexit?

Warwick Smith: Thank you, Mr Stewart—I was hoping that you would return to that topic. It concerns us on two levels. In answer to the convener's first question, I mentioned that volume is important to the operation of the generic industry. If we have to undertake a different regulatory process for the UK, compared with the

EU27, after the end of this year, that will make life much more difficult and expensive for us. Given that the UK is the lowest-priced market in Europe, that would bring into significant doubt our ability to supply medicines at current prices, if at all. The MHRA and the UK Government as a whole are aware of that. Liz Woodeson mentioned some of the commitments that ministers have made.

It is important to recognise that any deviation at all from the EU27 regulatory processes will add cost. People have said to me, "We can do it faster." That is not helpful. Companies have teams, which work to timetables. If a company has to put additional resource into a team to deal with a different timetable, even if it is faster, that will add to cost. We need to stick as closely as possible to the EU regulatory framework if we are to continue to supply the same volume of medicines at the same low price as we currently supply.

David Stewart: You have made an important point about price. What about timing? As you know, the frictionless borders between the 28 member states are a great success of the EU. Many pharmacies operate on a just-in-time model of drugs supply. Frictionless borders and just-in-time supply go together; just-in-time supply and massive delays at customs points do not. If we put price to one side, what is your assessment of physical availability and supply of drugs in the UK?

Warwick Smith: First, you are absolutely right: we launch first in the United States and secondly in the EU, because they are the largest markets and that makes the most commercial sense. We can treat more patients by launching in those markets, rather than elsewhere. I am sure that that will continue.

A lot of work has been done on the short straits crossing—Dover to Calais, to you and me—in the context of no-deal Brexit planning. It now looks as though we will have a deal and an implementation or transition period. It will be necessary for manufacturers and their logistics suppliers to fully understand the new customs arrangements at the borders. When we were looking at no-deal planning, we surveyed our members and found that the weakest point was their understanding of revised customs procedures when lorries turn up at Calais. There is still work to be done on that.

You will hear people argue, "Well, it's all set up online; you just need to do it online." We all know that sometimes that does not happen. If a truck full of medicines turns up at Calais with the wrong documentation and is sent off to a lorry park while the paperwork is sorted out, that is not good for security, it is not good for temperature control and it is not good for just-in-time supply.

Martin Sawer: The HDA, as the representative body for wholesalers in the UK, is very concerned about what friction might bring to the medicines system. We operate identically in the four countries of the UK: we charge the same prices everywhere and we distribute to Scotland from England, to England from Scotland, to Northern Ireland from Scotland and so on. Because of efficiencies, that is how it works. Any barrier that brought more cost into the process would be a concern.

We have worked closely with the Department of Health and Social Care in London on Brexit planning over the past couple of years, as have the BGMA and ABPI. That work will continue this year, because it is important that we all know and prepare for what might be down the track. I am sure that there will be preparation for 31 December, in the same vein.

David Stewart: Alison Culpan might want to comment on this. I was surprised to read in our papers that the figure for pharmaceutical imports is the same as the one for exports—it is £23 billion.

Some 75 per cent of our pharmaceutical imports come from Europe. Business gurus—I am not one of those—sometimes argue that being too dependent on one place is a problem. I think that the relationship has been good for Britain when it comes to security of supply and price, but 75 per cent is a hefty proportion. The rest of our imports are from America and basically come through Europe, in terms of customs and everything else. Do you have concerns about a change in tariffs, which will affect imports and exports?

Alison Culpan: The ABPI, too, is looking for a frictionless border so that our medicines can come straight in.

I read the bit in the Scottish Parliament information centre's paper about the £23 billion each way. My information is that 45 million packs of medicine go out of the UK to Europe and 37 million come into the UK from Europe every month. Therefore, there is definitely a hook for co-operation between Europe and the United Kingdom to ensure that our medicines come in without friction. The ABPI has made it clear that we should be looking for co-operation when it comes to the supply of medicines, academia and the workforce. There is a lot of work to be done.

It would be fair to report that we have worked very well with the Scottish Government officials who have been tasked with dealing with Brexit on the logistics of medicines supply to ensure that they do not get stuck at Dover. We have considered the logistics of medicines being flown in and other ways of getting them to patients in Scotland.

David Stewart: I am conscious of time, so I will move on to trade negotiations with the US, on which you will have heard my earlier comments.

As we all know, America is an extremely important market. It is also the home of big pharma, which, as I mentioned, has a lot of power and influence. It tends to be a much higher-priced market; from memory, I think that the top 20 drugs in the US cost five times what they cost in the UK.

Are there issues that you are concerned about with regard to our future relationship with the US? It is already the case that 20 per cent of our pharmaceutical exports go to the US, which is a pretty solid performance. Do you have any comments to make about price, security of supply and patent control, which is vital in the context of cost? I did not raise patent control with the previous panel.

Alison Culpan: The signals that we have had from the UK Government are that medicines will not be on the table in the trade agreement with the US. We already enjoy the benefit of good American medicines coming into Scotland. Those medicines go through our usual processes, which include the ultra-orphan process, the SMC's clinical effectiveness assessment and the national procurement negotiation process.

Medicines also form part of the voluntary arrangements, so they are covered by the 2 per cent cap. We have had the same deals with the Government for the past 60 years, and we do not see them changing. The American products fall within that. We think that it is probably too early to speculate on what will happen, but the signals that we are getting should give us comfort that medicines will not be on the table.

Warwick Smith: We are most concerned about US objectives on intellectual property rights. David Stewart mentioned patents, but our concerns are broader than that. Without going into the weeds, I point out that there are various provisions that the Office of the United States Trade Representative tries to bring into all the free trade agreements that it negotiates that would delay the launch of generic and biosimilar medicines in the UK, compared with what happens under the current European standards. That delay could be up to two years. Therefore, the savings that the NHS would get during that period would be lost. There would also be the impact on the industry of not being able to launch medicines.

I can speculate about the numbers. A blockbuster drug's sales figure could be, say, £400 million a year for the UK, which would equate to £40 million a year for Scotland. That would mean that, over two years, £80 million could be lost on one product. Therefore, we are very concerned about intellectual property rights. We know that the UK Government's Department of Health and Social Care understands that and is very supportive of our position. We are concerned that we might be collateral damage in the broader political play at senior levels.

The Convener: For clarity, your concern is not so much about a specific price-related proposal by an American trade team; it is about an American trade team changing the approach to removing a medicine from a high-price branded category to a low-price generic category.

Warwick Smith: Absolutely. That is as much about data exclusivity, which is a technical provision in the licensing field. In the US, a generic manufacturer has to notify the originator before beginning to work on the launch of a product. If that happens in the UK, we normally end up in court, we get injuncted and that causes delays. There are a range of features that US trade negotiators would try to seek that would be damaging to our industry and to the NHS.

