

BREXIT BRIEFING

A health service on the brink: the dangers of a 'no deal' Brexit





Foreword from Dr Chaand Nagpaul

In the coming weeks, MPs will have to make momentous decisions over the UK's future relationship with the EU. Key amongst them could be: should the UK crash out of the EU in a 'no deal' Brexit?

For the British Medical Association, the answer to that question is categorically: 'no'. The BMA is in no doubt that Brexit, and a 'no deal' Brexit specifically, will irreparably harm the NHS and the nation's health. That is why we oppose it. And yet, our warnings go unheeded. We are just weeks away from leaving the EU in a 'no deal' scenario, with all the catastrophic consequences this could have for patients, hardworking health professionals and the NHS. From disruption to essential medicine supplies, patient healthcare and the movement of highly skilled doctors to the potential return of a hard border in Northern Ireland, there are no winners.

To make a bad situation even worse, the NHS faces being plunged into a 'no deal' Brexit on the cusp of winter. The NHS has always faced increased pressure on its resources across the winter period, but this year, that pressure has been relentless. Performance levels across the NHS have been missed month after month, with many performance levels at their worst since records began.

Alongside this is a worsening workforce crisis. Nearly 22,000 thousand EEA doctors work in health services across the UK and yet a third of EU doctors have told us they are considering leaving the UK due to concerns around Brexit; other senior doctors are being forced to reduce their working hours because of punitive pensions rules. A 'no deal' risks pushing even more medics into making drastic decisions about their futures in the NHS. With around 10,000 medical vacancies in the health system, the loss of any more talented doctors risks exacerbating the workforce crisis and undermining patient care at a critical point.

The Government will say its 'no deal' planning will protect the NHS from the catastrophic consequences of Brexit. We are unconvinced. With less than two months to go until the UK potentially crashes out of the EU, we still have many questions about the impact of 'no deal' on patients and the NHS. Will NHS trusts be given extra funding and support if thousands of UK citizens currently living in the EU return to the UK to access healthcare? How will UK patients who rely on European rare disease networks for the diagnosis and treatment of their rare diseases be cared for if there's a 'no deal'? When is the Home Office going to publish further guidance on its 'no deal' immigration system? Can our already overstretched and under resourced health service cope with a 'no deal' Brexit and winter pressures?

There are many questions for the Government to answer. With the UK set to leave the EU in 59 days, time is running out.

Let us be clear: we are not 'the doubters, the doomsters or the gloomsters' the Prime Minister described on the steps of Downing Street. Nor is this 'Project Fear'. We are doctors who day-in and day-out, provide care for patients in the face of challenges that will only be made worse by a 'no deal' Brexit in the critical winter months following 31st October. We have a duty to speak out about matters that can harm patient care and we will continue to highlight the dangers Brexit presents in the weeks and months ahead.

On behalf of the medical profession, I ask our politicians to remember three critical points as they determine the nation's future for generations to come. First, 'no deal' will have catastrophic consequences for patients, the health workforce and health services. Secondly, given these dangers, every possible step must be taken to avoid a 'no deal' Brexit. Third, the public deserve the right to make an informed choice on leaving the EU. Give them the final say on Brexit.

A handwritten signature in black ink that reads "Chaand Nagpaul". The signature is written in a cursive style with a large initial 'C'.

Dr Chaand Nagpaul CBE
BMA council chair

Workforce and immigration

Approximately 65,000 EU nationals work in healthcare professions across the UK, providing key public services and carrying out vital medical research¹. Nine per cent of all licensed doctors in the UK are EEA graduates, making up 14% of all hospital consultants.² NHS Trusts in London and the South East, in particular, rely heavily on EU doctors.

Since the referendum, EU immigration to the UK has fallen and is now at its lowest level since 2013.³ EU applications to UK medical schools have fallen to their lowest point in a decade, suggesting Brexit is deterring prospective doctors from studying in the UK.⁴ Other healthcare professions are experiencing a similar impact. Figures from the Nursing and Midwifery Council show that the number of EU nursing and midwifery professionals joining the register declined from 9,389 in 2016 to 968 in 2019, while the number of those leaving has increased.⁵

To ensure the UK can continue to provide safe and reliable health care, and to remain globally competitive in the life sciences, the NHS must be able to recruit and retain doctors, nurses and other essential health care staff from abroad. There is a very real risk that many EEA nationals, including highly skilled doctors and medical researchers, will either choose to leave the UK, with many leaving Europe entirely, or will instead choose to train and work elsewhere due to the ongoing uncertainty. In the context of current workforce shortages, this would hinder the NHS's ability to provide adequate staffing on wards and in practices, thereby putting greater strain on health services as doctors and other healthcare workers face more intense workloads and longer working hours.

What could a 'no deal' Brexit mean for the health workforce?

