Northern Ireland Assembly

Committee for Health

OFFICIAL REPORT (Hansard)

Brexit Issues: Department of Health

17 September 2020

NORTHERN IRELAND ASSEMBLY

Committee for Health

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Members present for all or part of the proceedings:
Mr Colm Gildernew (Chairperson)
Mrs Pam Cameron (Deputy Chairperson)
Ms Paula Bradshaw
Mr Gerry Carroll
Mr Alan Chambers
Mr Alex Easton
Ms Órlaithí Flynn
Mr Colin McGrath
Mr Pat Sheehan

Witnesses:

Ms Cathy Harrison	Department of Health
Ms Patricia Quinn-Duffy	Department of Health
Ms Eimear Smyth	Department of Health
Ms Fiona Taylor	Department of Health

The Deputy Chairperson (Mrs Cameron): Departmental officials are here today to brief the Committee on health-related Brexit issues. I refer members to the papers in their pack.

I welcome in person Ms Cathy Harrison, the Chief Pharmaceutical Officer (CPO), who is heading up the Department's EU exit team, and Ms Eimear Smyth, who is head of medicines policy and EU exit. We are having some technical difficulties, but hopefully by video link we have Ms Patricia Quinn-Duffy, EU exit lead on reciprocal healthcare and workforce issues, and Ms Fiona Taylor, who is the EU exit lead on medicines.

You are very welcome here today. Thank you very much. It is nice to see people in person. Cathy, I believe that you are going to brief us initially and answer some questions.

Ms Cathy Harrison (Department of Health): Good morning, everyone, and thank you for the opportunity to provide an update to the Health Committee on the current EU exit health-related issues. In the Department of Health, I am the senior responsible officer (SRO) for EU exit. I lead an EU exit transition unit. It was established to oversee the Department's readiness in a number of different areas, and the unit has pulled together a range of expertise from across the Department, which has been working on EU exit for a number of years. It is because we are moving into an accelerated period of operational readiness and preparation for the transition date that the unit was established, under my leadership. As SRO, I propose providing regular updates to the Committee on EU issues that are relevant to the Department of Health.

Today, as an introduction, I will provide a broad overview of the EU exit considerations that are happening at the moment: the key issues. I propose providing more regular updates and am happy to have those timetabled for the Committee. That would allow us to drill down into specific issues in more detail. As you will hear when I speak today, there is a huge range of issues with a lot of detail, and those issues are worthy of further consideration, should the Committee wish to look at them.

I will begin with a brief and broad overview. You will all be aware that the UK left the EU on 31 January 2020 and moved into a transition period that runs until 31 December 2020. During that time frame, the UK will follow EU law and regulatory processes in line with the January 2020 withdrawal agreement, which outlined the negotiated terms of the UK's withdrawal from the EU.

At the end of the transition period, the Northern Ireland protocol to the withdrawal agreement will take effect in Northern Ireland. As you all know, the protocol was introduced with the aim of avoiding a hard border between Northern Ireland and the Republic of Ireland, whilst ensuring that the UK, including Northern Ireland, will leave the EU as a whole.

The protocol covers a range of areas, including the common travel area, customs, trade and the regulation of manufactured goods. I will outline some of the key issues related to health. I thought it might be helpful if I outline, as I go through, where those issues impact on North/South and on east-west, where that is relevant, and I will pepper my update with that. I will also point out, where relevant, what issues are like to be day-one issues from January and where there are likely to be longer-term implications.

For the past number of years, my colleagues and I in the Department have been working very closely with the Department of Health and Social Care (DHSC) in England and the other devolved Administrations on UK preparedness plans for EU exit. That work has already established a wide range of UK-wide mitigations. Our primary focus was always on the risk of leaving the EU without a deal, which is still a risk at this time. We could leave after the transition period without a deal. In medicine, for example, all of that work has established a complex, multilayered approach for contingencies relating to medicines. I can provide more detail on that at a future time. That covers, for example, establishing buffer stock. We are therefore holding more stock than the UK, and we have additional warehousing, have made rerouting and freight arrangements and have made enhanced arrangements for trader readiness, shortage management and regulatory considerations. Those are national plans that include Northern Ireland, and we have been included in the development of the plans. In addition to those UK-wide plans, there are specific considerations relating to the Northern Ireland protocol. That area also covers a broad range of issues, including the supply of medicines and medical devices, access to healthcare and food standards. I will focus on those today.

I will begin with medicine and, more widely, medical supplies. I will focus on medicines, but when I am in that area and providing updates, it will cover all medical supplies. I will cover a broad range of medical devices, consumables, blood tissues, organs etc. We can come back to any of those. Today, I am talking about medicines.

Mr Sheehan: Excuse me. Would it be possible to bring the microphone closer to you?

Ms Harrison: I will move a little closer. Some 98% of the medicines that we use in Northern Ireland are transported from Great Britain into Northern Ireland via the Northern Irish ports, and the majority of those medicines are distributed through the UK wholesale network. Currently, the whole of the UK is aligned with the EU acquis for medicines and medical devices. That will change after transition, when Northern Ireland will remain aligned with the EU acquis and GB will not. That has east-west implications for the supply and regulation of medicines in Northern Ireland. There is a dedicated work programme ongoing, involving my officials, DHSC and other stakeholders, in which all the issues are being looked at, as well as mitigations that may be needed.

