HOUSE OF LORDS Library Briefing

Leaving the EU: Health and Welfare of UK Citizens and Residents
Debate on 29 March 2018

Summary

On 29 March 2018 the House of Lords is due to debate a motion moved by Baroness Brinton (Liberal Democrat) "that this House takes note of the effect of the United Kingdom's planned withdrawal from the European Union on the health and welfare of United Kingdom citizens and residents". This House of Lords Library Briefing will examine current trends regarding EU workers in the NHS and social care, and will summarise the arguments on the impact of Brexit on funding available for public services. It will review existing arrangements for reciprocal healthcare provision in the EU and the current state of negotiations between the EU and UK in this area. It will also look at the potential implications of Brexit for access to medical products in the UK.

Many people from EU-27 countries, relying on the EU's rules regarding free movement, work in the UK's National Health Service (NHS). The proportion of NHS (excluding primary care) staff from EU-27 countries rose slightly between September 2015 and September 2017, from 4.99 percent to 5.56 percent. In social care, 7 percent of workers were from the EU-27 in 2016/17. Since 2012/13 the proportion of workers from non-EU countries in social care has fallen, and the proportion from EU-27 countries has risen.

It has been argued that when the UK leaves the EU more money will be available for public services, as a result of the UK no longer being required to make contributions to the EU budget. However, others have emphasised the potentially greater impact of Brexit on the UK's economy.

As a member of the EU, the UK currently participates in arrangements which allow UK citizens living in the EU and EU citizens in the UK, as well as those travelling for short periods, to access healthcare while abroad. The Government and the EU have stated that those exercising these rights before the end of the transition period will continue to be able to do so. The Government has also stated that it would like to negotiate continued access to these arrangements for those travelling after the transition period.

Upon its departure from the EU, the UK will cease to be a full member of the European Medicines Agency (EMA). The Prime Minister has said she would like the UK to become an associate member after its withdrawal from the EU, to ensure UK patients are not disadvantaged in accessing medical products.

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1. Impact on NHS and Social Care

1.1 Workforce

NHS

Many people from EU-27 countries, relying on the EU's rules regarding free movement of workers, work in the UK's National Health Service (NHS). In addition, workers from the European Economic Area (EEA) and Switzerland (countries which also participate in the EU's single market and abide by free movement rules) also have the right to work in the UK. A 2016 report by the House of Commons Health Committee emphasised the value to the NHS of its staff from the EU-27, in both clinical and non-clinical roles.[1]

The collection of data on the nationality of people working in the NHS has improved over time. For example, the available data for NHS hospital and community health service (HCHS) staff working in trusts and clinical commissioning groups in England (excluding primary care staff), show that in September 2017 there were 78,269 staff whose nationality was unknown, while this figure was 94,365 in September 2015.[2] Therefore, comparisons of numbers of staff from different countries across time should be made with caution, as numbers in each nationality group may increase over time as more staff provide nationality information and 'unknowns' decrease. Examining the nationality data as a percentage of staff whose nationality is known may provide a more useful comparison.

The following table shows the number and the percentage of NHS staff (of those whose nationality is known) in each nationality group.

Table 1: Nationality of NHS Staff (Excluding Primary Care)

	September 2015		September 2016		September 2017	
Nationality	Number	Percentage of Known	Number	Percentage of Known	Number	Percentage of Known
UK	934,075	88.34	955,090	87.77	976,267	87.54
EU-27	52,808	4.99	59,796	5.50	61,974	5.56
EEA and Switzerland	371	0.04	401	0.04	432	0.04
Rest of World	70,056	6.63	72,896	6.70	76,613	6.87

(Source: NHS Digital, *HCHS Staff in NHS Trusts and CCGs*, September 2017)

[1] House of Commons Health Committee, *Brexit and Health and Social Care—People and Processes*, 28 April 2017, HC 640 of session 2016–17, p 13.
[2] NHS Digital, *HCHS Staff in NHS Trusts and CCGs*, September 2017.

