European Affairs Committee

Protocol on Ireland/Northern Ireland Sub-Committee

Corrected oral evidence: Impact of the protocol on the provision of medicines

Wednesday 20 October 2021

4 pm

Watch the meeting

Members present: Lord Jay of Ewelme (The Chair); Lord Caine; Lord Dodds of Duncairn; Lord Empey; Baroness Goudie; Lord Hain; Lord Hannan of Kingsclere; Baroness O'Loan; Baroness Ritchie of Downpatrick; Lord Thomas of Gresford.

Evidence Session No. 1 Heard in Public Questions 1 - 15

Witnesses

I: Michelle Riddalls, Chief Executive, PAGB; Martin Sawer, Executive Director, Healthcare Distribution Association; Paul Williams, Senior Director Corporate Affairs, Teva UK.

Examination of witnesses

Michelle Riddalls, Martin Sawer and Paul Williams.

Q1 **The Chair:** Welcome to all three of you. You are extremely welcome to this hearing to give evidence to us today. This is the first in-person meeting of the committee on the Northern Ireland protocol, so we are particularly pleased to have you here. We are getting to know each other, and it is very good to be able to get to know you. We begin today detailed scrutiny of the Government's July command paper on the protocol, together with the EU's proposals as set out in the series of documents that were published last week.

We begin with a dedicated session on the implication of the protocol for the provision of medicines to Northern Ireland, which is an issue of concern, I think we can say, to all in Northern Ireland and, therefore, a very important subject for us as well as for the people in Northern Ireland. We have three distinguished representatives of the pharmaceutical industry giving evidence to us today, and, as I say, you

are all very welcome.

I will ask each of you to introduce yourselves the first time you speak. Today's meeting is an on-the-record evidence session, which means that it is being broadcast and a transcript will be taken for subsequent publication. The transcript will be sent to you shortly after this session just for correction of any factual points that we have got wrong in the course of the transcription. Can I finally ask all members to declare any relevant interests the first time they speak? That is by way of introduction, and perhaps I could ask Lord Caine to ask the first question.

Q2 **Lord Caine:** Welcome to each of our witnesses. It is very good to have you here this afternoon. If I may, I will open the bowling, so to speak, with a fairly general question about the current situation in Northern Ireland, and ask each of you in turn to explain or summarise the cost and operational impact of Brexit and the protocol on the industry model of medicine supply to Northern Ireland.

As a follow-up, could you outline the key pieces of EU legislation that continue to apply to the pharmaceutical industry in Northern Ireland as a result of the protocol? What is the practical impact of their application to Northern Ireland but not to the rest of the United Kingdom?

The Chair: I should have said right at the very beginning that we will aim to finish at 5.45 pm, if that is okay with you. We want to leave time for questions 8 and 9, which are rather important questions towards the end. I am sorry to interrupt.

Lord Caine: No, it is quite all right. Which of you wishes to bat first?

Michelle Riddalls: Good afternoon. I am the CEO of PAGB, which is the consumer healthcare association, and we represent manufacturers of branded over-the-counter medicines. Those are the kind of medicines that are sold in pharmacies with a pharmacist present or at shops, supermarkets and petrol stations.

To answer your question, it is worth looking at what Brexit has done to the UK and why it is then different for Northern Ireland. Brexit has meant that the UK as a whole has been seen as a third country outside the EU. There are very specific requirements under directive 2001/83/EC for importing medicines into the EU. One key area of importance is that it requires a medicine to be retested in a certified laboratory when it enters the EU. It means that the qualified person listed on a manufacturer's import licence needs to then check that that retesting has been done, look at all the administrative information behind that and rerelease that product.

That has already all been done in the country of the manufacturer, so this is a repeat test that has been happening. The company also needs to have a valid manufacturer's import licence. Prior to Brexit, medicines would have been distributed in the EU and UK without having to do any of that. They would have just gone in between the countries. That was

one reason why industry was so keen on a mutual recognition agreement that would prevent this duplicative work.

The Northern Ireland protocol, because GB is seen as a third country and the EU legislation is still relevant in Northern Ireland, has basically meant that we cannot distribute to Northern Ireland in the way we used to. The requirements that I have just mentioned kick in, and so it becomes an import into Northern Ireland. Those requirements are for all medicines, so they will all need to be retested and rereleased.

For over-the-counter medicines such as those I look after, there is an additional nuance that causes issues, in that retailers are the people selling these products. As I mentioned, they are sold in pharmacies or by shops and bought in petrol stations. The way the supply chain works generally for this type of medicines is that companies such as Tesco or Sainsbury's will buy the product here in Great Britain and then distribute it to Northern Ireland on demand. When they hear that they need product, they distribute it over there along with the rest of the products that will the stores over in Northern Ireland.

Of course, Tesco and Sainsbury's do not have the licence for my members. They are not the ones that have manufactured it. They do not own that licence, so it is impossible for them to retest or rerelease that product. Even if they could do that, there is no storage. It is going against the whole supply chain. The import requirements, retesting and rereleasing are fundamental issues for us.

Lord Caine: What kind of additional cost does that add to your business?

Michelle Riddalls: I do not have a specific cost figure, but it is duplicative.

Lord Caine: It sounds like it could be significant.

Michelle Riddalls: It would be very significant, yes, but in the scenario we are looking at companies cannot even get to do this within the logistical supply chain framework.

Martin Sawer: I am the executive director, as you know, of the Healthcare Distribution Association. We represent the middle part of the supply chain, the backbone of medicine supply. We buy products from manufacturers—OTC, generic or the branded sector—and we store them in warehouses and then distribute them on a twice-daily basis to all 14,500 pharmacies across the UK, all 400 hospitals and about 2,000 dispensing doctors 11 times a week. It is an intensive integrated distribution system.

To your question, Lord Caine, because of Brexit the manufacturing side of supply has changed somewhat. I know Paul and Michelle will describe that, so I do not really want to go into it. The supply within the UK, as our members operate, has not really changed much yet because of the unilateral recognition of licensing for two years since we left the EU, where we recognise the EU's legislation as it affects distribution. Good

distribution practice, which our members adhere to all the time, is an EU standard that the MHRA recognises and implements with us.

There are other pieces of EU legislation that are relevant to Northern Ireland specifically, which are challenges. We are very pleased about the current extended standstill that the UK Government announced only a few weeks ago. The falsified medicines directive, because we left the EU, is no longer applicable to the three countries England, Scotland and Wales, but is still applicable to Northern Ireland. Under the protocol, it is due to be applicable under the terms of the EU's latest offer.

That is a big challenge for our members, and I am happy to go into much more detail about that. That is a piece of European legislation that, because of the Northern Ireland protocol, is very costly for manufacturers but also impossible for us to administer. Perhaps I can briefly describe how our hub-and-spoke system works. Our major members have large warehouses around the country and they stock 20,000 to 25,000 single stockkeeping units, so a particular pack of medicine of a particular strength is one line. There are 25,000 of those that we typically use in the UK.

In Northern Ireland, physically, we keep only about 20% of those, which are the ones that the Northern Ireland pharmacies and hospitals need straightaway, that day sometimes. The rest are slower moving, so we keep them in a back stockroom in GB and ship them over daily, on two ferries from Scotland to Larne, based on orders from hospitals and pharmacies.

The population of Northern Ireland is the same as the population of Kent. We have lots of warehouses, as you can imagine, around the M25, and they are the large ones. In Kent, we have some smaller warehouses that supply the Kent hospitals immediately with medicines as they need them. If they need some overnight or they need to stock up a hospital, they will send a slower-moving line—there could be 16,000 lines held at the big warehouses—and stock those premises in Kent to keep them topped up because the demand is so small.

That is the problem with Northern Ireland. We have OTCs, branded medicines, generics and medicines at garages. A lot of them are kept in GB and they have been moving frictionlessly to Northern Ireland. The problem is that there is now a border in the Irish Sea for medicines because of the regulations that the EU will want to have on medicines if the Northern Ireland protocol assumes the form it does at the moment. We welcome the UK Government's command paper to try to take medicines out of the Northern Ireland protocol, because it is complicated.

