DÁIL ÉIREANN

ROGHCHOISTE SPEISIALTA AN TSEANAID UM AN RÍOCHT AONTAITHE DO THARRAINGT SIAR AS AN AONTACH EORPACH

SEANAD SPECIAL COMMITTEE ON THE WITHDRAWAL OF THE UNITED KINGDOM FROM THE EUROPEAN UNION

Dé Máirt, 19 Deireadh Fómhair 2021

Tuesday, 19 October 2021

Tháinig an Roghchoiste le chéile ag 12 p.m.

The Select Committee met at 12 p.m.

Comhaltaí a bhí i láthair / Members present:

Seanadóirí / Senators
Malcolm Byrne,
Timmy Dooley,
Robbie Gallagher,
Vincent P. Martin,
Joe O'Reilly,
Mark Wall.

Seanadóir / Senator Lisa Chambers sa Chathaoir / in the Chair.

The select committee met in private session until 12.14 p.m.

Cross-Border Healthcare Directive: Discussion (Resumed)

Chairman: I welcome everyone to today's meeting of the Seanad Special Committee on the Withdrawal of the United Kingdom from the European Union. I ask members and witnesses to ensure their mobile telephones are turned off. Apologies have been received from Senator Flynn. We went through the correspondence and minutes during our private session.

There are two sessions in today's meeting. The first session will be on the cross-border healthcare directive and the second session will deal with medical supplies in Ireland post Brexit. The witnesses for the first session on the cross-border healthcare directive are Mr. Muiris O'Connor, assistant secretary general, research and development and health analytics division, Department of Health, Mr. Jonathan Patchell, principal officer, international unit, Department of Health, Ms Emma-Jane Morgan, principal officer, eligibility policy unit, Department of Health, and Ms Catherine Donohoe, general manager, commercial unit, acute hospital services, the Health Service Executive, HSE. They are all very welcome and, once again, I thank them for coming back after our adjourned session earlier, when we had some technical issues. It is good to have everybody back in the room on this occasion.

I ask everyone to bear with me while I go through the privilege notice. Witnesses giving evidence from within the parliamentary precincts are protected by absolute privilege in respect of the evidence that they give to the committee. This means a witness has a full defence in any defamation action for anything said at a committee meeting. However, witnesses are expected not to abuse this privilege and may be directed to cease giving evidence on an issue at the Chair's direction. Witnesses should follow the direction of the Chair in this regard. They are reminded of the long-standing parliamentary practice to the effect that, as is reasonable, no adverse commentary should be made against an identifiable third party or entity. Privilege against defamation does not apply to the publication by witnesses outside the proceedings held by the committee of any matter arising from the proceedings.

Members are reminded of the long-standing parliamentary practice to the effect that they should not comment on or make charges against any person outside the Houses of the Oireachtas or an official either by name or in such a way as to make him or her identifiable. Members are only allowed to participate in this meeting if they are physically located on the Leinster House campus, and I ask them to confirm this before making their first contribution. Members participating from outside the campus are asked to note that the constitutional protections are not afforded in that regard.

In terms of Covid-19 guidelines, I ask everybody to adhere to all current public health guidelines.

I invite the witnesses to make their opening statements.

Mr. Muiris O'Connor: I thank the committee for inviting us back before it to provide an update on developments since our last appearance in March. I am joined by Ms Emma-Jane Morgan, head of our eligibility policy unit, and Mr. Jonathan Patchell, head of our international unit, in the Department of Health. I am also joined by Ms Catherine Donohoe from the HSE. We are here to give the committee an update on cross-border healthcare since the end of the

Brexit transition period.

EU-UK relations continue to be a focus at EU level, with priority given to the effective implementation of the trade and co-operation agreement, as well as the protocol on Ireland and Northern Ireland. The Department of Health is continuing to monitor developments closely. The Northern Ireland protocol is the joint EU-UK solution to mitigate against the disruptions Brexit causes for citizens and businesses on the island of Ireland. The EU remains firm that the protocol cannot be renegotiated but it is focused on identifying pragmatic solutions, as we have seen. There has been consistent engagement by European Commission Vice-President Šefčovič, including his recent visit to Dublin and Belfast, to hear directly from affected stakeholders. Technical engagement at official level between the EU and the UK is also ongoing. The Government is also paying close attention to developments in Northern Ireland and takes the concerns raised in respect of the protocol very seriously.

With regard to access to healthcare, the committee is aware that the utilisation of the EU cross-border directive by Irish patients has grown substantially in recent years. The loss of that access route to healthcare as a result of Brexit posed a real challenge. To mitigate this loss, the Government took a number of important decisions that have enabled our patients to continue to access private healthcare in Northern Ireland and the UK and be reimbursed by the HSE, provided such healthcare is publicly available within Ireland. First, a new Northern Ireland planned healthcare scheme was established on an administrative basis from 1 January and has been operationalised by the HSE. Second, transitional arrangements have also been put in place by the HSE to enable persons who had a legitimate expectation to continue to access care in the UK under the EU cross-border directive.

The latest data available from the HSE indicate that almost 2,000 reimbursements have been made so far this year for persons who have continued to access healthcare in Northern Ireland under either the cross-border directive transitional arrangements or the new Northern Ireland planned healthcare scheme. It is, therefore, welcome to confirm that despite Brexit, both these measures continue to ensure that patients have access to healthcare. I also note that patients are continuing to access care in other EU nations, as is their right, under the provisions of the cross-border directive. In establishing the new Northern Ireland planned healthcare scheme, the Government decided that it should be on an administrative basis, with the drafting of a general scheme to be prepared to place it on a statutory footing. Officials have undertaken detailed analysis to inform the design of the statutory scheme and that work is continuing at pace. It is likely, however, that this work will continue into 2022 but I can assure the committee that this remains a priority and the administrative scheme, which is operating successfully, will remain until such time that the statutory scheme is in place. It is also useful to inform the committee that the Northern Ireland Executive has similarly introduced an administrative Republic of Ireland reimbursement scheme for a period of 12 months, which enables residents of Northern Ireland to access private treatment in this State. The Department is engaging with relevant counterparts in Northern Ireland to ensure a continued shared understanding of both schemes.

In terms of other issues raised at our last appearance before the committee, members will be aware of the data adequacy decisions adopted by the European Commission for the UK on 28 June 2021. These adequacy decisions facilitate the continued free flow of personal data from the EU to the UK so long as it benefits from an essentially equivalent level of protection to that guaranteed under EU law.

The trade and co-operation agreement, TCA, between the EU and the UK also provides for a continuation of healthcare rights when on a temporary stay in a state covered by the agreement.

Residents of Northern Ireland can continue to use their current UK European health insurance card, EHIC, to access necessary care while on a temporary stay in an EU member state. When the EHIC expires, residents of Northern Ireland may obtain a new global health insurance card issued by the UK Government. As the trade and co-operation agreement has maintained the equivalent of EHIC rights, Northern Ireland residents will continue to be able to access necessary healthcare during a temporary visit within the EU and, therefore, it was not necessary to implement the Northern Ireland direct reimbursement scheme that we had prepared as a fallback.

