From: Julie Thompson

Date: 29 June 2016

To: Michelle O'Neill MLA

POTENTIAL IMPLICATIONS OF LEAVE VOTE FOR HEALTH AND SOCIAL CARE – FURTHER DETAIL ADDED ON FINANCIAL IMPLICATIONS

Issue:	A strategic summary of the potential implications of the leave vote for health and social care, including financial implications.
Timescale:	Urgent
Presentational Issues:	Media interest in the potential implications of leaving the EU for health and social care.
FOI Implications:	Disclosable
Executive Referral:	Not required.
Equality Implications:	No implications.
Position in the South:	Cross border implications highlighted in submission.
Special Adviser Comments:	
Recommendation:	That you note the potential implications of the leave vote for health and social care.

Background

1. The UK has voted to leave the European Union. Although the full implications of the leave vote are not yet known, as the terms of the exit will have to be negotiated, this submission sets out our initial thoughts on some of the potential strategic issues of the leave vote for health and social care in the North of Ireland. As you will appreciate, this position will continue to evolve in the coming weeks and months.

2. A table at Annex 1 provides a high level summary of the key potential financial implications identified to date.

Workforce Issues

Mobility

3. The impact of the loss of operation of the Single Market could complicate the ready movement of health professionals from other healthcare profession regulatory regimes. EU Directives are in place for the recognition of professional qualifications which allows freedom of movement for health and social care professionals across the EU.

Recruitment

4. There is a query over the future of professionals from the EU being recruited to and working in the H&SC system. For example, we are currently recruiting in Italy and Romania for nurses due to current shortages. Those nurses offered work may now think twice about accepting. We are also currently relying on Doctors from the EU and any future restrictions would impact negatively on what is already a shortage situation.

5. While there may be disparity between the various disciplines recruited, generally the costs (to HSC) are greater for recruitment outside EU. By way of illustration, the cost of recruiting nurses (the highest by volume) from across

the EU is c £3200 per capita, as opposed to c£9800 per capita outside EU. That said, EU nurses are in smaller supply and much more likely to move on (to elsewhere in the UK) than their international counterparts.

6. Access of EU students, but in particular from the South, to the pre-registration training commissioned by HSC, for example Nursing and AHP courses may be impacted. We will have to change the Departmental Determinations setting our access to bursary / tuition support. This could make it more difficult to recruit high quality students.

Professional Regulation

7. The wider HSC workforce could be impacted by any restrictions on North South mobility of health and social care professionals.

8. A new International Alert System has been established whereby regulatory bodies as 'competent authorities' log in the outcomes of Fitness to Practise procedures particularly if an individual has been removed from a register and can no longer practise in that profession. There may be implications for this going forward.

Funding

Exchange Rate

9. Fluctuations in the exchange rate will have implications for the Department. For example the Department is awaiting an €8 million payment from the South as their final contribution towards the construction of the Altnagelvin radiotherapy project. Exchange rates are always highly volatile. Comparing yesterday's rate to the prevailing rate at the South's contribution was agreed suggest a reduction in sterling value of £400,000 less which will have to be found from our 2016-17 capital budget.

10. The transfer of children's services at Glenmona Resource Centre to Belfast HSC Trust is subject to addressing a pension deficit which could increase/decrease depending on market fluctuations.

Procurement Issues

11. Public procurement in the north is governed by EU directives (as transposed into UK law) and treaties. Our preliminary view is that legal constraints on procurement will remain. On the one hand there would probably be a requirement for continued compliance with the EU procurement law as a quid pro quo of access to the common market. At the other end of the spectrum if there is no access to the common market then under UK law we would be left with a legal obligation to advertise within the UK, combined with paying import/trade tariffs to HMRC, should we purchase outside the UK. What is actually negotiated may be anywhere on a spectrum between these two extremes. It is too early to say what the effects would be but could include:
    a. If we pay trade tariffs - low prices might be more difficult to achieve in the HSC if trade tariffs apply to purchases from the EU, particularly of proprietary medicine or technology - western industrial economies, including the EU, are more likely to own and manufacture healthcare goods where intellectual property rights pertain – or in the context of care services in border areas. Imposition of trade tariffs could make existing EU contracts that have already been competed more expensive, and given our geography, trade tariffs may be more of an issue for the North than Wales, Scotland or England.
    b. If we have to follow the EU procurement rules – if we have less influence than before in setting the EU public procurement rules that we then have to follow, that may or may not suit how public services are organised locally or how we might want to organise them, but nonetheless we would be signed up.
    c. Uncertainty may lead to relatively conservative procurement decisions.

