NORTH-SOUTH COOPERATION ON HEALTHCARE: DRAFT UK NON-PAPER TO SUPPORT SCOPING WORK

Introduction:

1. The UK Government and EU Commission have agreed to undertake a joint mapping exercise on areas of North-South cooperation, with particular reference to those arising from, or connected to, Strand 2 of the Belfast 'Good Friday' Agreement. The attached scoping document sets out factual detail on each area of healthcare cooperation between Northern Ireland and Ireland and is structured as follows:

   - Cross-cutting areas of cooperation that have implications for healthcare:
     A. Common Travel Area and associated rights
     B. Free movement and healthcare for other EEA nationals
     C. Mutual Recognition of Professional Qualifications
     D. EU funding programmes
     E. Data sharing and procurement

   - Areas of healthcare cooperation identified by the North-South Ministerial Council (NSMC) as priorities:
     F. North West Cancer Centre
     G. All-Island Congenital Heart Disease Network
     H. Cooperation and Working Together (CAWT)
     I. Child protection
     J. Alcohol misuse
     K. Major Emergencies and Emergency Services Cooperation

   - Other areas of healthcare cooperation:
     L. Organs for transplantation
     M. Blood
     N. The Institute of Public Health in Ireland
     O. Controlled Drugs Licensing Group
     P. All Ireland Institute of Hospice and Palliative Care (AllHPC)
     Q. Movement of medicines, devices and other healthcare goods
     R. Human Milk Bank
     S. Cross Border GP Out of Hours Service
     T. Mutual recognition of prescriptions

2. This document has been provided on the basis that it is without prejudice to the positions that the UK or EU might wish to take with respect to the UK's withdrawal from the EU more broadly, and the nature and scope of the future relationship.

Belfast ('Good Friday') Agreement references to healthcare:

3. The Belfast ('Good Friday') Agreement addressed arrangements for the future organisation of relationships within Northern Ireland and the wider UK (referred to as 'Strand One'); on the island of Ireland between the Northern Ireland Executive and the Irish Government (referred to as 'Strand Two' of the Agreement dealing with 'North-South' relationships) and between the UK and Irish Governments ('Strand Three', dealing with 'East-West' relationships).

4. Strand One provided for the establishment of a power-sharing Executive within Northern Ireland, which is one of the three Devolved Administrations within the UK.

5. Under Strand Two, the Agreement provided for the establishment of a North-South Ministerial Council (NSMC), bringing together Ministers from the Northern Ireland Executive and Irish Government. The Agreement charged the NSMC with agreeing at least 12 subject areas for cooperation - at least six of which were to be matters common approaches would be agreed in the Council but implemented in parallel in each jurisdiction by existing bodies; and at least six of which were to be matters where the cooperation would take place through agreed implementation bodies, on a cross-border or all-island basis. The Agreement did not stipulate which areas should be covered by the NSMC's future decisions but included some examples of the sorts of areas that might be covered. These included 'health: accident and emergency services and other related cross-border issues'.

6. Under Strand Three, the Agreement provided for the establishment of a British Irish Council (BIC), which would bring together all three devolved administrations within the UK, the UK and Irish Governments and the governments of the Isle of Man, Jersey and Guernsey to 'promote the harmonious and mutually beneficial development of the totality of relationships among the peoples of these islands'. The purpose of the BIC was to exchange information, discuss, consult and use best endeavours to reach agreement on cooperation of matters of mutual interest within the competence of the relevant Administrations'. Health issues were identified as one of the 'early issues' for potential discussion at the BIC.

North-South Ministerial Council prioritisation:

7. The Council meets in the health sector across a range of agreed areas of cooperation to make decisions on common policies and approaches. Responsible departments are the Department of Health in Northern Ireland, and the Department of Children and Youth Affairs in Ireland. The Council's work programme includes:

   - Accident and Emergency Planning - the Cooperation and Working Together programme improves coordination between health boards in border areas for ambulance cover, joint training, sharing emergency admissions, and planning for major emergencies;
   - Cooperation on High Technology Equipment - cooperation relates to the procurement, funding, and use of high technology equipment;
   - Cancer Research - research collaboration, sharing information on cancer research, and participation in multi-centred trials; and
   - Health Promotion - sharing information and opportunities for cooperation in relation to health promotion on an all-Ireland basis, including scope for research, public

information campaigns and education in general, and in the areas of heart disease, cancer, and smoking, in particular.

8. The specific arrangements for cooperation in these areas are set out in more detail in this paper. The work programme is adapted to reflect the ongoing priorities of the NSMC and has continued to develop since the creation of the Council, for example, in 2008 child protection was added to Health meeting agendas as an area of cooperation.

