

Briefing note for House of Commons Health Committee on the Draft Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (WA), and the Outline of the political declaration setting out the framework for the future relationship between the European Union and the United Kingdom of Great Britain and Northern Ireland (Dec FR), as agreed at negotiators' level on 14 November 2018, from the point of view of health and the NHS

Nick Fahy and Tamara Hervey, 22 November 2018

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This briefing summarises key points from the Withdrawal Agreement and the Political Declaration on a Future Relationship and their impact on health and social care. It is broken down by four scenarios:

- No Deal: the UK leaves at the end of March 2019, without any agreement in place;
- Transition: the Withdrawal Agreement fully in force;
- Backstop: if the Northern Ireland Protocol comes into force, with neither the Withdrawal Agreement nor agreement(s) on (a) future relationship(s) in place;
- Future relationship: agreement on the partnership outlined in the Declaration.

		No Deal Brexit	Transition (the WA)	Backstop (NI Protocol)	Future relationship
Workforce	Recruitment and retention of EU nationals in the NHS	Absence of legal framework for mobility likely to have severe impact on migration	Legal framework continues with some changes, retention and recruitment continues	Except for those under WA, dependent on future relationship, and domestic law, no certainty	No provisions facilitating recruitment and retention of NHS workers
	Mutual recognition of professional qualifications	Potential to improve on current rules if political will exists Mutual recognition and protections it gives stops immediately	Legal framework continues	Potential to improve on current rules if political will exists No provisions for mutual recognition beyond end of transitional period	Potential for some weaker form of recognition than currently
	Employment rights for health workers	No protection of existing rights – can be amended by executive action under EU (W) Act 2018	Legal framework continues	Legal framework continues under NI Protocol level playing field rules	Depends on degree of integration and ‘level playing field’ requirements
Financing	Reciprocal healthcare arrangements	No rights in place as no legal framework. No framework for administration/offset between UK and EU countries	Legal framework continues	No provision for continued reciprocal arrangements	Potential for some weaker form of reciprocity than currently; but linked to free movement
	Capital financing for the NHS	Access to EIB stopped and capital financing generally undermined	Legal framework continues	No provisions for EIB cooperation and capital financing undermined	Potential to link to EIB; likely lower level of capital financing than currently
	Indirect impact on NHS financing	Severe effect on wider economy and thus NHS financing	Some effect on wider economy and thus NHS financing	Some effect on wider economy and thus NHS financing	Some effect on wider economy and thus NHS financing
Medical products, vaccines, and technology	Pharmaceuticals	Absence of legal framework for imports/exports drastically affects supply chains. Likely shortages as stockpiling plans cannot cope for more than a few weeks. Loss of global influence through EMA	Continued application of EU law to circulation of medicinal products UK is rule-taker. Loss of global influence through role in EMA	Circulation of medicinal products maintained under EU law Loss of global influence through role in EMA	Continued circulation of medicines; potential for some weaker cooperation with EU on medicines than currently
	Other medical products	Supply as for pharmaceuticals	Continuity of supply secured	As for pharmaceuticals As for pharmaceuticals	As for pharmaceuticals Radioisotope cooperation envisaged
Information		Absence of legal framework means end of information collaboration with drastic effects on research, surveillance ...	Legal framework continues, current activities continue	Lack of continued access to data structures.	No specific cooperation on health information envisaged.
Service delivery	Working Time legislation	Potential to improve on current rules if political will exists Existing protections can be removed by executive action	Legal framework continues	Legal framework continues under NI Protocol level playing field rules	Potential to improve on current rules if political will exists Existing protections can be removed by executive action
	Cross-border care	No framework for administration/offset between UK and EU countries	Legal framework continues	Not covered, except for island of Ireland implicitly and as part of CAWT	Cross-border health services not envisaged as part of the future relationship
Leadership and governance	Public health	Potential to improve on current rules if political will exists Existing protections can be removed by executive action	Legal framework continues but UK is outside EU institutional structures so loss of role No mention in WA but continued collaboration on public health at global level (eg: G7) and health security	Potential to improve on current rules if political will exists Existing protections can be removed by executive action	Impact of EU rules dependent on depth of partnership Continued collaboration on public health at global level (eg: G7) and health security
	Trade and competition	Potential to improve on current rules if political will exists Some existing protections could be removed by executive action	Legal framework continues but UK is outside EU institutional structures so loss of role	Legal framework continues under NIP level playing field rules	Impact of EU rules dependent on depth of partnership
	Research	Collaborations and funding from EU ended. No access to Clinical Trials Reg’s portal. Loss of global influence.	Collaborations and funding continue until end 2020	Collaborations and funding from EU ended. Access to Clinical Trials Reg’s portal unclear. Loss of global influence	Continued participation in research envisaged, but on worse terms for the UK
	Scrutiny and stakeholder engagement	Volume of new legislation already limiting scrutiny and engagement, will continue	Volume of new legislation and executive powers under EU (W) Act limits scrutiny and engagement	Volume of new legislation and executive powers under EU (W) Act, plus new trade agreements, limits scrutiny and engagement	Volume of new legislation and executive powers under EU (W) Act, plus new trade agreements, limits scrutiny and engagement

