European Affairs Committee

Protocol on Ireland/Northern Ireland Sub-Committee

Corrected oral evidence: Follow-up scrutiny of the provision of medicines to Northern Ireland under the protocol

Wednesday 18 January 2023

3.10 pm

Watch the meeting

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

Evidence Session No. 1 Heard in Public Questions 1 - 10

Witnesses

I: Michelle Riddalls, Chief Executive, PAGB (consumer healthcare association); Martin Sawer, Executive Director, Healthcare Distribution Association (HDA UK); Paul Williams, Senior Director Corporate Affairs, Teva UK Ltd.

Examination of witnesses

Michelle Riddalls, Martin Sawer and Paul Williams.

Q1 **The Chair:** Good afternoon to you all, and welcome to this public meeting of the Protocol on Ireland/Northern Ireland Sub-Committee. We are starting a short follow-up inquiry on the provision of medicines to Northern Ireland under the protocol, following an inquiry we undertook a year or so ago.

Today, we are meeting again with three witnesses who gave evidence to the committee in October 2021 to discuss with them how the situation has evolved since their last appearance. We have Michelle Riddalls, chief executive of PAGB, the consumer healthcare association; Martin Sawer, executive director at the Healthcare Distribution Association; and Paul Williams, senior director corporate affairs at Teva UK. You are all very welcome.

We are very grateful indeed for the evidence that you have submitted to us, which has been extremely helpful to us in our inquiry. Thank you very much for that. I know we know who you are, but would you mind introducing yourselves when you first speak so that our listeners and our audience know who you are?

Today's meeting is being broadcast and a transcript will be sent to you a day or so after it is finished so that you can check that it is indeed accurate. Since this is the first meeting, I should refer to the list of Members' interests on our website. That is by way of introduction.

Perhaps I could start by asking you to summarise the main issues facing the pharmaceutical industry on medicine supplies to Northern Ireland under the protocol as it is operating at present. Could you also say how, in your view, the situation has changed since you last gave evidence to us in October 2021? Can we start with Martin Sawer?

Martin Sawer: Thank you, Chair, and thank you very much for inviting us back to review the situation 18 months later. It is important that the committee knows that I represent the middle of the medicines supply chain, the wholesale distributors of medicines, largely prescription medicines. We distribute over 90% of NHS prescription medicines across the four countries of the UK through a 52-warehouse network twice a day on weekdays and once on Saturdays; 11 times a week. It is a very intensive logistical support network for pharmacies, hospitals and NHS doctors. It touches all healthcare institutions, which number about 17,000 in total.

The context, as you know, but it is worth repeating, is that Northern Ireland is a market of 1.8 million people, about 1 million people fewer than live in the West Midlands in England. We distribute UK-wide efficiently, so far, and it gives great value, we believe, to the NHS, but the challenge is that the Northern Ireland protocol is, we believe, building in cost, and that is what I would like to describe a bit more as we are now 18 months down the track.

I would summarise it like this. From our members' perspective, distributing medicines to Northern Ireland is challenging, problematic, inefficient and a slow strangulation by 1,000 cuts. All our members feel that the UK and the EU have done their best to interpret regulations sympathetically so that the supply of medicines is still okay for Northern Ireland. Most of our concerns are about the future and the uncertainty at the moment about that future. With medicines being highly regulated, obviously for safety reasons we need some certainty. I am sure the other witnesses will mention lead times on getting medicines on to market.

We have already seen signs of divergence in types of medicines not being supplied to Northern Ireland, so there are regulatory sticking plasters, which we will come on to. The tectonic plates between GB and NI are slowly moving apart, and all the regulations are being stuck on top like sticking plasters, but the actual fundamental core of the problem, in our view, is the Northern Ireland protocol because of Brexit. Medicines need to be available universally to all the citizens of the UK equally, and we

believe that divergence will put that under threat. It is making our members have to do a lot more manual regulatory work, which they do not always have confidence in because information is not always there in the supply chain, so they may unknowingly be supplying packs illegally to Northern Ireland that technically under the regulations are unlicensed.

Because 80% of the different lines of medicines come from bigger warehouses in GB, the smaller warehouses in Northern Ireland cannot hold all those medicines; normally, for 1.8 million people, there is no need. You always have a hub warehouse in Birmingham or Scotland where there are more people, and you send the slower-moving lines on the ferry the next day. The challenge is that some of the medicines going over are already illegal because of the licensing requirements.

The MHRA is catching up, but we do not know what to do when those medicines are found in the supply chain. We are not supposed to supply them to patients, but what does a doctor, pharmacist or hospital pharmacist do when they get one of those medicines in front of them? That is the challenge. It is a licensing issue at the moment. Medicines in GB are obviously perfectly safe, and they have been licensed properly, but our divergence of licensing is causing a problem.

My last point at this juncture is about the costs of the TSS declarations in the Irish Sea. For every consignment we send over, we have to declare what is on board by the 5th of the following month. In our sector, that amounts to about £2.5 million of extra costs in labour, IT and declarations per year at the moment. We have had two years, so that is £5 million already. We see no benefit in that at all. We have not yet agreed what to do with vital medical foodstuffs for people who need liquid foods because, of course, they are subject to phytosanitary checks, but that is on hold at the moment.

There are a lot of regulations in detail—probably too many for me to even remember—that have been kicked down the road until the end of 2023 or 2024. I am sure we will come on to that. That uncertainty is our key challenge and the fact that we are just doing sticking plaster stuff but nothing fundamental, in our view.

The Chair: Thank you very much for that. I am not sure I completely heard you. You mentioned the figure of 17,000. Could you explain very briefly what the 17,000 are, so that I am absolutely clear about that?

Martin Sawer: Of course. That is the total number for every hospital, pharmacy and dispensing doctor we distribute to in the whole of the UK.

The Chair: In the whole of the UK.

Martin Sawer: That is the total end points, yes.

The Chair: Do you know how many there are in Northern Ireland?

Martin Sawer: I do not, but I can find out and tell the committee. It is a good question.[1]

The Chair: That would be very helpful, to get a sense of Northern Ireland in the context of the United Kingdom as a whole. Thank you very much for that. Michelle Riddalls, can we pass to you?

Michelle Riddalls: Yes, thank you. I reiterate what Martin said. Thank you very much for having us and enabling us to provide further evidence. I represent PAGB, the consumer healthcare association, which represents manufacturers of branded over-the-counter medicines—otherwise known as OTC medicines—self-care medical devices and food supplements. Those are the kinds of products that you often buy off a shelf in a pharmacy, supermarket or petrol station, and include well-known brands such as Calpol, Nurofen and Gaviscon. They are the types of products that are vitally important to enable first point of care and for members of the public to self-care for their minor ailments and illnesses.

Our perspective is perhaps slightly different from Martin's; we are talking about the manufacturers at the very beginning of the supply chain. We distribute medicines slightly differently, in that a lot of our medicines go directly to a retailer, who then takes them over to Northern Ireland, rather than via a wholesaler. It is positive, and we have been very encouraged, that the UK Government and the EU have taken steps since our last meeting to bring in the new legislation in the EU. That agreement has helped to ensure that medicines we were worried about not getting supplied to Northern Ireland when we last met have continued to be supplied. Those agreements have been paramount in making sure that that continuity is happening. From our perspective, it has worked well for OTC medicines, and there are no real barriers for the OTC medicine side in getting products over to Northern Ireland.

One of our concerns is that any extensive changes—talking specifically about the Northern Ireland Protocol Bill—could cause further significant disruption and uncertainty. Martin has already touched on the certainty piece. Business needs certainty. We have been in this period of instability for so long, with changing laws. There are a few things that need to be sorted out and resolved, and we are very much in favour of doing that, but it should be via negotiation rather than any unilateral action taken by the UK alone.

The change that we have seen has been positive. We were facing a cliff edge a couple of months after the time we last met. That has been taken away because of the legislation introduced by the EU. There are a few things outstanding on centralised procedures—the falsified medicines directive—and, from my perspective, some aspects relating to the import of medical devices, but we are in a much better position than we were when we spoke last time.

The Chair: Thank you for that. I think I am right in saying, and perhaps

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[1] Note from witness: There are 834 healthcare end user locations (NHS and private hospitals, community pharmacies and GP surgeries) across Northern Ireland that wholesale distributors supply medicines and medical devices to twice every weekday.

it will not surprise you to know, that every business group that has appeared before us, of whatever sector, has said that business needs certainty, so we are very conscious of that point. Paul Williams, over to you.

Paul Williams: Good afternoon, my Lords. I represent Teva UK Ltd, which is a pharmaceutical manufacturer. By volume—in other words, by sheer number of packs—we are probably the biggest supplier of prescription medicines in the UK, and hence in Northern Ireland. We make medicines ranging from cancer chemotherapy treatments, asthma, migraine, all the way down to so-called generic medicines, which are off-patent medicines, and they make up the majority of our business by volume. We also make a small range of OTC medicines, so we are members of PAGB. The majority of our products go via Martin's members, the HDA wholesalers, to pharmacists and retailers.