I can also report that we continue to be in a good space in terms of medicines supply, given our preparation with suppliers and internally before the end of the transition period. In fact, many of the mitigations in place for Brexit served us very well in the fight against Covid-19.

As I mentioned at my last appearance, both the EU-UK trade and co-operation agreement and the Northern Ireland protocol provide for substantial continuity in the provision of health services between Ireland and the UK. The Government has maintained and is building upon existing healthcare co-operation through these frameworks. My colleagues and I will be happy to provide any further detail Senators may require and answer any questions.

Chairman: I thank Mr. O'Connor for his comprehensive update on the issues that we raised with him previously. There is a lot of good news there. With the consent of the witnesses, I will open the meeting to the floor for questions. We will direct the questions through Mr. O'Connor and he can decide which member of his team is best placed to answer. I call Senator Gallagher.

Senator Robbie Gallagher: I thank Mr. O'Connor for the presentation and update. As the Chairman said, there is some positive news within that. I note from Mr. O'Connor's comments that the new scheme to replace the current Northern Ireland healthcare scheme will not be in place before the end of the year, which most people were expecting. Is there a timeframe for that legislation to go through? Approximately 2,000 people have been reimbursed. Does that follow similar lines to the pre-Brexit years? I imagine it is much of a muchness but I would welcome Mr. O'Connor's comments. Mr. O'Connor mentioned that the current EU scheme continues. Are many people availing of that? What parts of the EU are people going to and what procedures are they availing of in those EU countries?

With regard to the Defence Forces, PDFORRA has an arrangement in place through the PDFORRA medical assistance scheme, PMAS. It is a very successful scheme that is availed of by PDFORRA members and only for PMAS being set up, many people would have had to discharge themselves from the Defence Forces for medical reasons. It has been a great success. Can Mr. O'Connor confirm that PMAS will continue until the necessary legislation is put in place on a more long-term basis? I thank Mr. O'Connor for the presentation.

Mr. Muiris O'Connor: I thank Senator Gallagher for those questions. I will pass the question on the timeframe for the legislation to my colleague, Ms Morgan.

On the question of the 2,000 reimbursements so far this year and how trends look *vis-à-vis* recent years under the current EU scheme, Northern Ireland accounted for the vast majority of destinations, about 92%, under the cross-border directive when the UK was in the EU. Ms Donohoe might be able to give a flavour of the other destinations in Europe, which accounted for less than 10%, and she will also speak to the PDFORRA arrangement. I ask Ms Morgan to address the timeframe for the legislation and the comparison on trends in recent years.

Ms Emma-Jane Morgan: I thank the Senator for the questions. Since we were last here, we have been working intensively on the future design of the statutory scheme. We have been taking on board a lot of the feedback we received from stakeholders and the recommendations from this committee and its interim report, and that has all been feeding into the work we have been doing to look at the design of the scheme. Unfortunately, that work has taken a bit longer than we would have expected but it means we are doing a comprehensive analysis to make sure the scheme is fully fit for purpose and is for the benefit of patients. It is likely, as Mr. O'Connor said, that it will continue into early 2022 before we will be able to bring that legislation through the Houses of the Oireachtas but we are looking to develop the general scheme as soon as possible. If I were to give a rough timeframe, the early part of 2022 is what we are aiming for.

Mr. Muiris O'Connor: Ms Donohoe might speak on the 2,000 reimbursements made so far this year. We have some data and charts and we can follow up with detailed tables on some of the trends from 2015 to 2020. There is a lot of detail that we can provide. The figure is lower than typical and 2019 is probably the most recent typical year.

Ms Catherine Donohoe: The figures I will give are up to the end of September and are preliminary. Activity under the provisions of the Northern Ireland planned healthcare scheme commenced in March 2021. Prior to March, there was no activity under the scheme. This refers to the Northern Ireland planned healthcare scheme, as opposed to the cross-border healthcare directive, and I will go into the cross-border healthcare directive afterwards. In quarter 1, the number of reimbursements under the Northern Ireland planned healthcare scheme was 11; this grew to 144 in quarter 2, which is a 13-fold increase, and to 460 in quarter 3, which is a threefold increase on quarter 2. Similarly, in quarter 1, the value of reimbursements was just over €4,000, which rose to €400,000 in quarter 2 and to €1.6 million in quarter 3, giving a total of just over €2 million for the Northern Ireland planned healthcare scheme since it was introduced. This shows the implementation of the scheme has continued to provide patients with access to healthcare in the private healthcare sector in Northern Ireland that they had previously availed of under the cross-border directive.

So far this year, under the cross-border directive we have 1,900 recorded reimbursements in respect of healthcare in Northern Ireland, which relates to treatments which commenced prior to 31 December 2020. This amount of 1,900 equates to 56% of the total activity under the cross-border directive and the remaining 44% accessed healthcare in the EU or EEA.

The greatest activity in the use of the Northern Ireland planned healthcare scheme is in counties Donegal, Dublin, Monaghan, Cork, Louth, Cavan, Kerry and Wexford. This shows that the greatest use of the scheme is in the Border region. This is in line with EU-wide experience in regard to cross-border healthcare, which is most used in border regions. The significant volumes in Cork and Kerry may be attributed to a large extent to organised logistical assistance given to patients in accessing healthcare.

In regard to PDFORRA, since PDFORRA established its medical assistance scheme, 327 of its members have availed of treatment under the medical assistance scheme; 227 of these medical interventions were under the cross-border directive and, to date in 2021, 100 have been under the Northern Ireland planned healthcare scheme. We welcome the intervention of any organisation which, in the interests of patients, provides assistance for accessing healthcare under the schemes.

Mr. Muiris O'Connor: On the general trends, the figure of 2,000 reimbursements made so far this year is down on last year. There was a big increase in the scheme between 2015 and

2020, from a few hundred to just above 2,000 in 2017, to 6,700 in 2018, to 7,700 in 2019 and then to 8,700, so we are down at 25% or 30% of a full year. We will have to see how quarter 4 plays out, but this is a quieter year with the restrictions that impacted health services, North and South.

Chairman: I thank Mr. O'Connor and the rest of his team.

Senator Malcolm Byrne: I thank the witnesses for their presentations. Senator Gallagher probably managed to steal most of the detailed questions, but I enjoyed Ms Donohoe's descriptions of those travelling from Cork and Kerry to the North as being the result of "organised logistical assistance". I will certainly remember to use that phrase in future. Following on from Senator Gallagher's questions and in respect of trends being noticed in specific areas of healthcare, I ask the witnesses to elaborate on the reasons for those trends occurring. Under Sláintecare, or other plans the health service may have more generally, are there plans to ensure health services are more likely to be available in the near future, in other words, there would no longer be a requirement to travel?

Mr. O'Connor mentioned the data adequacy decision. There are some concerns now that the UK Government has decided to review the data protection regime operating there. Naturally, there will be fears about what will happen if the data adequacy decision cannot be upheld. Does the Department of Health have concerns about the UK Government review?

