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Health and Social Care in NI - Areas of EU Competence, Action and Support - Potential Areas of Impact on Health and Social Care as a result of EU Referendum Decision

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1 Context

Health care systems in EU member states are a matter of national responsibility and therefore health is not an area of major EU competence, when compared to areas such as agriculture or the environment. The role of the EU is largely to support member states to effectively deliver related policy and services.

However, the result of the EU referendum is not without potential impact in the health field. There are aspects of health care such as access to unplanned care or certain planned care in another EU State (reciprocal access), working hours of medical staff, mutual recognition of qualifications and regulation of pharmaceuticals which are regulated in the UK (and therefore in Northern Ireland (NI)) to a greater or lesser extent by EU law.

In the UK health and social care is a devolved matter, with the Northern Ireland Executive, via the Department of Health, being responsible for the organisation and delivery of health and social care services and the protection and promotion of health.

The Department of Health sets the policy and legislative context and an annual Commissioning Plan Direction sets out Ministerial priorities, key outcomes, objectives and related performance indicators. The Health and Social Care Board (HSCB)¹, in conjunction with the Public Health Agency (PHA)² subsequently produce an annual Commissioning Plan.

The NI health and social care system is organised around a formal functional split between service commissioning (purchasing) and service provider functions. The HSCB, working in conjunction with the PHA, commissions services to meet assessed need and promote good health.

There are five local commissioning groups (LCGs)³, which function as committees of the HSCB. Each LCG is co-terminus with its respective HSC Trust area and is responsible for assessing needs and commissioning health and social care for its local population. As regards service providers, there are five health and social care trusts and one regional ambulance trust delivering services to the population of NI.

This briefing looks firstly generally at EU competence in the area of health and then focuses on a *selected range* of specific areas that will need to be negotiated and resolved:

- Reciprocal access to unplanned (urgent/emergency) and certain planned care
- Employment matters
- Procurement of goods and services
- Cross-border services and projects

¹ Health and Social Care Board, <http://www.hscboard.hscni.net/>

² Public Health Agency, <http://www.publichealth.hscni.net/>

³ Local Commissioning Groups, <http://www.hscboard.hscni.net/LCG/index.html>

- Development and licensing of medicines
- Medical and life sciences research
- General food law.

2 EU Competence in Health and Social Care

In order to envisage the potential impact to health and social care of the EU referendum decision, it is useful to look at the EU competence in this area, noting at the outset that across the UK it is more limited than in areas such as agriculture and the environment. There are also specific concerns for NI, for example, EU funded cross-border health and social care projects and services (see section 6.1).

The Treaty on the Functioning of the European Union (TFEU) states in **Article 168.7** that individual Member States are responsible for⁴:

...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.

Article 6 of the TFEU lists ‘**Public Health**’ as amongst a range of policy areas where the EU can support Member States in this regard⁵:

...support, coordinate or supplement the actions of the Member States. This can include for example supporting mutual learning through benchmarking and sharing of good practice between the different health care systems operating across the EU.

Article 168 further sets out the types of actions the EU can undertake within the field of public health, in summary⁶:

168.1 – EU action is directed towards improving public health, preventing physical and mental illness and diseases, and removing sources of danger to same. Such action includes the fight against ‘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

⁴ The Treaty on the Functioning of the European Union, Article 168.7, EUR-Lex, Access to European Union Law, Article 168, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>

⁵ The Treaty on the Functioning of the European Union, Article 168.7, EUR-Lex, Access to European Union Law, Article 6, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>

⁶ The Treaty on the Functioning of the European Union, Article 168.7, EUR-Lex, Access to European Union Law, Article 168, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT>

health....and action in reducing drugs-related health damage, including information and prevention.

168.2 - The EU has a role in encouraging cooperation between Member States in the areas referred to in Article 168 and, if necessary, lend support to their action and particularly encourage cooperation between the Member States in cross-border areas.

The EU operates early warning systems for communicable diseases, managed by the European Centre for Disease Prevention and Control (ECDC), which is at the centre of a network of communication between Member States in this regard. These systems facilitate the rapid sharing of information and expertise in response to potential pandemics and other cross-border health threats. For example, the collaboration during the H1N1 pandemic and tackling antibiotic resistance.⁷ Following negotiations, the UK may be able to continue to participate in the ECDC in a similar way to Norway and Switzerland. These countries work within the ECDC but do not have a decision-making role in the organisation.⁸

168.3 - The EU and the Member States:

shall foster cooperation with third countries and the competent international organisations in the sphere of public health.

168.4 – Measures can be taken by the EU in specific areas in order to meet common safety concerns:

- *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;*
- *measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;*
- *measures setting high standards of quality and safety for medicinal products and devices for medical use.*

168.5 - The EU may also adopt incentive measures to protect and improve human health. These include monitoring of, early warning of and combating serious cross-border threats to health, and also the protection of public health regarding tobacco use, alcohol and illegal drug misuse. For example:

- **The Tobacco Products Directive (2014/40/EU)**⁹ aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of

⁷ European Centre for Disease Prevention and Control, <http://ecdc.europa.eu/en/Pages/home.aspx>

⁸ Brexit: impact across policy areas (Edited by Vaughne Miller), House of Commons Library, Briefing Paper, Number 07213, 26 August 2006, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7213>

⁹ Revision of the Tobacco Products Directive, EU Commission, http://ec.europa.eu/health/tobacco/products/revision/index_en.htm

health protection for European citizens. The Directive became applicable in the EU Member States, including the UK, on 20 May 2016. It involved a number of key changes including¹⁰:

- Larger, mandatory pictorial health warnings to cover 65% of the front and the back of cigarette and roll-your-own (RYO) tobacco packs (EU states can take more stringent measures and all jurisdictions of the UK have already gone further by introducing regulations for plain standardised packaging from May 2016);
 - Ban on cigarettes and RYO with flavours such as vanilla or candy;
 - The tar, nicotine and carbon monoxide (TNCO) labelling on cigarettes and RYO tobacco will now be replaced with an information message that informs consumers that 'Tobacco smoke contains over 70 substances known to cause cancer';
 - Safety and quality requirements, and packaging and labelling rules for e-cigarettes - there were concerns expressed by e-cigarette users and manufacturers that the regulations would make it harder to access e-cigarettes and reduce their availability as a smoking cessation measure. However, in May 2016 the European Court of Justice decided that the Directive was valid in the face of legal challenges from tobacco companies and UK e-cigarette manufacturers¹¹; and
 - Measures to combat illicit trade;
- **EU Drugs Strategy 2005-2012** - to protect public health and promote social cohesion by preventing and reducing drug use. It focuses on two key dimensions of drug policy – reducing demand and supply – and has three cross-cutting themes: coordination, international cooperation and information, research and evaluation. It was supported by the EU drugs action plan 2009-2012 which set targets and identified 72 actions to significantly reduce illegal drug use and the resulting social and health damage;
 - **EU Alcohol Strategy 2006-2012** - Member States have the main responsibility for their national alcohol policy. The EU Alcohol Strategy was designed to help national governments and other stakeholders coordinate their action to reduce alcohol related harm in the EU. The implementation of the Strategy was assessed in 2009 and 2013.¹² Co-ordination at EU level includes:
 - **The Committee on National Alcohol Policy and Action (CNAPA)** - The European Commission established a committee in November 2007 to encourage cooperation and coordination between Member States and to contribute to further policy development. CNAPA has representatives from the

¹⁰ 10 key changes for tobacco products sold in the EU, EU Commission Press Release, http://europa.eu/rapid/press-release_IP-16-1762_en.htm

¹¹ Brexit: impact across policy areas (Edited by Vaughne Miller), House of Commons Library, Briefing Paper, Number 07213, 26 August 2006, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7213>

¹² EU Alcohol Strategy, EU Commission, http://ec.europa.eu/health/alcohol/policy/index_en.htm

national governments and shares information, knowledge and good practice on reducing harmful alcohol consumption;¹³

- **The European Alcohol and Health Forum** is a platform where bodies active at European level can debate, compare approaches and act to tackle harmful levels of alcohol consumption;¹⁴ and
- **The Joint Action on Reducing Alcohol Related Harm (JA RARHA)**, is a 3-year action (2014-2016) funded by the European Union under the second EU Health Programme aimed at supporting EU Member States to address and reduce the harm associated with alcohol.¹⁵

The European Charter of Fundamental Rights also includes a number of references to health and access to health care services, particularly in Article 35 Health care¹⁶:

Everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all the Union's policies and activities.

Beyond the specific measures in the TFEU on public health, there are a number of other ways in which health care and social care systems are affected by EU law, which link directly to the freedoms of movement within the EU (and in some cases the European Economic Area (EEA¹⁷) and Switzerland as well).

There is common legislation in place covering the EEA and Switzerland for **coordination of social security systems**, (Regulation (EC) No.883/2004) giving access rights for citizens of the participating countries to the various health and social care services,¹⁸ as described in section 3 below.

Once the UK withdraws from the EU the specific treaty provisions would no longer apply to the UK. The nature of the withdrawal agreement will determine the extent to which the areas highlighted in this briefing continue to remain pertinent to healthcare services in NI and the other parts of the UK. Co-operation across health and social security systems already extends beyond the EU Member States to include Switzerland, Norway, Liechtenstein and Iceland. The securing of reciprocal healthcare arrangements is likely to be a priority in negotiations on this subject.

¹³ EU Committee on National Alcohol Policy and Action, http://ec.europa.eu/health/alcohol/committee/index_en.htm

¹⁴ EU Alcohol and Health Forum, http://ec.europa.eu/health/alcohol/forum/index_en.htm

¹⁵ Joint Action on Reducing Alcohol Related Harm, EU Commission News, <http://ec.europa.eu/chafea/news/news310.html>

¹⁶ The European Charter of Fundamental Rights, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012P/TXT>

¹⁷ EEA - The EEA includes EU countries and also Iceland, Liechtenstein and Norway. It allows them to be part of the EU's single market.

¹⁸ Co-ordination of social security systems, Regulation (EC) No 883/2004, adopted in 2004, only became applicable 1st May 2010, <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:c10521&from=EN>

3 Reciprocal Access to Healthcare

EU citizens who can show that they are either employed or self-employed in the UK, or non-active in terms of employment but are ordinarily resident in the UK, are entitled to free healthcare in the UK. Any changes to the free movement rights could make it more difficult for EU citizens to obtain free healthcare on the basis of residence in the UK. Similarly, the rights of UK nationals living in the EU to access state healthcare will be subject to the terms under which the UK leaves the EU.¹⁹

3.1 Unplanned Care - European Health Insurance Card (EHIC)

This is a free card that gives an individual access to medically necessary, state-provided healthcare during a temporary stay (including holidays) in any of the EU countries and in addition Iceland, Lichtenstein, Norway and Switzerland, under the same conditions and at the same cost as people insured in that country. The Cards are issued by the national health insurance provider in the country of the insured person²⁰:

- The card does not guarantee free services, as each country's healthcare system is different. Services that are free in the home country may not be free elsewhere. The costs are then paid/reimbursed by the social security system of the individual's country of origin.
- The card is not an alternative to travel insurance as it does not cover any private healthcare or costs such as a return flight home or lost/stolen property, neither does it cover an individual's costs if they are travelling for the express purpose of obtaining medical treatment.

Entitlement to an EHIC is based on insurability under EU law, and not on a person's nationality. The UK operates a residency-based healthcare system which means that insurability in the UK is generally determined by residency and not by the past or present payment of National Insurance contributions or UK taxes. If a person is ordinarily resident in the UK then it is likely that they will be considered to be insured by the UK under EU law and will be entitled to a UK EHIC.²¹

Residents of NI apply to the NHS Business Services Authority to obtain an EHIC. The BSA has advised that there are currently 660,329 valid EHICs in circulation in NI.²²

¹⁹ Brexit: impact across policy areas (Edited by Vaughne Miller), House of Commons Library, Briefing Paper, Number 07213, 26 August 2006, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7213>

²⁰ European Health Insurance Card, European Commission, Employment, Social Affairs and Inclusion, <http://ec.europa.eu/social/main.jsp?catId=559>

²¹ Official UK Government website for EHIC, NHS Business Services Authority, <https://www.ehic.org.uk/Internet/startApplication.do>

²² Email response from Department of Health, Private Office, 17/08/16

If the UK remains in the EEA²³ it may be able to continue to participate in the EHIC scheme or to participate on a similar basis to Switzerland²⁴:

EEA and Swiss residents are entitled to hold an EHIC, which gives access to medically necessary, state provided healthcare during a temporary stay in another EEA country.

