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- The 'Brexit Health Tracker' pilot, funded by the Health Foundation (Nuffield Trust, University of Oxford, University of Sheffield, University of Michigan).

Summary

This written evidence on the topic of health covers nine areas. We have not covered public health, as we expect others responding will do so. Each section covers our assessment of UK-EU Trade and Cooperation Agreement's (TCA) impact, including what those provisions achieve, challenges arising and how they might be resolved, and our recommendations for what the UK and the EU should seek to accomplish going forward.

In some respects, the TCA retains previous arrangements for health and healthcare governance. There is a much sharper rupture for the regulation of medicines and medical devices than for cross-border healthcare. However, the legal basis for those arrangements has changed. The TCA has the character of international law and is fundamentally different from what came before. Many provisions are significantly dependent upon voluntary implementation and enforcement. Parts of the TCA are worded ambiguously. Collaborative forms of governance including regulators, businesses, employers, professional and patient organisations, non-governmental organisations, universities, and other stakeholders will be required to provide oversight of the TCA, including its ongoing implementation and enforcement.

1. EHIC/GHIC and health provision for residents including pensioners

- The provisions in the TCA are much better than No Deal.
- The same arrangements are in place for UK/EU residents, in terms of the EHIC card, which will be replaced by the 'GHIC'.
- The TCA's Social Security Protocol provisions are almost identical to the equivalent provisions of EU law.
- However, there is no provision for directly invoking the TCA in domestic law.
- Compliance, oversight and transparency will be crucial going forward.
- In certain instances, the Withdrawal Agreement may take precedence over the TCA.
- One interpretation of TCA provisions is that they can be implemented and enforced by UK courts.

We recommend

- Update UK website showing people's rights, or establish a new website.
- For prior authorisation treatments, clear decisions need to be made by relevant NHS authorities, and communicated clearly to patients, as soon as possible.
- Consider how the UK can reassure people that there will be equivalent protection of the rights of people covered by EU national health systems if they take up residence in the UK.

- The Specialised Committee on Social Security Coordination and the new Parliamentary Cooperation and participation of civil society will be important sites for scrutiny of compliance.
- The UK should take advantage of the EU's Electronic Exchange of Social Security Information to support administration of the TCA's provisions, with the UK paying its share of costs of this system.
- The UK should immediately begin to seek a supplemental agreement to the TCA to extend the Social Security Protocol.
- Before January 2036, the UK should communicate to the EU a wish to negotiate and agree an updated Protocol.

2. Mutual recognition of regulations and tests

- The UK is free to adopt divergent regulatory requirements, with the exception of 'good manufacturing practice'.
- Processes and practices are not mutually recognised, with extra costs on the UK side.
- Trade friction has been introduced for medicines, vaccines, medical devices and equipment used in health contexts.
- Possible resolutions to trade frictions create additional uncertainties for patients and unpredictability in patient care.
- The UK is unilaterally accepting some EU regulatory steps, and some scope for bilateral arrangements.
- Unexpected gaps likely to emerge as external market actors respond to a changing regulatory environment.

We recommend

- To maintain a relationship with the EU even if exploring divergence in medicines authorisation and medical devices, to see if the UK can find a new balance between scientific innovation, competitiveness, and protecting patient safety. Industry seems to prefer a mutual recognition agreement on batch testing, but this was rejected by the EU during TCA negotiations.
- In Northern Ireland, the Joint Committee formed by a UK minister and EU Commissioner should keep supply risks and difficulties under continuous review.

3. Patent protection and supplementary protection certificates for medicinal products

- Continued membership of the European Patent Office provides important institutional continuity. The UK remains a contracting state, but now in a minority of non-EU members.
- TCA requires both sides to have supplementary patent protection and "data exclusivity" in some form, but allows for extensive divergence.
- Scope for UK divergence within global Intellectual Property framework (TRIPS).
- UK could seek to redesign its IP system, or offer generous supplementary protection, but the benefits are slight.

We recommend

- Resolution of IP matters should take place through proper stakeholder engagement and consultation, generating evidence-led proposals, and scrutinized through parliamentary processes.

4. Mutual recognition of professional qualifications

- Short-term, near universal unilateral recognition by the UK of professional healthcare qualifications from EEA countries and Switzerland solves any immediate domestic problems for the NHS.
- TCA provides a structure for future arrangements to secure mutual recognition.
- The UK will need to develop new channels for communication of information about fitness to practice of migrant EEA health professionals.
- Better data needed on health and social care professionals' migration across ROI/NI border.
- Introducing barriers to the ability to recruit from EU will impede recruitment in the long term.

We recommend

- UK regulators will need to develop other channels of communication and data sharing with their counterparts in EU countries.
- Seek formal mutual recognition agreements for health professional qualifications.
- Health professional regulatory entities should work towards joint recommendations, as envisaged by the TCA.
- Regulators in healthcare professions could share training expertise or even collaborate on training.

5. Health and social care workforce labour standards/terms and conditions

- Regressive changes to employment rights would be covered by the TCA's 'level playing field' provisions.
- The UK has an opportunity to *improve* employment law rights and working conditions, consistently with the TCA, in order to attract health sector workers.
- NHS England is in a different position to NHS Scotland or Wales which are almost totally insulated from the market.
- However, Scotland and/or Wales cannot take advantage of the different structure of their NHS to make changes to employment rights.

We recommend

- Considering whether divergence from EU standards would potentially mean difficulties in attracting health and social care workforce from EU to UK.
- But ultimately employment terms and conditions are a matter for internal decision making.

6. Cross-border health services

- TCA provisions apparently cover all four GATS modes of cross border service supply, but wording in the TCA is unclear.
- Where the service itself moves but neither patient nor professional move, continuity is secured short/medium term.
- Medium/long term, it will be important to track changing EU and UK regulatory requirements.

We recommend

- Oversight of when UK and EU regulatory requirements diverge, to ensure cross border service provision in all 'modes' of supply offers equivalent

patient protection, including for liability from harms from healthcare, to where the service takes place entirely in the UK.
- Urgent domestic guidance for the NHS in respect of existing cross-border services (eg: remote radiography services) in Northern Ireland.

7. Medical research

- The TCA makes provision for the UK to participate in Horizon Europe, Euratom Research and Training, and Copernicus.
- There is, as yet, no Protocol listing programmes the UK will participate in, their duration, specificities of participation and budgetary modalities.
- UK and EU must make 'every effort' to facilitate entry and residence of scientists, students, researchers, trainees and volunteers.
- This is a reciprocal obligation, which is only enforceable as ordinary international law.
- TCA does not explicitly address most aspects of clinical trials regulation.
- TCA contains general, but quite vague, commitments to ensure cross-border data flows, as well as not creating restrictions through technical requirements.
- UK amended its data protection law to recognise the EU's data protection regulation (GDPR) as consistent with UK law.
- If UK changes its data protection law, its 'grace period' where UK data is not counted by the EU as 'third country data' (4 months initially) comes to an end automatically.
- The UK is a 'third country' for the purposes of access to the EU's clinical trials information system, impeding UK-based researchers' access to the clinical trials 'portal'.

We recommend

- UK should seek to have a participation agreement in place as soon as possible following the adoption of the Horizon Europe programme. In order to enable sustainable research and collaboration, the participation should be agreed for the full duration of this Union programme.
- UK should provide a clear basis for the entry and residence of students and others involved in programme (e.g. trainees and volunteers). UK should make it clear that these people will be *welcome* under the new immigration rules.

8. Health security

- EU cooperation on health security includes the Early Warning and Response System (EWRS) and through coordination in a Health Security Committee.

- The TCA obliges EU and UK to inform each other of potential cross-border health threats, and allows UK to ask for EWRS access and participate in Union emergency coordination (although this may be refused).
- Specific provisions on UK-EU collaboration on anti-microbial resistance.
- Challenges are partially mitigated by regional and global cooperation through the World Health Organization (International Health Regulations and the WHO's European region). However, these offer limited legal scope.

We recommend

- Medium term, UK should seek participation in some elements of the 'European Health Union'.
- UK should seek to strengthen international cooperation, in particular through the WHO.

9. Medical Radioisotopes

- TCA does not cover radioisotopes, which are covered by the EU-UK Nuclear Cooperation Agreement.

EHIC/GHIC and health provision for residents and pensioners

What provisions and what do they achieve?

The provisions on cross-border healthcare are a significantly better settlement than No Deal at the end of transition would have been, from the point of view of people who relied on EU law to receive healthcare and medical treatment in the UK or an EU Member State.

For UK/EU residents, in the UK/GB access to healthcare continues on the same basis as national residents, as before. For visitors, a form of EHIC entitlements is preserved going forward. For NI/ROI residents, the Common Travel Area rules continue.

What is different is the legal basis on which these rights are enjoyed, with corresponding implications for how rights are enjoyed and enforced. Compliance, oversight and transparency will be crucial to ensure public confidence.

The EU Member States and the UK are obliged to 'coordinate' their social security systems, in accordance with the Protocol on Social Security Coordination. The object and purpose of this coordination is 'in order to secure the social security entitlements of the persons covered therein' (Ch.SSC.1).

Enforcement of rights

This is one of the few parts of the TCA that has individual human beings as its focus. In general, the TCA does not confer rights or impose obligations on human beings or legal persons (Article COMPROV.16: Private rights). But that general rule is '1. Without prejudice to Article MOBI.SSC.67 [Protection of individual rights]' (Article COMPROV.16: Private rights (1))

There is no provision for directly invoking the TCA in domestic law. The TCA is an instrument of international law, conferring obligations on the Parties to the TCA (the EU, its Member States and the UK). It is totally different to EU law in this regard. It is also totally different to the Withdrawal Agreement, which includes a significant number of citizens' rights provisions, and special measures for its enforcement.

The social security rights under the TCA must be protected by each Party's domestic legal order (Social Security Protocol, Article SSC.67: Protection of

individual rights). The Parties have agreed that human beings (and companies) must be permitted, by domestic law (not by the TCA itself) to invoke the provisions of the TCA before domestic courts, tribunals and administrative authorities, and thus to seek 'adequate and timely' remedies for any breach. The word 'and' suggests that courts and tribunals must be included in the arrangements made for enforcing social security coordination rights under the TCA, and that only providing for an administrative process, such as Ombudsman or other complaints process, would not be compliant with the TCA.