You effectively asked two questions. One was about the outstanding issues, and one was about what has changed. As we see it, there are still six outstanding issues that we are very keen to resolve as soon as we can. I know that most, if not all, of those will be addressed in further questions today.

First, any outcome, any solution, that leads to the UK having two SKUs—stock-keeping units—is problematic; in other words, having a separate pack, a separate licence or a separate product for Great Britain and Northern Ireland. Martin pointed out how small the population of Northern Ireland is. For the majority of our medicines, it is not economically viable. In fact, not only is it not economically viable but it starts to drag down the rest of our business. Two SKUs for one country is very problematic.

Secondly, the centralised procedure licensing issue, known as CP or CAP, is a time bomb. It is a cliff edge. Michelle talked about a cliff edge that has gone. That is true for prescription medicines. For a particular subset of prescription medicines known as CP products there is another cliff edge that worries us greatly and could lead to the discontinuation of a large number of medicines in Northern Ireland by the end of this year. I am not making that point on behalf of my own company; I am making it on behalf of the industry.

The third point is NIMAR, which I know we will come to. It is a temporary fix, not a long-term solution. It is bureaucratic and it has grey areas. It is not something that anyone in the industry I have spoken to, or indeed the chief pharmaceutical officer of Northern Ireland, whom I spoke to last week, thought was a long-term sustainable solution.

Point 4 is that there is a lack of clarity for us on what dual regulation might mean. It has been talked about. We have not seen the proposals. It depends on what we see, but even given a dual regulation regime, which we will probably go into later, we have concerns, and in practice it would not be workable.

Point 5 is that the role of the falsified medicines directive, which Martin identified, needs to be clarified. Point 6 is exactly the point that Michelle and Martin have both made, which is that we need stability and clarity. We are making medicines this month that have just arrived at Martin's members' wholesalers and that will still be in date and being dispensed when the initial period of the protocol expires. It takes us 10 years to develop a new medicine, so we need that clarity.

The second part of the question was: how have things changed? In summer 2021, we wrote to the Secretary of State for Health and Social Care warning that it might be necessary for us to withdraw a very large part of our portfolio from Northern Ireland, because at the time it was believed that every medicine would need a separate Great Britain and Northern Ireland licence. That threat has receded. Michelle also alluded to that. It removed that cliff edge.

As things stand, the great majority of the portfolio that we imported at that time is still being supplied to Northern Ireland. However, the centralised procedure deadline at the end of December is a matter of grave concern to us. Every one of those packs is not a theory or a product but a medicine, and we have grave concerns that this process could ultimately damage the interests of the patients who really depend on medicines.

The Chair: Thank you very much. All three of you set the scene extremely well for a series of questions.

Baroness O'Loan: I did not catch the fifth point that you made, Mr Williams. What was the nature of the fifth point?

Paul Williams: The fifth point was about the falsified medicines directive and understanding its future role and place.

Baroness O'Loan: Thank you.

Q2 **Lord Hain:** First, apologies that I have to leave at 3.45 pm, but thanks very much for coming. How have you had to change or adapt your operating models because of the protocol? You mentioned £2.5 million of extra costs, Martin. Michelle said that, actually, things are better than when you last came to us 18 months or a little more ago. As a business, how have you had to adapt your operating model?

Michelle Riddalls: When we spoke in October 2021 we were concerned that all operating models would have to change because of the fact that the products would be seen as imports going into Northern Ireland. The good thing the EU legislation did was remove that requirement, so the products were now just seen as distributed into Northern Ireland, rather than the importing, which was what we were worried about and which was going to lead to the majority of the operating model changes at company level.

We recently surveyed our members, and only one of them has had a change in its operating model since the change in EU legislation. That

company supplies generic prescription medicines, and it has changed where it releases its product from. It is getting it released from the EU now rather than from the UK, as was the case before.

Lord Hain: Is it a diversion of jobs?

Michelle Riddalls: I could not say how it has done that. It just means that, if we had not had the EU legislation, the company could have carried on supplying to Northern Ireland. It was amending in anticipation of there not being the legislation, but as that has not happened and it has amended, it can still utilise that route to get through. From our side, it is quite positive that there have been hardly any wholesale changes in our businesses on how they get products to Northern Ireland.

Lord Hain: That is mainly because of what the EU did.

Michelle Riddalls: Yes.

Lord Hain: Martin, you referred to a sticking plaster. I was trying to understand your evidence. Is it because of the grace periods that things have been the way they have, in that we have not crashed—you mentioned a sticking plaster—or is it for other reasons? How have you adapted your model?

Martin Sawer: It is all of those. The three principal wholesalers that operate nationwide across the UK have the biggest challenges because they have hub warehouses, as I said, in GB. Before the Northern Ireland protocol they used the Belfast warehouses as if they were distributing from Bristol down to Cornwall, because in Cornwall you might have smaller warehouses. That was how Northern Ireland Belfast warehouses were viewed.

Because of regulations and grace periods—grace periods and the regulations have helped; they are both the sticking plaster—each of those businesses has had to work out where the industry would go. We have not changed our basic distribution model, but in Belfast those warehouses will probably now be stocking more products than they used to. They will be stuffed as full as they can be just because they want to be close to the patients and not have to worry about getting some medicines from GB, but they can by no means hold them all.

Secondly, they will have had to work with manufacturers that have rerouted their supplies. Instead of coming through the EU into Birmingham, Scotland or Bristol, the manufacturers may have rerouted—I am aware of this—from Germany to Belfast direct to avoid having to go through GB because of Brexit. We have had to work out how to receive those smaller quantities more often, because it is only for 1.8 million people. It was much easier in the past to get two pallet loads from an EU manufacturer. Now, in Belfast, they will get part of a pallet because that is all you need for a long time for the patient numbers.

Lord Hain: Why is that a problem?

Martin Sawer: It adds an extra layer of complication and not being able to put it away so quickly. You have more and smaller deliveries. We are employing more people in Belfast, so the cost has gone up. I know we are coming on to NIMAR and FMD. Both of those new regulatory approaches have created a much more manual approach for us in doing business in Belfast.

Lord Hain: And therefore costly.

Martin Sawer: And therefore costly. Seventy per cent of our medicines from our big three wholesalers are on automated machinery in GB, but in Belfast we will have to do much more manual stuff to check up on the licensing and on FMD, which now, of course, does not apply in GB, so immediately we have more regulations in Northern Ireland; the falsified medicines directive, which no longer exists in GB. We have to do something. Those regulations, as we will talk about, have changed anyway, and we have to do more in the wholesale supply chain.

Lord Hain: Have you had to recruit more workers in Northern Ireland?

Martin Sawer: Yes. I do not know how many, but there will be an increase in headcount.

The other point is the TSS declarations. Every day, we send medicines on a ferry from GB. There is certainly more headcount in GB that has to do those declarations, because we are doing them from GB. An online software adjustment has had to be made to satisfy the TSS requirements.

Paul Williams: It is very difficult for us to separate how we have adapted to the protocol from how we have adapted to Brexit. It is all one piece. I know that not everybody in the room will like to hear this, but Brexit overall has added a very large amount of cost and complexity to our services. Specifically on the protocol, the impact on our operations, the physical act of taking a product to Northern Ireland, has not changed for us that much, not least because a majority of the product is sent there by the wholesalers, not us.

The main impact of the operation of the protocol on us has been the licensing and regulatory component of what we do. For an industry such as ours, regulatory affairs, as we call it, is hugely important; it is the maintenance of licences to sell the product—so-called marketing authorisations. The complexity that the protocol and Brexit in general has brought to that has led to a very large increase in cost and complexity for us.

Lord Hain: When you say it is mainly Brexit, would you have a punt at the percentage of the cost due to Brexit compared with the cost due to the protocol, or is it too difficult to guess?

Paul Williams: May I answer the question in a different way?

Lord Hain: Yes.

Paul Williams: We have a factory in Cheshire that makes products for all over the world, and one of the markets it makes product for is the Republic of Ireland. Until Brexit, that factory would make the product in Cheshire, test it in Cheshire, 20 minutes up the road to Liverpool, ferry to Dublin—job done. Product for Ireland from that same factory is now taken to Dover, shipped to Rotterdam, driven to Germany where it is tested and released, driven back again, driven back up the M1 and M6, and then it gets on a ferry to Ireland.

Lord Hain: Really?

Paul Williams: Seriously.

Baroness O'Loan: Why on earth?

Paul Williams: Because EU countries elected at Brexit that they would not accept batch testing and release that was undertaken in the UK, so product that goes from the UK to a European market must be tested in a European market. I do not know exactly how many pounds and pence that costs every time, but the financial and environmental cost is considerable. That is just one example.

The Chair: When you say it has to be tested in the European market, would that exclude being tested in Northern Ireland?

