The immediate futures of health law after Brexit: Law, "A-legality", and Uncertainty

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Abstract

The European Union is a rules-based international organisation, with an exceptionally dense legal system. Likewise, the ways in which EU law has effects in domestic law are determined by (constitutional) law. The legal rights and obligations entailed for state and 'third sector' entities, companies and human beings of some 45 years of membership have had significant effects on domestic health law across the UK, even though health per se is a national competence. That said, the EU's relationships with national legal orders are also determined by the politically possible. We therefore sketch the key legal questions for UK health law, and health law in each of the 'devolveds', in two possible immediate post-Brexit futures. By immediate future, we mean after 29 March 2019, the date on which the Article 50 TEU notification period ends. It will not be possible to answer these legal questions until the politics have crystallised into legal texts, which is not the case at the time we write. We go on to argue that the ways in which UK health law, policy and practice are currently determined by the UK's membership of the EU, coupled with the short time frame within which the future EU-UK relationship must be determined, mean that law may be expected to be less of a determinant in immediate post-Brexit futures than it is at present. Our principal conclusion is that the uncertainties that surround the process of Brexit mean that at a level of specific policy and practice, such as in areas of health law, we might expect a period of 'a-legality', where the legal position of actors does not necessarily determine or explain their actions.

INTRODUCTION

As with so many areas, legal uncertainty about health post-Exit Day is significant. Moreover, it is difficult even to determine the extent of the uncertainty. On 29 March 2019, we may see a significant rupture in the fabric of (health) law as we currently experience it in the UK.

Given the high levels of legal uncertainty, and the compressed time-period forced by the processes mandated by Article 50 TEU which requires that the UK will leave the EU by 29 March 2019 unless a further transition period is agreed, we want to argue

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that 'legal centrism' – at least in an unmodified form – is misplaced. Rather, we want to explore the idea – familiar from socio-legal studies – that a practical desire among relevant communities for continuity and stability may involve the side-lining or even ignoring of formal legal positions. Rather than the current situation in which law is centre-stage, we may see a period of 'a-legality', in which law is less determinative of social and economic relations than at present.

The article proceeds as follows. After a brief outline of what we encompass in post-Exit Day UK health law, we consider some of the literature on 'legal centrism' and how this applies in the context of EU law. The heart of the paper sets out the key legal questions for post-Brexit health law, policy and practice which will need to be answered once the relevant legal texts become available. Where it is possible to begin to answer those questions, we do so. Where appropriate, we refer readers to other articles in this special issue. Where there is legal text agreed in principle, we tentatively suggest what the answers would be, were that text to be legally adopted. But for the remainder, all we can do is set out the questions that will need to be answered, and indicate what the answers might be if certain possible futures are encapsulated in legal text. Here we consider two possible futures for post-Brexit health law: under a 'former Member State special relationship' and under no Withdrawal Agreement.

The multiple uncertainties revealed by this exercise lead us to the final section of the article. Here we argue that the temporal aspects of leaving the EU mandated by Article 50,[1] coupled with the particularly fragile domestic politics pertaining in Westminster under the May government,[2] and in that government's relationships with the devolved governments in Wales, and especially in Scotland and Northern Ireland,[3] are key to understanding health law immediately post Exit Day. As there is insufficient time for technical legal details to be thought through and put in place, and because EU law has become such an embedded part of UK health policy and practice, we expect that the law will be less of a reflection of reality in the immediate post-Brexit period in the context of health than it is now. What we envisage is a period of at least partial 'a-legality', where relationships seek to continue as before, even though the legal underpinnings for those relationships are either missing or

[1] See KA Armstrong, *Brexit Time* (CUP 2018); P Craig, 'The Process: Brexit And The Anatomy Of Article 50', in F Fabbrini (ed) *The Law and Politics of Brexit* (OUP 2017), Ch 3; Oxford Legal Studies Research Paper No 37/2017.

[2] For example, the outcome of the 2017 general election which left the Conservative government with a reduced majority and reliance on the Northern Irish Democratic Unionist Party. Also, continuing political pressure within the Conservative party from 'Tory remainers' and right wing groups such as the 'European Research Group'. See H Stewart, 'We're The Opposition': Rees-Mogg And His European Research Group' *The Guardian* (2018) https://www.theguardian.com/politics/2018/jul/20/opposition-jacob-rees-mogg-european-research-group-profile accessed 1 September 2018.

[3] See, e.g., S Douglas-Scott, 'Brexit and the Scottish Question' and J Doyle and E Connolly, 'Brexit and the Northern Ireland Question', in F Fabbrini (ed) *The Law and Politics of Brexit* (OUP 2017), Ch 6; J Hunt, 'Devolution' in M Dougan (ed) *The UK after Brexit: Legal and Policy Challenges* (Intersentia 2017).

highly uncertain. This leads us to our conclusion, that we should neither understate nor overstate the importance of law in post-Brexit health law, policy and practice.

EU HEALTH LAW AND LEGAL CENTRISM

Although the precise scope of EU health law and policy is determined slightly differently by different authors,[4] there is broad agreement about what it encompasses. EU law has affected health law, policy and practice in the UK through two main mechanisms: the adoption of binding EU legislation in health fields, and the application of measures of more general EU law in health contexts. The latter is longer standing; the former enjoys a higher profile in academic literature and policy discussions.

In brief, the scope of EU health law includes law affecting people (professionals, patients); products (medicines, devices, equipment) and substances of human origin (blood, organs, tissues, cells); health systems; and public health. EU law gives some entitlements to patients, to receive health care services across borders within the EU. EU law governs the entitlements of healthcare professionals to take up employment or provide services across borders in the EU, through mutual recognition of medical qualifications, and through the rights of EU citizens and their families to live in any Member State and be treated as if they were nationals of that state. EU employment law governs some aspects of the terms of employment of medical professionals, such as health and safety at work, including (controversially) working time. All products marketed within the EU have to comply with EU trade law, which sets regulatory standards to protect consumers and ensure fair competition between traders, at the same time as ensuring that products can move freely throughout the EU's single market unencumbered by customs duties or measures having an equivalent chilling effect on cross-border trade. These rules apply to medical devices and equipment used in the NHS. They include rules on

[4] TK Hervey and JV McHale, *Health Law and The European Union* (CUP 2004); TK Hervey and JV McHale, *European Union Health Law* (CUP 2015); TK Hervey, CA Young and LE Bishop (eds), *Research Handbook on EU Health Law and Policy* (Edward Elgar Publishing 2017) 165-176; A den Exter and TK Hervey (eds), *European Union Health Law*: Treaties and Legislation (Maklu 2012); E Mossialos and others (eds), *Health Systems Governance In Europe: the role of European law and policy* (CUP 2010); SL Greer and P Kurzer (eds), *European Union Public Health Policy: Regional and global trends* (Routledge 2012). HEGM Hermans, AF Casparie and JHP Paelinck,(eds) *Health Care In Europe After 1992* (Dartmouth 1992); CEM Normand and P Vaughan (eds), *Europe Without Frontiers: The Implications For Health* n *London School of Hygiene and Tropical Medicine Public Health Forum 1992* (Wiley 1993); E Randall, *The European Union And Health Policy* (Palgrave Macmillan 2001); TK Hervey, 'Mapping The Contours Of European Union Health Law And Policy' (2002) 8 European Public Law, p 69; R Busse, M Wismar and PC Berman (eds), *The European Union And Health Services: the impact of the single European market on member states* (IOS Press 2002); M McKee, E Mossialos and R Baeten (eds), *The Impact Of EU Law On Health Care Systems* (PIE - P Lang 2002); J W van de Gronden, 'The Treaty Provisions On Competition And Health Care', *Health Care and EU Law* (TMC Asser Press 2011), p 265; L Hancher and W Sauter, *EU Competition And Internal Market Law In The Health Care Sector* (OUP 2012); A De Ruijter *EU Health Law and Policy* (OUP 2019 forthcoming).

public procurement. EU law requires pre-market authorization for medicines being put on the market in the EU, including within national health systems, through processes involving the European Medicines Agency or national authorisation bodies such as the Medicines and Healthcare Products Regulatory Agency. EU law also regulates human blood, tissues, cells and organs, seeking to secure patient safety through traceability and accountability mechanisms. Many aspects of medical and pre-medical research are covered by EU law, including data protection, clinical trials, and animal testing. EU law has made some attempts to embed bioethical standards, for instance in its rules on patentability of biomedical inventions. Some products that are harmful to human health are carefully regulated by EU law: chemicals, food, tobacco and alcohol being the key cases in point. Products from outside may not lawfully enter the EU's market without complying with EU-determined standards. EU States which want to go further in protecting public health, by restricting certain types of trade practices, must justify their protective rules under EU law.[5] EU agencies coordinate Member States' action on communicable diseases, environmental factors, food safety and the like, including through exercising powers to take administrative decisions. The EU coordinates with international bodies in many of these areas, to seek to secure global standards, for instance for medicines, food safety, tobacco control and communicable disease prevention.[6]

Studies of health systems, policies and practices within the EU pay due attention to these aspects of EU law that determine obligations and entitlements of the various actors concerned. The law matters: it is a significant determinant of what happens and what is possible, for patients, health professionals, health care providers and national public health systems. Although health is a national competence, EU law has nevertheless had significant effects on a great deal (though not all) of national health law. These effects have increased during the UK's 45 years of membership of the EU. They have increased as EU law itself has developed to encompass an ever wider range of matters concerned with health. But more importantly, they have also increased as the effects on health law of EU law concerned with trade, competition, employment, development and other areas of EU competence have been better understood. Some of that change has been driven by litigation. Some involves primary EU legislation, binding and applicable in UK law through the European Communities Act 1972. Much involves the dense web of EU administrative action and secondary law-making, as well as articulation of soft norms through collaborative decision-making involving national, EU and international regulatory entities.

EU law is thus a significant element of normative ordering[7] for health policy and practice in the UK. EU law's particular constitutional qualities accentuate this

[5] The Scottish rules on alcohol pricing are a case in point.

[6] See TK Hervey and JV McHale, *European Union Health Law* (CUP 2015), Part IV, Chapter 16.

[7] See, eg, Twining's definition of law as 'a species of institutionalised social practice that is oriented towards ordering relationships between subjects ...', W Twining, *General Jurisprudence* (CUP, 2009), p

significance: in many instances, EU health law entitlements can be enforced by individuals (companies, human beings) in domestic courts. So, for instance, the ability of Mr Kohll to use litigation to secure dental treatment for his daughter in Germany, paid for by the Luxembourg health system,[8] sent shock waves through health policy circles. It led to Mrs Watts' successful (settled) litigation to have her hip operation in France paid for by the English NHS,[9] and eventually to a reduction in some waiting times for elective procedures such as hip replacements, as NHS England changed its practice to allow primary care trusts to contract with private hospitals in England with unused capacity.[10]

(EU) legal scholarship in general often operates on the assumption that the law, as set down by authorities such as legislatures and courts, determines the social reality.[11] And yet this kind of 'legal centrism' has been the subject of critique for decades, if not centuries.[12] The law and society movement in the US, and socio-legal scholarship in the UK and elsewhere, have been decentring law and legal text since at least the 1960s. For instance, Ellickson's *Order without Law*[13] shows how legal variations (in liability for cattle trespass) do not account for how people (neighbouring cattle ranchers) actually behave. Informal norms and established practices can be weightier than formal written laws as tools to explain or predict behaviour. The governance turn in legal scholarship in the US and beyond[14] offered alternatives to 'legal centrism' in EU legal scholarship.[15] This trend continues, with, for instance, recent studies offering accounts of the EU with both international law

117; see also K Sideri, *Law's Practical Wisdom: The Theory and Practice of Law Making in New Governance Structures in the European Union* (Ashgate, 2007).

[8] Case C-158/96 *Raymond Kohll v Union des caisses de maladie* EU:C: 1998:171, [1998] ECR 1-01931.

[9] Case C-372/04 *Yvonne Watts v Bedford Primary Care Trust and Secretary of State for Health* EU:C: 2005:784, [2006] ECR 1-04325.

[10] See TK Hervey, 'EU Health Law' in C Barnard and S Peers, *EU Law* (OUP 2017), pp 632-633.

[11] Every EU Law textbook is written on the basis of this (often unspoken) assumption. See further, e.g. M Cappelletti, et al, *Integration Through Law* (de Gruyter, 1985); JHH Weiler, 'The Transformation of Europe' (1991) 100 *Yale Law Journal* 2403–83; G Garrett, 'The Politics of Legal Integration in the European Union' 49 *International Organization* (1995) 171–81; G Garrett, RD Keleman and H Schultz, 'The European Court of Justice, National Governments and Legal Integration in the European Union' (1998) 52 *International Organization* 149–76; M Poiares Maduro, *We, the court: The European Court of Justice and the European Economic Constitution* (Hart, 1998).

[12] As Ellickson notes, the ideas date at least back to Tacitus, see R C Ellickson, 'The Aim of Order Without Law' (1994) 150 *Journal of Institutional and Theoretical Economics* 97-100 at 98.

[13] R C Ellickson, *Order without Law: How Neighbours Settle Disputes* (Harvard University Press, 1991); see also R C Ellickson, *The household: informal order around the hearth* (Princeton University Press, 2008); B Yngvesson, 'Beastly Neighbours: Continuing Relations in Cattle Country' (1993) 102 *Yale Law Journal* 1787–801; B Yngvesson, 'Making Law at the Doorway: The Clerk, the Court and the Construction of Community in a New England Town' (1988) 22 *Law and Society Review* 409–48; P Ewick and SS Silbey, *The Common Place of Law: Stories from Everyday Life* (University of Chicago Press 1998).

[14] See, e.g., O Loebel, 'The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought' (2004) 89 *Minnesota Law Review* 262–390; CF Sabel and WH Simon, 'Destabilization Rights: How Public Law Litigation Succeeds' (2004) 117 *Harvard Law Review* 1015–101; G de Búrca and J Scott (eds), *Law and New Governance in the EU and the US* (Hart, 2006); J Scott

and international relations in centre-frame.[16] Law is not the only thing that matters, and law does not provide all the explanation we need to understand contemporary developments, or to undertake informed analysis of likely futures.

That said, neither do we want to *understate* the importance of law. The EU is a rules-based organisation, and its interactions with its Member States and with 'third countries' (states outside the EU) are based on legal texts, and legal rules about the EU's competences. The EU's claim to be a body based on the rule of law is stronger than that of other international organisations. The breadth and depth of EU law-making, and the particular deference or accommodation given to the Court of Justice of the EU by domestic courts and courts of other organisations, such as the European Court of Human Rights, account for the difference.