In terms of cost, the HMRC declarations that our members have been having to fill in to get into Northern Ireland have cost, in the first half of this year, about £5 million. I am sure you are aware of the forthcoming SPS checks, which have been moved down the timetable until next year. They are sanitary checks for feedstuffs, particularly liquid foods needed for hospitals and patients at home. They are all custom made and a lot of

them come from Great Britain. Only the very largest companies, maybe one or two, can afford to do those SPS veterinary checks, so a lot of the wholesalers and distributors will pull out of supplying Northern Ireland.

We have always been doing NHS medicines. We supply 92% and we have been doing this since the NHS was created, so it is part of the NHS. We are subject to the NHS pricing and that side of things, just to give you context.

Paul Williams: Good afternoon, everyone. I am senior director corporate affairs for Teva UK Ltd. Teva is a medicines manufacturer. It manufactures branded, generic and over-the-counter medicines. We believe that we are the largest supplier, not by value but by volume, of prescription medicines in the UK, in Northern Ireland and, as it happens, in Ireland. We are not here to represent an association. We are here to represent the largest-volume manufacturer of prescription medicines.

Lord Caine asked what legislation is affecting us. From a manufacturer's perspective, the legislation that is affecting us relates to the regulation of medicines, and specifically the granting and maintenance of product licences. Ms Riddalls talked about Great Britain becoming a third country while Northern Ireland stays. That is absolutely right. Previously, we have always had one product licence that is a marketing authorisation, or MA, for the whole of the UK. The practical implication of the protocol once the standstill period ends is that we will have to have an MA for Great Britain and a separate MA for Northern Ireland.

I have to hand some data on the cost of this. For a generic medicine, the initial fees for application are £17,330 for the first strength and £6,350 for a subsequent strength. If you have a prescription medicine that is in three strengths—20 milligrams, 40 milligrams and 100 milligrams—you apply for a licence, which is about £30,000 for the first year. In subsequent years, the fees vary between £2,428 and £9,710 for each strength, so for a three-strength medicine that is potentially anything between £7,500 and £29,000.

I have a couple of examples from our generic portfolio. We supply a medicine to Northern Ireland that is used to treat depression and migraines and helps to control severe pain. In 2020, we sold approximately 120,000 packs of that medicine in Northern Ireland. We made a gross margin, not net margin, on that product of £4,700. Straightaway, you can imagine that that medicine is no longer viable in Northern Ireland.

We have a large number of products that, at the moment, are profitable in a small degree because they benefit from the volume that we have across the whole of the UK. If we have to have a separate market authorisation for Northern Ireland, you can imagine that for us, and indeed for a lot of other manufacturers, it just does not work; the product is unviable. If you multiplied that by the hundreds of products in our portfolio, and we have over 600 products in our portfolio, suddenly you are starting to present very great difficulties. When the standstill period

ends, we are very concerned about the viability of these everyday generic medications in Northern Ireland.

Lord Caine: Clearly, there is much to be concerned about. Your answers have been an excellent introduction to this session. Thank you very much.

The Chair: Mr Williams, you gave some very interesting figures there. Would it be possible to write to us setting out some of them? It would be very helpful for us to have them in writing rather than in oral evidence.

Paul Williams: The regulatory fees are in the public domain. We will write to the committee confirming those numbers later. I am pleased to say that I have a subject matter expert in regulatory affairs behind me, who I am sure is making a note of doing that straightaway. As you can imagine, there is commercial confidentiality about our products, which is why I did not specify which product we are talking about, but I did want to talk about how this makes a difference for patients.

Those 120,000 packs represent 120,000 times when someone depends on a medicine from us. I would be happy to write to the committee with more detail, but I hope the committee will understand that there are commercial confidentiality issues in what is a very competitive generic medicines market.

The Chair: We understand that. Thank you very much indeed.

Q3 **Lord Hain:** Thanks again for joining us. Martin, you mentioned a figure of £5 million, figure for the paperwork or whatever. What is that comparatively against total turnover, so that we can get a sense of its scale?

Martin Sawer: A lot of that extra cost is IT and manpower, trying to develop systems to engage with HMRC and the declarations. We have to remember that the sector's turnover is based on the medicines we supply. The companies make a very small margin, but the turnover of the sector is several billion as a whole, because it is medicines that we are buying and then selling on to pharmacies, hospitals and doctors. It might not be a big proportion of that, but it is certainly a large figure for Northern Ireland, which is just 1.8 million people, in comparison to the rest of the UK. Imagine what that figure might be if we had to declare and do everything similarly for the rest of the UK.

Q4 **Lord Hain:** If it is possible, in the written material that the Chair has asked you to send us, to give the £5 million in relation to Northern Ireland's part of that several billion, that would be really helpful.

Coming on to my specific question, I will begin with Michelle. How significant is the scale and risk of product withdrawal from Northern Ireland? Which product lines have been most affected?

Michelle Riddalls: It is very significant. We did a survey of our members back in February this year, when they were analysing their portfolios. The

feedback at that time was that between 75% and 98% of OTC medicine products could be discontinued at the end of this standstill period, so a significant amount.

Prior to coming along today, I did a survey, again, with members. Obviously, the standstill period has now been extended and we have two options, which I know we will talk about. We have had feedback that that has gone down now and companies have managed to work through some of it, but they had anticipated about 52% of medicines still being discontinued. Not all our members responded, so it is an average of what came in, but it was up to 52%, so significant.

Lord Hain: Sorry. To understand that, it could be 98% or it could be 52%, or am I not clear?

Michelle Riddalls: At the beginning of the year when they were doing the analysis and trying to work through how it could work, they were looking at it being between 75% and 98%. As the year has progressed, new solutions have come in. We now have the standstill, so companies have been able to adjust slightly and work through some of the logistical piece that I mentioned to you. It is now looking more like around half—52%—could be discontinued.

Although I have not given you a monetary cost, the cost to the patient or consumer out there is that potentially they will not be able to go into a shop and buy the products that they can use to self-care and treat their minor illnesses at home. We are concerned that that means they could end up going to GPs or A&E because they are not getting the medicines they need in the normal ways they would, such as going to a pharmacy or a shop to buy them.

Lord Hain: In that 52%, roughly half of all the product lines, which type of products would there be?

Michelle Riddalls: We do not have that level of detail. When we got the first feedback earlier this year, we were very concerned that whole segments could be wiped out and that you could lose whole categories because the number was so high. We are seeing that some companies, especially the smaller companies—my colleagues have alluded to cost and impact—cannot always manage to get product over there.

Some of the larger companies that perhaps have more resource behind them could try to reroute and put money behind it to keep some of those products on the market, so we do not think that necessarily every SKU in a category will go, but there may be only one pack size of that left, you may only get it in certain shops and things like that. That still lessens choice and is not the same as what is out there at the moment.

Lord Hain: That is very helpful. Again, if you were able to write to us, being more specific about which ones fall on which side of the 50%, that would be really helpful.

The Chair: I am afraid we are asking you collectively for rather a lot of

extra information, but it is just a sign of how important the subject is and how the facts and figures that underlie it are really important when we come to write our report. Thank you very much for that.

Lord Hain: Maybe you can claim overtime from Parliament. Paul, could you respond to the same question, please?

Paul Williams: We did an assessment in the summer this year that looked at the regulatory cost that I talked about. It also looked at some of the other extra costs that would be borne under the new requirements. For example, as Martin will know better than I do, if you have to have a separate licence, that means that you have to have a separate stockkeeping unit—an SKU. That means a separate warehouse location, which increases warehousing logistic costs. If you are making a batch for a very small market, you are also likely to be getting much bigger write-offs at the end of its life when you simply have not used enough of the batch.

We put all that into a pot and assessed the viability of our full portfolio—610 products at the time. Initially, we excluded any medicine where we are exclusive or almost so, because if there is no alternative to the medicine we provide, the patient must be supplied come what may. We also excluded medicines where there would be patient safety concerns about switching. A specific example is epilepsy medicine. Even if you take a generic version of an epilepsy medicine, it is very inadvisable to swap to another generic version of that same epilepsy medicine. We also removed from the assessment medicines that fell into that category.