Grey = broadly unchanged; Green = positive; pale red = moderate negative; red = major negative

## **General orientation and the temporal elements**

### **Legal continuity during the transition period**

WA provides for a ‘transition period’ (A126), which runs from 29 March 2019 (A185) until 31 December 2020, as things stand.

During the transition period, with some exceptions\*, EU law continues to apply to and in the UK (A7; A127 ‘Unless otherwise provided in this Agreement, Union law shall be applicable to and in the United Kingdom during the transition period’). During transition, EU law has ‘the same legal effects’ as now, and has to be interpreted and applied using the same ‘methods and general principles’ (A127(3)). This means EU law as it stands at ‘Exit Day’ (29 March 2019) *and as it evolves* during the transition period will be part of UK law (A6). [NB this seems different to the EU (Withdrawal) Act 2018, which ‘freezes’ EU law on Exit Day as ‘retained EU law’. Of course, the EU (Withdrawal Agreement) Act or whatever it will be called would impliedly repeal contradictory provisions of an earlier act.] Decisions of the Court of Justice of the EU (CJEU) during the transition period are binding ‘on and in’ the UK (A89). Administrative procedures undertaken by EU institutions, bodies or agencies, about compliance with EU law by the UK, or entities within the UK, continue during transition (A92) and their results are binding on and in the UK (A95).

[\*The exceptions are for the parts of EU law that don’t apply to the UK now (about the Schengen area, home affairs, the Eurozone etc); and for citizenship democratic rights (citizens petition, voting in European Parliament and local elections etc) (A127(1)(a)&(b)).]

The transition period may be extended once, up to the end of any calendar year ‘[31 December 20XX]’, by a decision of the Joint Committee (a new institutional structure set up by the WA, see below), taken before 1 July 2020 (A132). In that event, the UK would continue to contribute to the EU budget, as determined by the Joint Committee (A132), although only as a third country (A132(2)(a)). This is significant because third countries must pay in an equivalent amount to what they receive from the EU budget.

The end of the transition period is not the end of the application of the WA in the UK: ‘In the interpretation and application of this Agreement, the United Kingdom’s judicial and administrative authorities shall have due regard to relevant case law of the Court of Justice of the European Union handed down after the end of the transition period.’ (A4(5)). This is important because people’s rights under the WA will continue after the end of the transition period in several important respects, eg to be able to achieve residence rights/settled status in the UK; to continue to benefit from social security entitlements such as pensions already accrued; to have personal data protected; and, potentially, under the ‘backstop’ arrangements (see further below).

### **The position of the UK during transition**

The UK is no longer a MS of the EU from Exit Day 29 March 2019 (A185; Preamble para 1, plus Article 50 notification).

The UK is excluded from EU institutions and agencies. It may not nominate, appoint or elect members; participate in decision-making; attend meetings, including of expert groups, except where the WA explicitly provides otherwise (A7). One place it does (A34) is the Administrative Commission for coordination of social security, where UK may observe and send an advisory representative. Another (A128) is meetings of EU agencies involving experts, which includes the decision-making procedures of the EMA. UK experts may be invited to attend, but may not vote in, meetings or parts of meetings where either the decisions apply to the UK or entities in the UK, or 'the presence of the UK is necessary and in the interest of the Union' (A128(5)(b)). But, from Exit Day, the UK is excluded from acting as lead authority in 'risk assessments, examinations, approvals or authorisations' (A128(6)).