12. Public procurement in the north is governed by EU directives (as transposed into UK law) and treaties. The clear premise is the competition is the best

guarantee of value for money in procurement. Legally, that precept entails competition, not only within the UK but, because of EU membership, across the 27 member states. There are specific provisions within the EU Regulations governing the procurement of health and social care services – a programme of work is currently underway to ensure full compliance with these regulations in a health context and would need to be reviewed in light of any change from such Regulations.

13. 3PD Funded projects – Minister Poots formally directed that two pilot Health and Care Centre Projects in Lisburn and Newry were to be taken forward using 3PD financing (a form of revenue financed investment) on the basis that they would be budgeted as revenue under the accounting and budgeting guidelines. The budgeting treatment is ultimately determined by the Office of National Statistics (ONS) who are responsible for final classification of the projects and determine whether the projects will be on / off balance sheet for budgeting purposes in line with National Accounts. However ONS base their classification on guidance issued by Eurostat who set the guidance for all EU member states. Therefore there may be some uncertainty as to whether future classifications will be based on Eurostat guidance and uncertainty as to how these and similar projects will be classified in budgeting terms.

14. Procurement for elective care services from the Independent Sector are currently carried out under the Official Journal of the European Union (OJEU) process which in the past has resulted in successful tender applications from providers in the South. Issues arising following Brexit on public procurement will affect the entire public sector, not just healthcare, and the obvious question would be whether the UK would still have access to OJEU, cumbersome as it is, or will the UK develop an alternative means to access potential providers outside the UK.

Potential Effect on European Funding Calls

15. There are a range of European funding opportunities, structural funds and competitive programmes, of which the Department and the HSC can avail.

These are used to support both service delivery and Research and Development.

16. The main structural funds programme we are working on currently is the Interreg VA Health and Social Care Call. The programme covers the north of Ireland, south of Ireland, and Scotland and has a total value of this is €53m. In addition to this, up to €9m match funding can be provided by the 3 Health Departments. The breakdown by jurisdiction is 60% north of Ireland, 30% south of Ireland, and 10% Scotland. The north of Ireland would therefore benefit from €31.8m in the period to 2020.

17. The purpose of the call is: "To improve the health and well-being of people living in the region by enabling them to access quality health and social care services in the most appropriate setting to their needs, through collaboration on a cross border basis." Project applications were requested under the following headings:

- Population Health;
- Disability Services;
- Mental Health;
- Children's Services;
- Acute Services;
- Primary Carte and Older People Services;
- Health Care Intervention Trials.

18. 14 applications were successful at Stage 1 and applicants were invited to submit detailed business plans, including costings etc; these are currently being assessed by the Department and Special EU Programmes Body (SEUPB). Final decisions on which projects will be approved will be taken by the Steering Group in late summer 2016. Project applications have been made by a number of organisations – either community/voluntary or bodies like CAWT (Co-operation and Working Together – a cross-border body which brings together health and care professionals from the north and south to

facilitate collaborative working). Leaving the EU may therefore cause uncertainty in the sector about the availability of this funding.

19. The HSC has been successful in 10 project applications, either as a lead partner or partner, under Horizon 2020 and the 3rd Health Call (both of which are competitive EU funding programmes). The total value of these projects, which are of varying durations between 2 years and 5 years, is €70m approximately, while the direct value to the HSC is €5m approximately.