Personal scope

The Protocol on Social Security Coordination applies only to 'situations arising between one or more Member States of the Union and the United Kingdom' (Ch.SSC.3 (1)). People whose situations are confined in all respects to either the UK or the EU Member States fall outside the scope of the Protocol (Ch.SSC.3 (2)). There is no further definition of this scope rule.

The definition of who is covered by the Protocol on Social Security Coordination is based on the EU law on coordination of social security: people who are 'subject to' the social security legislation of one or more States (the UK, EU Member States), their families and their survivors (Social Security Protocol, Article SSC.2). Curiously, 'subject to' is not further defined, either in this Agreement, or in the Withdrawal Agreement, or in EU Law. In many situations, being 'subject to' social security legislation will be obvious: if one is paying social security contributions (eg for a pension), or receiving benefits (eg for invalidity or unemployment), then one is obviously 'subject to' the legislation. But in other situations, it is less obvious. Is someone who contends that they fall within the scope of the relevant social security rules 'subject to' those rules? The TCA includes some provision on what happens if there is disagreement about whether someone falls within its scope (see below).

The TCA further specifies that, in principle, the Protocol on Social Security Coordination applies only to people who are lawful residents of the UK or an EU Member State (Ch.SSC.2 in the main TCA). But this rule does not affect 'entitlements to cash benefits which relate to previous periods of legal residence of persons covered by Article SSC.2'). So someone might no longer be lawfully resident in the EU or UK, but still fall within the scope of who is covered by this part of the TCA, for example if they are entitled to pension benefits under the TCA, but live outside of the EU and UK.

What is covered: general rules

The Protocol on Social Security Coordination covers all the main branches of social security that are covered by EU law and by the Withdrawal Agreement. These include 'sickness benefits' (Social Security Protocol, Article SSC.3 (1) (a)) (in cash or in kind) – that is, medical treatment and healthcare.

Like in EU law and the Withdrawal Agreement, medical assistance is not covered (Social Security Protocol, Article SSC.2 (4) (b)). Neither is voluntary social insurance, unless it is the only social insurance scheme for the particular branch of social security in the relevant State (Article SSC.13). Neither are 'assisted conception services' (Social Security Protocol, Article SSC.3 (4) (e)), defined as 'any medical, surgical or obstetric services provided for the purpose of assisting a person to carry a child' (Social Security Protocol, Article SSC.1 (c)). Just to be clear, Article SSC.5 explicitly excludes the matters listed in Article SSC.3 (4) from the general non-discrimination principle (Social Security Protocol, Article SSC.5).

Long-term care benefits are not currently explicitly covered by the EU rules on coordination of social security. Long-term care cash benefits are expressly excluded from the Social Security Protocol (Social Security Protocol, Article SSC-3 (4), Annex SSC-1, Part 2) but there is a proposal before the European Parliament and Council which would extend coordination of social security to aspects of long-term care that are not currently included in the provisions on sickness benefits, and to clarify the rules. If the proposal is adopted, there will be a whole new chapter of the relevant EU law (Regulation 883/2004) on long-term care benefits, which will bring needed clarity to that area.

The general rules (and there are exceptions) for the Protocol are that social security coordination rules are on the basis of non-discrimination between Member States of the EU (Social Security Protocol, Article SSC.4).

In general (again there are exceptions), the people who are covered by the Protocol enjoy the same benefits (and are subject to the same obligations) as the nationals of the relevant State (Social Security Protocol, Article SSC.5). In general, the Protocol applies a principle of 'equal treatment of benefits, income, facts or events' (Social Security Protocol, Article SSC.6).

There are two key aspects to this. First, if receipt of social security benefits (or income) has certain legal effects in one State, that State must also recognise equivalent benefits (or income) acquired under the legislation of another state. Second, where legal effects flow from facts or events taking place in one State, that State must take into account 'like facts or events' taking place in another State, as if they had taken place on the territory of the first State (Social Security Protocol, Article SSC.6 (a) and (b)). In general, the Protocol requires the aggregation of periods of social insurance, employment, self-employment or residence, completed in any of the States Parties to the TCA (Social Security Protocol, Article SSC.7). There is a whole section of ANNEX SSC-7: Implementing part on specifics of the aggregation rules (Article SSCI.11 and 12). In general, receipt of cash benefits under the Protocol must not be made conditional on residence (Social Security Protocol, Article SSC.8). All of these

provisions are similar to those in the Withdrawal Agreement (Article 31 WA) and in EU law (Regulation 883/2004/EC, Articles 4,5,6,7).

Again, as in the Withdrawal Agreement and in EU law, the 'single state rule' applies. In general, 'persons to whom this Protocol applies shall be subject to the legislation of a single State only' (Social Security Protocol, Article SSC.10). The starting point here is employment or self-employment, and only if neither applies does residence become relevant. If someone is employed or self-employed in a State, that State is the State whose social security legislation they are 'subject to' (Social Security Protocol, Article SSC.10 (3) (a) (b)). There are rules for people who normally are employed in both the UK and one or more EU Member States (Article SSC.12): basically if someone is resident where they perform a substantial part of their work, that is the relevant state; if not, the place in which the employer is registered; or the 'centre of interest' of the activities of a self-employed person is the relevant state. There is, obviously, lots of room for interpretation of these rules in specific situations.

If someone is neither employed nor self-employed, the general rule is that their residence (which means 'where the person habitually resides' Social Security Protocol, Article SCC.1 (aa)) determines the relevant State. There is a whole section of the ANNEX SSC-7: Implementing part on the elements for determining residence (Article SSCI.10) on this point. There are special rules for people who work on ships and aircraft (Social Security Protocol, Article SSC.10 (4) and (5)).

Like many international agreements, the Protocol on Social Security Coordination allows for States Parties to derogate from its general terms in some respects. The Protocol allows Member States to derogate from the single state rule for 'detached workers' (Article SSC.11). 'Detached workers' (the usual English term is 'posted workers' and this might be tidied during 'legal scrubbing' of the text) are either employed by an employer in a State which normally carries out its activities there, and sent by their employer to another State to work on the behalf of that employer; or self-employed and normally pursuing a self-employed activity in one State, and who go to another State to pursue a similar activity (Social Security Protocol, Article SSC.11 (1) (a) and (b)). There is no list of these Member States yet in the text (see p 1246). Article SSC.11 obliges the European Union to notify the UK, by the time the TCA enters into force, whether each Member State falls into one of three categories: A: the Member State wishes to derogate from the general rules of the Protocol on which state is the state responsible for social security (Social Security Protocol, Article SSC.10); B: the Member State does not wish to so derogate; or C: the Member State has not indicated either A or B. That list of three categories of Member States will become Annex SSC-8, when the TCA enters into force. One month later, categories B and C will cease to exist. Member States in category C will be deemed to be in category A for one month. After that, such a Member State can join category A by the Union notifying the new Specialised Committee on Social

Security Coordination (see below) to that effect. A Member State can leave category A in the future by the same mechanism. For Member States in category A, transitional rules for 'detached workers' will apply for a 24 month transitional period.

What is covered: cross-border healthcare

Title III of the Social Security Protocol sets out special provisions for each category of benefits (pensions, unemployment benefit and so on). Chapter 1 concerns sickness benefits. Like in EU law, there is a set of rules for 'insured persons' (people 'subject to' social security legislation of the 'competent state', and members of their families) and a separate set of rules for pensioners and members of their families.

'Insured persons' and their families who are resident in a State other than the competent state, are entitled to receive in the State of residence 'sickness benefits in kind' provided by the 'institution of the place of residence', as though those people were insured under the legislation of the place of residence (Social Security Protocol, Article SSC.15; Article SSC.21 (pensioners)). People in this category include frontier workers (who live in one state and work in another – special rules apply to them (Social Security Protocol, Article SSC.16)); posted workers (who are sent by their employer to work in another state); and also people who return home for intervals longer than a week (so do not satisfy the frontier worker definition).

So, if someone is 'subject to' UK social security legislation for the purposes of receiving healthcare in the UK, because under the UK legislation they are deemed 'resident' in the UK (that being the national rule determining access to the NHS), and they are employed or self-employed in the UK (see the single state rules above), but they are also deemed 'resident' in Spain by Spanish legislation, because they are in Spain sufficiently to count as 'resident' under Spanish legislation, this provision of the Protocol entitles them to access Spanish healthcare as if they were insured under the Spanish legislation. These provisions are almost identical to the equivalent provisions of EU law (Regulation 883/2004, Articles 17 and 18, 23-26).

Social Security Protocol, Articles SSC.17 and SSC.25 (pensioners) cover 'stay' outside the competent State. This is the equivalent of the EHIC provision in EU law. It entitles an insured person, and members of their family, who are staying in a state other than the competent state, to healthcare which becomes necessary on medical grounds during their stay. The determination of necessity must take account of the nature of the healthcare or medical treatment and the length of the stay. It is the healthcare provider in the state providing the healthcare that determines necessity. The entitlement under Social Security Protocol, Article SSC.17 or SSC.25 does not cover someone who travelled with

the purpose of receiving the healthcare or medical treatment. (There is an exception for a passenger or someone working on a ship or aircraft, who became ill during the voyage or flight). These provisions are almost identical to the equivalent provisions of EU law (Regulation 883/2004, Articles 19 and 20, 27).

Healthcare provided under these provisions must be fully reimbursed by the competent State (Social Security Protocol, Article SSC.30). The UK, along with Ireland, Spain, Cyprus, Portugal and Sweden, will claim reimbursement of the cost of benefits in kind on the basis of fixed amounts (Social Security Protocol, Annex SSC-7, Implementing part, Article SSCI 48 (1), and Appendix SSCI-3). Waiver agreements, for reimbursement of some, or all, aspects of benefits in kind (healthcare) under the provisions are in place for patients moving between the UK and Belgium, Denmark, Estonia, Finland, France, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Portugal, Spain and Sweden. Some of these, eg UK-Ireland, are for all 'benefits in kind' (healthcare). Others, eg UK-France, are only for costs of administrative checks and medical examinations, not for the cost of the medical treatment itself (Appendix SSCI-1).

A person seeking to receive healthcare or medical treatment during a stay outside the competent state must present a 'valid entitlement document'. The entitlement document is covered in Appendix SSCI-2. For EU Member States, the valid document is essentially the EHIC: it has to comply with the technical specifications of the relevant EU law determining EHIC cards (Decision No S2 of 12 June 2009 of the Administrative Commission concerning the technical specifications of the European Health Insurance Card) (Appendix SSCI-2 1). For the UK, the entitlement document has to contain the following information ((Appendix SSCI-2 2):

(a) surname and forename of the document holder;

(b) personal identification number of the document holder;

(c) date of birth of the document holder;

(d) expiry date of the document;

(e) the code "UK" in lieu of the ISO code of the United Kingdom;

(f) identification number and acronym of the United Kingdom institution issuing the document;

(g) logical number of the document;

(h) in the case of a provisional document, the date of issue and date of delivery of the document, and the signature and stamp of the United Kingdom institution.