Mr. Muiris O'Connor: I will start with the data protection questions, after which Ms Donohoe will address the areas of healthcare being assessed. Soon after the UK secured the data adequacy decision in June, the government there announced a consultation exercise to see if it would be possible to liberalise and adjust its approach. We will watch that activity closely, as will the EU. The equivalence decision does exactly what it says on the tin. It respects and permits the free flow of data based on comprehensive equivalence with the standards of the EU and the general data protection regulation, GDPR. That regulatory framework has been adopted well beyond the EU and it is becoming a type of global reference point for good management of data and balancing privacy with public interest.

We sincerely hope the UK is not minded to deviate from those norms as that would fundamentally impact not just health but banking and many trade and commerce aspects, as well as service-to-service co-operation. It was one of the most onerous bits of our mitigation. We had made hundreds of data-sharing agreements. All organisations, on a cross-border basis, had to do these data sharing agreements as a fallback in case the adequacy decision did not come through. I do not want us to go back there. The adequacy decision is what supports best international co-operation in health and right across other areas. The Senator's question is a very good one and we will keep a close eye on this area. Ms Donohoe will comment on the nature of the services being availed of.

Ms Catherine Donohoe: The nature of the services that people are availing of continues in exactly the same way as under the cross-border directive. Orthopaedics, ophthalmology, ear, nose and throat, ENT, and gynaecology services are the main services involved. The reason for that is the length of waiting times in Ireland. We know this because when people submit their forms we ask them to indicate the reason they are using the cross-border directive or the Northern Ireland planned healthcare scheme. We do so for no other reason than to allow us to understand why people are using these services, and 90% of respondents indicate it is because of the waiting times in Ireland. Mr. O'Connor will address the query on Sláintecare.

Mr. Muiris O'Connor: There will be plans in this regard. A task force is being assembled around waiting lists. I do not have the detail because the planning information has not yet been published. One of the lessons learned from Covid is that it was beneficial for the State to have access to the care available in acute settings in private hospitals. I am not briefed on that issue but my expectation is that it will factor into the setting of targets and the ambition that will be brought to the initiatives on waiting lists.

Senator Mark Wall: I also thank our guests for coming back to us today. It is important that we get to discuss these issues again. I thank them also for the good news on the extension of the Northern Ireland planned healthcare scheme. I have some questions on that. Senators Gallagher and Malcolm Byrne have asked some questions on it already. On waiting times, Ms Donohoe stated that 90% of those who responded on their forms indicated that waiting times here had forced them to use this scheme. Given what we are hearing about waiting lists, are we expecting increasing numbers of people to use the Northern Ireland planned healthcare scheme or whatever new scheme may emerge? Is there capacity in the system to meet such demand, if it occurs? That is a very important issue and I am sure the committee and our guests have looked at it.

Ms Morgan stated she hoped the new scheme would be introduced in early 2022. Are any problems envisaged with the old Northern Ireland healthcare scheme continuing if that target of early 2022 is not met? It is important that we let people know if that target is not going to be met. It can happen, unfortunately, that targets may not be met, and if that were to happen, it would be important for people to know that the old scheme can continue.

Senator Gallagher mentioned the PMAS, which is an excellent scheme, and Ms Donohoe described it as such in our previous conversation. PDFORRA had hoped to extend the remit of the scheme to family members. I take Ms Donohoe's point that the HSE welcomes groups availing of the scheme. Would an extension to family members be considered, encouraged or welcomed by the HSE and the Department? The same question may apply regarding capacity. Does the Northern Ireland healthcare system have the capacity to deal with demand if our waiting lists grow, as many of us expect they will?

I believe the Northern Ireland scheme has been extended until July. The witnesses might confirm that. Do we know how many people from Northern Ireland have availed of the scheme to come to the South for healthcare services? Are conversations taking place between the authorities here and the Northern Ireland Health and Social Care Board concerning an extension of its scheme and, if so, where do those conversations stand now?

Mr. Muiris O'Connor: I thank Senator Wall for his questions. I can take some of them. First, I assure the Senator that in the event of the legislative target of quarter 1 or quarter 2 of 2022 not being met, we commit absolutely to maintaining the administrative scheme until it is replaced by a statutory-based scheme. Ms Donohoe can come back in on the waiting times in respect of PDFORRA and Ms Morgan might then talk about the interaction with colleagues in Northern Ireland.

Many of the procedures that people avail of in private health facilities through the Northern Ireland scheme are in the areas of cataracts and ophthalmology. Those are procedures where we have substantially improved delivery here. Waiting times have come down, with the numbers waiting for cataract operations having halved in the last five years. Waiting lists in ophthalmology are going in the right direction now. A good deal of waiting is involved and there seem to be issues with the ophthalmology outpatient waiting list, where we are not getting similar

improvements. Some of the procedures the private health providers target are procedures on which we are improving. The scheme still serves as an important safety valve but this is an area in which we want to build capacity and address these needs in our own health system.

Ms Donohoe will discuss waiting times and whether waiting times are associated with the scheme, as well as access for the families of PDFORRA members. Ms Morgan might then address interaction with the authorities in Northern Ireland and the scheme there.

Ms Catherine Donohoe: We are expecting increased use of the scheme. We are already seeing that people are using it more as the Covid restrictions are being lifted and as people are feeling more at ease about accessing healthcare. When it comes to meeting the capacity that is something we struggle with to an extent. The processing of an application is time-consuming and paper-based. The internal audit team will come down to meet us again later this week to look at our systems. A lean process has been carried out in the office to try to drive efficiencies so that we can process applications more quickly than we have in the past and we will continue to do that. Ultimately we will require more resources and we will require a dedicated database. All these things are being worked on.

On PMAS and extending it to family members, I understand from Damien Quigley of PMAS that it is looking at doing so. It is not an issue for us. We have no input on who uses the scheme and whether they do it under PMAS or in their own right. I would have concerns if PMAS was to create a waiting list, not because it is another waiting list but because there would be no clinical oversight on such a waiting list and it could be considered that such a waiting list could be an interference with a person's right to access the scheme. I will work with Mr. Quigley to ensure that where a patient is seeking to use the scheme under the PMAS administrative scheme that it also notes that the patient equally has the right to access the scheme outside that arrangement as well. That will solve that problem.

Ms Emma-Jane Morgan: I might add to what Ms Donohoe said about capacity within Northern Ireland. That is something we are conscious of in the design of the statutory scheme and it is something one of the contributors also mentioned back in March. There was a concern that we would not want to create a scheme that could not meet the demand. That is something we are conscious of; we are looking at the design of the scheme and it is something we engage with our Northern Ireland counterparts on. On the new Republic of Ireland reimbursement scheme, I do not have full figures for how many people are availing of it but I understand that over 500 people have availed of it so far. They have modelled their scheme on ours, including the 12 months, the administrative basis for it and everything else. The decision taken by the Northern Ireland Executive at the time was to implement a 12-month administrative scheme. It may end up in a similar space to us in extending it but we are working closely with our Northern counterparts to discuss the parameters of our scheme, how it is working, the benefits for patients on both sides and the shared solidarity across the island to ensure people can access healthcare.