Paul Williams: Yes, it would. If products are going to Northern Ireland, it is treated as part of the UK. In practice, it still goes to Europe for testing even for the whole of the UK, because logistically it is simply not worth duplicating that testing function. If you are going to test a batch of medicine, which is quite a costly process, you test it once. If you have to test it in Europe, you have to test it in Europe. Even product that is made in Cheshire and will be used in Cheshire is taken to the EU for release.

Lord Hain: The same applies for Belfast.

Paul Williams: Absolutely.

Lord Hain: It goes from Cheshire to Germany.

Paul Williams: Yes, and comes back.

Lord Hain: Comes back to Cheshire.

Paul Williams: In practice, to Yorkshire, but yes.

Lord Hain: Okay. It changes county.

Paul Williams: And then goes via the wholesaler to the customer.

Lord Hain: Meaning, let us say, Belfast or Dublin.

Paul Williams: Yes.

Lord Hain: It is the same route for Belfast or Dublin, through that circuitous—

Paul Williams: Yes.

Lord Thomas of Gresford: When you use the word "batch", do you mean the whole consignment?

Paul Williams: Yes, sir, I do.

Q3 **Baroness Ritchie of Downpatrick:** I have a quick question to try to understand this issue and the whole cumbersome testing procedure. You have a factory in Dublin, do you not? Is that a distribution point?

Paul Williams: In Dublin, we had a factory. It was only a very small factory, and it is in the process of winding down and closing at the moment. We have a very large, very successful facility in Waterford, however.

Baroness Ritchie of Downpatrick: Is it not possible for testing to be done in the Republic of Ireland?

Paul Williams: The theoretical answer is yes, but the practical answer is no, because the factory in Ireland makes a particular kind of product and therefore has a particular skill set and facility to test the product that that factory makes. The factory in Cheshire, in Runcorn, has a completely different capability and testing capability, so the expertise to test that does not exist in Ireland. Bear in mind, too, that this is product that is going to Poland, Spain, Germany, wherever, so you would just shift the problem.

I apologise for shifting the point off the protocol, but it is an illustration of adapting to Brexit and to the protocol. I agree with Martin: there is no big, single "Oh, my gosh, this is the thing that's really killing us". It is that suddenly there is a bit more regulatory difficulty, a bit more supply chain difficulty and a bit more licensing difficulty, and it all adds up.

Lord Hain: If you did not have the protocol, where would you be?

Paul Williams: When the three of us appeared at the committee last time, we were asked directly about that, and at the time we said that a mutually negotiated end to the protocol would probably be a very good thing, depending on the outcome. A unilateral withdrawal from the protocol would be something that we would be very concerned about, specifically because we would be very concerned at what action the EU might take in response. The protocol is the best mechanism that exists today because it is the only mechanism that exists today. If it could be agreed that there might be a different mechanism, that would be great.

Lord Hain: You mean an adapted protocol.

Paul Williams: Or no protocol, as long as it is agreed between the UK and the EU.

Baroness Ritchie of Downpatrick: For medicines.

Baroness O'Loan: I do not want to labour this, but I really want to

understand the practical implications of what you are facing. To go back to the questions, you used to test in Great Britain, I assume. You produced in Cheshire and you tested in Cheshire—

Paul Williams: Yes.

Baroness O'Loan: —because we were all in the EU.

Paul Williams: Yes.

Baroness O'Loan: Margaret has established that we cannot do it in Ireland because of the fact that there is no capacity to do it.

Paul Williams: Because of the different capability of the facilities there.

Baroness O'Loan: Yes. You are going to do it somewhere in the European Union. I want to follow Martin Thomas's question. What is a batch? I do not know if you manage them, but if we take a product such as Anadin, does that mean that every new batch with its new use-by date is tested?

Paul Williams: Yes.

Baroness O'Loan: Every new batch?

Paul Williams: Yes.

Baroness O'Loan: If you take one drug, how many batches will be going to Europe for testing and going on that circuitous route and coming back?

Paul Williams: Medicines cannot be made in a continuous process. It is not like biscuits, for the sake of argument. I do not wish to denigrate the makers of biscuits; I am sure they are very diligent and skilled. If I might boil this down to the lowest common denominator, for medicines you typically put the ingredients into a stainless-steel vessel, you bake them and, lo and behold, you have a medicine. They have to be made in batches. The quality standards are so enormously strict—rightly so; you have to protect the patient—that every batch must be tested.

A qualified person, a QP, who is hugely skilled and very practised, has to sign personally that they certify that the medicine is fit for use by the patient. It is a very responsible task, so the batch has to be sampled at the discretion of the qualified person—"I want to look at that pack, that pack and that pack"—to be absolutely sure that there is no possibility whatever that that medicine is below standard. Every batch of medicine that is made in every factory around the world is tested in a laboratory as a sample, and a qualified person signs a sheet of paper and says, "Yes, I'm taking personal responsibility that this medicine is safe".

Baroness O'Loan: If I may clarify a little further, could that process of certification be the subject of negotiation between the UK and the EU so that you could continue to certify in GB?

Paul Williams: The short answer is yes. The long answer is that we have been calling for this ever since Brexit. We have been calling for a so-called MRA—mutual recognition agreement—so that the EU and the UK would recognise each other's testing. Our trade association, the British Generic Manufacturers Association, has been calling for it as well. At this moment in time, we are unable to get any traction with that, but it would simplify the whole medicines chain for the UK considerably if it was possible.

Baroness O'Loan: Presumably, also for the countries to which you export ultimately within and outside the European Union.

Paul Williams: Absolutely.

Michelle Riddalls: On the batches and licensing, we are also seeing some difficulties, and there are slightly different scenarios, because the way things are supplied depends very much on how they are licensed in the first place. OTC medicines are mainly national licences and, as such, we can test and release here in GB and the UK. There will be one licence that covers the whole of GB and Northern Ireland. That is what we asked for in the EU legislation—that they would be seen as being distributed rather than being imported.

One issue remains: that products that are via the centralised procedure have a different licence. They were the one category of medicines that were not afforded the same status as the national licence in the UK, which is why there are potentially two different licences behind what is being supplied to Northern Ireland. That adds to the complexity and means that there are differences in how you can supply. It is behind the reason why Martin's team is having problems. If they have a product that is only viable for GB, it cannot go to Northern Ireland. A lot of the issue as to where the supply goes is rooted in the way the licence was first registered and therefore the way it denotes what you can and cannot do in the future. That is to help explain why there are some differences between what all of us are saying.

Q4 **Baroness Ritchie of Downpatrick:** We have quite a bit of information to assimilate this afternoon, so we will need time to reflect on it and see what action can be taken regarding the negotiations. Does the protocol carry any current or potential beneficial effects from the point of view of medicine provision to Northern Ireland? What changes, if any, have taken place in relation to the scale of cross-border supplies of medicine on the island of Ireland since the protocol came into force? I can well recall that at our last session we discussed this issue, and you quite clearly referred us to different types, different brands, different weights and grams, and different components within each of those medicines.

Paul Williams: In the interests of time, I will make my answer brief. Does the protocol carry any current or potential benefits? In so far as it is better than unilateral withdrawal from the protocol, yes, it has benefit. Does it offer any benefit that was not available before Brexit? No, it does not. I suppose, in summary, our answer would be that the protocol as it

stands today is better than a unilateral withdrawal from the protocol would probably be.

What changes have taken place in the scale of cross-border supply? All three of us explained last time that it is at a very low level. To our understanding, it remains at a very low level.

Baroness Ritchie of Downpatrick: Could you explain why?

Paul Williams: Martin can probably answer more expertly than I can, but there are two basic reasons. One is that there are differences in custom, practice and brand. There is even different custom and practice with a pack of 28 compared to a pack of 30. Certain brand names are different. It is different for one of our own products, for example. There is also a difference in the logistics and supply chain. Customers in Northern Ireland buy from Northern Ireland wholesalers. Customers in the Republic of Ireland buy from Republic of Ireland wholesalers. I defer to Martin on this, but I do not believe that wholesalers in Northern Ireland, generally speaking, supply customers in the south, and vice versa.

Michelle Riddalls: I agree with what Paul said about the protocol. Having it available has meant that the medicines are carrying on, but that was as a result of the EU legislation change that got rid of the cliff edge. We would not want unilateral withdrawal from it, because we do not know what that would look like. The devil is always in the detail.

On dual regulation, we do not know what that means in reality. During the technical discussions to get the EU legislation changed, we worked very closely with the Department of Health and Social Care and the MHRA to look at what changes were needed, and how they could be implemented to make sure that the proposals the EU then made were in line and implementable so that they worked in practice. That is what we are seeing now. If it suddenly changed, you can talk about taking it out of the protocol or withdrawing unilaterally, but where does that leave us? How do we get products to Northern Ireland? Under what medical framework? What structure? We do not know, so it could cause more confusion than it could solve any problems.