The UK must notify the Specialised Committee on Social Security Coordination 'without delay' of the technical specifications of the UK document ((Appendix SSCI-2 3).

The UK government's GHIC website explains that people who have valid EHICs will be able to continue to use them from 1 January 2021, to access necessary healthcare on a visit to an EU country. When someone's EHIC expires, they will be able to apply for a GHIC for free.

Social Security Protocol, Annex SSC-7, Implementing part, Appendix SSCI-2 confirms that the entitlements under Article SSC.17 of the Protocol on Social Security Coordination include medical treatment for pre-existing illnesses and chronic conditions, as well as medical treatment in conjunction with pregnancy and childbirth, unless the purpose of the trip is to receive these treatments (see p 1244). But for vital medical treatment that is only available through a specialised medical unit, authorisation in advance is required before the trip. This includes (but is not limited to)

(a) kidney dialysis;

(b) oxygen therapy;

(c) special asthma treatment;

(d) echocardiography in case of chronic autoimmune diseases;

(e) chemotherapy.

So some medical treatments that used to be available under the EHIC scheme will after 31 December 2020 only be available if the relevant State (the UK or EU Member State) gives prior authorisation. This will be the case, for instance, for UK patients accessing kidney dialysis in EU Member States. As far as we are aware, the UK has not yet indicated whether it will authorise such treatments, or under what conditions.

Implementation, Administrative Arrangements and Dispute Settlement

Social Security Protocol, Annex SSC-7: Implementing Part sets out significant detail on the practicalities of implementing the parts of the TCA on Coordination of Social Security. There is an obligation on the UK and the EU Member States to 'provide or exchange all data necessary for establishing and determining the rights and obligations of persons to whom the Protocol applies' and to do so 'without delay' (Article SSCI.2). A Specialised Committee on Social Security Coordination is empowered to authorize – if it so decides – the use of the EU's Electronic Exchange of Social Security Information for exchange of information.

If this decision is taken, the rules applying to that system (which are rules of EU law) will apply (Article SSCI.4 (2)).

There is an obligation to make sure necessary information is made available, so that people concerned are able to assert their rights under the Protocol and Annex (Article SSCI.3 (1). Information must be forwarded, and documents issued, 'without delay' and in accordance with any time limits specified in national legislation (Article SSCI.3 (3)).

If a decision is made to refuse benefits, reasons must be given, and information communicated about remedies and time periods for appeals (Article SSCI.3 (3).

Where there is a difference of views between States on what is the applicable legislation or on which is the competent state which is responsible for providing cash benefits or benefits in kind (eg medical treatment), there is an obligation under the TCA to provisionally apply the legislation of one State (Article SSCI.6 (1) and (2)). For determining applicable legislation, this State is the state where the person actually pursues employment or self-employment, if there is such a state; or the state of residence if the person concerned pursues employment or self-employment in two or more States and performs part of their activity or activities in the State of residence, or if the person concerned is neither employed nor self-employed. In all other cases, it is the State to which a claim was first made, if the person pursues an activity, or activities, in two or more States. For determining the competent state, the legislation of the person's place of residence applies or, if that person does not reside on the territory of one of the States concerned, that person is provisionally entitled to the benefits provided for by the legislation applied by the institution to which the request was first submitted.

These provisions mean that people should not be left in limbo while complex cases are decided.

There is provision for bilateral procedures between States to depart from those in the Annex, provided that they do not have an adverse effect on people's rights (Article SSCI.8). The bilateral arrangements have to be notified to the Specialised Committee on Social Security Coordination and listed in the Appendix SSCI-1, thus securing (at least some) transparency. Any pre-existing bilaterals serving the same or similar purposes to the social security provisions in the TCA will continue to apply, but they must also be listed in Appendix SSCI-1.

Finally, the TCA includes provisions for a Specialised Committee on Social Security Coordination, which addresses matters covered by Heading Four of Part Two and the Protocol on Social Security Coordination (INST.2 (p)); and for Parliamentary Cooperation and participation of civil society (INST.5; INST.6; INST.7).

Under Article INST.2 (2) … Specialised Committees shall have the power to: (a) monitor and review the implementation and ensure the proper functioning of this Agreement or any supplementing agreement; … (c) adopt decisions, including amendments, and recommendations in respect of all matters where this Agreement or any supplementing agreement so provides or for which the Partnership Council has delegated its powers to a Specialised Committee in accordance with point (f) of Article INST.1(4) [Partnership Council]; (d) discuss technical issues arising from the implementation of this Agreement or any supplementing agreement; (e) provide a forum for the Parties to exchange information, discuss best practices and share implementation experience; (f) establish, supervise, coordinate and dissolve Working Groups; and (g) provide a forum for consultation pursuant to Article INST.13(7) [Consultations] of Title I [Dispute Settlement] of Part Six.

The Specialised Committee on Social Security Coordination will have power to make recommendations (which have no binding force) and decisions, by mutual consent (INST.4) Decisions adopted by the Specialised Committee on Social Security Coordination will have binding force on the Parties to the TCA (INST.4). The Committee will make decisions, for instance, on 'the structure, content and format of forms and documents issued on behalf of the States for the purposes of implementing the Protocol' (Annex SSC-7, Article SSCI.4 (1)). The Committee is tasked with reconciling differing points of view on 'information provided by the persons concerned, the validity of a document or supporting evidence or the accuracy of the facts on which the particulars contained therein are based' (Article SSCI.5 (4).

The TCA's general provisions on dispute settlement also apply to the social security coordination provisions (Article INST.10: Scope), although not in individual cases (Article INST.10(5)). Note that it is not possible, in the event of a successful complaint by one party about breach of the treaty, to retaliate by suspending the social security provisions (Article INST.24(3)(b)). This also applies to successful complaints about breaches of the Withdrawal Agreement (Article INST.24(4)).

Other people will already have written about this – but the basic message here is that this is international law, not anything like EU law. However, the specificities of this part of the TCA do give some protections to individuals for their rights.

What is covered: Northern Ireland

The social security coordination provisions in the TCA are without prejudice to the Common Travel Area arrangements between the United Kingdom and the Republic of Ireland (Social Security Protocol, Article SSC.4 (2)). To access Irish state healthcare, UK nationals need to show either an EHIC, or proof of their UK

residence. This continuation of the existing rules from 1 January 2021 is confirmed in the UK government's website.

As in EU law, there is scope under the Social Security Protocol for authorisation of medical treatment in another State under the TCA. If authorised, there is an obligation on the healthcare institution of the place to which the person authorised travels to provide the medical treatment authorised as if the person was insured in that State (Social Security Protocol, Article SSC.18). There is also, as in EU law, in effect an obligation to grant authorisation 'where the treatment in question is among the benefits provided for by the legislation in the State where the person concerned resides and where that person cannot be given such treatment within a time limit which is medically justifiable, taking into account their current state of health and the probable course of their illness' (Social Security Protocol, Article SSC.18). This provision also gives entitlements to family members of the 'insured person'. There is provision for if the family members and the insured person reside in different States.

This provision (the 'S2' in EU law, Regulation 883/2004, Article 20) is used relatively infrequently between Great Britain and the EU, but several hundred people a year do rely on it to receive health care across the border between Northern Ireland and the Republic of Ireland. The question of whether a time limit before which someone receives treatment is 'medically justifiable' is obviously contentious. When the UK was an EU Member State, EU law was used to seek judicial review of this question, and a number of English NHS Hospital Trusts reduced waiting times for elective procedures such as hip replacements in response. Apparently there is ongoing litigation in Northern Ireland which seeks judicial review of the NHS there for breaching waiting time limits, in part relying on EU law. Given the COVID-19 context, we might see further attempts to use litigation before domestic courts in a similar way in the future – reliant on the domestic legislation implementing the TCA, rather than the TCA itself.

Challenges and how could they be resolved?

Challenge 1: How do people know what their rights are in practice, as this is a complex area of law where national social security laws in each Member State, and the UK, interact in different ways, and where the details of the law, as well as administrative practice, change regularly.

Within the EU, a detailed website is maintained, which shows people at a glance what their rights under the social security coordination provisions are when they

move between any two Member States. Obviously this website used to include the UK, but no longer does.

This challenge could be resolved by either the UK being added back into the existing website, or a new website being created that shows the rights between the UK and each of the EU Member States. The latter is likely to be necessary because there are no provisions for the UK to 'track' changes to EU law in this area going forward.

Challenge 2: How will people covered by a UK NHS know what the rules are on prior authorisation for treatments that require such authorisation: kidney dialysis; oxygen therapy; special asthma treatment; echocardiography in case of chronic autoimmune diseases; chemotherapy?

This is not an exhaustive list: what other treatments might be included within the definition of 'vital medical treatment that is only available through a specialised medical unit'? Which do the relevant decision-makers in the UK intend to include?

Will authorisation entitlements differ in different parts of the UK?

This matter is internal to the UK, and can be resolved by clear decisions being made by the relevant NHS authorities, and communicated clearly to patients, as soon as possible.

This communication can include working with patient organisations such as Kidney Care UK, which has developed significant capacity for advising patients under the previously-applying EU law, and under the Withdrawal Agreement.

The grounds for review of a refusal of authorisation should also be made clear.

Challenge 3: Enforcement of rights in the UK

UK nationals who move to the EU after 1 January 2021 and are legally residing in the EU "for the purpose of work" have rights, as 'third country nationals' under the Single Permit Directive 2011/98/EU. Those who will be long term residents in the future will have similar rights under the Long Term Residents

Directive 2003/109/EC. These rights include equal treatment with nationals of the Member State of residence with regard to 'branches of social security under Regulation 883/2004/EC' / 'social security, social assistance and social protection as defined by national law'.

As measures of EU law, these rights are directly effective and enforceable, as a matter of EU law, against the national authorities of the host Member State. There is a possible reference to the CJEU if there is a question of EU law at hand. Domestic courts must accept the interpretation of the CJEU. There is a possible action brought by the Commission against a host Member State that is non-compliant, again before the CJEU. So, if you are a UK citizen residing in the EU, you have judicial protection by going to the host Member State authorities with a possible reference to an independent court (the CJEU). This is how the EU and its Member States will comply with the obligation in Social Security Protocol, Article SSC.67, which requires effective rights protection and that the provisions of the Protocol have the force of law, and can be invoked before domestic courts and tribunals.