The Committee may be aware of the fact that, after transition, Northern Ireland will still have to comply with certain EU directives relating to medicines, one of which is the falsified medicines directive (FMD). Supplies of medicines into Northern Ireland will continue to have to comply with the FMD after the transition date, but GB will not have to comply. The FMD affects the majority of our prescription-only medicines. In a nutshell, the FMD was introduced as an important measure to protect the medicine supply chain from the entry of fraudulent medicines. Manufacturers are required to put a safety feature, which is a unique barcode, on each pack. That information on each pack is uploaded to a central European database. On supply of the medicine to a patient, the medicine is decommissioned from the stock that is known about. There is therefore an end-to-end understanding of the system.

Our continued compliance with the FMD raises a number of issues relating to medicine supplies and regulation, and a 12-month derogation has been requested by the UK Government to the EU to allow time for the various mitigations to be put in place. Work is very active in that area at the moment.

Another issue relating to medicine supplies is the requirement for goods moving between GB and Northern Ireland to abide by importation requirements. There may be mitigations that we need to introduce to avoid the risk of any delay that may occur in our medicine supplies as a result of additional checks or tariffs. A lot of work is going on in the area of medicines supplies. A lot of legal advice is being sought, and a lot of mitigations are being worked up. The Committee will be fully apprised of those as they develop.

Access to healthcare is more of a North/South issue. From day one, a range of areas is relevant to accessing healthcare after exiting the EU, including continued access by UK citizens to emergency healthcare in the Republic of Ireland. The Department of Health and Social Care in England and the Department of Health in Dublin are working on an enduring reciprocal healthcare agreement between the UK and Ireland. This will not impact on any current North/South health services, which are based on a memorandum of understanding or a service level agreement.

A number of healthcare access issues have North/South and east/west implications. One is the cross-border healthcare directive. That enables UK citizens to access healthcare in any EU country and be reimbursed by their home country for care abroad. On the day after the end of transition, that facility will no longer apply to the UK. However, if someone has applied to use the conditions of the directive before the end of transition, reimbursements for treatments will be honoured for up to a year, on certain conditions. In the longer term, the Department is still considering the policy for the application of the principles of the cross-border healthcare directive.

Citizens' rights provisions in the withdrawal agreement provide a framework for the continued legal residence and rights of EU citizens living in the UK, and UK nationals living in the EU, at the end of the transition period. Westminster is coordinating the application of citizens' rights for access to healthcare. For day one, the Department of Health is working with the Department of Health and Social Care in England to establish processes and develop communications for more information on that. The longer-term implications of that are that people are likely to move in and out of the scope of the provisions, depending on their life decisions.

You may be aware that a new points-based immigration system will be introduced in January 2021. The Department is engaged with the EU exit workforce working group, including employers, regulators and unions from across health and social care. From day one post EU exit, any European Economic Area (EEA) nationals who are living in Ireland and want to work or study in Northern Ireland will have to apply for a visa. In the longer term, the new points-based immigration system may not facilitate people working in lower-skilled roles. Those are issues that apply not just to health.

Another workforce area relevant to EU exit is the recognition of professional qualifications, which will be covered by my colleague Patricia Quinn-Duffy under the next agenda item.

Finally, the Food Standards Agency (FSA) has been preparing a legislative programme to ensure that, for areas in its policy responsibility, GB and NI legislation is updated to keep pace with EU law during the transition period and to reflect the application of the Ireland/Northern Ireland protocol in GB and Northern Ireland by the end of the transition period.

Those were the key areas that I wanted to talk about. A number of issues have arisen recently, and I thought that I could update the Committee on those. There are also further issues that may be of interest.

The Committee may be interested to know the volume of legislative work that is likely to be associated with the EU transition. Our current estimate is that at least 11 statutory instruments (SIs) will be coming through the Committee.

I understand that you are to have a separate update on common frameworks. In health, a number of common frameworks relate to blood, the quality and safety of organs, tissues and cells, public health and reciprocal and cross-border healthcare arrangements.

The final issue is the Internal Market Bill, which was introduced in the House of Commons and given its First Reading on Wednesday 9 September 2020. This is a relatively new development, and we have sought legal advice on the implications of that for our work programme. That is pending.

In summary, since July and when you received the last written update, I can advise that there has been an acceleration of activity relating to national contingencies and work on the Northern Ireland protocol. That work, particularly on the Northern Ireland protocol, is continuing at pace. The new Department of Health EU transition unit, which I will lead, will progress a work programme in the coming months, and we will look at the areas that I have covered today, including healthcare supplies and regulation; issues relating to access to healthcare and movement of people; issues relating to data sharing; and the legislative programme. I will repeat: I propose that I provide regular updates to the Committee on this, given the wide scope of work that needs to be done in the coming months.