Senator Joe O'Reilly: I join with colleagues in welcoming our guests and thanking them for being with us. This is an important discussion. The degree to which we have succeeded in mitigating the potential worst impacts of Brexit is a marvellous credit to our public service, political leadership and diplomatic service. We have done that successfully in so many ways and this is another example of it. I want to ask about the timescale. Am I right in understanding that within 2022 the Department hopes to have the new scheme up and running? Does the Department see any potential changes in the scheme based on learnings from today? Are any modifications being looked at?

I have another question which is not dissimilar to the last question from my colleague, Senator Wall. Through my office I dealt with some cases of this recently and it is marvellous the degree to which the entire exercise can end with people receiving healthcare within weeks. There is a domestic initiative in the South to deal with waiting lists being brought forward, which is necessary and which will be a great thing. Despite that there should be a bulge in the numbers of those seeking and needing to go to the North next year. Will there be a capacity problem and will that result in waiting lists? Could we have two sets of bad waiting lists, North and South, which would be a great problem were it to be the case? I am encouraged to hear that the waiting list for ophthalmology cataracts is coming down south of the Border. We all know through our direct interactions with people in work that this can be a serious issue, particularly for older persons living alone. Will there be any change or will there be a problem around capacity because of the potential growth of numbers from the Republic, given the waiting lists here? Those lists are an understandable product of the pandemic but they will be addressed.

Since they have done so on ophthalmology in an encouraging way, maybe the witnesses would specifically comment on capacity in orthopaedics and where we are there? That is another impactful matter that affects our older population a lot. I will leave it at that; there is inevitably a level of overlap in the questions as the discussion progresses but it is important that we contribute, welcome what is happening here and urge that it continue to happen with the greatest possible alacrity in the interests of the people we represent.

Mr. Muiris O'Connor: I will hand most of those questions to Ms Morgan, including the question on the timescale for our legislation and any learnings that will inform the framing of that. Perhaps Ms Morgan will also have more reflections on the capacity challenges in the North and on orthopaedics. I thank the Senator for his compliments about the wider preparations across the public service for Brexit. We have mitigated the worst potential of same. It was an enormous programme in health and much of it did not need to be put into effect but it has served us well in understanding exactly where the vulnerabilities in our medical supply lines are. There has been an awful lot of rerouting of our supply lines in medicine and health that still stands to us. This includes direct ferries from Europe, reducing our dependency on the UK and building up our capacity of medicines with a short shelf life. Both Houses of the Oireachtas have stood by the public service in recent years in that respect.

Ms Emma-Jane Morgan: The timescale is likely to be the earlier part of 2022. That all depends on getting the slots within the Houses of the Oireachtas and getting the legislation passed. We have engaged significantly in extensive analysis of the scheme. It involves looking at what works well within the current administrative scheme, previous learnings from the EU cross-border directive and learning from stakeholder feedback through this forum and this committee's recommendations. That is taking a bit of time but it is helping us to understand where we can make potential changes to the scheme and where changes might have an adverse effect on the scheme. It involves the capacity issues referred to by the Senator. We need to make sure we do not make changes to the scheme that would create an issue of capacity and, ultimately, create waiting lists for people to access services in the North. This is something nobody wants. The fact that it is patient-led and patient-driven and access is very timely is a credit to the scheme. We must be very mindful.

Another area we are looking at is the shortfall in payments, which has been raised here previously. We are looking at this to see if we can protect patients in respect of this. Can we make sure they are better informed about the level of reimbursement they would get from the HSE so that when they go to the North, they understand the level of reimbursement they might get

and have better information in respect of a choice of provider and what shortfalls might exist? A situation has arisen previously where people have had shocks when shortfalls emerge when they are reimbursed.

Those are the type of areas we are looking at. We are looking to make sure we improve the scheme for the benefit of patients but we do not want to create a scheme that does not work or creates waiting lists. We are conscious of capacity in the North, which has its own waiting list problems. I am sure it is looking to its own private providers to provide services in the same way we do down here so we are conscious of that as well. We are trying to take account of all of that, which is leading to more detailed and thorough analysis before we are in a position to go to the Oireachtas with the statutory legislation on it.

Ms Catherine Donohoe: I am not up to date on orthopaedic waiting lists and would do the committee a disservice if I indicated to the contrary but I am aware that addressing waiting lists is a priority for the HSE specifically through the hospital groups and at hospital group level.

Regarding potential activity capacities within the schemes, Ms Morgan referred to shortfalls patients tend to encounter. We always encourage patients to examine both schemes - the cross-border directive and the Northern Ireland planned healthcare scheme. In Ireland, patients are not used to buying healthcare as a commodity and looking at the market as whole because there is significant value in other countries in accessing healthcare where a patient is capable of and comfortable with accessing healthcare in other jurisdictions and not restricting themselves to Northern Ireland. That is no reflection on Northern Ireland. It is just an indication that the market is quite large and there are lots of players in the market and lots of providers offering assistance to patients in the market to access healthcare in other countries as well as in Northern Ireland.

Chairman: I think that is everybody bar myself. Most of the questions have been asked but one question I wanted to ask is what the witnesses see being refused reimbursement. Do certain types of treatments or procedures not meet requirements? My second question concerns Ms Donohoe's point about making it easier to access healthcare beyond the island. Is information about the levels of reimbursement and where someone can go and information pointing him or her towards providers of healthcare in other jurisdictions readily available? Would it be completely off the wall to suggest that given the current situation regarding waiting lists, there might be some way of making it easier to afford? One of the things we raised last time with the Department was the fact that a person has to upfront the cost as a citizen. It would probably be of benefit to let more people access the scheme and go beyond the island - even in the short term - because of where we are with waiting lists. Is this being explored with the new scheme? Is the Department preparing to put it on a statutory footing; is it looking at making it more affordable?

Mr. Muiris O'Connor: I will pass over most of the questions to Ms Morgan. The scope is limited by what is publicly available here and probably what is on the menu in the private hospitals in terms of services. Ms Morgan will discuss making it easier for people to avail of the service and issues like upfront costs.

Ms Emma-Jane Morgan: There are certain things that are outside the scope of the scheme. If something is not publicly available within our legislation, it is not covered by the scheme. Equally, long-term care, public vaccination programmes and, if I am correct, enzyme replacement would not be covered but they are very small so a broad range of access to general healthcare services available in this State is covered by the scheme. There does not tend to be many refusals on the basis that something is not covered.

In respect of the future of the scheme, the removal of upfront payments is under consideration and is forming part of our analysis. It is a difficult one. If we remove it and make it even more affordable, we will create a capacity issue. We do not want to create waiting lists for this scheme either. We need to look at the benefits and drawbacks of such an approach. The benefits would certainly be for patients but, ultimately, what would this mean in terms of demand and availability of access to facilities in the North or other EU countries? We also need to look at the financial implications of that for the Exchequer, what that would mean for the State and if there are wider implications. For example, if people fall back on this scheme where they do not have to pay up front, what would people do around their private health insurance? Would they continue to hold it? They are the wider policy issues that need to be looked at and that form part of our considerations as we look to develop the scheme.