But what is the equivalent judicial protection for EU nationals resident in the UK? What is foreseen as regards enforcement of citizens rights with both State Parties (EU and UK)? The Social Security Protocol, Article SSC.67 (2) provides for effective rights protection *either* through courts *or* through a complaint procedure to an administrative body. This latter would be lesser protection than required by EU law (which, as noted above, will apply to some UK nationals in the EU as 'third country nationals'). How can the UK reassure people that there will be equivalent protection of the rights of people covered by EU national health systems when they take up residence in the UK after 1 January 2021?

Challenge 4: Interpretation challenges: For example, inconsistent interpretation of the Social Security coordination provisions of the TCA between the UK and the EU/EU Member States; uncertainty whether TCA or Withdrawal Agreement applies to a particular person or situation.

The Preamble to the TCA recognises that social security coordination is important to human beings, not just those who are migrating as 'economic entities' (providing services, for example), but also their families. The Preamble also recognises that social security coordination applies not just to people who move between the UK and the EU to reside, but also to 'stay', ie just for a visit:

> Preamble: "RECOGNISING the importance of the coordination of social security rights enjoyed by persons moving between the Parties to work, to

> stay or to reside, as well as the rights enjoyed by their family members and survivors,"

Provisions of the Preamble of an international agreement are an important reference point when it comes to interpretation of that agreement. Interpretation of the TCA is to be in accordance with international law (not EU or UK law). This approach includes taking account of the context of the legal text, and the 'object and purpose' of the TCA as a whole. It is possible – and perhaps in the context of the social security coordination rules, likely – that the interpretation of the provisions of the TCA on social security coordination will differ between the UK and the EU Member States. In the context of this Agreement, there is nothing like the Court of Justice of the EU, or the EFTA Court, to seek to prevent such divergent interpretation.

The rules in the Social Security parts of the TCA go quite a long way to protecting individuals when there is a difference in interpretation between the Parties to the TCA. The obligation to provisionally apply the legislation of one State (Article SSCI.6 (1) and (2)) will protect individuals in the event of a difference in interpretation as to applicable legislation, or the competent (hence responsible) State.

Where there is uncertainty as to whether the Withdrawal Agreement or the TCA applies, we would argue that the Withdrawal Agreement, or at least its provisions that give rights to human beings, should be applied in preference to the TCA. This is for the reasons set out below.

The TCA makes no explicit reference to the Withdrawal Agreement. The TCA provides (COMPROV.13) that its provisions shall be interpreted in accordance with their ordinary meaning', and 'in the light of the object and purpose of the agreement in accordance with customary rules of interpretation of public international law'. These rules, some of which are codified in the Vienna Convention on the Law of Treaties, include principles such as *lex posterior derogat legi priori* (Article 30 VCLT) (when parties to a treaty are also parties to an earlier treaty on the same subject, and the earlier treaty is not suspended or terminated, the earlier treaty is applied only to the extent that its provisions are compatible with those of the later treaty). But the *lex posterior* principle applies only in limited circumstances: it does not apply when the text of the treaties suggests that the parties intend otherwise (see, eg, Conclusions of the work of the Study Group 2006). In particular, according to Article 30 (2) VCLT, 'When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail.' Article FINPROV 2 states that the TCA and subsequent supplementing agreements apply 'without prejudice to any earlier bilateral agreement' between the EU and the UK, which of course includes the Withdrawal Agreement. So in the event of the possible application of the WA to a particular situation, the

Withdrawal Agreement may be applied in preference to the TCA: in this regard the TCA would not displace the WA. But we would argue that the Withdrawal Agreement also *should* be applied. This is also because the Withdrawal Agreement offers greater protection than the TCA, in terms of its enforcement, and thus in terms of fundamental human rights (including the right to social security and the right to healthcare), which are part of the European Social Charter, fundamental human rights treaties to which both the EU Member States and the UK are parties. Article COMPROV 4 TCA reaffirms the Parties' respect for fundamental human rights, as found in 'international human rights treaties to which they are parties'. (Technically speaking, the TCA is presented as between only the UK and the EU, but in practice it also concerns matters for which the Member States share competence, so even though the EU is not a party to any human rights treaties, Article COMPROV 4 TCA should be read in this light.)

Other differences of interpretation will have to be resolved through the dispute resolution provisions of the TCA. These are non-existent when it comes to matters relating to interpretation or application of the social security provisions of the TCA.

The Specialised Committee on Social Security Coordination has significant responsibilities, but does not appear to have the power to adopt decisions on which is the correct interpretation of the social security coordination rules, or their application, in situations when there is a disagreement. The Partnership Council has the power to 'adopt decisions in respect of all matters where [the TCA] so provides' (Article INST.1 (4)), and to delegate tasks and decision-making powers to the Specialised Committees (Article INST.2 (4) and (5). The Specialised Committees have the power to assist the Partnership Council in the performance of its tasks, including taking delegated decisions (Article INST.2 (4)). But these powers are *only* where the TCA provides for such decisions. The Specialised Committee on Social Security Coordination does have some decision-making power (see, eg Article SSCl.47 (2)), power to adopt 'guidance' on implementation (Article SSCl.74), and has power to undertake *consultations* on questions of interpretation or application of the Social Security Protocol when requested by the Parties to the TCA (Article SSC.59 (7)). But the Specialised Committee on Social Security Coordination has no power to take decisions on those matters. Neither does the Partnership Council, as the TCA does not provide for such a power.

Challenge 5: Inadequate implementation or enforcement of the provisions

The UK's European Union (Future Relationship) Act 2020, section 26, which gives effect to the TCA in domestic law, states simply that the social security provisions of the TCA 'form part of domestic law'.

One interpretation of this provision is that means that the TCA provisions themselves can be relied upon, enforced, and interpreted by UK courts and tribunals. In the UK, the process for protection of individual rights under the social security parts of the TCA is likely to be through the Social Security and Child Support Tribunals, in the first instance, with appeal to the Upper Tribunal (Administrative Appeals Chamber).

However, given the TCA as a whole, it is at least arguable that the provisions of the TCA do not have those qualities of EU law (or of the Withdrawal Agreement) which mean that they can be relied upon in domestic courts and tribunals. This interpretation of the TCA and of domestic law, I would argue, is not the correct one, because the social security provisions of the TCA *are* expressed in terms of their enforceability by individuals. In the case of the vast majority of the substantive provisions, the wording is identical to equivalent provisions of EU law, and the preamble and other elements of the TCA suggest such enforceability.

As part of domestic law, the provisions of the European Union (Future Relationship) Act 2020 are subject to the usual rules of domestic law, which include the possibility of explicit repeal by a later Act of Parliament. They do not, however, include implied repeal, as the assumption in UK law is that the UK legislature and executive intend to comply with the UK's obligations in international law.

Challenge 6: How to secure accountability for compliance with the Social Security provisions of the TCA

The Specialised Committee on Social Security Coordination and the new Parliamentary Cooperation and participation of civil society (INST.5; INST.6; INST.7) will be important sites for scrutiny of compliance with the TCA, any future divergence in interpretation of obligations, and (given that the role for an over-seeing court is non-existent) for legal contestation.

It will be important to ensure that the UK Parliament, and, where appropriate, the Parliaments in Northern Ireland, Scotland and Wales exercise oversight over executive powers; and to ensure that relevant NGOs are represented in the civil society processes.

Challenge 7: What happens when the EU rules change (which they might, quite soon, including to bring long-term care benefits into the system)?

There are no provisions within the TCA for the UK to automatically 'track' or 'recognise' changes to the EU's rules on coordination of social security. If nothing else happens, there will then (potentially quite quickly) be two different sets of rules: the EU rules for movement within the EU; and the TCA rules for movement between the EU and the UK. This will significantly increase complexity for people concerned and those trying to advise them.

The Specialised Committee on Social Security does have power to amend the Annexes and Appendices to the Protocol on Social Security (Article SSC.68). But amending the Protocol itself (which would be necessary if the UK wishes to secure equivalent entitlements to social security coordination, including access to health-care and related benefits, to those available within the EU to movements between the UK and EU) would have to be negotiated by the Parties.

Challenge 8: current arrangements do not include non-EU countries within the Single Market.

The EFTA states - Norway, Iceland, Leichtenstein and Switzerland - have adopted EU law on reciprocal healthcare as part of their relationships with the Single Market. As a result, reciprocal healthcare coverage and programmes for EU member states extends to these countries. However, the UK's access through the TCA does not extend to these countries, though it has reached a separate agreement with Norway. Negotiations have been started on trying to secure an equivalent agreement.

Challenge 9: The Protocol ceases to apply 15 years after the TCA enters into force.

Without provisions such as these, all access to cross-border health care in the EU through the EU's coordination of social security will cease. Any entitlements would be based only on the separate domestic laws in the different EU Member States, and any bilateral agreements into which the UK had entered. This would be a significant reduction in entitlements for people covered by the NHS in the UK.

The Parties to the TCA have power to negotiate to conclude an updated Protocol, if one of the Parties has indicated its wish to enter into such negotiations at least 12 months before the sunset clause takes effect (Article SCC.70 (2)).

What should the UK seek to do with the EU in the short and medium term?

Working through the Specialised Committee on Social Security Coordination, as per Annex SSC-7 Implementing Part, Article SSCI.72, the UK and EU should create and maintain an equivalent website on coordination of social security to the one that shows citizens their entitlements within the EU.

For the practical administration of the new system, the UK and the EU should take advantage of the powers in Annex SSC-7 Implementing Part, Article SSCI.71 1 (4) so that the EU's Electronic Exchange of Social Security Information can be used to support administration of the TCA's provisions. The UK should agree to pay its share of the costs of this system.

The UK should use the Specialised Committee on Social Security Cooperation and the new Parliamentary cooperation and civil society procedures to ensure compliance from the EU side, as well as to promote confidence that the UK side is compliant by involving Parliamentary and civil society accountability and oversight, including from the devolved jurisdictions.

The UK should immediately begin to seek a supplemental agreement to the TCA to extend the terms of the Social Security Protocol to those matters covered by the revisions to Regulation 883/2004, as envisaged by COM (2016) 815 final, if those revisions come into effect. These amendments would enhance access of UK residents to social security benefits of relevance in the health context, especially long-term care benefits.