Broader context on European Union competence and acquis on healthcare

9. Article 9 and Article 168(1) TFEU require the European Union to ensure a high level of protection of human health in defining and implementing its policies and activities. In general terms, the EU's role is to complement national policies and is predominantly a supporting competence. However, there are limited areas of shared competence in respect of common safety concerns, and the internal market shared competence legal bases are also relevant in respect of certain health policies.

10. Article 6(a) TFEU specifies that the protection and improvement of public health is an area where the EU only has supporting competence. Article 168 TFEU provides more detail in respect of Union action in the field of public health. It states that Union action shall complement Member States' action and national policies (168(1)). It includes the requirement that Union action shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. The Article expressly recognises that the management of health services and medical care and the allocation of the resources assigned to them is the responsibility of the Member State (Article 168(7)).

11. In some aspects of public health the Union shares competence with the Member State and these are provided for in Article 4 and Article 168(4) and (5) TFEU. Article 168(4) specifies the areas in which there is shared competence for common safety concerns for the purpose of: (a) setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives (Article 168(7) expressly recognises that these measures shall not affect national provisions on donation or the medical use of organs and blood); (b) measures which have the direct objective of protecting public health in the veterinary and phytosanitary fields; and (c) measures setting high standards of quality standards for medical products and medical devices for medical use. Article 168(5) TFEU, whilst setting out a shared competence, only provides for the EU to adopt *incentive* measures designed to protect and improve human health and in particular to combat major cross border threats to health and measures to protect public health in respect of tobacco and the abuse of alcohol. The harmonisation of national laws is specifically excluded under this Article.

12. The internal market shared competence legal bases are also relevant in the health context. Measures relating to medicines and medical devices are typically made under Article 114 TFEU on the approximation of laws for the purposes of the operation of the internal market and measures relating to the mutual recognition of professional qualifications are made under Article 53 TFEU.

CROSS-CUTTING AREAS OF COOPERATION WITH IMPLICATIONS FOR HEALTHCARE

A. Common Travel Area and associated rights for British and Irish Citizens

13. The absence of routine immigration controls on journeys from within the Common Travel Area (CTA) to the UK, in particular on the land border between Northern Ireland and Ireland, facilitates cross-border healthcare collaboration on the island of Ireland. The rights and privileges associated with the CTA also mean that British and Irish citizens are able to enter and reside in Ireland and the UK respectively without seeking permission from the authorities. Healthcare in the UK is based on a person's residence status. As Irish citizens are treated as resident from day one in the UK they qualify for healthcare. UK or Irish nationals visiting the other state are not required to present a European Health Insurance Card (EHIC) to demonstrate their entitlement to needs-arising healthcare; there are also no requirements for S1 forms to be registered to demonstrate healthcare entitlement, if a pensioner from one country retires to the other. Separate bilateral healthcare reimbursement arrangements apply between the UK and Ireland, albeit within the framework set out in EU Regulations. The CTA arrangements also clearly facilitate UK or Irish national cross-border workers in the healthcare sectors in Northern Ireland and Ireland.

14. The reciprocal nature of these arrangements also provides broader support for the citizenship rights enshrined in the Belfast ('Good Friday') Agreement. The rights relating to healthcare, for example, mean that citizens in Northern Ireland who assert their Agreement right to solely Irish identity do not have to assert British citizenship in order to access healthcare in Northern Ireland.

B. Free movement and healthcare for other EEA nationals

15. The reciprocal CTA rights apply only to UK and Irish nationals. The citizens' rights negotiations will determine the rights and entitlements for EU nationals resident in Northern Ireland, and indeed elsewhere in the UK, at the specified date. The rights of EU nationals currently residing in Northern Ireland, including frontier workers on the Ireland/Northern Ireland land border will be covered by the citizens' rights agreement. The UK and EU have discussed and agreed, for the purposes of the Withdrawal Agreement:

- Equal treatment within the limits of Article 24 of Directive 2004/38 and rights of workers, self-employed, students and economically inactive citizens with respect to healthcare.
- The rules for reciprocal healthcare will follow Regulations 883/2004 and 987/2009.
- Persons whose competent state is the UK and are in the EU27 on exit day (and vice versa) – whether on a temporary stay or resident – continue to be eligible for healthcare reimbursement, including under the EHIC scheme, as long as that stay or residence position continues.
- The withdrawal agreement will also cover entitlement to healthcare reimbursement under the S1 scheme that arises by virtue of past residence or work, in accordance with the personal scope of the agreement in relation to social security rights - meaning that UK nationals who have made contributions in another Member State before exit are in scope, even if they live in the UK on exit day.

- It will also protect the position of people who are undertaking a course of treatment started before the withdrawal date for the duration of that treatment course, irrespective of residence.

16. Future arrangements in relation to healthcare for EU nationals in the UK and UK nationals in the EU will need to be determined as part of the future relationship.