Figures provided by the Department of Health to the House of Commons Health Committee compared the number of EU-27 nationals joining and leaving the NHS in the six months following the EU referendum with the same period the preceding year:

> A total of 4,863 EU nationals joined the HCHS workforce between June 2016 and September 2016. This is just 126 fewer than who joined in the corresponding period of 2015. However, the number of leavers increased between the two periods by 604, from 3,254 to 3,858.
>
> Within this, the turnover of EU national doctors remained fairly constant between the two periods, with a slight increase of 79 in the number of joiners, from 1,212 to 1,291, whilst the number of EU national doctors leaving barely changed.
>
> The number of EU national nurses joining fell by 173 from 1,409 in [2015] to 1,236 [in 2016], whereas the number leaving increased by 298, from 1,017 to 1,315.[3]

Comparing the year to September 2016 with the year to September 2017, the proportion of people (for whom nationality is known) from the EU-27 joining the NHS fell from 10.25 percent to 8.3 percent.[4] The proportion of those leaving who came from EU-27 countries rose, from 6.89 percent to 7.91 percent.

Social Care

Skills for Care, a charity, provides information on the nationality of the social care workforce based on the National Minimum Data Set for Social Care, an online workforce data collection system for the adult social care sector.[5] According to the most recent publication of data, in 2016 there were 1.58 million jobs in the social care sector, 1.34 million of which were in the independent and local authority sectors.[6] All figures discussed below relate to people employed in the independent and local authority sectors, and exclude those working for private individuals and the NHS. Unless otherwise stated, the data was taken from local authorities as at September 2016 and from independent sector employers as at March 2017.

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[3] House of Commons Health Committee, *Written Evidence from the Director of Workforce (Department of Health) BRE0097*, 28 February 2017. Due to changes in the way that data are collected which took effect in March 2016, these data do include primary care staff.
[4] NHS Digital, *HCHS Staff in NHS Trusts and CCGs*, September 2017; and *HCHS Staff in NHS Trusts and CCGs in England*, September 2016.
[5] Skills for Care, *The State of the Adult Social Care Sector and Workforce in England*, September 2017, p 4.
[6] ibid.

In 2016/17, approximately 83 percent of the adult social care workforce were from the UK, 9 percent (125,000 jobs) had a non-EU nationality and 7 percent (95,000 jobs) had an EU-27 nationality.[7] The lowest proportion of EU-27 workers was in senior management roles, at 2 percent, and the highest were registered nurses, at 16 percent.[8] The proportion of the social care workforce made up of EU-27 nationals was highest in London, at 13 percent, and lowest in the North-East, at 2 percent.[9]

While the proportion of UK workers in social care has remained relatively steady over recent years, rising from 82 percent to 83 percent between 2012/13 and 2013/14 and remaining at 83 percent until 2016/17, the balance between EU-27 and non-EU workers has changed. Since 2012/13, the proportion of EU-27 workers has risen 2 percentage points and the proportion of non-EU workers has fallen 3 percentage points.[10] Skills for Care concluded that the result of the referendum on leaving the EU has not changed this trend, with the number of EU nationals continuing to increase and the number of non-EU nationals decreasing.[11]

Policy and Negotiations

In evidence given to the House of Commons Health Committee in January 2017, the Secretary of State for Health, Jeremy Hunt, emphasised the value to the NHS and social care sector of workers from EU-27 countries and stressed that the Government would prioritise securing their right to remain and work in the UK:

> The 90,000 staff from the EU who work in the social care system and the 58,000 who work in the NHS do a brilliant job. Frankly, we would fall over without their help. That is why it is a very early priority for us to secure, as quickly as we can, agreement for their right to remain in the UK and continue their great work.[12]

Following the triggering of Article 50 in March 2017, the Cavendish Coalition, a group of health and social care organisations which lobbies on post-EU referendum matters affecting the health and social care workforce, released a statement calling on the Government to guarantee immediately a right to permanent residence for all European Economic Area (EEA) nationals working in the health and social care sectors.[13] The Coalition also argued that the UK would continue to be dependent on workers from EEA