Before January 2036, the UK should communicate to the EU a wish to negotiate and agree an updated Protocol, so as to secure access to cross-border healthcare in the EU for UK nationals into the future.

Establish collaborative governance arrangements to build trust between the UK and EU that both parties' legal obligations under the TCA with respect to health will be adhered to and enforced. Collaborative governance arrangements involve

a coordinating agency or committee involving non-state actors (stakeholders in the public and private sectors, and civil society) in decision making about how best to monitor and enforce legal obligations, particularly in managing contentious, cross-jurisdictional legal and policy problems. Evidence from international data on collaborative governance arrangements shows that such arrangements are effective in building trust and ensuring cross-jurisdictional legal responsibilities are complied with (Douglas et al, 2020).

Mutual recognition of regulations and tests

What provisions and what do they achieve?

The TCA is on the basis that, for the vast majority of regulatory requirements for products including medicines, vaccines, medical devices and equipment used in health contexts, the EU and the UK are free to adopt divergent regulatory requirements. This comes at the cost, however, of processes and approvals not being mutually recognised - whether or not any divergence takes place. This will impose extra costs, and as the UK is the smaller market it may even be associated with withdrawal of products from the UK market, or later marketing of novel products in that market.

One exception to this general position concerns mutual recognition of 'good manufacturing practice' of medicinal products.

Another concerns the position of trade in goods on the island of Ireland.

The mutual recognition of "good manufacturing practice" is secured by ANNEX TBT-2 Medicinal Products of the TCA. This is the stage of medicines regulation involving assurance that the production of medicinal products is safe, consistent, and in line with what has been approved for sale. It is based on inspection by regulators and takes place at a frequency determined based on risk, as well as when new products are being approved. 'Medicinal products' are defined in Appendix C of Annex TBT-2 as 'marketed medicinal products for human or veterinary use, including marketed biological and immunological products for human and veterinary use; advanced therapy medicinal products; active pharmaceutical ingredients for human or veterinary use; and investigational medicinal products'. This definition is based on and is similar to (but not the same as) the definition in EU (and currently UK) law (Directive 2001/83/EC, as amended, Article 1 (2), which defines medicinal products by both presentation and function. The definition makes it clear that vaccines are included. But the definition probably excludes something like garlic capsules which are marketed as a foodstuff. And it probably includes homeopathic and traditional medicines, such as herbal medicines, which are *marketed* as medicinal products, even if they have no active ingredients.

The Annex sets out that generally, EU and UK bodies will accept the results of inspections carried out by those of the other party, and the certificates of compliance that result. Authorities are required to share documents with each

other on demand. The EU and UK "may" (Article 5) accept documents that relate to manufacturing sites outside either the UK and the EU.

These provisions eliminate *just one* non-tariff barrier to trade with the EU in medicines, by not requiring two sets of inspections. Costs for these inspections are passed on to producers, and from there to purchasers, so there will be small direct financial saving in addition to greater ease of trading.

However, the provisions in ANNEX TBT-2 are subject to limits at several levels. With notice, either party can still inspect the others' sites (Article 7). Either side can also suspend recognition altogether, a right that must be "exercised in an objective and reasoned manner" with written justification (Article 9). Power to amend the current measures that apply to good manufacturing practice (EU law and 'retained EU law', listed in Appendix B) is explicitly given (Article 8), with an obligation to give a 60 day notification only.

Challenges and how could they be resolved?

Trade frictions have been introduced for the vast majority of regulatory requirements for products including medicines, vaccines, medical devices and equipment used in health contexts. Possible resolutions to the associated increase in costs of this new dual regulatory burden raise further different problems and challenges. These include complexity and uncertainty for patients as market actors respond to a fluid regulatory environment, with consequences that are not always predictable from the point of view of continuity of patient care.

The TCA does not eliminate trade frictions at other levels, including:

- The marketing authorisation of medicines;
- The assessment of medical devices as conforming to standards;
- The recognition of prescriptions;
- The testing of batches of medicines to ensure they are fit for release;
- The tracing of medication within the EU to safeguard against falsified medicines;
- A wide array of requirements relating to customs, transport, and border checks.

All of these processes would otherwise be at least generally done once for the whole EEA, and all else being equal will now have to be done separately for UK and EEA markets. Research by Sussex University based on the experience of

other free trade agreements, which would typically have this fairly low level of alignment for medicinal products, estimates this to drive a cost increase of over 5% for pharmaceuticals in the UK. The NHS may be able to avoid this by using cost control initiatives such as the "voluntary scheme", but this would risk intensifying another probable dynamic whereby companies react to barriers by being less likely to introduce products to the UK market at all.

The UK has two types of unilateral options. In the short run, it can unilaterally accept EU processes and so eliminate costs and barriers to imports. The UK is doing this for all of these regulatory steps for a period of two years or more. It is even introducing deferrals for some customs processes. There is also scope for bilateral arrangements, as appears to be the case, according to this ministerial statement of 26 January 2021 with recognition of prescriptions for medicinal cannabis from the Netherlands, plugging a gap for some private patients who had been relying on EU law because the UK does not permit the prescribing of that medicine. Note that this arrangement lapses on 1 July 2021.

However, this alignment approach surrenders regulatory autonomy in a sensitive area with implications for patient safety, and is likely to deter investment. The UK is likely instead to explore changing regulations in order to compete, as we describe in our recent report on tracking the impact of Brexit on health. Policy for medicines authorisation appears to be at an early stage, and will face the knotty question of where to diverge and whether this effectively creates favoured sectors, or sub-sectors, and those where the UK accepts losing a global leadership position.

UK policymakers have discussed future policy for medical devices and equipment very little, and hardly at all in public. The EU system is highly decentralized, can vary in application by country, and has historically had fewer safety provisions than the US system, though the latter two are set to shift, for medical devices, under the 2017 Medical Devices Regulation finally coming into effect this year. There may therefore be scope for the UK to diverge on a positive agenda, but the options have been little explored. The potentially painful decision about ending alignment with the EU is more binary because the CE marks awarded by EU bodies, and currently being accepted by the UK, cover type approval, product conformity and safety.

The downside of the divergence approach is that unexpected gaps are likely to emerge as external market actors respond to a changing regulatory environment. While at a systemic level, this may result in the UK being well-positioned overall, at a patient level, it is likely to lead to unexpected breaks in provision of health care, as there is no overall structure or system within which mutual recognition takes place. It will be necessary to have careful oversight of a complex web of multi and bilateral arrangements, all with different parameters and different time frames after which they may lapse.

Northern Ireland is an entirely separate case in medicines regulation. As listed under Annex 2 of the Withdrawal Agreement's revised Protocol on Northern Ireland, nearly all EU law regarding medicines continues to apply, though Northern Ireland cannot be counted as part of EU territory for the purposes of the location of regulated persons and processes. While the UK also has the ability to authorise products specifically for sale there, for many companies, Northern Ireland will become part of the EU market, presenting possible issues where products available in Great Britain are not eligible for sale there (for example, because they do not comply with the Falsified Medicines Directive); or less likely in the short term, but imaginable in the longer term, where products available in Northern Ireland are not available in Great Britain.

What should the UK seek to do with the EU in the short and medium term?

There is a case for exploring divergence from the EU in medicines authorisation and medical devices, to see if the UK can find a new balance between scientific innovation, competitiveness, and protecting patient safety. However, for batch testing, procedures are relatively aligned globally and competition and innovation are almost irrelevant. The clear preference of industry in both the EU and UK is to arrive at a mutual recognition agreement on batch testing, and this would also be likely to maximise value and access to medicines for patients. The EU has arrived at such arrangements with countries such as Australia, Israel, Japan.

Even where the UK may choose to diverge, an ongoing relationship will be important. Having new models for clinical trials for the medicines authorisation process in the UK will be of limited value unless these also demonstrate validity for the EU and other global regulators to an extent. In a global market, trial spending which will only be relevant to a single, relatively small market, will be difficult to justify relative to trial spending which can be recouped on a global scale.

In Northern Ireland, the Joint Committee formed by a UK minister and EU Commissioner has wide powers to reinterpret and rewrite the laws applied under the Protocol. It has already used these to make allowances for medicines during 2021, and will need to keep supply risks and difficulties under continuous review.

Patent protection and supplementary protection certificates for medicinal products

The UK's continued membership of the European Patent Office provides important institutional continuity. Opportunities arising from powers to adopt divergent regulatory positions must be carefully scrutinized by all stakeholders to ensure that, on balance, they have positive effects for patients, healthcare organisations and the NHS in general.

What provisions and what do they achieve?

Article IP.33 explicitly provides that supplementary patent protection for medicinal products, to compensate for the time it takes for novel medicines to be licensed for marketing, must be provided by the UK and EU. However, 'the terms and conditions for the provision of such further protection, *including its length*, shall be determined in accordance with the laws and regulations of the Parties' (italics added).

Provisions are similar for "data exclusivity", which prevents firms from reusing data from the first approval of a product to get their competitors approved. Article IP.35 stipulates that such a system must exist, but not the duration of its protection.

This provision means that there is scope for divergence by the UK from the existing approach. Any such divergence would have to sit within global rules on intellectual property, particularly within TRIPS.

Challenges and how could they be resolved?

The UK will have to make tricky decisions about divergence from EU rules, in this context depending on the UK's wider strategy on innovation in this area. Offering more generous supplementary protection, or indeed greater general patent protection in the domestic system, might encourage companies to introduce products in the UK, but through a mechanism essentially no more sophisticated than paying them more. Alternatively, the UK could seek to more fundamentally redesign the incentive structures for medicinal products (rather than relying on intellectual property and thus indirectly higher prices as the core incentive), but discussion of alternatives has so far been limited.

A further complicating element is a US trade deal. Leaked negotiating documents show that US negotiators raised their system for data exclusivity, which gives a

longer period than the EU system of protection for "biological" drugs made from living tissue. This includes many cutting-edge treatments, especially for cancer. This would again allow companies to charge higher prices for longer.

Resolution of these matters should take place through proper stakeholder engagement and consultation, generating evidence-led proposals, and scrutinized through parliamentary process.

What should the UK seek to do with the EU in the short and medium term?

The mainstay of the UK's patent system will continue to be the European Patent Organisation, which accounts for the vast majority of intellectual property rights in medicines both here and in the EU. The UK remains a contracting state, but will now be among a minority of non-EU members.