C. Mutual recognition of professional qualifications

17. Mutual recognition of professional qualifications is a cross-cutting theme relevant to a number of areas of North-South cooperation outlined in this paper. Directive 2005/36/EC provides the framework for recognising professional qualifications across Member States. It harmonises the education and training for the following professions relevant to health: doctors, dentists, general care nurses, midwives and pharmacists. For other health professions, the Directive requires the host Member State to consider the qualifications on a case-by-case basis to determine whether the relevant qualifications and experience meet the same standard that the host Member State requires for that profession. If they do, then the professional is entitled to have the qualifications recognised. If they do not meet the required standard then the host Member State can impose compensation measures by way of an aptitude test or adaptation period. If the professional passes the test, or successfully completes an adaptation period, they are entitled to have their qualifications recognised.

18. Member States have competence to recognise, in accordance with their rules, the professional qualifications obtained in third countries, provided that all recognition respects any relevant minimum training conditions for that profession. Recital 10 of the Directive specifies that it *"does not create an obstacle to the possibility of Member States recognising, in accordance with their rules, the professional qualifications acquired outside the territory of the European Union by third country nationals"*. Furthermore, the European Commission's evaluation of the Directive in 2011[1], acknowledged that: *"The recognition of third country qualifications is left to Member States according to their national rules (Art 2(2))."*

19. Such recognition of professional qualifications could also involve an EU Member State making arrangements with a region of a third country. In 2008 France and Quebec entered into an Understanding governing the recognition of professional qualifications whereby they agreed to adopt a common procedure for recognition, which would facilitate the entry into force of mutual recognition agreements by respective regulatory authorities in France and Quebec[2]. Since the 2008 'Understanding', mutual recognition agreements have been agreed for professions and trades in a number of sectors under the auspices of the Understanding, including health professions such as doctors, dentists and pharmacists.

20. Linked to the first theme outlined above, the UK and Ireland have had long standing arrangements for the mutual recognition of health qualifications, including some that pre-

[1]http://ec.europa.eu/growth/single-market/services/free-movement-professionals/policy/legislation_en. See page 73

[2]http://www.mrif.gouv.qc.ca/en/ententes-et-engagements/ententes-internationales/reconnaissance-qualifications/documentation

date either country's accession to the European Union. Doctors and dentists were covered by an agreement between Great Britain, the then Irish Free State and Northern Ireland in 1927 (contained, within the UK, in the Schedule to the Medical and Dentists Acts Amendment Act 1927).

D. EU funding programmes

21. EU funding supports a number of areas of healthcare cooperation - for example, eight projects have been approved to date under INTERREG VA and all have commenced activity during 2017 (see CAWT section below for more detail). A further call for projects under the programme is currently in progress. Competitive EU funding programmes such as Horizon 2020 also provide opportunities to enhance cross-border collaboration and a number of cross-border projects are currently being undertaken through partnership arrangements between health and social care organisations in both jurisdictions.

E. Data sharing and procurement

22. As previously outlined, given the separate consideration of data protection issues in the UK-EU negotiations - and the granularity required to determine exactly how data is shared and handled in some local cross-border initiatives and organically developed collaboration - we have not sought to address all the links to data sharing and protection frameworks in this work on North-South cooperation.

23. Similarly, the application of EU procurement rules is a cross-cutting issue that is relevant to the procurement of goods and services in healthcare. We have not sought to address all the links to procurement processes in this paper as they are not unique to healthcare and will require separate, cross-cutting consideration in the UK-EU negotiations.

NSMC PRIORITIES

F. North West Cancer Care

24. North West Cancer Care is an initiative based on an agreement between Northern Ireland and Ireland Health Ministers.

25. The new Cancer Centre at Altnagelvin Area Hospital (in Northern Ireland) was opened on 28 November 2016. This service offers radiotherapy services closer to home for many patients from the North West of Ireland, reducing their travel time significantly.

UK legal and policy basis

26. The Centre is underpinned by a Memorandum of Understanding and Service Level Agreement between Health and Social Care Board, Health Service Executive (Ireland) and the Western Health and Social Care Trust both signed in 2014.[3]

27. The NSMC is not involved in the governance or oversight of the cross-border radiotherapy service, though it does provide a forum for the respective Health Ministers to discuss progress on areas of mutual interest. As a major collaborative project and high profile service which is jointly funded, the North West Cancer Centre features on the agenda of NSMC Health and Food Safety meetings and has also been discussed at NSMC Plenary meetings. Both the Northern Ireland Executive and the Irish Government have repeatedly reaffirmed their commitment to the North West Cancer Centre through the forum of the NSMC.

The links to EU legal and policy frameworks

28. The North West Cancer Centre is not directly underpinned by EU law. Specifically, the radiotherapy service provided by Northern Ireland to patients who reside in Ireland is not underpinned by Regulation 883/2004, nor by Directive 2011/24/EU on patients' rights in cross-border healthcare, as the service is based on an agreement between the respective health Departments of Northern Ireland and Ireland, and underpinned by a Memorandum of Understanding and Service Level Agreement. This sets out the patient catchment area both within Northern Ireland and in northwest Ireland. Patients who access this service are not doing so under their rights as enshrined in the Regulation or the Directive. The organisation and management of health services etc (as set out in 168(7) TFEU) is a Member State only competence.