On cross-border supply, the medicine supply chain is one of the most tightly regulated in the world because of the regulatory actions behind it. As I think I said before, I have worked in the regulatory field for the past 20 years, so I have been really involved in it all. The vast majority of OTC products are UK licences. In 2021, 98% of the licences for OTC medicines were national, which means that they have a unique UK product licence number on the packaging, and so are readily identifiable as UK products. Only 1% of products were joint with any other country, so if they were moved to Ireland they would be easily identifiable as illegal.

As we have mainly national licences in the OTC world, the licences for Ireland will also usually be national, and, as Paul alluded to, they may have completely different names. In the OTC world, ibuprofen is a pharmacy product in Ireland, but it is available in general sales in

Northern Ireland, so you can buy it off the shelf in a petrol station. There are completely different licensing regimes.

Because intrinsically nothing has changed for us since we last came here, the cliff edge was diverted. Yes, there are some problems, but everything is still working and being distributed pretty much in the same way. We do not think there would have been any difference now compared to what there was 18 months ago, which was very little from the OTC perspective.

Martin Sawer: Perhaps unsurprisingly, I do not differ at all from what Paul and Michelle said. We do not believe that the current protocol carries any benefits other than the fact that bringing it in was important for continuity. There are no benefits because it is there now. Regarding the Republic of Ireland, some people, including me, thought that if one of our members happened to have a very big warehouse operating as an Irish company in Dublin, some manufacturers might want to distribute to Northern Ireland from Dublin as it is not very far away, but, as Michelle mentioned, the licensing and how any manufacturer wants to market, promote and brand its product is so different.

Actually, Ireland is quite a small market in terms of the number of people. Northern Ireland has always benefited from piggybacking on a GB market of such a huge, strong market force that nothing changed. The distribution routes did not change. Quite a few of us thought they might for reasons you mentioned, but they have not changed at all as far as I can see, so I support what Paul said.

Q5 **Baroness O'Loan:** Listening to the evidence you have given so far, it seems to me that I can almost predict your answer to this question, although it is not the answer I might have expected. What has been the impact of the EU's medicines legislation, announced in December 2021 and enforced since April 2022? What has been the impact, if any, on the scale of product withdrawal from Northern Ireland?

Accepting all that you are telling me about no disruption of supply and all that sort of thing, as I move around Northern Ireland I see empty shelves and I see problems in getting medicine. I know some of those relate to specific issues such as the strep A thing and the lack of availability of antibiotics, but I think I am seeing an impact, yet you are telling me there is no impact. What do you think the impact is?

Paul Williams: The first part of the question was whether the EU's legislation on medicines has been beneficial. It was helpful in that it allowed us to continue to supply the vast majority of our portfolio in Northern Ireland. The hole in that was the so-called CP—centralised procedure—medicines issue. I know that we will come to that shortly, so I will not develop that point now.

However, I will now take off my Teva hat and put on my industry hat and say that it is onerous to have a Northern Ireland licence in addition to a GB licence. Companies in general are having to make choices and decide, particularly if they are bringing a new medicine to market, and,

particularly the smaller companies, whether they can afford, bluntly speaking, to have a Northern Ireland licence alongside a GB licence. We have anecdotal evidence that companies are starting not to apply for a Northern Ireland licence alongside a GB licence.

My company has withdrawn one product from Northern Ireland on cost grounds since the last time we spoke. To our understanding, there are fewer than six patients taking that medicine in Northern Ireland, and we are still supplying the medicine under the NIMAR procedure. To answer the question, companies are already having to think about whether it is viable to apply for two licences for one country for such a small patient population.

We feel our responsibilities to patients very strongly, and we have already committed in a couple of cases to having both licences come what may, no matter the cost, because there are no alternative medicines for the patient. They depend on us. I am sure the whole committee would expect us to say, "That's not a decision that we'll take". Nevertheless, companies in general are already having to think about that.

Michelle Riddalls: We do not have many centralised products, so we probably feel a little bit more positive about the impact of the EU legislation, in the sense that if it was not there, we would have reached the cliff edge that we spoke about when we were last here. At the time, we estimated that between 75% and 98% of OTC medicines could be discontinued. As it is, we have spoken to our members, and at the moment we are aware of only one product being discontinued in Northern Ireland, which was linked to a centralised procedure licence. We estimated in 2021 that there were between 1,550 and 2,325 branded OTC medicines, and we are only aware of one that has been discontinued.

It is fair to say from our side that the EU legislation has had a really positive impact, and if it was not there, there would be an issue. It was not just the EU that did that; we know that it was the result of a very close working relationship between UK Government officials and the EU and the very detailed technical discussions that took place. Although we were not involved as an industry, we were inputting to those to make sure that the solutions that we needed were there. It has been very beneficial. The EU changed the legislation, which I thought would never happen, but it was really positive that it did. Both sides made a lot of effort to get to that point.

The Chair: You talked about how you were involved, not in the negotiations but in input to the British position.

Michelle Riddalls: Yes.

The Chair: How important was that?

Michelle Riddalls: Really important. Later in the evidence, I know you will ask about what can be done. Having those detailed technical discussions with the people who were sitting in the room on the EU side and having similar technical discussions was really important. With my regulatory background, I was able to help to identify some of the issues and help to look for solutions. We had a very close working relationship with many colleagues at both the MHRA and the DHSC in saying whether an idea would or would not work and what that would mean.

Baroness O'Loan: Can I follow up on what you said about one product being withdrawn? Paul told us that they came up against one product that was in danger of having to be withdrawn and they decided to continue despite the cost, et cetera. I assume it is an OTC medicine.

Michelle Riddalls: Yes.

Baroness O'Loan: Is it a product for which there are alternatives available to the consumer, or is it of particular significance?

Michelle Riddalls: I am unsure about that. I do not know.

The Chair: Would you be able to check and let us know the answer? It is an important point.

Michelle Riddalls: Yes, I will come back.

The Chair: Thank you so much.

Baroness O'Loan: Martin, on the distribution side, can you help us, please?

Martin Sawer: Yes, of course. The first point is about the EU's legislation at the end of 2021. It came just in time, a bit like our deliveries, which are just in time sometimes. As Michelle said, the whole sector, supply chain manufacturers down to the pharmacy level, worked very closely with the MHRA and the Department of Health and Social Care to get to that UK position, which was only agreed at the last minute. The generics industry had to work hard to demonstrate—letters were sent in—that nearly 1,000 products were going to be discontinued before that legislation.[2]

From our perspective, yes, it would have been a terribly difficult time if the legislation had not been passed. We maintain the distribution of those 1,000 products.[3] Since then, there have been some discontinuations. In total, although there may be say, 90 products on the NIMAR list, that represents about 170 different presentations.[4] We will come on to talk

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[2] Note from witness: The figure is in fact nearer 2,000.
[3] Note from witness: The figure is in fact nearer 2,000.
[4] Note from witness: Figures taken from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1131206/list-of-medicines-that-can-be-moved-through-nimar-24-Jan-2023.csv/preview.

about NIMAR in the future, but that represents where there is a clinical decision that there is no alternative product available on the Northern Ireland market at that time. I deduce from that that there are quite a lot of discontinuations, because there will be alternative generics that can be supplied to Northern Ireland.

In answer to your point, it is difficult to unpick the shortages in Northern Ireland from the shortages that we experienced with antibiotics and HRT treatments earlier last year, as well as pressures on OTCs over the winter period. A community pharmacy in particular gets affected very quickly because it does not have much stock, so we have to keep supplying it. A community pharmacy is always inadvertently affected more; I spoke to CPNI (Community Pharmacy Northern Ireland) in Northern Ireland earlier this week. They feel that the shortages are worse than in GB, but it is difficult to disaggregate what is due to the supply to Northern Ireland under the protocol and what is actually a shortage for the UK. More work needs to be done on that. It is a good question.

Baroness O'Loan: We know that there are major shortages of OTC medication in countries such as Canada, particularly for children—paediatric medication and stuff like that. Is this in part nothing to do with Brexit, the protocol or anything else, but due to global shortages as a result of decisions made by manufacturers about the level of production? Have they cut back the level of production to result in this situation, Michelle?

Michelle Riddalls: It is nothing to do with cutbacks. There has been a lot of information in the press about potential OTC supply issues. Here in the UK, and I know elsewhere, manufacturers have not cut back on what they are doing. We had some statistics last week showing that there is a 59% increase in demand compared to the same time in 2019, so since the last time there was a proper cold and flu season, pre-Covid, it has gone up 59%. There is an increase of between 45% and 50% in flu compared to this time last year. There is a lot of increased demand that companies are trying to keep up with.

There are general ongoing global container issues as a result of the war in Ukraine and Russia, and China still having Covid, which has put a lot of pressure on some of the supply chain routes. The global supply chain piece is really big, but manufacturers, certainly the manufacturers we talk to, are working 24/7 or to as much capacity as they can to keep producing products. It is just that there is unusual demand at the moment, hence some issues.