Continued engagement with the EU will be important both because member states will have power over the EPO, and, as in other areas of medicines regulation, because industry decisions to introduce medicines will be based in part on the context of other jurisdictions.

Mutual recognition of professional qualifications

Short-term the near universal unilateral recognition of professional healthcare qualifications from EEA countries and Switzerland by the UK solves any immediate domestic problems for the NHS. The TCA provides a structure for future arrangements to secure mutual recognition of professional qualifications. Given the need to recruit NHS and social care staff from outside the UK for the foreseeable future, and the proximity of the EU as a possible place from which to recruit such essential staff, the UK should move towards using those opportunities as quickly as feasible. This will be a necessary, though insufficient, condition for securing patient wellbeing through having an adequate NHS and social care workforce, and is likely to be especially important for Northern Ireland.

Being outside the IMI means that the UK will need to develop new channels for communication of information about fitness to practice of migrant EEA health professionals offering healthcare services to UK patients.

Better data is needed on migration of health and social care professionals across the ROI/NI border for future planning purposes.

What provisions and what do they achieve?

A set of EU Directives (2005/35/EC as amended by Directive 2013/55/EU) and their individual implementing regulations give effect to the free movement of workers under Arts. 45-9 TFEU. They provide for the automatic recognition of certain regulated professional qualifications - including doctors, nurses (general care but not specialist), midwives, pharmacists and dentists – across the EU, EEA and Switzerland (provided they met the requisite standards for the professions). Up until the end of the transition period on 31 December 2020, they covered the UK.

Other qualifications (including health-related qualifications) fell under the 'general' MRPQ system, which allows (1) recognition where an EEA/Swiss qualified individual has full access to the profession in their home country of qualification, (2) recognition if the profession is not regulated but the individual has worked for 10 years full-time in their home qualifying country, or (3) compensation measures by individual member states (such as adaptation periods or aptitude test) to have their professions recognised, if the difference between professions is significant.

From 23.00 GMT on 31 December, these Directives ceased to apply. The TCA makes no provision for continuing recognition (Article SERVIN.5.13).

National regulatory bodies may designate their own qualification requirements. From 1 January 2021, UK regulatory bodies could change the requirements for individual qualifications, taking them off the quasi-automatic recognition list, if the Privy Council signs off these changes.

The TCA encourages possible future collaboration and the conclusion of mutual recognition agreements between individual countries' regulators after submission to the Partnership Council (SERVIN.5.13).

The TCA contains more general provisions and requirements for transparency and proportionality for national regulators (SERVIN 5.1 Regulatory Framework) such as licensing and publication requirements. These are not enforceable by medical professionals, or indeed hospitals or others seeking to employ health professionals from the EU/UK. Disputes arising from their application are to be resolved only through the dispute resolution processes set out in the dispute settlement provisions of the TCA. These are those of an ordinary trade agreement, including the possibility of arbitration.

There is no general exclusion for health professions from the provisions in the Services chapter. There are, however, several reservations.

Reservations from EEA countries for the health profession include:

(1) A requirement of Cypriot nationality and qualification in Cyprus.
(2) French nationality to set up forms of private investment or company in healthcare; foreign nationals may do this under limited legal forms and on a temporary (quota) basis.
(3) Establishment requirements for the purpose of pharmaceutical retail in Austria, France, Hungary, Greece. Additional adaptation is required in Germany and Latvia. Other member states have specific non-nationality related conditions for the establishment and retail activities of pharmacies.
(4) Individual restrictions on the provision of services such as social security or ambulances.

Reservations from the UK include a right to restrict establishment of doctors subject to manpower planning; a right to regulate the provision of all established or cross-border health services; restriction of mail orders and the supply of pharmaceutical products; and the regulation of private provision of health services.

Further provisions in the Withdrawal Agreement allowed EEA/Swiss qualified professionals to have their qualifications grandfathered in their host states, if these had been obtained before the end of the transition period.

The UK has legislated (see also here) to unilaterally continue to recognise EEA and Swiss qualified doctors, nurses, midwives, pharmacists and dentists (under the automatic recognition system) from 1 January 2021 for a period of time (up to 2 years for EEA-qualified healthcare professionals, 4 years for Swiss-qualified healthcare professionals), with pre-existing language tests and ad hoc fitness to practice checks.

Regulatory bodies will consider qualifications falling under the general regime like those of other applicants, granting recognition without added tests other than language tests, if considered comparable. Regulatory bodies have discretion as to how they will treat qualifications they do not deem sufficiently comparable. See The European Qualifications (Health and Social Care Professions) (Amendment etc.) (EU Exit) Regulations 2019, schedule 1-4.

Qualifications and favourable decisions on qualifications in place before 2021 will continue to be recognised. Applications in place before 2021 will continue to be processed, as amended in draft also specified in guidance for regulators.

There is no longer an obligation on regulators to ensure the mutual recognition of services on a temporary and occasional basis, and these are accordingly removed from the amended regulations (also amended in draft.) However, regulators have the discretion to offer less stringent conditions for the provision of temporary and occasional services, should they wish to. Under temporary and saving provisions, only contracts that were signed before 1 January 2021 and can be fulfilled within the duration of existing temporary permits (EEA) , or within the next five years (Switzerland, under a 2019 agreement on Citizens' Rights and the free movement of persons, art. 23), will be allowed to continue to term. This arrangement was due for review by 1 January 2021 for the EEA, and by 1 January 2025 for Swiss nationals.

MRPQ for health services primarily applies to (WTO, see GATS Article I:2) Mode 4 service supply (presence of natural persons - the health professional qualified in one state is employed or establishes herself in the territory of another state).

But some health service provision involves the other modes of service supply:

1. (Mode 1 Cross border trade) - the service itself moves through telecommunications or postal infrastructure - a patient in one state accesses medical treatment from a health professional established in another state; or a health institution such as a hospital in one state secures the services of a health professional established in another state, such as radiography services.
2. (Mode 2 — Consumption abroad) the service is provided in the territory of one state to the service consumer of any other state - the patient goes to another country to receive medical services. In some countries, this is

quite common in some private sectors of medical and dental treatment, but less so in the UK.

3. (Mode 3 — Commercial presence) by a service supplier of one state, through commercial presence, in the territory of any other state. Several of the reservations prevent UK-based service suppliers relying on the TCA to provide health services in EU Member States.

Health services across the Northern Ireland/Republic of Ireland border do involve regular temporary movement of both staff and patients between the EU and UK and could therefore also cover Mode 1 (from one territory to another - the service moves), and especially Mode 2 (provided in the territory of one member for a consumer of another member - the patient moves from ROI to NI, or from NI to ROI).

The ROI and UK agreed to maintain the Common Travel Area (CTA), which predates EU arrangements, irrespective of whether the UK reached a deal with the EU, in a MoU of May 2019. The Common Travel Area allows free movement of Irish and UK nationals to live, work and receive social security benefits between ROI, NI and GB.

However, other EU nationals will now qualify as 'third-country' nationals from the point of view of EU law, and hence their position in Irish Law. They are not covered by the MoU on the CTA. Some of these EU-26 nationals working in the health sector regularly cross the border from ROI into NI.

For EU-26 professionals in the UK, transitional provisions described above will apply, subject to revision. This includes Northern Ireland, as EU MRPQ arrangements - which ensure the recognition of professions, are distinct from the CTA, which merely ensures freedom of movement and work between ROI, NI and GB.

ROI has passed an amendment to the Medical Council of Ireland law to automatically recognise UK qualifications beyond the transition period. This will support continued movement of UK-qualified doctors across the ROI/NI border. It is unclear what progress has been made with extending this arrangement to other health related professions. For the moment, UK applications from healthcare professionals to be recognised in Ireland (except if they had applied and/or been recognised before the end of 2020) will be treated in the same way as those of third country applicants.

Whilst the rules are set to change for healthcare professionals with EEA/Swiss qualifications in the UK, a temporary system will exist for those previously qualifying for automatic recognition to be fast-tracked for registration - to be reviewed by the end of 2022.

Routine movement of people providing or receiving health care services across the NI/ROI border is poorly monitored, and better data should be collected on this in the future.

Challenges and how could they be resolved?

NHS (and social care) workforce shortages across the UK have been well-documented. The UK will need access to healthcare professionals who qualified elsewhere in the world to meet the needs of its patients well into the future. The potential introduction of barriers to the ability to recruit from the EU will impede recruitment from near neighbouring countries.

The unilateral UK near-automatic recognition of EEA/Swiss-qualifications will ease these challenges in the short term.

As the UK is outside the single market and its administrative arrangements (including the Internal Market Information System (IMI) which is used inter alia for exchange of data on fitness to practice of healthcare professionals), UK regulators will need to develop other channels of communication and data sharing with their counterparts in EU countries.

What should the UK seek to do with the EU in short and medium term?

Assuming that the UK will continue to be unable to fill its health professional workforce needs into the medium term, working through the Partnership Council, the UK should seek formal mutual recognition agreements for health professional qualifications.

UK regulators of health professionals should continue to engage with their counterparts in EEA countries. This might be achieved through governmental contacts, or indirectly through professional bodies. This continued engagement is particularly important for regulatory entities in the Republic of Ireland. Health professional regulatory entities should work towards joint recommendations, as envisaged by Article SERVIN.5.13, where they can show (through evidence) that mutual recognition of qualifications has a positive economic value, and the extent of compatibility of the two regimes. Given that as at 1 January 2021, there was no divergence between the regimes, and the UK has stated that it will recognise EEA healthcare qualifications for up to two years, this latter is unlikely to prove difficult in the short to medium term. The Partnership Council is obliged to consider any such proposal, and may take a decision to implement it, by a decision on an ‘arrangement’ for mutual recognition of professional qualification, at which point the ‘arrangement’ will become a formal part of the TCA. The

ANNEX SERVIN-6 setting out Guidelines for these arrangements is quite flexible. It includes the power to provide for the effects of recognition, any additional requirements (such as language competency or proof of good character), as well as procedural matters. In other words, should the UK and EU so agree, these arrangements could almost replicate the position when the UK was an EU Member State. But many steps have to be taken before reaching that position.

In the meantime, regulatory entities can keep connections with EEA counterparts alive. This will require new legal arrangements. Regulatory cooperation could go much further than merely sharing fitness to practice data. For instance, regulatory entities in healthcare professions could share training expertise or even collaborate on training. Such continued interaction will help with reaching mutual recognition agreements later in time.