11:30

Emma Harper: I have a supplementary question that I suppose I should have asked the previous panel, about guarantees for drug pricing and supply chains. Trade and trade negotiations are reserved to Westminster. The Channel 4 programme "Dispatches" showed secret meetings between US drug firms and civil servants, and there have been six meetings at which drug pricing has been discussed. I seek comfort and guarantees that drug pricing and the stable supply chain will not be affected by Trump trade-deal negotiations. Do you think that we should also be seeking guarantees from the UK Government?

Warwick Smith: I can speak as a former UK Government trade negotiator. Those talks being characterised as "secret" is a bit of hyperbole. I would have been amazed if they had not been held. If you look at the leaked minutes, you will see that all that they do is confirm that what was being discussed is what is already clearly set out in the US negotiating objectives. The meetings were no more sinister than that, but they underline my earlier point that the issues are on the table, on the US side.

The Convener: Thank you. That is helpful. David Torrance is next. No, it is George Adam.

David Stewart: That was frictionless, wasn't it?

George Adam: Aye. Nobody noticed.

Scottish Government officials told us that branded products cost more, but fewer are distributed through prescribing, and that more generic medicines are prescribed, but they cost a lot less. The generic market relies on competition, but there have been price hikes in generics,

normally when one manufacturer raises prices. How can we create competition to ensure that companies get involved in that market, and so possibly bring down costs?

Warwick Smith: Liz Woodeson mentioned that the Department of Health and Social Care in London has been looking at ways of bringing competition into the market when it does not exist. In many ways, a better way of differentiating is to look at when competition is effective and when it is not, rather than looking at branded versus unbranded. It is unfortunate that that is not how the various reimbursement schemes work, at the moment.

We are in discussion with the DHSC about its ideas on introducing competition. I am bound to say that we do not think that either side has yet come up with anything that will be effective. We might just have to acknowledge that for some products it is unlikely that competition will work. If use of a medicine across the four home nations is less than one batch in one year, it is really difficult to see why more than one manufacturer would produce that medicine. Some of the products that the DHSC has been concerned about and in which we have seen shortages have been in that category. We are talking about small numbers; it might be that for a small number of products we need to accept that, unless there is systemic change elsewhere, it will be difficult to make competition work.

George Adam: I asked the question for a specific reason. Earlier, I mentioned that my wife has multiple sclerosis. I met a consultant in Glasgow who works for NHS Ayrshire and Arran. In a presentation, he gave examples from Scandinavian countries of use of generic drugs for MS. The cost of those drugs is phenomenally lower than the branded products that we use here. His question was why we are not considering that. The drugs deliver the same as the branded products that we pay more for. What would you say to that type of argument from a neurological consultant?

Warwick Smith: Scotland has a good record of introducing generics once they are available and the intellectual property rights on the originator have expired. The unbranded prescription level is 84 per cent. The levels in other countries in Europe might be a couple of percentage points above that. The only country where the level is significantly above that is the US, where it is 90 per cent. I question whether that is clinically sound, because it is driven predominantly by money. We would want a clinical decision first, then a financial decision.

There is considerable scope to look at older medicines that can be repurposed for new uses. That might be the point that your colleague was making. We are doing a lot of work with NHS England on ways of repurposing generic medicines. There are barriers to that. A generics company might have to do basic research to get that new indication or disease added to the licence. However, once it is added, every generics company can market the product for that, so we need to get over that issue and work out what data we need. Those discussions are well advanced and there is positivity on each side to find a way of dealing with the barriers. That is exciting for the NHS and for the generics industry.

George Adam: That sounds hopeful. I asked earlier about branded products. You heard me say earlier that, when the latest MS wonder drug comes up, the pharmaceutical company rightly makes its pitch on the drug. It ends up in the media and people think that it is a wonder drug that will make a difference to people's lives, despite the fact that it has not yet been submitted to the SMC or NICE. How do we, including your industry, have a responsible conversation with the public, so that everybody is aware when products have not yet been tested and that what is being said is still only a claim?

Warwick Smith: The generic products that we launch will already have been on the market for maybe 15 years, and Alison Culpan's members will have had to demonstrate their efficacy to the MHRA. I like the restrictions that we have on advertising and making claims in the UK. The ABPI does effective work on enforcing the code of conduct on its members. We have a similar code but we are less exposed. I would not want to be in the position in the UK that I am when I am having my hamburger in the Marriott in Washington at 7.30 at night, with TV adverts badgering me to ask my GP for a new medicine that is no more effective than another one. The controls that we have in the UK are better than the controls in many other parts of the world. They are well enforced by the industry—principally, the ABPI—and the regulator.

Alison Culpan: I understand what George Adam means about the big flash headlines that raise expectations. Often, the work is upstream. On the article in this morning's *Scotsman* about the CAR-T therapies, that work is still at university level. From a public relations perspective, we have to be responsible about giving information to journalists; we tend to be hostages to what they do with it thereafter.

On direct-to-consumer advertising, our industry is not allowed to talk directly to patients. Therefore, we rely on the Scottish Medicines Consortium patient representatives, for example, who will hear the debate about what is good about the medicine and what is lacking in evidence. Representatives of the MS Society have attended

the SMC. They have represented the society very ably and have perhaps been the conduit to patients, basically in order to try to manage expectations.

George Adam: I asked about that because, as the husband of a wife with MS, I just want to see her walk down the corridor, so when something like that comes up, I automatically think that it would be great. However, as a politician who has been involved in the issue, I know how the process works. We have to consider how we manage expectation, because we are dealing with very emotional issues. One of my concerns is that we constantly see in the media big splashes relating to MS and other conditions. We can all complain about the media but, unfortunately, we all have to work with them.

Alison Culpan: We do. I was speaking to someone about data in Finland; I asked how the country has managed to get people to buy in to the fact that databases have been completely opened up. That person reckons that the media in Finland are very responsible in how they report, and that people trust the media.

I do not want to demonise the media, because they play an important role in our society. I am not sure that we have the answer: from a communications perspective, we perhaps have to give a bit of thought, with our members, to not raising expectations, especially when a very small cohort of patients might be eligible, yet everybody's hopes are up.

The Convener: An issue that occasionally arises is a drug being licensed for use for one condition but not another. Should we think about encouraging manufacturers to apply for licensing for different indications or for licensing of products that are not currently licensed in the UK?

Alison Culpan: When manufacturers look to license, they generally look for an unmet need, and they need to know that, if they do the research here, the product will be accessible for patients. In Scotland, that means that the drug would get through the SMC. Manufacturers want to know that they can broker in the costs of the breakthroughs of tomorrow. It is complicated and it might cost hundreds of millions of dollars more to go for another indication for a drug that might already have cost more than $1 billion to bring to market. A manufacturer has to satisfy those three conditions before it goes down that line.

The Convener: For clarity, how much might an additional licence cost?

Alison Culpan: That depends on the indication. For some, very complex studies would be involved, but for others the process could be fairly straightforward. You never know. To be frank, that is like asking, "How long is a piece of string?" It is difficult to assess.

Warwick Smith: I would split the question into two. Where there are no intellectual property constraints around a product, the answer is the same as the one that I gave to Mr Adam about repurposing something that we are working on and hoping to find a way forward on.