Chairman: I appreciate the challenges, which could open up a can of worms, but it strikes me that someone could be on a waiting list somewhere and you are just moving people around a bit but it could ease the pressure. I do not know how we are going to deal with waiting lists following Covid. I listened to Tony Canavan this morning talking about cancelling more elective surgeries in CHO2. I am sure it is being replicated across the country. I think the vast majority want to be treated in their own country. I think there is some capacity there. It is just about trying to find the sweet spot and not making so that people can dispense with all management of their own healthcare. I appreciate Ms Morgan's response in that regard.

I think we have asked all of our questions. On behalf of the committee, I thank the witnesses. We were very eager to follow up on this piece of work because when we first met the witnesses, we did not know about future plans for access across the island and beyond - particularly on the island because of the unique circumstances here - so it is really good to have some good news coming out of the Brexit scenario regarding healthcare. It is very positive and it is great to be able to put that on the agenda here. It will be included in our final report, which we will publish before the end of the year.

Sitting suspended at 12.58 p.m. and resumed at 1 p.m.

Chairman: This part of today's meeting is on the area of healthcare. This second session is on medical supplies in Ireland post Brexit. Our witnesses are Mr. David Delaney, chairperson, and Mr. Padraic O'Brien, vice chairperson, Medicines for Ireland. I ask them to bear with me while I outline the issue of privilege, which is required at the start of every meeting.

Witnesses giving evidence from a location outside the parliamentary precincts may not benefit from the same level of immunity from legal proceedings as a witness giving evidence from within the parliamentary precincts, and they may consider it appropriate to take legal advice. If witnesses are directed to cease giving evidence at any point, please follow the Chair's direction. Privilege against defamation does not apply to the publication by witnesses outside of the proceedings held by the committee of any matter arising from the proceedings. I ask the witnesses not to make any adverse commentary against any identifiable third party or entity during their evidence to the committee.

I invite Mr. Delaney to make his opening statement and, with his permission, we will refer back to members for their questions.

Mr. David Delaney: It is a great honour for us to be invited to appear before the committee today, and we are delighted to take part in the meeting. I will briefly introduce myself, our organisation and the vice chairperson, Mr. Padraic O'Brien. I am the chairperson of Medicines

for Ireland, a pharmaceutical trade association in Ireland whose members supply, on average, the majority of medicines every day across Ireland to the HSE, to pharmacists in the retail and hospital settings and to patients. Our medicines typically cover generic medicines, excellent value medicines to the Irish Exchequer that have saved billions of euro and driven up access over many years to key therapeutic areas. We also supply biosimilar medicines and over-the-counter medicines. It is a range of medicines, many of which are household names which we will not go into today. Some of our members include companies that are familiar to the committee, such as Pinewood Healthcare, Clonmel Healthcare and Accord Healthcare. My company is Viatris. It is a large American healthcare company. We have approximately 2,000 staff in Ireland, with production and research and development facilities in Galway, Cork and Dublin.

Rather than reading my opening statement, which I am sure the members of the committee have read, I will start by saying that the industry in Ireland has been in constant contact with all the authorities across Europe, particularly in Britain and Ireland and especially the regulators, preparing for Brexit. As Mr. Muiris O'Connor from the Department of Health said earlier, we are very happy to see that there have been no significant shortages of medicines in Ireland as Brexit became a reality. Our industry has been preparing for Brexit for at least three years. We have invested millions and millions of euro, not only in Ireland but also in our production facilities in India, Hungary, France and Germany, to change the production lines, to change the packs and to change the coding on the packs. As Mr. O'Connor mentioned, we have invested significantly in the shipping routes and the logistical efforts. Millions and millions of euro have been invested by our industry to ensure that in Ireland, hopefully everybody on the call today, and all of our friends and family, generally speaking, have experienced no shortages. We have come hell of a long way.

At this stage, in relation to Northern Ireland our companies are the companies that supply the majority of medicines in Northern Ireland. In general. we are represented through our UK trade association but we work closely with that trade association and we share our members. On the Northern Ireland piece, while it has been a success in the Republic of Ireland with no shortages due to Brexit, I am optimistic but a bit concerned that there is a job of work left to be done to give us some sort of certainty for the supply of medicines into Northern Ireland for our families, friends and communities. I am concerned and our organisation is concerned. We have had a massive investment to get ready for Brexit and a massive investment to prepare for Covid and to see Ireland through Covid with no shortages but at such a time of uncertainty there is one remaining uncertainty, which is Northern Ireland. While it is only 3% of the UK market, and it seems like a very small market, I am aware that it is a place that is very close to the heart of all committee members. I see the amazing work this committee has done by providing a platform for civil society to talk about these issues related to the UK's withdrawal from the EU and I am aware that the whole committee is very much focused on this issue.

We are optimistic but we are a little bit concerned. We welcome the EU's latest announcement last week from Commissioner Šefčovič. We continue to work hard with the European Medicines Agency, EMA, the Health Products Regulatory Authority, HPRA, and with the Department of Health but there are a number of challenges left to overcome. Mr. Padraic O'Brien and I will outline those to members shortly. We would love to hear the committee's views, and we want to give members a sense of where we are at and potentially some solutions to try to take away the uncertainty. Uncertainty is extremely unhelpful to patients in Northern Ireland, and certainly to my friends and family in Northern Ireland. Uncertainty is also quite disastrous for the industry. If one can picture it figuratively speaking, Mr. O'Brien and the rest of the leadership of the pharmaceutical companies in Ireland and those in our trade association, are asked

daily if not weekly "How many packs for Northern Ireland and how many for various small places across Europe?". The questions then quite quickly drill down into "What is the regulatory framework like, what is the price, how are you shipping?". When we cannot really answer those questions for Northern Ireland it poses a risk and an uncertainty, which is no good for pharmaceutical companies that need to plan in advance and it is certainly no good for patients who could begin to feel anxious and worried.

Chairman: I thank Mr. Delaney for his opening statement.

Senator Joe O'Reilly: I welcome our guests today. Of course it is a critical area. I will start by asking a question, which was addressed to a slight extent by Mr. Delaney, on the adjustments by Commissioner Šefčovič to allow medicines and pharmaceutical products to enter Northern Ireland unchecked now as part of the practical adjustments to the protocol. I note Mr. Delaney did refer to it and I presume that this will be of enormous assistance and will get over a major problem that was anticipated. Mr Delaney might elaborate further on that.

Obviously, it is great that we do not have domestic issues within the Republic but on the Border counties in particular, we feel a duty of care for and an affinity with Northern Ireland. While it is good news that we do not have shortfalls or threatened shortages, it is also good news that the problem in Northern Ireland could now be mitigated by the latest initiative from the EU Commission.

While today's meeting specifically concern Brexit, in the context of vaccines, the witnesses might comment on the TRIPS waiver. How important it is for the pharmaceutical industry not to have a TRIPS waiver or is that the case? If it is important not to have one, why and how more efficacious is it not to have a TRIPS waiver? I have heard the argument put in another forum recently to the effect that a lot of taxpayer money, right across the EU, has gone into the research to create the vaccines. While there is a profit element for the pharmaceutical industry, to which we have no objection *per se*, by virtue of the fact that it is taxpayers' money that has gone into creating the vaccines researching them, then surely there is a right to have a TRIPS waiver and to get the vaccines to the underdeveloped world. It might not be totally germane to today's meeting but it is a relevant question while we have the witnesses here.