3.2 Planned and Unplanned Care - EU Directive on patients' rights in cross-border healthcare- relationship to previous E112 route

In 2011 EU Directive 2011/24/EU introduced scope for citizens to apply for reimbursement of cross-border healthcare treatment for planned and unplanned care. It came into force on 25th October 2013 in the EU and then on 1st August 2015 also in the EEA. It does not apply to Switzerland.

Prior to Directive 2011/24/EU the only way for patients to access planned treatment abroad would have been with prior authorisation, through the E112 form (now referred to as the S2 route). This is granted by the patient's home health insurance institution certifying that it would cover the cost of the treatment abroad. In practice, that system was administratively complex with long waits for patients before getting the authorisation and there was also a lack of information about patients' rights in this context.

This led to some patients bringing their Member State to the European Court of Justice and it was recognised that there was a need to clarify patients' rights. So, in 2008, after a public consultation on health services in cross-border healthcare, the European Commission put forward a legislative proposal for a directive, which came into force on 25 October 2013.²⁵

Some of the key benefits for patients of the Directive are²⁶:

- Recognition for the first time in EU law that patients have a right to cross-border healthcare and are entitled to be reimbursed for it;
- Right to information on cross-border healthcare, and the creation of National Contact Points in each Member State to provide this;
- Right of patients to obtain a copy of their medical record and to get appropriate medical follow-up in the home country;
- Recognition of prescriptions made abroad;

²³ EEA - The EEA includes EU countries and also Iceland, Liechtenstein and Norway. It allows them to be part of the EU's single market. Switzerland is neither an EU nor EEA member but is part of the single market - this means Swiss nationals have the same rights to live and work in the UK as other EEA nationals.

²⁴ Brexit: impact across policy areas (Edited by Vaughne Miller), House of Commons Library, Briefing Paper, Number 07213, 26 August 2006, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7213>

²⁵ EU Directive 2011/24/EU on the application of patients' rights in cross border healthcare: Legislation Guidance for Patient Organisations (November 2013), European Patients Forum, Section 1.1, http://ec.europa.eu/health/archive/ph_overview/co_operation/healthcare/docs/impact_assessment_exs_en.pdf

²⁶ As above, Section 1.2

- Transparency on the quality and safety standards for healthcare that apply in each Member State;
- Legal basis for European co-operation on eHealth and Health Technology Assessment; and
- Better cooperation between Member States in rare diseases, including establishing a legal basis for European Reference Networks and centres of excellence.

Under the Directive, once a patient has been assessed as needing treatment and eligible to have that treatment in NI, they have the right to obtain that treatment in another EU member state, either privately or in the state sector. Patients pay the treatment costs directly to the provider and the HSCB will reimburse the patient for the actual cost of the treatment or the equivalent cost of treatment locally, whichever is the lesser. No other costs will be met, including travel.²⁷ Patients are advised to have medical insurance cover in the event of an emergency associated with the planned treatment as well as a valid EHIC card.

Except where legislation requires the seeking of prior authorisation, for example, where the treatment being sought requires an overnight stay in hospital or involves the use of highly specialised medical equipment or infrastructure, a patient may obtain healthcare in another Member State under the Directive without authorisation from the HSCB, whereas under the S2 route, **all** healthcare must be authorised in advance.

The key difference between the two routes is that the S2 route relates only to state-provided treatment and costs are dealt with directly between Member States, with the S2 acting as a form of payment guarantee. This means that in the majority of cases, the patient is not required to pay anything themselves.²⁸

Under the S2 route, Member States retain discretion as to whether to authorise planned treatment in another Member State except in cases where “undue delay” is relevant – i.e. where treatment cannot be provided by the NHS within a time that is medically acceptable, based upon an objective clinical assessment of the patient and their individual circumstances. Where this is the case, authorisation must be given.²⁹

Using the Directive route, in practice, patients contact the NI National Contact Point (in NI this is the Health and Social Care Board - HSCB) to determine whether they need prior authorisation. The HSCB can refuse authorisation if the treatment in question, or the healthcare provider in question, could present a risk to the patient. If the medical

²⁷ Cross-border EU Healthcare Directive, webpage updated 01/07/16, BMA, <https://www.bma.org.uk/collective-voice/influence/uk-governments/northern-ireland-assembly/ni-assembly-latest-evidence-and-briefings/cross-border-eu-healthcare-directive>

²⁸ Cross-border Healthcare and Patient Mobility in Europe, October 2013, Department of Health, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252940/Cross_Border_Healthcare_Information.pdf

²⁹ Cross-border Healthcare and Patient Mobility in Europe, October 2013, Department of Health, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/252940/Cross_Border_Healthcare_Information.pdf

treatment can be provided at home within a 'medically justifiable time limit,' authorisation can be refused with an explanation provided.³⁰

Since December 2013, the Board has approved 99 applications for reimbursement of cross-border treatment under the Directive. A further 26 applications are pending approval. In relation to patients coming to NI for treatment under the Directive, Health and Social Care Trusts have treated two patients to date. One further patient is currently waiting for an outpatient assessment.³¹

The Department of Health advises that both the Directive and the S2 route provide for patients to receive treatment in another EEA country. The Directive can apply to both *planned and unplanned* treatment, the S2 route covers *planned* treatment only³²:

Only treatment provided by the state health sector is covered by the S2 route, whereas under the terms of the Directive patients can be reimbursed for treatment received from either state or private healthcare providers. And where prior authorisation of treatment under the Directive is only required in certain circumstances, treatment under the S2 route must be approved in advance. An application for treatment under the S2 route will be considered where the treatment required is not available locally or within a medically appropriate time period, based on an objective clinical assessment of an individual's circumstances.

The Department advised that the number of approved applications for treatment under the S2/ E112 over the last five years is:

- 2011/12 - 14
- 2012/13 - 09
- 2013/14 - 18
- 2014/15 - 24
- 2015/16 - 16

In addition to the above S2 applications approved by the HSCB, pregnant women who wish to give birth in another EEA country can apply to the Department of Work and Pensions (DWP) for a maternity S2. Information on the number of maternity S2s issued to women in NI is only available from 2014. Since then, DWP has approved seven maternity S2s for people resident in NI - one in 2015 and six in 2016³³.

³⁰ Cross-border EU Healthcare Directive, webpage updated 01/07/16, BMA, <https://www.bma.org.uk/collective-voice/influence/uk-governments/northern-ireland-assembly/ni-assembly-latest-evidence-and-briefings/cross-border-eu-healthcare-directive>

³¹ Email response from Department of Health, Private Office, 17/08/16

³² As above

³³ Email response from Department of Health, Private Office, 17/08/16

The relevant Statutory Rule for NI is SR 2013 No. 299 and was considered by the then Committee for HSSPS on 15th January 2014³⁴:

Statutory Rule. SR 2013/ 299. The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013.

