Northern Ireland Assembly

Committee for Health

OFFICIAL REPORT (Hansard)

Health and Care Bill: Department of Health; Public Health Agency

14 October 2021

NORTHERN IRELAND ASSEMBLY

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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 Jonathan Buckley
Mr Gerry Carroll
Mr Alan Chambers

Witnesses:

Mr Peter Barbour	Department of Health
Ms Joan Hardy	Department of Health
Ms Patricia Quinn-Duffy	Department of Health
Ms Karen Simpson	Department of Health
Mr David Wilson	Department of Health
Dr Janice Bailey	Public Health Agency

The Chairperson (Mr Gildernew): Committee members are aware that the Health and Care Bill was introduced in Westminster on 6 July. The Minister of Health informed the Committee on 8 July that four provisions in the Bill require the legislative consent of the Assembly. Departmental officials are here today to brief the Committee on the four separate aspects of the Bill that require legislative consent. I refer members to the briefing paper and correspondence in their pack. I suggest that, for clarity, we take the legislative consent memorandums (LCMs) in order.

We will therefore take a short briefing on the international healthcare arrangements first, followed by members' questions, before moving on to the second LCM. Bearing in mind, members, that we have four LCMs to get through. I thought that it would be difficult if we took all four briefings together and then asked questions. We will therefore do them one at a time so that we can retain focus. Have the legislative consent memorandums been laid?

The Committee Clerk: No, Chair. I have had no notice of their being laid in the Assembly.

The Chairperson (Mr Gildernew): They have not been laid, so we do not need to arrive at decisions today, but we can take the briefings.

In the light of that, I welcome from the Department of Health Patricia Quinn-Duffy, who works on healthcare policy in the pharmaceutical directorate. I will ask Patricia to brief us on the provisions that relate to the international healthcare arrangements. Patricia, can you give us a short briefing of around five minutes, if possible? We will then have questions from members on that element. Patricia, can you hear me OK?

Ms Patricia Quinn-Duffy (Department of Health): I can, yes. Thank you, Chair. Thank you to the Committee for speaking to us today. You said that the LCMs have not been laid yet. We are still working on them. We are working to a very tight timeline that the Department of Health and Social Care (DHSC) has set. We really appreciate the opportunity to be here today to brief the Committee. I have a short introduction on all the LCMs. Would you prefer it if I addressed them individually and then took questions after each?

The Chairperson (Mr Gildernew): Yes. Address them individually, and we will ask questions after each one. It has the potential to get quite confusing if we take all four together. We will take each of them in turn in shorter sessions. Bear that in mind.

Ms Quinn-Duffy: All right. Thank you, Chair. With the international healthcare arrangements, the Health and Care Bill seeks to amend the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019 — the HEEASA Act — to enable the Secretary of State to implement comprehensive, bilateral healthcare arrangements with the rest of the world. That will enable the UK to pay for treatments outside the UK and facilitate the necessary data processing by expanding the scope of the Act to countries, territories and international organisations outside the EU, the EEA and Switzerland.

The clauses will allow the Secretary of State to make regulations to implement the international arrangements by amending regulation-making powers in section 2 of the Healthcare (European Economic Area and Switzerland Arrangements) Act. Having UK-wide legislation for international healthcare arrangements will ensure a consistent framework for the negotiation and implementation of those arrangements, but, because international relations is an excepted matter and health is a devolved matter, any future regulations taken forward that have a devolved implication are subject to a statutory duty to consult before those regulations are made. That duty is underpinned by a memorandum of understanding (MOU) that sets out the mechanisms by which the UK nations will work together to deliver on international healthcare arrangements, from negotiation to implementation. Officials are currently working on a revised MOU to set out in further detail how that will work and how the UK nations will work together to develop and implement any future international healthcare agreements.

That was a very brief introduction to the international healthcare arrangements. I am happy to take any questions.

The Chairperson (Mr Gildernew): Thanks, Patricia. When can we expect to see that revised MOU?

Ms Quinn-Duffy: It is still in the very early stages of being revised. The one that is there at the moment was agreed prior to the Assembly's returning. We are working very diligently on the MOU. There should be an agreement by the end of the year. The experience of working with the DHSC on text for MOUs previously suggests that it takes some time to get it fully agreed among the four nations.

The Chairperson (Mr Gildernew): The statutory duty to consult is fair enough, but that will replace the ability to make the legislation. In that context, it is almost a second prize. It is a mitigation. Will the LCM have any impact on cross-border healthcare here on the island of Ireland?

Ms Quinn-Duffy: No. North/South cooperation is under the Good Friday/Belfast Agreement. That does not involve international relations, so Northern Ireland can still work with Ireland on any North/South cooperation that is appropriate for us to do. It therefore does not have any impact.

The Chairperson (Mr Gildernew): Will the LCM impact on the ability of a future Health Minister to enter into deeper or closer arrangements with any particular area or state?