Before I ask my last question I will make the point that the pharmaceutical sector is of tremendous importance to the Irish economy and all of us in the Oireachtas are acutely aware that. We value that and do not in any sense take it for granted. With regard to prescription drugs such as opioids like tramadol for pain and so on, does the sector have much evidence of addiction to prescription drugs? It is not something one would want obviously, but has this been put to the sector at all within Ireland? I am aware that it could be a European problem and we all know it to be an American problem, albeit improving in recent times. Will Mr. Delaney comment on the degree to which he is aware of addiction to prescription drugs? What would the pharmaceutical sector be doing by way of social engineering, investment, or support to eliminate that problem? What are the exercises there? Perhaps the witnesses would also comment on non-prescription drugs but I am more specifically interested in to prescription drugs.

On the very specific Brexit question, am I correct in thinking that the recent initiative by the Commission would solve the supply problem in Northern Ireland? As a consequence, is it correct also that the position in the Republic, where we do not have shortfalls, would continue?

I thank our guests; it is very worthwhile to have them here.

Mr. David Delaney: I thank the Senator, there are some very interesting questions there, three of which I took a note of. I will go through them and then I will ask Mr. O'Brien to contribute to the other questions.

On the work by Commissioner Šefčovič last week, it is very much welcome. It is steady progress from the initial non-papers that the Commission had discussed with industry about a month ago. The industry has been heavily involved in discussions with Commissioner Šefčovič and with regulators. By industry, I mean ourselves, the wholesalers, pharmacists, parallel importers and distributors. It is very clear that Commissioner Šefčovič and team have listened acutely to the concerns of industry and not just the concerns; they also listened to the solutions. When we pointed out the various regulatory challenges that exist, including the fact that current temporary derogations and waivers expire at the end of this year, it is clear that the Commissioner and his colleagues in DG SANTE and around the Commission have really listened. I wish to thank the Commission and a number of the key actors in the Commission, such as Commissioner McGuinness, as well as a number of MEPs who have been extremely open to the evidence from industry to try to help Commissioner Šefčovič to craft a better set of policies. We welcome the latest iteration of the Commissioner's policies but I again caution that while this is a large step down the road, there remain a number of uncertainties that revolve around what I would broadly call licensing issues. A lot of the checks on many goods and services have diminished, or will diminish should the Commissioner's proposals be followed through in their entirety. That will mean a lot of checks will be reduced and that is to be welcomed. However, the questions that I, Mr. O'Brien and the leaders in our trade association think about at the moment relate to what is really going to happen with licensing. It would appear that the Commissioner's proposals will call on almost every professional person receiving medicine in Northern Ireland to have what is called a wholesale distributor's authority licence. That is quite impractical. Perhaps it is an unintended consequence of the Commissioner's proposals but we would like some clarity on that.

Without getting into the minutiae, the main regulatory issues remaining relate to whether the same box of medicine currently for sale in Birmingham will be available in Belfast on 1 January. That is somewhat unclear because we do not know if the licensing and supervisory authorities in the UK will be authorised to move that medicine to Northern Ireland. We do not know if that medicine will still be dispensable in Northern Ireland.

Some regulatory challenges come to my mind. Commissioner Šefčovič's proposals refer to another authorisation number being affixed to a box of medicine when it comes into the UK to show that it will go to Northern Ireland. Who will supervise that activity? Will it be the UK authorities? It would make sense for the UK authorities to supervise this new authorisation number. It would be politically challenging for the UK to foresee a circumstance where the European Medicines Agency, EMA, or another European regulatory authority, would have to attach an authorisation number to a box of medicines moving from the UK to Northern Ireland. There are a number of regulatory challenges which Commissioner Šefčovič's proposal has addressed. Before his proposal, it was inevitable that medicines that were licensed in Europe and not England, Scotland or Wales would not be available for sale and use in Northern Ireland. That appears to have been clarified but a number of outstanding questions remain. The solution is more discussion and detail. Let us hear the response from the UK authorities. The nub of the challenge for the UK is that a number of Commissioner Šefčovič's proposals revolve around European authorities having a supervisory or regulatory role within Britain which I think is a challenge that must be overcome because, obviously, Britain leaving the EU was a clear sign of its intention to step away from EU regulatory authorities.

The Senator also asked about the pharmaceutical sector, opioids and the TRIPS waiver. Mr. O'Brien may wish to come in on some of those questions. I will take the questions about the pharmaceutical sector, if that suits Mr. O'Brien.

Mr. Padraic O'Brien: Before we move on from the Brexit issue, it is worth pointing out, as Mr. Delaney noted, the enormous time, effort, energy and cost that MFI members have expended in preparing for continuing the supply to Irish patients post Brexit. Every industry has experienced logistical risks and delays because of Brexit. Given that the supply of medicines is such a regulated industry, as it should be, the impact of Brexit for our members in Ireland was profound. The decentralised procedure, DCP, is at the centre of the discussion for Northern Ireland and it had equal effect for MFI members who accessed the procedure known as share packs. For all intents and purposes, we could pool our demand with the UK in order to supply Irish patients. A share pack contained all the regulatory information to satisfy both the UK regulator, then the Health Research Authority, HRA, and the Irish regulator, the Health Products Regulatory Authority, HPRA. The required content was stated on the pack. That situation can no longer continue post Brexit, which means we had to perform all the regulatory tasks to make that happen, which was expensive and required a lot of effort. It also means compartmentalising the market. Demand could previously be pooled and one batch of products could be run off for both markets but, going forward, that can no longer happen. Efficiencies are therefore lost. Economies of scale could be triggered in the past, which meant that generics could be launched in markets because that demand was shared. Now, however, Ireland must access an Ireland-only pack and must stand alone and satisfy minimum order quantities, etc., which it did not have to do in the past.

Thankfully, MFI members have been very successful in ensuring we can avoid delays and continue to launch generic products. Not only do generic products provide savings for the State, which is the ultimate payer for the majority of our drugs, but those savings are reinvested in future novel medicines that are on patent. It provides the affordability for Irish patients to be able to access those products, as the committee knows. While MFI members have so far been very successful, it should be noted that the removal of the economies of scale that existed in the share-pack system under the DCP, which served the Irish market very well over a number of years, means the reduction of the viability of the supply of some products into the Republic of Ireland. Supply should never be taken for granted. We are in a good place and the evidence so far is that we will continue to supply in a controlled manner. However, at the same time, supply of medicines should never be taken for granted. The global supply of medicines is interconnected to supply in a small market like ours. Markets in Ireland are affected by dynamics in other countries across Europe. We are in a good place and that is because of the hard work, effort, energy and expense of members of MFI.