We also removed from the assessment medicines that, even after this extra cost and logistics burden, would still be viable and which we would still be able to afford to provide. When we had done all that, we still found ourselves with a significant number, over 250 medicines, which it simply does not make economic sense to supply to Northern Ireland.

That prompted us to write a letter to the Secretary of State for Health at the beginning of July—it is probably the hardest letter I have ever had to write in my 15 years in the pharmaceutical industry—telling him that these medicines could be at risk. It was a very difficult letter for us to write because our mission is to provide medicine to patients. That is what we do. These are not numbers, these are real conditions suffered by real patients, but if we cannot be viable it threatens our ability to supply all patients with medicine, not just those in Northern Ireland. We wrote, "We have over 250 medicines that could be at risk here". We received a reply from Lord Bethell, who assured us that everything is being done to rectify this, but this worries us greatly.

Lord Hain: Are some of those conditions life-threatening?

Paul Williams: I am not going to share the list of individual products with the committee, I am afraid, because of commercial confidentiality, but they include treatments for diabetes, erectile dysfunction, cardiovascular conditions and osteoporosis. I believe there might even be

one product that is used as part of HIV therapies. I will confirm that later. These are prescription medicines across a very wide range of conditions.

Lord Hain: They are for pretty serious conditions.

Paul Williams: Yes, they are. We have always made sure that if we are the only supplier of a medicine, come what may we will not discontinue that medicine in Northern Ireland. All the 250-odd products are medicines that are currently also supplied by someone else. However, we are not the only people who will be looking at this list of medicines in our industry.

Lord Hain: Could they be supplied across the border from the Republic?

Paul Williams: The scope for that is limited. It is a very good question. We supply something like 600 products in Northern Ireland. I can talk only about my own business. We supply about 300 in the Republic of Ireland, so the portfolio is smaller in Ireland. In addition, for licensing reasons and even reasons of habit of doctors in Ireland, the overlap of licences between the two is less than 100.

Lord Hain: I may be straying on to another question, apologies.

Paul Williams: Not at all. The straight answer to a straight question is that the scope is limited.

Martin Sawer: In a general sense, our members' manufacturing partners are talking to them all the time now about the possibilities of discontinuations. The uncertainty that has been going on for months over the Northern Ireland protocol is causing businesses to have to try to make decisions. As you can imagine, that is very hard, as Paul has just described.

All companies, where the product is similar to the type that Paul and Michelle have described—the larger-volume, cheaper and sometimes replicable medicines—are looking at the viability of that, because the competition is so intense. Whatever the Northern Ireland protocol implies, the cost of trying to put on licensing or FMD requirements means that they have to make decisions before the Northern Ireland protocol issue is resolved.

You are probably aware that, in the public domain, until the standstill was announced a few weeks ago, nearly 1,000 lines of medicines that were officially notified would have been discontinued from January next year. I know the Department of Health is talking to all the companies that made those communications, because you have to give six months' notice to discontinue a licensed medicine.

The Department of Health is working hard to reduce that number, but I am aware that there are still several hundred on that list in spite of the standstill. That is my understanding. The uncertainty is creating its own costs. Companies, especially smaller ones, have to make decisions, and they may well have made irrevocable decisions, because notice periods

for changing runs of medicines can run into months if not years. The uncertainty is the problem.

We are also finding companies setting up runs to make medicines just for GB, which would exclude Northern Ireland anyway. Medicines have already started to be manufactured like that, because companies know that the MHRA can issue GB licences, but we have not yet resolved what is happening in Northern Ireland. That, again, is a challenge. We are making sure that we distribute all the medicines we can get to Northern Ireland in the interests of patient safety. Some medicines are already in Northern Ireland with GB licences on, and technically under EU law they are illegal, but we are making sure that patients still get those.

We have had reports from community pharmacies in Northern Ireland that they are getting more concerned about supplies of medicines. Several small manufacturers or wholesalers are telling them that it is not worth the candle any more. The uncertainty is stopping them supplying Northern Ireland, and they will have to concentrate on something else because they do not know where the future will be.

Q5 **Lord Hain:** I have taken quite a lot of time. If you could be as succinct as possible on this, please, how significant is the risk of medicines entering the single market from Northern Ireland?

Martin Sawer: I can quickly answer that. It is not really significant, we do not feel. If the FMD system has to be in place in Northern Ireland, that can have a device in it to make sure that a Northern Ireland alert is activated. We think that the best way to stop any leakage would be to remove FMD from Northern Ireland. That means that the packs in Northern Ireland would not be able to go to the EU because they do not have the unique identifier. We think that removing the FMD from the Northern Ireland protocol would be the best way of ensuring no leakage at all.

Lord Hain: Is that view shared by you, Michelle and Paul?

Michelle Riddalls: We are slightly different in the OTC world, because we are not bound by FMD—the falsified medicines directive that Martin was referring to. We do not have the unique identifiers on our packs anyway, because only prescription medicines need that. The risk is very minimal anyway, because all licensed products have their own unique product licence number, which is stamped on the pack. It is part of the packaging, so if a product goes outside its jurisdiction it is very clear to see that it has a UK product licence number and therefore cannot legally be sold elsewhere. There are very few joint packs in the OTC world between different countries. The risk of it illegally going into any other country in the EU is very minimal, in my opinion.

Paul Williams: We have a different view from Martin, for a couple of reasons. First, the effect of the EU's falsified medicines directive is that every medicine's pack has a unique identifier—a barcode that is individual to that box. It cannot be dispensed until a pharmacist scans that and it

talks to a database, so that box number cannot be used again. It flags up if there is a problem with that box.

We are already using the falsified medicines directive. Most of our production is in Europe and goes to European markets. FMD measures are already in place. It is not a new and extra cost. That means that if a pharmacist in Dublin tries to dispense a product with a UK marker, that Dublin pharmacist's system should say, "No, this is a UK pack. You may not dispense it". There ought to be that measure in place.

In addition, what is bearing on me is that the latest EU non-paper made that kind of system a condition for UK-wide marketing authorisation. They said, "We want to have the ability for a pack to be rejected if it leaves the UK". The falsified medicines directive is not a particular problem for us. At the moment, the amount of trade of our product between Northern Ireland and Ireland is negligible anyway. If there is some kind of safeguard such as an FMD marker, meaning that a product leaving the UK gets flagged as a no-no, I do not see that as a problem.

Q6 **Baroness O'Loan:** The evidence you are giving us is very stark and concerning. This question is about the practical impact of the Government's unilateral extension of the one-year grace period. What impact has that had for medicine supply in Northern Ireland? There are two subsections to this. Has the Government's extension of the grace period stemmed the rate and pace of product withdrawal? You have already referred to that. What would be the impact if the grace periods were to expire without an agreed solution?

Paul Williams: The extension of the grace period has been helpful. I talked about the letter we sent to the Secretary of State in July. We have not implemented any of the steps in that letter that we outlined that we might have to take. We have put all those plans to discontinue products on hold, thank goodness. In that respect, the extension of the grace period has been extremely helpful.

However—and I would be surprised if my colleagues did not agree on this point—it only kicks the can down the road. It is the uncertainty, because the pharmaceutical industry works on long-time horizons. Lots of things take years to do, so one year is not a long time for us. Yes, it has been helpful, but all it does is move the problem down the road a little way.

What would the impact be if that grace period was to expire? We would resend that letter, although clearly we would first look at it again and again assess how many of our products are not viable. I hope it would be as small a number as possible, but we would probably have to reconsider an updated version of that notice to the Secretary of State, with huge regret and a very heavy heart.

Martin Sawer: It is good news for patients that medicines are continuing to be supplied as they were and as they are. It is not particularly good news for business because of the uncertainty as Paul has described. It probably means that there will eventually be less competition to supply

Northern Ireland, because some of the smaller companies, as I have earlier described, will just not wait to see what happens. They will either be doing GB packs only or be finding business elsewhere. It is good for supply and makes sure that our members can get as many of the manufacturers' products as they could before, which is good for patients, but it is not very good for business planning at all.

Baroness O'Loan: Do you know what proportion of the medicines coming in are from the smaller producers that you said may withdraw?

