FROM THE MINISTER OF HEALTH

Department of Health
An Roinn Sláinte
Männystrie O Poustie
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Your Ref:
Our Ref: CORR/3530/2021
Date: 12th November 2021

Dear Colm,

I refer to your letter of 19 October requesting further information on the Legislative Consent Motions related to the UK Health and Care Bill:

- A copy of the revised MoU in relation to North/South co-operation on provision of healthcare;
- Further information on how the Department plans to communicate changes in relation to the EHIC and GHIC changes and in relation to replacement certificates;
- A written briefing providing the Department's views on the UK Health and Care Bill;
- Detail of what local consultation and engagement has been undertaken by the Department on these four LCMs;
- If there are implications in relation to the recovery of human tissue related to the troubles; and
- Further information on the Code of Practice being worked on by the Human Tissue Authority.

My Department's response to your request is provided at Annex A.

Yours sincerely

Robin Swann MLA
Minister of Health

ANNEX A

1. **A copy of the revised MoU in relation to North/South co-operation on provision of healthcare;**

   North/South Healthcare cooperation is facilitated under the Belfast Agreement 1989 and is specifically carved out in the MOU on Devolution. This MOU is found here MoU between the UK and the Devolved Administrations.pdf (publishing.service.gov.uk) .

   Part one of the MOU specifically states at paragraph 19:
   '19. Arrangements for the handling of devolved administrations' interests outside the United Kingdom are set out in the international relations and EU concordats. The devolved administrations are able to develop bilateral or multilateral arrangements with other members of the British-Irish Council, including the Republic of Ireland, and to participate in the British-Irish Council itself, as set out in the Belfast Agreement. The Northern Ireland Executive Committee is also able to develop relations with the Irish Government through the North/South Ministerial Council provided for in that Agreement.'

   In Annex D: CONCORDAT ON INTERNATIONAL RELATIONS D4: Concordat on International Relations: Common Annex to the MOU states:
   'D4.6 The devolved administrations may hold working-level discussions on devolved matters with foreign national or sub-national governments or appropriate counterparts in international organisations. The devolved administrations may, in co-operation with the FCO, make arrangements or agreements with foreign national or sub-national governments or appropriate counterparts in international organisations, to facilitate cooperation between them on devolved matters, provided that such arrangements or agreements do not purport to bind the UK in international law, affect the conduct of international relations or prejudice UK interests. (It is an inherent part of the Belfast Agreement (Command Paper 3883) that, on matters within their competence, the devolved administrations may hold discussions and make arrangements with the Irish Government in the context of the British-Irish Council5). The devolved administrations will consult the FCO in advance about any contact, correspondence, or proposal that is novel or contentious, might create a contingent international liability or may have implications for international relations.'

   There is no specific overarching MOU for North South Healthcare cooperation but there are MOUs that are in place for specific healthcare arrangements.

   There is also an MOU that was negotiated between the UK and Ireland on reciprocal healthcare which was signed at an official level in December 2020 and is still subject to clarification of overlaps with the Trade and Cooperation Agreement Protocol on Social Security and a subsequent exchange of letters between the two countries.

   In terms of the amendments being proposed to the Healthcare (EEA and Switzerland Arrangements) Act 2020 in the Health and Care Bill, a revised MOU is currently being negotiated which will need to be agreed by the Minister and will be shared with the Committee before implementation.

2. Further information on how the Department plans to communicate changes in relation to the EHIC and GHIC changes and in relation to replacement certificates;

The issue of EHIC, GHIC and PRCs has been raised with the reciprocal healthcare team in the Department of Health and Social Care. They have been asked to consider how we can further promote the use of these cards and knowledge through other channels including travel companies. They have agreed to consider and come back to us with some further thoughts.

The Department will revise the information on NIDirect and the HSCB website about these cards and will consider how best to contact the travelling public. Once a plan is in place the Department will advise the Committee of that plan.