### **The Political Declaration on the Future Relationship between the EU and the UK**

Overall, the Political Declaration on the Future Relationship (PDFR) sets out a 'Canada plus' partnership, where the plus includes buying-in to European Union programmes (though not on the same footing as Member States), stronger cooperation on areas such as transport, energy and foreign affairs, and a security partnership. The Declaration is quite detailed on goods, and much sketchier on other factors of production (services, capital, companies) and people, which is consistent with a Canada-style free trade agreement. That type of future relationship is consistent with the UK's stated 'red lines', and what the EU has indicated is possible, given its negotiating mandate. Of course, either or both of those things could change.

And, as has been pointed out, the possibilities for the future relationship are far more open-ended than for the WA. In that sense, the WA is the easy bit. Bear in mind also that trade agreements take years to negotiate, and run to hundreds of pages, and the Declaration is only a few pages. Because of that temporal element, we should take seriously the possibility that the 'backstop' in the protocol on Northern Ireland comes into effect. It may in fact become the future relationship, at least for the medium term.

### **The Protocol on Northern Ireland**

An integral part of the WA, with the same legal value (A182), the Protocol runs to almost as many pages as the main WA. Although its stated objective is to be temporary (NIP A1(4)), the amount and depth of detail suggests that this has been drafted in a way that it can actually be used. And it is not time-bound: it applies until it is superseded by (a) subsequent agreement(s) (NIP A1(4)).

The way that the Protocol works does not just affect the island of Ireland. The Protocol establishes a single customs territory between the EU and the UK (NIP A6). That means no tariffs or taxes on products moving between the UK and the EU, and the same external tariffs for products from other countries coming into the UK and EU.

The Protocol does this by applying to all trade in goods between the EU and UK, as well as goods from ‘third countries’, the rules in Annex 2 (which set up the customs union); Annex 3 (on documents needed for movement of goods, unless the Joint Committee adopts new detailed rules (NIP A6); and Annex 4 (the ‘level playing field rules’, which covers a wide range of existing EU law on fiscal supervision; environmental protection; labour and social standards; state aids; competition; and state-owned monopolies with special privileges) (NIP A6). In this way, the UK government complies with its obligation not to ‘enter into arrangements under which Northern Ireland forms part of a separate customs territory to Great Britain’ (Taxation (Cross-Border Trade) Act 2018, section 55 (1)).

But for the *regulation* of goods (so non-tariff barriers, rather than the tariffs that apply under a customs code), the Protocol in effect creates a new legal concept/entity of ‘the UK in respect of Northern Ireland’. It’s neither a Member State nor a ‘third country’. Territorially speaking, this is Northern Ireland. The Protocol extends the application of EU goods law (product standards, marketing and product safety rules) to Northern Ireland. EU law on marketing and safety standards for goods (all listed at great length in Annex 5) will apply ‘to and in the United Kingdom in respect of Northern Ireland’ (NIP A6(2)). Where goods are imported into NI from the EU, Articles 34 and 36 TFEU also apply (NIP A8(1)), so no unjustified non-tariff barriers may be imposed.

The Protocol itself does not directly or formally require the same standards for products being produced or marketed in the UK, but if the UK wants to keep a single regulatory market including Northern Ireland, and avoid an internal border in the Irish Sea, then in practice the UK will need to align with EU standards.

We are grateful to the authors of the Constitutional Conundrums project (ESRC grant ES/S006214/1) [briefing](#) on the Protocol, especially Aoife O’Donoghue.

### **Health and Social Care Workforce**

Part Two on Citizens Rights covers the position of EU citizens in the UK, and vice versa. In general, EU citizens already in the UK are relatively well protected under the WA, although the protections are not identical to those of EU law. In fact, they offer less protection. For instance, primary carers of children residing in the EU currently have rights to remain in the EU even when the EU national parent of that child ceases to reside in the EU or ceases to be a worker. The WA gives these primary carers rights *only* when the child is in education and not when the EU national parent ceases to be a worker, creating a further insecurity for those in insecure labour markets.

The implication is that retention of NHS and social care workforce already in the UK will be less easy than if the UK were to remain in the EU, but much easier than under a no-deal Brexit, and the possibility to attract EEA nationals up to the end of transition will be in place. This is important, given current reliance on EEA nationals, especially in nursing, and particularly in some parts of the country.