The Committee considered SR 2013/ 299 - The Health Services (Cross-Border Health Care) Regulations (Northern Ireland) 2013 and had no objection to the Rule subject to the report of the Examiner of Statutory Rules.

For both planned and unplanned care, there will be a need to negotiate arrangements with the EU as to how both 'ordinarily resident' UK citizens and citizens from elsewhere in the UK will access health care. This may be via new reciprocal agreements or seeking to continue existing arrangements.³⁵

4 Relevant Employment Legislation

There are a number of pieces of EU legislation within the field of employment which also impact on the delivery of health care services. This includes legislation concerning:

4.1 Mutual recognition of professional qualifications

This enables health professionals from EU countries to work in the health care systems of other EU Member States:

The main European legislation is Directive 2005/36/EC³⁶ (as amended by Directive 2013/55/EU³⁷) on the recognition of professional qualifications. This sets out UK obligations for recognising the relevant professional qualifications held by staff, from within the European Economic Area. This Directive came into force on 20 October 2007 and replaced 15 sectoral directives, where different professions were covered by separate directives. The relevant UK regulations that transposed the Directive are the European Union (Recognition of Professional Qualifications) Regulations 2015.³⁸

³⁴ Committee for HSSPS, NI Assembly, Minutes of Proceedings, Wednesday 15th January 2014, <http://www.niassembly.gov.uk/globalassets/documents/health-2011-2016/minutes/2013-2014/15-january-2014.pdf>

³⁵ McKenna, H., Five Big issues for Health and Social Care after the Brexit Vote, The King's Fund, 30 June 2016, <http://www.kingsfund.org.uk/publications/articles/brexit-and-nhs>

³⁶ Directive 2005/36/EC, <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005L0036-20140117&from=EN>

³⁷ Directive 2013/55/EU, <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32013L0055>

³⁸ European Union (Recognition of Professional Qualifications) Regulations 2015, http://www.gmc-uk.org/EU_RPQ_regs_BIS_18Jan16_en.pdf_64343372.pdf

The King's Fund have recently proposed that through negotiations the UK should retain the ability to recruit staff from the EU when there are insufficient resident workers to fill vacancies³⁹:

By adding specific occupations to the Migration Advisory Committee's shortage occupation list, which currently enables employers to recruit nurses and midwives from outside the European Economic Area.

If the residency status of EU nationals currently working in the health sector in the UK is confirmed post-Brexit, there are still concerns that it may become more difficult to retain staff and attract new recruits from EU countries at a time when services are already under pressure.⁴⁰

4.2 Working Time Directive (WTD)

To protect workers' health and safety (including health and social care staff, working hours must meet the minimum standards of 2003//88/EC throughout the EU, including⁴¹:

- a limit to weekly working hours, which must not exceed 48 hours on average, including any overtime;
- a minimum daily rest period of 11 consecutive hours in every 24;
- a rest break during working hours if the worker is on duty for longer than 6 hours;
- a minimum weekly rest period of 24 uninterrupted hours for each 7-day period, in addition to the 11 hours' daily rest; and
- extra protection for night work.

The European Commission (EC) is currently reviewing the WTD through a 2 stage consultation of EU-level workers' and employers' representatives and a detailed impact assessment. The EC issued a public consultation on how the WTD should be updated.

One element is a health sector-specific study which covered a sample of member states (including the UK) looking at the impact of suggested working time options on real-life healthcare scenarios. With regard to this the NHS European Office suggested practical solutions on the way forward⁴²:

We have supplied the commission with further concrete examples of how delivery of health services has sometimes been constrained by compliance with over-prescriptive working time rules, and have used the evidence from

³⁹ McKenna, H., Five Big issues for Health and Social Care after the Brexit Vote, The King's Fund, 30 June 2016, <http://www.kingsfund.org.uk/publications/articles/brexit-and-nhs>

⁴⁰ Brexit: impact across policy areas (Edited by Vaughne Miller), House of Commons Library, Briefing Paper, Number 07213, 26 August 2006, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7213>

⁴¹ Working Conditions, Working Time Directive, <http://ec.europa.eu/social/main.jsp?catId=706&langId=en&intPagelId=205>

⁴² Working Time Directive, NHS Employers, <http://www.nhsemployers.org/about-us/nhs-european-office/nhs-workforce-and-the-eu/working-time-directive>

the taskforce which reported to the Secretary of State for Health in March 2014 as valuable information to feed into the commission's impact assessment. Once the future direction of travel is clear, we expect to work in 2017 to respond to and to shape the commission's thinking.

If the UK government decides to appeal or amend the WT regulations, which enacted the WTD, this would have implications for HSC employment contracts and require changes to the Agenda for Change pay framework and the negotiations with staff unions that would be required.⁴³

5 Public Procurement for Goods and Services

Along with other public bodies and authorities in NI, EU rules on public procurement provide the legal framework for procuring goods, works and services related to the management and delivery of health and social care in NI. The relevant EU Directives are already incorporated into UK legislation and apply to tenders whose monetary value exceeds a certain amount. For tenders of lower value, national rules apply. These national rules also have to respect the general principles of EU law.⁴⁴

The relevant UK laws would need to be repealed or amended if the UK wished to reverse current arrangements.

In NI responsibility for public procurement policy lies with the Procurement Board, chaired by the Finance Minister. All policies agreed by the Procurement Board must comply with EU legislation.⁴⁵

6 North-South Cross-Border Co-operation

6.1 EU-Funded Cross-Border Projects

6.1.1 Cross border health and social care services projects delivered with the EU INTERREG IVA funding

Certain projects of cross-border health and social care delivery may be substantially impacted by withdrawal from the EU, due to the fact that they are EU funded. Co-operation and Working Together (CAWT), since its inception in 1992, has created and sustained a variety of EU funded cross-border projects and services and has enhanced service provision to many rurally isolated and peripheral areas.