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[7] Skills for Care, *The State of the Adult Social Care Sector and Workforce in England*, September 2017, p 55.
[8] ibid, p 56.
[9] ibid, p 57.
[10] ibid, p 58.
[11] ibid.
[12] House of Commons Health Committee, *Brexit and Health and Social Care—People and Processes*, 28 April 2017, HC 640 of session 2016–17, p 13.
[13] Cavendish Coalition, *Statement on the Government Triggering of Article 50*, 29 March 2017.

countries in the years following the UK's departure from the EU, and called on the Government to create a post-departure immigration system for EEA nationals which is more liberal than that currently in place for non-EEA nationals:

> At this stage, the Coalition is already clear that extending the current work visa system for people from outside the EEA to include people from the EEA would not support continued delivery of high-quality social care and healthcare services. The current immigration system for non-EEA nationals proves very difficult to recruit individuals from outside of the EEA.[14]

In December 2017, a joint report from the negotiators of the EU and the UK announced that the two sides had agreed, in principle, that EU citizens living in the UK before the UK's withdrawal date of 29 March 2019 would have the right to remain and to apply for settled status after a period of five years.[15] In a subsequent document, the Government proposed that EU citizens who arrived in the UK after the withdrawal date of 29 March 2019 but before the end of the subsequent transition or implementation phase should be allowed to enter the UK on the same terms as before the withdrawal date, and should be given a temporary status which allows them to accumulate the five years' continuous residence necessary to apply for settled status.[16]

On 19 March 2018, the EU's negotiators and UK Government issued a draft Withdrawal Agreement. This draft specified areas of agreement, which included citizens' rights, and areas which are yet to be agreed. This document is yet to be formally adopted by either side. The draft Withdrawal Agreement appears to suggest that EU citizens arriving in the UK (and vice versa) during the transition period will enjoy the same rights as those arriving before 29 March 2019. In a letter to David Davis, the Secretary of State for Exiting the European Union, the chair of the House of Lords European Union Committee, Lord Boswell of Aynho, asked for clarification on this point:

> Can you confirm that under the 19 March text of the Agreement EU citizens resident in the UK and UK citizens resident in the EU 27 before the end of the transition period will enjoy in full the rights conferred by Part Two (Citizens' Rights)?[17]

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[14] Cavendish Coalition, *Statement on the Government Triggering of Article 50*, 29 March 2017.
[15] European Commission, *Joint Report from the Negotiators of the European Union and the United Kingdom Government on Progress During Phase 1 of Negotiations under Article 50 TEU on the United Kingdom's Orderly Withdrawal from the European Union*, 8 December 2017, pp 1–2.
[16] HM Government, *Policy Statement: EU Citizens Arriving in the UK During the Implementation Period*, 28 February 2018, pp 1–2.
[17] House of Lords European Union Committee, 'Letter to Secretary of State for Exiting the European Union', 21 March 2018.

Regarding the immigration system after the transition phase, in February 2018 the Government said:

> Leaving the EU does not mean the end of migration between the EU and the UK. The new framework will therefore be designed to support the UK economy, enable businesses and key public sector workforces such as the National Health Service to access the skills they need, and underpin our trading relationships with partners in Europe and around the world.[18]

The December 2017 joint report also included provisions regarding the mutual recognition of qualifications. This set out that EU citizens residing in the UK before withdrawal and relying on UK recognition of their EU professional qualifications, including doctors, nurses and midwives, would be able to continue to rely on this recognition after the UK leaves the EU.[19] The 19 March 2018 draft Withdrawal Agreement stipulated that applications made for recognition of professional qualifications during the transition period would be made in accordance with EU law, and qualifications recognised during this time will also continue to be recognised after the end of the transition.[20]

1.2 Funding

It has been argued that when the UK leaves the EU more money will be available for public services, as a result of the UK no longer being required to make contributions to the EU budget. For example, during the referendum campaign the Vote Leave campaign stated: "We send the EU £350 million a week. Let's fund our NHS instead".[21]