NHS and social care workforce from EEA and their families already in UK before end transition can remain (A13), and can in due course acquire permanent residence as now (As 15&16). Those who haven’t resided in the UK for 5 years at the end of transition can carry on accruing that entitlement afterwards (A16), even if their status changes eg from student to worker or self-employed person (A17). Rights continue on the basis of EU law for workers and migrant citizens, to equal treatment with national workers (A23), although not to student loans for people who acquire settled status under the WA (A23 (2)). Workers and self-employed people under the WA have

the rights of EU migrant workers, eg for their children to attend school, access to housing etc (A24). Mutual recognition of qualifications under EU law continues during transition period (A27). UK can use EU information systems for ongoing mutual recognition processes for up to 9 months after end of transition period (A29).

What changes is the way in which UK imposes administrative formalities on EEA nationals in UK. There will no longer be an automatic right to reside in the UK. The UK (and EU) may require resident EU nationals to apply for a new residence status under the WA (A18). The conditions of the process for applying for this new status are not covered in as much detail in the WA as they might have been. Deadlines can be extended because of 'technical problems' (A18(1)(c)): the very fact that this is in the text is recognition of the fallibility of such application systems, especially when under-resourced. There is an obligation to consider 'reasonable grounds' for failure to respect a deadline (A18(1)(d)). Administrative processes must be 'smooth, transparent and simple' (A18(1)(e)); forms 'short, simple, user-friendly'; costs 'free of charge or not exceeding that imposed on citizens for the issuing of similar documents' (£75.50 for adult passport; £65 for settled status documents); original documents held have to be returned 'without delay'; administrative authorities have to 'give applicants the opportunity to correct any deficiencies, errors or omissions' (A18 (1)(o)). All of these terms could have been more precisely specified, for instance whether an opportunity to correct incurs a further cost. The way these terms are interpreted will affect how EEA nationals working in the NHS and social care experience in practice their change of status from EU citizens in an EU Member State to EU citizens with entitlement to remain under the WA and the new UK settled status rules.

For instance, the WA itself refers to the need for non-economically active people to show that they have 'comprehensive sickness insurance' (A18(1)(k)). However, the UK government have confirmed that those applying for the new settled status will not need to show CSI, in a statement of intent (<https://www.gov.uk/government/publications/eu-settlement-scheme-statement-of-intent>). As it is not included in the WA, no one can rely on that statement of intent, should a future government reverse it. This is the kind of thing that the European Parliament might pick up, given its role in Article 50 (2) TEU (it has to consent to the WA).

During transition, health and social care workforce will continue to enjoy EU-derived employment rights (health and safety at work, including working time; non-discrimination on grounds of race, disability etc; rights on restructuring) as now: 'Unless otherwise provided in this Agreement, Union law shall be applicable to and in the United Kingdom during the transition period' (A127). Changes to those rights under the EU (Withdrawal) Act 2018 could only lawfully be made after transition.

UK compliance with Part Two on citizens rights is to be overseen by a new 'independent authority'. The Authority will be empowered to investigate alleged breaches of Part Two of the WA, on its own initiative, or on the basis of a complaint, and to bring legal action to remedy breaches (A159(1)). The Authority will be in place for at least 8 years after the end of transition (A159(3)). There will also be a specialist Committee on Citizens Rights (A165(1)), within the new Joint Committee structure.

### *NI protocol*

If the NI Protocol comes into effect, the UK will be obliged to remain aligned with EU employment law, as part of the 'level playing field' conditions of the customs union (NIP, A6 and Annex 4). Neither the EU nor the UK may reduce those standards that exist in EU law at the end of the transition period (NIP Annex 4 A1). Enforcement, though, will only be through existing domestic processes (NIP, A14), though at least arguably the relevant rules are 'directly effective' so must be applied by UK courts. The arbitration procedure in the WA will not apply.

### *Declaration*

The Declaration envisages an end to free movement, and does not envisage any specific conditions for entry and stay related to health in particular or public service in general (though it does for research, study, training and youth exchanges; paragraph 53). If the NHS or social care entities are to employ health and social care staff from EU countries after transition, this will be on the basis of domestic immigration law only. That immigration law is far from fit for purpose in terms of filling the significant staffing gaps in health and social care that currently exist. Plans to fill those gaps with domestic workers are lacking in concrete specificity at this time.

There is a gnomonic mention of ‘appropriate arrangements on professional qualifications’ (paragraph 36); this is already less ambitious than the Canada agreement, which has not yet led to any actual agreements, and indeed according to [this](#) source on the European Commission website, the first meeting envisaged by that cooperation is yet to take place.