⁴³ McKenna, H., Five Big issues for Health and Social Care after the Brexit Vote, The King's Fund, 30 June 2016, <http://www.kingsfund.org.uk/publications/articles/brexit-and-nhs>

⁴⁴ European Commission, Public Procurement, https://ec.europa.eu/growth/single-market/public-procurement_en

⁴⁵ Department of Finance (NI), Central Procurement Directorate, <https://www.finance-ni.gov.uk/central-procurement-directorate>

CAWT is the cross-border health and social care partnership for the Health Service Executive in the Republic of Ireland and the Southern and Western Health and Social Care Trusts, the Health and Social Care Board and the Public Health Agency in Northern Ireland.⁴⁶ The CAWT partnership evolved from an initial informal arrangement into an effective cross-border delivery and implementation structure for the partner organisations.⁴⁷

In the most recent tranche of projects CAWT managed a range of cross-border health and social care programmes funded by €30 / £24 million from the EU INTERREG IVA programme until 2014/2015. Under the overarching programme called 'Putting Patients, Clients and Families First,' 12 large scale, strategic, cross-border health and social care service projects were delivered across the border region and within the eligible area of Northern Ireland. CAWT works collaboratively with a range of non-statutory organisations in the border area to provide specific strands of the project.

The 12 cross border health and social care services projects delivered with the EU INTERREG IVA funding were:

1. Cross border acute hospital services (Vascular, ENT, Urology and Ophthalmology);
2. Additional and new sexual health / GUM clinics;
3. Eating Disorder services;
4. Alcohol abuse prevention/early intervention;
5. Improving outcomes for Children and Families;
6. Support for Older People via Telehealth and Social supports;
7. Citizenship for People with Disabilities;
8. Diabetes Education and Clinics;
9. Prevention and Management of Childhood Obesity;
10. Social Exclusion /Health Inequalities;
11. Cross Border Workforce Mobility; and
12. Autism Support.

One specific example (as listed at number 2 above) is the CAWT sexual health/GUM clinic. A total of €1.95 million from the EU INTERREG IVA programme was invested in new and additional sexual health/GUM clinics across the CAWT region. Across all the clinics, to the end of January 2014, a total of 7,195 patients were treated, exceeding the 5,000 target set for the project by the EU funder.⁴⁸

Four of the seven new sexual health/GUM clinics within the HSE West, Southern Health and Social Care Trust and Western Health and Social Care Trust areas have been continued as normal core services following the EU funding phase. The remaining three GUM/sexual health clinics, in the HSE Dublin North East region, continued until May 2014 when EU funding concluded.

⁴⁶ CAWT (2014) *CAWT Strategic Plan 2014-2020*,

<http://www.cawt.com/Site/11/Documents/Publications/Corporate/CAWT%20Strategic%20Plan%202014-19%20PDF.pdf>

⁴⁷ Heenan, D. and Birrell, D. (2011) *Social work in Northern Ireland: conflict and change*. Bristol: The Policy Press. p.96.

⁴⁸ Health Service Executive (2014) *Successful cross-border health project treats hundreds of patients in Donegal*, <http://www.hse.ie/eng/services/news/media/pressrel/newsarchive/2014archive/feb14/letterkennygumclinic.html>

CAWT observes that the 12 projects listed above have, for the most part, delivered economies of scale and have provided the critical mass of population on either side of the border which can justify provision of certain services.⁴⁹ Negotiations will continue with the individual partner organisations on how EU funded projects and services will be mainstreamed / integrated once the EU funding period has concluded.

The current CAWT Strategic Plan 2014-2019 asserts that the partnership is committed to supporting the change agenda in both jurisdictions i.e. 'Transforming your Care' in Northern Ireland and 'Future Health' in the Republic of Ireland.⁵⁰ EU strategies such as Europe 2020 (EU's growth strategy) will also provide direction for future CAWT activities.

The new INTERREG Programme for 2014-2020 is one of 60 programmes across the EU designed to promote greater levels of cross-border cooperation. The development of the Programme has been informed by the European Union's key policy instruments, namely the Europe 2020 Strategy and the Common Strategic Framework, and the European Commission's position papers on the UK and Ireland.⁵¹

Information was supplied by CAWT on the 12 projects from the EU INTERREG IVA funding regarding the extent to which the service has been mainstreamed/adapted into core services after the EU funding concluded (and therefore are now funded by the relevant Departments (Table 1 below)⁵²:

A substantial proportion of services funded by the EU INTERREG IVA programme have continued after the conclusion of EU funding as planned. CAWT delivered a 12-project programme called 'Putting Patients, Clients and Families First' which enabled a suite of cross border services and initiatives to be delivered in the border region which benefitted 53,000 service users. CAWT estimates that up to 80% of services/projects have been either fully or partially mainstreamed or adapted into core services. This high level of mainstreaming activity in a difficult economic climate is viewed by the CAWT Partnership as a successful outcome. In addition, 43,587 health and social care staff received training as part of the overall programme.

⁴⁹ Health Service Executive (2014) *Successful cross-border health project treats hundreds of patients in Donegal*, <http://www.hse.ie/eng/services/news/media/pressrel/newsarchive/2014archive/feb14/letterkennygumclinic.html>

⁵⁰ CAWT (2014) *CAWT Strategic Plan 2014-2020*, page 5
<http://www.cawt.com/Site/11/Documents/Publications/Corporate/CAWT%20Strategic%20Plan%2014-19%20PDF.pdf>

⁵¹ SFC 2014 (2015) [Online] Available from: http://www.seupb.eu/Libraries/2014-2020_Programmes/2015-01-28_INTERREGVA_FinalAdoptedbyEC.sflb.ashx [Accessed: 14 April 2014].

⁵² Email Response to RalSe request from Sadie Bergin, Communications and Corporate Governance Manager
Co-operation and Working Together (CAWT) Cross Border Health and Social Care, 5th August 2016

Table 1 - Mainstreaming of EU INTERREG IVA funded projects

Project/Service	Mainstreaming / adaption into core services after EU funding concluded
Acute Hospital Services - ENT	Cross border ENT services established between the Health Service Executive (HSE), Dublin North East area and the Southern Health and Social Care Trust (HSCT) have continued.
Acute Hospital Services - Ophthalmology	Ophthalmology / Eye Treatment services - mainstreamed in HSE (Louth County Hospital).
Sexual health / GUM clinics	Additional Sexual health / GUM clinics established in the Western HSCT & Southern HSCT have been adapted into core services. New Sexual health / GUM clinics established in the HSE border counties (Letterkenny, Monaghan, Dundalk and Drogheda) have continued.
Diabetes Services	Two new Diabetes services were established across all of NI and HSE border counties: 1. Structured Patient Education (SPE) programme called CHOICE for children and young people who have diabetes. 2. Pre-pregnancy Care (PPC) Clinics. Both services have continued in full or have been incorporated into core services.
Eating Disorders	Eating Disorder services enhanced /established across the Southern and Western HSCTs and HSE border counties. Mainstreaming fully achieved in all CAWT areas.
Border region alcohol project	Some activities have been mainstreamed: Strengthening Families Programme (SFP) in the HSE - has been incorporated into core services in the HSE border counties. SFP funded by the Public Health Agency in NI (operating in the Belfast, Northern, South Eastern and Western HSCT areas).
Older Person's Project	Some activities have been mainstreamed/incorporated into core services/secured alternative funding: Telecare/assistive technology element (HSE West, HSE DNE and Southern and Western HSCT areas)