Moreover, some literature that decentres law pays insufficient attention to the ways that legal and non-legal logics interact,[17] and especially roles of law as a 'shadow'[18] or 'backstop' to what appear to be informally or extra-legally determined relations.[19] Even if law is not determinative of ordinary relationships, the possibility of recourse to law, and especially litigation, sits in the background, and conditions behaviours in important ways.

More recently, sociolegal scholarship has begun to take account of the roles of legal texts in a different way from 'classical' or 'doctrinal' legal centrism. This newer scholarship seeks to explore how legal texts themselves act on social realities,

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and S Sturm, 'Courts as Catalysts: Re-Thinking the Judicial Role in New Governance' (2007) 13 *Columbia Journal of European Law* 565–94; D NeJaime, 'When New Governance Fails' (2009) 70 *Ohio State Law Journal* 323–99; N Gunningham, 'The New Collaborative Environmental Governance: The Localization of Regulation' (2009) 36 *Journal of Law and Society* 145–66.

[15] See, e.g. J Scott and DM Trubek, 'Mind the Gap: Law and New Approaches to Governance in the European Union' (2002) 8 *ELJ* 1–18, at 9–15; G de Búrca and J Scott (eds), *Law and New Governance in the EU and the US* (Hart, 2006); G de Búrca and J Scott (eds) *Narrowing the Gap? Law and New Approaches to Governance in the European Union* (2007) Special Issue 13(3) *Columbia Journal of European Law*; T Hervey, 'The European Union's governance of healthcare and the welfare modernization agenda' 2 *Regulation and Governance* (2008) 103–20; T Hervey, ' "Adjudicating in the Shadow of the Informal Settlement"?: The Court of Justice of the European Union, "New Governance" and Social Welfare' Vol 63 *Current Legal Problems* (2010) 92-152; C.F. Sabel and J. Zeitlin (eds) (2010) *Experimentalist Governance in the European Union: Towards a New Architecture* (OUP); M Dawson (2011) 'Three Waves of New Governance in the European Union', *European Law Review*, 36, 208-226; M Dawson, *New Governance And The Transformation Of European Law* (CUP 2011).

[16] D Hodson and I Maher, *The Transformation of EU Treaty Making* (CUP 2018).

[17] LB Edelman, C Ugger and HS Erlanger, 'The Endogeneity of Legal Regulation: Grievance Procedures as Rational Myth' (1999) 105 *American Journal of Sociology* 406–54; LB Edelman and MC Suchman, 'When the "Haves" Hold Court: Speculations on the Organizational Internalization of Law' (1999) 33 *Law and Society Review* 941; L Edelman, 'Overlapping Field and Constructed Legalities: The Endogeneity of Law' in J O'Brien (ed), *Private Equity, Corporate Governance, and the Dynamics of Capital Market Regulation* (World Scientific, 2007); W Heydebrand, 'Globalisation and the Rise of Procedural Informalism in American and European Law', in V Gessner and D Nelken, *European Ways of Law: Towards a European Sociology of Law* (Hart, 2007).

[18] R Mnookin and L Kornhauser, 'Bargaining in the Shadow of the Law: The Case of Divorce' (1979) 88 *Yale Law Journal* 950–97.

particularly through the mechanism of metaphor.[20] Work in this vein is in its infancy in EU law.[21] It has much to offer those, like us, who seek to strike a balance between both the over- and under-statement of the importance of law, and to apply those insights to particular domains of policy and practice, here health. But its methods do rely on the existence of legal texts, so we are unable to contribute to it in this article.

TWO POST-BREXIT FUTURES FOR HEALTH LAW, POLICY AND PRACTICE IN THE UK

As we write in July and early August 2018, there is no agreed legal text between the EU-27 and the UK on the terms of the UK's withdrawal from the EU. There is political agreement on a draft treaty between the EU and the UK (called the Withdrawal Agreement),[22] but the principle that 'nothing is agreed until everything is agreed' is a central part of the European Commission's negotiating mandate,[23] and has been stressed at every stage of the negotiations so far. Far from being an agreed legal text, there is not even political agreement on a future EU-UK relationship or set of relationships, either within the UK government,[24] or between the EU and the UK.[25]

There is existing EU law on the position of 'third countries' in EU law, concerning products seeking to enter the EU's single market from such third countries;[26] and

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[19] See, e.g. H Ross, *Settled Out of Court: The Social Process of Insurance Claims and Adjustment* (New York: Aldine Publishing, 1970); O Fiss, 'Against Settlement' (1984) 93 *Yale Law Journal* 1073; M Galanter, 'Reading the Landscape of Disputes: What we know and don't know (and think we know) about our allegedly contentious and litigious society' (1983) 31 *University of California Los Angeles Law Review* 4–71; B Bercusson, 'Maastricht: A fundamental change in European Labour Law' (1996) 23 *Industrial Relations Journal* 177–90; RH Steinberg, 'In the Shadow of Law or Power? Consensus-Based Bargaining and Outcomes in the GATT/WTO' (2002) 56 *International Organization* 339–374; G Subramanian, 'Bargaining in the Shadow of Takeover Defenses' (2003) 113 *Yale Law Journal* 621–86; S Macaulay, 'Freedom from Contract: Solutions in Search of a Problem' (2004) *Wisconsin Law Review* 777–820; D Campbell, 'The Relational Constitution of Remedy: Co-operation as the Implicit Second Principle of Remedies for Breach of Contract' (2005) 11 *Texas Wesleyan Law Review* 455–80; EU Petersmann, *Reforming the World Trading System: Rule-Making, Trade Negotiations, and Dispute Settlement* (OUP, 2005); L T Alexander, 'Stakeholder Participation in New Governance: Lessons from Chicago's Public Housing Reform Experiment' (2009) 16 *Georgetown Journal on Poverty Law and Policy* 117–85; GC Shaffer, 'How Business Shapes Law: A Sociolegal Framework' (2009) 42 *Connecticut Law Review* 147–82.

[20] A Riles (2005)'A New Agenda for the Cultural Study of Law: Taking on the Technicalities', *Buffalo Law Review* 53, 973-1033; M Valverde, 'Jurisdiction and Scale: Legal "Technicalities" as Resources for Theory (2009) 18 *Social and Legal Studies* 139; A Riles (2011) Collateral Knowledge: Legal Reasoning in the Global Financial Markets (University of Chicago Press); D Cowan, C Hunter, H Pawson, (2012) 'Jurisdiction and scale: rent arrears, social housing and human rights', *Journal of Law and Society*, 39, 269-295; D Cowan and D Wincott, (eds), *Exploring the Legal in Social Legal Studies* (Palgrave Macmillan 2016); D Gurnham, (ed), 'Law's metaphor' 43 *Journal of Law and Society* (2016); M Hanne and R Weisberg, (eds) *Narrative and Metaphor in the Law* (CUP 2018).

[21] See A Cohen, and A Vauchez, (2011) 'The Social Construction of Law: The European Court of Justice and Its Legal Revolution Revisited', *Annual Review of Law and Society*, 7, 417-431; P Craig, (2013) 'Pringle and Use of EU Institutions Outside the EU Legal Framework: Foundations, Procedure and

people from outside the EU seeking to work, provide and receive services in, and to visit EU countries.[27] There is existing UK law on the position of people who are not EU nationals.[28] There is newly adopted UK law on the constitutional position of EU law in the UK's legal system immediately post-Exit Day in the form of the EU (Withdrawal) Act 2018. There is some UK law in the pipeline. The Taxation (Cross Border Trade) Bill ('Customs Bill') is in the House of Lords and the Trade Bill has completed its third reading in the House of Commons. An Immigration Bill is promised for autumn 2018. A 'Withdrawal Agreement and Implementation Bill' has also been promised to implement the major elements of the Withdrawal Agreement.

As we still do not have any agreed legal texts, either on the Withdrawal Agreement, or on the future EU-UK relationship(s), we can answer only a few questions about the legal relationships in post-Brexit health policy and practice (post-Brexit health law). What we can do, however, is set out the questions that will need to be answered once we have the legal text. We do this below, and where feasible, we also indicate what the answers might be if certain possible futures are encapsulated in legal text.

Substance', *European Constitutional Law Review*, 9, 263-284; PJ Cardwell and T Hervey, 'The roles of law in a new intergovernmentalist EU' in C Bickerton, D Hodson and U Puetter, *The New Intergovernmentalism: States and Supra-National Actors in the Post-Maastricht Era* (OUP 2015) 73-89; PJ Cardwell and T Hervey, 'Bringing the Technical into the Socio-Legal: The Metaphors of Law and Legal Scholarship of a Twenty-First Century European Union' in D Cowan and D Wincott, eds, *Exploring the 'Legal' in Socio-Legal Studies* (Palgrave Macmillan 2016) 157-182.

[22] Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community highlighting the progress made (coloured version) in the negotiation round with the UK of 16–19 March 2018, TF50 (2018) 35 – Commission to EU27.

[23] European Council (Art.50) guidelines for Brexit negotiations, 29 April 2017, P.3, 1. (2) Core principles.

[24] See White Paper: HM Government, *The Future Relationship Between the United Kingdom and The European Union* (July 2018). This remains a source of much disagreement across parties and within the Conservative party itself. The EU has not yet formally responded but has indicated that many of the proposals will be unworkable. See DM Herszenhorn and M De La Baume, 'Barnier Dismantles UK's Brexit White Paper' *Politico* (2018) https://www.politico.eu/article/michel-barnier-brexit-white-paper-analysis/ accessed 1 September 2018.

[25] See 'Steps of doom' slide presented by Michel Barnier, European Commission Chief Negotiator to the Heads of State and Government at the European Council (Article 50) on 15 December 2017: https://ec.europa.eu/commission/sites/beta-political/files/slide_presented_by_barnier_at_euco_15-12-2017.pdf and the mismatch with the proposals in the July 2018 White Paper which continues to maintain UK 'red lines' of an independent trade policy, regulatory autonomy and no free movement, all of which would result in a 'No deal' response from the EU.

[26] For instance, consumer products, medicines and food sold in the EU must meet safety standards.

[27] See for example, blogs: D Acosta, 'The Security Of The Status Of Long-Term Non-EU Residents In The EU: Some Thoughts On Case C-636/16 *Lopez Pastuzano*' http://eulawanalysis.blogspot.com/2017/12/the-security-of-status-of-long-term-non.html accessed 1 September 2018;
Steve Peers, 'UK Citizens In The EU After Brexit: Securing Unilateral Guarantees After A 'No Deal' Brexit' http://eulawanalysis.blogspot.com/2018/07/uk-citizens-in-eu-after-brexit-securing.html accessed 1 September 2018.

[28] Immigration Act 2016.

We consider the most important legal questions which arise in four separate categories of UK health policy and practice relating to: people (healthcare professionals and patients); medicines, medical devices and substances of human origin; public health; and the devolved jurisdictions. We are not claiming to be exhaustive, but to illustrate the most significant issues.

For the purpose of this article, we model two futures for post-Brexit health law: a Former Member State Special Relationship; and No Withdrawal Agreement. The latter is the "no deal" scenario if negotiations break down. At the time we write, these are the only two options on the table. (Further options might be no Brexit at all, or a further extension of the transition period. Both have been ruled out by the May government and would in any case require EU agreement.)

To model a Former Member State Special Relationship, we draw on the May government's July 2018 White Paper,[29] as this indicates the UK's negotiating position at this time, albeit that the terms have been heavily criticised by both Remainers and Leavers, and led to the resignation of senior ministers David Davis and Boris Johnson. For its part, the EU negotiating team led by Michel Barnier has indicated that many points in the White Paper will be unacceptable. In an article of this length we have been unable to consider rules under EEA and EFTA, or the existing EU-Switzerland arrangements. Where there is enacted law (existing EU law on the status of "third countries"; the UK's EU (Withdrawal) Act 2018), we analyse its effects. Where text has been agreed in principle (parts of the Withdrawal Agreement), we consider what the effects would be if that text became legally binding.

The second possible future we consider is where no Withdrawal Agreement between the EU and UK is agreed. In this case, the proposed 2019-2020 transition period would not take place. In the absence of any other arrangements being agreed, the UK-EU relationship would fall back on WTO arrangements with regard to products and services. As so few countries in the world trade on that basis alone, it is extremely difficult to discern the effects on health policy and practice. UK citizens in the EU would be treated as "third party nationals" under applicable EU law. EU citizens in the UK would fall under UK domestic immigration law.

With either scenario, the EU (Withdrawal) Act 2018 will secure continuity of application of existing EU law *within* the UK, as 'retained EU law'. What differs – significantly – between the scenarios is the effect of law on relations *between* actors in the EU-27 and those in the UK.

PEOPLE (PROFESSIONALS, PATIENTS)

[29] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018).

RETENTION/RECRUITMENT OF HEALTHCARE WORKERS FROM R-EU COUNTRIES

Background

Large numbers of staff from EU-27 countries currently work in the UK NHS and in social care. The most recently available figures[30] showed that 61,974 EU-27 national staff are working in the NHS.[31] There is particularly high reliance on these staff in London where they represent 12% of the total[32]. In September 2017, around 90,000 EU-27 staff were working in social care[33] in the UK, with rural areas being highly dependent on these staff to meet demand. In many areas, posts remain unfilled.

Stated government policy is for the UK to become self-sufficient in clinical staff and additional training places have been created. However, such self-sufficiency is unlikely to be achieved for at least 10-12 years[34], if ever:

> *The requirement for the UK to maintain an immigration system which facilitates swift entry to the UK for the health and social care workforce is likely to continue for many years, despite the Government's increased investment in medical training and the expansion of nurse training posts. This is a particularly acute concern in adult social care where some parts of the country are highly dependent on EU migrants.*[35]

There are serious concerns that Brexit will lead to a failure to retain, and inability to recruit, sufficient clinical staff and social care workers. The former are needed not just to meet hospital and community health staffing needs, but also because highly skilled professionals with global expertise and experience will strengthen the quality of the service provided. Care workers may be lower paid and less qualified but they have a high social value, and an increasingly ageing population means that need will continue to increase. Nursing, but not care work, is on the shortage occupation list of the Migrant Advisory Committee.[36] If Brexit leads to large numbers of elderly UK pensioners returning to live in the UK, this is likely to put further strain on NHS and social care staffing needs.