The Deputy Chairperson (Mrs Cameron): Thank you, Cathy. This is an incredibly complex area of work, and I do not envy your role in it. I am sure that there will lots of questions from members.

You touched on the Internal Market Bill and said that you are waiting for legal advice to come back. Can you give any indication as to the extent of the challenges that you believe the Department will face as a result of the NI protocol? Do you have any indication at this point of how those concerns may be alleviated by the Internal Market Bill?

Ms Harrison: We have raised a number of questions for legal advice, and I cannot say that much today other than that my officials and I have read it. Our initial view is that it relates more to west-east issues than to east-west issues, and my primary concern, entering the next few months, is getting assurances that there will be no interruption to our medical and healthcare supplies when we eventually end the transition period. That is why I have asked a number of specific questions about the Bill. On reading it, the issues look more west-east.

The Deputy Chairperson (Mrs Cameron): When do you expect to get answers to those questions?

Ms Eimear Smyth (Department of Health): I do not have a specific reply, but it is urgent. As soon as possible.

The Deputy Chairperson (Mrs Cameron): Can you elaborate on the cross-border healthcare Bill? Is there a timescale for that? Can you confirm that it is not needed by the end of the transition period?

Ms Harrison: I will ask my colleague Patricia to answer that. Patricia, did you hear that?

Ms Patricia Quinn-Duffy (Department of Health): I am on the phone. I hope that you can hear me OK.

The Deputy Chairperson (Mrs Cameron): We can indeed. Thank you. You are very welcome, Patricia.

Ms Quinn-Duffy: We hope to give some information to the Minister shortly on the provisions and on whether we will continue the principles around a cross-border healthcare directive. At this point, I cannot really say what the decision will be. The Bill is a placeholder in case the decision is taken to continue with some principles, because some changes to primary legislation — the 1972 Order — will be required to apply any principles that we wish to continue. There is a transition period with the cross-border healthcare directive, and anyone who applies before the end of transition will have that honoured whether they have applied, have started treatment or have finished treatment and require their repayment to be made. There are at least provisions for that for the end of transition.

The Deputy Chairperson (Mrs Cameron): I understand that North/South cooperation is not necessarily directly reliant on EU membership, but to what degree is it fully protected? Or is further work required beyond the Bills that have been mentioned?

Ms Quinn-Duffy: No, the cross-border healthcare directive Bill was specifically for the principles of the EU directive, so North/South cooperation, all the healthcare provisions at the North West Cancer Centre, paediatrics in Dublin and out-of-hours services in the west of the Province. There are lots of — I think about 30 — SLAs and MOUs around North/South cooperation. None of those really has any bearing on EU regulations, and they should not be impacted. There should be no necessity for any Bill or legislation around those, so we are not expecting any impact on them.

EU reciprocal healthcare and people's ability to access healthcare for necessary treatment if they are on holidays or visiting the South from the North, or vice versa, will be part of the UK/Ireland enduring

reciprocal healthcare agreement. We hope that it will be in place by the end of transition to accommodate that.

The Deputy Chairperson (Mrs Cameron): OK. With regard to food standards — I am not sure whether you will want to answer this — I understand that nutrition food labelling and composition may be the subject of UK-wide common frameworks. To what extent is there an overlap or potential conflict with the NI protocol with regard to adherence to EU standards? What would be the impact of the Internal Market Bill on that?

Ms Harrison: I will have to take a note of that away and come back to you in writing. I do not have anyone on my team on the call to answer that specific question on food standards. I am happy to come back in detail.

The Deputy Chairperson (Mrs Cameron): I appreciate that. Thank you. We have had a couple of indications so far. I want to go first to the Chair, Colm Gildernew, who is attending remotely. Colm, can you hear us? Would you like to come in with your questions?

Mr Gildernew: Yes, I can hear you, Pam. Are you hearing me?

The Deputy Chairperson (Mrs Cameron): Yes, very clearly. Thank you, Colm.

Mr Gildernew: Thank you very much. Apologies to Pam for the short notice. My broadband is not supporting the camera at my end. That is why you cannot, I think, see me, but I can see and hear you and the proceedings clearly. Unfortunately, I have had to attend remotely today as a result of being in contact with someone who is awaiting a COVID-19 test. I preferred to attend remotely as a precautionary measure.

Cathy, thank you very much for your presentation. It is clear that there will be an awful lot of complexity and an awful lot of issues to be considered. You mentioned that 11 statutory instruments would be required. Can I clarify that those 11 statutory instruments will be Westminster legislation rather than Assembly statutory regulations?

Ms Smyth: Yes. That is my understanding.

Mrs Cameron: Did you hear that, Colm?

Mr Gildernew: Yes. In the light of that, Cathy, in your role in the Health Department and with regard to exiting the EU, are you concerned that these statutory instruments will add further complexity to the additional uncertainty that has been injected into the process now as a result of the Internal Market Bill?

Ms Harrison: At present, we are working through a programme of statutory instruments. We have not been advised that there is going to be any disruption to those as a result of the Internal Market Bill. Is that correct, Eimear?

Ms Smyth: Yes.