There may be some issues in community pharmacies via wholesalers, but, as I mentioned earlier, OTC medicines distribution is very different and it is not usually by a wholesaler. Usually, the companies supply the retailers and the big pharmacy chains directly. Something goes straight to Sainsbury's or to Boots, and they disperse it to their retail stores. It may be local and sporadic. You may not get it in one community pharmacy, but if you went to a Boots store or to Sainsbury's you could still get a product; it is just localised and different. All my companies

have assured me that they are continuing to supply some of those where they perceived issues; it is just that as soon as they go in, somebody buys them. They are put out in different places.

Q6 **Lord Thomas of Gresford:** You clearly identified issues that have arisen since we last met. I want to take up Paul's invitation to tell us something about the centralised procedure. Could you update us on that and tell us something about how the falsified medicines directive is working, and the supply of medical devices in Northern Ireland?

Paul Williams: Yes, of course. A centralised procedure medicine was authorised at EU level, with one authorisation covering the whole of Europe as opposed to a national licence. Latterly, over the past 10 years in particular, that has become a very common route for medicines to become authorised. They are typically assessed and passed by one EU member state, a so-called lead, which will then say, "Yes, this medicine is fine. I'll licence it and licence it on behalf of the EU". It is a centralised procedure medicine, or sometimes a centrally authorised procedure, so you may hear about CP or CAP.

Under the protocol, all CP licences that were applicable to Great Britain have been novated to Great Britain licences; effectively, they have been transferred en masse. All companies are currently in the process of migrating across, as GB licences, products that were sold in Scunthorpe, Devon or wherever under a CP licence. However, for regulatory purposes, Northern Ireland is still part of the EU. Therefore, as an EU quasi-member, the CP licence still applies. You cannot dispense or sell one of the products novated over to a GB licence in Northern Ireland because in Northern Ireland you still must have a CP-licensed product. I hope that makes sense.

We have until the end of 2023 to novate all those licences to GB licences. As of today, we have moved seven of our own products to a GB licence. For the rest, we are continuing to supply the whole of the UK for now, because we can continue to supply CP licences across the UK until December. So we are currently migrating the CP licences that apply to Great Britain to Great Britain licences. From the end of this year we will not be able to supply the same pack to Great Britain and Northern Ireland, because in Great Britain we must have a GB licence and in Northern Ireland we must have a CP licence. It is the same product, the same patient, the same illness, the same medicine, but we must have a CP licence in Northern Ireland and a GB licence in GB.

It goes straight back to the fundamental problem that we have always flagged all the way along, which is that two licences and two packs for the same medicine in the UK is not viable. There are simply not enough patients in Northern Ireland to make that worth while. We are thinking hard about how we address the issue. We have said that, where the patient has no practical alternative, come what may we will be there for them. There are medicines where there is an alternative, and I cannot speak for other companies and what they may do, but it worries us greatly that this represents a cliff edge from the end of this year.

Lord Thomas of Gresford: Do I understand you to say that from the end of this year a CP licence would not be good enough to sell a product in GB?

Paul Williams: That is correct. The protocol agreed that, by the end of this year, companies must migrate all CP licences that apply to GB to a GB licence. It is not about being good enough; it is just different. The protocol agreed that, by the end of this year, CP-licensed products must not be sold in GB under a CP licence; they must be sold under a GB licence.

Lord Thomas of Gresford: How tight is the deadline for you to do the migration?

Paul Williams: Astonishingly.

Lord Thomas of Gresford: If you sell in Northern Ireland, you still have to operate under a CP licence. Will the existing CP licence continue in Northern Ireland, or will there have to be a new application?

Paul Williams: The issue is that a CP licence will be valid in Northern Ireland but not in GB. It will be valid in the Republic, but we have already established this afternoon that the trade between the Republic and the north is minimal and very low. That means that you will have a GB licence that has been created just for GB. Although, in theory, a CP licence for Northern Ireland is a carryover—it simply continues to be a CP licence—in practice, it is subscale; there are not enough patients to justify supplying a CP-licensed product to such a small patient population. I know, and I have anecdotal evidence, that other companies are looking at this very hard and could well be planning to discontinue those CP-licensed products in Northern Ireland.

Lord Thomas of Gresford: You would regard it as a major negotiating aim to enable Northern Ireland to take GB-approved medicines instead of the CP licence that they have given up.

Paul Williams: In all the work we do on Brexit and on the protocol, the only issue that keeps me awake at night—I say this not as a metaphor but as reality—is the thought of a patient not getting a medicine they need. If there is a threat to a patient of not getting the medicine they need, it is the centralised procedure medicine.

Baroness O'Loan: The problem with the CP licences for you in GB is that Northern Ireland is a very small area, but do you export to other countries within the European Union using that CP licence? The pharmaceutical business is a very global business.

Paul Williams: Indeed.

Baroness O'Loan: Could you look at the costs not just in terms of Northern Ireland but in terms of all the other countries you might supply in the European Union market?

Paul Williams: Yes.

Baroness O'Loan: That reduces your costs.

Paul Williams: By definition, a CP licence is valid in all European countries. You are absolutely right to highlight that. Unfortunately, that CP licence is supplied in France with a French patient leaflet and a French pack, and in Germany with a German leaflet and a German pack, so in theory you are absolutely right, but in practice it does not work like that. It comes back to whether there are 28 or 30 in a pack, and a doctor's local custom and practice. In theory, you are absolutely right. In practice, it does not work like that because of the fact that there are different languages and different pack sizes in different markets. A licence to produce a medicine does not refer to how many in a pack there are or what the language on the pack is. It is a prescription for the recipe by which the product is made.

The Chair: Michelle had an answer to Lord Thomas's original question.

Michelle Riddalls: Yes. With regard to the centralised procedure, we have eight products in the OTC world that are centralised. There is an option to do a joint pack between the centralised licence and the GB licence, but that is then reliant on the two products not diverging when their licences are overseen by two different regulators. Some of our members have chosen to take that risk and make joint packs, bearing in mind that we have only a few. Another one, as I mentioned, was discontinued because they did not want to take a risk at that point. It is fair to say that it has not been easy, and guidance has not been available very easily to provide reassurances over getting joint packs in the first place, which would, in theory, be a potential solution.

There is the concern behind the divergence. What the EMA may say as a regulator and what the MHRA may say as a regulator is extremely risky and concerning, which is probably one reason why Paul's company is not doing it. If you have that risk, it is out of the control of the marketing authorisation and of the company. It is some external force suddenly coming to you and saying, "Oh, well, we think you should have this warning on your pack", the MHRA might not agree and want a different warning on the pack, and your packs will split. What do you do and how can you manage that? That increased complexity causes an awful lot of problems.

Divergence is potentially in the gift of the MHRA. During some of the discussions when we were looking at the EU legislation, the MHRA said that very strongly that it would not diverge from Europe for any reason; there would have to be a public health reason. It was trying to give some reassurances. However, I think it is fair to say that I have seen with my own eyes that there has been divergence in some of the products that we have been involved in at PAGB.

There needs to be better understanding as a regulator of the implications of divergence, because if more reassurance was given that there would

not be divergence for the sake of divergence, such as a very junior assessor at the MHRA just saying, "I want this", and not realising what the implications were, it might reassure companies more to do joint packs. I am not saying that it would completely—there are other factors at play such as FMD—but there is something there, and it is a risk that companies are taking from that side. I want to talk about medical devices, but I will let Martin talk about CAPs first.

Martin Sawer: Thanks, Michelle. Building on what Paul said, I am aware that, on the conversion point about CAP products, quite a lot of the 1,250 different manufacturers that our members have to deal with and supply their products to are telling our members that they are only going to make PLGBs because it is not worth making a CAP product for Northern Ireland. The planning is already going ahead because, as Paul says, the cliff edge is at the end of 2023, which is not long, and manufacturers need to plan, so we are becoming aware of that.

The manufacturer, as I am sure Paul knows, legally has to tell the Department of Health and Social Care that it is not going to supply Northern Ireland, but I am not sure that is happening in every case. Other companies are completely different. Are smaller companies with just a few products in a different part of the world aware that it is technically a discontinuation? Then it can be considered for the NIMAR list. I think this is a stealth issue that will hit the supply chain unless it is sorted out very soon.

Of course, it might be kicked down the road. The derogation may be extended, so to speak, but that does not solve the fundamental problem as to why CAPs and PLGBs exist in the first place. We would support a UK-wide licence, rather like Michelle. Actually, that is where it links into FMD, because Northern Ireland is the only place in the UK with FMD, the falsified medicines directive. As distributors, we do not believe that is working properly in Northern Ireland. I am happy to go into some of the detail.

We do not believe that compliance is as it should be. We had some helpful guidance from the MHRA in December about how wholesale should be verifying product, which is an increase in workload for us. We understand that if FMD is to be in Northern Ireland, it needs to be proper and compliant, because our regulatory members are rather concerned about any liability issues and whether products are being handled legally or not. This is all because there is a vacuum of final decision-making.

If it was our position to do so, we would suggest that FMD disappears from Northern Ireland, but I know that would be a real challenge for the EU for lots of reasons. Certainly, the falsified medicines directive, in our opinion, is not being used properly. Where is the evidence that it is needed in Northern Ireland?