The UK risks leaving the EU in a 'no deal' Brexit in little over two months and yet serious concerns remain over whether the Home Office has adequately prepared the UK's immigration systems for this outcome.

In the event of a 'no deal' Brexit, the Home Office will simultaneously have to deliver:

- The settled status scheme for the two million EU nationals in the UK who are yet to apply within a constrained time frame.
- A new and untested immigration system in the event of a 'no deal' (European Temporary Leave to Remain or a new, as yet, undefined system).
- The current immigration system for non-EU nationals.
- Development and implementation of 'the future immigration system' in early 2021.
- Completion of the parliamentary stages of the Immigration and Social Security Co-ordination (EU Withdrawal) Bill – required to end free movement – which has been stalled in Parliament since March 2019.

Settled status

Over one million people have been granted settled or pre-settled status⁶, leaving an estimated 2.4 million EU, EEA and Swiss nationals who still need to apply. If the UK crashes out with 'no deal', they will have until 31 December 2020 to do so (compared to 30 June 2021 if the UK leaves with a deal).⁷ This could mean that the Home Office will have, on average, to process applications from nearly 5,000 people a day over the next 14 months. It is essential that the Home Office's system can cope with any significant surges in application numbers.

Serious questions remain regarding the status of EU nationals, including highly skilled doctors working in the UK if they fail to apply under the settled scheme by either of the deadlines set by the Government.⁸ Settled status proves that individuals have the right to continue to live and work in the UK, and to access public funds and services in the future. As the Windrush scandal demonstrated, any failure by the Home Office to properly deliver the EU Settlement Scheme risks having a devastating impact not only on individual doctors and their families, but on health services across the UK, which rely on the recruitment of thousands of international doctors, nurses and healthcare workers each year to deliver vital health services.

Awareness of the scheme continues to be an issue. A BMA survey of over 1,500 EEA doctors⁹ in November 2018 found that 37 per cent of EEA doctors were not aware of the Government's settled status scheme for EU nationals. The Home Office must significantly increase its communications to EU nationals throughout its implementation phase to ensure maximum uptake, as well as providing more clarity on what will happen to those who fail to apply under the scheme.

Outstanding operational issues must also be addressed to ensure the settled status process is as straightforward and streamlined as possible for users. This will be essential to ease uptake, particularly in the event of a 'no deal' Brexit. Several options exist for EU, EEA and Swiss nationals to have their identity documents checked during the application process for settled status. However, Apple iPhone users are still unable to use their device to self-verify their identity using the App because Apple does not allow third-party access to the iPhone 'ID chip'¹⁰. The Home Secretary must ensure, as promised, that the App will be available on Apple devices later this year. Equally, reports that EU nationals have not been able to convert pre-settled status into settled status due to technical issues must be addressed as a matter of urgency.¹¹

European Temporary Leave to Remain

In January 2019, the Government stated that in the event of a 'no deal' Brexit, EEA nationals arriving in the UK after exit day who intend to stay for longer than three months would have to apply for European Temporary Leave to Remain (ETLR). This transitional system (due to operate from October 31st 2019 to December 2020) would entitle EEA citizens to stay in the UK for 36 months from the date of their application. It would be a temporary, non-extendable immigration status and would not give indefinite leave to remain (ILR)¹². EEA citizens wishing to stay in the UK for longer than 36 months would be expected to apply for an immigration status under the new (currently undefined) immigration system, which will come into effect from January 2021 – or apply through the current immigration system for non-EU nationals.

Recent developments have cast doubt on whether ETLR will come into effect at all. On 19 August 2019, the Home Office confirmed reports that freedom of movement will end on 31 October 2019 and stated that the arrangements for people coming to the UK for longer periods of time and for work and study will change. This signals a clear shift away from preparations by the previous government for a 'no deal' Brexit and suggests EU nationals may no longer be able to apply for ETLR, at least in its current form¹³. Although this may be a negotiating ploy, as some commentators have suggested, it introduces a new level of uncertainty for EU doctors, NHS employers and those thinking of coming to the UK. This could have significant consequences for the staffing of the UK health system.

If the Home Office does decide to introduce ETLR or an amended version of it, we are deeply concerned about the following:

- The lack of time to issue guidance or communications of any sort on the ETLR system to either prospective migrants to the UK or to employers. Many employers, particularly those who employ significant numbers of EU nationals, may not have engaged with either the immigration or ETLR system before. There is a very real risk then, that in the absence of guidance or guidance that is issued too late, employers and migrants will not be able to comply with immigration regulations.
- The Home Office will have had insufficient time to conduct user testing and/or respond to user feedback to improve the ETLR process (as occurred with the settled status scheme). This will inevitably increase the likelihood of errors.
- The implications of the three-year visa for the medical profession. Medical degrees and specialty training exceed three years. In practice, this would mean that an EEA medical student or doctor arriving in the UK after a 'no deal' Brexit would be required to apply for a new immigration status during either their degree or training.
- The introduction of visas acting as a major disincentive to EU nationals working in the NHS in the future. This could have particularly dire consequences for specialties already facing acute shortfalls, including general practice, emergency medicine, paediatrics, occupational medicine, radiology and psychiatry and on staffing levels on hospital wards, in GP practices and in community settings across the UK.
- We remain apprehensive about the ETLR process, its operability and the rights of medical students and doctors to remain in the UK should there be any errors or problems during the application process.