Project/Service	Mainstreaming / adaption into core services after EU funding concluded
	<p>Good Morning Louth service (HSE Louth)</p> <p>Armagh Men's Shed</p>
Prevention and Management of Childhood Obesity	<p>Project delivered in four sites in the border region. Childhood obesity is within remit of the PHA in NI and the HSE in the Republic of Ireland who continue to deliver activity in this area in partnership with community/voluntary sector and other statutory partners.</p>
Improving Outcomes for Children and Families	<p>Model developed by project incorporated into core services.</p>
Promoting Social Inclusion and Tackling Health Inequalities	<p>Selected activities continued to be delivered by the statutory health services, other statutory services and the community and voluntary sector.</p>
Autism Support Project	<p>Practical support provided to families and young people with ASD in relation to transitioning has continued within mainstream services.</p>
Cross Border Workforce Mobility – coaching skills	<p>Network of coaches developed across the health services. Coaching continues to support the change agenda in the health services in both jurisdictions.</p>
Cross Border Workforce Mobility – Manual Handling training	<p>Project resulted in standardised Manual Handling training being developed and delivered within both health services. Training continues to be delivered via on-line access.</p>
Cross Border Workforce Mobility Social Working Training	<p>Social work training continues to be delivered by the CAWT partner organisations.</p>

6.1.2 Implications of EU Referendum Result for CAWT and access to the new INTERREG Programme for 2014-2020

The CAWT Management Board has taken the following approach as a result of the EU Referendum outcome⁵³:

The key focus is to implement the CAWT 2014-2019 Strategic Plan⁵⁴ which underscores the core purpose of the organisation and sets out a number of strategic goals.

The plan states that⁵⁵:

The CAWT partnership is committed to supporting the change agenda in both jurisdictions i.e. 'Transforming your Care' in Northern Ireland and 'Future Health' in the Republic of Ireland. EU-wide policies such as Europe 2020 (EU's growth strategy) will also provide direction for future activities. CAWT will continue to create ideas and exploit opportunities to support these policies through cross border initiatives.

In the context of the outcome of the EU Referendum and in order to maintain and develop the working relationships between the health services in NI and in the Republic of Ireland., a strong emphasis has been placed in the 2014-2019 plan on particular strategic goals including:

- Achieving solutions to barriers to the cross border mobility of patients and professionals;
- Pursuing collaborative strategic alliances; and
- Engaging with policy makers and other key stakeholders in relation to the development and direction of cross-border health and social care; and
- Embedding cross-border planning and implementation in core activities where there is mutual benefit to be gained in terms of service efficiency and effectiveness.

The CAWT Partnership is of the view that it can play a positive and problem-solving role to assist the health and social care services in dealing pragmatically and in a positive mindset with issues which may arise when Article 50 is activated.

An immediate priority for CAWT is to co-operate with the Special EU Programmes Body (SEUPB) and the respective involved Departments of Health in Belfast, Edinburgh and Dublin in relation to ensuring a positive outcome to the implementation

⁵³ Email Response to RalSe request from Sadie Bergin, Communications and Corporate Governance Manager Co-operation and Working Together (CAWT) Cross Border Health and Social Care, 5th August 2016

⁵⁴ CAWT Strategic Plan 2014-2019, <http://www.cawt.com/Site/11/Documents/Publications/Corporate/CAWT%20Strategic%20Plan%2014-19%20PDF.pdf>

⁵⁵ CAWT Strategic Plan 2014-2019, page 5, <http://www.cawt.com/Site/11/Documents/Publications/Corporate/CAWT%20Strategic%20Plan%2014-19%20PDF.pdf>

of the Health & Social Care Measure in INTERREG VA. The SEUPB Statement on the EU Referendum decision dated 8th July 2016 is as follows⁵⁶:

The SEUPB, having received guidance from the Northern Ireland Finance Minister on the implications of the recent referendum decision in which a majority in the North voted to Remain, will continue to implement the delivery of PEACE IV and INTERREG VA in its role as Managing Authority for the Programmes.

It is anticipated that all EU Programmes, including PEACE IV and INTERREG VA, will form part of the discussions that are to take place between the devolved administrations, the UK government and the European Union during the upcoming negotiations.

The Irish Government and the NI Executive remain committed to the successful implementation of the PEACE and INTERREG Programmes.

CAWT advise that the INTERREG VA planning process is continuing as originally prescribed. The CAWT Partnership has made a number of submissions to the new INTERREG cross-border co-operation programme for the Border Region of Ireland, Northern Ireland and Western Scotland (2014-2020). These submissions, if successful, will involve the statutory health and social care services working in partnership with other sectors, in particular with the voluntary and community sector, in order to reach the vulnerable and socially excluded sections of the populations.

The CAWT partner organisations (Health Service Executive, HSCB, PHA, Southern HSC Trust and the Western HSC Trust), along with their Scottish partners, remain committed to the implementation of these submissions.

Both the UK and Irish Governments have indicated that they will continue to subscribe to the European Union up until the date of any exit from current arrangements. Article 50 has not been activated and there is no prerequisite alternative course of action to be initiated. Clearly there are a plethora of administrative and legislative changes to be effected and considered. Meanwhile, from a CAWT perspective, all work will continue as scheduled.

6.2 North-South Ministerial Projects

It is noteworthy that there are other cross-border health projects that do not rely on EU funding and a number of them have been orchestrated through The North South

⁵⁶ Special EU Programmes Body Statement, July 2016, http://www.seupb.eu/NewsAndEvents/LatestNews/16-07-08/SEUPB_Statement_on_EU_referendum_decision.aspx

Ministerial Council (NSMC).⁵⁷ Since 2000, in the area of health, actions have focused on five key areas:

- Emergency planning;
- Accident and Emergency services;
- Cooperation on high technology equipment;
- Cancer research; and,
- Health promotion.