The other part of the answer is that there might be products for which there is an indication and for which the period of the patent on use exceeds that of the patent on the molecule. There is, at the moment, an important case in that regard before the English Supreme Court. Once that case is through, it will be down to us to find a way of dealing with the issue in the most effective way that respects the rights of the originator and helps the NHS with costs and the patient with access.

The Convener: I thank all the witnesses for that extremely helpful session. We have covered a lot of territory in a tight timeframe. If there are other points that you think we should consider, please let us know.

11:44

Meeting suspended.

11:48

On resuming—

The Convener: We move on to our third panel of witnesses this morning on the supply of and demand for medicines, with a focus on issues of access and procurement. I welcome Dr Alan MacDonald, chair of the Scottish Medicines Consortium; Lindsay McClure, assistant director for medicines, pricing and supply at NHS National Services Scotland; Matt Barclay, director of operations at Community Pharmacy Scotland; and Dr Brian Montgomery, author of "Review of Access to New Medicines". I ask Emma Harper to begin our questioning.

Emma Harper: I am interested in pricing. You will have heard the earlier discussion about the differences in pricing and tariffs and the issues around that. I am interested in the key drivers of growth in the medicines budget. We are talking about medicines, but we have seen a lot of increases in technology and consumables in healthcare. For example, type 1 diabetics now have more pumps available as well as technology for testing and monitoring blood sugar, which we hope will keep them out of hospital. What are the key drivers of the growth in the medicines budget?

Lindsay McClure (NHS National Services Scotland): I am the lead pharmacist at NHS National Procurement, which centrally procures

medicines for all NHS Scotland hospitals. We work across the full life cycle of medicines—so, in patent brands, generics and biosimilars—and we can also source unlicensed medicines to meet individual patient need if, for example, a medicine is not yet licensed in the UK.

We see different challenges across those areas. As the committee heard earlier, last year was a record year, so overall there has been a slight deflation in medicine spend. From a national procurement and a secondary-care hospital perspective, the value of the medicines that we sourced centrally last year was around £400 million. We managed to secure around £58 million of savings from that spend.

I will give the committee a couple of examples. One is around the new hepatitis C medicines. Five years ago, there was a breakthrough in treatments and we had a range of medicines entering the market that, for the first time, could cure hepatitis C without the patient having to go through difficult treatment courses with a lot of side effects. However, affordability was a challenge, such that, for a three-month course of three packs of tablets, initial pricing was around £30,000 per patient.

We work closely with clinical leads and boards, so there is a very tight hepatitis C clinical community that, in parallel to tendering for the medicines, developed clinical guidelines that said that, because the medicines were broadly similar in clinical effectiveness and had only minor differences between them, the lowest-cost one would be on the first line in the guidelines. That was a strong incentive to the industry and the consequence has been a significant reduction in spend in the area. We know that new medicines are always coming into the market and that there are new pockets of competition, so we must continue that approach in order to control spend.

Another example is biosimilars, which are copies of biologic medicines. Biologic medicines are made from living organisms, so they are inherently a bit variable as they are from different cell lines. The regulator reviewed and scrutinised those medicines and said that they have comparable quality, safety and efficacy. The benefit of biosimilars is that, because they are a copy of a product that was on patent and had no competition, we now have competition and significant savings for the first time. In that area, we work closely with boards to ensure implementation and uptake of the most cost-effective biologic products. Over the next few years, more of those products will be coming off patent and we will have to continue to work to control spend.

Dr Alan MacDonald (Scottish Medicines Consortium): I can answer the question only as it relates to medicine spend, which I think is where Lindsay McClure is coming from, too, rather than in relation to devices and other things that promote good healthcare, which Emma Harper mentioned.

The committee heard quite a bit from the ABPI representative and in the written submissions about the extent to which medicines costs are rising or stable, both in absolute terms and in relative terms compared to the overall health budget. It is sometimes hard to get a single version of the truth as to how much costs are rising, but we have had discussion and debate on that.

The drivers of increased costs and the potential offsets are complex. It is clear that new hospital-based medicines are contributing substantially to increased costs, but there are offsets. To highlight one of Lindsay McClure's points, the biosimilars issue has been a good news story for the NHS in Scotland and, indeed, in the rest of the UK. I am a rheumatologist in my day job, so I have seen the effects. Clinicians working with finance and pharmacy colleagues have done a lot to ensure that the savings from biosimilars are used to mitigate some of the upward pressures on costs and to improve services.

Dr Brian Montgomery: The crux of what lies behind Ms Harper's question is the challenge posed by the success in recent years of providing healthcare. I recently retired but, over my career, I saw a sustained increase in the resource available to us when providing healthcare. However, the options that are open to us as we look to provide treatments have now outstripped that resource. We now have tests and treatments that were not available five, 10 or 20 years ago, and we are dealing with diseases that were not around five or 20 years ago.

Lindsay McClure's example of hepatitis C is a good one. When I started, hepatitis C was not even known as a disease and, when it emerged, we could do pretty well nothing about it, but we can now cure it. That gives patients and clinicians many more options, and it puts much greater pressure on the resource that is available.

Behind that, there is a challenge about how we prioritise the best and most effective spend from the finite resource that is available. There is also the issue of how we spend the money that we have in the most effective and efficient way. We could never claim that we are always using every penny to absolute best effect. A further issue that is particularly pertinent in medicines is how we can minimise waste.

We are dealing with the challenge of being able to do more for people and extend life in a way that gives much greater quality but, unfortunately, that quality comes at a cost and often with a requirement for on-going input.

Emma Harper: We are also seeing a transfer of the budget for medicines from secondary care to primary care. Hepatitis C patients are now being treated in primary care, and the budget shift will be reflected in that way.

Matt Barclay (Community Pharmacy Scotland): That is a good point. Community pharmacy wants to remain the port of call for the vast majority of supplies in primary care. That shift of medicines from secondary care to primary care has indeed happened in the case of hepatitis C. We supply hepatitis C medicines through community pharmacy, and the evidence shows that, thanks to community pharmacy supply, the outcomes for patients and for eradication in the patient population are greater, as community pharmacies are monitoring the uptake of what are highly expensive medicines.

That does not come without financial challenges for community pharmacy. We procure medicines on behalf of the NHS, and they sit on our shelves. If a patient does not use a box of hepatitis C medicine, which can cost a five-figure sum, a pharmacy can be left with it. There are issues when it comes to how pharmacies best use their stock in a primary care setting.

Broadly, pharmacy still wants to be at the forefront of medicine supply, and the move of medicines from secondary care to primary care—we might also mention biosimilars—has happened in pockets in community pharmacy. We certainly endorse that approach to build on the more than 100 million medicine interventions that we make in a year. However, we realise that the shape of medicine supply is changing. There are changes in the type of medicines, which now include stratified and personalised medicines, and community pharmacy will have to adapt.