Ms Harrison: Do you want to elaborate a little bit on your concern?

Mr Gildernew: Given that we had a protocol and withdrawal agreement in place that seemed to provide some clarity, and given that those arrangements now seem to have been thrown into severe doubt by the introduction of the Bill at Westminster, impacting on the potential to achieve a deal which would ensure a smooth transition, or as smooth a transition as possible, from your perspective, with regard to your responsibilities, are you concerned that the Internal Market Bill introduces further uncertainty and, potentially, further disruption in the delivery of health post-Brexit?

Ms Harrison: I said at the beginning that, within the context of my responsibilities in the Department of Health, I have sought specific legal advice to inform how it may affect the programme of work that we are working on, Colm. With that advice, I will be in a better position to understand if there is likely to be any disruption at all from the Internal Market Bill. At this moment, I cannot really say that an additional risk has been identified with regard to the legislative programme.

Mr Gildernew: If I may, Chair, I have a further question on that point. Can you also confirm that the use of statutory instruments is a choice by the Minister? He has the authority to make a choice on whether to use a statutory instrument or the devolved powers which we already have here. Can you confirm whether that is the case? Also, what areas are the 11 statutory instruments covering?

Ms Harrison: Eimear, do we have the areas?

Ms Smyth: Tobacco products and nicotine inhaling products; the electronic commerce directive; European qualifications; reciprocal and cross-border healthcare; human tissue quality and safety; quality and safety of organs; blood safety and quality; a further one on reciprocal healthcare one; another further one on reciprocal healthcare; mutual recognition of professional qualifications; and human medicines amendment. There are several relating to reciprocal healthcare.

Mr Gildernew: With regard to those being specific areas that the Minister has chosen to deal with via statutory instrument, can you explain the rationale for using a statutory instrument rather than primary legislation in the Assembly?

Ms Harrison: Colm, again I think I might come back to you on that, because that is quite a question. With regard to the programme of legislation that is coming through, statutory instrument is the chosen method by which we will introduce these changes into Northern Ireland. I will come back to you on your specific question on why that has been chosen.

Mr Gildernew: Ok. Finally, Chair — thank you for allowing me this — with regard to the ongoing day-to-day arrangements along the whole border corridor, where people from North and South may be accessing healthcare, you mentioned in your brief that that is being worked on. What guarantees have we that that very important healthcare will continue, in both directions, uninterrupted throughout the transition period and after?

Ms Harrison: I will invite Patricia to come back in; she is the expert on this particular area, Chair.

Ms Quinn-Duffy: There are a number of different ways in which people can access healthcare across the border. We have the North-South cooperative arrangements, which we do not expect to be interrupted because they are more contractual arrangements than based on EU legislation. There should not be any interruption, and we are not expecting any interruption, to those. With regard to reciprocal healthcare arrangements, where people can access treatments that are necessary if they have an accident or incident while in the other jurisdiction, the UK and Ireland are progressing a negotiation to put in place an enduring reciprocal healthcare agreement. Discussions on that are at a very advanced stage, and we expect that to be in place by the end of the year. We are looking at contingencies on the off-chance that it is not available but, at the moment, the signs look very positive.

Mr Gildernew: Finally from me, with regard to the ongoing continuity of supply of medicines, in light once again of the Internal Market Bill and the disruption that that might cause, Cathy, are you satisfied, or what guarantees or assurances can you give the Committee, in relation to the ongoing supply of medicines?

Ms Harrison: With regard to the Bill, I repeat that we have sought particular legal advice on the implications of it. Our initial analysis is that it mainly concerns the flow of goods from Northern Ireland to GB, which is not relevant to our medicine supply chain.

The Deputy Chairperson (Mrs Cameron): Will you forward to us Eimear's list and the speaking notes for your oral briefing, Cathy, if that is OK?

Ms Harrison: Yes, I am happy to do that.

The Deputy Chairperson (Mrs Cameron): That would be useful. Thank you. Colin, you indicated that you wanted to speak.

Mr McGrath: Yes. Thank you very much indeed. I need to go before 12 o'clock, so I might leave before the end of the presentation. What is the estimated number of people who are working in the Department in preparation for Brexit?

Ms Harrison: I am counting up in my head. There are seven.

Mr McGrath: In the whole Department?

Ms Harrison: At the moment. The way in which we are working is that, given the scope of our work, the expertise that resides across the Department will be drawn upon. We will work with the whole Department on policy areas, but, for this accelerated period, a unit has been pulled together. I will count the number of people in that unit again. Do forgive me. You are putting me on the spot here. I should have had that number in front of me — it is seven or eight. I am sorry. The number is in that region. That dedicated team has come together for the end-stage planning, for which I am the SRO.

Mr McGrath: That is not just the pharmaceutical side; that is right across the whole Department.

Ms Harrison: It is across the other areas.

Mr McGrath: It does not seem like very many.