In reaction to this statement by Vote Leave, the former chair of the UK Statistics Authority, Sir Andrew Dilnot, argued that it could be misleading:

> The UK Statistics Authority concluded on 21 April 2016 that the use of the £350 million figure, which is a gross figure which does not take into account the rebate or other flows from the EU to the UK public

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[18] HM Government, *Policy Statement: EU Citizens Arriving in the UK During the Implementation Period*, 28 February 2018, p 2.
[19] European Commission, *Joint Report from the Negotiators of the European Union and the United Kingdom Government on Progress During Phase 1 of Negotiations under Article 50 TEU on the United Kingdom's Orderly Withdrawal from the European Union*, 8 December 2017, p 5; and 'Questions and Answers—the Rights of EU27 and UK Citizens Post-Brexit, as Outlined in the Joint Report from the Negotiators of the European Union and the United Kingdom Government', 12 December 2017, p 21.
[20] European Commission and HM Government, *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*, 19 March 2018, p 20.
[21] Rob Merrick, 'Brexit: Vote Leave Chief Who Created £350m NHS Claim on Bus Admits Leaving EU Could Be "an Error"', *Independent*, 4 July 2017.

> sector (or flows to non-public sector bodies), alongside the suggestion that this could be spent elsewhere, without further explanation, was potentially misleading.[22]

A recent article by the think tank The UK in a Changing Europe further explored the impact of leaving the EU on the UK's finances, and therefore the resources available for public services:

> There are a number of reasons why the full £19 billion [the UK's annual gross contribution to the EU's budget] will not be available. First, this figure includes the UK's rebate—currently about £5 billion of the full amount—which has already been allocated domestically to the Government's priorities and simply cannot be spent again. The remaining £14 billion could theoretically be redirected to the NHS, but this figure also helps to fund EU spending in the UK (for example on farming subsidies) that the Government has already pledged to maintain for some years.
>
> The size of the UK's net contribution to the EU after taking into account both the UK's budget rebate and existing EU spending in the UK is about £8 billion. This represents a more realistic estimate of the sum that could be redirected to domestic priorities, including health spending. But even this does not take into account future payments that the UK may wish to make to the EU to ensure continued market access and participation in EU projects. In the short term, assuming some kind of transitional Brexit is agreed, the UK will continue to contribute a significant amount to the European Union and there may also be some additional payments as part of a "divorce bill" to settle various bills.[23]

Some commentators have argued that the effect of leaving the EU on the UK economy will ultimately be more significant than the impact of no longer paying for membership of the EU. Many economic forecasts, including the most recent forecast from the Office for Budget Responsibility, have projected that leaving the EU will have a negative impact on the UK's economy.[24] However, this is disputed by some; for example, a recent study by researchers at the University of Cambridge Centre for Business Research argued that some such studies use flawed models which "have the result of exaggerating the negative impact of Brexit".[25]

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[22] UK Statistics Authority, 'UK Statistics Authority Statement on the Use of Official Statistics on Contributions to the European Union', 27 May 2016.
[23] The UK in a Changing Europe, *Brexit and the NHS*, March 2018, pp 6–7.
[24] Office for Budget Responsibility, *Economic and Fiscal Outlook*, March 2018, p 52.
[25] Ken Coutts et al, *How the Economics Profession Got It Wrong on Brexit*, January 2018.

2. Access to Healthcare and Medicines

2.1 Healthcare

As a member of the EU, the UK currently participates in several arrangements which allow UK citizens living in the EU and EU citizens residing in the UK, as well as those travelling for short periods, to access healthcare while abroad.