3. DoH view on UK Health and Care Bill

The Health Research Authority is an England-only organisation, but has been acting on behalf of NI since 2013 under a previous Legislative Consent Motion and a Heads of Terms Agreement (in line with those in place with the other Devolved Administrations). To date, there has not been any local consultation on a proposal to move powers, as there has not been any definite intent raised to do so. Senior R&D committees in Northern Ireland would be consulted in detail over any such proposal, including the HSC R&D Directors Forum (Chaired by the Chief Scientific Advisor and Director of HSC R&D, Professor Ian Young) and the HSC R&D Governance Operational Sub-Group (Chaired by Assistant Director of HSC R&D Division, Public Health Agency, Dr Janice Bailie). Membership of these committees includes representatives the five HSC Trusts, and of both HEIs in Northern Ireland, all of which organisations would be potentially impacted by such changes.

In practical terms, there is co-owned IT infrastructure and an agreed framework of work processes between the four nations, with resources in place to deliver these in NI for ethical and governance review. For example ethical opinion will be provided by NI Research Ethics Committees for research studies led by any of the four nations, and this is reciprocated by the other nations for Northern Ireland studies. HRA provides administrative services on behalf of all four nations for various tasks relating to research management and governance, with reciprocal delivery of tasks by officers from NI and the other DAs (e.g. Chairing and providing secretariat for various committees and hosting of events). Capacity would not be available in NI alone to deliver the quantum of work that is possible on a UK-wide collaborative basis.

While the HRA does not make decisions on behalf of Northern Ireland, the impact of any such move may not be direct, but there are many benefits to UK-wide working due to the relatively small population of Northern Ireland. The collaborative nature of research means that the value is in the relationship developed with the Health Research Authority (and the other DAs) over the past ten years, with a collective goal of delivering the highest standard of health and social care research for all citizens, and we would wish to build a similar relationship with any new authority undertaking these functions.

Issues relating to the points raised are being considered in the draft MoU, and while the option of consent has not been agreed, we are reassured by the confirmation that there would be early engagement, continuity of Board membership and maintenance of financial and operational arrangements in relation to any transfer of functions for the Health Research Authority.

4. Detail of what local consultation and engagement has been undertaken by the Department on these four LCMs.

The Reform of the Regulation of Healthcare Professionals is being developed on a 4-country basis and hence activity is led by DHSC but with input on the Northern Ireland perspective provided by DoH.
Pre-consultation on proposals was undertaken in 2016. This included a consultation event with NI stakeholders in Belfast on 2nd August 2016.
Consultation on these specific reform proposals took place over the period 24 March 2021 to 16 June 2021. DoH provided a list of NI stakeholders whose input was specifically invited by DHSC.

The Government White Paper was published in February 2021 which contained a very small reference to the International Healthcare Agreements policy and strategy. This was the main route for consultation. There was engagement at an official level and notification to the Minister but no specific engagement with operational bodies or other groups.

The ALB Transfer of Functions provision introduces a new primary power to allow the Secretary of State (SofS) to transfer functions to and from specified England Arm's Length Bodies, and to delegate the SofS's functions to them – this includes NHS Blood and Transplant (NHSBT) and the Human Tissue Authority (HTA). As we are unaware of any specific proposals at this time and the draft legislation as currently drafted is about transferring powers to another body, not stopping or altering the service currently provided, we have not consulted directly with local organisations at this point. Should any proposals that may affect the service provided to NI be brought forward, we would discuss them with the local organisations that may be affected in order to assure that there is no detriment to NI.

Each of the four LCMs is reflective of a proposed enabling primary power, with the subsequent detail of any resulting changes being contained in secondary legislation. Please see below the various measures with respect to each of the LCMs that have are being put in place to ensure future consideration at a NI level with respect to any future changes.

i) Medicines Information Systems

Information of the policy proposals with regards the Medicines Information System has been shared with Information Governance leads in each of the HSC Trusts and the Business Services Organisation, who will be data controllers for the information that exists in NI that will be relevant for the Medicines Information Systems once developed. These information governance leads will also be fully consulted and

engaged on regulations to be taken forward for the Medicines Information System, as well as on draft Data Protection Impact Assessments, Privacy Notices, and any data sharing agreements which will set out the governance arrangements for the Medicines Information Systems.

Furthermore 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 new section 7A in the Medicines and Medical Devices Act 2021, for the Medicines Information System, the Department will be the appropriate authority in making regulations either alone or jointly with the Secretary of State and therefore the Department's consent is necessary. These regulations will be subject the draft affirmative procedure and any joint regulations must be laid before and approved by a resolution of— (i) each House of Parliament, and (ii) the Northern Ireland Assembly.

