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The NHS in Northern Ireland post-Brexit: the legal position on product supply

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Abstract (150 words)

The UK left the European Union's single market on 1 January 2021. A Withdrawal Agreement made special provision for Northern Ireland. However, 'grace periods' concerning supply of goods were agreed, delaying full application of the new rules.

The Northern Ireland NHS is heavily reliant on supplies from Great Britain. If these supplies are disrupted, the quality of care offered to patients will diminish. This article shows the legal details of applicable law once the 'grace periods', which are currently securing supply, cease to apply. It reveals significant costs and uncertainties associated with supply of products to the NHS in Northern Ireland.

The direction of travel, unless something changes, is that new products will reach patients later than in Great Britain, and there is a real possibility that some products become difficult or impossible for the NHS in Northern Ireland to source. The result will be reduced quality of patient care.

Key words: patient care, medicines supply, Brexit, Northern Ireland

1. Introduction

Access to medicines, medical devices, equipment, consumables, and substances of human origin (blood, organs, tissue, cells) is a fundamental aspect of patient care, indeed even of the human right to health.¹ In a well-functioning national health system, patients are entitled to be confident of secure, predictable, planned and sufficient product supply to ensure that the health professionals treating them are able to offer appropriate treatment, within the 'basket of care' offered by that particular National Health Service (NHS). Patients are entitled to be confident that these products are safe, and efficacious.

¹ See, for example, Hunt, Paul, and Rajat Khosla. 'The human right to medicines'. *Sur. International Journal on Human Rights* 5 (2008): 100-121; the articles in the special issue of *Public Health Ethics* edited by Thomas Pogge, for the editorial, see, Thomas Pogge, Access to Medicines, *Public Health Ethics*, Volume 1, Issue 2, July 2008, Pages 73–82, <https://doi.org/10.1093/phe/phn023>. Much of the literature on this issue concerns access to medicines in the global south. But we would argue that the arguments for intervening with market forces to secure a right to health also apply to access to medicines for vulnerable populations in the global north.

The NHS in Northern Ireland serves a population of 1.9 million.² A small number of specific health care services³ are shared with the population of the Republic of Ireland.⁴ Hospitals in the NHS in Northern Ireland, as a devolved entity from the United Kingdom as a whole, treated nearly 600 000 day case and in-patients in 2019/20.⁵ Supplies of products to the Northern Ireland NHS are overwhelmingly secured from Great Britain (GB) (mainly England): some 98% of medicines reach Northern Ireland from there.⁶ The NHS in Northern Ireland relies on the UK's Medicines and Healthcare products Regulatory Authority (MHRA) and the European Medicines Agency (EMA) for decisions about licensing of medicines for the Northern Irish market, and on the London-based National Institute for Health and Care Excellence (NICE) for 'health technology assessment'⁷ decisions about which medicines are available to patients within the NHS.⁸

The relationships between the Department of Health and Social Care in the UK government in Westminster, the Northern Ireland Executive in Stormont, the English NHS, the Northern Ireland NHS, and the Irish NHS were already quite complex. They became significantly more complex on 1 January 2021, when the transition period following the UK's exit from the EU came to an end.⁹ The population of Northern Ireland, which voted to remain in the EU,¹⁰ and, crucially, shares the only land border between the UK and the EU, is now subject to the legal settlement embodied in the Protocol on Ireland/Northern Ireland, annexed to the EU-UK Withdrawal Agreement 2020.¹¹

² Northern Ireland Statistics and Research Agency, 2021, '2020 Mid-Year Population Estimates for Northern Ireland', 25 June. <https://www.nisra.gov.uk/publications/2020-mid-year-population-estimates-northern-ireland>.

³ Such as the cancer hospital in Altnagelvin; the children's heart hospital in Dublin; child and adolescent mental health services in the north of the island of Ireland. These provisions, part of 'Cooperation and Working Together', operational since the Ballyconnell Agreement 1992 and under the Belfast/Good Friday Agreement 1998, have drawn significantly on 'INTERREG' funding from the European Union, see <https://cawt.hscni.net/about-us/what-we-do/>.

⁴ Some 4.9 million, see Ireland's Central Statistics Office, 2020, 'Population and Migration Estimates', 20 August. <https://www.cso.ie/en/releasesandpublications/er/pme/populationandmigrationestimatesapril2020/>.

⁵ See NI Department of Health, 2020, 'Release of Northern Ireland inpatient, day case and outpatient hospital statistics for 2019/20', 6 August. <https://www.health-ni.gov.uk/news/release-northern-ireland-inpatient-day-case-and-outpatient-hospital-statistics-201920>. Figures for 2020 onwards will of course be significantly affected by the COVID-19 pandemic.

⁶ Northern Ireland Assembly, 2021, 'Order Paper: Sessions 2021-2022', 17 May, <http://www.niassembly.gov.uk/assembly-business/order-papers/session-2020-2021/17-may-2021/>.

⁷ For an overview of health technology assessment see D. Banta, 'The development of health technology assessment', *Health Policy* 63(2) (2003) 121-132.

⁸ See, eg, Global Health PR, 2020, 'The Global Guide to Market Access' <https://www.globalhealthpr.com/services/northern-ireland/>.

⁹ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (WA) [2019] OJ C1 384/1, Article 126.

¹⁰ The Electoral Commission, 2019, 'Results and turnout at the EU referendum', 16 July, <https://www.electoralcommission.org.uk/who-we-are-and-what-we-do/elections-and-referendums/past-elections-and-referendums/eu-referendum/results-and-turnout-eu-referendum>.

¹¹ Supra n 9.

On 28 July 2021, Lord Frost, Minister of State at the Cabinet Office of the UK Government, wrote to Lord Jay of Ewelme, the Chair of the UK Parliamentary Committee scrutinising the outworkings of the Ireland/Northern Ireland Protocol. Lord Frost's letter¹² warns that the Department of Health and Social Care has received formal notification of '280 to 290 confirmed medicines discontinuation of supply to Northern Ireland', and that further discontinuations are expected in 2022. Other actors within the NHS in Northern Ireland have expressed similar concerns about continued supply, not only of medicines, but also of medical devices, equipment, consumables, and human blood, organs, cells and tissue (substances of human origin). This article elaborates the effects of the EU-UK legal settlement on supply of products to the Northern Irish NHS. If health lawyers are to understand the effects of that legal settlement on patient care for the population of Northern Ireland, they must understand the detail of the settlement in a non-superficial manner.

2. Methodology and outline

Our primary research method is legal doctrine: we explain the meanings and effects of the legal texts that apply to product supply to the Northern Irish NHS. We support our legal analysis with data from a small number of semi-structured interviews with key stakeholders, carried out between 2019-2021,¹³ and from collaborations with the Brexit Health Alliance.¹⁴

The analysis proceeds as follows. First, we briefly outline the historical background to the contemporary position. We explain how the developments of recent months have shaped current concerns about supply of products to the NHS in Northern Ireland. We note here that the full effect of the legal settlement is yet to be felt. This is due to a number of political agreements, or unilateral legal actions on the part of the UK or EU, to postpone full application of the agreed legal rules: 'grace periods' or 'standstill periods', in non-technical language. We then outline the future expected timeline (if nothing changes) to the ending of each of these 'grace periods'.

Second, we elaborate the legal position for import and export of products, and substances of human origin, arriving in Northern Ireland from each of the possible routes of supply. We first consider the dominant pattern of supply of the Northern Ireland NHS: products arriving in Northern Ireland from GB, having been manufactured in GB according to

¹² Letter from Lord Frost to Lord Jay of Ewelme, Chair of the Protocol on Ireland/Northern Ireland SubCommittee, House of Lords, 28 July 2021, <https://committees.parliament.uk/publications/7011/documents/72907/default/>.

¹³ These interviews were carried out under the UK Economic and Social Research Council-funded project *Health Governance after Brexit*, granted research ethics approval by the University of Sheffield, Reference Number 0022929.

¹⁴ An umbrella body bringing together a wide range of health sector stakeholders, see NHS Confederation, 'Brexit Health Alliance: supporting the healthcare sector as the UK leaves the EU', <https://www.nhsconfed.org/topic/brexit/brexit-health-alliance>.

standards applicable in GB. We then consider the position of products arriving in Northern Ireland from GB, having been manufactured in the EU in accordance with standards applicable in the EU. Following this, we turn to the position of products arriving in Northern Ireland from GB, having been manufactured elsewhere in the world, in accordance with either British or EU standards. Next we consider the legal requirements for a product manufactured in GB, according to British standards, moving from England via the European Union (including the Republic of Ireland) to Northern Ireland. Finally, noting that this is not the current main route of supply, we consider the position where a product arrives in Northern Ireland without transiting through GB, having been manufactured in the EU in accordance with EU standards. For each, we consider the rules applicable to medicines; to medical devices, equipment and consumables; and to substances of human origin. We cover rules, documentary and procedural requirements both associated with customs and tariffs, and concerning regulation of quality, safety, efficacy, and patient protection. All of these modalities are potential inhibitors of free movement. We show, in this detailed legal analysis, the position under which NHS supply in Northern Ireland will operate, once the various 'grace periods' have elapsed, unless there are any further developments.