European Health Insurance Card

The European Health Insurance Card (EHIC) allows eligible residents of EU and EEA countries (and Switzerland) to access healthcare during stays of less than three months in these countries.[26] This includes treatment needs that arise during the trip, treatment for chronic conditions and existing illnesses, and routine maternity care (except if the person has travelled with the intention of giving birth abroad).[27] The EHIC allows holders to access healthcare from state providers on the same basis as a resident of the country they are visiting, at reduced cost or free of charge. The country providing the treatment claims the cost back from the EHIC holder's home nation.[28]

In evidence given to the House of Lords European Union Home Affairs Sub-Committee, Catherine Bernard, Professor of EU Law at Cambridge University, emphasised the particular value of the EHIC card to older people and those with pre-existing conditions, who can be charged high premiums for private travel insurance.[29]

S1, S2 and S3 Schemes

The S1 scheme allows individuals from one nation to receive on-going health and social care in another, with the costs of that care met by the state that they would either ordinarily reside in or that provides their exportable benefit (eg a pension). According to the British Medical Association (BMA), 190,000 UK pensioners living elsewhere in the EU or EEA are registered to the scheme, which allows them to access health and social care services in their country of residence, but with funding provided by the UK Government.[30]

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[26] British Medical Association, *Reciprocal Healthcare between the UK and the EU*, 26 February 2018, p 4.
[27] NHS Choices, 'How Do I Get an EHIC (European Health Insurance Card)?', 1 June 2015.
[28] British Medical Association, *Reciprocal Healthcare between the UK and the EU*, 26 February 2018, p 4.
[29] House of Lords European Union Home Affairs Sub-Committee, *Oral Evidence: Brexit: Reciprocal Healthcare*, 11 October 2017, p 5.
[30] British Medical Association, *Reciprocal Healthcare between the UK and the EU*, 26 February 2018, p 3.

Under the S2 scheme, individuals are able to travel to another EU or EEA country, or Switzerland, to access specific healthcare treatments with the cost of that treatment met by their country of residence. Individuals need to apply for S2 funding ahead of their treatment, and provide evidence that they meet the eligibility criteria and a clinician's statement regarding their case. The S2 scheme only covers treatments that are provided by a state-run or contracted service and that would be available, in the UK, under the NHS or Health and Social Care Northern Ireland.[31]

The S3 scheme provides a certificate of entitlement that allows individuals to access healthcare in a country in which they were previously employed. This scheme would, for example, allow individuals previously posted to another EEA country who have either left a role or retired to continue to receive treatment in that nation.[32]

Cost Recovery

The EHIC, S1, S2 and S3 schemes all provide for the recovery of the costs of healthcare from the patient's home nation. In response to a recent written question, the then Minister of State for Health, Philip Dunne, provided figures relating to claims by and against the Government for recovery of these costs:

Table 2: Claims By and Against the UK for Healthcare Costs

	Claims against the UK (£)	Claims by the UK (£)
2012/13	172,851,876	28,414,283
2013/14	154,575,752	29,855,832
2014/15	141,295,617	28,286,351
2015/16	130,613,105	31,329,735
2016/17	156,383,608	31,707,086

(Source: House of Commons, 'Written Question: Health Services: Reciprocal Arrangements', 18 October 2017, 108442)

Residents Exercising Free Movement Rights

Under free movement rules, EU, EEA and Swiss workers have the right to move to another of these countries for the purposes of employment.[33] People exercising their free movement rights have the right to equal treatment with nationals regarding social programmes, including healthcare; the basis on which this care is provided varies between countries.

[31] British Medical Association, *Reciprocal Healthcare between the UK and the EU*, 26 February 2018, p 3.
[32] ibid, p 4.
[33] European Commission, 'Free Movement—EU Nationals', accessed 16 March 2018.