The situation is different for Medical Devices Information System, which the Committee supported legislative consent for last autumn, where the Secretary of State has sole authority, but there is a statutory consultation clause contained in the Medicines and Medical Devices Act 2021, stating that no regulations can be made without proper consultation with the devolved administrations.

5. If there are any implications in relation to the recovery of human tissue related to the troubles

The HTA regulates activities concerning the removal, storage, use and disposal of human tissue and bone marrow and peripheral blood stem cell donation. However, in order to assess if the HTA has any role relating to human tissue related to the Troubles, it is first necessary to confirm certain information relating to such human tissue. As this is not within the remit of the Department of Health (DoH), a request for information has been sent to the Department of Justice. Once information has been received, officials will further engage with the HTA and will provide the Committee with a response to this query.

6. Further information on the Code of Practice being worked on by the Human Tissue Authority

The HTA produces various clinical codes of practice in line with the statutory requirements set out in the Human Tissue Act 2004; this includes relating to organ donation and transplantation. While the HTA does not promote organ and tissue donation, it does play a central role in ensuring public confidence in the safe and ethical use of human organs and tissue with proper consent.

The HTA's *Code of Practice F (Part Two) Deceased organ and tissue donation* (the Code) aims to support organ and tissue donation and transplantation, where appropriate consent is in place, and provides anyone undertaking activities relevant

to this sector with a reference source, which gives practical advice on the steps necessary to comply with the relevant legislation and HTA.

As DoH is currently progressing legislation through the Assembly to introduce a system of deemed consent for organ donation, following discussions with the HTA, it has been agreed that HTA will amend the existing version of the Code to include NI in deemed consent provisions, rather than create a standalone code.

As it is hoped that the deemed consent legislation will be passed in the NI Assembly in February 2022, work on the revision of the Code could commence after that and it is anticipated that a first draft of the revisions by May 2022 with a final version ready for September 2022 to allow NHSBT colleagues six months to train staff in the new requirements.

Drafting the changes to the Code is only one element of this process. Under sections 26(1) and 25(5)(a) of the Human Tissue Act, the HTA is required to "consult such persons as it considers appropriate." HTA has confirmed that it will be consulting with the experts on DoH's Organ Donation Clinical Advisory Group, but it may also be necessary to engage in a targeted consultation with other stakeholders in NI as appropriate.

Additional information
Question from Pam Cameron – Deputy Chair of the Committee

The Deputy Chairperson, Pam Cameron, also asked a question that officials said they would come back on, with regards the Medicines Information System. This question is 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 out-workings of the separate regulatory regimes under the protocol.

Officials have discussed this question with Information Governance and EU Exit colleagues and can confirm that the NI Protocol does not impact on the sharing of medical data across the UK.

The purpose of a medicines information system is to look at data on medicines that have already been prescribed and supplied, in order to generate evidence regarding their use, benefits and risks. These insights can then be used to inform regulatory decision making, support local clinical practice and provide patients and prescribers with the evidence they need to make better informed decisions.

Committee for Health

Wendy Patterson
DALO
Department of Health

By email: Wendy.patterson@health-ni.gov.uk

Our Ref: C284/21

19 October 2021

Dear Wendy,

RE: Legislative Consent Motions

At the meeting on 14 October, the Committee was briefed by officials on 4 Legislative Consent Motions related to the UK Health and Care Bill. Officials agreed to provide further information to the Committee on a number of issues:

- A copy of the revised MoU in relation to North/South co-operation on provision of healthcare;
- Further information on how the Department plans to communicate changes in relation to the EHIC and GHIC changes and in relation to replacement certificates;
- A written briefing providing the Department's views on the UK Health and Care Bill;
- Detail of what local consultation and engagement has been undertaken by the Department on these four LCMs;
- If there are any implications in relation to the recovery of human tissue related to the troubles; and
- Further information on the Code of Practice being worked on by the Human Tissue Authority.

I understand that three of the LCMs were laid in the Assembly on Friday 15 October, the Committee has 15 working days to Report on these LCMs and therefore I would appreciate a response as soon as possible.

Yours sincerely,

K McBride

Keith McBride
Clerk
Committee for Health

Cc: Suzanne.Howe@health-ni.gov.uk
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