Martin Sawer: I do not know. Community Pharmacy Northern Ireland told me this. The difficulty is that you find out only afterwards, once you stop getting the medicines, because the smaller companies in particular will not necessarily have the networks or communications set up to let them know. They provide a lot of the competition, and it gives pharmacies more choice to buy different and more competitively priced medicines, particularly in the generics world. The trouble is that you do not really know until after it has happened. We are aware of that type of conversation and of some smaller members and companies in Northern Ireland, which is particularly competitive, stopping supplying.

Baroness O'Loan: I do not know whether Michelle can answer that question for me, but I would have expected there to be some analysis of the market share of these smaller producers that may withdraw, so that we can get some understanding of the scope of the impact.

Martin Sawer: There is no analysis because we have always treated the UK as the UK. Northern Ireland has never been treated as a separate market. It is, as I say, like distributing to Kent from the M25, so I am afraid we do not have that detail.

Michelle Riddalls: From our side, the unilateral extension of the standstill is positive. As I mentioned, just over 50% of products looked like they were going to get discontinued in January if we reached the end of the standstill. With that cliff edge removal, our members have come back and said to us that all those plans are on hold now, which is similar to what Paul had said. It has definitely made an impact in the sense that, although they thought they would have to discontinue if the new regime kicked in, people have not had to make that choice and are carrying on. That is positive.

There are still a few concerns about what it could mean, because it is unilateral. By that, I mean that the EU has not agreed to that extension. It has agreed not to take the UK to court over it, but it has not positively affirmed it. There is some concern that some of the things we were doing within the grace period require EU support, because otherwise things could grind to a halt. Some of those things are more in the background to do with regulatory procedures carrying on working properly, because they are reliant on the EU agreeing that certain things can be in a licence.

When the grace period was originally agreed, if you had a licence approved after the end of January of this year, it was not subject to the

grace period. I have concerns about new products coming on. What does that mean going forward? Will they be covered by it? Will they not? That is an outstanding question that we have with the DHSC at the moment.

Baroness O'Loan: Paul, you told us that you would not discontinue the supply of medicines where you were the sole supplier. In the situation you were describing—the grace period expires, there is no agreement, you send a letter and you tell the Secretary of State that you will withdraw—does that mean that you would be withdrawing medicines or be unable to supply medicines where there is no other supplier?

Paul Williams: No, it does not. When we wrote to the Secretary of State, the 200-odd products that we specified as being at risk were all medicines where there are alternatives available from other suppliers. We made a commitment to the Secretary of State that, come what may, if the patient has no alternative, we will supply them as long as we are physically able to do so. In other words, as a reasonably large company, we could absorb the costs for vital medications where the patient has no alternative. We have a duty of care to those people.

The list of medicines that we specified to the Secretary of State were all medications where there is currently an alternative. If the grace period ended, we would have to consider that list again. If we do so, we are committed to continuing to supply medicines where there is no alternative for the patient, so long as we are physically able to do so.

Baroness O'Loan: Presumably that would have price implications for the health service in Northern Ireland.

Paul Williams: That is a very good question about price implications, because, as Martin said, the UK generally is an extraordinarily competitive market for medicines. It has among the lowest prescription medicine prices in Europe, particularly for generic medicines.

Let us say for the sake of argument that, on that list of 200-odd products, there was one where there are currently 10 suppliers. Therefore, competition is intense and prices are extremely low, so the product is not viable with a second marketing authorisation required in Northern Ireland. What would happen to pricing if there were six suppliers, or four, two or one? I do not know. It is essentially a free market pricing environment. I do not know what would happen to pricing, but if there were 10 companies all supplying the same medication for gastric reflux or whatever, and all except one left the market, the law of supply and demand and history would tend to indicate that the last remaining supplier would be charging a higher price than when there were 10 suppliers in the market.

Q7 **Baroness Goudie:** Good afternoon. I have found what you have had to tell us really interesting but also very worrying. It is very helpful. Does the protocol carry any current or potential beneficial effects from the point of view of medicine provision in Northern Ireland? Supplemental to that, how feasible, whether in the short or long term, is a model of cross-

border medicine provision on the island of Ireland? That is quite important going forward.

Michelle Riddalls: At the moment, as we said in our June written evidence, we cannot see any beneficial output for medicines as a result of the Northern Ireland protocol from an over-the-counter perspective.

To the second point about using product within Ireland, there are some difficulties with that, and I will explain them from our perspective. A manufacturer that is already in Great Britain, for example, if it had to supply product via Ireland, would be subject to the same import requirements as Northern Ireland, so it could still have that potential barrier going forward.

If they are making it in Europe, they could divert around GB to go into Ireland, but we still have the retail ways of working for our medicines, as I explained earlier, that would have to change in Northern Ireland. How the supermarkets and pharmacies get their product is not via Ireland, so that still causes a problem.

If you look at it from the other side, and we touched on it earlier, for over-the-counter medicines the licences in Ireland are not really compatible with Northern Ireland licences, in the sense that you definitely need different licences between each country and they are monitored by different regulatory authorities. Even if the licences were similar, our over-the-counter products are often national licences that have their own names, so they may not even have the same name in Ireland as they do in Northern Ireland. They may not have the same pack size or legal status in Ireland as they do in Northern Ireland.

We are talking about pharmacy medicines and GSL medicines, which means that you can buy them on the shelf. In Ireland, for example, ibuprofen is a pharmacy medicine and you can buy it only in a pharmacy. As those of you who live over here know, in the UK you can get ibuprofen from anywhere.

Baroness Goudie: It is on the supermarket shelf.

Michelle Riddalls: Exactly, so you cannot use the same product. Similarly, the maximum size of paediatric paracetamol that you can buy in Ireland is 60 millilitres in a bottle. Over here, it is 100 millilitres. To complicate matters even further, there are statutory warnings that you have to write on any paracetamol-containing product, and they are different between Ireland and the UK, so you cannot just take the product that you have in Ireland and import it into Northern Ireland, because it is not legal. There is no licence for it, but actually they are different in our perspective. I hope that is helpful.

Baroness Goudie: That is a really helpful answer.

Martin Sawer: First, no, we have not found any benefits in the Northern Ireland protocol for the supply of medicines, which is obviously what we do, across all types of medicines. Secondly, one of our members owns

and runs one of the larger wholesalers in the Republic of Ireland, so you might have thought that might be an alternative. As Michelle says, across the different types of medicines, the licensing and the brands are very different. Again, the Republic of Ireland is quite a small market, so it has a smaller range of licensed medicines. A lot of unlicensed medicines used in the Republic of Ireland come from the UK, or used to, so we have not found many synergies in trying to distribute from the Republic of Ireland.

Some of the originated brand companies, if they have centrally authorised EU products, which they often do, will be working out alternative routes into Northern Ireland, and they have invested a lot of money in doing this. They may be coming directly from continental Europe or through the Republic of Ireland, avoiding GB because of the uncertainties. We are losing some of that business. That might be going from the Republic of Ireland but not coming through the normal routes through GB. The answer is no to both questions, really.

Paul Williams: I interpret the question as asking whether there are potential benefits compared to how this system used to work.

Baroness Goudie: Yes, that is it.

Paul Williams: No, there are no benefits of that sort. The status quo evolved over many years, worked extraordinarily well and allowed pretty much seamless access to medicines for patients. We have not found any evidence of an actual benefit, either to industry or to patients, from the protocol. I mentioned earlier that, exactly as Michelle and Martin described, the amount of cross-border trade, for various reasons, is virtually nil.

One point that has not been mentioned in relation to this particular question is that there is usually quite a significant price differential between Ireland and Northern Ireland. I do not wish to oversimplify, but in general Ireland pays more for its medicines than Northern Ireland does, so I am not sure how that would help medicines move from Ireland to Northern Ireland even if there were not those licensing and pack size issues.

Baroness Goudie: Thank you so much. That is very helpful.

Q8 **Baroness Ritchie of Downpatrick:** I want to move on to the area of the potential solutions. Last week, Vice-President Šefčovič produced non-papers, for want of a better technical phrase, and one of those dealt specifically with medicines. In view of that, what is your overall assessment of the EU's proposals in its non-paper on medicines published on 13 October? Do they go far enough to meet your concerns?