There are broader ethical questions which have been brought into sharp relief by the COVID-19 pandemic, about the migration of health professionals from less developed to more developed countries. We assume these are outside the scope of this Inquiry.

Health and social care workforce labour standards / terms and conditions

Even though health services are not 'traded' in Northern Ireland, Scotland or Wales, changes to employment law which affected terms and conditions of the health workforce would have to take effect across the UK, as employment law is not a devolved matter. This would mean that regressive changes to employment rights would be covered by the TCA's 'level playing field' provisions. The UK has an opportunity to *improve* employment law rights and working conditions, consistently with the TCA, in order to attract health sector workers.

What provisions and what do they achieve?

The TCA's 'level playing field' provisions, chapter 6, cover labour and social standards. These include 'fundamental rights at work' (such as the right to collective representation); 'occupational health and safety standards' (which include working time rights); 'fair working conditions and employment standards; and rights of employees on restructuring. All of these apply to the health and social care workforce as much as the workforce in any other sector.

Article LPF.6.2 (non-regression) provides that the EU and UK have regulatory autonomy in these areas, but that this is subject to the requirement that neither shall 'weaken or reduce, *in a manner affecting trade or investment between*' (italics added) the UK and EU, labour and social standards below the levels in place at the end of December 2020.

Enforcement of this provision is domestic measures (Article LPF.6.3) and procedures set out in the level playing field part of the TCA (Articles LPF 9.1-9.3) involving some transparency both in the consultations stage; and in the stage involving a panel of experts with specialist knowledge in labour law.

The requirement that non-regression obligations apply only where the law or policy change affects trade or investment between the UK and the EU means that not all changes to law or policy concerning the health workforce would necessarily breach this obligation. So, for example, while a general change to working time rules across all economic sectors would at least arguably 'affect trade and investment' between the UK and the EU, if a change to working time applied only, for instance, to doctors working within the NHS, it would not be possible to show the necessary effect on trade and investment. This is because a sector has to be exposed to the wider market for a link to be made to trade and/or investment, and health care services are not 'traded' in that respect.

In this context, therefore, NHS England is in a different position to that of NHS Scotland or Wales which are almost totally insulated from the market. So the level playing field provisions of the TCA would not be engaged by changes to the rights of people working in NHS trusts in Scotland and Wales. In England, depending on the extent to which a market is implicated, they might be. Nonetheless, employment law is not a devolved matter, so any changes to rights of workers in Scotland or Wales would by necessity also have to apply to workers in England. This means that neither Scotland nor Wales could take advantage of the different structure of their NHS to make changes to employment rights which were not, de facto, potentially engaged by the TCA level playing field provisions.

Challenges and how could they be resolved?

This is not a challenge arising directly from the TCA, but divergence from EU standards would potentially mean difficulties in attracting health and social care workforce from EU to UK. There is already evidence of retention problems in health and social care sectors arising from the (perceived) deterioration of terms and conditions over the past decades. This could be exacerbated by (perceived) worsening of employment terms such as for holiday pay, working hours and so on.

What should the UK seek to do with the EU in the short and medium term?

Nothing. Working terms and conditions for the health and social care workforce is an internal matter.

Cross-border health services

Assuming that the TCA supports continued UK access to services of health professionals established in EU countries, where the service itself moves but neither the patient nor the professional moves, continuity in the short to medium term is secured. However, oversight will be necessary if UK and EU regulatory requirements diverge, to ensure that the professionals established in the EU offer equivalent patient protection, including for liability from harms arising from healthcare, to that offered where the service takes place entirely in the UK. In the medium to longer term, it will be important to track both changing EU regulatory requirements and those in the UK.

What provisions and what do they achieve?

Cross-border health care may take place through any of the four 'GATS modes of service':

- Mode 1 Cross border trade - the service itself moves through telecommunications or postal infrastructure - a patient in one state accesses medical treatment from a health professional established in another state; or a health institution such as a hospital in one state secures the services of a health professional established in another state.
- Mode 2 — Consumption abroad - the service is provided in the territory of one state to the service consumer of any other state - the patient goes to another country to receive medical services.
- Mode 3 — Commercial presence - service is provided by a service supplier of one state, through commercial presence, in the territory of any other state - health service providers from one state set up and provide services in another state, subject to the regulatory requirements for establishment in the latter state
- Mode 4 — Temporary movement of natural persons - service is provided by health professional established in one state, who provides services in another state

As noted above, the services provisions of the TCA (SERVIN) apparently cover all four GATS modes of cross border service supply. However, they are not presented organised in that way in the TCA, nor does the TCA use the GATS wording, and therefore the exact correspondence between the instruments is unclear. Instead SERVIN.1.2 (e) defines cross-border trade in services as the supply of a service '(i) from the territory of a Party into the territory of another Party; or in the territory of a Party to the service consumer of the other Party'.

Assuming that the TCA applies to all four modes, it is worth also (modes 2, 3 and 4 have been considered in the above) considering the extent to which the TCA supports mode 1 health service provision between the UK and EU. Examples of this include health services like diagnostic imaging functions, or laboratory functions, or even doctors sending notes to be typed up by someone in another country. So, for example, an image is taken in a UK hospital, which is sent electronically to a radiographer in Poland. The Polish radiographer reads it, and sends her interpretation/analysis/results electronically to the medical professionals in the UK hospital.

When the UK was an EU Member State, this type of cross border service provision was covered by the E-Commerce Directive. For cross-border health service provision, the EU's Patients' Rights Directive also applies. These provisions are currently 'retained EU law' to the extent that they apply within the UK, but obviously the cross-border trade aspects of them are not covered by internal UK law.

There is nothing explicit in the main TCA text which limits its application to this kind of cross-border service provision in health contexts.

There is an exclusion for services supplied 'in the exercise of governmental authority' (SERVIN.1.2 (o), (p) and (a)). Services so supplied are 'supplied neither on a commercial basis nor in competition with one or more service suppliers'. So this is not the case for the Polish radiography services in this example, because the contract for this service has been agreed in a situation where the Polish radiography provision has been chosen from several tenders, in competition with each other.

There are, as noted above, a number of reservations to the services provisions applicable to health contexts. The UK's reservations include a right to regulate the provision of all established or cross-border health services. This reservation would permit the UK to insist on UK regulatory standards, including qualifications rules, for providers of cross-border health services, including the Polish radiography service provider in this example. However, if the UK did not do so, then the Polish regulatory standards, including qualifications rules, would continue to apply as is usual in 'mode 1' service provision (sometimes called 'home state control'). Of course, both sets of regulatory standards might apply in which case, even if the standards were compatible with one another, there would be the additional costs associated with a dual regulatory burden.

These matters will become more important if the UK departs from the EU's regulatory standards for health services workforce in the future.

Challenges and how could they be resolved?

The TCA supports continued UK access to services of health professionals established in EU countries, where the service itself moves but neither the patient nor the professional moves. This arrangement will secure continuity in the short to medium term. However, oversight will be necessary if UK and EU regulatory requirements diverge, to ensure that the professionals established in the EU offer equivalent patient protection, including for liability from harms from healthcare, to that offered where the service takes place entirely in the UK. In the medium to longer term, it will be important to track both changing EU regulatory requirements and those in the UK and the relationship between them.

What should the UK seek to do with the EU in the short and medium term?

Nothing obvious. This is a medium to longer term issue.

However, there will be a need for urgent domestic guidance, such as for the NHS in respect of existing cross-border services (eg: remote radiography services), which is likely to be particularly relevant for Northern Ireland. This may be important in particular in relation to the practical implementation of health aspects of the cross-border PEACE programmes.

Medical research

Funding, regulatory standards and information exchange are all important to medical research, which has been and is likely to continue to be an area where it is in the UK's interests for UK-based researchers to cooperate with researchers based in the EU.

What provisions and what do they achieve?

Funding

The TCA makes provision for the UK to participate in Horizon Europe, Euratom Research and Training, and Copernicus (at least according to Para 165 of UK government summary of the TCA). According to UNPRO.1.3, the UK need not participate, 'in exceptional cases' in the whole of a programme. There is, as yet, no Protocol I (as envisaged in UNPRO.1.3 (2) and (3)) which lists the programmes in which the UK shall participate, their duration, specificities of participation and budgetary modalities.

The largest practical barrier (negotiation of cost) is already resolved (UNPRO.2.1).

The TCA does not cover EU cohesion funding Article UNPRO.0.1 (2) which did include some health-related projects. Further, the Erasmus programme, in which the UK will no longer participate, also benefited (biomedical) researchers, not just students.

The UK and the EU and its Member States must make 'every effort' (UNPRO.1.5) to facilitate entry and residence of scientists, students, researchers, trainees and volunteers. This provision is explicitly 'without prejudice to' UK-Ireland Common Travel Area arrangements UNPRO.1.5 (5)

This is a reciprocal obligation, with only the quality of ordinary international law, in terms of its enforceability. But of course, as discussed above, for UK nationals going to the EU, there are provisions *of EU law* that give entitlements which are enforceable, and from which EU Member States may not depart from (see above EHIC section).

Research-specific regulation

The EU-UK TCA does not explicitly address clinical trials regulation.

In practice, there is likely to be a high degree of continuity in substantive requirements for clinical trials in the UK. Core technical requirements for clinical trials ("Good Clinical Practice") have been agreed by the International Conference on Harmonisation and as such have a common global reference point.

Significant aspects of clinical trials regulation are not fully covered by global standards, leaving interpretative space which leads to variation across jurisdictions. These include:

- The registration of trials, which US rules do not require in as many circumstances as the EU.
- The information required for the authorisation of trials, the process for submitting it, and the overseeing bodies making decisions. These are currently being altered in the EU by the 2014 Clinical Trials Regulation: some implications are discussed further below.
- Publication requirements: the new Regulation is also increasing the level of transparency.
- Restrictions on participants, for example by age.

In these instances, the UK might diverge in its regulatory framework for clinical trials. In the short run it must decide whether or not to mirror the changes passed in 2014, which otherwise will not apply because they were not in effect at the time the UK left the EU.

However, even if it fully mirrored these changes in a domestic form the UK will have a very different status to EU countries, because it will be a 'third country' for the purposes of the EU system. This is discussed below, under 'challenges'.

General relevant regulation: Information sharing and data protection

The EU-UK TCA includes a general 'right to regulate' digital trade clause (Article DIGIT.3), for public interest reasons including public health protection, safety, privacy and data protection, which covers current and future regulation (Article DIGIT.4). The EU-UK TCA also includes general, but quite vague, commitments to ensure cross-border data flows, as well as not creating restrictions through technical requirements (Article DIGIT.6).