Mr. David Delaney: I will pick up on the Senator's question about the TRIPS waiver. Our companies are not traditionally involved in the manufacture of vaccines. A couple of our companies are involved in the seasonal flu vaccine, including Viatris, my company. We are one of the main suppliers of the seasonal flu vaccine to Ireland and a number of other countries. Another trade organisation in Ireland principally covers vaccine manufacturers so I will not answer in any great detail on that. Suffice to say that in terms of intellectual property rights across the broader piece, our members are very strong on the protection of intellectual property rights for the full period of patents unless instructed otherwise by national and international authorities. We are very strong on the protection of patents. A number of our medicines are patent protected but, of course, the majority of our medicines are generic so when the patents fall, companies such as mine and Mr. O'Brien's, Pinewood Healthcare, Clonmel Healthcare, Rowa Pharmaceu-

ticals and other companies that are strong across Ireland step in and bring generic versions of the medicines across the world. That includes the amazing HIV generic medicines we typically bring to Africa and across Europe. We are very strong on post-patent medicines.

I do not think we would be entitled to comment too much about a TRIPS waiver for Covid-19 medicines as we are not particularly involved in their manufacture, albeit we make the seasonal flu vaccine and supply some components for Covid-19 vaccines. I hope that answers that part of the Senator's question. The Senator's final question concerned opioids and potential addiction in Ireland. A number of our companies manufacture pain management medicines, all of which are supplied, licensed and regulated by the HPRA and, essentially, by the EMA, by extension. All the medicines are fully compliant and are supplied through retail and hospital pharmacists in Ireland. The care pathway for those medicines is managed by the regulators and is instigated and protected by local community pharmacists or hospital pharmacists in the case of the dispensing of hospital medicines. We are very much aware of the impact of all our medicines across the patient populations. Whilst no data have been brought to our attention recently on opioid or other significant addiction issues in Ireland, it is certainly something that we would be willing to look at. We remain in close contact with hospital and retail pharmacists, who, we feel, are the guardians of the patient pathway in the community and the hospitals. All of our medicines are fully regulated and authorised by the HPRA and EMA. Hopefully, that addresses the Senator's three questions.

Senator Robbie Gallagher: First, I thank Mr. Delaney and Mr. O'Brien for taking time out of their busy schedules to be with us The information they are providing us with is most beneficial. I thank them for their work on the supply of medicines to such an extent that has not been, and is not, a problem for us in the Republic of Ireland, thankfully. I acknowledge their work in that respect.

With regard to our friends and cousins in Northern Ireland, unfortunately, the picture, as presented by the witnesses, is not as rosy. I was interested to hear from Mr. Delaney that the Northern Ireland market only amounts to 3% of the entire UK market. Perhaps that is a statement in itself, along with all the others. Like Senator O'Reilly, I am interested in the witnesses' take on the impact of the EU Commission's most recent work. It seems to be a step in the right direction, but it still appears that there is some way to go. It can be impossible to put a timeframe on this, but how far away are we from resolving the issues? Are we 70% or 80% of the way there?

From our perspective in the Republic, I believe Mr. O'Brien stated that heretofore we attached ourselves to the UK for the purpose of purchasing medicines. In respect of the Covid vaccine, we hitched our wagon to the EU and it proved successful. Is the fact that we cannot collaborate, as it were, with the UK authorities an issue for us now? Where does that leave us going forward? Do we hitch our wagon to the EU train in respect of medicines? What is our pathway forward?

Mr. David Delaney: I might respond to the first part of the Senator's questions and then hand over to Mr. O'Brien in respect of the joint pacts. In terms of the journey, it takes two to tango. While we may think we are very far down the line as Europeans, through Commissioner Šefčovič's hard work and proposals, it revolves around what the other negotiating parties in London believe is the solution and what is workable for them. The Commissioner and his team made a big step forward with the proposals. On the question of a timeline, I was in Brussels last week and spoke to a number of stakeholders. They have a tight legislative agenda in the parliament, like the Members in Ireland. Given that a number of the Commissioner's proposals

would require a legislative amendment, it is almost impossible for me to guess on the timeline, but when I said I was optimistic but cautious earlier, my caution comes from the fact that time is ticking away. There is very little time left before the end of the year when the current waivers, derogations and grace periods expire, especially when it comes to the non-paper perhaps being discussed or negotiated with the UK based on its set of priorities and concern for the welfare of patients in Northern Ireland. I imagine that would take two to three weeks. The Commissioner's team has told us that it could perhaps take three weeks. Hopefully, we will get a chance to engage with him and the team again. Perhaps that will be in three weeks, but I am concerned that some of these changes require legislation, and as the Senator will be aware, the timeline is a how-long-is-a-piece-of-string issue. I picked up concerns from a number of MEPs last week that they are ready, willing and able to give their advice and data and to look at and scrutinise the legislation, but we are a number of weeks away from the legislation appearing in the European Parliament and the Members there having the opportunity to give their opinion on it. I will hand over to Mr. O'Brien to respond on the joint pacts piece.

On the third point the Senator made, in respect of international procurement and perhaps learning some of the benefits from procuring vaccines internationally as a collective in Europe, the point on the vaccines is well made. Vaccine procurement has been a great success for small countries such as Ireland. However, in terms of the day-to-day generic buying of similar over-the-counter medicines, a fast moving, flowing, borderless and efficient supply chain is already moving these medicines around Europe. Ireland has some of the best value prices, representing some of the best value that the HSE is saving year on year, compared to previous years when it was paying relatively high prices for unpatented medicines. In terms of the international procurement of generic medicines, the day-to-day medicines, there really is not a need, and in fact, it could be quite inefficient if Ireland was to join, say, a tendering system for basic antibiotics or other medicines. Fortunately, and I will lead into the joint pacts piece, our members moved significantly away from joint pacts over the past few years to Irish stand-alone pacts or Irish pacts with Belgian, French or other European entities. We invested millions of euros in moving away from the Irish-UK pact. We are already benefiting from joint pacts. I will hand over to Mr. O'Brien, who can add some colour to that.

Mr. Padraic O'Brien: On the issue of carving out from the joint share pact with the UK, Ireland always partnered with the UK because we are both English-speaking states, so it made sense. The point that we are trying to raise and address on that issue is the pressure that it puts on what is referred to as the minimum order quantity, where Ireland has to stand on its own two feet in relation to having a viable launch or buying the supply.

Ireland is well represented with generic suppliers. MFI has 11 members. Most of the big European generic suppliers in Europe are committed to Ireland, have a presence and large workforces in Ireland. However, when a market is compartmentalised from being a larger market into a smaller market, there can be issues. On a European and global scale, Ireland still remains a small market. Understandably, it will have pressures that a larger market will not have, from a viability perspective.

At every opportunity, the environment should provide for as many generics to be dispensed as possible to support generic suppliers in achieving the necessary minimum order quantities. Ireland has improved significantly over the past decade in generic penetration. That is testament to the savings that have been delivered, which is in the order of €1.6 billion over the past seven or eight years. The situation has improved and the use of generics in Ireland has increased significantly to such an extent that the market is well represented with big generic

suppliers. However, that is not to say that there is not further room for greater generic penetration that would probably bring us up to higher levels that we see in other European countries.

The Senator may well be aware that when a patent loses exclusivity or expires, it can go through a process of interchangeability. This facilitates pharmacists to dispense generics, which triggers these savings for the State. MFI welcomes any mechanism that means that a pharmacist is in a position to choose to dispense a generic. When that is done, a very important component of the lifecycle of all drugs in Ireland is underpinned.