I am looking at the workforce considerations that you mentioned. Has a scoping exercise been done in the workforce to find out how many people might have to leave, how many can stay and how many will have to apply? Is there assistance to enable people in the workforce to stay? What might happen if there are flashpoints for somebody who has not applied for something? Do they get a period to stay so that they can fill in the information? On potential vacancy management, there is already a series of vacancies, but will this contribute further to it, or do you feel that that will all be completely covered?

Are staff who cross the border and work on either side of the border under the same rules as everybody else in the EU, or is there a special North/South element to the rules for them?

Ms Quinn-Duffy: There are probably three questions there. First, for the workforce in general, unfortunately, EU nationality is not part of the collection of data at the point of hiring. As we do not know the number of EU citizens who work in health and social care in the trust, it is a bit difficult to estimate and quantify. However, the Department for the Economy has been doing some work on how many people were leaving, and it seems to have settled down since the referendum in 2016.

All European citizens who are currently in Northern Ireland and were working and living here before the end of transition are able to apply for the EU settlement scheme. We have been working with the EU workforce working group, which includes, as Cathy pointed out, the trusts, employers in the independent sector, unions and regulators. We have been promoting the scheme and putting out information to staff in those areas on how to apply for the EU settlement scheme and what help is available in Northern Ireland to apply. The EU settlement scheme will be open until June 2021, so there is a six-month buffer. We will start to increase the communications to staff to ensure that people apply for the settlement scheme and regularise their settlement status in the UK.

You asked about the workforce programme. There is a programme of work right across the workforce. As you said, there are other impacts on the workforce, such as COVID and international movement. There is a programme of work on workforce and, in particular, on international recruitment, on which we can give you more information in writing. I do not have the full details because it is slightly outside my remit.

With the new immigration system, from January, all EU citizens who come to work or study in the UK will be required to have a proper visa to remain in the UK. This will include EU citizens who live in the Republic and wish to work in Northern Ireland. Irish and British citizens who live in the Irish Republic and want to work in Northern Ireland do not have to apply for one. That means that they will need to have a work visa. However, the British Government have introduced an NHS visa, which fast-tracks the process and is a slightly cheaper option than the normal visa for other work areas. They have also started to introduce a waiver of the immigration health surcharge for those working in health and social care, which will be available in the future. I hope that that answers your question.

Mr McGrath: Yes, thank you. Are there any plans to try to manage the workforce? It is commonly accepted — I am not sure of the figures and the factual element — that quite a sizeable proportion of the health workforce is from outside Northern Ireland and the rest of the UK. Is that a movable feast? Do x number of hundreds join one year and leave the next; then, another few hundred come in and another few hundred leave? Is the introduction of visas and a points-based system likely to cause any slowing in the freedom of staff to come here?

A possible worst-case scenario is that hundreds of staff go home but hundreds of others do not come here to make this their home, and we are left with a staffing deficit. How would that be managed? If we do not have information on that, it could just arise in May, June, July or August of next year. There could be a shortage of staff right across the UK, meaning that we would not have other people to draw in from across the UK to fill the gap. Is any work on preparedness being carried out so that we are ready for a scenario like that?

Ms Quinn-Duffy: I should probably give you a written response on that, if that is OK. International recruitment is not my area. EU citizens, from next year, will be classified as international recruitment.

Mr McGrath: I have a second question. If the worst-case scenario kicks in — there is no deal — and we are required to go with the stock that we have, in general, how much stock of critical medicines is available? How long would it take to replenish that or set up new procedures? You used the term "shortage management". What is involved in preparation for shortage management? Boris's normal answer is, "We will get a planeload of things for that", but I think that we have run out of planes. Are concrete preparations being made in the Department? How much stock is there?

Ms Harrison: I referred to a multilayered approach, and that is exactly what is in place. In the last number of years, since we started our work on EU exit, an enormous amount of work has been done to understand our medical supplies chain. We have been working hand in hand with DHSC on this. It has put considerable resources into enhanced surveillance of the medical supply chains, and that has informed this multilayered approach. Its risk analysis looked at the likely areas where we could have a problem with supply interruption. A lot of the stock that flows into the UK comes through the short straits, Dover/Calais and other ports on the south coast. Analysis was done early, and it has been continuously revisited around the pinch points. The analysis has resulted in some different things happening. The UK now has a lot more stock than normal. At one point, we had at least six weeks' supply of some products, and more of others. Stock levels vary depending on what the product is. We have different arrangements for items such as vaccines and insulin. We have buffer stocks in place to support the enhanced warehousing arrangements. We have arrangements in place that will reroute our supplies of medicines from the short straits, should there be a pinch point, into less busy ports in GB, enabling that stock to travel uninhibited across GB and into the wholesale chain.

You specifically asked about shortages. A dedicated team in the Department of Health and Social Care works in that area. The team links to dedicated teams across each of the devolved Administrations. I have a team in Northern Ireland, which is led by Fiona Taylor. We now have very early intelligence about shortages, and it is much better information than we have ever had before. The information allows us to think far ahead about what mitigations may be needed. For example, it allows us to consider a change in prescribing guidance or to advise prescribers to move from one product to another early in order to prevent a shortage arising at the point when the medicine is not available to us. There has been a huge amount of work in this area, and there are very good established arrangements, including those in Northern Ireland that cover both primary care and all of our trusts.