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[30] NHS Digital, 'NHS Workforce Statistics, September 2017, Provisional Statistics' (NHS Digital 2017) https://digital.nhs.uk/data-and-information/publications/statistical/nhs-workforce-statistics/nhs-workforce-statistics-september-2017-provisional-statistics accessed 2 September 2018.

[31] C Baker, 'NHS staff from overseas: statistics', (HC Briefing Paper Number 7783, 7 February 2018) 6.

[32] C Baker, 'NHS staff from overseas: statistics', (HC Briefing Paper Number 7783, 7 February 2018) 4.

[33] HC Health Committee 'Brexit and social care – people & process', 8th Report [Session 2016-17] para 28.

[34] HC Health Committee, 'Brexit and social care – people & process', 8th Report [Session 2016-17) para 54.

[35] HC Health Committee, 'Brexit and social care – people & process', 8th Report [Session 2016-17] para 61.

[36] The Migrant Advisory Committee is an independent, non-statutory, non-time limited, non-departmental public body that advises the government on migration issues. It is sponsored by the Home Office: https://www.gov.uk/government/organisations/migration-advisory-committee.

A further concern is the impact of Brexit on research scientists. Here there is of course an overlap between highly specialist clinical care and biomedical research. The UK currently enjoys a global reputation as a leader in scientific research. The UK has received significant research funding from the EU, including from the Horizon 2020 programme, with the UK having received 15% of all funding to date, totalling around €4 billion.[37] Unless specifically agreed, the UK will no longer be eligible for such funding, and its potential to collaborate on major research projects will be limited. There are considerable concerns about the adverse impact on the UK's reputation, the financial loss to UK research institutions, and the fear that there will be an exodus of leading research scientists from the UK.

Issues and Legal Questions - Some Answers but Many Legal Uncertainties

The principal issues concerning people arise from uncertainty over rights of health and social care professionals and workers from the EU-27, and their families, to enter the UK, to continue to reside in the UK, and to enjoy associated rights such as owning property, transferring pensions or capital, accessing education and housing. It is difficult to quantify or predict the effects of a change in status from 'EU citizen' to 'third country national', particularly where these are affect-based, rather than derived from the content of rights. There have been numerous reports that EU-27 nationals in the UK feel undervalued, and a consequent fall in morale of those health and social care workers.

The emerging legal landscape has exacerbated these feelings. This includes the bureaucratic processes entailed in applying for permanent UK residency.[38]

> *The existing immigration system is characterised by bureaucratic and financial barriers to recruitment from outside the EU which do not currently exist for those from inside the EU. If such a system was extended to R-EU after Brexit it would create serious problems for the health and care sector*.[39]

It also includes the much-miscommunicated requirement for Comprehensive Sickness Insurance for non-economically active EU migrants, which affects spouses or partners of healthcare workers (potentially up to 1 million people[40]) and is a

[37] Department for Business, Energy & Industrial Strategy, 'UK Participation in Horizon 2020' (HM Government 2018).

[38] Eligibility for permanent residence requires proof of residence in the UK for 5 years, and the applicant usually needs to be either working or financially self-sufficient. An applicant will be ineligible if they are financially dependent on a family member, or financially responsible for any other family members. A new criterion of "settled status" will be introduced in March 2019: https://www.gov.uk/uk-residence-eu-citizens, accessed 2 August 2018.

[39] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] para 66.

[40] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] para 49.

leading cause of rejection of permanent residency; and uncertainty over continued recognition of foreign professional qualifications. Uncertainty about research funding has led to concerns about an exodus of leading research scientists, including in biomedicine.

Key legal questions that arise are: What will be the rights of EU-27 and EEA nationals already in the UK after May 2019? Will health and social care workers be treated differently in terms of migration status to workers in other sectors? If so, how? Will health and social care workers from EU-27 countries or EEA countries be treated differently to such workers from outside the EEA? If so, how? The *basis* of the migration rights of current health and social care workers from EEA countries, and their families, will change after May 2019, but will the *content* of those rights remain the same or similar?

Given that highly skilled specialists from EEA countries can have a beneficial impact on the quality of UK healthcare, how will they be encouraged to work in the UK? As social care workers are not on the shortage occupation list in UK migration law, how will they be recruited in sufficient numbers for current needs – whether from the UK or from other countries? Given the current, and likely future, increased shortfall in clinical staff, are there any plans to change the law to incentivise expansion of training places? Similarly, are there plans to change the law to avoid an exodus of leading biomedical research scientists from the UK, given the future impact of reduced research funding?

Many of these questions are matters of UK immigration law, and to date, no post-Brexit Immigration Bill has been presented. Publication of an immigration White Paper has been delayed several times and is now promised for the end of 2018, with an Immigration Bill in early 2019 to set rules which will come into force in 2021.[41] The rights of EU-27 and EEA nationals in the UK post-March 2019 is of course unilaterally in the control of the UK government and legislature, but to date no unilateral guarantees have been given. Rather, the position of those people has been conceptualised as a bi-lateral matter, of reciprocity, leading to claims that human beings are being used as 'bargaining chips' in the Brexit negotiations.[42]

Former Member State Special Relationship

[41] HC 434 Oral evidence given by Rt Hon Amber Rudd MP, Home Secretary to the Affairs Select Committee, 28 March 2018.

[42] See for example, J Quint, 'I will not be used as a bargaining chip in the Brexit negotiations' *Independent* (2 March 2017) https://www.independent.co.uk/voices/letters/brexit-house-of-lords-theresa-may-brexit-bill-eu-nationals-a7608061.html accessed 3 September 2018;
T Bueltman, 'The Tories tell us the rights of EU citizens are now secure. It's a lie' *The Guardian* (8 December 2017) https://www.theguardian.com/commentisfree/2017/dec/08/eu-citizens-rights-brexit-bargaining-chips accessed 3 September 2018;
T Colson, ' British citizens living in Europe will lose key freedoms and rights next year' *Business Insider UK* (6 June 2018) http://uk.businessinsider.com/britons-living-in-europe-fear-losing-rights-during-brexit-withdrawal-2018-6 accessed 3 September 2018.

The status of EU workers in the UK and vice versa, post-Brexit, is a particular cause of anxiety for these citizens. The concerns are partly answered in the Joint Reports of the phase 1 negotiations,[43] although of course these have not (yet) resulted in an agreed legal text. If the Withdrawal Agreement is agreed on these terms, citizens and their families who are legally residing in either region before the end of the transition period will be entitled to continue to do so, during the transition period, which ends at the end of December 2020.[44] The basis of their rights during that time will be the Withdrawal Agreement, and its implementation in national/EU law, rather than EU law itself, with all that entails for the enforceability of rights. The negotiators are yet to reach agreement on dispute settlement.[45] Thus, it is not clear whether the Withdrawal Agreement will preserve the current direct and indirect effect of rights under it in the UK. International agreements occasionally have direct effect in EU law, and are a point of interpretative consistency.[46] The EU (Withdrawal) Act suggests that direct effect will no longer apply to 'retained EU law', but it is not explicit on the constitutional status of the EU-UK Withdrawal Agreement in UK law. Another Act, required by the EU (Withdrawal) Act,[47] but as yet not available even as a White Paper, is expected to deal with that matter. In general, international treaties are not directly enforceable in UK law, although when courts interpret domestic legislation they presume that Parliament intends to comply with the UK's international obligations.[48]

The status of health and social care workers from EU-27 and EEA countries in the UK after 2020 is even less clear. The EU's negotiating position is that the single market is indivisible, and so free movement of people would need to be guaranteed by the UK in any future relationship that sought free movement of products and services. The EU has also so far held firm that there will be no 'sector by sector'

[43] European Commission and the United Kingdom Government, 'Joint Report from the Negotiators Of The European Union And The United Kingdom Government on progress during Phase 1 of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union' (European Commission 8 December 2017); European Union and the United Kingdom, 'Joint Statement from the negotiators of the European Union and the United Kingdom Government on progress of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union' (19 June 2018).

[44] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018) p 32.

[45] European Union and the United Kingdom, 'Joint Statement from the negotiators of the European Union and the United Kingdom Government on progress of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union' (19 June 2018).

[46] For discussion see, e.g. P Eeckhout, *EU External Relations Law* (OUP 2011); PJ Kuijper and others, *The Law Of EU External Relations: cases, materials, and commentary on the EU as an international legal actor* (OUP 2013).

[47] See EU (Withdrawal) Act 2018, section 7(2), which requires a further Act to bring into effect the EU-UK Withdrawal Agreement, if successfully negotiated.

[48] For example, *Ghaidan v Godin-Mendoza* [2004] 2 AC 557.

agreements.[49] But human migration appears to be a 'red line' for the UK. The May government has stated:

> *Any future mobility arrangements will be consistent with the ending of free movement, respecting the UK's control of its borders and the Government's objective to control and reduce net migration…the UK will make a sovereign choice in a defined number of areas to seek reciprocal mobility arrangements with the EU, building on current WTO GATS commitments…*[50]
>
> *The UK will also discuss how to facilitate temporary mobility of scientists and researchers, self-employed professionals, employees providing services, as well as investors.*[51]

Barnier's 'steps of doom' slide[52] suggests that, because of the May government's 'red lines', the best the UK can hope for in terms of a future relationship with the EU is one modelled on a free trade agreement such as the EU-Canada agreement, which has extremely limited elements of human migration.[53] The UK has conceptualised matters differently, seeking, as a former Member State, to have a relationship with the EU that is different from any other state, embracing some elements of reciprocity but ending free movement of people. The UK's approach is thus politically challenging, to say the least.

No Withdrawal Agreement

If there is no Withdrawal Agreement, UK domestic law will apply to EU-27 and EEA nationals in the UK. The May government has said that it is keen to continue to attract skilled workers from overseas, and it will need to do so to meet NHS and social care staffing requirements. But until the promised post-Brexit Immigration Bill is presented, it is deeply unclear how the government will reconcile the

[49] European Council of the European Union, 'European Council (Art.50) Guidelines for Brexit negotiations' (2017) http://www.consilium.europa.eu/en/press/press-releases/2017/04/29/euco-brexit-guidelines/ accessed 3 September 2018.

[50] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018) section 1.4.2 Future mobility arrangements, para 76.

[51] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018) section 1.4.2 Future mobility arrangements, Business and services, para 81

[52] See 'Steps of doom' slide presented by Michel Barnier, European Commission Chief Negotiator to the Heads of State and Government at the European Council (Article 50) on 15 December 2017: https://ec.europa.eu/commission/sites/beta-political/files/slide_presented_by_barnier_at_euco_15-12-2017.pdf.

[53] Comprehensive Economic and Trade Agreement, Chapter 10: Temporary entry and stay of natural persons for business purposes. This facilitates entry for certain business persons who are citizens of Canada and EU member states by removing the requirement for Labour Market Impact Assessments. The categories of visitors may be Key personnel; Contractual service suppliers and independent professionals; or Short-term business visitors: https://www.canada.ca/en/immigration-refugees-citizenship/corporate/publications-manuals/operational-bulletins-manuals/temporary-residents/foreign-workers/international-free-trade-agreements/canada-eu.html.

competing political demands of reducing immigration and ending free movement of people, yet also retaining and recruiting not only skilled healthcare workers, but also less qualified but socially valuable care workers.

MUTUAL RECOGNITION OF FOREIGN QUALIFICATIONS

Background

The regulation of medical professionals is covered by the Mutual Regulation of Professional Qualifications (MRPQ) Directive 2005/36/EC which provides for automatic recognition of the formal qualifications of specified health professionals, such as doctors, midwives and nurses.[54] These professionals do not need to show any other proof of fitness, apart from linguistic ability, in order to practise their profession in another EU Member State. Other medical professionals, such as physiotherapists, are also covered under a different part of the Directive, which requires mutual recognition of equivalent qualifications.

The General Medical Council and Nursing and Midwifery Council see Brexit as an opportunity to introduce a common assessment of competency testing (to include testing of doctors, nurses and midwives trained in the UK).[55] But they also warn against future non-alignment with EU standards. The Royal College of Nursing has warned that the MRPQ Directive includes language checks and a duty to inform other health regulators about suspended or banned professionals:

> *We are concerned that a potential disassociation from these jointly developed standards could lead to a loss of safeguards, loss of access to alert mechanisms, and other exchange between regulators and potentially much slower recognition mechanisms for both inward and outward mobility*.[56]

Here, the Brexit process is taking place alongside a consultation on domestic law reform on health professional regulation.[57] Thus Brexit could be used to circumvent

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[54] Doctor, specialised doctor, nurse, dental practitioner, specialised dental practitioner, pharmacist, midwife: TK Hervey and JV McHale, *European Union Health Law* (CUP 2015)142-143.

[55] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] paras 72-75

[56] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] para 78.

[57] See consultation paper: Department of Health, 'Promoting Professionalism, Reforming Regulation.' (2017) and responses from the RCN: *Royal College Of Nursing Response To The Department Of Health And Social Care Consultation Promoting Professionalism, Reforming Regulation* (RCN 2018) https://www.rcn.org.uk/-/Media/Royal...Of.../Consultation-Responses/.../Conr-5217.Pdf; and AHCS: JS Stevens, Chair, AHCS Board; P Le Rolland, Chair, AHCS Regulation Council and B Cooper, President to UK Healthcare Professional Regulatory Reform Team, Department of Health, "Consultation 'Promoting Professionalism, Reforming Regulation'. The Response from the Academy for Healthcare Science" (23 January,2018).

normal law reform processes. The House of Commons Health Committee has advised that:

> *The Government is considering new primary legislation to reform the professional regulation of health and social care and this should be the vehicle to reform the implementation of the MRPQ directive in UK law. It should not be amended using delegated legislation under provisions granted by the 'Great Repeal Bill' ... it would not be in the interests of patients to lose access to the alert mechanisms which identify potentially dangerous practitioners and which exist as a central part of EU law on mutual recognition of qualifications.*[58]

Issues and Legal Questions - Some Legal Answers but Many Legal Uncertainties

Post-Brexit, the UK will continue to need to ensure consistently high professional standards of both UK and non-UK trained health professionals in order to protect patient safety, and also avoid harm to the public purse if standards are not met and expensive settlements ensue. There have been suggestions that the UK could benefit from departing from EU standards under the MRPQ Directive, but these do not take account of the UK's need to continue to recruit health care professionals from outside the UK. Ideally, to meet those needs and protect patient safety, the UK would continue to have access to alert mechanisms through which EU Member States share information about potentially dangerous practitioners. Furthermore, if the UK is to continue as a place that is attractive to build a bio-medical professional career, there will be a need to ensure that UK health qualifications continue to be recognised in other countries.