A final brief section considers legal requirements for products and substances of human origin moving from Northern Ireland to GB; and to the EU, including Ireland. Our analysis here shows potential future opportunities for businesses in the medicines, medical devices/equipment/consumables, and substances of human origin sectors in Northern Ireland. We conclude by noting that any opportunities for the Northern Ireland NHS are relatively remote, and do not outweigh the significant challenges faced by the NHS as shown by the analysis in the main part of the article.

3. Historical background and future timeline

Brexit involves a disjointed process of legal separation:¹⁵ it is a process, not a moment. The UK formally left the EU on 31 January 2020. The EU-UK Withdrawal Agreement, with the Ireland/Northern Ireland Protocol, came into force on 1 February 2020. The Withdrawal Agreement provided for a transition period until 31 December 2020, at the end of which EU law ceased to be applicable in GB.¹⁶ The purpose of the transition period was to allow the relevant actors, such as government agencies and private companies, some time to adapt, and to resolve remaining legal matters of separation. This was unfortunately not achieved by 1 January 2021, and many legal changes happened after that date, and are yet to happen.

Furthermore, EU-UK negotiations are ongoing, particularly as the UK explores legal and political boundaries embodied within the Withdrawal Agreement and its Protocol on

¹⁵ On the temporal aspects of Brexit, see, seminally, K Armstrong *Brexit Time* (Cambridge University Press, 2017). The Northern Ireland Assembly has provided a useful timeline: <http://www.niassembly.gov.uk/assembly-business/brexit-and-beyond/timeline-and-key-documents/>.

¹⁶ WA supra n 9, Article 126.

Ireland/Northern Ireland. The interpretation and implementation of the Withdrawal Agreement and the Protocol, in conjunction with the existing Northern Irish, UK, and EU legislation, is a continuous and live process. Furthermore, even if the legal effects of the Protocol were to become better understood for the next three years, the review of the Protocol by the Northern Ireland Assembly on 31 December 2024 holds the possibility of the Protocol being disapplied in the near future. At that point, further complexity to the existing status quo on the relationship between the EU, the UK and Northern Ireland would arise. This volatile legal environment is problematic for the NHS in Northern Ireland, which, like every other national health system, needs to be able to plan, well in advance, the procurement of products and substances of human origin necessary to treat its patients.

The EU-UK Trade and Cooperation Agreement came into effect provisionally on 1 January 2021 and formally on 1 May 2021.¹⁷ But the Withdrawal Agreement, with its Ireland/Northern Ireland Protocol, also continues to apply.¹⁸ In accordance with the Protocol, Northern Ireland remained aligned with Union goods legislation, whereas GB did not. Some of the principal changes in the health sector on 1 January 2021 include the following. The EU ceased to recognise UK-established Notified Bodies. These are now known as ‘Approved Bodies’ within UK law.¹⁹ Pharmacies in GB disconnected from the National Medicines Verification System and are no longer required to conform to Falsified Medicines Directive processes.²⁰ A wholesale dealer in GB can no longer import Qualified Person certified medicines from the EEA without certain checks being made by the Responsible Person (import).²¹ Establishments in Northern Ireland need an import license from the Human Tissue Authority to receive human tissues and cells from GB.²²

These legal changes are supported by new institutions. The EU-UK Joint Committee, established by Article 164 WA,²³ plays a critical role. Decisions of the Joint Committee are binding and have the same legal effect as the Withdrawal Agreement.²⁴ The

¹⁷ Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part [2021] OJ L 149/10 (TCA); see also European Commission, ‘The EU-UK Trade and Cooperation Agreement’, undated, https://ec.europa.eu/info/strategy/relations-non-eu-countries/relations-united-kingdom/eu-uk-trade-and-cooperation-agreement_en.

¹⁸ TCA supra n 17, Article 775. For an initial analysis of the relationship, see Katy Hayward, 2021, *What the UK-EU Trade and Cooperation Agreement means for Northern Ireland*, <http://qppl.qub.ac.uk/what-the-uk-eu-trade-cooperation-agreement-means-for-ni/>.

¹⁹ The regulatory standards applicable in Great Britain to medicines are contained in over 340 domestic regulations, consolidated as the Human Medicines Regulations 2012. The Medicines and Medical Devices Act 2021 gives broad executive powers to amend the relevant Regulations. These powers have been exercised by the MHRA, acting as the executive agency of the Department of Health and Social Care. See <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk>.

²⁰ Human Medicines (Amendment etc) (EU Exit) Regulations 2019, SI 2019/775 as amended by the Human Medicines (Amendment etc) (EU Exit) Regulations 2020, SI 2020/1488.

²¹ The Human Medicines Regulations 2012, regulations 45(1) and (2).

²² Human Tissue Authority, 2021, ‘UK Transition licensing FAQs’, 13 September, <https://www.hta.gov.uk/guidance-professionals/uk-transition-guidance/transition-FAQs>.

²³ Article 164 WA.

²⁴ Article 166 (2) WA.

Committee has helped to ensure that the process of exiting the EU did not cause major disruptions to product supply in the immediate aftermath of 1 January 2021. For example, a phased approach for implementing medicines regulations, agreed on 5 November 2020 by the Joint Committee, aimed to secure the 'undisrupted supply of medicines' to Northern Ireland.²⁵ Similar 'grace periods', allowing for delayed application of the rules, have been negotiated throughout the process, pertaining to an array of different issues, from medicines to chilled meats. These grace periods have also been legally unpredictable: for example, the chilled meats grace period, originally intended to end on 30 June 2021, was extended until 30 September 2021. The UK government then declared a further extension on its own prerogative,²⁶ with no defined end date, and EU officials stated that pushback from the EU is unlikely.²⁷ The end of these grace periods signify the commencement of new regulatory requirements on goods: for example, as things currently stand, on 31 December 2021, medicines supplied from GB to Northern Ireland will need to comply with all EU medicines regulations, including the Falsified Medicines Directive and importation requirements such as batch testing and Qualified Person certifications.

Despite the Joint Committee, the process has not been without contention. Some UK actions have been challenged by the EU for breach of the Withdrawal Agreement. In March 2021, the UK Government announced that it would delay the introduction of full import checks by an average of 6 months for British goods being imported into the EU.²⁸ The EU responded by issuing a letter of formal notice for a breach of the Withdrawal Agreement (though the process was paused in July 2021).²⁹ Similarly, attempts by the UK Government to call for a fundamental rethinking of the Northern Ireland Protocol on 21 July 2021 were rebuffed by the EU.³⁰

As mentioned above, both the EU and the UK have sought to avoid the disruption of medical supplies to Northern Ireland, as this is an area of particular concern due to both

²⁵ European Commission, 2020, 'Press statement following the fourth meeting of the Specialised Committee on Ireland and Northern Ireland Protocol', 5 September, https://ec.europa.eu/info/publications/press-statement-following-fourth-meeting-specialised-committee-ireland-and-northern-ireland-protocol_en.

²⁶ Peter Foster, 2021, 'UK extends Northern Ireland 'grace periods' for third time', *Financial Times* 6 September.

²⁷ *Ibid.*

²⁸ Joe Marshall, 2021, 'Delaying Brexit border checks solves some problems but creates others', 12 March, <https://www.instituteforgovernment.org.uk/blog/delaying-brexit-border-checks>.

²⁹ European Commission, 2021, 'Statement by Vice-President Maroš Šefčovič following today's announcement by the UK government regarding the Protocol on Ireland / Northern Ireland', 3 March, https://ec.europa.eu/commission/presscorner/detail/en/STATEMENT_21_1018; European Commission, 2021, 'Withdrawal Agreement: Commission sends letter of formal notice to the United Kingdom for breach of its obligations under the Protocol on Ireland and Northern Ireland', 15 March, https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_21_1132/IP_21_1132_EN.pd; Hans von der Burchard, 2021, EU pauses both Brexit lawsuits against the UK, 28 July, <https://www.politico.eu/article/eu-uk-legal-actions-paused/>.

³⁰ HM Government, *Northern Ireland Protocol: The Way Forward*, 21 July 2021, CP 502; European Commission, 2021, 'Statement by Vice-President Maroš Šefčovič following today's announcement by the UK government regarding the Protocol on Ireland / Northern Ireland', 21 July, https://ec.europa.eu/commission/presscorner/detail/en/statement_21_3821.