### **Financing**

**Reciprocal healthcare arrangements.** (Part Two, Title III, As 30-36). Coordination of social security (including EHC and S1/S2) continues during transition, and beyond, for people ‘for as long as they continue without interruption to be in one of the situations set out in that paragraph involving both a Member State and the United Kingdom at the same time’. Situations are being resident in EU/UK and ‘subject to’ coordination of social security rules (A30). Everyone ‘subject to’ social security legislation in EU/UK before end of transition can aggregate entitlements (A32). Includes EHC care until the end of the stay in the other state after the end of transition, plus reimbursement; health care for resident pensioners (‘for as long as the conditions in [the social security legislation] are fulfilled’ (A32 (1) (e)); reimbursement for planned healthcare (A32). Includes EEA/Swiss nationals (A33). Reimbursement, recovery and offsetting continues after transition for people covered by A30 and A32 (A35).

WA Annex I, part II includes a list of all the current detailed rules of EU social security coordination. These include the rules on EHC; health care for EU nationals resident in the UK and vice versa, including pensioners; and the arrangements under the EU Regulations whereby the UK waives reimbursement for some or all medicals treatment with Belgium; Denmark; Ireland; France; Luxemburg, Finland and Sweden, on a reciprocal basis.

Application of new EU law on coordination of social security after end of transition period continues in UK for those covered (A36). The Joint Committee (new institution set up under WA) will amend Annex I, part II accordingly. Some exceptions about not necessarily having to do that when EU changes exportability of cash benefits.

People covered by this part of the WA enjoy the rights it gives for their lifetime, so long as they continue to meet the requirements of the WA: ‘The persons covered by this Part shall enjoy the rights provided for in the relevant Titles of this Part for their lifetime, unless they cease to meet the conditions set out in those Titles’ (A39).

The practical application of the WA presumably will require UK nationals in EU countries to formally register their residence, otherwise they will not be formally ‘subject to’ that legislation. Many Brits, for example, in Spain, have not yet done so: we know that there are discrepancies between the number of people present and the formal figures. People who don’t register may find themselves outside of the protection of the WA.

*NI Protocol*

There are no provisions to continue reciprocal healthcare arrangements as part of the Protocol.

*Declaration*

There is a weak reference to “consider addressing social security coordination in the light of future movement of persons” (paragraph 54); this suggests that reciprocal healthcare arrangements will only continue if the UK accepts a significant degree of free movement.

**Capital financing for the NHS.** As noted in the Lancet article, the European Investment Bank has provided over €3.5 billion in low-cost capital to the NHS since 2001;<sup>15</sup> a source of funding that has become increasingly important as part of the shift to public-private partnerships for infrastructure improvement. The WA empowers the European Investment Bank to continue operating in the UK during the transition period (A124).

Thereafter, unless it is part of a future EU-UK relationship, the UK will be treated as a ‘third country’. The EIB can lend to entities outside of the EU, but 90% of its lending is within the EU. A search of its database found no health lending to a non-EU country. There is a reference to the UK exploring some way of continuing to work with the EIB (paragraph 15), but no firm commitment.

**Indirect impact on NHS financing.** The overall effect of Brexit on the economy remains unchanged from previous advice. The overwhelming consensus of economic forecasts, including that of the Office for Budget Responsibility, is that Brexit in any form will have a substantial long-term negative impact on the UK economy, and thus can be expected to put additional pressure on financing for the NHS. The government’s own economic impact analysis suggests that a no-deal Brexit will be particularly bad for the economy, and thus by extension indirectly for NHS financing.

**Medical products, vaccines, and technology**

These are ‘goods’, covered by WA Part Three, ‘Separation Provisions’, Title I, ‘Goods placed on the market’ (As 40-46). What is critical here is the difference between this and a no-deal Brexit. Any goods placed on the market in the UK or the EU before the end of the transition period may circulate between these markets, and made available or put into service in either of those markets (A41). The current Treaty rules on free movement of goods apply (A41). During transition, the UK must accept authorisations carried out by EU (EMA, national bodies for decentralisation authorisation of pharmaceuticals, ‘competent authorities’ in other EU MS for medical devices and equipment), and the EU must accept the UK’s authorisations (A41). UK and EU continue to share market surveillance information about dangerous goods (A43). UK and EU obliged to share information about past authorisations of pharma by sharing dossiers (A45). UK ‘competent authorities’ (including the UK’s MHRA) must transfer information to the EU on ongoing authorisations led by the UK before Exit Day (A44) [NB no reciprocal obligation of EU competent authorities to transfer info to UK]. ‘Notified bodies’ in UK and EU obliged to share information on conformity assessment (A46).