I note that we received a further submission from PAGB, Michelle, so maybe you would like to start. I know you were talking about a need for a negotiated settlement between the UK and the EU in respect of these matters.

Michelle Riddalls: We have welcomed the non-paper from the EU, because in our original written evidence to you back in June we said that our current framework will not work. We have given you a lot of the reasons why. We have called for there to be a political solution. We have seen both the UK and the EU come up with political solutions, so we are pleased with that.

The non-paper goes some way to addressing our concerns for OTC medicines. We can see that the EU listened to some of the concerns that industry has been raising over the summer, because it has adapted from its original plan for the non-paper to the one that we saw in October. That is really positive.

There remain concerns, and there are things that need to be worked through and understood. I mentioned, for example, products needing to be rereleased. The EU does not specifically say in the non-paper that they do not need to be rereleased going into Northern Ireland. I believe that is the intention, but it does not have it in words, so we would want to see that in there.

There is some interesting wording on the need for a wholesale dealer's licence, which is usually what people need who are moving products to and from different places, such as in Martin's companies. They are saying that the one that imports it, which could be a petrol station or an independent pharmacist, could be the one that is responsible and would need a wholesale dealer's licence, which is an impossibility. They will never get that.

There is further confirmation on the requirement for having a code to determine that the product is for Northern Ireland. We understand that they are saying that the UK competent authority is responsible for that. Again, we would want confirmation that that was understood.

There is a concern that the paper mentions only national licences. There is a whole raft of products that are done under a different regime within Europe called centralised products. In the OTC world, we do not have that many centralised products, but there are some. There are eight centralised OTC products, and it does not propose a solution for those. We would like to see the same importation flexibilities that have been proposed for the other licences we have talked about, because otherwise it will prevent those products going from GB to NI, not only in the retailer scenario but in the wholesaler scenario, which, as Martin mentioned, has also been used.

There are certainly some clarifications that would be needed, but we are of the opinion that we should not necessarily look to one or other of the solutions in a unilateral way. There should be a negotiated solution between the two parties. As all my colleagues here have mentioned, business needs certainty, and if there is no agreement between the two sides, there is always uncertainty as to how the other will react as a result of unilateral views being put forward. That is where we are.

Baroness Ritchie of Downpatrick: Moving on to Martin, I suppose it is the other area of regulatory function which your medicines would be particularly applicable to. The Commission has set out proposals at paragraphs 9 and 10 of the non-paper to ensure that regulatory compliance functions for medicines supplied to the Northern Ireland market may be located only in GB. Are these sufficient to meet industry concerns, and how feasible are they in practice?

Martin Sawer: The second EU non-paper, which is the recent one, has come a long way. It has taken businesses' and pharmaceutical companies' concerns on board. It also mentions continuing the dialogue, which is important. There are some clarifications that we would like to see, as Michelle has already referred to.

The paragraphs you mentioned are good news. A big concern in the early days was that not allowing batch release and batch control from GB would be really problematic, because under the EU single market you would have to be located in a member state. The EU was applying that to Northern Ireland, which, of course, is not a member state. So 9 and 10 can be welcomed. I am sure Paul may have more to say about that.

We, as wholesalers and distributors, have to take the lead from the licensing regime that these discussions will result in. The problem is that trying to apply a legal and regulatory framework to an operational situation is complicated and has unforeseen consequences. I do not believe we are there yet.

It slightly contradicts what Paul was saying earlier, but we are hearing that several companies do not want to apply FMD unique identifiers to their packs and will therefore do only GB packs. So applying the FMD, which the non-paper still does in Northern Ireland, is a major hurdle for some companies supplying us with medicines for Northern Ireland. That is one challenge.

The paper has come a long way, and we welcome that, but it is not quite there yet. We would much rather see an agreement, and I hope that there could still be some agreement on these last hurdles.

Baroness Ritchie of Downpatrick: Would such an agreement remove the falsified medicines directive from being applied in Northern Ireland?

Martin Sawer: Yes, correct.

Paul Williams: The non-paper has a lot to commend it. As Martin has said, they have moved a long way. In my first answer, I talked about the fact that one country with two marketing authorisations does not make sense. For existing treatments, the non-paper concedes one marketing authorisation for the whole of the UK. It also means that the step that was envisaged earlier on of having to move qualified persons and batch release facilities en masse in Northern Ireland, which frankly was never going to happen, has been removed. So, for existing treatments, we think that the paper has moved a long way.

I completely agree with what has been said about multilateral rather than unilateral agreement on this. There is one huge hole in the non-paper. If I might trouble the committee with an acronym, that is MRP/DCP. MRP/DCP stands for the mutual recognition and decentralised procedures. That means that, in the EU, one country, known as the reference state, goes through the process of assessing and licensing a new treatment or product. Once that country agrees and approves that product, it is approved in other countries via what is known as mutual recognition, hence the mutual recognition and decentralised procedures.

The paper admits that for new treatments they are not conceding one marketing authorisation for the UK. They are talking about a GB national licence for a new treatment, and Northern Ireland would continue to have products licensed under the MRP/DCP. Taking a hypothetical example of a new treatment, which might be a new generic treatment and not necessarily a completely new breakthrough in treatment, the MHRA assesses that product and approves the treatment. Meanwhile, that same treatment is being approved in Poland, France, Germany or wherever, and at the point at which Ireland adopted that mutual recognition the product would be available in Northern Ireland. That is the first issue.

The second issue is, if you will indulge me with a hypothetical example, where - let us say - that the MHRA says, "Yes, we approve this on the basis that the patient leaflet says, 'You must never take this medicine with paracetamol'". Let us go further and assume that that product was assessed in another EU country that says, "Yes, the patient leaflet must include the phrase, 'This product must not be taken with paracetamol or aspirin'". This is not the same product any more. We are back at two authorisations for one country.

The EU non-paper acknowledges that this is a problem. Last week, I saw an early draft—I have not seen a final one—of a letter from the European generics trade association, Medicines for Europe, to the Commission expressing grave disappointment that this MRP/DCP issue had not been addressed fully. Also, as Michelle said, the CP—the centralised procedure—which is a direct approval from the European Medicines Agency, is not even mentioned in the non-paper. We have over 40 CP products in our portfolio. We have no idea what this means for those CP products.

On the supplementary question about how reasonable and practical it is for the UK authority to accept, the main question is for the MHRA in that respect. Going back to the hypothetical example where you have an equivalent licence, if the MHRA and the reference member state agree on what that restriction will say in the patient leaflet, that is fine, but we do not know what the MHRA strategy will be in future. What if the MHRA decides in the medium term, long term or indefinite future that it will no longer be precisely aligned with European standards and wants to carve out its own future? At that point, the MHRA would have questions about whether it will be subject to the conditions that the non-paper sets out in paragraph 11.

Baroness Ritchie of Downpatrick: There are many areas that require further clarification. You are all in agreement that there have been welcome steps but that there is further work to be clarified, and it requires the EU and the UK to work together to do that.

Q9 **Lord Hannan of Kingsclere:** Thank you very much to all three of you. The whole presentation was very enlightening, particularly that last point as we move on to possible solutions. Let me phrase my question like this. Everyone in this room would regard the optimal outcome as being what you have set out—in other words, fixing the faults in the non-paper. I had never heard that MRDCP point before that. That was fascinating.

For the sake of argument, let us assume that there is no such agreement and that the two sides cannot finalise a complete agreement, probably not because of the medicines issue but because of other things. What would be the less bad scenario? Would it be to take something along the lines of the imperfect non-paper that we have just been talking about, assuming that you could not improve it, or would it be a UK unilateral maintenance of the status quo?

I was very struck, if I may say so, by something you said earlier. All three of you said that there is no real danger of cross-border leakage, and you all explained why that was. I was very struck by what Michelle said about the rules, even on very basic things such as paracetamol, being different on either side of the border. I am not sure that anyone has ever suggested that that requires border checks. In all the years since partition, I do not think anyone has said that we need to have a border in Northern Ireland because paracetamol cannot be sold across the counter in Dundalk.