You asked where the growth in drugs spend is happening. Without doubt, it is in those innovative areas and branded medicines, so that is probably where we need to focus. The generic supply is relatively well controlled—indeed, the spend on it came down in the past year.

The Convener: Moving on to that subject of innovative medicines, we have asked about the processes for the approval of drugs and medicines by the SMC and more widely. Most of the submissions have been positive about the appraisal process, but a couple of concerns have been raised, and I would like to ask Alan MacDonald and the other witnesses about those.

One concern is about an erosion of the robustness of the processes, whether under pressure from Government, members of Parliament or other external bodies. The second concern is about a centralisation of approvals, which I guess will be of interest to Lindsay McClure. Currently, area drug and therapeutic committees have a good deal of autonomy or decision-making powers, and there is a sense that that might be under pressure.

I am interested in your comments on those two points.

12:00

Dr MacDonald: The first conclusion of Dr Montgomery's report was that the SMC had delivered on the policy aim of increasing access to medicines for rare conditions and cancer. I suspect that it is that increase in access to cancer medicines and medicines for rare conditions that has driven some of the comments on affordability and whether there has been some kind of weakening of the process.

I would like to take the opportunity, on behalf of the SMC, to refute the notion that the process of HTA in Scotland has been eroded or weakened. That is not correct, as anyone who has witnessed our processes or sat round our table and listened to the quality of the discussion and debate and the work in the background will know. I have been chair for the past three years, I was vice-chair for three years before that and a member for seven years before that, and at no time have I thought that the process was carried out with anything other than the utmost rigour.

People can judge the desired outcomes and whether access is too high. People can and should debate that. However, I refute any notion that our working processes are anything other than completely rigorous.

The Convener: Is there rigour in applying the criteria of clinical and cost effectiveness, which are in your remit?

Dr MacDonald: Yes, absolutely.

I want to pick up on the comments that were made earlier—by Mr Adam, I think—about MS drugs and how we can have a debate about those. One thing that is missing from the public debate is that people, perhaps reasonably, do not go much beyond the decision to accept a drug or not to recommend it. Sometimes, the debate goes so far as to cover the cost, which is one side of the coin, but it rarely touches on the SMC's unique selling point, which is that it is the only body that looks completely independently at the evidence and asks, "Is this better than what we already have and, if so, is it a little bit better or a lot better?" Sometimes, in the public debate, our critical role in using the best evidence that we can to comment on how much a medicine adds to the therapies that we already have gets a bit lost.

Lindsay McClure: There have been a few questions this morning about the voluntary

scheme for branded medicines and transparency clauses. There is provision for purchasing authorities in one part of the UK to share confidential pricing information with those in another part of the UK. There is also comparability so, if a manufacturer were to provide a better deal to another part of the UK, there is provision for comparable arrangements to be offered to other home countries. That is an important safeguard, so we are delighted to see it in the VPAS agreement.

That is in the process of being implemented, but we have some way to go to ensure that it is fully implemented. It needs to continue to be a priority to ensure that Scotland has a safeguard so that, if we make access decisions that are different from those made in England, we do not pay higher prices.

Dr Montgomery: I have little to add on what is currently happening, but I would like to pick up some of the points that Dr MacDonald made. When I carried out my review, I was absolutely of the view that the SMC was not broken. However, at that time, I was concerned by several examples of drugs that the SMC said that it was not recommending for use but that were still finding their way into use via alternative routes. My concern was that, because of those alternative routes, we were at risk of undermining the robustness of the SMC processes. Hence, some of my recommendations related to bringing in other considerations for the very small number—it is a tiny fraction of the SMC's overall workload—of drugs for very rare and unusual conditions.

Having read the papers that were submitted to the committee, my feeling is that the actions taken have given us a modified situation that has not compromised the SMC, but has given it more flexibility, which has improved the direct access to certain drugs, rather than people having to access them by a circuitous route.

The Convener: Thank you—that is helpful.

Sandra White: I thank the witnesses for their written submissions, which were interesting and helpful.

I want to ask about procurement in community pharmacies, which Matt Barclay and I have spoken about on many occasions. Some of the written submissions highlighted the increasing amount of time that community pharmacies are spending procuring medicines from wholesalers. It has been mentioned that more expensive branded drugs, such as those to treat hepatitis C, are still prescribed in hospitals, but are also prescribed in the community, yet the system is not reimbursing community pharmacists properly. According to some of the submissions, the procurement model means that community pharmacies are taking on a greater financial risk when procuring such products.

How can community pharmacy procurement be made more efficient? Is that possible or is it efficient enough? To be a wee bit more controversial, is there a role for NHS National Procurement to procure on behalf of community pharmacies? I will just throw that out there.

Matt Barclay: Your first question was about the amount of time spent by community pharmacy teams to get the medicines to patients in a timely manner. We are presented with prescriptions from prescribers, who are primarily GPs, although there are other prescribing healthcare professionals out there. We have a statutory obligation to get the prescription to the patient in a timely manner—that is part of our terms of service.

The wholesale model has changed. It was the first thing that got me politically active in the area, when I was a full-time practising pharmacist—I still practise occasionally at the weekend, just to keep my hand in. The first time I ever wrote to my local MP—it was a reserved issue at that time—was to ask about the first direct to pharmacy scheme, which was mentioned earlier. That probably piqued my interest to the point where I am sitting in front of you today talking about all this.

Unfortunately, procurement from multiple wholesalers is now part of the day job for community pharmacy teams. It is a reality that we have had to put up with. That is unfortunate, because it takes the pharmacy team and pharmacists away, more than they would like, from the job of providing face-to-face care. There are several circuitous routes that molecules and medicines can take to get to community pharmacies. Quite often, the pharmacy systems and quotas can take longer than we would like.

When the first scheme started in 2007, the genie was let out of the bottle and it is hard to put it back in. I look back on the good old days when I could just press a button on the pharmacy computer and the supplies would come in from the main wholesaler. However, those days are gone. Pharmacies deal with that and they do so efficiently. In my experience, patients are not waiting any longer for medicines.

The second point was about the nature and cost of the medicines that we are procuring. That is a challenge for community pharmacies. I have had discussions with Lindsay McClure at NHS National Procurement about ways in which that can be supported and about the wider NHS Scotland systems. Traditionally, pharmacies have paid pounds for packages, rather than tens of thousands of pounds. For pharmacies to procure certain medicines comes at great financial risk.

We want to procure them, for all the reasons that I have outlined.

For example, community pharmacies are part of the eradication strategy for hep C and if we were to eradicate hep C, that would be a tremendous success story for patients, NHS Scotland and community pharmacy as part of that. However, we need to be supported in that. Consideration needs to be given to how our reimbursement system works, because we tend to be paid two or three months in arrears through the NHS systems, whereas suppliers want 30-day terms from us. That means that we often have to pay for medicines before we are reimbursed. There are systems whereby we can ask health boards to pay up front for significant supplies, but those are quite clunky.