Mr McGrath: So, today, we can give an assurance that nobody will be without their medication in January or February.

Ms Harrison: I can give an assurance that the work being done on medical supplies is comprehensive. There is no need for anyone to do anything different when ordering their medicines or prescriptions.

Mr McGrath: That is a really good political answer. However, is it definite that no one needs to worry about access to their medicine from January onwards? Will the supply chain be there?

Ms Harrison: The supply chain has over 7,000 lines. All that I can give you is an assurance that every single one of those lines is being considered within the plans. A huge number of contingency arrangements are in place right now to maintain those supplies.

Mr Easton: Thank you for your presentation. You are working on two plans: one for no deal; one for a deal. Let us go to the Northern Ireland protocol. You mentioned that about 98% of our medicines come from the rest of the UK. Under a new deal, there will be checks and tariffs at our ports. Is that correct?

Ms Harrison: There is a risk that there could be, yes.

Mr Easton: If that is the case, is there the potential that medicines from the rest of the UK will be delayed because of these new checks and tariffs?

Ms Harrison: It is one of the areas that we have identified in our work programme, and we are working on it right now. When I talk about mitigations, we are looking at a range of things, such as legal interpretations. As written, without mitigation, there is a risk. However, it is important to focus on those mitigations. Without mitigation, there is a risk.

Mr Easton: There is the potential that our medicines could be delayed.

Ms Harrison: There is a risk, but the mitigations that are being worked up will ensure that arrangements are in place to avoid that. That is what we are working towards.

Mr Easton: You hope, but you cannot be 100% sure.

Ms Harrison: It is what we are working towards.

Mr Easton: However, you are not 100% sure.

You mentioned that, because we are staying with EU rules on new medicines, if there were to be new medicines, the rest of the UK can bring those in but we would have to follow EU rules in Northern Ireland. In theory, a new superdrug for a serious medical condition could be brought into the United Kingdom, but the EU might not have approved it. Is my interpretation correct that Northern Ireland may lose out on that new drug coming into the rest of the UK because it has not been approved through the EU, whose rules we are following?

Ms Harrison: You are correct, in that we will follow EU acquis after transition and GB will not. That has raised a number of issues for medicines licensing. Our regulator for medicines licensing is the Medicines and Healthcare products Regulatory Agency (MHRA), which has been working on a range of areas. On 1 September, it issued a raft of guidance — the first tranche — for the pharmaceutical industry. The purpose of that guidance is a smooth transition. On day one, all the medicines that are used in all four UK countries are EU-regulated, because they have all been licensed through the EU arrangements. In the short term, the risk that you describe will not arise. In the longer term, without putting any arrangements in place to avoid it, there would be a risk that there would be divergence in Northern Ireland. That is a fundamental issue that we are working on with the regulator to make sure that we maintain our equitable access to new medicines in line with other citizens in the UK.

Mr Easton: However, the potential exists.

Ms Harrison: You are getting a flavour of the many implications of our leaving at the end of the transition period, and there is not a single answer or a single assurance that can be given. We will need to think through every single issue carefully and advise you in more detail in terms of our principles, which are that citizens in Northern Ireland should have access, on an equitable basis to the rest of the UK, for our medicines.

Mr Easton: There is no guarantee at the moment.

Ms Harrison: That is our intention and the intention of the work programme. There is no risk in the short term because all our medicines are EU-regulated at the moment.

Mr Easton: In the longer term, there could be risks. OK. Thank you.

Mr Carroll: You have been asked this question twice, but I will try again. I know that you have a research paper and legal advice coming back on the Internal Market Bill. Can you give a broad sense of the themes that are being looked at? I presume that medicines supply is one, but is there any detailed consideration of state-aid rules? The Bill proposes to change state-aid rules, and it is my understanding that that is to allow the British state to intervene more in the economy. I understand that it is mostly about Boris Johnson and the Tories trying to give a hand to technological companies, but I imagine it would not preclude intervention and financial assistance to pharmaceutical and medical companies. Has there been any research into that or any thoughts or discussions? It would be helpful if you could comment on that.

Will you expand on the enduring reciprocal healthcare agreement? Is that the agreement on access to surgery and hospitals? What is in it and what is not in it? That information would be useful.

Ms Harrison: I will take the first two items and then ask Patricia to take over. With the Internal Market Bill, I am focusing specifically on the areas that are in our work programme. There is a lot more in it. We have submitted a number of legal questions, primarily related to the flow of medicines and medical devices. That is my primary concern, and I want to understand to what extent the Bill has any influence, particularly on east-west movement, and we have asked for clarity on movement in both directions. The state aid issue is not really one for the Department of Health. I am obviously interested in it, because of our work with the pharmaceutical industry, but it is probably more a question for the Department for the Economy to advise on. It is not something that I have sought advice on, and I do not intend to, particularly for the work programme that I am working on.

Mr Carroll: I take your point that it is for the Department for the Economy generally, but do you not accept that it has a bit of a knock-on effect on medicine and health, especially if pharmaceuticals could get a handout or financial encouragement, if I put it that way?