Northern Ireland and other small markets historically dependent on GB for their medicine supplies, especially in the Republic of Ireland. These efforts began in December 2020 in the form of a Joint Committee meeting, after which unilateral declarations were made by the EU and the UK detailing the EU's 'pharmaceutical *acquis* in regards to Northern Ireland.'³¹

As things currently stand, to summarise, some aspects of the full legal consequence of the UK becoming a 'third country' (non-EU Member State) apply already in Northern Ireland; the application of some has been delayed; and some aspects may never apply to Northern Ireland, or at least not for some considerable time. The position of Northern Ireland, as partially 'within' the EU's legal regime for products, creates considerable uncertainty for the NHS in Northern Ireland, as the granularity of the legal regime becomes understood, while at the same time that legal regime continues to be unusually volatile.

4. Legal requirements for supply of products and substances of human origin to the NHS in Northern Ireland after the end of any transitional arrangements

Movement of products³² between GB and Northern Ireland is subject to the Withdrawal Agreement's Ireland/Northern Ireland Protocol.³³ When products move from GB to Northern Ireland in a trade context,³⁴ this has implications for customs duties, export duties, taxes (VAT), and regulatory standards that must be met in order to access the market in Northern Ireland. It has implications for the formalities and (electronic) paperwork that must accompany such exports/imports. That, in turn, has implications for the NHS in Northern Ireland, and the patients whom it treats.

For products, the effect of the Protocol is that the border on the island of Ireland is not an external border of the EU. The Protocol seeks to avoid 'a hard border, including any physical infrastructure or related checks and controls'.³⁵ Movement of products across that border does not constitute an import or export. No checks associated with imports or exports apply when products move across that border.³⁶

³¹ HM Government, 2020, 'Unilateral declarations by the European Union and the United Kingdom of Great Britain and Northern Ireland in the Withdrawal Agreement Joint Committee on human and veterinary medicines', 17 December, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/946659/Unilateral_declarations_by_the_European_Union_and_the_United_Kingdom_of_Great_Britain_and_Northern_Ireland_in_the_Withdrawal_Agreement_Joint_Committee_on_human_and_veterinary_medicines.pdf. The European Notice on this matter was later replaced by another on 25 January 2021: Commission Notice – Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period [2021] OJ C 27/11.

³² The Protocol applies to all movement of goods, not only to goods that are traded, see for instance Article 5 (7) I/NIP.

³³ Article 182 WA.

³⁴ As opposed to being brought by an individual for personal purposes.

³⁵ I/NIP, Recital 9.

³⁶ Stephen Weatherill, 'The Protocol on Ireland/Northern Ireland: What is says is not what it does', EU Law Analysis 2020, <http://eulawanalysis.blogspot.com/2020/03/the-protocol-on-ireland-northern.html>; S.

This article considers movement of products for which the manufacturing process, packaging and labelling processes are complete. Whether this is the case has implications for determining the 'origin'³⁷ of the products, which matters when it comes to determining customs duties. For the purposes of this article, products are treated as originating in the place indicated in the title of each sub-section which follows. Where a product still needs to be further processed once moved into Northern Ireland, different rules apply.³⁸ However, even though the Protocol envisages special and preferential rules for products originating in GB and being moved into Northern Ireland, to secure application of those rules, evidence of origin is necessary.³⁹ This requirement adds a further level of formality and paperwork. The added formalities and associated paperwork mean increased costs for companies involved in supplying the NHS in Northern Ireland.⁴⁰

4.1 Products moving to Northern Ireland from GB having been manufactured in GB in accordance with standards applicable in GB (after the various 'grace periods' have elapsed)

What are the requirements when something like a steel implement used by the NHS in Northern Ireland, made in Sheffield, for example by a company like Swann Morton which makes precision steel instruments, is shipped to Belfast from Liverpool or Cairnryan in Scotland?

A product in this category is subject to the customs rules applicable when a product crosses the EU's external customs border.⁴¹ Where the customs tariff in the EU's customs code is zero, no customs duties are payable.⁴² This is the case for pharmaceuticals⁴³ and

Weatherill, 'The Protocol on Ireland/Northern Ireland: protecting the EU's internal market at the expense of the UK's', 45(2) *European Law Review* 2020 222-236.

³⁷ 'Origin' is a technical trade term, concerning the determination of where a product has come from, for the purposes of application of trade rules. See, for example, Institute for Government, 2020, 'Trade: rules of origin', March 16, <https://www.instituteforgovernment.org.uk/explainers/trade-rules-origin>.

³⁸ I/NIP, Article 5(1). Products are not subject to 'commercial processing' where the processing takes place in Northern Ireland and is for the sole purpose of 'direct provision to the recipient of health or care services by the importer in Northern Ireland', see Decision No 4/2020 of the Joint Committee Established by the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 17 December 2020 on the determination of goods not at risk [2020] OJ L 443/6, Article 2 (b) (iii).

³⁹ This is implicit in Article 5 (1) I/NIP, read alongside the Decision No 4/2020 supra n 38, Article 3.

⁴⁰ This has been clear, and indeed officially confirmed by the UK government (see HM Government, *The UK's Approach to the Northern Ireland Protocol*, (CP 226, 2020)) with regard to all trade in products to Northern Ireland, since at least May 2020. See Michael Gaiorek and Anna Jerzewska, *The Unresolved Difficulties of the Northern Ireland Protocol* UK Trade Policy Observatory, Briefing Paper 41, June 2020.

⁴¹ Article 5 I/NIP. The drafting of this provision is convoluted, but this is its legal effect in terms of the default position. There are exceptions to this default position, outlined below.

⁴² Traders may discover the relevant duty payable for a specific product category using UK government guidance, see HM Revenue & Customs, 2020, 'Claiming preferential rates of duty between the UK and EU', 28 December, <https://www.gov.uk/guidance/claiming-preferential-rates-of-duty-between-the-uk-and-eu>; and GOV.UK, 2021, 'UK Integrated Online Tariff: look up commodity codes, duty and VAT rates', 13 September, <https://www.trade-tariff.service.gov.uk/sections/6>.

⁴³ See, for example, this type of product: European Commission, 2021, 'Access2Markets', 17 September, <https://trade.ec.europa.eu/access-to-markets/en/results?product=300212&origin=GB&destination=IE>

substances of human origin.⁴⁴ Some medical devices, equipment, and consumables are subject to tariffs under the EU's Common Customs Code.⁴⁵ No duties are payable, however, where an authorised UK trader makes a declaration that those products are not 'at risk' of onward movement into the EU,⁴⁶ and can provide evidence to that effect.

Though the EU and UK did not agree to be part of a customs union in the EU-UK Trade and Cooperation Agreement (TCA), the TCA prohibits customs duties on imports/exports of goods originating in the EU/UK, 'except as otherwise provided for in this Agreement'.⁴⁷ This preferential tariff treatment applies only where formalities are met.⁴⁸ The exceptions provided for in the TCA include the trade remedies provisions.⁴⁹ These provisions allow (after due process) for suspension of obligations in the event of breach, so, in the event of a breach by the UK, the EU would be permitted to impose tariffs on a particular sector of goods. Importers of those goods to Northern Ireland, including from GB, would be required to pay those tariffs, although would be entitled to reimbursement afterwards.⁵⁰

Irrespective of whether a customs duty is payable, the formalities of the EU's customs rules apply, in terms of (electronic) paperwork that must accompany the product when it crosses the border.⁵¹ Supporting evidence is needed, for example when claiming that no customs duties are payable because the product is not 'at risk' of onward movement to the EU.⁵² Under the Protocol, the UK may reimburse or waive customs duties payable on products moving from GB to Northern Ireland, or otherwise compensate companies

⁴⁴ For instance, the supply of human organs is exempted from customs duties and VAT in EU Law, see Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax [2006] OJ L 347/1, Article 132.

⁴⁵ See, for example, this type of product: European Commission, 2021, 'Access2Markets', 17 September, <https://trade.ec.europa.eu/access-to-markets/en/results?product=9001109040&origin=GB&destination=IE>.

⁴⁶ Article 5 I/NIP provides, in effect, that no duty will be payable for a product brought into Northern Ireland from GB unless there is a risk of that product being moved into the EU. The Joint Committee was obliged to establish the criteria according to which a product is not at risk of being subsequently moved into the EU by the end of December 2020 (Article 5 (2) I/NP). It did so in Decision No 4/2020, supra n 38, Article 3.

⁴⁷ Article 21 TCA.

⁴⁸ For details of the UK legislation, see The Trade Preference Scheme (EU Exit) Regulations 2020, Part 4.

⁴⁹ Articles 32 and 749 TCA.