For data flow from the UK to the EU, the UK has amended its data protection law in effect to recognise the EU's data protection regulation as consistent with UK law.

The key concern associated with a 'No Deal' Brexit - the costly and burdensome personal data protection measures that would have been necessitated for data to move lawfully from the EU to the UK from 1 January 2021 - has been temporarily alleviated (though not removed) by Article FINPROV.10A, which

provides that transmission of personal data from the EU to the UK 'shall not be considered as a transfer to a third country under Union law', for a period of 4 months, extendable by 2 months, from the date of entry into force of the TCA. 'Entry into force' here means formal, not provisional, entry into force, which will take place on the first day of the month following notification by the UK and the EU that all their respective internal requirements have been completed (see Article FINPROV.11 (1)). While the UK has completed those requirements with the adoption of the European Union (Future Relationship) Act 2020, the EU has yet to complete its requirements. The legal basis for the relevant Council Decision, at least as proposed by the European Commission, is Article 217 TFEU, in conjunction with Article 218(6), Article 218(7) and the second subparagraph of Article 218(8) TFEU, which requires the consent of the European Parliament. This will take some time, perhaps until spring 2021.

Personal data transfer from Iceland, Liechtenstein and Norway is also covered so long as those states expressly notify the EU and UK in writing of their acceptance.

This grace period (or *de facto* extension of the transition period) applies only as long as the UK does not amend its data protection law as it stands on 31 December 2020 (Article FINPROV.10A). If the UK does so without the agreement of the EU secured through the Partnership Council, the grace period immediately comes to an end.

In that event, or if the European Commission (on behalf of the EU) does not recognise the UK as 'adequate' for data protection regulation either now, or in the future, alternative (and costly) measures would have to be put in place for data to be shared within the context of bio-medical or other health research projects that involve partners in the UK and one or more EU Member States.

For clinical trials, it is not only the data protection aspects that need to be considered. There are also important practical ramifications of the UK leaving the single market.

The EU's Clinical Trial Regulation (Council Regulation (EU) No 536/2014 on Clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC of 16 April 2014 OJ 2014 L 158/1) sets up a new database called the Clinical Trials Information System (CTIS). Its predecessor, the EU clinical trial portal and database, created under Directive 2001/20/EC, is presently in use, in light of ongoing EU-wide issues with the implementation of the CTIS and its repeated delay.

Third country access to CTIS is very limited: the EMA's website notes that the overarching purpose of the CTIS is to provide for '[i]mproved collaboration, information-sharing and decision-making *between and within Member States*' (emphasis added). Thus, access to the secure part of the database is predicated

on EU membership. Under EU law, there is no full or partial access to the Clinical Trials Information System for any entity incorporated or established in a non-EEA country. Rather, access is on a trial-by-trial basis.

The EU regulatory arrangements acknowledge that, due to third countries' involvement in some clinical trials, it is necessary for them to have some access to this database and the information contained within it. This is known as a sponsor workspace. It allows the clinical trial sponsor (that is, the company or organisation which conducts a clinical trial) limited access, on a trial-by-trial basis, to enable them to submit data to the system for Member States' assessment. The sponsor of a clinical trial is an individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research. The sponsor workspace allows sponsors to, inter alia, 'search and access clinical trials', 'supervise their own clinical trials and check progress', and 'respond to requests for information and view deadlines'.

Moreover, the Regulation outlines the process in cases where clinical trials are carried out between one or more EU Member States and third countries. In these multi-state clinical trials involving the EU, sponsors in third countries must have a legal representative established in the EU somewhere, who is responsible for compliance (Clinical Trial Regulation EU No. 536/2014, Article 74 (1)). That legal representative would have full access to the database so as to comply with EU law obligations. They would be liable for compliance breaches, and subject to EU law and CJEU jurisdiction as established in an EU Member State.

Where a clinical trial is to be conducted solely on one Member State's territory, or on theirs and a third country's, a legal representative as per above is not necessary 'provided that they ensure that the [trial] sponsor establishes at least a contact person on their territory' (Clinical Trial Regulation EU No. 536/2014, Article 74 (2)).

Finally, there is a publicly-accessible website which includes, for example, an overview of clinical trial statistics, data and reports, and an advanced search. This is a last resort option for UK researchers post-transition, and in the event that the individual seeking access is not a sponsor.

Challenges and how could they be resolved?

Challenge 1: Progress towards agreeing a Protocol for UK participation in Horizon Europe is of necessity delayed because the multiannual framework programme Regulation is yet to be adopted by the EU (see current position here).

There is no obvious resolution to this challenge until the provisions for the Horizon Europe programme have been adopted by the EU.

Challenge 2: The UK is a 'third country' for the purposes of access to the EU's clinical trials information system (CTIS) which will impede access of UK-based researchers to the clinical trials 'portal'. This will add a layer of complexity, and hence cost, when going from the clinical trial reporting stage to the marketing authorisation stage for medicines.

There is no obvious resolution to this challenge.

The possibility of an inter-agency agreement, between the EMA and MHRA, whereby full access to the CTIS is provided to the UK, could be explored. But there is nothing obvious in the TCA which would enable such an agreement.

Furthermore, there is no existing precedent for such an agreement. No other EU agency database provides an analogous example. It is likely to be considered unlawful from the point of view of the EU.

Alternatively, individual clinical trial sponsors established in the UK will need to have a legal representative established in the EU somewhere, or in the case of a trial taking place only in one EU Member State or just one EU Member State and the UK, just a contact person in the EU, adding a layer of cost and complexity to the UK's ability to conduct collaborative research with EU partners.

Challenge 3: The CTIS will present practical difficulties for trials requiring numbers or types of participants that are difficult to obtain within the UK

alone, such as for rare diseases. These difficulties are exacerbated by exclusion at the same time from the European Networks for Rare Diseases, in which UK centres had played a disproportionately strong role, especially in leadership, and which provided a platform for research, as well as for health care provision.

There is no obvious resolution to this challenge.

What should the UK seek to do with the EU in the short and medium term?

Challenge 1:

The UK should seek to have an agreement in place as anticipated in UNPRO.1.3 as soon as possible following the adoption of the Horizon Europe programme by the EU, to be set out in 'Protocol I' to the TCA. In scope, this participation agreement for the UK should enable participation in all of Horizon Europe, and in any event should enable participation in all aspects having relation to health and environment. In order to enable sustainable research and collaboration, the participation should be agreed for the full duration of this Union programme.

This will also require domestic provisions that meet (and are seen to meet) the conditions in UNPRO.1.5. In particular, the UK should provide a clear basis for the entry and residence of students and others involved in programme (such as trainees and volunteers); and moreover, should make it clear that these people will be *welcome* under the new immigration rules.

The current provisions are imbalanced, with protection of the rights of UK nationals going to the EU under this programme whereas the reverse protection is lacking (see further above under EHIC discussion). This imbalance has the potential to undermine the effectiveness of the collaboration envisaged under the programme.

Challenges 2 and 3:

It is not clear what action the UK could take, short of persuading the EU to change the existing limits on third country participation in the clinical trials database in their own legislation.

In the short term, the UK must not amend its data protection law as it stands on 31 December 2020 if the UK is to benefit from the up to six month grace period of recognition provided for in the TCA.

Health security

What are the provisions and what do they achieve?

EU cooperation on health security includes data exchange the Early Warning and Response System (EWRS) and coordination in a Health Security Committee (set out in Decision 1082/2013/EU). This provides for coordination of preparedness and response planning, joint procurement of medical countermeasures, epidemiological surveillance (in practice largely coordinated through the ECDC), information sharing about threats and potential coordination of responses. The TCA (in HS.1) obliges the EU and the UK to inform each other of potential cross-border threats to health, and allows the UK to ask to be allowed access to the EWRS and to participate in Union coordination for a specific emergency, although this request may be refused. There are also specific provisions encouraging international cooperation involving both the EU and UK on antimicrobial resistance (Article SPS.17).

The Commission has made proposals to strengthen cooperation under the branding of a 'European Health Union'. This puts the existing cooperation onto a stronger legal basis, and puts greater practical cooperation that has developed during the COVID-19 pandemic around the development, licensing and monitoring of medicines, supply of health-related products as well as preparedness and surveillance on a clearer legal footing. These proposals are under discussion in the EU Parliament and Council.

What are the challenges and how could they be resolved?

While there are challenges for the UK in being outside these information-sharing and coordination mechanisms, these are partially mitigated in this case by wider regional and global cooperation mechanisms through the World Health Organization (in particular the International Health Regulations (IHR) and cooperation within the WHO's European region). These also provide for information-sharing and cooperation between states. However, their scope is more limited; while the scope of the IHR is the international spread of disease, the scope of EU cooperation on cross-border threats to health is much broader, including threats to health of biological origin, but also chemical, environmental or other origin. For such threats, ad-hoc participation in the EU's cooperation mechanisms would continue to be the best solution.

What should the UK seek to do with the EU in the short and medium term?

The UK should make such requests as are necessary for ad-hoc participation in cooperation against cross-border threats to health, and should seek over time to establish such participation on a more regular footing. In the medium term, the UK should seek to ensure that it can participate in the strengthened cooperation mechanisms currently being proposed as part of the 'European Health Union'.

Outside the EU, the UK should seek to strengthen international cooperation, in particular through the WHO.

Medical radioisotopes

The EU-UK TCA does not cover radioisotopes. These are covered by the EU-UK Nuclear Cooperation Agreement, which sets up a framework for cooperation on peaceful uses of nuclear energy. The Joint Committee established under that Agreement is explicitly tasked with:

'(f) coordinating action for cooperation in non-power uses of nuclear energy, in particular, in order to minimise the risks of shortage of supply of medical radioisotopes, and to support the development of novel technologies and treatments involving radioisotopes, in the interest of public health.' (Article 19 NCA).

Much of the NCA is facilitative (the Parties 'may' cooperate in various ways), but there is an obligation to 'facilitate trade' (Article 9 NCA), and an obligation to set up administrative arrangements (Articles 15 and 16 NCA).

The NCA does not involve the UK continuing to participate in the EU's cooperation structures. As far as we are aware, there is no provision in the relevant EU legal framework for a third country to be part of the European Observatory on the Supply of Medical Radioisotopes. The Statutes of the Euratom Supply Agency, within which the Observatory appears to sit, certainly make no such provision.