As I said, we are working with NHS Scotland, and we have had discussions with Lindsay McClure about the issue. Discussions are going on in the background. If we are to take on more risk and supply more of the medicines that we are talking about—ultimately, we want to supply such medicines through community pharmacy—we need to think about how the reimbursement system can work.

Lindsay McClure: We have been working with Community Pharmacy Scotland and a range of stakeholders, including the ABPI, to try to support the move of specialty medicines to community pharmacies. Moving such products brings up a range of challenges. One challenge is the supply chain; when a product costs £10,000 per pack, the normal distribution route might not be appropriate. There are also pricing challenges: we are talking about medicines that have traditionally been seen in secondary care, and we have had very confidential discounts to enable patient access, so we have had to put in place different systems with manufacturers to ensure correct reconciliation of pricing back to the NHS.

Cash flow is a big outstanding problem for community pharmacies that handle such medicines. Another part of my organisation, NHS National Services Scotland, that is responsible for prescription payment is trying to introduce faster payments, so proposals are under development in that regard. We have work to do, but things are going in the right direction.

On Sandra White's broader challenge about whether we should move to central procurement of medicines, my personal view is that we should not do so, because the system works well at the moment. As the committee heard earlier, there is evidence that the UK has among the lowest prices in Europe for generic medicines. The system works well and can achieve the same results as central tendering could achieve.

However, there can be use cases in which central tendering is an option worth considering. Back in 2016-17, we moved from community pharmacy procurement of flu vaccines to central procurement and distribution. A key reason for that was to do with security of supply. Vaccines are predominantly made through complex egg-based production methods, and every year something can and does go wrong. Having central procurement allowed us to split our business across multiple suppliers. The approach provided for more resilience and gave us central oversight—we knew where the vaccines were at any point in time—and control, because we had the ability to introduce quotas so that, if there was a delay in a vaccine coming from a manufacturer, we could ensure fair distribution across the country. Central tendering might be an option in specific use cases, but in general it is not.

The Convener: Is it your view that the price of medicines, in the broad sense, is competitive? Even in cases in which there is an argument that the price that is paid is higher than the value of the drug, is the price still as good as the market will deliver?

Lindsay McClure: Yes. In the round, that is what all the international evidence tells us.

Miles Briggs: My MSP colleagues will all have dealt with cases in health boards that are about access to non-routine medicines and tier 2 of the peer-approved clinical system. In my experience, there is a postcode lottery in Scotland when it comes to accessing such medicines. Do you agree?

Dr MacDonald: The purpose of the SMC is, first and foremost, to promote access to medicines for the people of Scotland, where we can, at a price that represents good value for money. Therefore, our existence in itself should to a large extent work against any notion of postcode prescribing. If SMC decisions are implemented, that really should help to prevent postcode prescribing.

PACS tier 2 was introduced to allow individual requests to access medicines, and it is important that there be such a process. Of course, PACS tier 2 operates outwith the SMC, so I cannot easily comment on how it is operated across the health boards.

Miles Briggs: Each board operates its own PACS tier 2—that is the point that I am making.

Dr MacDonald: It is possible that each board might apply the principles of PACS tier 2 differently. Ultimately, of course, there is a national review panel that can look at any challenges.

12:15

The Convener: Brian Montgomery wants to come in on that point.

Dr Montgomery: I hope that my comments will help to address the points that Miles Briggs raised. My experience relates mostly to the situation before the introduction of PACS tier 2, but the principles that we are trying to address remain the same.

The SMC makes population-based decisions. The reason behind the peer-approved clinical system—or the individual patient treatment request system, as it was known previously—was to give individuals an opportunity to find out whether there were individual circumstances over and above population considerations that might mean that they could access a medicine. The crucial word is "individual". The reality is that, although the system is often portrayed as postcode prescribing, health boards apply the same principles to a completely different set of individuals, and therefore we see differing consequences.

The aim of PACS tier 2 is to try to reduce the variation beyond the individuality, if I can put it that way. I believe that there is some evidence that it is doing that, but I have not yet seen the data to show just how effective it has been.

Miles Briggs: Do you know of any health boards that are outliers in the sense that they are presenting more appeals to the national appeals panel?

Dr MacDonald: I do not know the answer to that.

Miles Briggs: You can maybe have a look at that.

The issue of non-pharmaceutical alternatives was raised earlier. I am referring specifically to the idea that prescriptions should not always be the first option. We are all aware of the work being done on type 2 diabetes. How do you see that developing in the future? We have done some work around social prescribing and lifestyle coaching; those aspects could be data driven in order to capture the value of non-pharmaceutical interventions.

Matt Barclay: Yes—I certainly see social prescribing supporting the primary care review in respect of referral pathways, which I have probably discussed with the committee previously. The minute there is an element of social prescribing, there is probably more communication between other healthcare professionals, social groups and community groups. Such an approach can enable and support communication for patients and communities.

You mention the data, which is interesting; I know that earlier evidence panels have highlighted that aspect. Community Pharmacy Scotland, as an end point for many of the supplies on the medical side—and for social prescribing, perhaps not at the minute but certainly in the future—could be an excellent asset for capturing that data, because we give the medicines to patients. We would be interested in looking further at how our work can align with both medical intervention and social prescribing.

Dr MacDonald: The SMC's remit extends only to medicines, so other important issues—devices, social prescribing and so on—are not primarily our business. However, that question speaks a little to the previous discussion about VPAS implementation and the uptake of innovative medicines, which we heard a bit about from Alison Culpan and others in the earlier evidence session.

Our advice is permissive. When we approve a medicine, we are saying that it would appear to be a drug that could be used in Scotland in a cost-effective way. That approval does not mandate its use or imply any level of uptake. Prescribers should be aware of which medicines are available, and they may well choose other options as part and parcel of the principles of the NHS in Scotland. Some of the VPAS principles might work differently here in comparison with England, which perhaps relates to the comments from Miles Briggs on social prescribing and other issues.

Brian Whittle: I want to take that topic a little further.

I was interested to hear Matt Barclay talk about pharmacy possibly being a conduit into non-pharmaceutical interventions. Does he agree that the current system is set up for pharmaceutical interventions; that connectivity is lacking between pharmaceutical intervention and social prescribing or other non-pharmaceutical intervention; that in order to make that aspect effective, the current system has to change; and that that requires a serious intervention, involving the development of technology and communication? When we talk about technology, we are talking about the ability of healthcare professionals to communicate and understand.

For example, there is a link between obesity and musculoskeletal problems. As someone's weight reduces, we would imagine that the medication required would also reduce, but there is no system for doing that. Where are we in terms of getting to a position where a technological system enables that kind of intervention?

Matt Barclay: We are just at the start of the journey. As Brian Whittle has outlined, I do not think that we are anywhere near those two being aligned.

There is a public health element to the pharmacy contract, and we deal with smoking cessation and sexual health. Brian Whittle touched on other areas, such as weight management, that we could build on, and I see social prescribing ultimately forming part of that. To support it, communication needs to be more joined up, not just between healthcare professionals, but between local organisations within communities, third sector organisations, and social care providers. That would mean that, as part of a weight management consultation, for example, I as a front line practitioner could recommend that a patient should take a particular non-pharmacological course of action, alongside any pharmacological intervention decision that might be made elsewhere on the patient's journey.