Will UK legislation remain aligned with EU law on medical qualifications? If not, will changes be made by primary or delegated legislation? What will they entail? Which medical professionals will be affected and how? As the UK will continue to employ medical professionals from EU-27 and EEA countries for the foreseeable future, what alert mechanisms, if any, will be in place to secure patient safety? What, if any, bilateral arrangements will be agreed with the EU to ensure continuing and future recognition of medical qualifications of UK-qualified health professionals working in the EU and vice versa?

Former Member State Special Relationship

If the Withdrawal Agreement is agreed, this will secure continued mutual recognition of qualifications for the duration of the transitional period, unless or until the UK changes those rules with which the UK currently complies in setting out the bases for qualification as a health professional in the UK. The points made above

[58] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] paras 83-84.

about the lack of clarity or enforceability of the Withdrawal Agreement also apply here, obviously.

The issue of mutual recognition of professional qualifications into the future is also addressed in section 1.3.2 of the July 2018 White Paper. The May government seeks a future partnership with the EU that includes "ambitious provisions for the recognition of professional qualifications". The UK proposal is for a system that

> *is predictable and proportionate, enabling professionals to demonstrate that they meet the necessary requirements, or to undertake legitimate compensatory measures where there is a significant difference between qualifications or training, in a timely way; and*
>
> *provides transparency, with cooperation between regulators to facilitate the exchanges of information about breaches of professional standards, and to review changes to professional qualifications over time.*

This suggests that post-Brexit the May government does intend to introduce a new system of competency testing for health professionals, and a concern that the UK should continue to be part of alert mechanisms. However, the White Paper provides no specifics on the professional standards that would be required or the professions affected. While rejecting the legal rules securing mutual recognition under EU law, and under EEA law, the White Paper simultaneously stresses that the new system "should not be constrained by existing FTA precedents" which only seek to have processes for specific negotiated recognition agreements of third country professionals, but which do not provide for *mutual* recognition, and the enforceability of EU law and EEA law.

If the competency standards of multiple professions are to be reviewed and mutual recognition agreements negotiated separately, this could take a considerable time to be resolved, especially if all key stakeholders are involved, including the professions and patient groups/NGOs, as well as the general public. In the meantime, for EU-27 nationals in the UK, the EU (Withdrawal) Act provides the basis of rights as 'retained EU law'. But post-2020 the legal position of UK health professionals seeking recognition of their qualifications to work in the EU-27 will remain unclear until it is specified in the legal texts pertaining to the future EU-UK relationship(s).

No Withdrawal Agreement

If no Withdrawal Agreement is agreed, UK nationals in EU-27 countries will no longer be nationals of an EU Member State or hold a qualification from an EU Member State, so will no longer have rights under the MRPQ Directive in EU law.

They will be considered to be 'third country nationals' and covered by domestic law in each EU-27 Member State.[59]

The EU (Withdrawal) Act will mean continuity of recognition of professional qualifications from EU-27 countries in the UK, unless and until the UK domestic law changes. It is unclear for how long the UK might continue to follow the MRPQ Directive, given that it has already stated an intention to deviate from these terms. Without a negotiated agreement, the UK would obviously no longer be part of the alert mechanisms on professionals whose practices raise concern for patient safety.

WORKING CONDITIONS

Background

Working conditions in the NHS must comply with the European Working Time Directive (EWTD), which seeks to restrict working time hours, but includes many opt-outs, several of which are the result of amendments to the EWTD in which UK governments have played a key role. The application of EU working time rules in clinical contexts remains controversial in several EU countries, including the UK, where some feel it places unnecessary constraints on junior doctors' training. Junior doctors themselves, however, negotiated the rules as part of their contracts.[60]

The House of Commons Health Committee sees an opportunity post-Brexit to improve matters, including a range of stakeholders in the process:

> *The profession should advise how the junior doctors' contract could be adapted to improve training, team working and flexibility. The Government should then work with the profession to achieve the legislative and contractual changes which Brexit might enable.*[61]

Issues and Legal Questions - Few Legal Answers

Will the UK amend working time rules post-Brexit, across the board, or for health professions only? If so, what will the new rules provide? Will the process lawfully involve delegated legislation under the enabling powers in the EU (Withdrawal) Act 2018, or will new primary legislation be needed? Or will the future EU-UK relationship require regulatory alignment on matters of working time?

In the immediate future, the status of the EWTD will be that of 'retained EU law' in the UK. There are questions about how the UK courts will respond to future non-

[59] European Commission, 'Notice to Stakeholders: Withdrawal of the United Kingdom and EU rules in the field of regulated professions and the recognition of professional qualifications' (21 June 2018).
[60] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] para 89.
[61] HC Health Committee, 'Brexit and social care – people & process'. 8th Report [Session 2016-17] para 92.

alignment with EU law which arise from interpretations of the EU directive after March 2019. The EU (Withdrawal) Act 2018 is clear that UK courts will no longer be obliged to secure the direct effect or supremacy of retained EU law as they are currently obliged to do under the European Communities Act 1972. But judicial practice may be to secure continued alignment, particularly if the future EU-UK relationship (if one is agreed) involves an intention to align.

Beyond that, with no legal texts to analyse, it is impossible to say what the future legal position on medical professionals' working time will be.

PATIENTS: RECIPROCITY OF CARE

Background

Currently a system of reciprocal healthcare applies between the UK, EU-27 and EEA countries by means of the EHIC card, S1 and S2 and the Patient's Rights Directive. The system, based on the concept that free movement of people within the EU/EEA should not result in worsening of their social security entitlements, relies on complex set of administrative arrangements, overseen by the European Commission. Unless something specific is negotiated, the UK will no longer have access to these arrangements after leaving the EU, or, if the Withdrawal Agreement is agreed, after the transitional period. The May government has indicated an intention to negotiate a reciprocal healthcare arrangement but nothing specific is currently proposed, let alone agreed.

Although there is a disparity between amounts paid out by the UK government for treating UK citizens in the EU-27 and amounts received from the rest of the EU for treating their citizens in the UK, this disparity is largely because of the volume of UK-'insured' pensioners living in the EU-27 (190,000 people) who are in fact treated at lower cost to the NHS than if receiving care in the UK. Nevertheless, the government has set targets for greater recovery of costs from other EU governments.[62]

Issues and Legal Questions - Few Legal Answers

Reciprocal health care post-Brexit has received some political attention but is surrounded by significant uncertainty about future access to healthcare for UK citizens resident in or visiting EU-27 countries; and for citizens from EU-27 countries resident in or travelling to the UK. The position of residents has been discussed above: here we focus on entitlements of visitors. NGOs such as Kidney Care UK have raised issues about post-Brexit inequity for UK citizens who are elderly/disabled/chronically ill who wish to travel to R-EU countries but for whom

[62] See Department of Health, 'Visitor & Migrant NHS Cost Recovery Programme: Implementation Plan 2014-16' (HM Government 2014) and Department of Health & Social Care, 'Department of Health And Social Care Single Department Plan' (HM Government 23 May 2018).

private health insurance, or private access to kidney dialysis or other treatment when visiting an EU-27 country, is unaffordable.

What sort of reciprocal healthcare arrangements will the UK negotiate with the EU, and what entitlements will they give to patients? How will they provide immediate protection to UK citizens resident in and visiting EU-27 countries on Exit Day? What longer term protection, if any, will they offer to UK citizens visiting the EU-27? What will be the effects on UK citizens who are elderly/disabled/chronically ill who cannot secure private health insurance for travel to EU-27 countries? Given that there is insufficient capacity in the NHS to manage a possible large number of pensioners returning to the UK post-Brexit, are any legal changes or other provisions being made to increase capacity?

If no reciprocal health care arrangements can be negotiated with the EU, will the UK enter into bilateral negotiations with each EU country? What legal entitlements will each give, and how will they be enforced?

If a reciprocal health care arrangement cannot be negotiated with the EU, will citizens of EU-27 countries visiting the UK be treated in the same way as non-European visitors under the UK's Overseas Visitors Regulations 2017? That is, unless in an exempt category, will they be charged upfront at a 150% tariff for NHS care (except in an emergency)[63]? If so, would that amendment to 'retained EU law' – which, according to the EU (Withdrawal) Act 2018, will continue the current entitlements – be made through delegated legislation, or would primary legislation be necessary?

It is possible to answer a few of these questions, but only if the Withdrawal Agreement is agreed. Otherwise, significant legal uncertainty continues.

Former Member State Special Relationship

The UK negotiating position is set out in the July 2018 White Paper, at paragraphs 84 and 89:

> *The Government wants UK and EU nationals to continue to be able to use the European Health Insurance Card (EHIC) to receive healthcare should they need it while on holiday…*
>
> *… There should be reciprocal healthcare cover for state pensioners retiring to the EU or the UK, continued participation in the EHIC scheme and cooperation on planned medical treatment. This would be supported by any necessary administrative cooperation and data-sharing requirements.*

[63] The National Health Service (Charges to Overseas Visitors) Regulations 2015, Part 2 (Regulation 7(3)).

The points made above about the political difficulties surrounding this position, and its incompatibility with the EU's stated negotiating position, apply equally here.

In the short term, if the Withdrawal Agreement is agreed on the terms set out in the EU-UK Joint Statement, entitlement to reciprocal healthcare will continue for UK and EU citizens who are in each other's region/country on Exit day, but only as long as that cross-border situation continues.[64]

Again in the short term, the UK will maintain the status quo on reciprocity of healthcare under the Withdrawal Act 2018, which provides that the relevant EU law incorporated in UK domestic law as 'retained EU law' will continue to apply unless or until changed by secondary or primary legislation. EU nationals will retain their rights to access health care services if working in the UK or to use the EHIC card as visitors, as these rights are currently incorporated in UK Social Security legislation, under the UK's obligations as an EU Member State.[65]

No Withdrawal Agreement

The UK's Overseas Visitor Charging Regulations, amended in 2017,[66] tighten residency requirements for entitlement to free NHS care in England.[67] In order to receive free NHS care, unless within an exempt category, visitors from outside the EU must not only be "ordinarily resident", but must also have indefinite leave to remain. Without a Withdrawal Agreement, although UK domestic law will continue to entitle EU visitors or workers in the UK to healthcare in the short term under the EU (Withdrawal) Act 2018, a lack of reciprocity may make it politically expedient for the UK government to withdraw this entitlement. This could be effected relatively easily by amending the statutory instrument, so that the current Overseas Visitors Regulations requirements apply to EU-27 visitors post-Brexit.

Without a Withdrawal Agreement, UK citizens would be treated as ordinary "third country nationals" (TCNs) in EU law. There are some entitlements in EU law for long-term resident TCNs,[68] but none of this type for visitors.[69] Where the EU does

[64] European Commission and the United Kingdom Government, 'Joint Report from the negotiators of the European Union and the United Kingdom Government on progress during Phase 1 of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union' (European Commission 8 December 2017), para 29.

[65] The National Health Service (Charges to Overseas Visitors) Regulations 2015, SI 2015/238, reg 12. In the devolved jurisdictions the relevant regulations are the NHS (Charges to Overseas Visitors) (Scotland) Regulations 1989; The NHS (Charges to Overseas Visitors) (Wales) Regulations 1989, as amended 2007; Provision of Health Services to Persons Not Ordinarily Resident Regulations (Northern Ireland) 2015.

[66] National Health Service (Charges to Overseas Visitors) (Amendment) Regulations 2017.

[67] Different rules apply in Wales, Scotland and Northern Ireland. See HL Select Committee on the European Union. Home Affairs Sub-Committee on Brexit: Reciprocal Healthcare. 11 October 2017. Oral evidence of Professor McHale, Q20.

[68] Residents would still be entitled to apply for residence under the long-term residents Directive 2003/109/EC if they had lived in the EU country for at least five years. If granted, this would provide

not have competence, domestic law on access to health care in each EU-27 Member State will apply to UK visitors and other residents. In some parts of Spain, for instance, it is possible that retired UK nationals may be able to access health care on the basis of entitlements in Spanish law.[70] The arrangements will be complex, and by definition significantly more confusing for individuals than the current situation, particularly for UK nationals who move around the EU during their lives.

Moreover, if there is no Withdrawal Agreement, any of the EU-27 countries, or the EU itself where it has competence, may decide to withdraw health care rights of UK visitors or residents. If this took place, UK visitors to EU-27 countries for work or pleasure would need to have private health insurance in place before travel. This scenario would cause considerable hardship. It would have a disproportionately adverse impact on UK citizens with chronic illness or disability, for whom insurance might be unaffordable. UK citizens resident in the EU for fewer than five years would have to make other arrangements, presumably also taking out private insurance. There would be the risk of large numbers of elderly pensioners returning to the UK, with resultant additional pressure on the NHS and social care.

In summary, even if the Withdrawal Agreement and future EU-UK relationship is successfully agreed and embodied in legal text, and especially if no such agreement is reached, the legal uncertainty for people in the context of UK health policy and practice is significant. We note the ways in which health care professionals act, especially when faced with what they perceive to be medical need, in the context of their professional identities. Health professionals do not typically ask questions about legal statuses in such situations: they treat patients. We are reminded of a study from the 2000s,[71] which found boxes of unprocessed E111 forms (the precursor to the EHIC) in a Spanish hospital. Legally, the Spanish NHS was entitled to be reimbursed for the treatment that had been provided to visitors from other EU countries. In practice, that reimbursement would never be claimed. The legal position (obligations of other EU Member States to reimburse Spain) did not follow social practice (Spain treating patients from other EU Member States for free), not least because of insufficient administrative capacity to process the forms. Brexit is similar: administrative capacity is severely challenged. We thus suggest that, immediately post-Brexit, EU health law is unlikely to be as reliable a predictor of social practice as it is as present.

MEDICINES, MEDICAL DEVICES AND SUBSTANCES OF HUMAN ORIGIN

entitlement to assistance in case of illness, pregnancy, parental assistance and long-term care. See Directive Preamble (13) and Article 11. 1(d).

[69] Council Directive 2003/109/EC of 25 November 2003 concerning the status of third-country nationals who are long-term residents.

[70] See J Cayon-De Las Cuevas and TK Hervey, 'A place in the sun? Healthcare rights of retired UK citizens in Spain post-Brexit' (2017) 12 *Health Economics, Policy and Law*, pp297-307.

[71] M Rosenmoller, M McKee, R Baeten, (eds), *Patient Mobility in the European Union: Learning from Experience* (European Observatory on Health Systems and Policies, 2006), p 68 http://www.ose.be/files/publication/2006/baeten(Coord)_2006_Patient_Mobility_Book_WHO.pdf.