Lord Thomas of Gresford: Could you explain the impact of FMD? What exactly does it require of the manufacturer or distributor?

Martin Sawer: I can talk about the distributors. Under the new guidance issued in December, for every batch or delivery received by the wholesalers in Northern Ireland, we now have to do a sample verification to make sure that it will be successfully decommissioned at the point of dispensing by the pharmacist, doctor or hospital doctor. We have to verify that the pack has been put on the European hub, has a tamper-evident seal and is fully FMD-compliant. Our role is verification. We did not have to do that for every batch or delivery received prior to December last year under FMD. We were allowed to accept a manufacturer's product, without verification, that was delivered direct to an HDA company warehouse in Belfast or that arrived via a registered pre-wholesaler. We did not have to verify a sample of all packs. Now, we have to do that. That is an increased workload, clearly, when we receive goods.

Secondly, we have to decommission, which means making sure that the pack is verified and then we have to decommission every pack off the European hub which is going to every healthcare institution in Northern Ireland that is not a hospital, pharmacy or doctor. The medicine might be going to a paramedic, a health clinic, a dentist, an optician, or other types of organisations that receive medicines. We have to fully check and decommission those before giving them to what are called Article 23 organisations in Northern Ireland. We do not have to do that now anywhere else in the UK. We are not convinced of the value of it, or that everybody in the supply chain is aware of what they are supposed to do or is compliant. I am not suggesting that manufacturers do not know that; I suggest that it probably happens lower down in the supply chain.

Lord Thomas of Gresford: Michelle wants to say a word about devices.

Michelle Riddalls: Yes. From a device perspective, there are still outstanding issues, and it was something I touched on in our written evidence recently and previously. At the moment, there are import requirements for a medical device that goes from GB to Northern Ireland, and it remains a concern to PAGB. The responsibility is put on those who are seen to import, and that is detailed as a shop, a petrol station or a pharmacy in Northern Ireland.

There is a very wide-ranging, diverse population that could be seen as an importer. They are asked to provide information that they are the importer at the point of sale. If a corner shop was about to sell a customer a pack of plasters, which are medical devices, they would be obliged to give that customer the information that they are the importer of the product to Northern Ireland. That is a big issue of practicality.

As well as that, there are regulatory obligations that they have to fulfil, understanding what happened in the supply chain and that the medical devices are appropriately certified. At the moment, as a result of some work that we did a couple of years ago, a letter of comfort was issued by the MHRA to help to enable that supply to continue. However, as and when it ends, there will be problems importing products into Northern Ireland. In a recent survey with members, five of seven that were

involved in medical devices said that they were relying on that letter of comfort to continue supplying to Northern Ireland.

What we need to see and what we are calling for is a longer-term solution. That could be by some guidance on the responsibilities via the MHRA, based on EU guidance because it is for a CE mark, or it could be looking at how the implementation of dual regulation works. There are different scenarios that could work. At the moment, because the letter of comfort is outstanding, nobody is really looking at it or addressing it; it is there. Because things are moving and happening okay at the moment, the actual issue behind it has not been addressed. We feel that that also has to be addressed as part of ongoing discussions.

Lord Thomas of Gresford: Did I understand you to say that if a corner shop sells a pack of Elastoplast, it has to hand over some piece of paper saying, "I am the importer"?

Michelle Riddalls: Yes, that is exactly what it says.

Lord Dodds of Duncairn: Paul, give us a few examples of CP medicines that are in Northern Ireland. We have the examples of medical devices and plasters, but what are we talking about with better-known medicines?

Paul Williams: I can only speak to the medicines that my company makes. As of today, we have 48 stock-keeping units covered by CP licences in the UK. Those are not 48 different medicines; they are 48 SKUs. I can give you three examples. We have an innovative migraine medicine called Ajovy; Effentora, which is for breakthrough cancer pain—in other words, for people who are very poorly and in huge pain; and Olanzapine, an antipsychotic that is given to patients who are having psychotic episodes.

If I can overgeneralise, they are all prescription medicines. There are very few CP licences outside prescription medicines. They tend to be newer, which does not mean that they are brand new but came in perhaps in the last 10 or 15 years or so, and they tend to be products that are for more serious conditions. That is a generalisation.

Lord Dodds of Duncairn: They are currently being used and supplied in Northern Ireland to patients.

Paul Williams: Yes, they are.

Lord Dodds of Duncairn: At the end of December 2023, that comes to a head.

Paul Williams: By the end of 2023, companies have a choice between having the logistics, supply chain and regulatory issues by continuing to have a CP licence just for Northern Ireland, or supplying only to GB under a GB licence.

Q7 **Lord Dodds of Duncairn:** It always helps to get an example of what we

are talking about. For patients with migraines, cancer pain and psychotic episodes, and with all medicines, it is very important that we get the issues understood properly and solutions found to them.

Coming to the issue of the MHRA authorised route—NIMAR—did I pick up right, Paul, that you said in your evidence that you found that it was bureaucratic, temporary and not a long-term sustainable solution?

Paul Williams: Yes.

Lord Dodds of Duncairn: Explain to us how it works and why you say that it is bureaucratic, not a long-term solution and not sustainable.

Paul Williams: Certainly. I would be delighted to answer that, but I would like to ask the Chair if at some point we can return to FMD, because it is an issue of some concern to us.

NIMAR is a mechanism for supplying medicines in Northern Ireland where otherwise it would not be possible. It is as simple as that. It is a safety net. It only applies to a prescription medicine that has a GB licence. It does not apply to OTCs. It does not apply to medicine where you can go into a pharmacy and ask for it, a so-called P-medicine.

As of 21 December, the industry as a whole had 135 SKUs on the NIMAR list, covering 79 different medicines. From the conversations we have had with the chief pharmaceutical officer of Northern Ireland, whom I do not wish to represent—of course she has her own opinions—my understanding both from my perspective and from the anecdotal evidence I have from others is that each of those is a step outside the normal process; it represents an extra step that has to be undertaken, so there is extra complexity. In addition, there are rules around NIMAR, in particular that those products may not be promoted or detailed in Northern Ireland. Effectively, you are not allowed to speak to doctors about those products. That leaves some ambiguities.

I will give you a hypothetical example. This is a real product where there is not a problem because it is not supplied on a NIMAR. There are products where it is not just a little white tablet that you take three times a day. There are products where there has to be what is known as a wraparound. They are typically serious medicines, and I will give you an example of one that we provide.

There is a medicine that we provide for cancer, and it is utterly vital that a patient must not become pregnant while they are taking that product. Therefore, there is a patient online portal. There is interaction between us and that portal. There is interaction between the patient and the doctor. It is hugely important that the patient does not become pregnant, so there is a whole wraparound beyond that product.

Would NIMAR allow us to interact with the doctor in making sure that that so-called wraparound and patient online portal works? I do not know. In theory, we are not allowed to promote it or to detail it to the doctor. Does that mean that we are also not allowed to reach out to the doctor to say,

"How are things? Are your patients using the portal?" I do not know. Let us just say that it is an ambiguity that we would like to do without.

You asked me for examples of products that are being supplied under NIMAR. I had a look at that list of 79 medicines. None of these examples is supplied by Teva, by the way, but they are supplied by other companies. I see insulin and Metformin, which are both diabetes treatments; Clopidogrel, which is a heart disease product; Imatinib, which is for leukaemia; and Remdesivir, which is used in respiratory medicine and, in fact, Covid. Those are just examples. None of those is supplied by Teva under NIMAR.

You can see how each of them is helpful individually, but as a package, suddenly the Northern Ireland Department of Health is dealing with a 135—and growing, I understand—list of medicines. Each of those is supplied to a relatively small number of patients. I mentioned earlier in this session that we are supplying one medicine under NIMAR. To our understanding, that is being supplied to six patients, or possibly fewer. It is a layer of additional bureaucracy that no one values.

Lord Dodds of Duncairn: It is temporary. You said that it was not sustainable.

Paul Williams: No.

Lord Dodds of Duncairn: Why is it temporary and not sustainable in that form to continue using that route to plug gaps?

Paul Williams: I guess it is potentially permanent. It is a step that does not have to happen anywhere else in the UK. It does not have to happen in GB. Over time, as more products are added to the list, it is another example, as Martin alluded to earlier, of little incremental extra pieces of paperwork, bureaucracy, cost. I stress that it is probably more onerous for the Northern Ireland Department of Health than it is for us, because we only have one product that we are supplying under NIMAR. The last time I looked at the list, which, as I said, was in December, the Northern Ireland Department of Health was administering 135 NIMAR SKUs and growing. Over time, it just grows and grows, and becomes more and more onerous.

Martin Sawer: The NIMAR process for us is very bureaucratic and, we feel, has been brought in as a desktop exercise to justify the need to supply a legally regulated, or in this case unlicensed, medicine for Northern Ireland. For our members, we have to chase the tail. We do not always know when things are going on the NIMAR list until they do. The list is growing every two weeks, roughly. It is incrementally increasing. It will get close to 200 SKUs shortly.