That is the endpoint and the vision for joining social prescribing and traditional prescribing. That word illustrates the point perfectly: "traditional" medical interventions. It is a culture thing.

Dr Montgomery: I absolutely agree with the point about the system being skewed towards pharmaceutical interventions. In days gone by, the evidence of a successful consultation with a GP was the production of a prescription. Fortunately, we are moving, and have moved significantly, away from that. Social prescribing, and all that it implies, is potentially very exciting in terms of looking at non-pharmaceutical interventions.

My word of caution is that it comes back to the issue of data and metrics. How do we know that what we are offering—that what we are doing—has the desired effect?

In my "Review of Access to New Medicines", I made the point that the data that was available to me—in Scotland we have no shortage of data; what we lack is data that answers the questions that we want to ask of it—comprised good managerial information about the number of medicines that were being prescribed, dispensed, and perhaps even swallowed, but that what was missing was data about the impact that they were having, the benefits that patients were accruing or not, and information about when the medicines were being stopped because of side effects and things like that. We lack that total picture.

If we are going to head into social prescribing, as I think we should, we need to have a bit of a pause to make sure that we have the right metrics and the right data, to convince us that what we are offering, by way of that social prescribing, is having the desired effect and is actually a worthwhile alternative.

Alex Cole-Hamilton: Good morning to the panel. Before I ask my question, I just want to say something following on from Miles Briggs's questions about the PACS tier 2 system and the changes that have come in since that was introduced. Dr Montgomery, you said that you did not have sight of the data as to the efficacy of PACS tier 2 in relation to its predecessor, the individual patient treatment requests. For the record, it is vital that the committee sees any existing data so that we can compare those two systems. We were given assurances when PACS tier 2 came in, and it would be good to see how valid those assurances were.

I will now come on to my question. Some submissions to the committee state that the focus is usually on investing in new products, but disinvestment in certain products and activities needs to be more routinely discussed. That seems to be quite an apposite suggestion, given what we know about NHS inflation. Is there a role for any national body to decide what should no longer be used for routine prescribing in pharmacy?

Lindsay McClure: There is not a specific national focus at the moment, but there are different national groups, as well as local groups at health board or regional level that will focus within their specialist clinical areas. In health boards in particular, area drug and therapeutics committees have a really important role in maintaining formularies and ensuring that they indicate the most cost effective products to be prescribed at any point in time—given that the market is dynamic—and to ensure that support is available in health boards to transfer patients from a medicine that is less cost effective to one that is now more cost effective according to the evidence.

The Convener: Do those groups use that opportunity to disinvest or to dis-indicate, where appropriate?

Lindsay McClure: Biosimilars provide a really good example. The molecule is the same, but a lot of work is still involved in transferring from the established product to the new, more cost-effective biologic medicine. Although the focus might be local, many things can be done and are done nationally to support boards.

Matt Barclay: Lindsay McClure has explained well what happens at health boards regarding formularies and choices for clinicians who are prescribing for patients. Part of the "Achieving excellence in pharmaceutical care" strategy—alongside other policy documents such as "Realising Realistic Medicine"—is about having conversations with patients about what they actually require and what is right for them.

In what was formally known as the chronic medication service—now medicines care review—we are starting to consider how medication reviews can become routine in community pharmacy and other areas of the primary healthcare system, so that people can have those

conversations with patients. It might be that patients themselves will make a decision, after an informed discussion, not to take a medicine, perhaps for reasons of harm or side effects or perhaps because the medicine is just not doing what the patient wanted it to do. That is at an individual patient or clinician-to-patient level.

Dr Montgomery: Under the horizon, there has been an awful lot of what I would call casual or reactive disinvestment. In many instances, there has not been a planned strategic process. By that I mean that, not just with regard to pharmaceuticals but with regard to other tests, treatments and interventions, an approach has been taken to interventions that are thought to be of limited value. One thinks, for example, of tonsillectomy among children. That is the one that is always trotted out, but it is a good example: it is now very unusual for people to have their tonsils removed whereas, many years ago, it was done to very high numbers of children.

The problem is that, although practice has changed, having often been driven by the Scottish intercollegiate guidelines network, we have never sat down and worked out how much we were spending on a particular thing so that we could then release that money and put it somewhere else to spend on a different thing. Because of the challenges and demands that we are all aware of, any money that is liberated will quickly get absorbed someplace else to help manage a development or an overspend or whatever it happens to be. Disinvestment and reinvestment tends to be a casual, reactive process, rather than a planned exercise.

Dr MacDonald: I will make one or two brief points in relation to what Brian Montgomery has said. First, I will just emphasise the potential role of SIGN.

Secondly, when there is natural competition, as we have seen with hepatitis C medicines, that is a mechanism whereby the most cost-effective drugs will get used, and those that are not so cost effective will not get used.

The bigger question of the disinvestment of drugs can get quite complex. If a medicine has been on the market for a few years and further data comes in to show that it is unacceptably toxic, it is straightforward to propose to disinvest. If the efficacy data has not been borne out in real life, the licence for a medicine could be withdrawn.

That is relatively easy, but let us say that you are looking at a medicine several years later and you find that it works, but not as well as you thought that it did. It could still be used but it might not command the same price. That could be a much bigger question to deal with, and we will probably have to address it at some point, as our interim acceptance option becomes more mature.

12:30

Alex Cole-Hamilton: I get from what Dr MacDonald and Dr Montgomery have said that there is no process of planned obsolescence in pharmaceuticals, or any kind of therapy for that matter. Instead, there is a kind of incremental shift over, and there is often a legacy prescription of the old drug. In the case of diseases or conditions where a wonder drug that is much better than any of its predecessors can come in, there is no process for wholesale migration to the wonder drug and the obsolescence of its predecessor.

Dr MacDonald: A wonder drug usually comes at significant additional cost, and the original drug might still have a role because it is effective. Forgive me for going back to what I understand well. Methotrexate remains the biggest drug for arthritis, and it has been around for 60 years. Anti-tumour necrosis factor drugs, which were introduced in 2002 and subsequently, are better, but they are not 200 times better. Sometimes there is still a role for the existing drug.

Having said that, our job is to say how much of a wonder drug something is, although I am not particularly fond of the term. However, I guess that what we do at the SMC is to say, “This is this much better and it costs this much more.” That can be acceptable in some but not all circumstances.

Mr Cole-Hamilton, your basic point is right that the obsolescence of drugs is sometimes not completely planned—some of it is ad hoc. You made a reasonable point but, like I say, the introduction of a new medicine may not necessarily render the existing therapeutics obsolete.