29. The Common Travel Area, associated rights, and EU free movement law and MRPQ Directive are covered above as cross-cutting issues. It is also important to note radiation is used to diagnose and treat a wide range of health conditions, including cancer. Exposures to radiation are regulated by the Basic Safety Standards Directive 2013/59/Euratom.

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[3] *Memorandum of Understanding for the Development of a Radiotherapy Unit at Altnagelvin Hospital and the Provision of Radiotherapy Services* – signed in 2014 by (the then) DHSSPS, the Health and Social Care Board, the Western Health and Social Care Trust and the Irish Department of Health and Health Services Executive.
Service Level Agreement – Radiotherapy Unit at Altnagelvin, dated 31 July 2014. Signed by the Chief Executive of the Western Health and Social Care Trust and the Director General of the Health Service Executive.

G. All-Island Congenital Heart Disease Network

30. The Network was established following an agreement between the Northern Ireland and Ireland Health Ministers in 2014.

31. The Network has a single surgical centre in Dublin and a specialist children's cardiology centre in Belfast, supported by cardiology expertise in local hospitals and an all-island academic programme which is under development. The Network facilitates collaboration between healthcare providers in both jurisdictions to ensure that vulnerable children receive treatment on the island of Ireland.

UK legal and policy basis:

32. The Network was established following an agreement between Northern Ireland and Ireland Health Ministers. A Framework Document outlines the model for the implementation and operation of the Network by a Network Board which is overseen by the two health departments. Cooperation is underpinned by a Service Level Agreement between commissioner and provider organisations in Northern Ireland and Ireland.

33. There were a number of key developments leading to the policy statements and framework that underpin the CHD Network:

    (i) International Working Group's *Assessment of Cardiology and Cardiac Surgery for Congenital Heart Disease in Northern Ireland and the Republic of Ireland* – October 2014.

    (ii) Joint Ministerial Policy Statement in October 2014 following their receipt of the above report: *Joint Policy Statement by the Minister of Health and Social Services and Public Safety Northern Ireland, Jim Wells and the Minister of Health in the Republic of Ireland, Leo Varadkar on the report of the expert International Working Group (IWG) on the Assessment of Cardiology and Cardiac Surgery for Congenital Heart Disease in Northern Ireland and the Republic of Ireland* - 14 October 2014.

    (iii) A further Statement by Minister Jim Wells to the Northern Ireland Assembly on 3 March 2015, announcing joint agreement with Minister Leo Varadkar to implement the recommendations of the above report and announcing publication of the framework for the all-island CHD Network: *Congenital Cardiac Services: Future Delivery Model.*

    (iv) *Framework for All Island Clinical Network for Congenital Heart Disease* – published 3 March 2015.

34. The situation for the All Island Congenital Heart Disease Network is very similar to that of the North West Cancer Centre. The NSMC is not involved in the governance or oversight of the network; however, it is regularly discussed at NSMC Health and Food Safety and NSMC Plenary meetings. Both the Northern Ireland Executive and Irish Government have used the NSMC as a forum to reaffirm their commitment to this collaboration.

The links to EU legal and policy frameworks

35. The service is not underpinned by EU regulations. However, the Common Travel Area and associated rights, EU free movement law, and MRPQ Directive are covered above as cross-cutting issues.

H. Cooperation and Working Together (CAWT)

36. CAWT is a voluntary partnership between the Health Service Executive, Western Health and Social Care Trust, Southern Health and Social Care Trust, Health and Social Care Board and the Public Health Agency. It facilitates cross border cooperation between the health and social care systems in both jurisdictions and is responsible for ensuring that EU-funded and other cross-border projects are administered in accordance with the standards set out by the Special EU Programmes Body (SEUPB), CAWT partner organisations and other funders such as the Department of Health in Ireland and the Department of Health in Northern Ireland.

37. Its Management Board comprises the Chief Executives/Senior Managers of the Western and Southern Health and Social Care Trusts, Public Health Agency and Health and Social Care Board in Northern Ireland and the Health Service Executive in Ireland.

38. CAWT was established in 1992, and during its time has successfully promoted a wide range of cross border service and collaborative activity. Its progress is reported via the NSMC.