Ms Quinn-Duffy: International arrangements are an excepted matter, so the Minister would not be able to come to agreements with states. The LCM does not cover contracts with providers, however. The Department and the Minister have powers under the Health and Personal Social Services (Northern Ireland) Order 1972 that allow us to procure and purchase healthcare outside Northern Ireland. For example, extra-contractual referrals would still be able to go ahead with other countries so that we could still purchase healthcare. The LCM also means that we would be able to enter into contracts with providers, but not with states, so to speak.

The Chairperson (Mr Gildernew): How do the data-processing aspects of the arrangements comply with GDPR? Which would take precedence?

Ms Quinn-Duffy: Section 5 of the Healthcare (European Economic Area and Switzerland Arrangements) Act sets out the data-processing arrangements. Those are in compliance with GDPR. That refers particularly to planned care, where a patient is having care that is specifically planned under an international arrangement. That was known as an S2 under the European arrangements. There would be data sharing between Northern Ireland and the UK and between the UK and a third country. That arrangement is in the HEEASA Act.

The Chairperson (Mr Gildernew): What are the current rules for accessing healthcare in Europe, more particularly in the EU?

Ms Quinn-Duffy: Those are under the social security protocol in the Trade and Cooperation Agreement (TCA). The arrangements are almost completely the same as those under regulation 883 on the coordination of social security systems. For EU countries, there is full maintenance of healthcare cooperation and reciprocal healthcare. UK residents would have to apply for a global health insurance card (GHIC) rather than a European health insurance card (EHIC). That is opened up for everyone. It also sees the continuation of the S2 planned care route and arrangements for posted and frontier workers, for retiring to other nations and back to the UK, and for having arrangements paid for by the state in which a person lives.

Negotiations are still ongoing with the European Free Trade Association countries and Switzerland around future arrangements there. All pre-end of the transition period people are covered by the withdrawal agreement and by the EFTA and Swiss agreements at that point.

The Chairperson (Mr Gildernew): If someone does not have a GHIC in place before travelling, what happens there, or what arrangements are in place? In your view, has it been communicated widely enough to the public that the system has fundamentally changed since Brexit?

Ms Quinn-Duffy: The arrangements are the same, and the applications will be the same. I think that EHIC or GHIC applications have not changed as such. One applies for them at the same place. I do not think that enough people know about being able to get a provisional replacement certificate (PCR). If people do not have an EHIC or a GHIC when they travel, and they end up needing to use one, they can apply for an immediate PCR that allows them to get the healthcare that they need paid for by the UK. I do not think that that is as widely known as it should be, but applications for a GHIC or an EHIC will be the same. If people know to get an EHIC and go to apply, they will be directed to the GHIC application.

The Chairperson (Mr Gildernew): Will you commit to taking back to the Department that issue about communicating for it to be addressed?

Ms Quinn-Duffy: Yes.

The Chairperson (Mr Gildernew): As travel becomes more possible, as it is at present, that becomes a bigger and bigger issue.

Ms Quinn-Duffy: Yes, I can, Chair. I make a commitment to do that.

The Chairperson (Mr Gildernew): Thank you.

Mr Carroll: There has been general concern about the Bill's full content. How does it impact on people here? Unite the union have said that the Bill is a recipe for more privatisation and cronyism in England. How does it affect us here? Unite stated that the Bill:

"invites private companies to make further inroads into our NHS".

There is also a question around, as I understand it, the Secretary of State's power to interfere and go over the head of healthcare workers, if not that of chief executives and heads of trusts. Those are some concerns that are being expressed generally about the Bill. Has there been any discussion or any clarity provided around that? If I heard you correctly, you said that the Bill is about agreements

with providers and not states. To me, that indicates that it would be private providers. Alarm bells are ringing in my head about that. Some clarity around that would therefore be useful.

Ms Quinn-Duffy: Thank you for the question. Unfortunately, because I am dealing specifically with the international healthcare arrangements piece, I do not have a full understanding of the Bill. I can take that away and have information sent to the Committee on the Bill in general.

I spoke about how people will be able to purchase healthcare internationally. Under the current system, we have extra-contractual referrals, which allow the Health and Social Care Board (HSCB) in Northern Ireland to buy in services that we cannot provide in Northern Ireland. If we cannot get them in the rest of the UK, we can go further afield. Rather than privatising, it is about trying to manage the delivery of care that patients in Northern Ireland need but that may not be able to be delivered either in Northern Ireland or even on an all-Ireland basis, potentially because of rarity of the service provision.

Mr Carroll: I would appreciate it if you could provide more information on that. No disrespect, but, if we are being told that only small aspects of the Bill affect us here but that a gamut of areas will impact on the provision of healthcare and lead to the opening up of the NHS, that will have a massive impact on people here, so a bit of clarity would benefit other members and me. Thank you.

The Chairperson (Mr Gildernew): Patricia, I will go back to a related issue. You said that something is an excepted matter but that health is a devolved matter. I understand that there is a difference between providers and states. If we were looking to enhance cooperation with, say, Spain on health matters, is there anything in the Bill that would prevent a Health Minister from doing so?