Under the MHRA regulations, the trouble is that we have to record every NIMAR pack we supply. That means that when the NIMAR list is manually updated—it goes on the website GOV.UK—we have to work out exactly what that presentation is, which sometimes is not very clear. We talk to

the manufacturer, work out which product they are talking about, and then change our automation systems to try to identify that product. Often, if it is supplied from GB and not in Belfast warehouses to start with, it is difficult to disentangle from one column of medicines that is going to the rest of the UK from a big warehouse. We have no electronic system yet of identifying NIMAR products or even PLGBs at all, because we have our own coding system in warehouses that covers all UK packs. If we identify separate types of packs, we will need double the space for the same medicine, because they are on big, vertical pickfaces, as they are called.

NIMAR is a real challenge. What happens when we are inspected and we have not recorded the information correctly? We have not yet had to demonstrate to the MHRA what an inspection looks like or to demonstrate what we are supposed to say about where we have supplied a product so that there is a full track and trace of the particular product. The NIMAR process is all very manual and obviously time-consuming at the moment. If we do an FMD scan on a product that fails, it might be on the NIMAR list, so we suddenly have to check that. Quite a lot of FMD scanning is failing at the moment, but it might still be legal to supply it in Northern Ireland.

Michelle Riddalls: I have a very short answer. OTCs are not under NIMAR and it is only prescription medicines, so we are not really impacted, although we gave input on some of the draft guidance. My one point would be that there is still some guidance outstanding on NIMAR that has yet to be received by industry, which does not make it terribly helpful in implementing, and that is guidance on PLGBs—how to manage licences that are just for GB—and the CAP-bridging mechanism that NIMAR was also brought in for. If a product is approved in GB before it is approved in the EU, how can you supply that product to Northern Ireland at the same time as the rest of GB while the EU procedure is going on? It would be helpful to ensure that that guidance was readily available.

My only other point is that, if NIMAR did not exist, those products would not be going into Northern Ireland. Yes, it is bureaucracy. It is an issue. I worked closely with MHRA and DHSC colleagues when it was being looked at and how to work through it. If it did not exist, those products would not be going there. It is not a perfect solution by any means. There needs to be a better solution, but as a stopgap at least products are getting through in that way, maybe not as easily or as smoothly as anybody would like.

Q8 **Lord Godson:** Welcome to our witnesses in their informative session. I am sorry that as a most recently minted member of the committee I was not here for your last one. I want to go through some basic points to summarise things.

The European Commission's solution was set out in its October 2021 non-paper and then in the legislation in April 2022. It was designed in the Commission's official announcement. It said that the objective was that "the long-term supply of medicines from Great Britain to Northern Ireland

can be ensured". The point has partially been answered, but I would like to get your sense of whether that aim of ensuring the long-term supply of those medicines to Northern Ireland has been achieved by the EU legislation.

Martin Sawer: It has not achieved a long-term solution. At the time, it was critical in stopping almost 1,000 discontinuations for Northern Ireland,[5] and it recognised the value of a UK-wide licence. That was very important to maintaining supply at the time, in December 2021. The legislation early in 2022 amended the falsified medicines directive to be clear on how that system would be protected in Northern Ireland. It is not a long-term solution, in our view, because, as we have heard today, the divergence of certain other types of products and the licensing issues are now approaching other deadlines. There are other issues to agree to. It was not a solution for everything.

Michelle Riddalls: The national licences and the licences that are UK-wide have come out of MRP and DC procedures, which are another European procedure, and UK procedures were covered in general by that EU legislation. The fact that CAPs and FMD only had certain timeframes around them meant that some of the longer-term pieces have not been fully resolved, so they need to be addressed.

For the products that I represent from an OTC perspective, it has meant that the long-term solution is available because of the nature of those licences. As I mentioned earlier, the way something is licensed impacts on the way it is supplied. The solution that came from the EU certainly supports the OTC and the national licence route, but it does not help with the CAPs or with FMD, because they were just kicked down the path for a couple of years for derogation purposes.

Paul Williams: I completely agree with Michelle. It averted a cliff edge at the end of 2021. Martin talked about the numbers. How many did you say?

Martin Sawer: Nearly 1,000.[6]

Paul Williams: That might be a conservative estimate. We alone notified the Secretary of State that it threatened 289 of our products. That cliff edge was taken away, and that was helpful and good. However, we still have the issue with CAP. That needs to be addressed. Earlier, all three of us talked about the plea for stability and certainty over the coming years. We still do not have stability and certainty over the coming years. It feels like we steered away from one cliff edge, but there is still more to come.

Lord Godson: In summary, it is a year and a bit on from your previous testimony here. What do you now think about *Northern Ireland Protocol: The Way Forward,* the Command Paper put forward by Lord Frost when Minister in mid-2021, where he said that medicines should be removed from the protocol entirely? I think there was support for that in the

[5] Note from witness: The figure is in fact nearer 2,000.
[6] Note from witness: The figure is in fact nearer 2,000.

previous testimony. I would like you to reflect on that now as we stand at the start of 2023 with negotiations in play.

Paul Williams: The issues are fundamentally about licensing and logistics. They are ultimately technical problems that require a technical solution and outcome. We strongly believe that that is achievable. It will require compromise and negotiation on both sides. There are red lines for industry—all of us. You have heard about the cost and complexity that have been introduced. In particular, we have all said that one licence for the UK would be hugely helpful for us all. There are burning platforms that must be addressed soon. The CAP issue is probably the most urgent of all of them.

It is fundamentally, however, a devil-in-the-detail question. It is an issue of logistics and licensing. As the biggest supplier in the UK, we would like to invite this committee, either as a group or individually, to come and see our regulatory team, our subject matter experts, and our distribution centre where one in six of the UK's prescription medicines are grouped together. It is at that point that you see the real impact, and it is at the point when you see a patient pack going to a pharmacy that it brings home to you that pragmatism will be desperately helpful in the months ahead.

Michelle Riddalls: As regards the Command Paper and just taking medicines out, there are various ideas that seem very simple, as I alluded to earlier, but it comes back to understanding what that means. If you take something out, what do you do? What framework are you working to? How does it work? We would be in no better position having had that happen than we are now, because that in itself would have led to more uncertainty than we have at the moment. As Paul and I have said, we want a negotiated solution. Lord Frost's Command Paper was proposing taking medicines out, and that was potentially unilateral action, as per the Northern Ireland Protocol Bill. Dual regulation is a unilateral action. There may be some merit in both ideas, but they have to be worked out and gone through, with technical discussions.

You have to remember that many companies that are under my remit and that of others are global companies. They have EU centres, and the UK is just one of the affiliates, usually within the EU. If you start pulling out and saying that the UK is different, it adds more complexity to an EU profile. If you have arguments between the EMA and the UK as to what is allowed and what is not allowed, the easier solution for a company within the EU is to refer to the EU 27 and pull out of the UK and Northern Ireland.

We saw that start to happen in 2020 and 2021 when there were negotiations, and different interpretations of the same regulations that had been agreed through the protocol. The EU said one thing and the MHRA said another. It then prevented people getting licences in the EU because the UK address was being put on licences for the EU. The EU said, "If you don't take the UK address off, you're not getting these

products in the other countries in the EU". You think it does not have an impact, but it actually affects everything.

The story is that most of the companies were then going to take the UK off, not lose the licence in all the EU countries. It is really important to be sure about what a general idea means. What is the impact, how can you implement it, and is it viable? That is what we have tried to do to support both DHSC and MHRA when any proposals come forward.

Martin Sawer: Logistics loves simplicity. The Northern Ireland protocol has driven complexity and uncertainty into the supply chain. We can probably all remember that before Lord Frost was even Brexit Minister the whole medicine supply chain supported taking medicines out of the Northern Ireland protocol. Our position has not changed. We do not want it to be done unilaterally. We would much prefer an agreement.

It would seem to me that both sides could justify taking medicines out of the Northern Ireland protocol on public health grounds and patient safety grounds, and not lose face. We would still stick to that as a principle. If that is unachievable, we think that a possible key to unlock some of the logjam, given that the MHRA has now unilaterally recognised batch testing in the EU and extended that, might be to remove FMD from Northern Ireland. For the EU, that would not allow for any leakage of Northern Ireland product into the EU because they would no longer have QR codes uploaded.

I know that the challenge for the EU negotiators is that UK packs valid in Northern Ireland can also go to Malta, Cyprus and the Republic of Ireland, but a piece of work could be done to try to analyse how that might be achieved in a different way. If you remove FMD from Northern Ireland, we can get the UK PL licence valid and we can go back to one licence for the UK. For logistics reasons, that would be much simpler.

Q9 **Lord Empey:** Thank you for your evidence this afternoon. I am sure any viewers we have will be astonished at the immense complexity we are facing. There is a whole new alphabet that we are learning this afternoon. How are the UK and the EU engaging with industry on these outstanding issues? It is fundamental that if we are to find solutions there has to be proper engagement. Have you been contacted, by whom have you been contacted, and what is your sense of their level of engagement?