The UK is obliged to continue to protect IP rights registered or granted before the end of the transition period (A54). There is provision for supplementary protection rights (which extend patents so that they take into account the time it takes for a new pharmaceutical to receive marketing authorisation) for pharmaceuticals (A60).

By end of transition, UK must comply with relevant international law for all products covered by Euratom (A80), with a system of 'equivalent effectiveness' (A81).

### *NI Protocol*

Longer term, the Protocol on NI establishes a single customs union between the EU and UK, 'until the future relationship becomes applicable' (NIP, A6), in other words, potentially for many years given how long it takes to negotiate trade agreements. This means no tariffs or quotas on products moving between the UK and the EU. As many products relevant to the health sector (eg pharmaceuticals) are zero rated anyway, it isn't tariffs that matter so much as 'non-tariff barriers'.

The Protocol on NI deals with non-tariff barriers in two ways. Some non-tariff barriers, like environmental and labour standards, and state aids rules (listed in Annex 4), are within the rules of the common EU-UK customs territory, as necessary for a level playing field. As EU law develops, the Joint Committee is empowered to modify Annex 4 to lay down higher standards (NIP A6). So these rules apply to the whole of the UK.

But other non-tariff barriers, including EU law on product safety (applicable to medical devices), EU law on substances of human origin (blood, organs, human tissue), and EU pharmaceuticals law (including marketing authorisation rules, labelling, reporting, clinical trials, etc) (listed in Annex 5), are covered by NIP Article 8. This states, gnomically:

'Without prejudice to the provisions of Union law referred to in Annex 5 [the whole of/large swathes of EU legislation regulating products], the lawfulness of placing goods on the market in Northern Ireland shall be governed by the law of the United Kingdom as well as, as regards goods imported from the Union, by Articles 34 and 36 TFEU.'

So products in Northern Ireland will be subject to both EU law and UK law. Article 8 doesn't tell us what happens if they diverge. Those product rules must be aligned 'in respect of Northern Ireland' only. Of course, if the UK wants to have a single market within the UK, it would need to align with those rules, but the WA *itself* does not require that.

To make this a practical reality, NIP Article 8 creates a new category of product labelling, pertaining to goods approved for marketing in Northern Ireland (NIP A8(2&3), plus Annex 5). Products so marked by an entity in Northern Ireland shall be distinguished from those authorised from elsewhere in the UK (indicated as UK(NI) on the product) (NIP A8(2&3)). This UK(NI) mark certifies where the product has been manufactured, and that it complies with the relevant product safety rules. Where product safety checks take place on site in Northern Ireland, they will be recognised by the EU (NIP A8(2)para 3). That is why labelling becomes important: so that products travelling on from NI to the EU market can be spot-checked, to make sure they don't 'leak' into Ireland. The implication of the 'swimming pool' which is the metaphor being used to explain the zone established by the NIP is that checks can be lighter if the UK chooses to be more aligned (in the deeper end of the pool).

Where product safety checks take place outside NI, compliance will have to be checked by a body established in the EU, or an EU agency (NIP A8(2)para 2). British product safety checks won't be recognised by the EU. So there may be a greater role for entities in Dublin in securing product safety on the island of Ireland.

For pharmaceuticals, there is a specific and explicit provision in Article 8 NIP, which makes it clear that the ‘test and release by a qualified person in Northern Ireland of a batch of a medicinal product imported into or manufactured in Northern Ireland’ will continue to be permitted under the WA and, for as long as it applies, the Protocol (NIP A8 last para). The practical aspects of testing and certification of those specific products is reflected in the WA’s NIP, with a settlement that provides for continuity of current practice in Northern Ireland into the future.

By contrast, to clarify the general rule for product certification applicable to *medicines*, according to Annex 5 (p405), ‘a medicinal product authorised in the UK in respect of Northern Ireland shall not be considered a reference medicinal product in the Union’. So it will not be possible for pharmaceuticals companies to get MHRA authorisation for marketing in Britain for sale in Northern Ireland, and then rely on that authorisation to sell that product in the EU.

So, to summarise: if a medicine is licensed in the UK, although it will be able to be sold in NI, it will not be able to be sold in the EU without their regulatory approval. A medicine licensed in the EU can be made in Northern Ireland and sold in both the EU and the UK; but such a medicine made elsewhere in the UK will not automatically be able to be exported to the EU.