20. The Department received €30 million as part of the Interreg IVA programme "Putting Patients, Clients and Families First". The programme ran from 2009 until the second quarter of 2015 and supported a range of cross-border health based projects including GUM, ENT services, as well as projects aimed at tackling social exclusion and fostering positive mental health for people in the border area. In the wider sense, the premise underpinning the Interreg programmes is that the presence of a border has been shown to negatively impact on the health and well being of people living in border areas. It would follow that the re-establishment of any "hard" border brings with it the potential to exacerbate these conditions.

21. Recently we have partnered in a number of other structural fund calls under the broader Interreg programme. Decisions on these will be taken later this year but brief details of our applications are set out below.

Interreg North West Europe

22. Detection of pre-frail older population and provide appropriate interventions to prevent decline and improve quality of life through the use of technologies to support independent living and improve health and well-being. Value: €8.6m; North of Ireland share: up to: €2m, including match funding.

Interreg Europe

23. Increase the impact of best practices and innovative strategies supporting 'Active and Healthy Ageing' on regional innovation and healthcare policies.

The project aims to analyze, revise and scale up the best practices implemented by Reference Site partners, improving regional policy instruments through a comprehensive and common approach and methodology. Value: €1.5m; North of Ireland share: up to: €240k, including match funding.

Interreg Atlantic Area

24. Through an alliance of Reference Sites in the Atlantic Area to improve health and quality of life, sustainability and efficiency of care systems, and growth and expansion of industry in Atlantic area, through establishing transnational and international innovation networks, acceleration schemes for health and care innovation, and knowledge transfer, which will empower health and care providers and the older population. Value: €2.45m; North of Ireland share: up to: €197k, including match funding.

Collaborations and Partnerships

25. More broadly, in keeping with the Executive's European priorities and to increase the drawdown of funding available to the north of Ireland (and along with the need to identify alternative sources of funding to support the wider reform and transformation of health and social care) we have become more focussed in identifying the range of funding opportunities and building collaborations and partnerships with Regions across Europe.

26. We are currently a leading Reference Site for the European Innovation Partnership on Active and Healthy Ageing (which is facilitated and led by the EU). This has allowed us to promote and share our innovative practices and solutions in delivering health and care services. At the same time it allows us to learn from other regions and to identify and form collaborations with other regions to address common challenges, including forming partnerships for EU funding calls. The Department also established, and leads, the Reference Site Collaborative Network (RSCN). This brings together all 75 Reference Sites in

Europe and provides a forum for developing collaborations, sharing innovation, Twinning, and informing European Commission policy in this area.

27. Leaving the EU could have implications for the relationships we have developed, access to knowledge transfer, and the adoption and transfer of innovative solutions. Through this transfer of innovative solutions there is the potential to contribute to economic growth.

28. There could also be implications for future participation in funding calls. Learning about different service delivery models, undertaking R&D and pursuing innovation are important to improving health and care outcomes. Whilst funding calls would allow for partner countries outside the EU to be involved on projects, participation for us could be at the behest of other regions in Europe with no guarantee of involvement.

Regulation

29. The area of regulation is multi-faceted and consideration will need to be given to a number of scenarios, for example, continuance of existing regulations, need to replace existing regulations and decisions on pending regulations.

State Aid

30. The EU has set up a system to control State Aid in order to prevent policies that advance local or national interests at the expense of others. Until the United Kingdom leaves the European Union obligations are likely to continue in place.

Quality and Safety

31. In the area of EU statutory regulation of quality and safety what will be the position going forward in policy making in terms of setting standards when the UK leaves the EU. For example next month we are due to start work on the new Basic Safety Standard Directive (BSSD) Euratom 2013/59 for radiation protection which supersedes a number of radiation protection directives. The

UK, including the NI Assembly, needs to transpose it into UK legislation by February 2018. Such EU regulations provide protection for patients and healthcare staff. What will the UK, including NI, replace this with?

Access to cross-border healthcare

32. EU regulations provide for people to seek treatment in the European Economic Area (EEA) and have the costs of that treatment met by the state with which they are insured (the competent state). There are a number of different routes (and funding flows) for cross-border treatment, depending on the particular circumstances, and these are summarised below.

33. For patients from other EEA countries receiving treatment here under one of these routes, there is scope for the state of treatment to recover costs from the competent state, or for HSC Trusts to charge the patient directly for treatment.