If we just said, "Look, we're going to carry on as we are now with the downside of not having an agreement and not having bilateral approval", would that be better or less good than taking, without amendment, the position paper?

Paul Williams: If the UK was to trigger withdrawal of medicines from the protocol unilaterally, I would have some concerns about what the EU's response might be to that. It would be unpredictable. I can completely understand the question. I can completely understand how suddenly we would say, "We have a national licence for everything", and that is that. Nevertheless, there are interdependencies with Europe in medicines beyond the issues we have been talking about that we would have to be careful with.

I hope you do not mind if I give you a specific example of that. In fact, I can think of two examples. First, there has been a very effective system of creating safety alerts. Let us say, for the sake of argument, a patient takes a medicine and turns blue. It is a one-off. But what if 20 patients' faces turned blue from the same batch of medicine? We have a safety signal, so the interchange of data on that to help safeguard patient safety is very important. It has already become more challenging after Brexit to have that free interchange of data.

Lord Hannan of Kingsclere: On that point, is that unique to the EU? If somebody turns blue in Australia, do we get notified?

Paul Williams: No, not necessarily.

Lord Hannan of Kingsclere: Okay, nowhere else in the world does it.

Paul Williams: No, not in such a systematic way. What would happen to that system? I would hope that the EU, in the interest of patients, would continue with it. As I said, it has already become more challenging because of data provisions. I would not want that to go away.

A second example that affects us, and it has been alluded to but not talked about specifically, is what is known as a mutual recognition agreement on batch release. I will write to the Chair, because I believe that the subject is a little technical and lengthy. I do not wish to take up too much time.

The Chair: That would be very helpful.

Paul Williams: We have been urging the Government to conclude a mutual recognition agreement on batch testing, and in that letter to the Chair I will explain why it is important. The EU is already resistant to that mutual recognition agreement. If the UK acted unilaterally to withdraw medicines from the protocol, I do not know what the EU's response would be. It is unpredictable.

Martin Sawer: My answer is probably a bit more straightforward, because it is an upstream issue about the manufacturing and the interrelationship of businesses around the world. As UK distributors, we could probably live with a unilateral declaration of the status quo where we are now. Several of my members are pan-European and have connections with the USA, so longer term the upstream implications would have challenges for them because they move packs around the world.

Obviously, we unilaterally recognise EU regulations on medicines at the moment. The complications and the extra layers of cost of doing our own thing without an agreement would probably come home to roost after some time. Initially it would be fine.

Lord Hannan of Kingsclere: Presumably, we could carry on unilaterally recognising any competent serious countries.

Martin Sawer: The MHRA has said that it would do that only for another two years on EU medicines. It would have to come up with other agreements.

Lord Hannan of Kingsclere: From your point of view, if our regulator said, "Look, anything that's approved by the FDA, the EMA or anything that we regard as a serious regulator in a functioning state is fine for us", would that be a retrograde step?

Martin Sawer: That is really a question for the manufacturers up stream, because, again, some of that will be about data exchange and the fact that safety concerns about patient information are built in. As you can imagine, it is a very complicated area, so it would depend on whether the manufacturers up stream would be comfortable with that.

Paul Williams: Do not forget that the UK is a significant manufacturer of medicines and the EU is a very good market for the UK, so we would have to be very concerned to make sure that that ability to send product from the UK to the EU would be safeguarded.

Michelle Riddalls: Yes, I agree with what has been said previously. It would be very difficult going forward unilaterally. We and our members feel that the negotiated outcome is what is needed. We have managed over the past few years to get some negotiation. Getting the grace period for medicines for one year is a good example of that in the first place, so we would hope that there was some ground that they could meet on in between.

Also, as has been alluded to, a lot of our members are part of European and global companies, so just carving out something unilaterally for the UK would make it very difficult for a company to see what to do. Medicine and pharmaceutical companies are naturally compliant because we have such high regulatory levels to meet all the time and are inspected on those. It can be very difficult when, if you are in a European role, the EU is saying one thing and the UK is saying, "It's all right here".

That is where we found ourselves in the last couple of years where there has been disparity in the agreements of what is going on. I have likened it previously to a mother or father in a divorce saying to the child in the middle, which is us companies, "You can do that", and the other saying, "No, you can't". We are stuck in the middle, which is really why we need this negotiated outcome.

Lord Hannan of Kingsclere: In that situation, I think the child just does it, not to push your parallel too far. Sorry, I have taken up enough of your time. Thank you. That was very useful.

Q10 **The Chair:** I wanted to ask one or two questions about the Commission's proposals, but I am conscious that these are rather detailed, technical questions. If it would be easier for you to reply in writing, that would be fine. What is your assessment of the Commission's proposals in relation to the continued use of a single medicine pack and a single leaflet for patient information for the whole UK market, and in relation to investigational medicinal products, safety features for medicinal products for human use, and veterinary medicines?

I do not know whether any of you would like to answer any of those questions now or whether you would prefer to write about them. Shall we start with Michelle?

Michelle Riddalls: Yes, I am happy to link up at the beginning. The single medicinal pack and the single leaflet that we have been talking

about comes back to what Paul alluded to when he mentioned the MRPs and DCPs. It is linked to the fact that there are two marketing authorisations that could end up in different SKUs.

Currently, the MHRA has what is called the reliance route. That is published guidance out there at the moment. When a DCP is going through the process now, the MHRA is looking and can look under its reliance route at the outcome of that DCP and MRP, and then recognise that within 67 days. There is a process at play already whereby the MHRA is acknowledging what the EU is doing under DCPs and MRPs, so there are definitely grounds to negotiate on that a lot more, because that is what is in place now.

To come back to what Paul was saying, though, it restricts the MHRA in some ways, because it will then have to keep being reliant. It would have an input into the MRP and DCP for Northern Ireland as a concerned member state, so it is allowed to comment as things go through the DCP, although not to the same extent perhaps as it would have done before.

So all is not lost in that area, and there are points on the negotiation that could work. However, we are all agreed that having one single medicinal pack and patient information leaflet is what will ensure that those products can carry on going into Ireland, as long as we also have the import side sorted.

I cannot really talk too much to the other points, because, as I said, we are not involved in the safety features, which concern FMD. I can hand those other areas over to other colleagues, if they have things to add.

The Chair: Martin, do you have thoughts?

Martin Sawer: Of those four factors, I would like to address two. We do not really deal with veterinary medicines or investigational medicinal products. Regarding the other two, we support the fact that the EU has proposed the continued use of a single medicine pack for the whole of the UK, because that is what we do at the moment and that essentially is what is important.

If you have a separate medicine for Northern Ireland, you will have to create an identical replica but with some variation. Whether it has an FMD code on it, or whether it has a different licence or just a Northern Ireland licence, you will need twice as much warehouse space, because you will have exactly the same medicines side by side—one for Northern Ireland and the rest for GB. Segregation of packs is anathema to our business, so we need a single one for the whole of the UK. That is great.

The EU may have put this out there because it understands businesses' concerns, but the catch, I think, is in the regulatory application of that. It implies that the EMA would have authority over the MHRA to allow that to happen, as that means that GB packs would have to be compliant with Northern Ireland, because the EU is proposing a single pack. The MHRA

would then become subservient in that licensing regime, so this is a challenge.

FMD proposes the same challenge, because to be FMD compliant in Northern Ireland and to have a single pack for Northern Ireland as in the rest of the UK, every pack in the UK would have to have FMD. This would mean that we would have to upload all UK prescription medicines to the European database—we are currently uploading for the next three years—because FMD applies only to prescription medicines. Therefore, they can be decommissioned in the single market.

Our single market part of the UK, under the Northern Ireland protocol, is 1.8 million people out of the UK. Again, that part of it makes the MHRA subservient to the EMA and the European regulatory authorities. I would suggest that this is a negotiating point that has been put out there.

Paul Williams: In the interests of brevity, one pack, one SKU, one marketing authorisation and one country works terribly well for us. The new treatment issue that we have all talked about is a major problem, because it is not fully addressed. I can only build on what has been said—so I will not do so—because I think it has huge implications for the role of the MHRA.