Ms Quinn-Duffy: International arrangements with the Government is an excepted matter. We would, however, be able to make arrangements with regions or with hospitals to provide services or to have better cooperation on healthcare. Those are not excepted matters. Rather, they are contractual matters.

The Chairperson (Mr Gildernew): OK. Thank you.

Jonathan had his hand up, but it has gone down again. I will come back to him.

Mr Buckley: Chair?

The Chairperson (Mr Gildernew): Go ahead.

Mr Buckley: The question that I have, most of which *[Inaudible owing to poor sound quality.]* In relation to *[Inaudible owing to poor sound quality]* in the Department of Health budget, how does granting the national Government power to provide for agreements with the rest of the world affect that?

Ms Quinn-Duffy: The provision of reciprocal healthcare is managed centrally by the NHS Business Services Authority (NHSBSA), on behalf of the UK. It has a budget, which is used to pay other countries for healthcare provided in that country, be it under an EHIC, a GHIC, an S2 or, indeed, an S1. What that means is that, where someone, for example, arrives in Northern Ireland as a visitor and is using an EHIC, that cost is absorbed by the health service in Northern Ireland. It then registers that healthcare provision through the EHIC system with NHSBSA, which then reclaims that money from the other country. The trust can claim back 25% of the cost directly under an incentive scheme to try to encourage trusts right across the UK to register the use of EHICs and reciprocal healthcare for third-country nationals.

Where we probably benefit from reciprocal healthcare is around the use of S2s, which are for planned care. Northern Ireland predominantly uses S2 planned care routes for bone marrow transplants in the Republic. We use quite a number of them every year. In a normal year, rather than in a COVID year, there would be between 15 and 20 bone marrow transplants done in the South. Those treatments cost about £300,000 each, and they are paid for out of an NHSBSA central fund, rather than out of the board's budget. Although there is a deficit in trying to absorb the cost of EHICs, there is a benefit from the planned care treatments that are taking place abroad.

Mr Buckley: Thank you. That answers that question. I have a follow-up question on the consultation that has been carried out. Which professional bodies have been consulted on the nature of any potential changes to the regulatory framework? Specifically, have senior managers been consulted?

Ms Quinn-Duffy: I do not have the detail of the consultation here, but I can get it to you.

Mr Buckley: OK. Thank you.

The Chairperson (Mr Gildernew): We will move on to the second LCM, which is on medicines information systems. Patricia is now joined by David Wilson, who is a deputy Chief Medical Officer, and Karen Simpson, who is from the pharmaceutical directorate and will be leading the briefing on this LCM.

Ms Karen Simpson (Department of Health): Thank you for the opportunity to brief the Committee on the Health and Care Bill, with particular reference to the provisions that deal with medicines information systems.

It is important to point out at the outset that the Health and Care Bill is being used as a legislative vehicle to make an amendment to the Medicines and Medical Devices Act 2021. The Committee will recall that it gave support to a legislative consent motion last autumn to be considered by the Assembly for a similar power to establish a medical devices information system.

The amendment to the Medicines and Medical Devices Act is to enable NHS Digital to collect a range of information about the use of medicines and their effects in the UK and to hold that data in one or more information systems. The Medicines and Healthcare products Regulatory Agency (MHRA) would then be able to use the information held in an information system to establish and maintain comprehensive UK-wide medicines registries.

It is important for the Committee to note that it is not the intention to create a registry for all medicines used in the UK. The need to establish a particular medicines registry will be justified on public health grounds and when alternative approaches to capturing sufficient data are not feasible.

The proposal for the establishment of a new registry will be presented to the Commission on Human Medicines (CHM), an independent advisory group to the MHRA. The CHM would issue a formal registry-specific recommendation if it were considered essential to supporting patient safety. The proposed registries will support MHRA's regulatory functions, and a UK-wide registry is more robust for pharmacovigilance reasons. That is particularly important for high-risk medicines, because if there is the potential for the registries to be mandatory, their ability to reduce harm will be improved.

The powers will initially be used to capture the data needed to establish a registry on the use of sodium valproate and other anti-epileptics, as recommended in 'The report of the Independent Medicines and Medical Devices Safety Review' by Baroness Cumberlege.

The Committee should note that clause 85 of the Health and Care Bill will also make technical amendments to section 19 of the Medicines and Medical Devices Act, on the medical devices information system. The amendments are intended to align with the new provisions for the medicines information system and will enable NHS Digital to share information that it receives from data linkage to other sources and information that contains commercially sensitive technical information about devices.

The Department recognises that, for those enabling provisions that deal with medicines and medical devices information systems, proper safeguards need to be in place to ensure that regulations to be developed take account of Northern Ireland's legislation on disclosure of information, alongside information governance and the code of practice on the sharing of patients' identifiable information for both direct care and secondary use.