Questions for the Government to answer:

- Are you confident that the Home Office has the capacity to register over two million EU nationals who are already in the UK by the end of December 2020, if the UK leaves the EU without a deal?
- Are you confident that the EU settlement scheme can cope with any significant surges in application numbers in the lead up to 31st October 2019?
- What will happen to EU nationals, including highly skilled doctors working in the UK, if they do not apply to the EU Settlement Scheme by 31st December 2020?
- What plans do you have to increase communication with EU nationals throughout the implementation of the EU Settlement Scheme?
- Can the Home Secretary guarantee the EU Settlement Scheme App will be available on Apple devices later this year, and ideally before 31st October 2019?
- When is the Home Office going to issue guidance on the ETLR immigration system for prospective migrants to the UK and employers?
- If the ETLR is overhauled, what system will likely take its place, and what communication strategy has the government put in place to inform employers and EU nationals of this?

Winter pressures

The NHS across the UK is now caught in a cycle of deteriorating performance, where increasingly pressurised winters lead to unprecedentedly difficult summers, leading to a vicious cycle.

Trusts in England have now experienced two consecutive, catastrophic winters¹⁴. In January, February and March of 2018 and 2019, five of those six months saw new record lows established for the four-hour wait target. The 440,000 trolley waits from the same period was almost as many as the combined trolley waits recorded in the winters of all six years between 2011 and 2016 (450,000).

Inevitably, the NHS has struggled to recover this summer. Traditionally, pressures decrease significantly from winter, and by June, trusts tend to show improved performance. This summer there has been no respite however. In June and July alone, there were more trolley waits of four or more hours recorded than during the whole of 2011. Similarly, a recent BMA report also found that the number of escalation beds¹⁵ in England that were in use in the first week of April of 2019 were comparable to those in use in early January 2019, and only marginally lower than during the height of winter.¹⁶ Over nine in every ten (92%) respondents to the BMA's quarterly survey highlighted this normalisation of NHS pressures, reporting that 'The NHS is now in a state of year-round crisis'.¹⁷

Despite this, planning for seasonal pressures has remained broadly unchanged in recent years, with preparations largely revolving around ad-hoc winter funding allocations and contingency planning. In the last few years, pressures have been mitigated slightly by these allocations, such as the £240 million announced in October 2018 for extra winter funding to social care to relieve pressure on NHS beds. Winter funding is typically used for additional beds, filling rota gaps and funding new, pressure-mitigating schemes.

What could a 'no deal' Brexit mean for winter pressures in the NHS?

How the NHS will be able to plan for another difficult winter in addition to a potential 'no deal' Brexit at the worst of times, is unclear. We note that NHS England wrote to NHS organisations in July 2019 clarifying that all providers and commissioners were expected to have full contingency plans in place to ensure safe services for patients could continue to be provided in the event of a 'no deal' Brexit. NHS England intends to undertake an 'assurance exercise' from August 2019 onwards to confirm these teams are in post and ready; it is not clear if this exercise will explore preparedness for winter pressures in the event of 'no deal'.

What is clear is that the NHS is already routinely overwhelmed by seasonal pressures and that the addition of another, complicating factor is certain to dramatically exacerbate that problem. Existing winter preparedness funding for healthcare providers is unlikely to be sufficient to maintain performance standards and deliver patient care safely.

Questions for the Government to answer:

- How does the Government plan to support healthcare providers through another difficult winter coupled with a 'no deal' Brexit?
- Will additional funding be made available to mitigate pressures that occur as a result of Brexit, either in addition to the ad hoc winter funding allocations, or in lieu of it?
- Can the government guarantee that patient safety will not be compromised as a result of a 'no deal' Brexit?
- Will the Government publish the details of the planned 'assurance exercise' of NHS organisations to provide reassurance about the preparedness of the NHS in a 'no deal' scenario?
- What measures will be put in place to support those NHS providers who do not have full contingency plans in place?

Reciprocal healthcare arrangements

EU reciprocal healthcare arrangements allow citizens of EU and EEA nations, as well as Switzerland, to access the same health and social care services as local residents while in any of those nations, usually at no or low cost to the individual.

The schemes include the EHIC (European Healthcare Insurance Card), which provides access to state-provided healthcare for short-term visitors, and the S1 scheme, which allows ongoing access to health and social care services for individuals living abroad, such as pensioners.