Northern Ireland and the Republic of Ireland

There are currently arrangements in place which allow residents of Ireland and Northern Ireland to access healthcare in any part of the island. The Common Travel Area (CTA), an agreement between the UK and the Republic of Ireland, facilitates the free movement of people and provides for a number of reciprocal rights, including access to health services.[34] Some healthcare services are only provided in one part of the island, and in some cases people regularly travel back and forth to use services.[35] The Government has stated that the CTA will continue to operate after the UK leaves the EU, and "the rights to work, study, access social security and public services will be preserved on a reciprocal basis for UK and Irish Nationals".[36]

Future Arrangements for Those Currently Benefiting from Reciprocal Healthcare

The December 2017 joint report from the EU and the UK Government stated that both sides had agreed in principle that anyone taking advantage of reciprocal healthcare arrangements on the day the UK leaves the EU would be able to continue to do so as long as that stay continues.[37] UK citizens living in the EU-27 and EU citizens living in the UK on the date of the UK's withdrawal will not only continue to be able to access healthcare in their place of residence, but will also be able to use the EHIC when travelling to other EU countries. This statement did not address healthcare for those travelling after the UK's exit from the EU.

The draft Withdrawal Agreement, agreed by the UK and the EU's negotiators on 19 March 2018, extended the reciprocal arrangements to people beginning their stay during the transition period.[38] This section was highlighted as having been agreed by the EU Commission and the UK, however, it is yet to be agreed with the EU-27.

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[34] Department for Exiting the European Union, 'Citizens' Rights—UK and Irish Nationals in the Common Travel Area', 22 December 2017.
[35] House of Lords European Union Home Affairs Sub-Committee, *Oral Evidence: Brexit: Reciprocal Healthcare*, 11 October 2017, p 3.
[36] ibid.
[37] European Commission, *Joint Report from the Negotiators of the European Union and the United Kingdom Government on Progress During Phase 1 of Negotiations under Article 50 TEU on the United Kingdom's Orderly Withdrawal from the European Union*, 8 December 2017, p 5.
[38] European Commission and HM Government, *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*, 19 March 2018, p 22.

Future Arrangements for Those Travelling or Taking Up Residence After Brexit

In a policy paper published in June 2017, the Government said it would "seek an ongoing arrangement akin to the EHIC scheme as part of negotiations on our future arrangements with the EU".[39] It said it would aim to protect the ability of individuals who are eligible for a UK EHIC before the UK's exit from the EU to continue to benefit from similar arrangements after its withdrawal.

In evidence given to the House of Lords European Union Home Affairs Sub-Committee Lord O'Shaughnessy, Parliamentary Under Secretary for Health, reiterated this aim:

> What we want to achieve is a continuation—albeit necessarily in a new form—of the current arrangements, in terms of continued involvement in the EHIC process or a version of that; reciprocal healthcare for future pensioners, ie, those resident in the UK now but who may move abroad; and the continued possibility for UK and EU residents to come to one another's countries for planned care and for that to be funded by their respective governments.[40]

Martin McKee, Professor of European Public Health at the London School of Hygiene and Tropical Medicine, argued that as healthcare is a national competence the EU would not be able to conclude an agreement with the UK, and arrangements would have to be made bilaterally.[41] While agreements have been concluded at an EU level with the EFTA countries and Switzerland these, Professor McKee argued, are linked to these countries' acceptance of free movement of workers. In addition, in evidence given to the House of Lords European Union Home Affairs Sub-Committee, both Professor McKee and Professor Barnard stated that the EU does not consider the reciprocal healthcare arrangements with Switzerland to be satisfactory, largely because there is no dispute resolution process set out in the arrangement, and the EU does not wish to replicate this type of agreement.[42]

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[39] Department for Exiting the European Union, 'The United Kingdom's Exit from the European Union: Safeguarding the Position of EU Citizens Living in the UK and UK Nationals Living in the EU', 26 June 2017.
[40] House of Lords European Union Home Affairs Sub-Committee, *Oral Evidence: Brexit: Reciprocal Healthcare*, 29 November 2017, p 2.
[41] Martin McKee, 'The Devil is in the Detail—Why Retaining the European Health Insurance Card May Be an Impossible Dream', *BMJ Opinion*, 16 November 2017.
[42] House of Lords European Union Home Affairs Sub-Committee, *Oral Evidence: Brexit: Reciprocal Healthcare*, 11 October 2017, p 9; *Oral Evidence: Brexit: Reciprocal Healthcare*, 29 November 2017, p 9.