Brian Montgomery: I have direct experience of a couple of what we would have called therapeutic substitutions, which is when we look at the treatments that a group of patients are on and consider what the alternatives might be. That was driven by cost effectiveness. We were able to look at statins in one of the health boards and see that, in the main, patients there seemed to be being prescribed a very expensive branded statin, and yet there was no demonstrable benefit compared to the cheaper statins used by other health boards. With their co-operation and permission, patients were moved from the expensive statin to one that was available generically, releasing something significantly north of £1 million for reinvestment elsewhere in the health board’s budget. We did it to a lesser degree with a couple of other medicines. However, those opportunities

are rare, and they are generally about when you can use a substitution towards a generic medicine.

The issue that we run up against that tends to cancel that out is the one that Alan MacDonald has highlighted, which is that a new drug comes along that offers benefits over and above existing treatments, and you find that it either has to be used in addition to or instead of its predecessor, at a greater price than its predecessor. That is not often as fruitful at liberating funds as in the statins example.

Brian Whittle: I want to labour a point, if I may. An effective disinvestment strategy would require the ability to gather and access appropriate data. The thread that seems to have been running through all of this, and many other investigations, is the lack of ability to gather and access appropriate data. Is that a correct assumption on disinvestment?

Lindsay McClure: Better outcomes data would definitely help us once a product is on the market. We might have based the initial market access decision on clinical trials. Patients in clinical trials are highly selective, so they might not be representative of the average Scottish population.

Having that real-world evidence over time could greatly help us to evaluate what is the most cost effective, once there is experience of using the medicine. However, to do that, we need much more efficient IT systems to collect outcomes data. As we have already heard, there are some great initiatives, such as the cancer medicines optimisation programme, but it is still early days and there is more work to be done.

Matt Barclay: The data is there to do the type of thing that Brian Montgomery suggested around generic substitution. That does happen in primary care, with decisions being made at health board level about moving from a branded product or a certain generic product to another one. That does happen and it is communicated to community pharmacies so that we can adapt our stockholding and so on, and have an awareness of what is coming down the line. That generally happens in a relatively joined-up way.

A small, additional point is that we in pharmacy do not have the authority to generically substitute. It sits under reserved legislation, but it is something that pharmacists, as experts on medicines, could embrace, albeit that it happens relatively rarely nowadays, as Brian Montgomery rightly pointed out. However, we said in our written submission that pharmacists could do that in the future.

Miles Briggs: In terms of the discussion that we have had on effectiveness and outcomes, where would you benchmark the methadone programme that we have in Scotland when we look at it through that lens?

Matt Barclay: I was not expecting that issue to come up in the meeting. However, we have a statutory obligation to supply the product and we interact on a daily basis with those patients, who are often also the hep C patients that we have been talking about. The evidence base for the economic argument around methadone is well recognised at an international level. There is a socioeconomic argument about what the situation would be for patients if they were not on that therapy, which includes their quality of life.

The picture is complex, but we are working in health boards and, to a degree, nationally to see what additionality we can bring to services to support patients in that area. It is not just about supply. For example, in my practice, we have done things with patients' lifestyles, oral hygiene, needle exchange and all sorts to support those patients. In my opinion, success is based on some of those factors.

Emma Harper: There is an issue about disinvestment or changing how we will invest. For example, warfarin use requires frequent blood testing, so there are additional costs. New drugs are coming along that might replace warfarin and tests of change are currently being done that will look at how to switch patients off meds and what benefits that has.

Another issue involves a question for Matt Barclay. The panel will have heard my previous question about how paracetamol can be bought for 20p in the high street. Prices vary because of how the Scottish drugs tariff is negotiated with community pharmacists, so the NHS will pay community pharmacies more for drugs such as paracetamol. How do we reconcile that or make changes to it?

Matt Barclay: I will take up the second point. The issue is the drug tariff basket that we have talked about. As a clinician, I know that paracetamol has a strong evidence base as an analgesia for mild to moderate pain. The use and cost of paracetamol comes primarily from patients with chronic pain conditions. If we took that product away, there is the risk that we would move up the World Health Organization pain ladder. Next to paracetamol is ibuprofen, which is also an effective analgesia, but it has a different safety profile. Beyond that, we go on to low-dose opioids and then right up the chain.

Self-care by the public primarily involves treating mild to moderate pain with paracetamol or other analgesia, which we see in every supermarket and petrol station. If I have a cough or cold, I will buy it myself when I am in a supermarket. However, with regard to patients who need analgesia for

significant acute conditions or chronic pain, I would focus more on the overall value than the individual cost of the medicine, although I appreciate that the differences in cost could be significant.

Brian Montgomery: To pick up on the example of warfarin, it has often been suggested that there would be an opportunity to make savings if everyone who is currently on warfarin was put on to one of the newer agents, as that would remove the requirement for blood tests and all that goes with it. That is a possible answer, but in fact no longer doing blood tests would remove resource only if employees were lost—in other words, if either the people or the laboratories doing those blood tests were no longer required. Neither of those scenarios is going to happen, because the blood tests form only a small part of the activity of a practice nurse or a local haematology laboratory.

The currency that we really need is capacity—if we were to take that route, it would release some capacity for additional nurse appointments or a bit more space in the lab to carry out more tests or do current tests in a different timescale. However, if we are looking at the potential for disinvestment and reinvestment, we have to be a bit more sophisticated. We cannot just say that we are no longer doing something and we will therefore save a certain amount of money that will come out of the system. Increasingly, our currency will involve capacity and how we use it. Let us face it: capacity is what we need to help us address some of our challenges, such as waiting times.

David Torrance: I have a question for Dr MacDonald. Some of the written submissions to the committee raised questions about how well the SMC's appraisal process is currently working and whether it is in a position to deal with advances in medicines. Can you go into more detail about what you are doing to prepare for a new generation of medicines?

Dr MacDonald: I am sorry—can you briefly repeat the question? I did not catch the whole thing.

David Torrance: Some of the written submissions say that the SMC's processes for new medicines are not up to scratch. Can you go into more detail about what you are doing with regard to advances in medicines?

Dr MacDonald: As per my previous answer, I take the opportunity to reject any suggestion that the process is any less robust overall. In many ways, our process is the same process that we implemented in 2002, taking into account the 2013 and 2016 changes. The process has changed to allow greater access to medicines for cancer and rare conditions, which was a specific policy intent. As I mentioned, the first point that Dr Montgomery's review made was that we had done that.

We introduced a lot of additional processes to help us get to that point, many of which have included patient and public involvement. It is difficult to identify the exact extent to which those processes have contributed to a higher acceptance rate, but they have been positive in themselves by bringing patient and public voices closer to the process.

We would like to think that the changes since 2013, and the changes in 2016 that Brian Montgomery outlined, have enhanced the process. If submissions to the committee have highlighted weaknesses in particular areas, I will be happy to address them, either now or after the meeting. We feel that the changes that we have introduced since 2013 have met the policy intent and enhanced the process overall, and we believe that the changes that we are introducing now will likewise continue to help us evolve in a positive way. As I said, I am more than happy to pick up on any specific point with regard to where respondents to the committee's call for evidence feel that there has been a weakening.