The UK Government has consistently claimed that it hopes to retain existing reciprocal healthcare arrangements following the UK's exit from the EU, whether with the EU collectively or with individual member states.

What could a 'no deal' Brexit mean for reciprocal healthcare?

UK nationals in the EU

In a 'no deal' scenario, access to reciprocal healthcare arrangements for UK citizens and residents within the EU, and EU citizens and residents within the UK, would end. Guidance published by the Government on 28 January 2019 for UK nationals living in the EU/EEA and Switzerland confirms that their existing access to healthcare may change if the UK leaves the EU without a deal. EHIC and the S1 certificate will only be valid until exit day if there is a 'no deal' and residents are advised to buy insurance to cover their healthcare after this date, as they would if visiting a non-EU country¹⁸. The UK Government has since clarified that, in the event of a 'no deal' exit, those registered to the S1 scheme prior to Brexit will continue to have their care funded for a period of one year and that those returning to the UK will be able to access free NHS treatment. Despite this limited reassurance, it is clear that loss of access to reciprocal schemes will lead to significant disruption to those individuals' healthcare arrangements, a longer-term increase in their costs of insurance and uncertainty regarding accessing healthcare abroad.

Moreover, the NHS could face a drastic increase in demand for services, which could dramatically increase NHS costs and place even greater pressure on doctors and clinical staff than they are already under. For example, in a worst-case scenario, should the 190,000 UK state pensioners currently signed up to the S1 scheme and living within the EU return to the UK to receive care, the additional cost to health services is estimated to be between £500 million and £1 billion per year¹⁹. The demand on already stretched health services and staff would be significantly increased, necessitating further recruitment and the commissioning of additional beds and services. There would be a requirement for an additional 900 hospital beds, and 1,600 nurses to meet demand²⁰. At present, the UK's exit from the EU is also likely to coincide with what is widely expected to be the worst ever winter for the NHS – any further, unplanned spike in demand could therefore have potentially catastrophic consequences for patient safety.

EU nationals in the UK

In the event of a 'no deal' Brexit, there will be significant changes to the way EU and EEA visitors are able to access care in the UK. Minor protections are in place to ensure that visitors already in the UK at the point of Brexit will be able to continue to use their EHIC card or other schemes until the end of that visit. But, beyond that, a 'no deal' Brexit will mean that EU and EEA visitors will no longer be able to use any reciprocal schemes to access health and care services in the UK.

In an announcement made on 6th February 2019, the Government clarified that the UK was seeking to agree new reciprocal arrangements prior to exit day²¹. In March 2019, it passed the Healthcare (European Economic Area and Switzerland Arrangements) Act 2019, which allows the Secretary of State for Health and Social Care to make new reciprocal agreements with either the EU or individual EU/EEA states. However, it is currently unlikely that any such agreements will be in place on or prior to the 31st October.

As a result, there will be significant upheaval in individual's healthcare arrangements and a drastic increase in the complexity of the already highly complicated system of cost recovery in the UK.

This was highlighted in an August 2019 DHSC briefing which stated that, following a 'no deal' Brexit, NHS bodies will need to charge EU and EEA visitors for NHS care in line with existing overseas charging rules²². These rules vary across England, Northern Ireland, Scotland and Wales, all involving a range of eligibility criteria and exemptions. In England, overseas charging regulations have been made increasingly restrictive since 2015 with the introduction of higher fees for care and upfront charging, as well as an extension of services that are chargeable. The BMA is deeply critical of these regulations, which deter vulnerable patients from seeking care, negatively impact on doctors and NHS staff and pose a significant risk to public health²³. The extension of these rules to EU and EEA visitors is, therefore, hugely troubling.

The guidance also states that EU and EEA nationals who are ordinarily resident in the UK, and therefore entitled to NHS treatment, will need to provide evidence of their eligibility for free care in order to avoid being charged. This has been seen by some as a potential new frontier of the hostile environment, with the same rules having already caused many long-term residents and even citizens of the UK to be wrongly denied NHS treatment, as highlighted by the Windrush scandal. It will also dramatically increase the complexity of the charging system, forcing hospitals to attempt to determine where a patient was born, and, if they are from one of the 27 EU nations, whether they are eligible for free care or not. Given that patients typically do not carry the documentation to prove this and that the deadline to apply for settled status is not until the end of December 2020, this will be an exceptionally difficult task which risks not only limiting countless patients' access to care, but also diverting vital NHS resources away from providing it.