Two of the recent examples are now briefly outlined:

The Radiotherapy unit at Altnagelvin Area Hospital provides an example of cross-border provision in specialist care funded by the relevant Departments in NI and the Republic of Ireland. Planning permission for the new facility was granted in March 2013, and construction work began in July 2014. The Service will be managed by the Western Health and Social Care Trust, working with the Cancer Centre, Belfast, the Northern Health and Social Care Trust, and Letterkenny General Hospital.⁵⁸ The then Health Minister, Simon Hamilton, announced in March 2016 that £1.5million would be made available to allow for the recruitment of 35 posts to facilitate the opening of the Altnagelvin Radiotherapy Centre in autumn 2016.⁵⁹

In a second example, the first formal all-island clinical network has been established to treat congenital heart disease. On 3 March 2015, the then Ministers for Health in Northern Ireland and the Republic of Ireland, published the framework for the All-island Congenital Heart Disease Network based on proposals by an International Working Group (IWG).⁶⁰

The new all-island children's heart surgery network is to benefit from £42m worth of investment announced at the opening of a new hybrid cardiac catheterisation laboratory at Our Lady's Children's Hospital, Dublin. In the future, children from Northern Ireland and the Republic of Ireland will all receive treatment there. Children's heart surgery services at Belfast's Royal Victoria Hospital (RVH) ceased in 2015. The £42m investment includes contributions from both Northern Ireland and the Republic of Ireland health departments, £1m of which will enhance existing facilities in Belfast. The phased implementation of the transfer of all urgent surgical cases from Northern Ireland to the new Dublin centre should be complete by the end of 2017, with all elective surgical cases transferred by the end of 2018.⁶¹

⁵⁷ North South Ministerial Council (2006) *Welcome to the North South Ministerial Council* [Online] Available from: <http://www.northsouthministerialcouncil.org/>

⁵⁸ Western Health and Social Care Trust (2012) *Radiotherapy Unit Altnagelvin Hospital* [Online] Available from: <http://www.westerntrust.hscni.net/pdf/RadioT exhibit.pdf> [Accessed: 4 March 2015].

⁵⁹ Recruitment underway for new radiotherapy centre at Altnagelvin, Department of Health, Press Release, 24th March 2016, <https://www.health-ni.gov.uk/news/recruitment-underway-new-radiotherapy-centre-alt-nagelvin>

⁶⁰ Framework for All Island Clinical Network for Congenital Heart Disease, Department of Health, Republic of Ireland,

⁶¹ Children's heart surgery: £42m for all-island congenital heart disease service, BBC News, online, 4th July 2016, <http://www.bbc.co.uk/news/uk-northern-ireland-36708448>

7 Development and Licensing of Medicines

EU legislation provides a harmonised approach to medicines regulation across Member States and is intended to ensure a high level of public health protection and to promote the functioning of the internal market, including innovation.

It is based on the principle that the placing on the market of medicinal products is subject to a marketing authorisation by the competent authorities⁶²:

A large body of legislation has developed around this principle, with the progressive harmonisation of requirements for the granting of marketing authorisations since the 1960s...Community authorisation procedures (centralised, mutual recognition) are in place since the mid-90s and in addition the system is supported by a Community regulatory agency in charge of providing the EU institutions with scientific advice on medicinal products: the European Medicines Agency.

The marketing authorisation for medicinal products for human use, as well as the rules for the constant supervision of products after they have been authorised, are laid down in **Directive 2001/83/EC** and in **Regulation (EC) No 726/2004**.

The most recent revision of EU law in this area in 2004 established the **European Medicines Agency (EMA)** – a decentralised agency of the EU. The EMA is responsible for the scientific evaluation of human and veterinary medicines developed by pharmaceutical companies for use in the EU.

Each EU member state has its own medical regulatory body, in the UK's case the **Medicines & Healthcare Products Regulatory Agency (MHRA)**⁶³. In the UK, companies wanting to sell new drugs or devices have to get them licensed by the MHRA.

An alternative route for major pharmaceutical companies is to get approval through a centralised procedure from the EMA. Manufacturers of drugs to treat cancer and rare diseases often use this central approval route. The centralised authorisation is valid both in member states and countries in the European Economic Area (EU plus Iceland, Liechtenstein and Norway). The EMA is currently based in London and it is predicted that following Brexit the EMA will move its headquarters out of London to an EU country.⁶⁴

If the UK negotiates to stay in the EEA there would not, in practice, be much difference to regulation. If not, drug companies would need to go through a separate process with

⁶² Legal framework governing medicinal products for human use in the EU, EU Commission, http://ec.europa.eu/health/human-use/legal-framework/index_en.htm

⁶³ Medicines and Healthcare Products Regulatory Agency (MHRA), <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

⁶⁴ Reality Check: What might Brexit mean for medicines and clinical trials?, <http://www.bbc.co.uk/news/uk-politics-eu-referendum-36599417>

British regulators for new products as the centralised European route would no longer be applicable to the UK.

EU legislation also provides for common rules for the conduct of clinical trials in the EU. The EU Clinical Trial Regulation (EU-CTR) was approved in April 2014 and published and entered into force on 16 June 2014 – but will apply no earlier than 28 May 2016. The new legislation, once adopted, will take the form of a Regulation to ensure a greater level of harmonisation of the rules of conducting clinical trials throughout the EU. It replaces the EU Clinical Trials Directive (EUCTD), which was approved in 2001 and implemented in May 2004.⁶⁵

The harmonisation will allow a single point of entry for companies wishing to carry out trials of new drugs in different countries. Concerns have been expressed by the pharmaceutical industry that leaving the EU would result in loss of benefit to UK patient groups from certain drug trials.⁶⁶

8 Medical and Life Sciences Research and Innovation

Research and innovation is another area where the EU dimension is of particular interest to health and social care. This includes participation by NI universities and research teams, through competitive bidding, in the EU's research programme 'Horizon 2020'. 'Horizon 2020' is described as⁶⁷:

the biggest EU Research and Innovation programme ever with nearly €80 billion of funding available over 7 years (2014 to 2020) – in addition to the private investment that this money will attract... with its emphasis on excellent science, industrial leadership and tackling societal challenges. The goal is to ensure Europe produces world-class science, removes barriers to innovation and makes it easier for the public and private sectors to work together in delivering innovation.