David Torrance: Will Scotland also be required to appraise every new medicine as a result of the voluntary price regulation scheme, and, if not, what will the status of NICE appraisals in Scotland be?

12:45

Dr MacDonald: The VPAS arrangements have, in fact, brought NICE processes closer to SMC processes. With one or two exceptions, which we do not need to go into, it has been—and remains—our process to look at all new branded medicines. We have no intention of changing that process, but, in order to make sure that we are responding to the needs of the health service, we might produce different types of advice and different products for certain types of medicines.

I said that, with VPAS, NICE processes are more closely aligned with what we have been doing. However, with changes here and with NICE, processes sometimes align and sometimes unalign. It is important that we keep a clear focus on making sure that our processes best meet the needs of the NHS in Scotland.

David Stewart: Earlier, Dr Montgomery talked about data in Scotland. If I understood him correctly, he said that there is enough data out there, but it needs to be a bit more appropriate.

How important is it to get prescribing data in hospitals right? I would certainly welcome any feedback about the HEPMA—hospital electronic prescribing and medicines administration—project.

Perhaps someone can think of a slightly trendier title. Nevertheless, I am interested in information around prescribing data in hospitals.

Dr Montgomery: I have nothing to offer on that, I am afraid.

The Convener: Are there any volunteers for that question?

David Stewart: If not, I will have to ask about Brexit again, and you do not want that.

The Convener: You have had your warning.

Dr Montgomery: I will respond to Mr Whittle's comment. In all cases, more data is helpful, and more robust data is more helpful. That is true in every bit of the system that we are looking at. That is a statement of the obvious, to some extent.

Matt Barclay: I agree. Data is really important for the safe transfer of information between secondary care, primary care and community pharmacy, and for things such as medicines reconciliation. Getting the HEPMA programme right in secondary care is also crucial to improving the safety element in primary care.

Dr Montgomery: Given the opportunity that HEPMA might be about to give us, my only encouragement would be that we do not fall into the trap of seeing it as a system only for administering medicines. It also has to be about capturing clinical outcome data, so that we know what benefits we are getting from those medicines.

David Stewart: Perhaps that is a question for the cabinet secretary.

George Adam: I will ask about pricing models and the cost of drugs in general. You will guess where I am coming from because I will talk about multiple sclerosis in particular, but also the fact that there are branded and generic drugs.

I spoke earlier about the neurological consultant who did a presentation about how generic drugs are used in Scandinavia, and asked why we cannot use them here. Those drugs work in a similar way to some of the branded products that we pay for here, and they cost a lot less. Are we open to that as we consider pricing and value for the NHS in future? Logic dictates that, if you can deal with something at less expense, you will be able to help more people in general. Is there a way that we can consider that?

In addition, you guys have flung biosimilars into the discussion and added that to my further reading material—that looks like another interesting side of the argument.

Lindsay McClure: When decisions are made about a medicine, they do not consider whether it is a brand or a generic; they consider the price and clinical effect of the medicine, and make a decision in the round.

George Adam might be referring to the handful of cases where there is a licensed medicine on the UK market, and evidence that another medicine has comparable effectiveness, but it is not licensed for use in that indication. I am aware of one example in multiple sclerosis. However, the most high-profile example at the moment is probably in macular degeneration, where there are two in-patent medicines on the market—Eylea and Lucentis—and another medicine, Avastin, which is a cancer medicine and not licensed for macular degeneration, although the evidence suggests that there is comparable clinical effectiveness. In that particular case, there was a movement in the north-east of England to prescribe Avastin, even though it was not licensed for that particular indication. The subsequent legal challenge is going through the courts, and everybody is watching the case very carefully, because it could be a game changer in that particular scenario.

Dr Montgomery: To amplify that slightly, there is also the issue that, as a doctor, I am required by the General Medical Council to prescribe the licensed product, not the unlicensed ones. As such, even if I think that something is—basically—the same medicine in a differently-coloured box with the same effect, if it does not have the licence and there is a licensed alternative available, I cannot prescribe it.

George Adam: Unsurprisingly, I am the convener of the cross-party group on MS; my wife just does not let me away from these things. Talking about drugs in general and how the SMC goes through its process, one of the drugs that promised a lot, but which has failed the SMC on a number of occasions, is Ampyra. As I said earlier, even if my wife could just walk down that corridor, that would be a benefit—and it claimed that it could do that. That goes back to what Dr MacDonald was saying, in that if you have that debate with me, as the husband of someone who has MS, I want that to happen and I want to see her do that. However, as a politician, I am looking at your submission and seeing that Ampyra did not do what it promised.

The debate in the media tends to be about why people are not getting a drug, which puts you in an unfortunate position and makes it difficult to have this debate. I use that one example; I do not doubt that you could tell me of numerous others.

Dr MacDonald: That partly relates to my previous comment about how our job is to look at a medicine and say, objectively, how much better it is. I think that a comment was made earlier about the quality of evidence from the European Medicines Agency, and it is true that some drugs come to us with less evidence than before.

However, if a medicine that is licensed by the EMA comes to us, we have to assume that it has been shown that the benefits outweigh the risks. However, our job is different; it is to say whether the benefits justify the cost.

We have to accept that any drug that we consider does some good; however, in some circumstances, the benefits may be modest compared to what is there. It is our job to say that, which is the bit that is often missing from public discourse. It is not about saying, "This is a wonder drug"—again, that is not our language—but about saying that something is a real advance, or that something is a modest advance. A modest advance might still get acceptance if the pricing reflects it. If we say that we are not sure about the benefits of a drug, but that there might be some, and they might be useful, we can still approve it if the pricing—or, I should say, reimbursement—reflects that.

In the context of MS, George Adam is correct that we have looked at a number of drugs for relapsing remitting MS where it has been possible to say yes. In the context of progressive MS, where—arguably—there is a greater unmet need, medicines in that space have, perhaps, been less positive. However, as I said, if we have a medicine that seems to offer even a modest benefit, we can still approve it if the cost reflects that.

George Adam: Just for the record, when you consider the costs, what do you take into account? Are research costs that might be getting bumped on by the pharmaceutical company part of it?

Dr MacDonald: We look at the list price with any patient access scheme that is offered; that is the cost of the medicine that we consider. We consider the overall cost of the new medicine against what was there before. What we do at the moment has costs, and there are costs of the new medicine. For example, with warfarin, we would bring in some of the service costs of internationalised normal ratio monitoring. In our economic analysis, the cost of the medicine is the list price minus any patient access scheme. Of course, one of the best ways of reducing uncertainties is for companies to give a bigger patient access scheme. We look at specific costs, but we look at overall service costs as well, and we compare that to the cost of what is currently in place in NHS Scotland.

The Convener: I thank the witnesses. I know that we will return to issues that are of interest to community pharmacy, as well as to other areas, later in the inquiry. That was a very helpful evidence session—thank you once again. As I said to the earlier panels, if there is anything additional that you would like to draw to the committee's attention after you leave here today, simply let us know.

12:54

Meeting continued in private until 12:56.

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