Questions for the Government to answer:

- How are you communicating changes in reciprocal healthcare arrangements to EU nationals in the UK in the event of a 'no deal' Brexit?
- What measures are you putting in place to ensure EU nationals know they need to provide evidence that they live in the UK on a lawful basis to access healthcare in the UK in the event of a 'no deal' Brexit?
- Will you provide additional funding to NHS trusts and health boards to meet any additional costs if thousands of UK citizens currently living in the EU return to the UK to access healthcare?
- What additional training has been or will be provided to non-clinical NHS staff to administer the extension of the charging regime?
- Can you ensure doctors will not be asked to determine patients' eligibility for healthcare in the event of a 'no deal' Brexit?
- Will individuals with active but incomplete applications for settled and pre-settled status be entitled to free NHS treatment?
- Will EEA visitors be charged at 100% of the NHS tariff as they are currently, or at the rate of 150% of the tariff, currently paid by non-EEA visitors?
- What consideration has been made of the differing charging and eligibility criteria across England, Northern Ireland, Scotland, and Wales? Has or will nation-specific guidance and communication material be produced for staff and patients?
- What forms of evidence will EU & EEA patients be expected to provide to NHS providers in order to prove their residency status and eligibility for NHS care?
- What guidance has been issued to NHS providers regarding the evidence they require from EU & EEA patients when assessing their eligibility for NHS care?
- As the deadline for applications for settled status is December 2020, will EU & EEA who are resident in the UK but who have not yet applied for settled status be able to access NHS care freely up to that point?

Northern Ireland

Northern Ireland will be affected by all of the issues covered in this briefing. However, given it is in the unique position of being the only region of the UK that shares a land border with another EU country – the Republic of Ireland – it will be affected more acutely by a number of issues including the provision of cross border healthcare services and freedom of movement. The lack of a current government and executive in Northern Ireland further complicates these issues and increases our concerns around the impact of 'no deal' on Northern Ireland.

The existing open border arrangement between Northern Ireland and the Republic of Ireland currently enables healthcare professionals based on both sides of the land border to travel freely to provide healthcare to their patients. Alongside the open border arrangement, the EU's principles of freedom of movement and MRPQ have enabled many health and social care professionals from countries within the EU, but especially those from the Republic of Ireland, to practise in Northern Ireland.

Northern Ireland, with a population of just over 1.8 million, has insufficient demand to provide some specialised medical services alone. Co-operation between Northern Ireland and the Republic of Ireland, which is in part funded by the EU, has been crucial in facilitating and delivering these services whilst also ensuring that highly skilled clinicians can be attracted and retained in Northern Ireland. There are a number of areas where cross-border healthcare service arrangements have been established and are currently providing high quality care for patients, such as in primary care, cancer services and paediatric cardiac²⁴ surgery. It is vital that these health services are not destabilized during, or after, the Brexit process.

What could a 'no deal' Brexit mean for Northern Ireland?

'No deal' risks the return of a hard border between Northern Ireland and the Republic of Ireland. At a minimum, this could deter cross border workers (upon which the Health and Social Care [HSC] system in Northern Ireland relies heavily) from making their daily commute. This risks putting an already pressurised service under even more strain. Without cross border cooperation in the delivery of vital health services, Northern Ireland could not sustain specialised services. This risks not only forcing patients to once again travel considerable distances to receive care but could exacerbate existing difficulties within HSC to retain experienced, specialised doctors.

The nature of the border between Northern Ireland and the Republic of Ireland, which meanders across 310 miles/499 kilometres of land, presents another significant challenge for health professionals, which must be considered. Doctors travelling from one point in Northern Ireland to another point around the border area may have to go through the Republic of Ireland. Doctors and healthcare workers, who are often in possession of medication, would need assurances that they are covered legally to both be in possession of medication in an EU country and be legally insured to drive there.

The Common Travel Area pre-dates either country's membership of the EU and means that Irish nationals can enter and work in the UK freely, regardless of the UK's decision to leave the EU. It will not be impacted by whether the UK leaves the EU with or without a deal.

Given the unique challenges to the island of Ireland, it is of paramount importance that the Good Friday Agreement, ratified in 1998, is fully protected if the UK leaves without a deal. Failure to do so could destabilise the region and put at risk the ongoing peace in Northern Ireland, making it a less attractive place to work as well as more difficult to attract and retain doctors to work there.

We also seek reassurance that changes to the 'settled status' scheme, would not challenge the Good Friday Agreement in Northern Ireland and that those born in Northern Ireland may choose Irish citizenship and retain the rights that go with that (the rights of Irish citizens include those under EU law).

Questions for the Government to answer:

- What measures will you put in place to minimise disruption to patients, health workers and health services in Northern Ireland in the event of a 'no deal' Brexit?
- Will you provide assurances to doctors and healthcare workers in Northern Ireland that they will be legally covered to be in possession of medication in the Republic of Ireland?
- How will current cross border services be sustained and developed in the future?
- Has funding been identified and allocated to replace funding that has come directly from the EU?