Following discussions with the Department of Health and Social Care in England at official and ministerial level, the Department is content that no regulations can be taken forward on the medicines information system without the consent of the Department, as, when regulations are to be made under the proposed new section 7A in the Medicines and Medical Devices Act for the medicines information system, the Department will be the appropriate authority, either alone or jointly with the Secretary of State. The Department's consent is therefore necessary, in recognition of medicines being a devolved matter.

Regulations will be subject to the draft affirmative resolution procedure in the Assembly, and the Committee will be able to scrutinise the regulations fully before they are debated in the Assembly. The situation is different for the medical devices information system, where the Secretary of State has sole authority, because the subject of medical devices is a reserved matter, but the Committee will recall that, last year, the devolved Administrations (DAs) negotiated the inclusion of a statutory consultation clause in the then Medicines and Medical Devices Bill. No regulations can therefore be made without proper consultation with the devolved Administrations. That means that the DAs can legally challenge the Secretary of State if there is a failure to consult properly.

Furthermore, all regulations need to be made within the boundaries of data protection legislation, including GDPR and the Data Protection Act 2018. The Department has provided further details on the medicines information system clause, which can be found in the Committee's briefing pack, to help with its report to the Assembly. We are happy to take any questions that members have on the specific provisions.

Thank you, Chair, for the opportunity to brief the Committee.

The Chairperson (Mr Gildernew): Thank you. The clarification on the ability to consult here is welcome.

Will this link or interact with similar European monitoring systems? Is it being done as a result of our falling out of some of those monitoring systems? Is that its purpose?

Ms Simpson: No, Chair. It is purely to link with the MHRA's regulatory function as the UK regulatory body for medicines and medical devices.

The Chairperson (Mr Gildernew): OK. Does the MHRA registry have any potential impact on movement of medicines from the EU into the North?

Ms Simpson: No, Chair. There is no potential impact.

Mrs Cameron: Thank you for that, Karen. To what extent does Northern Ireland's participation in the common medicines information system across the UK depend not on the exercising of powers in the LCM but on the outworkings of the separate regulatory regimes under the protocol?

Ms Simpson: I will have to take that question away. I would need further advice from our information governance colleagues on that matter, unless David has anything to say on it.

The Chairperson (Mr Gildernew): Can you hear us, David?

Ms Simpson: David may be having sound problems. He sent me a message.

Mrs Cameron: Chair, that is fine. If Karen wants to come back to me, that is grand.

Ms Simpson: I will come back to you. I need to take that question away with me.

Mrs Cameron: Thank you.

Ms Bradshaw: Thank you, panel. My question is about collecting the information in Northern Ireland to feed into the overall process. You mentioned the Cumberlege review. The review is known for its focus on vaginal mesh implants. I work with men and women who have had hernia mesh implants. For many years, they have been concerned that the data on the material being put into people's bodies and its side effects is not being collected properly. Are you satisfied that the systems in Northern Ireland are adequate for collecting information when people feel that procedures have gone wrong and that devices have not been fit for purpose? Can that data feed into UK-wide processes?

Ms Simpson: Thank you for your question. The issue of medical devices sits with David, but he is having sound problems. No system is perfect, and that is why we are looking at the Cumberlege recommendations, such as registries for medical device information systems and medicines information systems. Those systems will make sure that any gaps in the information can be pulled together on a UK-wide basis. For example, the medicines information system for sodium valproate is

on NHS Digital. The MHRA has looked at a registry for sodium valproate, because it presents a danger to the fetus of pregnant women. The registry that it has looked at is based on NHS England's prescribing data, however. The MHRA therefore wants to look across all the systems to avoid creating new measures whereby clinicians have to input separate data. The data that the devolved Administrations hold on their systems will be looked at to see what information is there for making data linkages, what the gaps are and what improvements can be made. It is all very much about patient safety and making sure that the measures are in place going forward.

Ms Bradshaw: That is reassuring. I would like to be kept up to date on that. Thank you.

Ms Simpson: OK. Thank you.

The Chairperson (Mr Gildernew): We will move on to the third LCM, which relates to professional regulation. We are joined by Peter Barbour, who is head of workforce policy development in the Department. Peter, I ask you to brief the Committee on the LCM, after which we will take some questions from members.

Mr Peter Barbour (Department of Health): I will make some introductory comments. The LCM is an enabling provision to allow further action to be taken in due course as part of the wider process of reform of the regulation of healthcare professionals in Northern Ireland.

The regulation of healthcare professionals is a devolved matter, but the Department's policy approach is to work with Health Departments across the United Kingdom, on a four-country basis, to reflect the practical reality that the vast majority of healthcare professions are regulated by regulatory bodies that operate on a UK-wide basis, such as the General Dental Council (GDC), the General Medical Council (GMC) and the Nursing and Midwifery Council (NMC), to ensure that a consistent approach is taken across the wider NHS.