#### *Declaration*

The free trade agreement approach of the declaration means that medicines and other medical products will be able to flow freely between the EU and the UK. The negative impact, however, will come at a regulatory level, where the UK’s role in the licensing system will be reduced. Exactly how far the UK’s role will be reduced will depend on how closely the UK chooses to remain aligned with EU law (paragraphs 24-25). However, cooperation on radioisotopes is specifically provided for, and may be able to continue largely as it does now (paragraph 71).

#### **Information**

The European Centre for Disease Control is not explicitly mentioned in the WA. That means that the UK is excluded from the ECDC under A7. It may not nominate, appoint or elect members; participate in decision-making; attend meetings, including of expert groups, except where the WA explicitly provides otherwise (A7). I cannot find an explicit exception for this particular agency. So the UK will no longer be part of the ECDC’s decision-making processes from 29 March 2019.

However, the UK will have access to the ECDC’s information system until the end of the transition period under A8. The UK and the EU will continue to share information on communicable diseases, and indeed take collective decisions about communicable disease threats, through WHO (Europe).

There will be ongoing application in the UK of EU data protection law (GDPR, but also ‘general principles of EU law’ and the EUCFR ‘any other provisions of Union law governing the protection of personal data’) during the transition period. EU data protection law will also apply after transition to personal data of data subjects outside the UK processed before end transition period, or under the WA (A70). The EU is obliged to treat data from UK the same as if from a MS until the end of transition (A73).

Access to networks, information systems, databases ceases at end of transition (A8) – so everything that is needed to import products; the Clinical Trials Portal; information sharing about pharmaceuticals and SUSARS; information sharing about medical professionals operating across borders; networks on substances of human origin; research

networks ... all ceases unless covered in the future relationship(s). But access to (and commitment to pay for) the Administrative Commission and the Electronic Exchange of Social Security Information (the information system behind EHIC and S1/S2) continues as an express exception (A34).

### *Declaration*

In the longer term, the UK will be a 'third country' in the terms of the GDPR, and so will need to have a data protection adequacy decision. The Declaration envisages the European Commission 'endeavouring' to adopt adequacy decisions by the end of 2020 (paragraph 9). So long as the UK remains aligned with the EU, this should not pose any problems other than administrative ones. But should the UK diverge, then cooperation involving data sharing in a range of health contexts (disease surveillance, research, rare diseases ...) may prove more challenging.

### **Service delivery**

Some of the service delivery points have been covered above: the rights of EEA nationals in the UK's health and social care workforce; the labour regulation rules (eg continued application of the Working Time Directive during transition, and if the Joint Protocol's 'backstop' comes into play, thereafter); access to finance through the EIB.

EU rules on public procurement rules will continue during transition (A76), and could apply up to 9 months after end of transition (A78). There are no provisions on procurement in the NIP.

The Declaration envisages access to each other's public procurement markets beyond those required in WTO law.

Service delivery on the island of Ireland: The 'Common Travel Area' between UK and Ireland may continue, 'while fully respecting the rights of natural persons conferred by Union law' (NIP A5). However, this does not address the cross-border provision of services as such (eg: referral of patients, use of laboratory facilities, or remote reading of imaging).

### **Leadership and governance**

Outside the EU, the UK will lose opportunities to lead in regulation from the beginning of transition.

During transition, the UK will become a 'rule taker', with no opportunities for parliamentary scrutiny or for stakeholders to engage formally. Health-related EU legislation in the pipeline includes a proposal on Health Technology Assessment, as well as 'REFIT' legislation aimed to improve and simplify rules, for instance in health and safety at work re carcinogens; supplementary patent certificates for medicinal products; and the semi-regular revision of Regulation 883/2004 on coordination of social security. However modest these legislative changes may be, the UK will have no formal opportunities to influence or scrutinise them.

The NIP binds the UK in a non-regression clause for some aspects of public health, particularly environmental standards (NIP Annex 4). Other public health rules, in particular the EU's tobacco regulation provisions, are in NIP Annex 5. The UK must apply those rules in Northern Ireland, but need not do so in the rest of the UK.

Many of the relevant regulatory rules, eg the Clinical Trials Directive, will continue to have relevance in the UK under the Protocol on Northern Ireland. As the EU changes these rules, the UK will be excluded from those decision-making processes, de facto also excluding parliamentary scrutiny and stakeholder engagement from the UK.