39. In total there are six strategy groups comprised of Senior Managers from Acute, Mental Health, Disability, Population Health, Primary Care and Older People and Children's Services. These strategy groups develop projects for submission to the INTERREG 2014-2020 programme which are focused on bringing benefits to the region by adopting a cross border approach. The following projects are among those which have been approved under INTERREG VA and all have commenced activity during 2017:

    1. Acute – €8,810,775 (HSE lead partner)
    2. Children's – €5,010,240 (HSE lead partner)
    3. Mental Health – €7,614,750 (HSE lead partner)
    4. Population health – €5,010,370 (HSE lead partner)
    5. Primary Care and Older people – €8,708,618 (Scotland lead partner)

UK legal and policy basis:

40. CAWT predates the Good Friday Agreement originally, and was set up in 1992 following an agreement between health boards in Northern Ireland and Ireland (the "Ballyconnell Agreement"). However, the new structures and bodies established subsequent to the Agreement and flowing from Strand 2 have supported the work of the CAWT, and the NSMC has committed to extend and strengthen the initiative in certain respects.

The links to EU law framework

41. CAWT is not underpinned by EU legislation. However, CAWT has been successful in bidding for a number of EU funds. EU funding programmes are covered above as a cross-cutting issue.

42. CAWT's cross-border projects are also carried out against the backdrop of the CTA and associated rights and the EU free movement law, which are covered above as cross-cutting issues.

I. Workstreams on Child Protection

43. There is an NSMC cross-border group of officials to intensify work on child protection. Since 2008, child protection has been on the agenda of Health meetings of the NSMC and work streams cover: knowledge exchange forum; quality and effectiveness; deaths of children in care; cultural competence in safeguarding; specialist services.

UK legal and policy basis

44. Cooperation in the above workstreams is not directly underpinned by EU law. However, there are wider child protection policy obligations - for example, specific child protection cases with an inter-jurisdictional element must be handled in compliance with international and domestic law, and in accordance with frameworks intended to ensure the efficient handling of child protection cases across borders, avoid delays and deliver positive outcomes for the children involved.

45. The 1980 Hague Convention on the Civil Aspects of International Child Abduction aims to ensure the return of children who have been wrongfully removed from one contracting state to another without delay.

46. The 1996 Hague Convention on Jurisdiction, Applicable Law, Recognition, Enforcement and cooperation in Respect of Parental Responsibility and Measures for the Protection of Children provides an agreed set of legal provisions and cooperation arrangements to cover the handling of inter-jurisdictional cases where children's safety or welfare may be an issue. It also covers a range of civil measures including those relating to parental responsibility and contact and also public measures of protection or care.

The links to EU law framework

47. As stated above, the specific areas of cooperation in the child protection work streams of the NSMC Health Sector meetings is not underpinned by EU law. However, some relevant EU regulation in the broader issues of child protection include: European Council regulation EC 2201/2003, known as 'Brussels IIa', which deals with the recognition and enforcement of judgments in matrimonial matters and in matters of parental responsibility (including residence and contact) in EU Member States. It also includes child abduction provisions, which set out certain procedures to facilitate proceedings in the state to which the child has been abducted and in the state of habitual residence of the child.

J. Addressing Alcohol Misuse

48. A North South Alcohol Policy Advisory Group was set up, at the request of the Chief Medical Officers of Northern Ireland and Ireland, to provide advice and a platform for information sharing and joined up action. The group informally reports to the NSMC Health and Food Safety Sectoral Group. The group is operated by the Institute of Public Health in Ireland and involves the appropriate departments and delivery bodies in both jurisdictions.

UK legal and policy basis

49. This is an informal arrangement. This group was established by the two Chief Medical Officers in each jurisdiction in 2012. While not formally established under the NSMC, it was agreed the outcomes from this group would be reported to the NSMC Health and Food Safety meetings to ensure it is aligned with ongoing North/South cooperation and policy direction.

The links to EU law framework

50. There is no EU legal basis for this advisory group.

51. By way of background, it may be helpful to note that Article 168(5) TFEU has been used to develop the EU alcohol strategy (see Annex 2 for full text).

52. There is no explicit link between the work of the North South Policy Advisory Group and the EU alcohol strategy. The group is primarily focussed on supporting the delivery, and where appropriate enhancing collaboration, on alcohol misuse policy in both jurisdictions. However, alcohol policy in Northern Ireland and the Ireland may be informed by the wider EU alcohol strategy.

K. Major Emergencies and Emergency Services Cooperation

53. Accident and Emergency planning falls within the auspices of the NSMC. This includes mutual support in ambulance cover, joint training and sharing emergency admissions where hospitals are under pressure. Work continues on a mass casualty plan and emergency services have informal arrangements with Ireland counterparts in the event of a large scale incident. Local arrangements are also in place between health trusts and their counterparts in relation to the treatment of patients in border areas.

54. Regarding preparedness and response to larger scale health emergencies, there is a civil contingencies framework, which is the responsibility of the Executive Office, in Northern Ireland and work continues on a mass casualty plan, and emergency services have informal arrangements with Irish counterparts in the event of a large scale incident. These plans and actions are not underpinned by EU legislation.