⁵⁰ See Katy Hayward, 2021, 'What the UK-EU Trade and Cooperation Agreement means for Northern Ireland', 4 January, <http://qpol.qub.ac.uk/what-the-uk-eu-trade-cooperation-agreement-means-for-ni/>.

⁵¹ Article 23 TCA permits such formalities. For details of the relevant rules and processes, see UK Guidance here: <https://www.gov.uk/guidance/check-if-you-can-declare-goods-you-bring-into-northern-ireland-not-at-risk-of-moving-to-the-eu#processing>, and, for VAT, here: <https://www.gov.uk/guidance/claim-vat-refunds-in-northern-ireland-or-the-eu-if-youre-established-in-northern-ireland-or-in-the-eu>, and see EU Guidance here: European Commission, 'Access2Markets: guide for import of goods', undated, <https://trade.ec.europa.eu/access-to-markets/en/content/guide-import-goods>, though note that this does not include Northern Ireland in its dropdown menus.

⁵² See UK.GOV, 2020, 'Declaring goods you bring into Northern Ireland 'not at risk' of moving to the EU', 14 December, <https://www.gov.uk/guidance/check-if-you-can-declare-goods-you-bring-into-northern-ireland-not-at-risk-of-moving-to-the-eu#processing>.

involved.⁵³ Where reimbursement or compensation applies, duties will have to be paid up-front. Formalities are necessary to claim reimbursement, for waivers,⁵⁴ and for other compensatory mechanisms. Even if the relevant products do not attract customs duties, or if the duties payable are eventually reimbursed, the additional formalities required result in additional costs for importers of products to Northern Ireland from GB. It seems that the early difficulties with supply of the NHS in Northern Ireland, at the start of 2021, are now easing, as companies acquire expertise in the necessary formalities. However, some instances of difficulty of supply continue: it is not always clear why a shipment has been held up by the border authorities. But, even if those problems ease entirely, the increased costs will continue.

The EU may not impose any restrictions on the quantity of products imported into Northern Ireland from GB.⁵⁵ Nor may the EU impose any taxes on such products which are greater than taxes imposed on EU-produced products.⁵⁶ We have not covered the VAT position in this article: in summary, it imposes a further layer of complexity and procedural and paperwork formalities which must be met.⁵⁷

In general, with some small exceptions,⁵⁸ once the various ‘grace periods’ come to an end, the EU no longer recognises UK standards, marketing authorisations or other processes or licences, which warrant that a product may be sold on the EU market. To access the EU market, products imported to the EU, from the UK (as a ‘third country’) must meet EU-mandated standards. The EU protects its market by requiring evidence that products meet these standards when they enter the EU.

⁵³ Article 5(6) subject to Article 10, so as long as the UK does not breach state aid rules, provides that the UK may (a) “reimburse duties levied” under Article 5 (3); (b) “provide for a waiver”; (c) “provide for circumstances in which customs duties are to be reimbursed in respect of goods that can be shown not to have entered the Union” and (d) compensate undertakings to offset the impact of the application of paragraph 3. See UK.GOV, 2020, ‘Claim a waiver for duty on goods that you bring to Northern Ireland from Great Britain or countries outside the UK and EU’, 21 December, <https://www.gov.uk/guidance/claim-a-waiver-for-duty-on-goods-that-you-bring-to-northern-ireland-from-great-britain>.

⁵⁴ See UK.GOV, 2020, ‘Check if you can bring your goods into Northern Ireland from Great Britain without paying duty’, 14 December, <https://www.gov.uk/guidance/check-if-you-can-bring-your-goods-into-northern-ireland-from-great-britain-without-paying-duty#trade-agreement>; and UK.GOV, 2020, *supra* n 53.

⁵⁵ Article 5 (5) I/NIP.

⁵⁶ *Ibid.*

⁵⁷ See, for example, Alfred Artley and George Peretz, ‘Customs and the Northern Ireland Protocol’ *Tax Journal* (2020) 14-16; Mattias Cruz Cano, ‘MNEs Struggle to Prepare for Northern Ireland post-Brexit Compliance’, *International Tax Review* 31(4) (2020) 78-89. The European Commission confirmed in a press statement on 17 December that ‘From 1 January 2021, imports of goods from Great Britain to an EU Member State will be subject to VAT in the Member State concerned, at the rate that applies to the supplies of the same goods in that Member State and will generally be payable to customs authorities at the time of importation. Goods entering or leaving Northern Ireland to/from a non-EU country, including the rest of the UK, are subject to EU VAT rules’: European Commission, 2020, ‘Questions & Answers: Joint Committee formally adopts a set of implementation measures related to the EU-UK Withdrawal Agreement’, 17 December, https://ec.europa.eu/commission/presscorner/detail/en/ganda_20_2472.

⁵⁸ In particular, the EU will continue to recognise batch quality testing inspections of medicinal products carried out in the UK, see Annex 12, Article 5 TCA.

The Ireland/Northern Ireland Protocol has the effect of applying the standards of EU law for products being moved to Northern Ireland.⁵⁹ An importer of products to Northern Ireland from GB must show that the products meet the EU's standards. There are two consequences. First, there is an added element of formality when products are moved to Northern Ireland from GB, which does not apply when products are moved between, say, Ireland and Spain, or when products are moved between England and Scotland. This is a consequence of the Protocol to do with formally demonstrating that the applicable standards (the EU's) are met. This effect of the EU-UK relationship inevitably involves greater costs, *irrespective of* whether the standards applied in GB are substantively identical to those applied by the EU. Importers of products to Northern Ireland have to tackle the relevant set of (electronic) paperwork for the EU.

Second, there is a potentially more serious consequence, in the case that the *substantive* standards applied in UK law are different from those applied in EU law. Substantively speaking, with some relatively minor exceptions,⁶⁰ the two sets of market access standards laws were identical on 1 January 2021. But where standards diverge,⁶¹ companies seeking to supply both the market in Northern Ireland and the market in GB must meet two different substantive standards and must formally provide the requisite evidence that they do so. This dual regulatory burden involves significantly greater costs, and is likely to result in changes in industry behaviour. Divergence of substantive standards concerning medicines, medical devices, equipment, consumables, or substances of human origin arises from either or both of the EU changing its law or the UK changing its law.

4.1.1 Medicines

The regulatory standards applicable in GB to medicines are contained in over 340 domestic regulations, consolidated as the Human Medicines Regulations 2012.⁶² These cover manufacture, import, distribution, packaging, labelling, advertising, sale and supply, as well as post-market surveillance. The general rule is that only licensed medicines may be lawfully sold or supplied. A licence, or 'marketing authorisation', is granted according to specified criteria concerning quality, safety and efficacy, and requires assessment of specified clinical trial data. It is granted by a licensing authority,⁶³ which in GB is the Medicines and Healthcare products Regulatory Agency (MHRA), acting as the executive agency of the Department of Health and Social Care. There is scope for supplying unlicensed medicines to individual patients.⁶⁴ A manufacturer must hold a manufacturer's

⁵⁹ Article 5 (4) and Article 18 1/NIP.

⁶⁰ See further below. In general, the UK's Withdrawal Act 2018 retained all relevant EU laws as domestic law. But some aspects of EU law, in particular those pertaining to trade, were not retained as 'retained EU law'.

⁶¹ Power to adopt Regulations covering medicines and medical devices was given to the Secretary of State for Health for GB, and the Department of Health in Northern Ireland in the Medicines and Medical Devices Act 2021, section 2.

⁶² As noted above, the Medicines and Medical Devices Act 2021 gives broad executive powers to amend the relevant Regulations.

⁶³ The Human Medicines Regulations 2012, regulation 6.

⁶⁴ The Human Medicines Regulations 2012, regulation 167.

license,⁶⁵ which itself requires certain conditions to be met.⁶⁶ Importers must hold a manufacturer's license or a wholesale dealer's license.⁶⁷ Medicines may not lawfully be distributed without a wholesale dealer's licence⁶⁸ or sold or supplied without a marketing authorisation license.⁶⁹ Furthermore, a manufacturer's or wholesale dealer license holder must enlist a UK-based Responsible Person in order to ensure compliance with the conditions under which the license has been granted.⁷⁰ Rules on packaging and labelling stipulate both standard and special requirements for packaging and labelling human medicines, such as the type of information that must be written on labels,⁷¹ and the order in which this information is presented.⁷²

At present, the *substance* of the vast majority of these rules is aligned with the substance of the equivalent rules in the EU.⁷³ There is one key exception, concerning falsified medicines regulation. Some parts of the EU's Falsified Medicines Directive,⁷⁴ concerning safety features and a Commission Delegated Regulation,⁷⁵ do not apply to medicines marketed in GB.⁷⁶ For the British supply chain, there are no formal legal obligations to follow the scanning and decommissioning processes that apply for products for the EU supply chain. Suspected falsified medicines in the British market should be reported through the MHRA's 'Yellow Card' scheme.⁷⁷ Packs of medicines compliant with the EU rules continue to be accepted in GB after 1 January 2021.⁷⁸

A medicinal product having been manufactured in GB in accordance with standards applicable in GB may not lawfully be moved to Northern Ireland. Under the Protocol, such movement legally constitutes an import of the product to the EU, meaning the EU's rules

⁶⁵ The Human Medicines Regulations 2012, regulation 17.