As other papers in this special edition explore in more detail the importance of the biomedical life science industry to the UK and the potential impact of Brexit upon it, we can be briefer in our analysis here than in the section above. Many aspects of UK health policy and practice here are fundamentally underpinned by EU law, with its legislative provisions for pharmaceuticals, medical devices and substances of human origin. The NHS is the primary market for such health-related products in the UK. The ways in which products reach patients in the UK are constrained by EU law on clinical trials,[72] marketing authorisations,[73] safety standards,[74] and the like. Even areas of UK health law such as bioethics governance[75] or contracting relationships within the NHS, that appear to have little to do with EU law, are indirectly affected. In addition to EU legislation and soft law on health-related products, general EU internal market law governs all transactions across the border between the EU-27 and the UK. The legal basis of this activity will change post-Brexit. Our aim is to give a flavour of the complexity of the legal questions that arise and show the significant levels of legal uncertainty.

Background

MEDICINES

Pharmaceuticals may only be traded in the EU if they have a prior marketing authorisation, either from a national regulatory authority or from the EU. The overarching regulatory authority for pharmaceuticals is the European Medicines Agency (EMA), currently based in London but relocating to Amsterdam in 2019. The national UK authority is the Medicines and Healthcare products Regulatory Agency (MHRA). In 2016 the MHRA took a lead role in 45% of EU regulatory procedures[76], and on 20%-35% of the EMA's licensing and vigilance work[77]. Both the EMA and MHRA draw on global standards set by the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The MHRA is currently part of the EU delegation to the ICH. Only representatives of EU Member States can act as decision makers in EMA processes, or represent the EU in ICH procedures.

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[72] See in this issue E Cave, 'EU Clinical Trials Regulation 2014: Fetter or Facilitator' and G Laurie, 'How do we make sense of chaos: Navigating health research regulation through the liminality of the Brexit process'.

[73] See in this issue ML Flear, 'Ensuring post-Brexit UK is a 'maker' rather than a 'taker' of global norms and standards: the case of the International Council on Harmonisation'.

[74] See in this issue JV McHale, 'Brexit and Medical Devices: a question of legal regulation and patient safety'.

[75] See in this issue J Montgomery, 'Bioethics after Brexit: Brexit an opportunity to rationalize bioethics governance in the United Kingdom'.

[76] Office for Life Sciences, 'Life Science Competitiveness Indicators' (HM Government April 2017) p 27.

[77] HC Health and Social Care Committee, 'Brexit: medicines, medical devices and substances of human origin'. 4th Report [Session 2017-19] para 38.

In practice, EU marketing authorisations require compliance with EU clinical trials legislation and soft law. The current regulatory framework for clinical trials is Directive 2001/20/EC. This had been heavily criticised for being costly and overly-bureaucratic and it is to be replaced in late 2019 by Clinical Trials Regulation 536/2014, which provides for a streamlined single EU application for cross-border clinical trials. The UK had a major role in the drafting of this Regulation, which will be implemented during the transition period.

EU pharmaceuticals law also includes mechanisms for post-market surveillance ('pharmacovigilance'). These are coordinated through the EUDRA-VIGILANCE system, an electronic system for compulsory exchange of information between Member States on unexpected adverse reactions to medicines that have marketing authorisations for the EU.

The May government has said that its objective is "to ensure that patient access to medicines will not be adversely impacted by Brexit".[78] The Department of Health and Social Care (DHSC) has commissioned Ernst & Young[79] to oversee research being conducted by DHSC teams on the potential impact of Brexit on the supply chain for medicines and medical devices used in the NHS. The Ernst & Young report has not been made public or shared with Parliament, but UK regulatory alignment with EU standards is one of the initial concerns identified.[80]

There are also issues about pharmaceuticals supply chains. Evidence to the House of Commons Health and Social Care Committee suggests that the process of producing many pharmaceuticals in common use in the NHS involves components crossing the UK-EU-27 border, sometimes multiple times. The industry currently operates on the basis of trade across that border based on EU law, and its administrative procedures and practices, in particular the electronic paperwork that makes the EU's single market in goods a reality.

MEDICAL DEVICES

Unlike pharmaceuticals, medical devices sold in the EU do not have to have a prior marketing authorisation but must show compliance with EU safety standards. Products sold in the EU's market which enter or interact with the body must have a CE mark certifying conformity. CE marks are given by a "notified body", and five such bodies are incorporated in the UK. EU safety standards draw on global guidance set by the International Medical Device Regulators Forum, of which the EU is a member, along with Australia, Brazil, Canada, China, Japan, Russia, Singapore and the US.

[78] HC Debate, 28 February 2017, Commons Written Answer.

[79] Department of Health and Social Care, 'Brexit: Medicines, Medical Devices and Substances of Human Origin: Government Response to the Health and Social Care Committee's Fourth Report of Session 2017-19' (HM Government May 2018) p 2, para 2.

[80] Other concerns are: Border clearance; Tariffs; Cost of change; Foreign exchange fluctuations; Supplier readiness and response; Workforce; Maintaining product quality.

The robustness of this regulatory approach was brought into sharp relief by the Poly Implant Prothèse breast implants scandal, in which it was found that industrial, rather than medical, grade silicone had been used in medical devices implanted in thousands of women. The EU has amended its medical devices laws since then, and the new EU legislation came into force in May 2017,[81] though with an implementation period until 2020 and 2022 to allow CE certificates granted under the previous law to remain valid for two or four years after issue.

As with pharmaceuticals, the EU operates a post-market surveillance system, with the EUDRA-MED database, through which Member States exchange information about medical devices already on the market, and traceability requirements, linked to a new unique device identification database. A 'European authorised representative' must be designated by each medical device manufacturer, who is responsible in the event of a future liability claim or breach of the EU's safety legislation. It is estimated that around half of such authorised representatives in the medical devices industry are based in the UK.[82] The UK medical device market is significant: third in the EU (after France and Germany) and sixth in the world.[83]

SUBSTANCES OF HUMAN ORIGIN: BLOOD, PLASMA, ORGANS, TISSUE, CELLS

The 1980s and 1990s saw many cases of HIV infected blood transfusions in Europe, particularly to haemophiliacs, resulting in thousands of deaths.[84] This tragedy led to the EU Blood Safety Directive 2002 which applies to the collection and testing of human blood and blood components. The Directive covers whole human blood and red cells, white cells, platelets and plasma.[85] EU law provides guidance about safety, and prohibits financial gain from blood and other substances of human origin, but many matters of regulation of substances of human origin are domestically determined, including culturally sensitive rules about opt-in or out of organ donation, and rules on consent.

[81] Medical Devices Regulation: EU 2017/745 for implementation in 2020 and In Vitro Diagnostic Devices Regulation: EU 2017/746 for implementation in 2022.

[82] See blog: <https://www.hlregulation.com/2018/02/26/brexit-whats-next-for-medical-devices/> accessed 3 September 2018.

[83] See blog: <https://www.emergobyul.com/resources/market-united-kingdom> accessed 3 September 2018.

[84] See for example: D MacKenzie, New Scientist, 15 January 1994: *How safe is Europe's blood?: Cases of HIV infection in Germany have highlighted the risks of blood transfusion. But better technology may not be enough to ensure clean blood supplies across Europe*: https://www.newscientist.com/article/mg14119082-200/;
Infected Blood Inquiry: <https://www.infectedbloodinquiry.org.uk> accessed 3 September 2018.

[85] By contrast, 'medicinal products' involving plasma are covered by the EU pharmaceuticals law. Plasma for these products is currently imported from the US, and must comply with EU law. HC Heath Committee, Brexit – medicines, medical devices and substances of human origin, HC 392, Oral evidence from Liz Carroll, Q64, 5 December 2017.

The EU takes a precautionary risk approach to blood safety, and its overall legislative approach has also been applied to organs, tissues and cells. A group of EU Directives follow a similar model, providing that only duly accredited, authorised or licensed national establishments may collect and process substances of human origin.[86] Competent authorities must be registered, with systems for inspection, quality control according to the EU's common criteria for testing of donations to ensure quality and safety, and traceability.[87] In addition, the EU has actively supported Member States to improve their organ donation programmes with the main focus being on safe supply and promoting sufficient supply.[88] The EU Commission Health Directorate General, DG Sante, hosts two rapid alert systems for blood and tissues and cells, which allow Member States to communicate with each other about serious adverse reactions and events. Furthermore, recognising that the use of substances of human origin raises ethical and human rights issues, EU human rights law prohibits "making the human body and its parts as such a source of financial gain".[89] The EU is currently conducting a formal evaluation of EU blood, tissues and cells legislation.[90]

These Directives have been transposed into UK law through various pieces of secondary legislation.[91] NHS Blood and Transplant (NHSBT) is the body responsible for overseeing the regulations about blood safety. Organ donation and transplantation, as well as human tissues and cells, are regulated by the Human Tissue Authority.

The UK is not self-sufficient in plasma because of vCJD. NHS BT imports fresh plasma from Austria for patients born after 1996.[92]

Issues and Legal Questions – Few Legal Answers

[86] Implementing Directive 2012/25/EU; Directive 2004/23/EC quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells; Organ Transplant Directive 2010/53/EU.

[87] For instance, the Single European Code for Tissues and Cells (SEC) was introduced in 2015 to ensure traceability of tissues and cells from donor to recipient and vice versa. The SEC requires medical establishments and authorities to apply a unique identifier to every unit of tissues or cells. This is supported by a publicly accessible IT platform so that users may access information on the origin and specifications of tissues and cells circulating in the EU https://ec.europa.eu/health/blood_tissues_organs/overview_en. Accessed 10 August 2018.

[88] For example, the EU Action Plan on Organ Donation and Transplantation (2009-2015): https://ec.europa.eu/health/ph_threats/human_substance/oc_organs/docs/organs_action_en.pdf.

[89] EU Charter of Fundamental Rights. Article 3 (2) Right to integrity of the person.

[90] EC Evaluation of the EU blood and tissues and cells legislation: https://ec.europa.eu/health/blood_tissues_organs/policy/evaluation_en.

[91] The Blood Safety and Quality Regulations 2005; the Blood Safety and Quality (Amendment) Regulations 2007; Quality and Safety of Organs Intended for Transplantation Regulations 2012; The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018.

[92] House of Commons Health and Social Care Committee. Brexit: medicines, medical devices and substances of human origin, HC392. Oral evidence from Ian Bateman, Q75, 5 December 2017.

Similar legal questions arise for medicines, medical devices and substances of human origin post-Brexit. These concern trade rules, regulatory alignment, and institutional arrangements.

In the future EU-UK trade relationship, what rules will apply to pharmaceuticals, medical devices, and substances of human origin? What tariffs (if any) will apply? Will rules having equivalent effect, including, for instance, procurement processes, be prohibited? On what basis? On a practical level, what administrative arrangements will apply when pharmaceuticals, devices and substances of human origin cross the EU-UK border, in either direction? What electronic paperwork will be required?

Will the UK secure an agreement involving continued membership of the EMA, for instance on a similar basis to Norway, or Switzerland? Will the UK nonetheless align with EU regulatory standards, and processes for checking the safety of pharmaceuticals, such as batch testing? Will the UK continue to be aligned with EU law on data protection? Will the UK seek alignment with the new Clinical Trials Regulation? Will it be included as 'retained EU law' within the EU (Withdrawal) Act 2018? Even if it is, how will practical access to the associated database be regulated? Will the UK continue regulatory alignment with the EU on medical devices, and on safety and traceability standards for substances of human origin?

Or will the UK choose to align with another global regulatory block, such as the US's FDA? What will be the content of those new laws, and how effective will they be at protecting patients, and the NHS as the principal purchaser in the UK? For instance, will rules on procurement, or on direct-to-consumer advertising of pharmaceuticals, change?

Will the UK seek membership of the ICH and on what basis? In what ways will the law governing the MHRA change to reflect its changed global and national status?

Will the UK seek continued access to the EU's rapid alert systems for blood and tissues and cells, for unexpected suspect adverse reactions to pharmaceuticals or medical devices?

Will the UK legally prohibit pharmaceutical or medical devices companies from using IP rights to prevent imports from EU countries, for instance in the Trade Bill?

MEDICINES

Key issues for pharmaceuticals immediately post-Brexit involve security of supply. Some 90% of drugs in the UK are imported, with 45% of those coming from the EU.[93] Over 80% of radioisotopes are imported from Europe.[94] In August 2018 the

[93] House of Commons Health and Social Care Committee. Brexit:medicines, medical devices and substances of human origin, HC392. Oral evidence from Martin Sawer, HDA, Q2, 5 December 2017.

government issued the Medicines Supply Contingency Planning Programme, which provides guidance for stockpiling medicines, as a contingency against a failure to agree the Withdrawal Agreement.[95] Some medicines and health-related products have such a short shelf-life that even relatively small delays on a border mean they would be useless when they eventually reached their destination. Of course, other sources of supply of pharmaceuticals exist, as this is a global industry, and the UK pharmaceutical industry could increase its capacity, if the right incentives are offered. But all of this will require legal and policy change, and increased costs.

Alignment with EU pharmaceutical regulation, particularly the EMA's standards, which draw on EU law such as the Clinical Trials Regulation and Data Protection Regulation, will be necessary if the UK is to continue to trade with the EU in pharmaceuticals, and to protect the UK pharmaceutical industry from losses incurred by losing its principal market. Questions of alignment raise issues of the future role of the MHRA, representation of the UK on EU and international regulatory bodies, and, critically on a practical level, access for the UK to the Clinical Trials Regulation's portal and database, as well as EUDRA-VIGILANCE.

Without regulatory alignment with one of the globally recognised systems, such as the EU's or the US's FDA, new drugs typically reach markets around 18 months later than in countries that are aligned.[96] It may be possible to offer incentives to the global pharmaceutical industry to compensate for the otherwise inevitable harm to patients in the UK. Current EU law prohibiting the use of intellectual property rights to divide up the EU market means that the NHS is able to purchase drugs on the market in other EU countries at lower costs than would otherwise apply.[97]

MEDICAL DEVICES

Similar supply issues arise as for pharmaceuticals. Approximately 60% of medical devices sold in the UK are imported, with 75% of these being imported from EU-27 countries.[98] Of course, other sources are available globally: in 2015, some 20% of

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[94] House of Commons Health and Social Care Committee. Brexit:medicines, medical devices and substances of human origin. HC392. Oral evidence from Dr Jeanette Dickson, Q19, 5 December 2017.