UK 'competent authorities' (including the UK's MHRA) must transfer information to the EU on ongoing authorisations led by the EU before Exit Day (A44). The Headquarters Agreement on the location of the EMA in London terminates when the EU notifies the UK that the transfer of the EMA to Amsterdam is complete (A119).

Working through and with the WHO or the UN *Codex Alimentarius* system as the UK, rather than as part of an entity the size of the EU, will inevitably entail a loss of influence.

## **Research**

Funding under Horizon 2020, and other health research funding available from the EU's Multi-annual Financial Framework 2014-2020, will continue during transition, as part of the financial settlement (A135).

There is no provision for collaboration to continue under the Northern Ireland protocol. The Declaration does specifically envisage arrangements for the UK to participate in EU-funded programmes on terms yet to be agreed; this is likely to be equivalent to 'third country' participation (meaning contributing a similar amount to what is received by UK-based beneficiaries; limits on leading projects; and no input into the overall design and priority-setting of the programmes).

## **Enforcement of the WA**

WA and the provisions of EU law it makes applicable have the same legal qualities in the UK as in the EU. So, if a provision 'meets the conditions for direct effect', it will be able to be relied on in litigation. UK primary legislation is necessary to secure the supremacy of the WA (the 'disapplication' of contrary ('inconsistent or incompatible' law), and the UK will adopt that primary legislation (A4).

The CJEU's jurisdiction over the UK and people and companies residing in or established in the UK continues during transition (A131). The CJEU continues to have jurisdiction in disputes brought by or against the UK, and to hear preliminary references from the UK, during transition (A86). Up to four years after end of transition, CJEU can hear cases that UK breached EU law or part four of the WA (the part on the transition) (A87); and that the UK failed to comply with a decision of EU administrative bodies or agencies under A95 WA (A88). As well as general breaches of EU law, there is an explicit reference to the procedure whereby the Commission can bring a MS before the CJEU if they breach EU state aids law (A87). Up to eight years after transition, UK courts may (though need not) refer to the CJEU on the interpretation of the citizens rights part of the WA, which includes the provisions on workforce, and social security rights, which include cross-border healthcare (A158).

But disputes about the interpretation of the WA are resolved through a new institutional process, involving a Joint Committee and an arbitration panel (As167-181). The arbitration panel has to refer questions of interpretation of EU law to the CJEU (A174), but otherwise it is the place where disputes that cannot be politically resolved by mutual agreement will be resolved. In the event of non-compliance with an arbitration panel ruling, the panel may impose a financial penalty, and if continued non-compliance, the UK or the EU may suspend the WA (A178). This is much more like ordinary trade law than EU law. The parts on citizens rights and the financial settlement may not, however, be suspended. The decisions of the arbitration panel are, in principle, transparent (A180(2)). The arbitration panel is comprised of 5 independent members, drawn from a list of 25 (A171). It decides by consensus, or if necessary, majority vote, but no dissenting opinions are published (A180).

The WA establishes a new Joint Committee (A164), made up of representatives of the UK and EU, responsible for implementation and application of the WA. The Joint Committee may establish and delegate to specialist committees (A164(5)). Some such committees are established in the WA, eg on citizens rights (A165). The Joint Committee (and its delegates) may make binding decisions by mutual consent (A166). This is a bit like the arrangements for the EEA, where the EEA Joint Committee operates by mutual agreement.

### **Enforcement of the NIP**

The exception here is probably more important than the general rule. The general rule is simple: the UK is responsible for implementing the parts of EU law that the Protocol makes applicable 'to and in the United Kingdom in respect of Northern Ireland' (NIP A14(1))

But the exception applies to the EU's customs code, plus all the regulatory goods law (NIP A8-12), plus the rules on state aids (NIP Annex 4, A7). It provides that EU institutions, bodies, offices and agencies (ie all the entities that make free movement of goods a reality) shall 'have the powers conferred upon them by Union law' (NIP A14(4)). Those powers apply 'in relation to the United Kingdom' and to people residing and companies established in the UK (NIP A14(4)). The CJEU has jurisdiction and the preliminary reference procedure applies 'to and in the United Kingdom in this respect' (NIP A14(4)). Acts of EU institutions, bodies, offices, agencies 'have the same legal effects' as in EU law (NIP A14(5)). The UK may participate in proceedings and UK lawyers may represent parties (NIP A14(6&7)).