⁶⁶ See e.g. the Human Medicines Regulations 2012, regulation 37(2)(a), regulation 41(2) and Schedule 7.

⁶⁷ Manufacturer's License: The Human Medicines Regulations 2012, regulation 17; wholesale dealer's license: The Human Medicines Regulations 2012, regulation 42, as amended by The Human Medicines (Amendments etc.) (EU Exit) Regulations 2019, regulation 37. See also GOV.UK, 2005, 'Import a human medicine,' 9 August, <https://www.gov.uk/guidance/import-a-human-medicine>.

⁶⁸ The Human Medicines Regulations 2012, regulation 18(1)(a).

⁶⁹ The Human Medicines Regulations 2012, regulation 46.

⁷⁰ The Human Medicines Regulations 2012, regulations 45(1) and (2).

⁷¹ The Human Medicines Regulations 2012, regulation 257 and Schedules 24, 25 and 26.

⁷² The Human Medicines Regulations 2012, regulation 257.

⁷³ See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311, as amended.

⁷⁴ Falsified Medicines Directive Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products [2011] OJ L 174/74.

⁷⁵ Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use [2016] OJ L 32/1.

⁷⁶ Human Medicines (Amendment etc) (EU Exit) Regulations 2019, *supra* n 20.

⁷⁷ UK.GOV, 2018, 'Implementing the Falsified Medicines Directive: Safety Features', 24 October, <https://www.gov.uk/guidance/implementing-the-falsified-medicines-directive-safety-features#guidance-and-useful-resources>. See also YellowCard, 'Reporting a Counterfeit Product', undated, <https://yellowcard.mhra.gov.uk/counterfeit-products/>.

⁷⁸ Human Medicines (Amendment etc) (EU Exit) Regulations 2019, *supra* n 20.

on medicines apply. The vast majority of the UK's regulatory standards and processes for medicines are not recognised by the EU. This is the case even though the substance of those standards remains, for the vast majority of aspects concerned, the same as the substance of the EU's rules. For example, MHRA marketing authorisations are not recognised in EU law; additionally, there is a lack of clarity as to whether the MHRA even has the authority to issue Northern Ireland-inclusive UK-wide Marketing Authorisation.⁷⁹ Under the terms of the Protocol, therefore, in order to market a medicine in Northern Ireland, a marketing authorisation from the European Medicines Agency (or from a national regulatory authority in one of the Member States under the 'decentralised' procedure) is necessary.⁸⁰ That is the case even though the UK is no longer represented within the European Medicines Agency's structures. A marketing authorisation may only be granted to an entity established in the EU.⁸¹ Likewise, the EU's rules on importation,⁸² distribution,⁸³ labelling,⁸⁴ advertising⁸⁵ and to protect the market against falsified medicines,⁸⁶ must be complied with for medicines to be lawfully placed on the market or supplied to the NHS in Northern Ireland. The UK has partial access to the EU's database and system for pharmacovigilance, for medicines circulating in Northern Ireland.⁸⁷

The one exception to the EU's lack of recognition of UK standards and processes is that inspections and documentation certifying good manufacturing practice for medicines

⁷⁹ European Affairs Committee, "Report from the Sub-Committee on the Protocol on Ireland/Northern Ireland Introductory Report," 2nd Report of Session 2021-22, 29 July 2021, paragraph 99.

⁸⁰ See Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136 and Directive 2001/83/EC, *supra* n 73.

⁸¹ Directive 2001/83/EC, *supra* n 73, Article 8 (2).

⁸² All goods imported must be declared to the customs authorities of the respective Member State using the Single Administrative Document (SAD), the common import declaration form for all Member States, laid down in the Union Customs Code adopted in Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code [2013] OJ L 269/1, as amended, and the Union Customs Code Transitional Delegated Act adopted in Commission Delegated Regulation (EU) 2016/341 of 17 December 2015 supplementing Regulation (EU) No 952/2013 as regards transitional rules for certain provisions of the Union Customs Code where the relevant electronic systems are not yet operational and amending Delegated Regulation (EU) 2015/2446 [2016] OJ L 69/1. A customs declaration should be lodged upon importation, Article 48 UCC, with the customs office where the goods were or will shortly be presented, Article 159(3) UCC. For imported goods with a value exceeding EUR 20 000, a Customs Value Declaration must be presented with the SAD, Article 158-187 UCC. It must conform to form DV1, see Annex 8 to Regulation (EU) 2016/341 [2016] OJ L 69/1.

⁸³ All wholesale distributors must hold a distribution authorisation and comply with the good distribution practice rules (GDP) laid down in Directive 2001/83/EC and specified in Commission guidelines based on Article 84 and Article 85b(3).

⁸⁴ Directive 2001/83/EC, *supra* n 73.

⁸⁵ Directive 2001/83/EC, *supra* n 73.

⁸⁶ Falsified Medicines Directive, *supra* n 74, Article 54, and Commission Delegated Regulation (EU) 2016/161 *supra* n 76.

⁸⁷ Commission Decision granting the United Kingdom acting in respect of Northern Ireland access to networks, information systems or databases established on the basis of Union law, 16 October 2020 COM (2020) 7126 final, Annex.

under UK law must be recognised by the EU.⁸⁸ This is just one aspect of the entire regulatory framework that applies when a medicine is imported from GB into Northern Ireland.

The practical consequence of the application of EU regulatory requirements for marketing of medicines in Northern Ireland is that continued supply from GB is likely to be challenging. A survey of members of a pharmaceutical trade association for small and medium sized companies, with 300+ Member companies and organisations, representing c. 50% of UK branded medicines sales, found that 6% of respondents have already withdrawn trading products in Northern Ireland via GB and 56% plan to do so following the end of the grace period, assuming there is no extension.⁸⁹ The Department of Health and Social Care has received formal notification of '280 to 290 confirmed medicines discontinuation of supply to Northern Ireland', although further specific details are deemed commercially sensitive information.⁹⁰ A leading pharmaceuticals distributor and wholesaler warns that 'Unless the current derogation is extended, or replaced by a more permanent arrangement, Northern Ireland risks becoming a small and uneconomic marketplace, which could lead to product withdrawals or supply issues'.⁹¹ The UK government has also raised concerns about continued medicines supply to patients under these circumstances.⁹² The UK government's suggested solution is 'to remove all medicines from the scope of the Protocol entirely'.⁹³

4.1.2 Medical devices, equipment, consumables

The regulatory standards applicable to medical devices, equipment and consumables in GB are based on laws which originally embodied EU law into UK law.⁹⁴ These provisions form part of 'retained EU law' under the EU (Withdrawal) Act 2018. The Medicines and Medical Devices Act 2021 grants power to amend these laws by Regulation.⁹⁵

The regulatory process for ensuring the safety of these types of products, unlike for medicines, is based on a system of standards certification. Many products used in the NHS in Northern Ireland, such as electrical and other equipment, machinery and personal

⁸⁸ Annex 12, Article 5 TCA. The possibility of recognition of good manufacturing practice conformity in a non-EU country is foreseen in Regulation (EC) No 726/2004, *supra* n 80, Article 18 (2).

⁸⁹ European Affairs Committee, "Report from the Sub-Committee on the Protocol on Ireland/Northern Ireland Introductory Report," 2nd Report of Session 2021-22, published 29th July 2021, paragraph 96; Ethical Medicines Industry Group, 2021, 'Evidence to the Protocol on Ireland/Northern Ireland Sub-Committee, House of Lords,' 11 June, <https://committees.parliament.uk/writtenevidence/36863/html/>.

⁹⁰ Lord Frost Letter, *supra* n 12.

⁹¹ Alliance Healthcare, 2021, 'Evidence to the Protocol on Ireland/Northern Ireland Sub-Committee, House of Lords,' 12 June, <https://committees.parliament.uk/writtenevidence/36862/html/>.

⁹² HM Government, *supra* n 30, paragraph 20.

⁹³ HM Government, *supra* n 93, paragraph 61.

⁹⁴ The Consumer Protection Act 1987, the Medical Devices Regulations 2002, and the General Product Safety Regulations 2005.