UK legal and policy basis:

55. On Accident & Emergency Planning, there is a civil contingencies framework, which is the responsibility of the Executive Office in Northern Ireland. Local arrangements are in place between Health Trusts and their counterparts in relation to the treatment of patients in border areas. Work continues on a mass casualty plan, and emergency services have informal arrangements with Irish counterparts in the event of a large scale incident. These plans and actions are not underpinned by EU legislation. They are covered by Memoranda of Understanding and Service Level Agreements between emergency services and health trusts in border areas - for example, Northern Ireland Ambulance Service and Northern Ireland Fire & Rescue Service work closely with counterparts.

56. The Common Travel Area and associated rights are covered above as cross-cutting issues.

The links to EU law framework

57. This cooperation is not directly underpinned by EU legislation. EU free movement law and the MRPQ Directive are covered above as cross-cutting issues.

COOPERATION BEYOND THE NSMC

L. Organs for transplantation

58. There is an established practical relationship between the two jurisdictions concerning the sharing of organs. In respect to gametes, we understand there are no significant imports from Ireland.[4]

59. No organs were shared between Northern Ireland and Ireland in the past three years and almost all of the organs in the table below were transferred to or came from England. The table below sets out figures for organ sharing between the UK and Ireland over the last three years:

Year	From UK to Ireland	From Ireland to UK
2016/17	6	20
2015/16	3	9
2014/15	2	7

UK legal and policy basis

60. The UK legal and policy basis is the Human Tissue Act 2004, which covers England, Wales and Northern Ireland. It established the Human Tissue Authority to regulate activities concerning the removal, storage, use and disposal of human tissue. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue.

The links to EU legal and policy frameworks

61. **Organs:** Directive 2010/53/EU sets minimum standards for the quality and safety of human organs intended for transplantation. Commission Implementing Directive 2012/25/EU lays down information procedures for the exchange, between Member States, of human organs intended for transplantation. Between them the Directives cover the donation, testing, characterisation, procurement, preservation, transport, transplantation of organs intended for transplantation. A national competent authority ensures compliance with EU quality and safety standards and traceability and reporting systems for serious adverse events/reactions have been established.

62. NOTE: Disposal is not within the stated scope of either Directive (article 2 of 2010/53/EU, and article 1 of 2012/25/EU). Disposal is covered in a limited way in Directive 2010/53/EU in that it is something that must be within the safety and quality frameworks (essentially

[4] This refers to relationship between Ireland and the UK as a whole, as Northern Ireland is part of the UK-wide system for sharing organs and tissues which is run by NHS Blood and Transplant (NHSBT).

because it is the alternative end result to transplantation). The Directives do not set out specific procedures or requirements for disposal of organs.

63. Article 20 of Directive 2010/53/EU concerns organ exchange with third countries, It states that this process is supervised by the competent authority. The competent authority and European organ exchange organisations may conclude agreements with third country counterparts, provided organs can be traced from the donor to the recipient and vice versa, and that the exchange meets quality and safety requirements laid down in the Directive.

M. Blood

[redacted]

UK legal and policy basis

65. There are no UK-Ireland agreements relating specifically to blood.

The links to EU legal and policy frameworks

66. The EU law in this area sets out a framework to ensure there is a consistent standard of blood safety everywhere in the EU:

- Directive 2002/98/EC sets out quality and safety standards for the collection, testing, processing, storage and distribution of human blood and blood components. Article 14 of the Directive sets standards of traceability of blood and blood components and requires that where these are imported from third countries, Member States shall ensure that there is an equivalent level of traceability of each unique donation and type of component. It also requires Member States to ensure that the third country's systems comply with EU systems and that traceability data is held for at least 30 years.

- Directive 2005/62/EC, which implements Directive 2002/98EC, sets out certain quality standards which must be in place in blood establishments. Article 2(3) of the Directive requires Member States to ensure that blood and blood components imported from third countries meet equivalent standards to those set out in the Directive

- Directive 2004/33/EC concerns technical requirements relating to blood standards. Article 6 requires blood from third countries to meet equivalent standards on quality and safety.

67. More broadly, Article 168 TFEU concerns public health and has aspects of both (a) supporting and (b) shared competence (see Annex 2 for full text – specifically, Art 168(3) (4) and (7)). The quality and safety standards of imported blood products from third countries falls within shared competence (category (b)).

N. The Institute of Public Health in Ireland

68. The Institute of Public Health in Ireland (IPH) was established in 1998 by the Departments of Health in both jurisdictions, specifically at the request of the respective Chief Medical Officers. Its remit is to support cooperation on public health North and South to promote collective action for health improvement – in the areas of research and information, policy advice and capacity building – with a particular focus on addressing health inequalities.