Chairman: I thank Mr. O'Brien and Mr. Delaney. Much of the ground has been already covered in terms of the opening statements and responses to questions from Senators Joe O'Reilly and Gallagher, but I would like to ask a couple of questions. We have heard of other products and supply chains on the island being disrupted by Brexit. There is some evidence to show that supply chains have adjusted somewhat, that trade North-South has increased and that trade between Northern Ireland and Great Britain has reduced a little. In terms of the products under discussion, are those who are purchasing looking to other locations? Are they moving ahead because of the concern that this is not being addressed as quickly as it needs to be?

On the national medicines reserve which is mentioned in the document, are the witnesses in a position to give the committee a little more information on that? I take the point about there being an oil reserve but not a medicines reserve and that we need, perhaps, to adjust our priorities somewhat. Given what we have been through, there is definitely merit in that argument. We do need to look at this, particularly given our neighbours have already moved ahead on it. I would welcome further detail on why we do not have a medicines reserve, if there are motions in train to put one in place and what putting that in place might entail?

Mr. David Delaney: I will take the question on the medicines reserve and ask Mr. O'Brien to respond to the question on the logistics.

As I mentioned earlier, we have come through the brunt of Covid quite well in Ireland in terms of medicine supply and no shortages. That is down to the extremely flexible forward-thinking regulators that we have in Ireland, the policymakers in the Department of Health and the civil and public servants around the system, in particular in the HSE on the procurement side in the corporate pharmaceutical unit. They have been helpful and visionary. We did not sit on our laurels, move licences around and panic and worry behind the scenes in terms of trying to get the medicines, in particular ICU medicines, to the right countries in Europe. Last March 12 months, when we were on various calls throughout the weekends and late at night to make sure medicines were moving around Europe sufficiently to help people in ICU, we also commissioned an independent think-tank in Europe through a trade association in Europe, Medicines for Europe, to look at what longer-term solutions we need such that if we are hit by a large external shock we will not have try to reinvent the wheel, assess where the licences are in Europe, where the medicines are and who is manufacturing what and when. We took the step to invest heavily in this piece of data. At the same time as we were moving the medicines around we worked with DG Competition in Brussels to try to get clearance for them, in respect of which we were successful and are grateful for. We engaged with DG Competition on whether, at an Irish and European level, we could share among our members the data around the, generally speaking,15 ICU medicines used for the treatment of Covid patients, the information on supply and commercial availability of the medicines and the APIs to try to ensure that we have enough of these medicines in every European country. Traditionally speaking, that could have been a breach of competition law or it could have been a commercial problem for our members, but DG Competition very quickly came back to us with the legal opinion that we could share

all of that information, to try to map out where the barriers are and which country has particular medicines. There is no point in one company making a huge amount of the top 13 ICU medicines when we might not have the other two in Italy or Ireland. We did all of that. We also fed all of that into a survey of our members to identify the potential policy options to make sure that we are not scrambling again in the face of an unprecedented external shock.

One of the polices, thoughts and potential interventions we came to via the independent economist in Brussels was a national medicines reserve. When Europe went through the oil shocks of the 1970s, one of the good policy choices made by a number of countries at a policy level and at a commercial level was to build an oil reserve in each country. We have shared with the committee the full paper around what a national medicines reserve would look like for Ireland, for other countries in Europe and how we would mitigate some of the potential challenges. The big challenges that come to mind include what price the NHS or the HSE would pay. Let us come up with a system for a fair and reasonable price. If the HSE is buying in bulk, obviously it should get a more competitive price.

On what happens to the medicines if they are not used after a year or two, we need to come up with a risk-sharing option whereby the industry might pay up anything from 10% to 50% of the cost to dispose of medicines in an environmentally-friendly way, with the state bearing the rest of the cost. There are other issues around where and how they would be warehoused. The Chairman raised an interesting point. The concept of a national medicines reserve could be something that is worthwhile, particularly for small countries like Ireland. It could work. We discussed this with some policymakers in Ireland as Covid was evolving over a year ago. We were alerting the policymakers to the fact that a lot of the generic medicines might take six to ten months to make, but the biological medicines take two years to make. While we could decide in the morning to establish a national medicines reserve, in terms of Covid a year ago, we really needed to try to make quick decisions because a lot of the HSE-type organisations across Europe were instigating huge tendering processes, essentially creating their own mini-medicines reserves, in particular in the UK, although it is not called a medicines reserve. The UK engaged in innovative and aggressive procurement policies. I take my hat off to the policymakers in the UK. They did this to protect patients across Great Britain. To be fair to them, the size, scale and rapidity with which they went at this problem hoovered up a huge amount of medicine supply for the British population, which it is, of course, the duty of the British authorities to do. We need everybody to work aggressively towards a medicines reserve or super procurement. If other external shocks like Covid were to hit, small countries like Ireland could be in some difficulty. We believe a medicines reserve is a great idea. We are happy to have a further engagement with the committee on that. I will hand over to Mr. O'Brien to respond to the question around the logistics and supply chains.

Mr. Padraic O'Brien: If I understand the question it is whether Northern Ireland pharmacists are exercising contingencies to access medicines from other jurisdictions in light of the risks that are in front of them. The supply chain of medicines is highly complex. It is very difficult to turn on a new supply that satisfies the very strict regulatory requirements that are necessary for the supply of medicines to Northern Ireland patients. The reality is the solution being proposed, as published by the EU, appears to be the only solution, that is, the incumbent supplier, our colleagues in Great Britain, who are today supplying medicines to Birmingham and Belfast can continue to do that. That appears to be the most straightforward and practical solution going forward.

Chairman: I thank Mr. Delaney, chairperson, and Mr. O'Brien, vice-chairperson, Medi-

cines for Ireland for taking the time to engage with the committee on what is an important issue. We take some hope in that negotiations are, at least, ongoing and the matter, to a certain extent, is being addressed. We know it is on the radar of the EU Commission and Maroš Šefčovič, which is a positive, in large part due to the work of Medicines for Ireland in making sure it was at the top of agenda. We hope for a solid resolution to this issue that serves the interests of all citizens on the island, in particular those in Northern Ireland who, as in regard to many aspects of Brexit, have been most impacted.

The next meeting of the committee is at 12 noon on Tuesday, 2 November 2021, when we will meet the Economic and Social Research Institution, ESRI. I seek the agreement of members on the following matter. We had agreed to invite the Minister for Foreign Affairs, Deputy Coveney, to the committee. The date proposed by his secretary is 5.30 p.m. on Wednesday, 24 November 2021. Is that agreed? Agreed.

Tomorrow, the select committee will travel to Stormont in Belfast to engage, once again, with the Northern Ireland Executive Committee on the issue of Brexit, which again is a timely engagement in the context of all that is going on. We look forward to that engagement. Some members will be travelling and meeting in-person, while other members can join by StarLeaf remotely as well. We look forward to that engagement.

The select committee adjourned at 1.50 p.m. until 12 noon on Tuesday, 2 November 2021.