What we are talking about is the impact on the nine UK-wide regulatory bodies that regulate healthcare professions. The powers sought through the provision are part of the process of regulatory reform that has been ongoing since 2017, when there was a UK-wide consultation that set out high-level principles for reform. Those were widely recommended by stakeholders, including stakeholders in Northern Ireland, and the subsequent joint response of the four UK Governments in July 2019 set out plans to modernise the legislation for the nine UK-wide regulators through the Westminster secondary legislative route, which is provided for under section 60 of the Health Act 1999.

The measure has been brought forward and supports the UK-wide agenda. Just to remind members, the objectives of the reform are to ensure that the level of regulatory oversight of healthcare professionals is proportionate to the risk to the public now and in the future; that the bureaucracy of healthcare regulation is reduced; and that the professions protected in law are the right ones.

Section 60 of the Health Act 1999 provides powers to make changes to the UK-wide professional regulatory landscape. Any use of section 60 can extend to Northern Ireland only with the consent of the Northern Ireland Assembly. Section 60 is a pre-existing power that dates back to the 1999 Act. The provision that is being brought forward in the legislative consent motion seeks to extend the use of that section 60 power in some specific ways. Those specific ways, related to the reform process that I outlined, are: the power to remove a profession from regulation; the power to abolish an individual health and care professional regulator; the power to amalgamate regulators; and the power to clarify the scope of section 60 to potentially bring senior NHS managers and leaders under the scope of regulation, should that subsequently be decided as the policy direction.

The legislative consent motion will seek the approval of the Assembly to extend the pre-existing section 60 power in that way. The actual use of any section 60 Order would be subject to a further process of consultation and a legislative consent motion in the Assembly in order for it to extend to Northern Ireland.

The Chairperson (Mr Gildernew): OK. Thank you, Peter.

The provision largely focuses on a range of professional bodies that cover Britain and the North. The deputy First Minister is concerned that it could result in the North's Pharmaceutical Society being wound up and consumed by a wider regulatory body. The Committee Clerk and I met the Pharmaceutical Society on that issue. Is there the potential for that associated loss of input in this LCM?

Mr Barbour: Thank you for that point. The Department is aware of that concern. The statute that affects the Pharmaceutical Society of Northern Ireland is Northern Ireland legislation — the Pharmacy (Northern Ireland) Order 1976 — so there is no question of any change being made that is not controlled by the Northern Ireland Assembly. I reassure members that, if the use of any section 60 Order of the 1999 Act extends UK-wide to the extent that it impacts on Northern Ireland's devolved competence, a legislative consent motion of the Assembly has to be granted. That should provide assurance that there will be no arbitrary change that the Northern Ireland Assembly is not fully signed up to.

The Chairperson (Mr Gildernew): Thank you. Beyond that, what consultation has the Department conducted more broadly in relation to that item?

Mr Barbour: Chair, I mentioned the ongoing wider reform process. That started in 2015 when the various Law Commissions of the United Kingdom, including the Northern Ireland Law Commission, issued a report. There was then a UK-wide consultation in 2017. Northern Ireland was fully involved in that. Meetings were held locally at which stakeholders were able to contribute. There was very positive support from stakeholders for the general principles, which were subsequently set out in the Government's response in 2019. It is now about taking forward that process. The implementation of any individual element of it would be subject to further consultation. For example, any change to the regulatory landscape that might be permitted by the widened section 60 power would involve further consultation with stakeholders, a further legislative process through Westminster and a separate legislative consent motion, given devolution and the need to consult and to ensure the consent of the Northern Ireland Assembly. Much further consultation needs to be undertaken in that area, but stakeholders are very supportive of the general objectives and principles.

The Chairperson (Mr Gildernew): OK. Thank you, Peter. Your briefing states that regulations will be required. Will those regulations be made through Westminster or through the Assembly, or through both?

Mr Barbour: Anything at all that impinges on the competence of the Assembly will require a legislative consent motion. If changes are taken forward under the section 60 process at Westminster that will impact on the UK-wide regulators, a separate legislative consent motion about that route being used would need to be approved by the Northern Ireland Assembly.

The Chairperson (Mr Gildernew): OK. Thank you. This is the final question from me. There is reference to allowing the regulation of senior management. Has that been put in for a specific purpose? Are there plans to regulate senior management in that way?

Mr Barbour: Thank you for picking up on that, Chair. In a sense, that reflects the fact that this is a UK-wide provision. I suppose that that reflects the fact that there may be emerging thinking in the DHSC in England in particular. It is simply a permissive power. They are scanning ahead and looking at the fact that they might want to do that. Again, however, they would clearly need to have a separate process of consultation and so on. The extent to which that would or would not apply to any other country of the United Kingdom would need to be worked through. If it were to be applied in Northern Ireland, it would certainly require the consent of the Northern Ireland Assembly.