Cross-Border Healthcare in Ireland After Brexit

Both the Government and the EU's negotiators have stated their intention to avoid new border checks or controls between Northern Ireland and the Republic of Ireland.[43] However, it has been noted that as the two countries will have different immigration policies, there may be challenges in continuing an open border between the UK and the Republic of Ireland after the UK leaves the EU.[44] The House of Commons Northern Ireland Affairs Committee summarised:

> If any post-Brexit agreement between the UK and EU did not extend to the free movement of labour with the rest of the EU, there are fears that the border with the Republic would become a "back door" by which UK border controls could be evaded (though measures already in place to restrict the ability of what would be illegal EU migrants to live and work in the UK would reduce its attractiveness).[45]

Border controls could pose problems for the continuation of cross-border care on the island of Ireland. In evidence given to the House of Lords European Union Home Affairs Sub-Committee, Jean McHale, Professor of Healthcare Law at the University of Birmingham, said:

> My understanding is that children's cardiac surgery finished at Belfast Royal Victoria Hospital in 2015, and children from Northern Ireland are treated in Dublin as a whole. If we are moving towards a hard border situation, that is a practical problem.[46]

2.2 Medical Products

Authorisation Procedure

As a member of the EU, the UK is a member of the European Medicines Agency (EMA). The EMA is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU and EEA.[47] As part of its work, the EMA evaluates applications from pharmaceutical companies for authorisation for drugs and medical devices to be sold in Europe and monitors their safety after they reach the market. It also contracts national regulatory agencies to

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[43] House of Commons Northern Ireland Affairs Committee, *Oral Evidence: Brexit and Northern Ireland*, 22 January 2018; and Prime Minister's Office, 'PM Statement on EU Negotiations', 11 December 2017.
[44] House of Commons Northern Ireland Affairs Committee, *The Land Border Between Northern Ireland and Ireland*, 16 March 2018, HC 329 of session 2017–19, p 12.
[45] House of Commons Northern Ireland Affairs Committee, *Northern Ireland and the EU Referendum*, 26 May 2016, HC 48 of session 2016–17, p 26.
[46] House of Lords European Union Home Affairs Sub-Committee, *Oral Evidence: Brexit: Reciprocal Healthcare*, 11 October 2017, p 3.
[47] European Medicines Agency, *About Us*, 16 February 2017, p 3.

undertake this testing on its behalf.

The EMA works with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA). The MHRA is responsible for:

- ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy;
- ensuring that the supply chain for medicines, medical devices and blood components is safe and secure;
- promoting international standardisation and harmonisation to assure the effectiveness and safety of biological medicines;
- helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use;
- supporting innovation and research and development that's beneficial to public health; and
- influencing UK, EU and international regulatory frameworks so that they're risk-proportionate and effective at protecting public health.[48]

At present, medical products can obtain authorisation to be sold in the UK in one of four ways:

- The centralised procedure allows applicants to obtain an EEA-wide marketing authorisation that is binding on all member states. Applications are made directly to the EMA and are scientifically evaluated by the appropriate EMA committee.
- If medicines are to be marketed in the UK only, an application can be submitted to the MHRA (the national procedure).
- The mutual recognition procedure is available for medicines that have already received a marketing authorisation in one EEA member state. The application for mutual recognition may be addressed to one or more member states. One member state will decide to evaluate the medicine, at which point the other member states suspend their own evaluations and await that state's decision on the medicine. If the decision is favourable, a report is communicated to the other states, who must then each recognise the decision.
- The decentralised procedure is similar to the mutual recognition procedure and relies on the recognition by national authorities of a first assessment performed in one member state. However, the decentralised process can also be used for medicines which

[48] Medicines and Healthcare Products Regulatory Agency, 'About Us', accessed 20 March 2018.