I have already disagreed once with Martin about FMD, and I shall disagree again, but that is because we are a big company that is already providing products all over Europe and that already has FMD. We invested in that years ago. We did it, we are doing it. For companies like ours, it is not a real burden. In particular, if that is the price of the EU allowing a single MA for the whole of the UK, some companies will find that a challenge. Larger, more well-resourced companies like ours will find it less of a challenge.

The Chair: That is very helpful. Thank you very much.

Q11 **Lord Thomas of Gresford:** The command paper that was produced in July 2021 said, in paragraph 61, "The solution proposed by the EU in June was a welcome start, but is potentially complex to operate because of its need to work within the broader EU framework for regulating medicines; and furthermore it would not satisfactorily deal with certain medicines (such as new cancer drugs)". It ended in this way. "Given the range and depth of these challenges, the simplest way forward may be to remove all medicines from the scope of the protocol entirely".

Was that desperation sounding? You have already said some things about the unwisdom of taking the medicines out of the protocol. What is your view?

Paul Williams: I wish to clarify that what I said earlier, I hope, was that I would have concerns about the unilateral removal of medicines from the protocol. If the removal of medicines from the protocol was on the basis of a negotiated settlement, that would have far fewer challenges. This is because, as I said a few minutes ago, if the UK was to withdraw medicines from the protocol unilaterally, we would have concerns about

what the EU response to that move might be. If it was as a result of a negotiated agreement, that might be different.

Martin Sawer: Yes, I think the command paper is implying that it would be part of a negotiated agreement, so in that context we would support the removal of medicines from the Northern Ireland protocol. We have now had the best part of two years of discussion about the implications and it is so multifactorial and layered. It seems to me that, the more you go forward, as the EU non-papers have done, the less likely it is that we will finally agree on all the dots on the regulations.

As I mentioned earlier, it is a legal and regulatory framework for something that is operational as one UK market. We would agree to it in the interests of public health and security of supply for patients. Both sides might want to think about that, because medicines are one of the top four priorities, I think, in the negotiations. Taking medicines out of the Northern Ireland protocol would be sensible.

Lord Thomas of Gresford: Do I understand you to be talking about having a separate agreement?

Martin Sawer: It would, I hope, be part of an agreement on the Northern Ireland protocol, but taking medicines out would revert to the status quo.

Michelle Riddalls: We welcomed the command paper and its proposal. It appears to be a simple solution. However, we have not seen the detail or legislation as to how it would work. We talk a lot in meetings about how the devil is in the detail. The theory sounds fine, and, as I mentioned earlier, there is the potential for either solution to work on its merits. I would say that, if it is a negotiated outcome rather than unilateral, there is definitely some viability, but we would want to see how it would work going forward, because there is no detail behind it.

Lord Thomas of Gresford: In paragraph 59, the command paper suggested that the way forward was a full dual regulatory regime in Northern Ireland, so the manufacture of SPS goods should be able to circulate within Northern Ireland if they meet either UK or EU rules as determined by UK or EU regulators and should be labelled accordingly. Do you think that is a solution, Paul?

Paul Williams: No. Let us go back to the hypothetical example earlier where the European approval for a medicine is on the basis that you should not take it with aspirin or paracetamol, and the UK's assessment by the MHRA is that you should not take it with paracetamol. You now have two different sets of safety advice for the same medicine, one from Ireland and one from the UK. Which leaflet does the patient see? Michelle has just talked about the devil in the detail. She is absolutely correct. That is exactly the level of detail that would have to be looked at before you could look at implementing paragraph 59.

Lord Thomas of Gresford: Martin, do you see any benefit to the dual

regulatory system?

Martin Sawer: At face value, if you allow a GB pack in Northern Ireland and an EU pack in Northern Ireland, it makes sense on a piece of paper. As Paul says, it is down to who regulates that and therefore what details are required to support a medicine. Our sector is very highly regulated, unlike other goods markets, so it would not really work on the regulatory side. That would be our concern, as described by Paul.

Michelle Riddalls: I have nothing more to add. I agree. Those are exactly the problems that we would face.

Lord Thomas of Gresford: The problem with that would be that there would be no overall regulator to determine which pack you buy in the chemists, whether it is the European pack or the UK pack, and each would have different implications in the way in which they would affect people. I see you are all nodding.

Lord Hannan of Kingsclere: Sorry, I do not quite see why that is a problem. Why is it a problem if one pack says, "Don't take with aspirin and paracetamol", and the other does not? Who is suffering?

Michelle Riddalls: The patient could. Especially for OTC medicines, you are sometimes buying those products without pharmacist interaction, so if you are picking up one pack that has one warning on it, which is from the UK, and the next time you get it you have a different warning, you do not know what you should be doing.

It could go as far as having different dosing regimes as well, so that patients could end up in more confusion and taking four tablets when they should have taken only three. There is real risk to patient safety and understanding. There are enough issues with patient compliance and understanding of what is on the pack anyway without having two packs that could say two completely different things.

Lord Thomas of Gresford: If there were damage to the patient, a legal case could come out of it. They could sue the manufacturers for not saying in their advice, "Don't have this with aspirin", as opposed to, "Don't have it with paracetamol".

Lord Hannan of Kingsclere: Then everyone in the UK could sue them. If you assume that both regimes are basically safe, I do not see why that is an issue.

The Chair: We should have the discussion among ourselves afterwards.

Q12 **Lord Dodds of Duncairn:** Thank you very much for your evidence today. The idea of having a specific evidence session on medicines has proved to be extremely worthwhile, because it illustrates the seriousness of these issues when it comes to patients. This evidence today has been very helpful in guiding our deliberations, and certainly, despite the criticism at the time and calls for rigorous implementation from day one, it points out how important it was that the Government extended the

grace period in medicines. We are all agreed upon that now.

You are saying that the UK command paper offers a way through this by removing medicines completely from the protocol, and if that is by agreement, that is great. Is there any room for compromise, any middle ground, between the EU non-paper's proposals and the Government's proposals, or is it a matter of tweaking whatever the EU paper has to bring it more into line with what needs to be done on a practical level?

Martin Sawer: At the moment, from our perspective, it boils down to two issues: the licensing requirements, particularly the detail that Paul went into on the national licensing mutual recognition; and the role of the regulators and regulator, which is a fundamental challenge.

The second EU paper has come a long way, so there is clearly a much better understanding of the concerns. I think there is willingness on both sides on medicines anyway to try to work something through, because it is such a critical issue. I know they are having intensive talks, and the Department of Health's engagement here with all the businesses and trade associations has been second to none. I know there is a real will to try to work something through, but there is that complicated licensing conundrum to try to sort out. Whether we get those medicines in Northern Ireland will be dictated by that.

Paul Williams: If you look at the various publications from the UK Government and the EU Commission, it is fair to say that both sides are really trying very hard to reach an agreement. I do believe that, as long as both sides recognise that they are working on behalf of the patient, there is the room to reach an agreement here. The EU's concession of one marketing authorisation for the UK for existing treatments was a big and worthwhile one. I do believe that it exhibited a willingness to move on the part of the Commission.

We have already talked about things that the Commission has not addressed adequately. I believe that the elements that the Commission has not addressed adequately could be addressed working with the UK Government, including on the MRP/DCP issue.

Lord Dodds of Duncairn: That is the issue of mutual recognition.

Paul Williams: It is what I talked about earlier, where they are new products that are approved in an EU member state. There is no solution in the EU non-paper. There was no specific solution for it in the UK command paper. I agree with everything that Martin said there, by the way. I completely agree that the regulation is the major issue. I believe that those are essentially technical rather than political issues. With good will, and in particular bearing in mind the needs of the patient, I believe that an agreement is possible.

Michelle Riddalls: Yes, I do too. We have seen willingness on both sides to look at solutions. As I mentioned earlier, the UK proposed getting the grace period in the first place, and we have got to that. There are tweaks that could be made and which the EU non-paper could get agreed.

Likewise, the EU could completely change its stance and agree with the UK. There is definitely room there for manoeuvring. I do not know if you want us to mention the other points about mutual recognition now.