⁹⁵ Medicines and Medical Devices Act 2021, section 15.

protective equipment, are covered by the system.⁹⁶ A ‘notified body’ (the EU term) or ‘approved body’⁹⁷ (the UK term) is authorised to warrant the safety of a product for release onto the market, in accordance with a set of industry standards. It is an offence to manufacture, import, or distribute products that do not comply.⁹⁸ A manufacturer must make a formal declaration of conformity with the relevant regulatory/statutory provisions, and give information about the ‘notified body’/‘approved body’ that carried out the conformity assessment procedure. In the EU, meeting these standards is evidenced by affixing a ‘CE’ mark. In the UK, a new system of ‘UKCA’ marks was brought in from 1 January 2021. However, as the UK continues to recognise CE marks until 1 January 2022,⁹⁹ our interview data suggests that few companies in the sector have yet used the new UKCA system in preference to the CE marking system, although some medical devices companies have applied for UKCA marks.¹⁰⁰

Special rules apply for most medical devices.¹⁰¹ CE marks will continue to be recognised for medical devices put on the market in GB until 30 June 2023.¹⁰² But, from 1 January 2021, manufacturers of medical devices for the British market must either be established in the UK and register with the MHRA, or appoint a ‘responsible person’ to act on their behalf and be so registered.¹⁰³ Manufacturers based in GB seeking to supply the Northern Ireland market must appoint an authorised representative based in the EU or in Northern

⁹⁶ See, for example, The Electrical Equipment (Safety) Regulations 2016; The Supply of Machinery (Safety) Regulations 2008; The Personal Protective Equipment (Enforcement) Regulations 2018.

⁹⁷ For example, the list of approved bodies for medical devices for the GB market is in MHRA Guidance 2020: GOV.UK, 2021, ‘UK approved bodies for medical devices’, 30 July, <https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies/uk-approved-bodies-for-medical-devices>.

⁹⁸ See, for example, The Personal Protective Equipment (Enforcement) Regulations 2018, regulation 7, by reference Regulation (EU) 2016/425 of the European Parliament and of the Council [2016] OJ L 81/51, Articles 8, 10 and 11.

⁹⁹ See BEIS Guidance 2020, updated 2021: GOV.UK, 2020, ‘Using the UKCA marking’, 31 December, <https://www.gov.uk/guidance/using-the-ukca-marking>.

¹⁰⁰ See, for example, Feedback Medical, 2021, ‘Bleepa affixed with a UK medical device certification’, 29 June, <https://fbkmed.com/bleepa-affixed-with-a-uk-medical-device-certification/>.

¹⁰¹ Medical Devices Regulations 2002, as amended by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019; The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019; The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020; The Medical Devices (Amendment) (EU Exit) Regulations 2021; The Medical Devices (Northern Ireland Protocol) Regulations 2021; The Medicines and Medical Devices Act 2021; The European Union (Future Relationship) Act 2020. As the editorial team at legislation.gov.uk has yet (as at 18 August 2021) to update the Regulations with the changes, it is almost impossible to read this legislation without significant (disproportionate) effort. There are literally thousands of inline changes yet to be made to the official government source of the relevant law. Some class 1 medical devices fall under the general UKCA rules, see BEIS Guidance 2020, updated 2021: GOV.UK, 2020, ‘Using the UKCA marking’, 31 December, <https://www.gov.uk/guidance/using-the-ukca-marking>.

¹⁰² MHRA Guidance: UK.GOV, 2020, ‘Regulating medical devices in the UK’, 31 December, <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk>.

¹⁰³ Medical Devices Regulations 2002, as amended. MHRA Guidance: UK.GOV, 2020, ‘Register medical devices to place on the market’, 31 December, <https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market>.

Ireland,¹⁰⁴ and manufacturers based outside of the UK seeking to supply the Northern Ireland market must have a UK 'responsible person' to act on their behalf, including for registration with MHRA.¹⁰⁵ Medical devices on the British market and on the market in Northern Ireland must be registered with the MHRA: registration must take place by different dates (1 January, 1 May, 1 September 2021; 1 January 2022) depending on the type of medical device.¹⁰⁶

Products to be marketed in Northern Ireland must comply with EU rules¹⁰⁷ and have a CE mark to certify such compliance. The EU no longer recognises UK notified bodies/approved bodies as authorised to grant CE marks. UK approved bodies may conduct conformity assessments for products placed on the market in Northern Ireland. Such products must have both a CE and a UKNI mark. Products with a 'CE&UKNI' mark may not be placed on the market in the EU, only on the market in Northern Ireland.

The EU brought in new rules on medical devices in May 2021,¹⁰⁸ and will do so for in vitro medical devices in June 2023.¹⁰⁹ As the EU's new medical devices regulations did not take effect before the end of 2021, they are not part of EU law that is automatically retained in the UK by the European Union (Withdrawal) Act 2018.¹¹⁰ But they (will) apply to medical devices on the market in Northern Ireland.

The consequence of these rules is that it is more difficult for British-based businesses to supply products to the Northern Ireland market than for the market in the rest of the UK. The UK Government noted, in July 2021, that the current arrangements have already caused 'difficulties for businesses trying to put goods from GB onto the market'.¹¹¹ According to our interviews, the expectation is that things will worsen when the UKCA regime is fully implemented, and there are consequently, according to the UK Government, 'significant risks that many businesses in GB simply give up trying to produce goods for the Northern Ireland market'.¹¹²

¹⁰⁴ Medical Devices Regulations 2002, as amended by The Medical Devices (Northern Ireland Protocol) Regulations 2021.

¹⁰⁵ UK.GOV, 2020, *supra* n 102.

¹⁰⁶ *Ibid.*

¹⁰⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC [2017] OJ L 117/1; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, repealing Directive 98/79/EC and Commission Decision 2010/227/EU [2017] OJ L 117/176.

¹⁰⁸ EU Medical Device Regulation, *supra* n 107.

¹⁰⁹ In Vitro Diagnostic Medical Device Regulation, *supra* n 107.

¹¹⁰ Section 3. Regulatory divergence is considered a significant threat to medical devices supply across the whole UK, see Regulatory Horizons Council, 2021, 'Report on Medical Devices', 19 August, <https://www.birminghamhealthpartners.co.uk/wp-content/uploads/2021/08/Regulatory-Horizons-Council-Report-on-Medical-Devices-19-August-2021.pdf>.

¹¹¹ HM Government, *supra* n 30, paragraph 58.

¹¹² *Ibid.*

4.1.3 Substances of human origin

Many of the regulatory standards applicable to human blood, tissue, cells and organs ('substances of human origin') in GB are based on laws which originally brought EU law into UK law.¹¹³ These provisions form part of 'retained EU law' under the EU (Withdrawal) Act 2018, as modified by Statutory Instruments which came into effect on 1 January 2021. Other rules are national law only, as the EU gives Member States significant powers over the details of regulation of substances of human origin, so long as a minimum floor of safety standards set by the EU are met. Only entities licensed by the Human Tissue Authority may procure, test, process, store, distribute, import or export human tissue and cells for 'human application',¹¹⁴ which includes patient treatment. Licensed entities must meet safety standards which are specified by the Human Tissue Authority in guidance and Directions.¹¹⁵

Amendments made by Statutory Instruments in 2019,¹¹⁶ and again in 2020,¹¹⁷ entered into force on 1 January 2021. The 2020 Statutory Instruments give effect to the Ireland/Northern Ireland Protocol. They distinguish between the rules applicable to and in GB, and those applicable to and in Northern Ireland.¹¹⁸ The Protocol provides that EU legislation on blood, tissues and cells, and organs applies 'to and in the United Kingdom in respect of Northern Ireland'.¹¹⁹ Movement of human blood, tissues, cells and organs

¹¹³ Key provisions are the Human Tissue Act 2004; the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and the Quality and Safety of Organs Intended for Human Transplantation Regulations 2012.

¹¹⁴ Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended), regulation 7.

¹¹⁵ Human Tissue Authority, Directions 001/2021; Human Tissue Authority, 2021, 'HTA Guide to Quality and Safety Assurance of Human Tissues and Cells for Patient Treatment', 3 June, <https://www.hta.gov.uk/guidance-professionals/regulated-sectors/human-application/hta-guide-quality-and-safety-assurance>.

¹¹⁶ Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019; Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019; Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; and Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019.

¹¹⁷ Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020; Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2020; Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020.

¹¹⁸ See Explanatory Memorandum to the Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020, the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020, the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020 and the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2020, https://www.legislation.gov.uk/ukdsi/2020/9780348213003/pdfs/ukdsiem_9780348213003_en.pdf.