UK legal and policy basis:

69. There is no statutory basis for the institute. It is a company limited by guarantee receiving core financial support and co-sponsorship from the Departments of Health in Northern Ireland and Ireland. The Ireland Health Department contributes about 73% of the core funding and the Department for Health in Northern Ireland about 27%. The Institute has occasionally submitted papers for the consideration of NSMC Health and Food Safety Sectoral meetings.

The links to EU legal and policy frameworks

70. IPH has received and is currently in receipt of funding from the EU Public Health Programme to participate in, and deliver elements of, specific projects. It is currently a delivery partner in:

- JANPA (Joint Action on Nutrition and Physical Activity) which aims to contribute to halting the rise of overweight and obesity in children and adolescents by 2020; and
- JA-CHRODIS (EU Joint Action on Chronic Disease) which aims to promote the implementation of policies and practices that reduce the burden of chronic diseases and which effectively promote healthy ageing across the life-cycle.

O. Controlled Drugs Licensing Group

71. The Cross Border Controlled Drugs Licensing Group is an informal group consisting of representatives from the Northern Ireland Department of Health and the Irish Healthcare Products Regulatory Agency. The Group provides a forum to: promote better understanding of the respective national controlled drug licensing policies and of operational matters; share learning and best practice methodologies and drive improvements that support the safer management of controlled drugs licensing in each nation; share analysis of trends and associated risks pertinent to licensing of controlled drugs; and to provide a forum for contributing to the formulation of policy at a regional and national level and contribute to forward planning for the strategic agenda.

72. The group has no statutory basis, although the area of mutual interest (i.e. Controlled Drugs licensing) is underpinned by legislation in both jurisdictions.

UK legal and policy basis

73. The Misuse of Drugs Act 1971 provides the legislative framework for the regulation of "dangerous or otherwise harmful" drugs i.e. controlled drugs; the Act applies to the whole of the United Kingdom.

74. The UK is signatory to the United Nations Conventions for the prevention of drug misuse and trafficking, namely the Single Convention on Narcotic Drugs 19611 and the Convention on Psychotropic Substances 19712, which are complemented by the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988. The 1971 Act implements the UK's international obligations under the United Nations Conventions for the prevention of drug misuse and trafficking.

The links to EU legal and policy frameworks

75. The EU has limited competence in relation to action in reducing drug-related health damage – it can take action to complement action by Member States in this area.

P. All Ireland Institute of Hospice and Palliative Care (AIIHPC)

76. AIIHPC is an all island organisation, comprising a consortium of hospices, health and social care agencies and universities[5], all working to improve the experience of supportive, palliative and end of life care on the island of Ireland. AIIHPC advances education, research and practice in palliative and end of life care both across and within Northern Ireland and Ireland to improve the palliative care experience of people with life limiting conditions and their families, focusing on cross-jurisdictional learning opportunities and possible cooperation, as well as furthering key local and national policy issues. It also makes policy submissions to government, government bodies and other agencies.

77. Earlier this year its Palliative Care Research Network received an investment of £180,000 from the Health Research Board (Ireland) and HSC Research and Development Division, Public Health Agency (Northern Ireland). Its financial statement for 2016 did not detail any European Union funding.

Interaction with NSMC

78. The AIIHPC sends updates to the NSMC which are reported within its health and food safety joint communiqués[6].

The links to EU legal and policy frameworks

79. The Institute is not underpinned by EU legislation. AIIHPC is a member of the European Association for Palliative Care, a non-governmental organisation recognised by the Council of Europe (http://www.eapcnet.eu/Corporate/AbouttheEAPC/EAPCMemberAssociations.aspx).

[5] Including a number of Health and Social Care Trusts in Northern Ireland, Universities in both Ireland and Northern Ireland, Public Health Agency (Northern Ireland), Royal College of Surgeons in Ireland, Irish Hospice Foundation and others. Full list available at: http://aiihpc.org/about/governance/council-of-partners-2/

[6] https://www.northsouthministerialcouncil.org/publications/sectors/health-15

Q. Movement of medicines, devices and other healthcare goods

[redacted]

The links to EU legal and policy frameworks:

81. The movement of medicinal products and medical devices are governed by EU rules made under the single market legal base (Article 114 TFEU). European Union legislation dealing with medicinal products and medical devices is extensive, including a very substantial amount of tertiary legislation (see Annex 1 in relation to an illustrative list of EU legislation).

R. Human Milk Bank

82. The Human Milk Bank based in Irvinestown, Co Fermanagh, under the auspices the Western Health and Social Care Trust, was opened in 2000 to provide neonatal support to babies throughout the island of Ireland. It is not dependent on EU funding and nor is it underpinned by any EU legislative framework.

S. Cross Border GP Out of Hours Service

83. There are local arrangements in Northern Ireland and Ireland which facilitate cross-border out of hours access to General Practitioners. Patients living in a part of Donegal in Ireland may access GP Out of Hours in Altnagelvin Hospital in Derry in Northern Ireland, whilst patients from South Armagh in Northern Ireland may access GP Out of Hours Services in Castleblayney in Ireland. These services are provided on the basis of local arrangements, including the payment mechanisms, and should not be impacted post EU exit.