Martin Sawer: From the HDA's perspective, the distribution sector, the engagement with the UK Department of Health and Social Care and occasionally the Northern Ireland Department of Health, and the MHRA in the UK, has been, I would suggest, exemplary. The officials have worked really hard since before Brexit and continue to do so on all these issues. There are often no surprises for us about the regulatory changes, and they try to understand what the impact is and they talk to our members about that. The engagement has been really good.

I share some of Michelle's concerns mentioned earlier that at this point in the negotiations, as we understand they are going on at the moment, we

do not have access to the negotiating representatives as much as we did in 2021. I do not know whether that is significant or not, because obviously it is the whole protocol and not just medicines. I raise that as a flag. From our perspective as the HDA, we have had no formal engagement with the EU. We have a trade association in Brussels that represents our concerns about Northern Ireland, and has done so, to the Commission.

I am a bit concerned that, when it comes to distribution issues, the Commission seems to be talking through the EMVO, which is the body that organises and administers the FMD system. It seems to me that the FMD system is almost held up as a shining example, perhaps—although I am removed from it—as part of the single market, and therefore Northern Ireland has to have the FMD. That concerns me. Our engagement with the UK has been really good, but we have had very little direct engagement with the EU or the European Commission.

Lord Empey: It struck me that the general public had been led to believe that medicines issues were fixed and that was the big selling point, but anybody hearing today's testimony will have that illusion clearly nailed down.

Michelle Riddalls: I concur with Martin; industry is very much involved and worked closely with MHRA and DHSC colleagues to help identify the issues and help to resolve them. That was really important in 2021 and moving forward. The medicines team at DHSC and MHRA has continued to engage with industry and to try to further understand the issues and look for potential solutions. Over the last six months or so, there have probably been fewer interactions than we had previously on some of these topics.

I mentioned that there is guidance outstanding. It seems to be a bit difficult to find a solution for everything at the moment. I would appreciate further detailed deep-dive meetings and a review of proposed guidance so that they can utilise the technical regulatory experts to say whether that is a solution, actually find the barrier to the problem, and then come up with a solution and an ask for the EU. At the moment, on any of the outstanding topics that we are talking about—I include medical devices—I do not think there is a harmonised ask that I have seen come out from DHSC or MHRA yet.

There is a lot of discussion about the problems and what we cannot do, but I have not yet seen a tangible solution that the whole of industry is aligned behind as to what we want to do to change that. There are potential solutions: maybe dual regulation, maybe guidance, maybe allowing a PLGB licence to go into Northern Ireland and having a PL UK-wide licence, or removing the import requirements for medical devices. A lot of help can be given. Perhaps a little more action needs to be taken currently to go through that and agree and define solutions.

When there are discussions going on between the EU and the UK, it is important that the technical people also have the discussions. I know that

was how they got the resolution last time. It was not just the politicians discussing it; it was down in the technical detail where colleagues from DHSC were talking with colleagues from the Commission on a very detailed basis as to what was meant and what legislation needed to change. That is really important.

On the EU side of things, we have not been involved with anything with regard to the EU in recent times but hope that, as necessary, detailed technical discussions could happen there as well.

Paul Williams: First, I have to say that the people we speak to at the DHSC, the NI DoH and the MHRA have all been unfailingly courteous, constructive and open with us. We have relationships that we hugely value in those three places. However, I worry that that is not the same as getting traction where the decisions are really made. I agree with Michelle that the frequency of the interaction seems to have dropped off a bit. I think there is a perception, which has been talked about, that it is sort of fixed when it is clear that it is not.

We have an office in Brussels that has been working very hard to deal with the Commission. We are joined up. We try to speak to both sides of the debate. If anything, our fear at the moment is that at a top level there is a feeling that things have moved on, but, actually, they have not.

On how engagement can be improved, again I agree with Michelle; telling us what is going on and understanding is one thing, but get people like us in the room at the design stage and get us involved in the solution, because as representatives of three different parts of the industry we are very close to the issue. It is very much our day to day, and we want to be as constructive as we can be. It is a real tribute to the civil servants I have mentioned that they are being as open as they can be with us. I can only repeat what I said a few minutes ago: these are fundamentally technical issues that can be resolved, but it will require pragmatism and detail.

Lord Empey: Thank you for that. It is a bit disconcerting that all our witnesses have recorded a diminution in the degree of contact with the potential negotiators, and that is something that the committee may wish to address. Thank you all very much for your answers.

The Chair: Paul Williams wanted to say something about the falsified medicines directive. Would it be possible for you to write to us instead?

Paul Williams: I was about to make the exact same suggestion.

Q10 **The Chair:** We certainly want your advice, so that would be the best thing.

There is one issue that we have not talked about on which we would welcome your views: the proposed dual regulatory regime. If you could all be brief and let us know what you think, that will be very helpful.

Martin Sawer: I can be brief, because I am not a regulatory expert. I have no evidence from anywhere in the world of a dual regulatory system working. From a layperson's point of view, it would seem that, ultimately, one regulator would have to have authority over the other in some instances. We are concerned about how that might work. We have asked that question many times of the Department of Health and Social Care and the MHRA, but we have not yet had an answer from them. Maybe that is something the committee can consider, because we certainly are none the wiser than the words on the paper. It sounds quite exciting, but we do not know how it would work, I am afraid.

Michelle Riddalls: It comes back to the devil being in the detail. There is an overall idea that you could have dual regulation, but what does that mean in reality? As we have mentioned, we would not want dual regulation brought in unilaterally; it would have to be through negotiation with the EU. If it was brought in, we would need to ensure that there were not extensive changes to the current agreements that would cause significant disruption and uncertainty, because people have made changes to adapt and carry on with Northern Ireland.

In general, if the concept of the dual regulatory system is to be evaluated, you should be looking to apply it across the whole of the UK and not just Northern Ireland. If you just restrict it to Northern Ireland, suddenly Northern Ireland is different and then you cannot get it into GB, so you will end up again with different requirements across the country. The fact that dual regulation is being proposed only for Northern Ireland seems strange to us. If you are seriously looking at dual regulation, you need to have it across the whole country; otherwise, you have the complexity again—you have one part of the country doing something different from another. Everyone wants a reduction in complexity, and the fact that you are using two different regimes could cause complexity, but it may also help reduce unnecessary burdens. There are some specific considerations.

If a PLGB licence, which is UK only, could be utilised in Northern Ireland for all products, including new innovations, that could solve some of the supply issues. You would not have the CAP issue that we have been talking about. In theory, that could work, but, again, you would have to work through what it means and how that is allowed. With dual regulation for medical devices, if you get a UKCA mark, as we will all have to do in the near future, the product would only be distributed to Northern Ireland, so some of the importer requirements could go. It could definitely help, but it would have to be in a negotiated way rather than unilateral, and then agreeing the specifics.

Paul Williams: I shall be as brief as possible, but I would like to bring this topic to light with two examples. My overall answer is that in theory it sounds fine, but in practice the devil really is in the detail.

First, at the moment, we are going through an exercise to update the artwork on a pack to make it safer and easier to distinguish for someone who is taking more than one tablet at a time. We are going through the

process of getting that pack approved by the MHRA for the UK and the EMA for the rest of Europe. The MHRA wants the name on the front of the pack to be in dark navy blue. The EMA wants it to be in black. The EMA wants us to have the presentation—in other words, whether it is a tablet or a capsule—as a little pictogram on the front of the pack. The EMA says, "We want a little pictogram on the pack saying that it's a tablet or a capsule". The MHRA says, "You mustn't do that. We don't like that". That is divergence. Dual regulation only works in practice if there is no regulatory divergence.

Let me give you the other example, which is possibly more powerful but at the moment, thankfully, theoretical. From time to time, the EMA or the MHRA will say, "There's a particular ingredient in a tablet. Laboratory tests showed that there's a theoretical risk of it causing cancer. We're going to prohibit that. It's not allowed any more". What happens if the EMA says, "This ingredient in the tablet is now prohibited. It's illegal to supply that", and the MHRA says, "Well, the risk is theoretical. It's fine. The risk is not worth considering"? Is the tablet now legal to supply in Northern Ireland or illegal? It is Schrödinger's tablet; it is both legal and illegal at the same time. In theory, I completely agree with what the others have said. In practice, we do not understand how it will work.

The Chair: Thank you. I like the idea that we are ending our discussion with Schrödinger's tablet. It is rather nice. Thank you all very much indeed. You have given us a huge amount to think about. You have given us very clear evidence and a lot of very good examples, so thank you for being with us. May I also say that it is a great pleasure sitting here to have people behind our witnesses, and you have been very welcome as well? We have been rather used to having empty rooms apart from our witnesses, so it is very nice to see you. It is always nice to see Lord Bew at our meetings, because that, we know, means we have to be absolutely up to the mark. Thank you very much indeed.