34. Similarly, in cases where a patient from the north travels for treatment in another Member State, the costs of that treatment may be borne directly by the Health and Social Care service here or met by the UK government as part of state-to-state funding arrangements, depending on which route is used.

European Health Insurance Card (EHIC)

35. The European Health Insurance Card (EHIC) is a card provided by national healthcare authorities in EEA countries to those people who are publicly insured there. This card gives individuals access to medically necessary, state-provided healthcare during a temporary stay in any EEA country, under the same conditions and at the same cost (free in some countries) as people insured in that country.

36. Funding matters relating to cross-border healthcare schemes including the EHIC are managed by the UK Department of Health on behalf of the devolved administrations. The practical administration of the EHIC scheme is managed

by the Department of Work and Pensions on behalf of the devolved administrations.

37. An EHIC incentive scheme was introduced by the UK government in October 2014, in an effort to improve the recovery of costs for the treatment of EEA patients. Under this scheme, hospitals who report the treatment of EHIC patients to the Department of Work and Pensions are reimbursed for the costs of that treatment and receive an additional payment of 25%. In 2015/16, HSC Trusts reported treating 167 EHIC patients and recovered costs of over £180,000. To date in 2016/17, HSC Trusts have recovered costs of approximately £26,500 for the treatment of 20 EHIC patients.

EU Directive 2011/24

38. EU Directive 2011/24 on the application of patients' rights in cross-border healthcare allows patients to seek treatment in another EEA country and have the costs of that treatment reimbursed by their home State. Only treatment which is the same as or equivalent to treatment that would be made available to the patient in their state of residence is subject to the Directive. The amount that will be reimbursed will be the actual cost of treatment or the equivalent cost had treatment been provided by the home state, whichever is less.

39. Unlike the S2 route, under the provisions of the Directive patients can seek treatment in either the state or private sectors. Prior authorisation is only required in certain circumstances, for example if the treatment requires an overnight stay in hospital or involves highly specialised equipment or infrastructure.

40. In 2015/16, the HSC Board received 81 applications for reimbursement of treatment under the Directive. 57 applications were approved, 12 are pending, nine were rejected and three were withdrawn. 46% of applications were for treatment in the South of Ireland. The total estimated expenditure on

Directive applications in 2015/16 (including those that are pending) was approximately £256k.

41. Between 1 April and 8 June 2016, the Board has received 28 applications for reimbursement of treatment under the Directive. 12 have been approved, 12 are pending, two have been rejected and two withdrawn. 61% of applications are for treatment in the South of Ireland. The total estimated expenditure on Directive applications to date in 2016/17 is approximately £107k.

Cross-border healthcare for frontier workers, posted workers, pensioners and their family members (S1 route)

42. Individuals insured by one EEA country (the competent state) who move to live in another EEA country (the state of residence) may be entitled to help with healthcare costs in their state of residence, by applying for an S1 certificate from the competent state. Once registered with the appropriate institution in the state of residence, a valid S1 certificate entitles the holder to access state-funded health services on the same basis as someone who is ordinarily resident. Cross-border workers, posted workers (that is, individuals who are employed in one Member State but posted by their employer to another Member State for a limited period of time), and pensioners or people in receipt of long-term incapacity benefits who move to another Member State may all be entitled to treatment under this route. The costs of S1 treatment are met by the UK government and are paid state-to-state, exchequer-to-exchequer.

Travelling for planned treatment (S2 route)

43. Individuals may be able to access state-provided treatment in another EEA country or Switzerland using the S2 route, where they have been medically assessed as requiring the treatment and where that treatment is not available locally within a clinically appropriate timeframe. Applications for treatment using the S2 route must be authorised in advance by the Health and Social

Care Board. The S2 route can also be used for women who wish to give birth in another EEA country or Switzerland.

44. In 2015, the Health and Social Care Board authorised nine applications from patients here seeking treatment under the S2 route—five of these applications were for treatment in the South of Ireland. The costs of S2 treatment are met by the UK government and are paid state-to-state, exchequer-to-exchequer.