[95] DHSC Medicine Supply Contingency Planning Programme, 23 August 2018. https://www.gov.uk/guidance/medicines-supply-contingency-planning-programme.

[96] HC Health and Social Care Committee, 'Brexit: medicines, medical devices and substances of human origin'. 4th Report [Session 2017-19] para 67.

[97] Estimates of savings vary, but Dayan (https://www.nuffieldtrust.org.uk/research/brexit-relationship-eu-shape-nhs#finding-a-system-that-works-for-medicines) suggests £100million a year seems credible, citing P Kavanos, J Costa-i-Font, S Merkur and M Gemmill, *The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis*, (LSE Health and Social Care, 2004) and U Enemark KM Pedersen and J Sorensen *The economic impact of parallel import of pharmaceuticals* (CAST paper 2006).

[98] GlobalData Healthcare. *Brexit: impact of 'no deal' on the UK medical devices industry.* 29 March 2017 https://www.medicaldevice-network.com/comment/commentbrexit-impact-of-no-deal-on-the-uk-medical-devices-industry-5774942/.

medical devices in the UK were imported from the USA.[99] Issues of capacity building arise if the UK is to become more self-sufficient. There are also questions of patient safety, especially if the UK is excluded from EUDRA-MED. The powers of the UK-based 'notification bodies' will need to be clarified: depending on the type of Brexit negotiated, their decisions may be valid only in the UK post-Brexit. 'European authorised representatives' based in the UK will no longer be recognised in EU law unless explicitly agreed in the future EU-UK relationship. Post-Brexit, the UK will no longer be part of, or capable of informing, the EU's delegation to the International Medical Device Regulators Forum.

SUBSTANCES OF HUMAN ORIGIN

As with pharmaceuticals and medical devices, the issues that arise concern the terms on which the UK continues to import and export substances of human origin from and to the EU post-Brexit. There are concerns among patient organisations, and the broader health sector, that safety standards for substances of human origin should remain high, given the history of regulation in Europe, and the existence of different regulatory models elsewhere in the world, particularly in the USA. Further, given that the UK is reliant on EU-27 supplies of plasma for younger patients, there will be a particular need to secure that supply, or find other sources.

Former Member State Special Relationship

If the UK secures a Withdrawal Agreement, many short term issues concerning continuity of supply of medicines, devices, equipment and substances of human origin will be addressed during the transition period. The Joint Negotiating text gives details on free movement of products during transition, including the practical administrative aspects involved when products cross the EU-27 UK border during that time. The essential aim is to secure continuity of trade in goods until December 2020.

Thereafter, the May government's stated intention is "to continue to participate in the European medicines regulatory network partnership between the EU, EEA and the EMA".[100] The UK intends to seek associate membership of the EMA and states that it will bring domestic legislation into alignment with the Clinical Trials Regulation. In addition, "the UK would want to secure access to relevant IT systems", and with regard to the EMA, "with UK regulators still able to conduct technical work, including acting as a 'leading authority' for the assessment of medicines, and participating in other activities like ongoing safety monitoring and the incoming clinical trials framework".[101]

[99] See https://www.export.gov/article?id=United-Kingdom-Medical-Equipment.
[100] Amended clause to the Trade Bill. See HC Consideration of Bill (Report Stage): 17 July 2018, p35: https://publications.parliament.uk/pa/bills/cbill/2017-2019/0122/amend/trade_daily_rep_0716.pdf.
[101] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018) Section 1.2.3 Manufactured Goods, para 30.

The White Paper seeks a UK-EU relationship based on a 'common rulebook', which would mean that products such as medical devices and equipment would only have to be tested as conforming with safety rules, good manufacturing guidance and quality assurance processes in one market, in order to be sold in either. This 'mutual recognition' approach appears similar to the EU's arrangements with Switzerland. Whether the EU would be prepared to agree to this type of agreement will depend on negotiations. Barnier's responses to the White Paper are cautious, stressing the indivisibility of the internal market's four freedoms and pointing out that regulatory alignment involves not only border controls, but also enforceability of EU law, while at the same time hoping for 'a future partnership between the EU and the United Kingdom that is unprecedented in scope and depth'.[102]

The Health and Social Care Committee's Fourth Report to the government stressed the importance of securing "the closest possible regulatory alignment with the EU"[103] in order to ensure continued supply of substances of human origin. This seemed to be accepted by the government in its response:

> *With regard to substances of human origin, the current regulatory framework is well established and sets high quality and safety standards for patients in the UK. The Government's priority is to maintain the same high standards after the UK exits the EU. The current arrangements support the free movement of blood, blood components, organs, tissues and cells across the EU and continued collaboration and a close relationship between the UK and EU would be of great benefit to patients.*

This suggests, without stating explicitly, that the UK government wishes to maintain the current EU-derived regulatory framework after the transition period ends in 2010. The import and export of blood plasma products could also continue unhindered if agreement can be reached. Any agreement would require the EU to formally recognise the acceptability of UK regulatory procedures. The UK would also need to negotiate continued access to the alert systems and the EU's traceability platform.

The comments above about the EU's negotiating position, and Barnier's interpretation of the implications of the UK's 'red lines' on human migration, apply in force here. The UK's position, which seeks to sever one aspect of the EU's 'internal market' (products), from others (people, services), appears fundamentally incompatible with the EU's position on the integrity of its internal market law.

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[102] M Barnier *An Ambitious Partnership with the UK after Brexit* https://ec.europa.eu/commission/news/ambitious-partnership-uk-after-brexit-2018-aug-02_en.

[103] HC Health and Social Care Committee, 'Brexit: medicines, medical devices and substances of human origin'. 4th Report [Session 2017-19] Section 4: Aligning with the EU on market authorisation and regulation, para 71.

No Withdrawal Agreement

Without a Withdrawal Agreement, trade between the EU-27 and the UK in pharmaceuticals, medical devices and equipment, as with all products, and also substances of human origin,[104] would be only on the basis of WTO arrangements. Trade with other countries that is currently regulated by EU law because the EU has negotiated a free trade agreement with that country, would also be on that basis, as the EU's trade agreements with 'third countries' would not automatically become bilateral UK-other country agreements.

It is extremely difficult to discern what this would mean, as so few countries currently trade on that basis. Most global trade is on the basis of free trade agreements of more or less density, and with different parameters. Although pharmaceuticals are zero-rated in terms of tariffs under WTO law, the real issue is 'non-tariff barriers to trade', that is to say the complex network of laws and regulatory standards with which producers of (health-related) products must comply if they wish to sell on the EU's market. WTO membership does not guarantee recognition that such standards have been met, so UK producers would be unable to sell to the EU-27 unless the EU decided unilaterally to recognise UK standards, perhaps on the basis of previous compliance and the EU (Withdrawal) Act 2018. Such unilateral action seems highly unlikely, especially given that the EU has explicitly stated, in its 'Brexit preparedness notices' that the legal status of the UK will be that of a 'third country' in the event of no Withdrawal Agreement.[105]

For instance, the European Commission's *Notice to Stakeholders. Withdrawal of the United Kingdom and EU rules in the field of substances of human origin (blood, tissues and cell, and organs)* of 23 January 2018 notes that, in the event of no Withdrawal Agreement, the UK will become a 'third country', and the EU's rules will no longer apply to the UK. This means that imports of blood from the UK into the EU-27 will need to be tested in conformity with EU requirements (UK testing will not be recognised), tissues will need to be imported by authorised establishments in an EU-27 state, and organ exchanges will need to be supervised by an EU-27 competent authority. Traceability will need to be secured in all cases.

Where EU law requires a designated 'European authorised representative', as in the case of medical devices and substances of human origin, any such person based in

[104] See the European Commission's 'Brexit preparedness notices', available from https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en, especially 23 January 2018, *Notice to Stakeholders: Withdrawal of the UK and EU Rules in the Field of Substances of Human Origin*.

[105] See the European Commission's 'Brexit preparedness notices', available from https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en, especially 23 January 2018, *Notice to Marketing Authorisation holders of centrally authorized medicinal products for human and veterinary use*, and the information on the EMA's website giving detailed advice to private parties.

the UK will cease to be recognised.[106] Similarly, UK-based 'Notified Bodies' will cease to be recognised as such by the EU and will be removed from the EU's database on such organisations. UK-based Notified Bodies will no longer be able to show product conformity with EU legislation on products subject to the CE system.[107]

Some have argued that WTO law imposes some obligations on the EU in the event of no Withdrawal Agreement.[108] But even if it does, which is disputed,[109] those companies or other entities seeking to trade health-related products across the EU-UK border post-Brexit do not have the kinds of rights under WTO law as they do in EU law. WTO membership falls woefully short of the procedural and remedial aspects of EU law where there has been a breach. Even if WTO 'law' had been breached, it would not be possible in practice for a company or NHS entity to enforce it to secure movement of health-related products across the border.

The UK's market will continue to recognise EU standards in the short term, because these will be embodied in UK law as 'retained EU law' under the EU (Withdrawal) Act 2018. Whether that assurance will be sufficient for EU-based traders with whom NHS entities in the UK seek to contract is one of the significant legal uncertainties of a no Withdrawal Agreement Brexit. Certainly a UK Act of Parliament provides significantly less security in the event of, say, contractual litigation, than membership of the EU, and hence compliance with EU law. The underpinning legal basis on which cross-border contracts for health-related products are formed, or organs are exchanged between entities in the EU and those in the UK, will change fundamentally in the event of no Withdrawal Agreement. Whether that changes practice and policy is also a huge unknown quantity at the time we write.

Some Leave supporting politicians have suggested that the UK could 'simply open its borders' in the event of no Withdrawal Agreement being agreed.[110] The detailed

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[106] See the European Commission's 'Brexit preparedness notices', available from https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en, especially 22 January 2018, *Notice to Stakeholders: Withdrawal of the UK and EU rules in the field of industrial products*.

[107] See the European Commission's 'Brexit preparedness notices', available from https://ec.europa.eu/info/brexit/brexit-preparedness/preparedness-notices_en, especially 22 January 2018, *Notice to Stakeholders: Withdrawal of the UK and EU rules in the field of industrial products*.

[108] P Minford, 'World Trade Rules Are Nothing To Be Scared Of: UK Will Flourish Without Dead Hand Of EU' *Express* (2018) <https://www.express.co.uk/comment/expresscomment/992795/brexit-wto-world-trade-rules-uk> accessed 3 September 2018.

[109] Full Fact: EU facts behind the claims: trade rules. 25 April 2016: https://fullfact.org/europe/eu-facts-behind-claims-trade-rules/.

[110] L O'Carroll, 'Rees-Mogg: No Need For Customs Checks At Dover In No-Deal Brexit' *The Guardian* (2018) <https://www.theguardian.com/politics/2018/jun/11/rees-mogg-no-need-for-customs-checks-at-dover-in-no-deal-brexit> accessed 3 September 2018; R Perring, 'Britain's borders betrayal: Brexit could see borders flung WIDE OPEN if there's no deal' *Express* (2018) <https://www.express.co.uk/news/uk/933241/brexit-news-border-customs-union-EU-no-deal> accessed 3 September 2018.

practicalities of this suggestion are yet to be fully understood, or embodied in legal text, or administrative procedures. The idea that any products, wherever from, could enter the UK without any border controls, in April 2019, seems far-fetched: how would consumer/patient protection standards be secured? And if products from the EU-27 and/or from countries with which the EU has free trade agreements are to be treated differently from those from elsewhere, then some kind of border control will be necessary. It has also been suggested that this might breach WTO obligations of trade on a basis of non-arbitrary discrimination. The May government has indicated[111] that they would recognise marketing approvals where given by the EU, but there would not be reciprocal approval of medicines or devices developed and produced in the UK in the EU-27.

In the absence of specific agreements, post-Brexit, the UK will no longer have access to post-market cross-border monitoring and notification schemes for pharmaceuticals, devices or substances of human origin. The UK would no longer be a member of the EMA or its approval processes. Without an agreement to the contrary, the UK will no longer be part of (or capable of informing) the EU's delegation to the ICH[112] or to the International Medical Device Regulators Forum. Cross-border clinical trials involving the UK and any EU-27 Member State could not continue without securing compliance with EU data protection law, as the UK would be treated as a 'third country' for compliance purposes.[113]

Attempts to remain within the clinical trials database would be disrupted, with adverse impact on clinical trials, including cross-border clinical trials currently in progress. The UK would no longer be part of the global regulatory body, ICH, and would need to lobby for membership in its own right.

> "*Overall, the impact on pharmaceutical research would be immediate and adverse…large pharmaceutical companies would have to plan well in advance…which would presumably mean moving some or all of their research and development activities*." [114]

[111] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018), Section 1.2.3 Manufactured goods, Para 31; HM Government, 'Continuity in the availability of goods for the EU and the UK. Position Paper' (13 July 2017): https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/638958/Continuity_in_the_availability_of_goods_for_the_EU_and_the_UK_Position_Paper.pdf.

[112] M Flear, 'Optimising the UK's Post-Brexit Influence in Global Standards-Setting – Example II: Brexit and Medical Devices' Regulation', 25.10.17: https://markflear.wordpress.com/2017/10/25/optimising-the-uks-post-brexit-influence-in-global-standards-setting-example-ii-brexit-and-medical-devices-regulation/.

[113] European Commission Directorate-General Justice and Consumers, 'Notice to Shareholders. Withdrawal of the United Kingdom from the Union and EU Rules in the field of Data Protection' (9 January 2018).

[114] The UK in a Changing Europe, 'Cost Of No Deal' (2018) 17 <: http://ukandeu.ac.uk/wp-content/uploads/2017/07/Cost-of-No-Deal.pdf.> accessed 3 September 2018.

PUBLIC HEALTH

As matters pertaining to many public health issues, such as environmental controls, air and water quality, and risks from chemicals, unsafe products, food, tobacco and alcohol essentially involve the same considerations as health-related products, in this short section we focus only on aspects of communicable disease control.

Background

Regular global outbreaks such as the pandemic of H1N1 Influenza ("Swine Flu") in 2009-10 and Zika in 2015-16 demonstrate that infectious diseases do not respect national borders. The UK is a member of numerous international organisations which work to strengthen global health security[115], including against the threat of serious communicable diseases with pandemic potential. It is also a signatory to international legal instruments such as the WHO's International Health Regulations (2005) (IHR) which set obligations and guidelines for preparedness and response to public health emergencies of international concern. These memberships and obligations will be unaffected by the UK leaving the European Union.