Ms Harrison: It is more a Department for the Economy issue, because it is more about decisions that the pharmaceutical industry would make around setting up and maintaining business here. My remit is much more to do with the medicine supply system, which is not really reliant on whether we have a pharmaceutical industry in Northern Ireland or on whether it accepts state aid. It is not within my remit. It is more for the Department for the Economy to provide information on that.

The Deputy Chairperson (Mrs Cameron): Was Patricia coming in on —?

Mr Carroll: Yes. The enduring reciprocal healthcare agreement, please.

Ms Quinn-Duffy: The enduring reciprocal healthcare agreement that the UK and Ireland are negotiating is on the principles in the EU social security regulations around needs-arising healthcare, which would be used with a European health insurance card (EHIC); around an S2, which is for planned care in the public sector in another member state; around an S1, which would include pensioners living in the other state having their healthcare paid for; and around frontier workers. Those are the areas at which the negotiations on the enduring agreement is looking.

Mr Sheehan: I noticed, Cathy, that you skirted around the elephant in the room during your presentation. You said that the Internal Market Bill had recently been introduced and that you were seeking legal advice to see how it affected the work that you are doing. I hear what you are saying about the supply of medicines: that there are 700 lines and that you are working on every single one of them. Can you, however, as Chief Pharmaceutical Officer, guarantee that, after 31 December, there will not be shortages of medicines?

Ms Harrison: I do not think that there has ever been the level of surveillance of our medicine supply chain that there is at the moment. At present, even without any issues, we would always have a certain amount of medicine shortage. I cannot guarantee that there will never be any shortage of medicines, because, at any time, shortages arise for a multitude of reasons. Our pharmaceutical industries are global, so anything that arises in any country around the world relating to medicines —.

Mr Sheehan: I understand that, but —.

Ms Harrison: I cannot give a guarantee that there will be no medicine shortages, but I can give a guarantee that there has never been more emphasis put on maintaining the medicine supply chains. The level of rigour and understanding that we have around where our medicines come from and how they will be maintained would not be seen across the rest of the UK. I am working with all the right people to make sure that the Northern Ireland issues, which I am primarily concerned about, are dealt with and that the flow of our medicines into Northern Ireland is maintained without any interruption.

Mr Sheehan: You, as Chief Pharmaceutical Officer, are therefore saying that, effectively, the Internal Market Bill will not affect the supply of medicine.

Ms Harrison: I said before that we have sought legal advice on that.

Mr Sheehan: You therefore do not know.

Ms Harrison: It is a pretty recent development. We have sought quite detailed legal advice on it. I will be in a better position to understand the impact on medicines when we get that advice. Our initial reading of the Bill is that it is primarily concerned more with west-to-east flow and that it will not impact on the work that we are doing on maintaining supplies from GB to Northern Ireland, which is my priority.

Mr Sheehan: The fact that you are seeking legal advice must mean that you do not know what impact the IM Bill will have.

Ms Harrison: The Bill is complex and detailed, so we are doing the right thing. We are seeking legal advice in our particular areas, which are detailed and are under my responsibility. We have done the right thing in having sought the advice. We are just waiting for it now.

Mr Sheehan: There is therefore the potential for supply lines to be interrupted.

Ms Harrison: Under the Bill? I do not know.

Mr Sheehan: You do not know?

Ms Harrison: I will not know until we get the legal advice.

Mr Sheehan: OK. Thank you.

Ms Harrison: What we will do with that advice is that we will return to our assumptions on the work that we are doing with medicines.

This is a constantly moving situation. I have to say to the Committee that we are moving towards change. Things are changing. I cannot tell you that everything will be the same as it was before. We are changing. The Northern Ireland protocol puts us in a position in which Northern Ireland is different from GB. We are working through a range of mitigations to ensure that our medicine supplies will not be affected. We will work through things such as the Bill and any other changes that arise in the coming weeks to understand how they affect our assumptions.

Mr Sheehan: Thank you.

Ms Bradshaw: Some of my questions have already been asked. First, it is my understanding that a North/South Ministerial Council meeting (NSMC) is coming up shortly and that health will be on the agenda. To what degree will some of the finer details of the cross-border healthcare directive be hammered out at that meeting so that there is a wee bit more political agreement on it?

Secondly, I would say that the South will get quite a poor deal under such an arrangement. When you think of how many people we have on our waiting lists here, it is very difficult to see how we would have any capacity for people from the South coming North. To what degree are you reading across to the management board of the Department of Health, which is overseeing the transformation and reconfiguration?

Ms Quinn-Duffy: I will answer your questions on the cross-border healthcare directive. A paper will go to the North/South Ministerial Council. It is being prepared at the moment. The cross-border healthcare directive will not apply, as it does at present, to the UK. Ireland has to make the decision as to whether it continues to use the cross-border healthcare directive. We are looking at that in the Department as well.