Medicines and medical devices regulation

The UK has developed a well-functioning medicines and medical devices regulatory system, working closely with the EMA (European Medicines Agency) and built on EU regulations and directives. Collaboration across borders on the way that medicines and medical devices are regulated has been a key advantage of the UK's membership of the EU. Establishing a robust common framework for assessing and monitoring drug safety and efficacy has been a key success and allowed patients across Europe to have timely access to new therapies and technologies and helped make sure the drugs in circulation are safe. The CE (Conformité Européenne) marking system for medical devices has similarly facilitated access to innovative medical devices from across Europe.

What could a 'no deal' Brexit mean for the regulation of medicines and medical devices?

'No deal' would lead to considerable uncertainty about the UK's ability to ensure a continuous supply of medicines into the UK. In the months building up to March 2019, the Government and NHS put in place a series of measures designed to ensure continuity of the supply of medicines and devices in the event of 'no deal'. This approach included: stockpiling, regulatory flexibility, purchasing additional freight capacity on alternative routes into the UK and building intelligence on medicines supply chains.²⁵ Despite this, there remained multiple media reports of shortages, with the Pharmaceutical Services Negotiating Committee reporting an all-time high of 96 medicines in shortage in March 2019.²⁶ While there were likely to be a number of contributing factors, it is reasonable to suggest that the possibility of a 'no deal' Brexit, and the public uncertainty that was created, may have had some role in these shortages.

This uncertainty highlights a clear need for concise, and easy to understand messaging for the whole healthcare sector, including those that support it, such as the pharmaceutical industry and – importantly – the staff that work within it, such as doctors and nurses. As we move into winter, and the NHS pressures²⁷ that are now associated with this time of year, it is particularly vital that this messaging is delivered early enough to allow the NHS to properly prepare and put in place measures to reduce shortages.

In July 2019, legislation came into effect which allows Ministers, in the event of a medicine being in short supply, to issue protocols to allow community pharmacists to dispense alternatives to the drug prescribed instead of a prescription having to be returned to the prescriber to be amended.²⁸ While the legislation has wider aims than ensuring continuity of supply in the event of a 'no deal' Brexit, it may be used in this scenario.

While such protocols may speed up access to medicines in the event of shortages, there are real risks with such a blanket approach, which allows pharmacists to provide therapeutic equivalents when a prescribed drug is not available. Patients can respond differently to drugs that are therapeutic equivalents or may even be allergic to some, and the pharmacist will not know what has already been used or have access to this patient data. Prescribers are best placed to manage this.

Over the longer-term, a 'no deal' Brexit could also significantly impact the speed of availability of new drugs for patients in the UK. The Government's 'no deal' guidance confirms that the MHRA (Medicines and Healthcare products Regulatory Agency) will take on the work of the EMA.²⁹ Regulating medicines on its own, outside of the EMA, the UK will be a much smaller market for medicines, coupled with already tight margins for medicines, this means the UK will be less of a priority market leading to delays in new products being brought to market in the UK. For example, it has been suggested that a separate regulatory system to the EMA could lead to delays of 12 to 24 months for UK patients being able to access life-saving cancer drugs³⁰.

There would also be considerable adverse impacts on the future capacity of the UK and EU in relation to pharmacovigilance, which for the UK would be compounded by a potential loss of expertise given the EMA's physical move from London.

Questions for the Government to answer:

- What measures will the Government put in place to ensure the shortage protocol does not negatively impact patient safety?
- What are the Government's plans to avoid the UK becoming a third-tier market for medicines and ensure UK patients are able to get access to new drugs in a timely way?
- In the event of no-deal what advice will the Government provide to doctors if there is a shortage of medicines?
- What plans does the Government have to clearly communicate what the shortage protocol is and is not, to clinicians and the public?

Euratom

Euratom ensures a secure and consistent supply of radioisotopes, which have a range of applications in medicine. They are vital for diagnosing particular diseases through nuclear medicine imaging techniques, treatment of cancer through radiotherapy, as well as palliative relief of pain and biochemical analysis in clinical pathology.

What could a 'no deal' Brexit mean for access to medical radioisotopes?

As isotopes have a short half-life and cannot be stockpiled, continuous and timely access is vital for patient safety. The UK does not have access to a domestic supply, close to the point of use, and so relies on imports from Europe and beyond. As a member of Euratom, this supply is largely fulfilled by EU countries and has largely been stable and consistent in recent years. Leaving Euratom will risk supply issues. Breaks in supply can lead to delayed diagnosis and treatment, as occurred in 2009 and 2013 when maintenance of reactors resulted in facilities going offline temporarily.³¹

A 'no deal' scenario would force the UK to operate outside of Euratom and source radioisotopes from outside of this EU framework. This would remove the guarantee of consistent and timely access to radioisotopes, potentially resulting in delays in diagnosis and cancelled operations for patients. Over the longer term, it would also restrict the ability of the UK and EU to benefit from sharing expertise in radiation research, radiation protection and the disposal of radioactive waste.