In recent years, the EU has been making efforts to ensure that Member States are prepared for infectious disease outbreaks. Key EU legislation is the implementing Decision 1082/13 on serious cross border threats to health. This supports compliance with the IHR and also encourages greater coordination between Member States.

The EU has established a number of bodies and systems to strengthen the ability of Member States to respond to communicable disease threats. For example, the UK is part of the EU's Health Security Committee, which holds regular meetings to share information on health-related threats in Europe. In 2005 the European Centre for Disease Prevention and Control (ECDC) was established as an EU agency with headquarters in Stockholm.[116] The ECDC monitors public health threats in Europe from communicable disease and provides risk assessments and other technical expertise to Member States. The ECDC also runs several online surveillance and data collection systems[117], including the Early Warning Response System (EWRS), which notifies Member States of outbreaks and provides for exchange of information; the European Surveillance System, a data collection system which analyses, aggregates and reports data provided by Member States on communicable diseases; the Epidemic Intelligence Information System, which allows nominated public health experts to exchange technical information on current and emerging health threats; and the Threat Tracking Tool, a database of verified events which is

[115] For example, the Global Health Security Initiative: http://www.ghsi.ca/english/index.asp.
[116] www.ecdc.europa.eu.
[117] Faculty of Public Health, 'The UK and the European Centre for Disease Prevention and Control (ECDC). Blueprint for a Post-Brexit Relationship' (FPH June 2018) Section 3. Current relationship with ECDC.

used to assess communicable disease threats. The ECDC is also a centre for international collaboration between communicable disease experts from Member States.

In June 2018, the UK Faculty of Public Health (FPH) published "The UK and the European Centre for Disease Prevention and Control. Blueprint for a post-Brexit relationship", which sets out the benefits provided by the ECDC. The FPH also conducted a poll of UK health protection experts:

> *Respondents unanimously felt that it was very important (mean score 9.6/10) to retain a working relationship with ECDC post Brexit to be able to respond effectively to cross-border threats and for UK health security … many felt their ability to manage future outbreaks post-Brexit would be weakened if the UK were to move outside of ECDC, mainly due to the loss of EWRS and professional collaborative opportunities.*

The FPH suggested three possible options for the UK's future relationship with the ECDC, in order of preference. Firstly, and ideally, would be to retain full membership status with the ECDC. The FPH calculated that this would require annual contributions of approximately €6 million. Secondly, the creation of a bespoke relationship with ECDC and other international Health Security organisations, although "this would be a long-term project and would require significant investment in system strengthening." If neither of these options is possible, the FPH suggests a bilateral "European Neighbourhood Policy Agreement", such as the ECDC is currently negotiating with non-EU countries in Northern Africa and Eastern Europe. "However this type of agreement is unlikely to go much further than basic technical cooperation."[118]

Additionally, the FPH argued "whether the UK is part of ECDC or not, we would urge the Government to ensure that the UK remains a member of the Health Security Committee and continues to benefit from its coordinated action on cross border health threats".

Issues and Legal Questions

Key issues are to ensure that UK health security is not weakened by reduced access to European web-based surveillance and data sharing systems; and to maintain the UK's access to the ECDC, and its collaborative processes.

The following key legal questions arise: What will be the legal relationship between the UK and the ECDC? Will the UK secure full or associate membership? Will the relationship include access to the full range of ECDC activities and data, such as the

[118] Faculty of Public Health, 'The UK and the European Centre for Disease Prevention and Control (ECDC). Blueprint for a Post-Brexit Relationship' (FPH June 2018) Section 10 Options for UK-ECDC post-Brexit.

EWRS? What provisions will be made to ensure a coherent response to cross-border threats with EU-27 countries once the UK is no longer a member of the Health Security Committee? Will it seek Observer status?

Will the UK remain aligned with Decision 1082/13 on cross-border threats to health? Or will amendments to the implementing legislation be made under the EU (Withdrawal) Act 2018?

Former Member State Special Relationship

The UK stated in the July 2018 White Paper that it wishes to maintain close collaboration with the ECDC "including access to all associated alert systems, databases and networks, to allow the UK and the EU Member States to coordinate national responses".[119] The ECDC does work with EEA/EFTA countries (Norway, Iceland and Liechtenstein), but there is no certainty that the ECDC will grant similar status to the UK. The FPH has pointed out that "the UK is unlikely to have the arrangements around immigration and trade that are currently in existence in other partner countries".[120] The draft Withdrawal Agreement text does not include any provisions about the ECDC.

Nevertheless, an outbreak of serious communicable disease in the UK during the transition period, or thereafter, would likely impact on neighbouring European countries. Therefore, for security reasons, if withdrawal terms are agreed with the EU, continuation of the current arrangement, i.e. UK membership of the ECDC, the Health Security Committee and participation in the various surveillance and data sharing systems would be mutually beneficial and might be negotiated, whether within the Withdrawal Agreement, the future trade agreement or within another agreement altogether. If such matters are interpreted as 'security', rather than 'trade', it may be feasible to reach agreement that does not breach the EU's stated negotiating position *for trade agreements*, for instance as articulated in the Barnier 'steps of doom' slide. It is unclear whether the UK could be a full member, or would have to be an associate, and it would be subject to payment by the UK of appropriate financial contributions.

EU Decision 1082/13 closely follows the requirements of the IHR.[121] As a signatory to the IHR, the UK will likely remain in alignment with the Decision, although the basis for this will be compliance with the UK's international law obligations, rather than EU law, unless it is specifically covered in the EU-UK future relationship. This may not be a priority for negotiations, especially in the shorter term. The UK's

[119] HM Government, 'The Future Relationship Between the United Kingdom and The European Union' (July 2018) Section 2.5.5 Health security, Para 113a.
[120] Faculty of Public Health, 'The UK and the European Centre for Disease Prevention and Control (ECDC). Blueprint for a Post-Brexit Relationship' (FPH June 2018) Section 10 Options for UK-ECDC post-Brexit.
[121] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health [2013] L 2 293/02.

ability to achieve greater coordination with neighbouring states may be hindered if it is unable to gain access to the same surveillance data and technical advice from the ECDC as EU Member States.

No Withdrawal Agreement

If negotiations collapse, as a 'third country', the UK will immediately lose access to all the EU health security bodies and systems from which it currently benefits as an EU Member State. The UK might then seek an alternative arrangement of the type suggested by the FPH, i.e. a bespoke arrangement or a basic bilateral agreement, to regain some access to EU systems, particularly the ECDC, the EWRS and the Health Security Committee. Either option would require time to negotiate and in the meantime, the UK's health security would be left vulnerable with surveillance systems disrupted.[122]

THE DEVOLVED JURISDICTIONS, ESPECIALLY ON THE ISLAND OF IRELAND

Background

Responsibility for public health and the NHS is devolved to the separate jurisdictions of England, Scotland, Wales and Northern Ireland. When the UK leaves the EU, powers currently held at EU level will be repatriated, but the question of how these competences will be redistributed back to the devolved level remains disputed. The UK's constitutional settlement has been described as evolving, and certainly the relationships between Westminster and the governments in Cardiff, Edinburgh and Stormont are quite different now from when the UK joined the then EEC in the 1970s.

There are reported to be 141 areas of overlap between the EU's powers and devolved powers in Northern Ireland, 111 in Scotland, and 64 in Wales.[123] While the majority of policy areas concern the environment and transport, some cover health matters, and some are within the domain of the Department of Health. As well as having distinct NHS arrangements, the devolved jurisdictions have developed their own laws and policies in areas such as minimum alcohol pricing, obesity and tobacco regulation.

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[122] A Matthews-King, 'No-Deal Brexit Will Be 'Catastrophe' For NHS And Increase Risk From Deadly Pandemics, BMA Warns' *Independent* (2018) <https://www.independent.co.uk/news/uk/home-news/brexit-no-deal-nhs-pandemic-bma-final-say-voters-referendum-a8493221.html> accessed 3 September 2018.

[123] Institute for Government, 'Brexit, devolution and common frameworks' (IFG 2018) <https://www.instituteforgovernment.org.uk/explainers/brexit-devolution-and-common-frameworks> accessed 3 September 2018.

For Northern Ireland, the situation is more complex. Despite different health systems in Northern Ireland and the Republic of Ireland there is a high level of cross-border integration of those health systems:

> *...unhindered by border checks and supported by reciprocal arrangements between healthcare providers in Northern Ireland and the Republic of Ireland, an ambulance can travel to wherever is closest and best for any particular patient on either side of the border. Such arrangements would be in doubt if a "hardening" of the customs border between the UK and the EU produced restrictions on the movement of pharmaceutical products or medical devices, or even medical staff.*[124]

Some health facilities are currently shared, with patients from both Northern Ireland and the Republic of Ireland. These include the North Western Cancer Centre at Altnagelvin Hospital in Northern Ireland, which serves patients in the western part of Northern Ireland and north and west Donegal; and Our Lady's Children's Hospital in Dublin, which provides heart surgery for children across the island of Ireland.

The EU has provided funding for a number of health projects in and across the devolved jurisdictions.[125] For instance, a €7.6 million project on mental health for Northern Ireland and the Republic of Ireland was announced in March 2018, supported by the health strand of the EU-funded 'Cooperation and Working Together'.[126] All of this integration has taken place within the broad parameters of the peace process, following the Good Friday Agreement, in which the EU has been closely involved. Health care thus plays a (small) role in security, peace and stability on the island of Ireland. It is therefore arguably not only a matter of trade. This is important in terms of the basis of future EU-UK relationships concerning the island of Ireland, which can be conceptualised as part of the EU's external relations security competence, not only its trade relations. As noted above, conceptualising matters as 'security' rather than 'trade' might give the EU more leeway in its negotiating position.

Issues, Legal Questions but few Legal Answers

Key issues here concern restoration of EU level powers to the devolved jurisdictions. If each jurisdiction gains significant powers, for instance in public health fields,

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[124] M Flear, K Hayward and T Hervey, 'Brexit, Health And The Devolved Regions And Nations' (The UK in a Changing Europe 17 March 2018) <http://ukandeu.ac.uk/brexit-health-and-the-devolved-regions-and-nations/> accessed 3 September 2018.

[125] For example, Interreg: https://www.seupb.eu/iva-overview and PEACE: https://www.seupb.eu/piv-overview.

[126] Belfast Telegraph Digital, 'New €7.6M cross-border project to tackle increase in mental health issues' (9 March 2018) <https://www.belfasttelegraph.co.uk/news/northern-ireland/new-76m-crossborder-project-to-tackle-increase-in-mental-health-issues-36687691.html> accessed 3 September 2018.

regulatory deviations may jeopardise the UK's 'internal market' for products. While this may or may not be a problem internally, it will certainly make it more difficult for the UK to offer access to the whole of its market when it negotiates trade agreements with the EU and/or with other trading blocs or countries.

A loss of EU funding for health projects in the devolved jurisdictions may result in possible adverse impact on health indicators.

In Northern Ireland, the challenges of disentangling what is in effect a single health workforce and, in some areas, shared patient provision are significant. The legal arrangements that underpin the 'common travel area' on the island of Ireland were adopted on the basis that both countries were members of the EU.[127] The extent to which they can operate on a free-standing basis is unclear, although the relevant legal provisions are embedded in the laws of Northern Ireland and the Republic of Ireland. The range of issues to be considered include whether health services can continue to share staff, which will depend on continued mutual recognition of qualifications. Whether ambulances can continue to cross the border as now will also depend on the basis on which the products they carry are permitted to cross the border.

Which EU health competences will be restored to the devolved jurisdictions post-Brexit? What legal protections will representatives of the devolved jurisdictions have in the decision-making and process of restoring such health competences post-Brexit? How will the devolved jurisdictions use their powers, and will health law become more diverse *within* the UK post-Brexit? What will be the implications for patients, and for health professionals, especially in border areas and particularly on the island of Ireland? How will the legal position of currently shared health facilities and the services of health professionals be secured? Will legal provision be made to secure continued funding for health projects, such as PEACE in Northern Ireland and Interreg in Scotland?

As many of these questions concern matters internal to the UK, and the laws underpinning its constitutional settlement, the type of Brexit and future EU-UK relationship is less relevant here than in the other health policy and practice questions considered above. The significant caveat is the potentially chaotic consequences of no Withdrawal Agreement for the island of Ireland. There, the comments above about the arrangements for people under the legal provisions that underpin the common travel area, and the provisions for products under WTO law and the imposition of a border on the island of Ireland, apply.

Former Member State Special Relationship

[127] J Curtis and others, 'Briefing Paper Number 8042, 17 July 2017. Brexit Negotiations: The Irish border question' (House of Commons Library 2017) Section 4. Free movement of people and the Common Travel Area.

The draft settlement in the Withdrawal Agreement for the island of Ireland is based on a 'backstop' agreement in principle, to the effect that, if no other solution is reached, a North/South 'hard border' must be avoided.[128] The UK's preferred solution here is 'through the overall EU-UK relationship', but no detail on how this will be achieved has yet been agreed.[129] The May government is investigating technological solutions, but none are elaborated in sufficient detail to be acceptable to the EU. The Joint Negotiating text goes on to say:

> *In the absence of agreed solutions, the United Kingdom will maintain full alignment with those rules of the Internal Market and the Customs Union which, now or in the future, support North-South cooperation, the all-island economy and the protection of the 1998 Agreement.*
>
> *In the absence of agreed solutions, as set out in the previous paragraph, the United Kingdom will ensure that no new regulatory barriers develop between Northern Ireland and the rest of the United Kingdom, unless, consistent with the 1998 Agreement, the Northern Ireland Executive and Assembly agree that distinct arrangements are appropriate for Northern Ireland. In all circumstances, the United Kingdom will continue to ensure the same unfettered access for Northern Ireland's businesses to the whole of the United Kingdom internal market.*

Of course, this 'backstop' provision will only apply if the EU agrees to the Withdrawal Agreement.

No Withdrawal Agreement

The EU (Withdrawal) Act 2018 provides that current restrictions on devolved competence, which arise because of the UK's obligations to comply with EU law, will be removed by the Act.[130] However, there is a controversial exception to this default of devolved powers back to the devolved administrations. This comes under a power in the Act for UK ministers to freeze by Regulation aspects of existing EU law, and with it the constraints on competence.[131] The intention then is to subsequently introduce new UK-wide legislative frameworks in these areas.[132] At both the stage of making the freezing Regulations, and the future common frameworks, there is a

[128] European Commission and the United Kingdom Government, 'Joint Report from the Negotiators Of The European Union And The United Kingdom Government on progress during Phase 1 of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union' (European Commission 8 December 2017) para 49.