You asked about capacity and waiting lists. Most people who use the cross-border healthcare directive use the private healthcare sector. The vast majority of people who come North and those who use the healthcare directive going South and to other parts of the European Union — Ireland is not the only recipient of patients from Northern Ireland — go to the private sector, not to the public sector. Whether people from the Republic use the cross-border healthcare directive in the North really does depend on capacity.

Ms Bradshaw: OK. You say that a paper is being prepared for the next meeting. What do you envisage the timescales being for the negotiation? When will there be transparency in the decision-making? When will the Health Committee and the general public be aware of when that negotiation will be concluded?

Ms Quinn-Duffy: The paper on the cross-border healthcare directive will go to the Minister shortly for him to look internally at what the decision-making process is. The reciprocal healthcare agreement with the UK is a UK and Ireland negotiation. The communications will come out of those negotiations towards the end of the year, and those will make clearer what the protocols are between the UK and Ireland.

Ms Bradshaw: Thank you.

Ms Flynn: Thanks, Cathy, for coming along and for your answers so far. I should start by saying that all Committee members would most certainly welcome getting updates as regularly as we can. There is so much detail contained in the work that you are doing and so much detail that we need to wrap our heads around, so I would welcome future updates.

The Internal Market Bill has been covered enough thus far, but I am wondering about the legal advice that you have sought on it. Do you have an indication of when you will receive that legal advice? I assume that it will have an impact on your unit's planning. Do you have any idea when you expect to receive it?

Ms Harrison: No. I will be on the phone straight after this meeting to find out where they are. We will chase it up today. We gave them a number of questions to consider and are expecting a response imminently. They understand that it is urgent.

Ms Flynn: You said that things are changing, and we will be in a different scenario in relation to the divergence of the North and Britain. You said that your transition unit team was working closely on plans with colleagues in England and the other devolved Administrations. Are any of those conversations happening between the transition unit and with the Department of Health here and the South?

Ms Harrison: I have a contact in the South to whom I stay close on health issues. However, our primary focus at the moment is on working with DHSC and the devolved Administrations.

Ms Flynn: You referred to citizens' rights provisions and that you are working on day-1 plans. You said that you were looking at what your day-1 issues will be and the longer-term concerns and issues. We know that citizens' rights are being considered as a day-1 concern. Could you provide us with a wee breakdown of what the day-1 concerns are and the longer-term issues that the unit is looking at?

Ms Harrison: I am happy to do that. I can do that in writing.

I should have said that, in the relationship with the Republic, I am speaking from the medicines point of view. Patricia referred to engagements that have been going on for quite a long time with the Republic of Ireland. I was speaking as the pharmacist and the engagement that I am involved with.

Mr Chambers: Patricia reassured us about the various things that Cathy referred to, namely cross-border cooperation between hospitals and other medical facilities.

My understanding is that, in the past, the NHS purchased has surgical procedures from clinics in the Republic of Ireland, and NHS patients went to the Republic for the procedures. Will that still be the case, or there obstacles to that continuing? I do not think that there should be, but just to get a little bit of reassurance from Patricia that that facility will still be available.

Ms Quinn-Duffy: Because of the waiting list initiatives and purchasing block treatments for surgery, those treatments will be almost like commercial contractual arrangements, and there should be no EU issues that block, or exit issues that would hinder, those arrangements from continuing or to be on an ad hoc basis.

In terms of patients using treatments that are under current EU regulations, because we have a number of patients who go to the Republic to have treatment under what is known as an S2

arrangement, the procedures under those are part of the negotiations for the enduring reciprocal healthcare arrangement. We hope that those very particular treatments will be able to continue under that type of arrangement, which is coordinated through the NHS Business Services Authority in London. We believe that there should not be an impact on patients in those circumstances.

Mr Chambers: Chair, can I place on record that I acknowledge and appreciate the work that Cathy and her team are carrying out on our behalf? It cannot be easy trying to establish a game plan when the rules are constantly changing. Thank you for your efforts.

The Deputy Chairperson (Mrs Cameron): If there is no further agreement with the EU on recognition of professional qualifications, will that pose a risk to recruitment for us, and are there any implications for staff from the Republic of Ireland who work in Northern Ireland?

Ms Quinn-Duffy: I do not know whether you want me to discuss that now or wait until the next agenda item, but there are a number of provisions in place to facilitate that if there is no arrangement in the future negotiations with the EU. A transitional provision will be arranged in the UK for recognition of professional qualifications for EU citizens, for EFTA citizens from Iceland, Norway and Liechtenstein and for Swiss citizens who have qualifications from their home territories.

If there is no agreement with the EU, come the end of the transition period, on this free trade agreement, there will potentially be divergence in the UK. Last year, the UK and Ireland signed an overarching MOU that highlights continued recognition and working together to recognise professional qualifications in the common travel area. At this point, I do not have detail on where that will end up because it is part of the continuing negotiations.

The Deputy Chairperson (Mrs Cameron): Thank you, Patricia. As you mentioned, you will be staying on for the next item. I thank Cathy, Eimear, Patricia, who is staying on, and Fiona for their attendance. We wish you well with your very heavy workload and look forward to seeing you at your next visit to the Committee. Thank you for your time.