In August 2019, a letter from the Royal College of Radiologists, British Nuclear Medicine Society and UK Radiopharmacy Group to the Prime Minister raised concerns about the readiness of suppliers of radioisotopes as well as the impact changes at the border may have on these time-sensitive products.³² While the Government has been proactive in mapping supply chains and working with industry to try to identify solutions to possible issues, there is clearly a significant risk that these products with a short half-life may be delayed in reaching the NHS in the event of a 'no deal' scenario.

Questions for the Government to answer:

- What guarantees can be made that radioisotopes will continue to be imported into the UK without delay in the event of 'no deal'?
- What contingency steps has the NHS taken to ensure that radioisotopes will be supplied uninterrupted to hospitals across the UK?

Rare diseases: impact on patients

Across the EU, around 30 million people are affected by up to 8,000 rare diseases. One rare disease may affect anything from only a handful of people to as many as 245,000³³. Worldwide, about one out of 15 people could be affected by a rare disease. Due to the low prevalence of a single rare disease, patients are usually scattered across different countries making it harder for them to access the right treatment from a health professional who is a disease expert. To support these patients, EU legislation encouraged the development of European Reference Networks (ERNs) so that health professionals and researchers could share expertise, knowledge and resources.

ERNs covering the majority of disease groupings such as bone disorders, childhood cancers, and immunodeficiency. Each ERN has a co-ordinator who convenes a 'virtual' advisory board of medical specialists across different disciplines to review patient cases. This ensures that specialists can review a patient's diagnosis and treatment without the patient having to leave their home environment. There are 24 networks, involving over 900 medical teams in more than 300 hospitals from 25 EU countries, plus Norway³⁴. The UK co-ordinates a quarter of the 24 networks and participates in nearly all, with around 40 NHS hospitals involved. ERNs receive support from several EU research funding programmes, including Horizon 2020.

What could a 'no deal' Brexit mean for patients with rare diseases?

A 'no deal' Brexit would lead to UK patients, experts and hospitals being excluded from the ERNs. This could have a damaging impact on the nearly one million patients a year – 150,000 of whom are British – who are currently seeking diagnoses and treatment abroad.

The exclusion of the UK from the ERNs also risks having a devastating impact on the sharing of medical expertise amongst UK and EU healthcare staff, which is critical to the diagnosis and treatment of rare diseases. Recent reports suggest UK experts who currently lead six of the 24 networks would be stripped of their roles in the system in preparation for Brexit. The implications for the UK hospitals currently involved in the system are as yet unknown.

Excluding the UK and its expertise in rare diseases after Brexit would be a loss not just for the UK, but for Europe as well.

Questions for the Government to answer:

- Can you confirm whether the UK will be excluded from ERNs in the event of a 'no deal' Brexit?
- If so, how will you support UK patients who rely on ERNs for the diagnosis and treatment of their rare diseases?
- How will you ensure UK experts in rare diseases continue to be able to collaborate with their EU colleagues to share expertise and ensure patients are able to receive the best possible care?

Recognition of professional qualifications and patient safety

The EU directive on mutual recognition of professional qualifications facilitates the free movement of EU citizens by making it easier for professionals qualified in one member state to practise their profession in another. In the UK, nearly 22,000 doctors gained their primary medical qualification from another EEA country. The mutual recognition of qualifications is a particularly vital issue in Northern Ireland, where clinicians move freely between both jurisdictions.

The Internal Market Information System (IMI) alert system, which is a part of the MRPQ Directive, allows the General Medical Council (GMC) and medical regulatory authorities within the EU to communicate with each other when a doctor has his or her practice restricted in one of the other 27 EU member states. As the UK will no longer have access to the IMI in a 'no deal' scenario, it will be important to consider how health regulators ensure doctors working in the UK are fit to practise medicine should the UK withdraw from the MRPQ directive after Brexit.

What could a 'no deal' Brexit mean for the recognition of professional qualifications and patient safety?

The DHSC has implemented changes to the Medical Act to ensure the vast majority of European qualifications will be recognised³⁵ 'no deal' Brexit. These amendments, which would allow the GMC to continue to register EEA qualified doctors in a timely and streamlined way, will last for a period of two years, when the system will be reviewed by Government.

However, as only a small number of European countries like France and Ireland are reciprocating this move, a 'no deal' Brexit would have significant repercussions for UK qualified doctors, be they UK nationals or citizens from another EEA country, seeking to return home or to work in other European countries. These doctors, including thousands of EEA citizens currently studying medicine in the UK, will be in the hugely disadvantageous position of being treated as 'third country nationals' and risk being significantly disadvantaged when they register to work.