¹¹⁹ Article 5 (4) I/NIP, by reference to Annex 2, section 22 I/NIP, which lists Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [2003] OJ L 33/30; Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L 102/48, and Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation [2010] OJ L 207/14.

from GB to Northern Ireland constitutes an ‘import’, and must comply with the EU’s rules for imports of substances of human origin.¹²⁰ Imports of human blood and blood components must be tested in conformity with the requirements of the EU’s blood safety legislation,¹²¹ which include traceability and safety requirements.¹²² Imports may only be undertaken by licensed entities, located in the EU. Organs exchange between GB to Northern Ireland must be supervised by EU-recognised ‘competent authorities’¹²³ and meet requirements of traceability and quality and safety, as specified by EU law.¹²⁴ Under the Protocol, the European Commission treats entities established in Northern Ireland as EU-based entities for the purposes of the licensing, authorisation, accreditation and designation provisions of this legislation.¹²⁵

As with medicines, medical devices, equipment and consumables, the consequence of these rules is that it is more difficult for British-based entities to supply substances of human origin to Northern Ireland than to supply the rest of the UK.

4.2 Products moving to Northern Ireland from GB having been manufactured in the EU in accordance with standards applicable in the EU (after the various transitional or grace periods have elapsed)

Turning now to a slightly different supply route for the NHS in Northern Ireland: what is the position when a product used by the Northern Ireland NHS is made in the Netherlands, and sent to a distribution centre in England before being shipped to Belfast from Liverpool?

A product in this category meets all the requisite standards applicable in Northern Ireland under the Ireland/Northern Ireland Protocol. However, the (electronic) paperwork is still required to show these standards are met. This is because a product in this category constitutes an ‘import’ to Northern Ireland from a ‘third country’ outside the EU: the UK.

¹²⁰ Directive 2002/98/EC, supra n 119, Article 21.

¹²¹ Directive 2002/98/EC, supra n 119, Annex IV.

¹²² Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells [2004] OJ L 102/48, Article 9. Testing is according to procedures established by the European Commission, under powers granted by Directive 2004/23/EC [2004] OJ L 102/48, Article 7(5) and Article 29 for this purpose. The current version is Commission Decision 2010/453/EU of 3 August 2010 establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council [2010] OJ L 213/48. Compliance with EU requirements is also necessary for exports of human tissues and cells from Northern Ireland to GB, see Directive 2004/23/EC [2004] OJ L 102/48, Article 9 (2).

¹²³ Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation [2010] OJ L 207/14, Articles 17-19. Competent authorities may delegate responsibilities to human donor exchange organisations, see Article 20(2).

¹²⁴ Directive 2010/53/EU supra n 123, Article 20.

¹²⁵ See European Commission, ‘Notice to Stakeholders: Withdrawal of the United Kingdom and EU Rules in the field of Substances of Human Origin (Blood, Tissues And Cells, Organs)’, Rev 2, 8 June 2020, p 4-5, and ftn 20.

As such, the import rules, customs formalities, and any duties or taxes requirements apply, as discussed in detail above.

It is likely that trade patterns have already altered to take into account the increased complexity and associated costs of moving a product through GB to Northern Ireland. A direct movement of a product from the Netherlands to Dublin, and onwards to Northern Ireland by land, is less complex administratively speaking, because that movement across the border on the island of Ireland is not an import, under the terms of the Ireland/Northern Ireland Protocol. Trade between Northern Ireland and Ireland has increased across the board.¹²⁶

4.3 Products moving to Northern Ireland from GB having been manufactured elsewhere in the world in accordance with standards applicable in GB or standards applicable in the EU (after the various transitional or grace periods have elapsed)

Some products used by the NHS in Northern Ireland are made outside Europe. What is the legal position for a product used by the NHS in Northern Ireland, made, for example, in India, and sent to a distribution centre in England before being shipped to Belfast from Liverpool?

This constitutes an import to Northern Ireland (see above in 4.1), so the relevant import rules, customs duties, taxes, and associated formalities apply. (Of course, there is *also* a set of customs formalities to be carried out when the product arrives in England. If the product was imported directly to Northern Ireland from India, that latter would not be necessary.)

If the product is manufactured in accordance with GB standards only, it cannot access the NI market, as it is necessary to show compliance with EU standards. The exception to this general rule is inspections and documentation certifying good manufacturing practice for medicines, where UK law must be recognised by the EU (see above in 4.1).¹²⁷

If the product is manufactured in accordance with EU standards, that product meets the requisite standards for supply in NI, but because the movement across the GB-NI border constitutes an import from a ‘third country’ outside the EU (see above in 4.1), the appropriate paperwork demonstrating compliance is required for import.

The consequence is that manufacturers/suppliers seeking to access both markets (GB and NI) will need to secure evidence of compliance with standards from both UK-based compliance authorities, and EU-based compliance authorities. This is a logical consequence of the EU no longer recognising, after 31 December 2020, the UK’s processes and bodies, as discussed above. The UK continues to recognise EMA marketing authorisations for medicines until 1 January 2023, but there is an extra

¹²⁶ HM Government, *supra* n 30, paragraph 21.

¹²⁷ Annex 12, Article 5 TCA.

procedure associated with this route for market access.¹²⁸ The UK continues to recognise CE marks for some medical devices until 30 June 2023, but after this date only UKCA marks will be recognised (see above). The need to meet this ‘dual regulatory burden’ arises *irrespective of the substance* of the standards applicable. It is the processes, the entities entrusted with their administration, and the associated paperwork that are no longer mutually recognised.

4.4 Products moving from England to Northern Ireland from the European Union, including Ireland, having been manufactured in GB in accordance with standards applicable in GB (after the various transitional or grace periods have elapsed)

Product supply to the Northern Ireland NHS, as with national health systems across Europe, can often involve supply chains and distribution patterns involving several countries. What is the position for a product used by the NHS in Northern Ireland, made in England, and sent to a distribution centre in the Netherlands before being shipped to Belfast from Rotterdam, or shipped to Rosslare (Ireland) from Cherbourg and then taken by road to Northern Ireland?

A product in this situation is a non-Union good,¹²⁹ not in free circulation in the EU, and will be covered by the EU’s transit provisions.¹³⁰ The purpose of transit rules is to allow exporters to move products quickly through different customs territories, to avoid having to complete customs declarations or pay customs duties or other charges in every country through which a product moves, and delay paying customs duties until products reach their destination. Under transit rules, exporters may complete some customs processes away from the border, either at departure or destination, or, with appropriate authorisation, at the premises of the consignor or consignee.

Non-Union goods can be moved through the EU via the Union Transit Procedure. The Procedure has two aspects. The External Union Transit Procedure (T1), which applies under either the Common Transit Procedure Convention 1987¹³¹ or the TIR (Transports Internationaux Routiers) Convention 1975,¹³² of which the EU and UK are both

¹²⁸ MHRA Guidance: UK.GOV, 2021, ‘European Commission (EC) Decision Reliance Procedure’, 4 January, <https://www.gov.uk/guidance/european-commission-ec-decision-reliance-procedure>.

¹²⁹ Regulation 952/2013 supra n 82, Title 1, Chapter 1, Article 5(24).

¹³⁰ Article 5 (3) I/NIP. See also: ‘Goods brought to Northern Ireland by direct transport and released for free circulation there will be subject to UCC rules and procedures, including to the Common Customs Tariff 51 according to Article 5(3) of the IE/Ni Protocol, if those goods risk entering the EU’s Single Market.’ European Commission, 2020, ‘Guidance Note: Withdrawal of the United Kingdom and EU Rules in the field of customs, including preferential origin,’ 23 December, https://ec.europa.eu/info/sites/default/files/brexit_files/info_site/guidance-customs-procedures_en_0_0.pdf.

¹³¹ See Convention between the European Economic Community, the Republic of Austria, the Republic of Finland, the Republic of Iceland, the Kingdom of Norway, the Kingdom of Sweden and the Swiss Confederation, on a common transit procedure [1987] OJ L 226/2, as amended by Decision No 1/2021 of the EU-CTC Joint Committee of 1 June 2021 as regards the amendments of Appendices I and III to the Convention on a common transit procedure [2021] OJ L 240/5. The Customs Transit Procedures (EU Exit) Regulations 2018, Schedule 1 brings the CTC into domestic UK law.

¹³² Regulation 952/2013 supra n 82, Article 226 (3)(b)(i).

members,¹³³ is engaged here when the product moves from England to the Netherlands (i.e. the transit begins outside the EU). The Internal Union Transit Procedure (T2)¹³⁴ aids the movement of non-Union goods through the EU's custom's territory.¹³⁵ In brief, the Union Transit Procedure works by suspending customs rules and formalities that would apply, until a product reaches its destination.