T. Mutual recognition of prescriptions

84. Article 11 of Directive 2011/24/EU on the application of patient's rights in cross border healthcare deals with the recognition of prescriptions issued in another Member State. This is relevant to mutual recognition of prescriptions between Northern Ireland and Ireland.

ANNEX 1

Medicinal products - EU legislation
Overarching
Directive 2001/83/EC on the Community code relating to medicinal products for human use provides for medicines which do not fall to be licensed by the Commission, to be licensed by member States.
Regulation 726/2004 establishes the European Medicines Agency and the Committee for Medicinal Products for Human Use; and provides for certain medicines to be subject to licensing by the Commission.
MA decision making
Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products
Commission Regulation (EC) No 1662/95 laying down certain detailed arrangements for implementing the Community decision-making procedures in respect of marketing authorizations for products for human or veterinary use
Commission Regulation (EC) No 2141/96 concerning the examination of an application for the transfer of a marketing authorization for a medicinal product falling within the scope of Council Regulation (EEC) No 2309/93
Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004
Paediatrics
Regulation 1901/2006 on medicinal products for paediatric use
Orphans
Regulation 141/2000 on orphan medicinal products

Commission Regulation (EC) No 847/2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and 'clinical superiority'
ATMP
Regulation 1394/2007 on advanced therapy medicinal products
Commission Regulation (EC) No 668/2009 implementing Regulation (EC) No 1394/2007 with regard to the evaluation and certification of quality and non-clinical data relating to advanced therapy medicinal products developed by micro, small and medium-sized enterprises
Pharmacovigilance
Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004
Commission Implementing Regulation (EU) No 198/2013 on the selection of a symbol for the purpose of identifying medicinal products for human use that are subject to additional monitoring
Commission Delegated Regulation (EU) No 357/2014 supplementing Directive 2001/83/EC and Regulation (EC) No 726/2004 as regards situations in which post-authorisation efficacy studies may be required.
Commission Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004
GMP
Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use
Commission Delegated Regulation (EU) No 1252/2014 supplementing Directive 2001/83/EC with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use
Commission Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use

Fees
Regulation 297/95 on fees payable to the European Medicines Agency for the Evaluation of Medicinal Products
Regulation 658/2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use
Commission Regulation (EC) No 2049/2005 laying down, pursuant to Regulation (EC) No 726/2004, rules regarding the payment of fees to, and the receipt of administrative assistance from, the European Medicines Agency by micro, small and medium-sized enterprises
Other
Regulation 469/2009 concerning the supplementary protection certificates for medicinal products (extends patent protection to take account of time required for licensing application)
Directive 89/105/EEC relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.
Directive 2009/35/EC on the colouring matters which may be added to medicinal products
Directive 2009/41/EC on the contained use of genetically modified micro-organisms
Commission Implementing Regulation (EU) No 699/2014 on the design of the common logo to identify persons offering medicinal products for sale at a distance to the public and the technical, electronic and cryptographic requirements for verification of its authenticity
Commission Delegated Regulation (EU) No 2016/161 supplementing Directive 2001/83/EC by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (directly applicable from early 2019)

Commission Implementing Decision of 22 November 2012 establishing a list of third countries with a regulatory framework applicable to active substances for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union, in accordance with Directive 2001/83/EC
Commission Implementing Decision of 23 January 2013 on the assessment of a third country's regulatory framework applicable to active substances of medicinal products for human use and of the respective control and enforcement activities pursuant to Article 111b of Directive 2001/83/EC
Council Decision 75/320/EEC, of 20 May 1975, setting up a Pharmaceutical Committee
Commission Communications (82/C 115/05 and COM/2003/839) on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted (parallel imports are not governed by secondary or tertiary legislation, but must be allowed in accordance with free movement of goods – article 34)

Clinical Trials
Directive 2001/20/EC makes provision for the approval of clinical trials and for the manufacturing and importation of products used in clinical trials
Regulation 536/2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [not yet in force and not expected to be in force pre-exit]
Commission Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. .

Good Laboratory Practice (GLP)
Directive 2004/9/EC (requires each member State to have a NCA responsible for GLP inspections and for NCA monitoring and inspection to be of prescribed (OECD) standards; also requirements on reporting and internal market (mutual acceptance of data).
Directive 2004/10/EC (requires safety studies on chemical products to comply with the OECD Principles of GLP Directive).

Medical Devices
Directive 93/42/EEC and Reg 2017/745 (medical devices)
Directive 98/79/EC and Reg 2017/746 (in vitro diagnostic medical devices)
Directive 90/385/EEC (active implantable medical devices)

ANNEX 2

Article 168 TFEU

1. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges,

measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.

6. The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.

7. Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.