If I may say this, Chair, there is a precedent for that. A few years ago, it was decided that a new part of the nursing workforce — nursing associates — would be brought under a regulation. That regulation does not exist and is not used in Wales, Scotland or Northern Ireland. The actual regulatory provision was extended only to England, even though it operates through a UK-wide regulator, which is the Nursing and Midwifery Council. Just to reassure you, that is simply the DHSC looking ahead, but I am not aware of it being on our agenda. Again, in Northern Ireland, the Assembly and the Minister would be fully in control of that process should it be decided to apply it here.

The Chairperson (Mr Gildernew): Leading on from that, there is a level of commitment that there will be an LCM and regulation here should that be progressed, but is there anything in the LCM that would prevent us from initiating that here if we decided to have such an approach? Does the LCM prevent us from initiating and taking our own regulations in that respect or for similar issues?

Mr Barbour: To an extent. Given that the education and movement of healthcare professionals operate on a UK-wide basis, the general approach is to operate on a UK-wide basis. You mentioned the separate issue of the Pharmaceutical Society of Northern Ireland, which is geographically limited

to our region specifically. Generally, we move forward on the basis of consensus across the four countries because there is a common interest in ensuring that it operates for the benefit of all parts of the NHS.

The Chairperson (Mr Gildernew): OK. Thank you, Peter. I see no indications from any other members wishing to speak, so I will move to the final LCM: arm's-length bodies (ALBs) and the transfer of functions.

We are joined by Dr Janice Bailey, the head of research and development at the Public Health Agency (PHA), and Joan Hardy, who is in the secondary care directorate. Janice and Joan will brief the Committee on provisions relating to ALBs and the transfer of functions. Janice, go ahead with your opening remarks or briefing, and then we will go to members' questions.

Dr Janice Bailey (Public Health Agency): Joan and I will deal with separate parts of the LCM. My involvement is in relation to the proposal that the Secretary of State would be enabled to transfer the functions of various ALBs simply with consultation with the Northern Ireland members.

Our work is with the Health Research Authority (HRA), with which I, as a member of the four nations policy group, have a well-established relationship. We are involved in the ongoing approvals through ethics and research governance for UK-wide research studies and clinical trials of medications and medical devices. As part of that, we have mutually owned IT assets, which are open for applications to researchers across the four nations, which cover ethical opinion and governance approval applications. Around that IT infrastructure, we have processes to ensure UK-wide compatibility. As a result, staffing resources in Northern Ireland are in place to deliver in response to those processes and to ensure that any researcher from any part of the UK can make an application to lead a research project in any of the four nations at a given time.

We have been working with the HRA since it was established in 2011. We developed a relationship on a consultative basis alongside the HRA and other members of the four nations policy group, which includes the MHRA and other UK-wide regulatory bodies.

In terms of the process of consultation, we are working up the MOU with colleagues to ensure that we are content with the consultative process that will be in place. We are reasonably reassured by the confirmation that there will be early engagement, continuity of board membership and ongoing financial and operational issues via the MOU. Essentially, that sums up our involvement with the LCM. I will pass over to Joan.

The Chairperson (Mr Gildernew): Joan, can you hear us OK?

Ms Joan Hardy (Department of Health): I can, Chair. Thank you very much. Can you hear me OK? My system is being a bit strange.

The Chairperson (Mr Gildernew): We can hear you clearly, but we cannot see you, Joan.

Ms Hardy: Oh, sorry. My camera is on, so I do not know what the issue is. Sorry about that.

The Chairperson (Mr Gildernew): OK. Not to worry.

Ms Hardy: As Janice said, we are jointly briefing on the LCM for the ALB transfer. My areas of interest are NHS Blood and Transplant (NHSBT) and the Human Tissue Authority (HTA). The LCM provides assurance on the ALB transfer of functions provision. It introduces a new primary power to allow the Secretary of State to transfer functions to and from specified bodies. Although those are transferred items, we operate under the Human Tissue Act 2004, which covers England, Wales and Northern Ireland. Organ donation is done on a UK-wide basis by NHSBT, and we are part of that UK-wide organisation. It is the same for the Human Tissue Authority: it provides advice and oversight regulation for the whole of the UK. In the legislation, there is provision, as Janice said, for consultation. The MOU will go into greater detail. We are working on that. We are reassured that the arrangements that we have in place will continue and that, if there were any change at all, we will be consulted early on that.

My main areas of concern, before we got that reassurance, were ensuring that services would continue and that we would continue to have full representation on the boards, plus governance of the organisations. The legislation provides that assurance, particularly on NHS Blood and Transplant,

because we pay it a considerable amount of money for that. More importantly, Northern Ireland is too small to be able to sustain an organ donation and transplantation service without being part of the UK service. I am therefore reassured by the legislation.

The Chairperson (Mr Gildernew): OK. Is that you, Joan?

Ms Hardy: It is, yes. I am happy to take questions on those two organisations.

The Chairperson (Mr Gildernew): OK. I have a couple of questions, and then I will go to members. Similar to the previous LCM, regulations will be required. Again, will those regulations be made through Westminster or the Assembly?