45. We may have an issue of older people returning to the UK from EU to access social care once their entitlements under EU law expire.

Medicines Safety

46. Falsified Medicines Directive - The Falsified Medicines Directive introduced by the EU in October 2015 introduces measures which aim to prevent the entry of falsified medicines into the legal pharmaceutical supply chain. That includes the placing of safety features consisting of a unique identifier and an anti-tampering device on the packaging of certain medicinal products for human use, for the purposes of enabling their identification and authentication. The MHRA is leading on the implementation of the Directive with the aim of having new Regulations in place by early 2018. Medicines safety implications will have to be considered if it is decided not to proceed with implementing the FMD.

47. EU Simpathy Project - The Department (through the Northern HSC Trust) is a partner in this EU project to identify best practice across the EU to stimulate, promote and support innovation in the management of multiple medicines (polypharmacy) and the ability of older people to take medicines in accordance with their prescription (adherence). Although there are no short term implications for that specific project, EU source of funding for change and innovation may become more difficult to access in the future.

48. Licensing/importation/exportation of medicines - The MHRA acts as the licensing authority for the whole of the UK in relation to medicinal products for

human use. The MHRA will lead on any changes required to the arrangements for EU medicines which would be considered for application locally. Alterations in exchange rates can also influence the supply chain by driving the dynamics of exportation or importation of medicines.

49. Mutual recognition of prescriptions - Currently, legislation allows prescriptions written by a doctor, dentist, prescribing nurse or a prescribing pharmacist from another EU country to be dispensed in the UK. This arrangement may need to be considered in the light of future agreements with the EU although again MHRA would lead on behalf of the UK.

50. The Medicines Optimisation Innovation Centre (MOIC) was established in 2015 to help deliver the Department's strategic vision for medicines optimisation by helping to develop and test service and technology solutions to improve the use of medicines for our population. In addition the MOIC aims to promote North of Ireland across the EU as a centre of expertise for Medicines Optimisation, commercialise and market solutions that work here to other countries and develop collaborative research and innovation partnerships.

51. Currently MOIC is the recipient of £75k EU funding from the 3rd Health programme SIMPATHY project and has two applications pending, one for £6m EU Horizon 2020 R&D and the other for £7m EU INTERREG NWE Programme funding. Further details on EU funding associated with MOIC are set out below:

- EU Horizon 2020 R&D: 225 billion EURO up to 2020 - MOIC has already benefited from this fund and is part of the SIMPATHY project with £75k funding already allocated. MOIC submitted a bid in April 2016 to lead a project on scaling up the STEPSelect technology seeking a budget of 6 million EURO;

- EU INTERREG NWE Programme: MOIC is a leading partner in a bid submitted end of May 2016 with a budget of 7.8 million EURO focussing on introduction of biosimilars in hospitals;

- EU Conflict Resolution Fund: about 700 million EURO over the next five years - new to the programme are health and social services and MOIC had plans to submit bids.

52. EU-wide surveillance of infectious diseases including antimicrobial resistance The European Centre for Disease Control is an EU body. The implications for the surveillance of diseases or for professional training are unknown.

Public Health

53. EU Tobacco Products Directive **-** While the main provisions of the revised EU Tobacco Products Directive were transposed into national law on 20 May 2016, there are some elements which have yet to be transposed, namely the application of a "track and trace" system. This is intended to combat the illicit tobacco trade and was due to be introduced by May 2019 for cigarettes and roll-your-own tobacco and by May 2024 for other tobacco products e.g. cigars. In addition, while a ban on flavourings in tobacco products is currently in place, an extension until May 2020 was allowed for menthol products. The TPD also includes a number of requirements in relation to the regulation of e-cigarettes, which has proved to be controversial with motions tabled in Westminster. There is a risk that these regulations could be revoked given that the Directive would no longer have any authority in the UK.