To mitigate risks to patient safety arising from the loss of the IMI, the GMC will need to work with regulators in EU member states to establish a new system to communicate when doctors have restrictions placed on their right to practise. It is highly unlikely any new system would be as effective or as timely as the IMI in sharing fitness to practise concerns, which could have serious consequences for patient care.

Questions for the Government to answer:

- What conversations have you had with health regulators to ensure doctors working in the UK are fit to practise medicine should the UK withdraw from the MRPQ Directive after Brexit?
- What conversations have you had with the EU to ensure UK qualified doctors, be they UK nationals or citizens from another EEA country, seeking to return home or to work in other European countries are able to do so without being disadvantaged?

Medical research

The EU provides a unique platform for medical research collaboration by supporting the sharing of research staff and expertise, cross border trials, and the development of world class facilities. The UK has been a leading partner in this. Between January 2007 and March 2017, the UK received the highest level of funding (£1.2 billion)³⁶ among all EU countries for health-related research projects from EU funding programmes FP7 (Framework Programme 7) (2007-2013) and Horizon 2020 (2014-2020).

Beyond providing financial resources, these programmes facilitate and actively promote international collaboration between researchers and research institutions. Six of the UK's current top ten international collaborators are also members of EU Framework³⁷. While the UK's decision to leave the EU does not in itself prevent collaboration, it damages the UK's scientific reputation and appeal for researchers. This in turn could reduce training and career opportunities for researchers.

'No deal' also risks limiting the UK's ability to translate research into medicines and medical devices into products to bring to the market. By being outside this network, and disrupting funding arrangements, Brexit will increase the burden of conducting multi-centre clinical trials and create barriers to working collaboratively and sharing expertise, facilities and datasets. This will ultimately delay the development of and access to new medicines and devices across Europe.

What could a 'no deal' Brexit mean for medical research?

The research community is already facing significant uncertainty about future funding sources and opportunities for collaboration with EU partners. A 'no deal' scenario exacerbates this. With grant applications having long lead times, current and ongoing applicants are unclear about the future of funding sources. While it is important that this is addressed in the long-term through agreements in future programmes to guarantee funding, the current uncertainty that has been created may potentially lead to the UK losing academic expertise and a decline in demand from researchers to work in the UK, which would ultimately damage the UK's research outputs and reputation.

Questions for the Government to answer:

- What will the Government do to ensure that the UK can continue to participate in EU-wide clinical trials in the event of 'no deal'?
- Will the Government guarantee funding from EU programmes in the event of 'no deal'?
- How will the Government ensure the UK associates to Horizon Europe in the event of no deal?

Trade agreements

For over 45 years, the UK's international trade policy has been determined through its relationship with the EU. As an EU member state, the UK currently benefits from frictionless trade within the European single market and preferential market access to more than 70 countries around the world under the EU's free trade agreements.³⁸ These agreements receive a high level of democratic scrutiny and include explicit controls which protect the NHS, safeguard the UK's right to regulate in the interest of public health and set high health and safety standards on imported products.

What could a 'no deal' mean for trade agreements?

In a 'no deal' scenario, the UK would be forced to trade with many countries, including all EU member states, on WTO (World Trade Organization) rules. This would increase taxes on imports and exports in some sectors and could cost the UK an additional £80 billion per year by 2033.³⁹ The UK would be under significant economic pressure to secure new trade agreements to minimise the cost of a 'no deal' Brexit.

In early discussions, non-EU countries including the United States⁴⁰ and Australia⁴¹ have indicated that securing a trade agreement would require the UK to liberalise its trade policy in ways that could negatively impact the NHS and the nation's health, such as lowering standards on imported foods. Were the NHS to be included within the scope of trade agreements, this could increase the amount of care being provided by the private sector and lock in competitive procurement. Investor protection and dispute resolution mechanisms, which are found in many modern trade agreements, could also be used to delay or block the UK Government from introducing new public health measures.

Given these potential risks it is crucial that Parliament has the ability to adequately scrutinise any new trade agreements. Currently UK Parliament does not have sufficient powers to guard against these potential impacts through scrutiny of trade negotiations, including access to negotiating texts and an automatic positive vote on the final text of trade agreements. It is unlikely that a more robust and transparent procedure could be put in place before 31 October.

Questions for the Government to answer:

- How will the UK Government ensure that Parliament is able to scrutinise trade negotiations and vote to approve any final agreement ahead of accelerating trade talks with the US?
- What actions will the UK Government take to ensure that economic benefits are not given priority over the nation's health in a rush to secure trade agreements to offset the cost of a 'no deal' Brexit?
- Will the Government provide a meaningful commitment to exempt the healthcare sector from rules on competition that could lock in or extend competitive procurement of publicly funded healthcare services?
- Will the UK Government also commit to exclude investor protection and dispute resolution mechanisms from any future trade agreement?

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