Ms Hardy: Chair, if those regulations relate to NHSBT and the Human Tissue Authority, they are UK-wide legislation. I will have to check that. The legislation for those organisations is done through Westminster, because it is to do with the Human Tissue Act. I will check that out and come back to the Committee.

The Chairperson (Mr Gildernew): Would there be any direct impact on current services such as organ donation as a result of those LCMs?

Ms Hardy: We have been given an assurance that the service would continue and that any current services would transfer to the new organisation. We will want to drill down into that in greater detail in the MOU. The legislation provides an assurance that Northern Ireland will be fully considered, as will the other devolved Administrations. We will drill down deeper into that in the MOU to make sure that those assurances are there and that steps are put in place if any variation is proposed.

The Chairperson (Mr Gildernew): Will that MOU be available in advance of the LCM being brought forward?

Ms Hardy: As Patricia said, it is still at an early stage, but they are working at pace. I do not have a timeline for that. I imagine that they will have similar timelines, as Patricia said. I can check that out and come back to you.

The Chairperson (Mr Gildernew): It is a bit of a concern that you are almost having to make that decision before the detail is made available. What level of consultation has there been specifically with the North on that and the impact that it may have?

Ms Hardy: We have been in touch with officials in DHSC. Discussions have been ongoing over the summer. That is when the issue came to our attention. I would say that, since May or June, discussions have been ongoing about this legislation.

The Chairperson (Mr Gildernew): Other than the DHSC officials who are bringing it forward, have you had any consultation with arm's-length bodies here on how they feel that it might impact on them?

Ms Hardy: We have not, Chair, because we have not had any indication that any of that would happen. No details have been provided. At the moment, it is just about giving the powers if they felt that it were necessary. There are no details of which powers, if any, would transfer across, or to whom.

The Chairperson (Mr Gildernew): If no changes are being planned, what need is there for us to sacrifice, if you like, some of our scrutiny? Instead of a legislative approach, we would be giving ourselves a consultative angle. If no changes are planned, what is the urgency or need for the LCM?

Ms Hardy: The LCM would put in place that, if England wants to go ahead, it would consult with us. Without that, it is all under the Human Tissue Act 2004, which is a three-country Act, so we would have to be consulted because of that.

The Chairperson (Mr Gildernew): If that went through, would we not lose out on our core legislative ability and have that replaced with a consultative one?

Ms Hardy: I am not sure about that, Chair. I would have to check. At the moment, the legislation lies in Westminster, even though it is a reserved matter, for NHSBT and the HTA. They are established under Acts at Westminster rather than in Northern Ireland.

The Chairperson (Mr Gildernew): What benefit is expected to flow here other than, perhaps, efficiency or an easier system? What benefits are expected to flow to any of those bodies as a result of those changes?

Ms Hardy: They are the only benefits that have been highlighted in the legislation. At the minute, it does not go into any great detail because we are not aware what proposals there are, if any, to move them across. DHSC is saying that that is what the legislation is for, if it feels the need to move them because of those issues.

The Chairperson (Mr Gildernew): I have to say that I have concern about the lack of clarity and purpose. It almost look likes a bit of a pre-emptive power grab, and then we would deal with the consequences and be consulted. Some of the consultation in general around LCMs has been very scant, particularly with regard to how they impact in the North. I will go to members' questions. I have Pam Cameron indicating, and then Gerry.

Mrs Cameron: Thank you, panel, for your attendance. Do the powers that are granted under the LCM to the Secretary of State in respect of the arm's-length bodies have the potential to disrupt current four-country arrangements with regard to shared research or regulation that underpin health services in Northern Ireland?

Dr Bailey: I will speak initially about research. In the same vein as the previous conversation, the HRA is an England-only body. Therefore, any conversations and discussions around research and the management and governance of research is a devolved matter. We have our own decision-making powers with regard to the operational discussions on that. At the moment, I cannot really envisage that having an impact on research, particularly in Northern Ireland. Hopefully, it would be a beneficial one if there were any.

Mrs Cameron: Thank you for that, Janice. I will ask this question, but I think that the Chair has already asked it. Have the Government given any indication about what they intend to do with the powers to regulate the functions of arm's-length bodies?

Dr Bailey: Specifically, I have not heard anything about a plan to make any adjustments to the current arrangements of the Health Research Authority. I certainly cannot speak for any of the other ALBs that are listed, but I have not heard anything about a specific plan.

The Chairperson (Mr Gildernew): As a follow-up to that, what bodies have you identified here that will be impacted by this in the future? If everything is being done at Westminster, what bodies are included within the scope from here?

Ms Hardy: I can address that, Chair. There are no bodies that are actually in Northern Ireland, but the three that are interested in Northern Ireland are the NHS Blood and Transplant and the Human Tissue Authority, both of which provide services, and, as Janice said, the Health Research Authority. There are no bodies here, but the service is provided here. The kidney transplant service is at Belfast City Hospital, and donation of organs can take place around the country. The Human Tissue Authority licenses bodies as well, so that could affect different areas of Northern Ireland.