Lord Dodds of Duncairn: Yes. You have dealt to some extent with the idea of unilateral actions, I presume, in relation to the Article 16 invocation and the Government going down that line.

Michelle Riddalls: Yes. On the questions about the mutual recognition agreement, prior to the negotiations and the treaty we know that the UK side was very in favour of what industry wanted, which was a mutual recognition agreement to help both UK going into EU and EU coming into UK. If there was a mutual recognition agreement, that could help the Northern Ireland side as well as the bigger picture for the UK, but there would need to be amendments on some of the outstanding issues that we have already mentioned. At some point in time, the UK was willing to have mutual recognition. That is something that we would look at as standard with other countries as well, so that is important.

The uncertainty that Article 16 would bring, as we mentioned when we talked about unilateral solutions, would be very unsettling. The lack of certainty about what companies would do and how they would function could lead to more withdrawals, and more immediately, because, as I mentioned, pharmaceutical companies are very compliant. We work in very tight regimes, and nobody really knows what Article 16 would mean. Therefore, what would you be operating under in Northern Ireland? There would be a concern about that.

Lord Dodds of Duncairn: Article 16 can be very narrowly focused or very wide, but clearly we do not know, so there is that uncertainty. Presumably it would just maintain the status quo.

Michelle Riddalls: Potentially. Then, again, it would come down to what that means in reality, because we keep finding that things look okay on paper or in thought, but the devil is in the detail. We do not necessarily know what natural legislation we would go to.

Martin Sawer: From our perspective, we also supported the mutual recognition agreement. On the Article 16 point, a review could be built in, I think, so for us as national businesses it could work for the short term. As we mentioned, unilateral action on our suppliers and the manufacturers—international businesses—would have longer-term implications if it was not a short-term Article 16. That would be our concern.

Lord Dodds of Duncairn: You are nodding in agreement.

Paul Williams: I have nothing to add to that. I agree fully.

Q13 **The Chair:** This may sound like trying to reduce all this to the personal level—I do not mean me. If you were a patient in County Donegal, you got seriously ill and you were sent to Altnagelvin hospital across the border in Derry/Londonderry, how would any of this affect you as an

individual?

Martin Sawer: At the moment, it would not, because we are maintaining supply and ensuring that patients get the medicines they critically need, whether they are licensed correctly or not. We would make sure that there is a supply, and I hope that is what we would end up trying to do, because that is our first and foremost objective.

The Chair: Would you both agree with that?

Paul Williams: Yes. I have to say that it is an excellent question. It is really important that patients continue to get access to the treatments that they do now. The case of a patient who lives in Donegal but is treated in Derry/Londonderry is very interesting, because, as Martin has mentioned, there are many more medicines available already in Northern Ireland than there are in Ireland.

If you live in the Republic of Ireland, the way you co-pay—in other words, pay—for your prescriptions is very different from the way you do in Northern Ireland. I am not entirely sure how it works, if I am being really honest with you. What I would say is that we supply the Republic of Ireland and Northern Ireland. Our goal would be to do everything we can to make sure that we continue to do everything that we do now.

Michelle Riddalls: We do not deal with hospital products, but things are probably functioning at the moment only because we have the grace period and we have not had the cliff edge. If you were asking this question in a year's time and there had been no solution or the grace period had stopped, it could be a very different story. That is why we have been so passionate about coming to things like this and responding to evidence. We could see that cliff edge, and we could see what could be coming. We are trying to do everything in our power to prevent that happening and to find a solution so that patients do not end up with no product and are treated. That is why we are taking it so seriously.

Martin Sawer: Could I add one more point? I was perhaps a bit brief, but working with the regulator, the MHRA, we would be able to supply a medicine to any patient anywhere in the UK, whether it is licensed or not. I should have made it clear that unlicensed distribution is possible. In that instance, we could make sure that a patient in Northern Ireland could get a medicine.

Q14 **Baroness Ritchie of Downpatrick:** As a follow-on to the Lord Chair's question, already there are children from Northern Ireland who get specialised treatment in Dublin at St Vincent's. There is that north-south arrangement; it is a mini protocol. There are other people who have hip replacements, which are done on a fairly regular basis in Dublin, but there is a charging mechanism back to the Department of Health in Belfast. How would that fare under this medications regime? Who would pay?

Paul Williams: St Vincent's is a significant customer of ours because we supply the Republic of Ireland, and a very good job it does too. I do not

believe that there would need to be any difference in those arrangements at all, because at the moment, as we have already established, very little product moves across the border.

The terms of the non-paper from the EU would eliminate the risk, low as it is now, and I believe that whatever medicines are available in the Republic of Ireland to that particular patient at St Vincent's would continue to be available to that patient. I do not believe that that patient would be disadvantaged.

Michelle Riddalls: Martin was talking about the Government ensuring that product got over to Northern Ireland in that scenario. That is for prescription medicines only. We can find no solution at the moment that would allow non-licensed OTC products to continue to be supplied going forward. I wanted to clarify that it was only prescriptions that that would work for.

Q15 **The Chair:** What practical steps can the UK and the EU take to engage industry stakeholders in the context of the forthcoming negotiations? What would you like to see them doing?

Martin Sawer: From our perspective, the UK's engagement has been exemplary. I have never had so much good, regular contact with the officials, and we have met Lord Frost a couple of times. The engagement is really good on this side. The challenge for us as UK industry bodies comes because we have to be filtered through the EU versions of our industry bodies when the European Commission is talking to industry. The Commission has not talked to our body, the Healthcare Distribution Association, on the Northern Ireland protocol. It may have talked to other UK industry bodies, but I have to filter it through our European representatives, who have been working quite hard on it.

The Commission has met them three times, I believe, on this issue. That is working quite well, but there is not the direct contact that we have with the UK representatives. Maybe that is a matter of fact rather than something we can do anything about.

Paul Williams: I would echo what Martin said. I want it to be entered on the record that the dialogue we have had with colleagues at the DHSC, the Cabinet Office and the Northern Ireland Executive has been very constructive indeed, so I want to thank them for that.

I would like to make a practical suggestion. As we have heard this afternoon, all these issues are essentially technical. This meeting has been liberally strewn with acronyms and quite difficult concepts of regulatory affairs, not all of which I understand, trust me.

We have found it difficult, particularly at an EU level, to be let into these discussions in confidence before they are published. We have already said that the big miss in the EU non-paper was the MRP/DCP issue. I am not excluding the UK Government from this point entirely, although the UK Government have engaged very constructively, but please get some subject matter experts in the room. Someone could have asked, before

that non-paper was published, "Can I have a chat about what this means for CP medicines, or DCP/MRP?", instead of playing your cards close to your chest so that the first the trade associations hear about it is the press release.

Get those technical specialists in the room, both in the EU and in the UK, because they understand the issues that I do not understand and that, with respect, this panel does not understand. They are well into that detail, because these are issues of detail.

Michelle Riddalls: I would reiterate exactly what everybody said about collaboration with the DHSC and Ministers. I have been involved in many meetings. I co-chaired deep-dive meetings looking at solutions with the DHSC last year, so I think it has taken what we are saying very seriously. Obviously, the EU has too, although I echo some of the comments. Having industry present and going through the detail of what things might mean is really important. Also, as we go forward with the negotiations between the EU and the UK, there should be openness in feeding back what is being proposed.

Sorry to use the phrase again, but the devil is in the detail. What may appear to be a solution at the theoretical level is not always a solution when you ask industry. I am talking as someone who has worked in regulatory for the past 20 years. My ask would be that, as negotiations progress and solutions are put forward, there is a check step, perhaps on both sides, to come back to industry and the trade associations to double check what those implications might be and to ensure that they are on track, so that it provides the solutions that we all need.

The Chair: Thank you to all three of you. That has been a fascinating and discouraging, rather than encouraging, session, but we are extremely grateful to you. It was highly technical at times, but it is a highly technical subject to resolve and an extremely important issue for the people of Northern Ireland. Thank you very much indeed for coming and giving evidence to us. Thank you also for offering various extra pieces of paper, which we will find extremely useful.