[129] European Union and the United Kingdom, 'Joint Statement from the negotiators of the European Union and the United Kingdom Government on progress of negotiations under Article 50 TEU on the United Kingdom's orderly withdrawal from the European Union' (19 June 2018) para 7.

[130] European Union (Withdrawal) Act 2018, section 12.

[131] European Union (Withdrawal) Act 2018, section 12.

[132] Those areas have been identified following policy-specific intergovernmental 'deep-dives' between officials – see the frameworks analysis https://www.gov.uk/government/publications/frameworks-analysis.

political undertaking[133] by the UK government to 'not normally' proceed without the consent of the devolved jurisdictions. However, there is significant concern that these assurances designed to protect the powers of the devolved jurisdictions do not in fact attract any enforceability through judicial process.[134] The lack of legal enforceability of the so-called Sewel Convention (that Westminster will not normally legislate in devolved areas without devolved consent) was confirmed in the *Miller* judgment.[135]

But the legal/constitutional landscape is more than usually fluid and uncertain here. Scotland did not consent to the devolution parts of the EU (Withdrawal) Act. As we write, the Supreme Court is yet to rule[136] on Scotland's UK Withdrawal from the European Union (Legal Continuity) (Scotland) Bill,[137] which has been through the Scottish parliamentary process but has not yet received Royal Assent. This Bill's aim is to secure continuity of EU law in Scotland, much as the EU (Withdrawal) Act 2018 does for the UK. But it also seeks to place on a legislative footing the Scottish government's understanding of its devolved powers and how Brexit affects those. A similar Act for Wales[138] is to be repealed, following a political settlement.

Some of the areas identified in the 'frameworks analysis'[139] as matters which will rest with the devolved jurisdictions concern health policy and practice. These include elements of EU social security coordination (which is where EHIC sits; for Scotland and Northern Ireland); elements of employment law such as working time (in Northern Ireland only); and rules on genetically modified microorganisms (relevant for public health protection via the food chain). But some areas, such as access of non-UK nationals to benefits (which could include health care); medical devices regulation; data protection are in the areas identified by the UK government as reserved for UK-wide legislative frameworks. None of these is marked for consideration by the Department of Health and Social Care, which may be important when it comes to scrutiny of proposals, as ministries outside health ministries often miss health-related impacts of the legislation they sponsor.

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[133] Intergovernmental Agreement on the EU (Withdrawal) Bill and the Establishment of Common Frameworks, 24 April 2018 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/702623/2018-04-24_UKG-DA_IGA_and_Memorandum.pdf.

[134] So much so that the Scottish Parliament refused to give its legislative consent to the Withdrawal Act.

[135] *R (Miller) v Secretary of State for Exiting the European Union* [2017] UKSC 5.

[136] BBC News: Supreme Court hears defence of Scottish Brexit Bill. 25 July 2018: https://www.bbc.co.uk/news/uk-scotland-scotland-politics-44938747.

[137] UK Withdrawal from the European Union (Legal Continuity) (Scotland) Bill <https://digitalpublications.parliament.scot/ResearchBriefings/Report/2018/3/6/UK-Withdrawal-from-the-European-Union--Legal-Continuity---Scotland--Bill> accessed 3 September 2018.

[138] Law Derived from the European Union (Wales) Act 2018.

[139] HM Government, 'Frameworks Analysis: Breakdown of areas of EU law that intersect with devolved competence in Scotland, Wales and Northern Ireland (HM Government 9 March 2018): https://www.gov.uk/government/publications/frameworks-analysis.

Several areas of health policy are listed in the 'frameworks analysis' where non-legislative coordination may be required: these include health and safety at work (which is where working time sits in EU law); marketing authorisation for pharmaceuticals; transparency of pharmaceutical pricing; substances of human origin (excluding embryos and gametes); clinical trials and good laboratory practice; elements of tobacco regulation; and pandemic health threats. These are understood to be areas of devolved competence, where there is a need to coordinate matters at UK level, but in a way that falls short of UK-wide legislation.

However, the most important, and most contested, group of areas is that considered to be 'subject to more detailed discussion to explore whether common legislative frameworks may be needed, in whole or in part'. These matters fall within devolved competence, but there is a claimed need for UK-wide legislation which harmonises matters for the whole of the UK. This list includes some very important matters for health policy and practice, such as public procurement, mutual recognition of professional qualifications, coordination of social security (EHIC), and a range of EU food law, such as food compositional standards, food and feed safety, and labelling, including nutrition and health claims.

Without any detailed legislative proposals it is impossible to analyse the effects of new legislation, or softer coordination, on health policy and practice, either at UK level, or in any of the devolved jurisdictions. In the case of the latter list, we do not even know which legislature (Westminster or one or more of the devolved legislatures) would be responsible for adopting the relevant new law.

CONCLUSIONS: 'A-LEGALITY' IN POST-BREXIT HEALTH LAW

The overview of some of the most important issues for health law post-Exit Day above reveals significant – indeed probably unprecedented – levels of legal uncertainty. EU law *directly* affects the areas we have discussed above, which of course exclude many aspects of UK health law. But further, EU law *indirectly* affects many more domestically-determined aspects of UK health law,[140] including, for instance, the law that governs the structures of the NHS and its operations, the types of treatments to which patients are entitled, and the circumstances in which they may access such treatment, tortious liability for medical harm, consent to treatment rules and other human rights protections, and so on. Legal uncertainty about health post-Exit Day is thus significant, and, moreover, it is difficult to determine the extent of the uncertainty. The biggest challenges concern people and products, which is where we have focused our analysis. While there are a few aspects that are relatively clear, the majority of legal questions about the short term effects of Brexit on UK health law, policy and practice simply cannot be answered at present, as we do not have sufficient clarity in the legal texts that will govern relationships at that time. That is probably the most important conclusion from our analysis.

[140] Including through the Human Rights Act 1998, which is the primary mechanism by which the Council of Europe's European Convention on Human Rights takes effect in the UK.

But one thing that is certain is that – unless something different is negotiated, and time is running short for that – the UK will leave the EU on 29 March 2019. And there simply is no time to make the technical legal arrangements that will be necessary to ensure the 'smooth, orderly Brexit' that the UK government claims it desires.[141] Even with the powers in the EU (Withdrawal) Act 2018 to adopt delegated legislation, and even if the UK and the EU agree the terms of withdrawal, there is scant time in the transition period envisaged by the Withdrawal Agreement to work through what changes will be needed to health law at UK level and in each of the UK's 'devolveds', and adopt those into legal text. Effective scrutiny of those changes will be a remote possibility. Parliaments in Westminster, Edinburgh, Cardiff and Stormont are over-stretched by the challenge of Brexit in general. There is unlikely to be time or capacity to consult other health stakeholders[142] who could provide effective scrutiny, and make sure leaving the EU 'does no harm' to health.[143] If the UK leaves the EU at the eleventh hour without agreeing a Withdrawal Agreement, all of this will become impossible.

Yet, unlike the airline industry, where it is expected that 'No Deal' will mean an abrupt disruption of services,[144] from 30 March 2019, the NHS will continue to provide care to patients, employ staff, contract with suppliers, and protect public health. The NHS has been operating for longer than the 45 years that the UK has been a Member State of the EU, although of course its policies and practices have changed during that time in part because of the obligations of EU membership. Just as Ellickson's cattle ranchers found ways to arrange their affairs, resolve liabilities and disputes so that they could continue to interact as neighbours, so we expect the myriad of actions and actors which make up the NHS in England, Scotland, Wales and Northern Ireland to seek to continue as before. Where this involves interaction with our European neighbours, we predict that, at a micro level, the practice will be to aim for no change, or as little change as possible. Some of this hoped-for continuity will be feasible on the basis of 'retained EU law'. Working time for health professionals, and recognition of health professional qualifications from EU-27 Member States, for instance, will remain as is, at least in the short term, though with a different new source of UK law under the EU (Withdrawal) Act 2018.

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[141] Theresa May speech 17 January 2017. Available at: https://www.gov.uk/government/speeches/the-governments-negotiating-objectives-for-exiting-the-eu-pm-speech.

[142] Although we note that the then Health Secretary, Jeremy Hunt, told the House of Commons Health Committee in oral evidence that he had met members of the global pharmaceutical industry, but not yet other health stakeholders. House of Commons Health Committee. Oral evidence: Brexit and health and social care, HC 640. 24 January 2017.

[143] See the Faculty of Public Health's 'Do No Harm' amendment, agreed by the Government during the passage of the EU (Withdrawal) Bill through the House of Lords.: https://www.fph.org.uk/policy-campaigns/campaigns/brexit/a-do-no-harm-amendment-to-the-eu-withdrawal-bill/.

[144] For further detail see https://ec.europa.eu/transport/sites/transport/files/legislation/brexit-notice-to-stakeholders-aviation-safety.pdf.

But where the basis of the legal provision is not solely internally determined, however much individual actors involved may *seek* no change, and a continuity of existing 'neighbourly' relations, this will not be always be possible. For example, while the UK can decide to unilaterally recognise qualifications from EU-27 countries, or authorized medicines or certified devices, the *mutual* recognition of medical qualifications, medicines or devices requires agreement from the EU. And the processes that underpin that regulatory alignment involve institutional interactions, including sharing of expertise and data, that require such agreement too.

Here the insights from socio-legal scholarship tell us to expect that social practice will not necessary follow the legal position. For instance, in the event of no Withdrawal Agreement, a Spanish hospital employing a UK doctor, or using a UK-certified medical device, would be in breach of EU law by not immediately treating the doctor as a 'third country national' and that device as non-compliant with EU product safety law. But it would take some time for enforcement procedures to come into play. Certainly in the short term, the EU is unlikely to be able to prevent the Spanish hospital from continuing to recognise the qualifications of a UK doctor working there or the safety of medical equipment which they have used for years. The position on the ground, therefore, would not represent the legal position: it would be a situation of 'a-legality'.

But no entity wants to be in such a situation, and certainly not in the longer term. What we may see, therefore, is entities seeking to future-proof their existing relationships at a micro level, irrespective of the legal provisions that apply at macro level. An early example in health is the concordat between the Royal College of Midwives and the Irish Nurses and Midwives Organisation.[145] This seeks to 'Brexit-proof' mutual recognition of midwifery qualifications on the island of Ireland. Described as the 'first international collaboration of its kind', it will involve sharing learning resources and professional development, and the Irish Nurses and Midwives Organisation will offer future routes to influence in the European Commission for the Royal College of Midwives.

And, furthermore, although 'a-legality' offers some short-term solutions, we can expect problems to arise where the law is needed: where there is a dispute, for instance. Problems will also arise where the practical administrative aspects of continuity with what has gone before become impossible. Here, the extent to which law will determine 'street level' action, of public or private actors or entities, is very difficult to predict.

[145] The Royal College of Midwives, 'RCM launches international partnership with INMO aimed at Brexit proofing midwifery learning and practice' (22 January 2018) < https://www.rcm.org.uk/news-views-and-analysis/news/%E2%80%98rcm-launches-international-partnership-with-inmo-aimed-at-brexit> accessed 3 September 2018.

An NHS Trust, for instance, that regularly contracts with companies in EU-27 countries to procure drugs, devices, or substances of human origin may well seek to continue its practice, whatever type of Brexit takes place. In the event of no Withdrawal Agreement being negotiated, how will officials processing (components of) health products that cross the UK-EU border to fulfil those contracts operate? The EU has indicated, in its 'Brexit preparedness notices',[146] that it will treat such products as 'third country' products: in other words, civil servants at the border of EU-27 countries will require paperwork and processes as if the product or component comes from a country with which the EU trades on WTO terms. That might well mean that health-related products, or components for those products, are held up at the border between, say, the UK and the Netherlands. The consequent increased costs may mean that companies seek to renegotiate contracts,[147] or simply breach them by failing to supply products. There is an outside chance that lack of underpinning EU law, or any EU-UK agreement, may be treated as a legitimate frustrating circumstance, allowing non-compliance without breach.[148] Perhaps NHS contracts are being 'future-proofed' already: there is scant formal evidence in the public domain on this matter.[149]

Moreover, whether in practice products will be treated as if the UK were a 'third country' on the island of Ireland, where the border is extremely porous, and physical infrastructure to check people and products crossing that border is non-existent, remains highly doubtful. In April 2019, will ambulance crews refuse to cross the NI/RoI border on small roads where the border is invisible in practice, if that is the quickest way to get a patient to hospital in an emergency, for fear that the products in the ambulance breach WTO trade rules? We think not.

In the analysis above, we have sought neither to under- nor over-state the importance of law in post-Brexit health policy and practice. The kind of legal analysis that will be necessary to understand the rights and obligations of all kinds of entities, and of human beings, in the future, needs legal texts that are not available

[146] European Commission, 'Read more on Brexit preparedness notices': https://ec.europa.eu/info/brexit-preparedness/brexit-notices-explanation_en.

[147] There are some indications that contracts are being re-negotiated against a 'no deal' Brexit at the present time, for instance through discussions on social media.

[148] Under English law the doctrine of frustration of contract states that a contract may be set aside if an unforeseen event renders contractual obligations impossible or whose purpose is thwarted through no fault of the contracting parties: Law Reform (Frustrated Contracts) Act 1943. However in this case it is unlikely that a contract is actually frustrated as it can still be performed, just with greater expense (e.g. the paperwork and processes associated with trading on WTO terms, rather than under a FTA or EU law).

[149] A Twitter thread on 13 August @JasonJHunter highlighted the position of a global company that manufactures in the UK, importing raw material from the EU, with a 4-5 month delivery period. Given that the company cannot know the terms of import from April 2019 onwards, how can it place an order in November 2018? The supplier will surely decline the order if they do not know the costs of delivery, shipping time (i.e. time held up at ports), insurance, and so on. This company is also a supplier to other companies which process their product for another 3-6 months and have the same questions for the UK company about 2019 deliveries. Therefore, says the Twitter thread, 'is the UK going to be short of life saving products for 8 months or more?'.

at this time, even though Exit Day is less than 8 months away. By setting out the key questions that will need to be answered for post-Brexit UK health law, and answering those that can be answered at this time, this paper is a step along the way. But without legal text, we can go no further with that research agenda. Instead, we have offered an analysis based on the uncertainties that our paper has uncovered.

In short, we expect that the law will be less of a reflection of reality in the immediate post-Brexit period in the context of health than it is at present. Until the legal texts 'catch up', we expect a period of 'a-legality', where law is less of a determinant of policy and practice than it has been before.