The Chairperson (Mr Gildernew): I am conscious that we are looking at the Organ and Tissue Donation (Deemed Consent) Bill. We have also heard evidence about the importance of cross-border cooperation on some of that and the advantage that we have here, in some ways, because of that. It is important that nothing happens to impinge on or impede that cooperation. I have a sense that Westminster does not always have a full understanding of or give full consideration to our particular circumstances: the particular challenges or the particular opportunities. That is for further scrutiny.

Mr Carroll: I have a couple of questions. I share your concerns, Chair, about what, in many ways, seems like a power grab. A lot of questions remain unanswered about that.

You referred to the Organ Donation Bill. We are processing our own legislation. As I understand it, the Bill, if passed, will allow the Minister to override some of those decisions. That may not be directly in

the Bill, but it is about the wider issue of organ donation. What assurances have been sought, or what assurances can we get, that the Bill and everything connected to it, as well as that issue generally, will remain in the hands and the power of the Assembly? That is my first question.

Human tissue was referred to. My second question is about whether there has been any consideration or thought about human tissue or whether any work has been progressed. There is concern about the recovery of tissue of loved ones during the Troubles. Is there any work connected to that? There may be increased powers for the Secretary of State to protect that work or to stop information being released about that kind of activity. I do not know whether that is connected, but the issue has been flagged up to me. I know that you may not have an answer, but I would appreciate some exploratory work on that issue.

Ms Hardy: I am afraid that I do not have any information in relation to your second question about tissue from loved ones from the Troubles, but I will certainly look into that and get back to you.

I lost the connection a bit. May I double-check what your first question was?

Mr Carroll: It was similar to what the Chair said. We are progressing the Organ Donation Bill, but, as I understand it, if it is passed, the Bill will allow the Secretary of State and the Health Secretary to override certain decisions related to organ donation, blood and transplant. I am trying to ascertain whether all aspects of organ donation remain in the power of the Assembly, the Minister and the Executive, or whether there are aspects whereby the Secretary of State and the Health Secretary can override certain decisions around organ donation.

Ms Hardy: I am not sure about the legal aspects of that, but organ donation is a devolved matter, and these proposals are about the operational aspects of NHS Blood and Transplant. It is about the delivery of organ donation. It is about the operational side of collecting and allocating organs. It is about that, rather than making a policy decision on what way we collect those organs. That is a completely separate thing. I cannot see that impacting on the opt-out legislation, because it is about the operational side of it.

The Human Tissue Authority is working quite closely with my colleagues who are working on the opt-out legislation to develop codes of practice, because we will obviously need those, if and when the change comes into law. However, the clause or the LCM are not about the decisions on how we donate.

Mr Carroll: OK. Thanks.

Ms Hardy: OK. Thank you.

Ms Quinn-Duffy: Chair, if I may, I will add a bit of the background on organs, tissues and blood and the common quality frameworks that are being established. I reassure the Committee that work is ongoing in the four nations and, where there is to be divergence, the common frameworks will allow for a process for working together, consultation and dispute resolution.

We shared summaries with the Committee, and we were expecting the common frameworks to be with you last month, but, unfortunately, there have been some further discussions about the internal market and divergence. We hope that they will be with the Committee before the end of December, which will hopefully give you some assurances about how the divergence between the four nations will be managed for blood, tissue and organs and, in particular, quality.

The Chairperson (Mr Gildernew): Did you finish on "quality", Patricia? I was not sure.

Ms Quinn-Duffy: Yes. I did.

The Chairperson (Mr Gildernew): Your line cut off rather quickly, so I just wanted to check that.

OK. You raised a significant point, Patricia. Moving into the future, there is uncertainty about the divergence that you referred to. Indeed, there has been a focus in recent days on the European Court of Justice and how disputes will be resolved. With those very sensitive and complex issues, that is a concern. We will be moving into uncharted waters but, at the same time, putting powers in place that will impact on our ability to navigate those uncharted and potentially troubled waters. That is of

concern. Again, I link it back to the very significant additional or particular challenges and opportunities that we have in the North and on a small island.

Thank you for your presentations and answers and for your commitment to providing the Committee with some additional pieces of information that were sought. I wish you all the very best. Thank you for appearing at our Committee today. Go raibh maith agat.

Ms Hardy: Thank you, Chair.

The Chairperson (Mr Gildernew): OK. I advise members that, once an LCM is laid in the Assembly — it has not been laid yet —the Committee has 15 working days to report back to the Assembly on its consideration of it. Do members have any further issues that they wish to seek clarification on?

Mr Carroll: We need more information, Chair. As the questions and answers highlighted, there is clearly a gap in what is being brought forward and there are some concerns. We need to make sure that officials present the LCMs to the Committee before we can make an informed choice.

The Chairperson (Mr Gildernew): Yes. Given the concerns, do members agree that we will take additional information from the Department on the LCMs?

Members indicated assent.