54. Minimum Unit Pricing for Alcohol **-** It has been legal challenges in respect of incompatibility with EU free trade laws that have created uncertainty around the ability of jurisdictions to implement minimum unit pricing for alcohol – and led to the current court case being held in Scotland. Leaving the EU may provide greater ability for jurisdictions to proceed in areas such as this – should they wish to. Obviously EU trade laws remain in place at the minute – and future trade deals may impact on our ability to act in the longer term.

Children's Issues

55. EU Brussels Regulations allows for the placement of a child outside the North of Ireland in another Member State. This allows HSCTs (with the relevant court order) to place children in foster care or residential care in the South of Ireland and *vice versa*. The impact of removal of EU legislation will need to be assessed.

56. Child protection agreements have been negotiated on a bilateral basis with the South of Ireland. On that basis and, on the assumption that the South continues to be willing to enter into agreements of this nature with a non-European partner, we consider that the impact on this specific issue is minimal.

57. Clarification will be required with the Home Office and DfE (England) on future Inter Country Adoption applications from non-UK citizens following the outcome of the referendum.

North South Collaboration

58. Consideration will need to be given to legal enforcement of agreements in the unlikely event of a dispute. For example, disputes in relation to our MOU/SLA on Altnagelvin Radiotherapy Service.

59. There may be possible implications for reciprocal operational delivery arrangements with the South in relation to Fire and Rescue Services.

60. With regard to the development of acute services Networks across the island of Ireland the leave vote should hopefully not change this unless new employment rules are introduced making it more difficult for staff to provide services cross-jurisdiction. For example, Belfast Trust paediatric cardiologists carry out procedures in Our Lady’s Children’s Hospital, Crumlin and surgeons from that hospital have operated on children in the Royal Belfast Hospital for Sick Children. The only requirement was to complete registration with the respective professional bodies.

61. Currently our North/South working arrangements on public health are managed through the North/South Ministerial Council and the British Irish Council), though implications for the Belfast Agreement are unknown. We do not think there would be any direct implications on our current joint working – but future options to bid for EU funds to support specific work or programmes may be removed.

62. Regarding NSMC and FSPB (Safefood), implications for the Belfast Agreement are unknown. FSPB's budget is set in Euros and this Department's contribution (£1.5m) may have to increase.

63. Martina Anderson has organised a delegation visit from the North West Health Innovation Corridor to Brussels on 27 June. The purpose of the visit is to introduce representatives from the NWHIC to Europe. The NWHIC was launched in May 2013 and has a cross-border dimension, spanning the arc of the northwest including Londonderry, Coleraine, Letterkenny, and extending into Sligo and Galway. An EU exit could have implications for the NWHIC and its relationships with Europe, particularly the role of partner organisations in the North.

JULIE THOMPSON

cc:

Richard Pengelly

TMG

Linda Devlin

Annex 1

Area	Para no.	Issue	Amount
Workforce	5	Disparity between recruitment costs inside and outside EU. For example cost of recruiting nurses	£3200 per capita across EU £9800 per capita outside EU A difference of £6600 per capita.
Exchange Rate	9, 62	Fluctuations in the exchange rate will have implications for the Department.	Potential impact of change in exchange rate of c£400,000 to be met from capital budget. Potential increase in the Department's contribution to Food Safety Promotion Board: currently £1.5m
EU Funding Calls	16	Interreg VA Health and Social Care Call to 2020	Total Value: €53m Benefit to the North: €31.8m
	19	Horizon 2020 and 3rd Health Call	Total Value: approx €70 m Direct value to HSC: approx €5m
	22	Pending application – Interreg North West Europe.	Value: €8.6m North of Ireland share: up to €2m including match funding

	23	Pending application – Interreg Europe	Value: €1.5m North of Ireland share: up to €240k including match funding
	24	Pending application – Interreg Atlantic Area	Value: €2.45m North of Ireland Share: up to €197k including match funding.
Access to cross border healthcare	37	European Health Insurance Card	HSC recovered costs in 2015/16: over £180,000
Medicines Optimisation Centre	51	Existing and pending EU funding	SIMPATHY Project: £75k Received Pending application: £6m from EU Horizon 2020 R&D Pending application: £7m Interreg NWE EU Conflict Resolution fund: total value €700m MOIC had plans to submit bids