As the UK is a signatory of both the CTC and the TIR Convention, traders may choose which transit procedure to fulfil depending on the characteristics of both the goods being moved and the transit route taken. Under this scenario, the TIR applies as the goods cross multiple borders and part of the journey is made by road.¹³⁶

Transit declarations have to be submitted electronically, using the 'New'¹³⁷ Computerised Transit System' (NCTS).¹³⁸ The entity moving the product in this scenario (whether the manufacturer, or a logistics company) will need to register for that system, where the transit movement begins in GB, and transit is through the EU. For transit movements starting in GB and ending in the EU, it is also necessary to register for the National Export System, which operates within the CHIEF system.¹³⁹ Northern Ireland counts as the EU for these purposes.

The entity moving the product will also need an Economic Operator Registration and Identification (EORI) number.¹⁴⁰ Under the transit system, the relevant entity must secure a guarantee,¹⁴¹ to cover the duties that are suspended on the goods. The guarantee reference number is registered to the GB EORI number. The relevant entity chooses a UK customs office of departure, to which they present documentation.¹⁴²

The point of explaining this detail is to show that, even though the product here is made in England, and ends up in Northern Ireland, the associated customs-related paperwork treats the product as an export from England and import to Northern Ireland. The transit rules simplify matters to some extent, but they still add a significant layer of complexity which was not present before 1 January 2021. Additionally, as the movement of goods

¹³³ See UN Treaty Collection, available at https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XI-A-16&chapter=11&clang=en, Customs Convention on the International Transport of Goods under TIR Carnet 1975.

¹³⁴ Not applicable here as the product is not in free circulation in the EU.

¹³⁵ Regulation 952/2013 supra n 82, Title 1, Chapter 1, Articles 226 and 227.

¹³⁶ European Commission, 2016, 'Transit Manual', 27 April, https://ec.europa.eu/taxation_customs/system/files/2017-06/transit_manual_en.pdf.

¹³⁷ 'New' does not mean recent. The NCTS was implemented in 2003, see https://ec.europa.eu/commission/presscorner/detail/en/IP_03_500.

¹³⁸ Commission Implementing Regulation (EU) 2015/2447 [2015] OJ L 343/558, Article 273.

¹³⁹ See supra n 23.

¹⁴⁰ See above.

¹⁴¹ Regulation 952/2013, supra n 82, Articles 89-98; The Customs Transit Procedures (EU Exit) Regulations 2018, Schedule 1, paragraph 29(1)(c), which the HM Commissioners are empowered to enact by virtue of the Taxation (Cross-border Trade) Act 2018, Schedule 6, paragraph 6.

¹⁴² The Customs Transit Procedures (EU Exit) Regulations 2018, Schedule 1, paragraph 26(1).

within this scenario involves the Netherlands, it would appear that businesses will be unable to avail themselves of the support of the Trader Support Service (TSS)¹⁴³ in order to help navigate the procedural requirements involved. If the transit procedure occurred from England only via the Republic of Ireland to Northern Ireland, the Trader Support Service would be able to aid in the necessary logistics.¹⁴⁴

4.5 Products moving to Northern Ireland from having been manufactured in the EU in accordance with standards applicable in the EU

Finally, what about a product used in the NHS in Northern Ireland, made in France sent directly to Belfast from a distribution centre in Rotterdam? This is not currently a common pattern of products supply for the NHS in Northern Ireland. As noted above in 4.3, this movement between the EU and Northern Ireland is not an import or export: it is similar to free movement of goods in EU law.¹⁴⁵

5. Opportunities for Northern Ireland-based manufacturers of medicines and medical devices / equipment / consumables

Although overwhelmingly, our analysis and interview data suggests concern for continued supply of products to the Northern Ireland NHS, some of our interviewees mentioned opportunities for manufacturers and/or notified/approved bodies established or to be established in Northern Ireland. This information is supported by data which suggests that trade patterns concerned with supply on the island of Ireland have significantly changed since the end of the transition period. Ireland's Central Statistics Office data from July 2021¹⁴⁶ showed increases in exports from Ireland to Northern Ireland and from Northern Ireland to Ireland, and the Irish Maritime Development Office¹⁴⁷ showed that the number of shipments of goods between Ireland and the EU avoiding the UK has doubled in the first six months of 2021. Of course it is difficult to disaggregate changes to trade patterns due to COVID-19. However, it is appropriate to suggest that, while there remains volatility and uncertainty about the implementation of the Ireland/Northern Ireland Protocol, avoiding GB altogether is becoming a more appealing strategy for logistics companies,

¹⁴³ Trader Support Service, 2021, 'Trader Support Service', <https://www.tradersupportservice.co.uk/tss>; Northern Ireland Customs & Trade Academy, 2021, 'Trader Support Service - A Beginner's Guide', 14 September, <https://www.nicustomstradeacademy.co.uk/pdf/introduction-to-the-trader-support-service/>.

¹⁴⁴ Northern Ireland Customs & Trade Academy, 2021, 'Using Transit for moving goods from GB to NI via Ireland', 5 May, <https://www.nicustomstradeacademy.co.uk/pdf/using-transit-for-moving-goods-from-gb-to-ni-via-ireland/>.

¹⁴⁵ I/NIP, Article 5. See also Revenue: Irish Tax & Customs, 2021, 'Customs implications of trade with Northern Ireland', 21 April, <https://www.revenue.ie/en/customs-traders-and-agents/brexit/information-for-businesses-trading-with-ni/trade-with-ni/index.aspx>.

¹⁴⁶ Reported by BBC: John Campbell, 2021, 'Northern Ireland businesses increase value of external sales', 28 July, <https://www.bbc.co.uk/news/uk-northern-ireland-57999870>.

¹⁴⁷ Reported in Financial Times: Harry Dempsey and Peter Foster, 2021, 'Britain-Ireland freight falls 29% amid post-Brexit trade friction', 12 August, <https://www.ft.com/content/1a2f7736-f949-48b2-b5c5-6fd7e4f1fcb8>.

as there is no risk of products being held up by formalities, even though the costs associated with new routes, such as Cherbourg-Rosslare, are significantly higher. These data are general, and it is unclear whether movement of medicines, medical devices, equipment and consumables, or substances of human origin is experiencing similar changes. However, opportunities for the medical devices sector in particular have been noted.¹⁴⁸

While these emerging new trade patterns may mean opportunities for businesses based on the island of Ireland, it is difficult to see these translating into opportunities for the NHS in Northern Ireland. It is conceivable that a few new health technologies being developed on the island of Ireland might be made available to NI patients on an experimental basis. But this is a very small potential opportunity, compared with the significant concerns about detriment to patients in the Northern Ireland NHS outlined above.

6. Conclusion

The preceding legal analysis has shown in some detail the depth of complexity of the new legal regime for product supply to Northern Ireland. Of course, interpretation of these novel legal texts is ongoing, and while their administrative application in practice remains untested by litigation, it is not possible to provide certainty or clarity in terms of the granular detail of the rules that apply to product supply for the NHS in Northern Ireland. Which legal texts are currently in force is also unpredictable, as new bi-laterally and unilaterally declared 'grace periods' emerge, sometimes only weeks before the previous ones are due to elapse. Moreover, there are ongoing discussions of new binding legal texts.

Political developments, both within the EU and the UK, and between the EU and its constituent Member States and the EU undoubtedly affect the way that the relevant legal texts are interpreted and applied by the institutions involved. This is exacerbated by sometimes tense and deteriorating relationships between the EU and the UK: rather than parties collaborating over how best to resolve a tricky legal situation, a conflictual pattern of behaviour is emerging. Complex and sometimes fraught relations between the various relevant public bodies, including governments/administrations in the UK and Northern Ireland, the EU and the Republic of Ireland, but also including the European Medicines Agency and Medicines and Healthcare products Regulatory Authority, make it very difficult for private entities to navigate the unfolding situation. It is hard for companies in the sector to make market decisions on how or even whether to continue to supply the NHS in Northern Ireland, and to communicate those decisions in a timely manner. All of

¹⁴⁸ Regulatory Horizons Council, 2021, 'Report on Medical Devices', 19 August, <https://www.birminghamhealthpartners.co.uk/wp-content/uploads/2021/08/Regulatory-Horizons-Council-Report-on-Medical-Devices-19-August-2021.pdf>.

this difficulty occurs in the broader context of a global pandemic, from which the world is slowly emerging.

In turn, the fluidity of the market and its legal regulation makes it almost impossible for the Northern Ireland NHS to plan effectively its procurement of medicines, devices, equipment, consumables and substances of human origin. This difficulty has arisen because pre-Brexit patterns of supply were so heavily dependent on GB and this dependency has continued post-transition into 2021 because of the application of the 'grace periods'. Ultimately, unless a new settlement is reached, the ongoing uncertainty, and the likely outcome of Northern Ireland emerging as a very small market, will detrimentally affect patients in Northern Ireland. Those patients are entitled to a better settlement.