Key areas of research that attract funding from 'Horizon 2020' are – food and healthy diet, health, social sciences and humanities and biotechnology. In addition, research in the area of the key societal challenge of health, demographic change and wellbeing has been highlighted.⁶⁸

Speaking at the recent NI Confederation for Health and Social Care annual conference⁶⁹, Colette Goldrick, Director of Association of the British Pharmaceutical

⁶⁵ What You Need to Know About the EU Clinical Trial Regulation, Pharmafile, 20/04/15,

<http://www.pharmafile.com/news/198121/what-you-need-know-about-eu-clinical-trial-regulation>

⁶⁶ McKenna, H., Five Big issues for Health and Social Care after the Brexit Vote, The King's Fund, 30 June 2016,

<http://www.kingsfund.org.uk/publications/articles/brexit-and-nhs>

⁶⁷ What is Horizon 2020, EU Commission, <https://ec.europa.eu/programmes/horizon2020/en/what-horizon-2020>

⁶⁸ Horizon 2020, EU Commission, <https://ec.europa.eu/programmes/horizon2020/find-your-area>

⁶⁹ NICON 2016, 28th June 2016, Cultural Evolution – Is the future in our own hands,

<http://www.nhsconfed.org/events/2016/06/nicon>

Industry NI, highlighted that Brexit will lead to diminished UK competitiveness in life sciences:

Academic researchers and Small and Medium Enterprises SMEs will find it more challenging to collaborate with EU experts. National funding will not replace lost European research funding. Limitations on the free movement of people will impact negatively on both UK and EU academic research and SMEs.

The Innovative Medicines Initiative (IMI) is another area where the UK may be impacted. IMI is a partnership between the European Commission and the European pharmaceutical industry (represented by the European Federation of Pharmaceutical Industries and Associations – EFPIA) which is⁷⁰:

working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need. It does this by facilitating collaboration between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators.

IMI is the world's biggest public-private partnership in the life sciences. During its first phase (2008-2013), IMI had a budget of €2 billion, half of which came from the EU's Seventh Framework Programme for research, and half of which came from 'in kind' contributions by EFPIA companies. Through the IMI 2 programme, it has a €3.3 billion budget for the period 2014-2024, with half coming from Horizon 2020, over €1.4 billion from EFPIA companies; and over €200 million can be committed by other life science industries or organisation as members or Associated Partners in individual projects.⁷¹

IMI currently has over 50 projects. Some focus on specific health issues such as neurological conditions, diabetes, lung disease, oncology, inflammation & infection, tuberculosis, and obesity. Others focus on challenges in drug development like drug and vaccine safety, sustainability of chemical drug production, use of stem cells for drug discovery, and antimicrobial resistance.⁷²

9 General Food Law

A series of food safety incidents in the late 1990s drew attention to the need to establish general principles and requirements concerning food and feed law at EU level. The European Commission developed an integrated approach to food safety 'from farm to table', covering all sectors of the food chain, including feed production,

⁷⁰ Innovative Medicines Initiative, <http://www.imi.europa.eu/content/mission>

⁷¹ EFPIA companies and other Associated Partners do not receive any EU funding, but contribute to the projects 'in kind', for example by donating their researchers' time or providing access to research facilities or resources.

⁷² Innovative Medicines Initiative, <http://www.imi.europa.eu/content/mission>

primary production, food processing, storage, transport and retail sale. This was to ensure protection of human life and consumers' interests in relation to food and the effective functioning of the internal market

In 2002, the European Parliament and the Council adopted **Regulation (EC) No 178/2002 (General Food Regulation)** laying down the general principles and requirements of food law. The General Food Law Regulation provides principles, requirements and procedures that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution. It also set up the European Food Safety Authority (EFSA) and created the main procedures and tools for the management of emergencies and crises as well as the Rapid Alert System for Food and Feed (RASFF).⁷³

10 Discussion

As stated earlier, health care systems in EU Member States are a matter of national responsibility and therefore health is not an area of major EU competence, particularly when compared to areas such as agricultural or environmental policy and law. The role of the EU in healthcare is largely limited to supporting member states to effectively deliver related policy and services.

In the UK health and social care is a devolved matter, with the Northern Ireland Executive, via the Department of Health, being responsible for the organisation and delivery of health and social care services and the protection and promotion of health.

However, the result of the EU referendum is not without potential impact in the health field and this briefing has covered a selected range of aspects of health care where Brexit has the potential to have an impact across the UK, and therefore for NI residents.

There are potential impacts for patients accessing unplanned care and certain planned care in another EU State (reciprocal access), healthcare staff (working hours of medical staff and mutual recognition of qualifications), the pharmaceutical industry (regulation of pharmaceuticals in order to market across the EU), research and innovation; and food safety.

In addition, for NI sharing a border with the Republic of Ireland, there are some specific likely impacts in the area of cross-border health and social care delivery as many of the past projects, although now main-streamed, have been initiated with EU funding. CAWT, the relevant organisation is at present co-operating with the Special EU Programmes Body (SEUPB) and the respective Departments of Health in Belfast, Edinburgh and Dublin in relation to ensuring a positive outcome to the implementation

⁷³ General Food Law, EU Commission, http://ec.europa.eu/food/safety/general_food_law/index_en.htm

of the Health & Social Care Measure in INTERREG VA in order to progress future projects planned in its 2014-2019 Strategic Plan.

The impact of the UK's vote to leave comes at a time of substantial operational and financial pressures on health and social care systems across the UK and particularly for NI during a period of significant reform of how services are delivered. At present, the NI Assembly, its Health Committee and the wider health and social care community are anticipating the publication of the report of the clinically-focused expert panel (chaired by Professor Rafael Bengoa)⁷⁴. The Bengoa report is currently with the Minister for Health, Michelle O'Neill MLA, who is due to present her vision of the way forward for the service in the Autumn of this year.

The Chief Executive of the NHS, Simon Stevens, has recently highlighted a new NHS Europe Transition Team to be established to work with the Westminster Cabinet Office and the Department of Health (England) regarding negotiations around health-related post-Brexit arrangements.⁷⁵ The team has been established to help ensure that UK negotiators are well informed and understand the impact on the NHS of the different exit models from the EU.

⁷⁴ Hamilton appoints Expert Panel to lead debate on delivering world class Health and Social Care for Northern Ireland, Department of Health, press release, 7/01/16, <https://www.northernireland.gov.uk/news/hamilton-appoints-expert-panel-lead-debate-delivering-world-class-health-and-social-care>

⁷⁵ Brexit: impact across policy areas (Edited by Vaughne Miller), House of Commons Library, Briefing Paper, Number 07213, 26 August 2016, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/CBP-7213>