> have not received a marketing authorisation at the time of application. [49]

The MHRA currently undertakes product testing on behalf of the EMA, for which it is paid by the EMA. In evidence given to the House of Commons Health Committee, the Secretary of State for Health estimated that the MHRA undertakes approximately 40 percent of the EMA's testing.[50]

Leaving the EU

Concerns have been expressed that if, once the UK leaves the EU, the UK ceases to be a part of the EMA, this could result in delays in new medicines being sold in the UK. This is because companies would not prioritise going through the UK's licensing procedure. For example, in evidence given to the House of Lords Science and Technology Committee, Professor Sir Michael Rawlings, chair of the MHRA, said:

> One of the biggest worries I have about Brexit and standing alone as a regulator is that we are only 3 percent of the world market for new drugs and if we are not careful we are going to be at the back of the queue. Japan, America and Europe will be at the front of the queue and we will be at the back.[51]

A September 2016 report by the Association of the British Pharmaceutical Industry and the BioIndustry Association argued that not being part of the EU's regulatory mechanisms could result in:

- delayed or no regulatory submission to the UK for new medicines, due to the UK effectively becoming a "second priority" launch market, resulting in delayed (relative to European patients) or no access to new products, for UK patients;
- disruption to the supply of life saving medical technologies as a result of border inspections for products going to or from Europe; and
- falsified medicines reaching UK patients if the UK is not part of EU-wide monitoring systems.[52]

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[49] TaylorWessing, 'Types of Marketing Authorisation', accessed 20 March 2018.
[50] House of Commons Health Committee, *Oral Evidence: Brexit and Health and Social Care*, 24 January 2017, Q67.
[51] House of Lords Science and Technology Committee, *Brexit: Regulation and Standards*, 10 January 2017, p 10.
[52] Association of the British Pharmaceutical Industry and BioIndustry Association, *Maintaining and Growing the UK's World-Leading Life Sciences Sector in the Context of Leaving the EU*, 6 September 2016, p 12.

In June 2017, the Government published a position paper on collaboration in the fields of science and innovation after the UK's exit from the EU. Regarding the licencing of drugs and medical devices, the Government said it would seek to cooperate with the EMA, basing collaboration on existing agreements:

> The UK will therefore look to continue to work closely with the EMA and other international partners. In areas such as inspections, safety of medicines and exchange of information, the EMA cooperates with regulatory bodies around the world and the EU has specific agreements in place with the USA, Canada, Japan, Switzerland, Australia, New Zealand and Israel that enable this. These provide precedents which the UK and the EU could seek to build on.[53]

In her Mansion House speech, delivered on 6 March 2018, the Prime Minister stated for the first time her ambition that the UK could continue to participate in the EMA after Brexit, as an associate member.[54] The Prime Minister outlined the possible advantages of such an arrangement:

> Membership of the European Medicines Agency would mean investment in new innovative medicines continuing in the UK, and it would mean these medicines getting to patients faster as firms prioritise larger markets when they start the lengthy process of seeking authorisations. But it would also be good for the EU because the UK regulator assesses more new medicines than any other member state. And the EU would continue to access the expertise of the UK's world-leading universities.

The British Medical Association welcomed the Prime Minister's announcement:

> We are also pleased to see that the Government wants to explore associate membership of the European Medicines Agency. The EMA helps provide the UK with timely and safe access to medicines, and likewise helps the EU access medicines that are developed here in the UK. We want to see the Government work closely with the EMA through a formal agreement to continue to support and participate in their assessments for medicines approvals.[55]

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[53] HM Government, *Collaboration on Science and Innovation: A Future Partnership Paper*, 6 September 2017, p 14.
[54] Prime Minister's Office, 'PM Speech on our Future Economic Partnership with the European Union', 2 March 2018.
[55] British Medical Association, 'BMA Responds to Prime Minister's Speech on Brexit', 2 March 2018.

Medical Isotopes

Medical isotopes are used to detect and treat certain types of cancer.[56] A large proportion of those used in the UK come from Europe, the export of which is governed by the European Atomic Energy Community (Euratom). In July 2017, the British Nuclear Medicine Society, supported by the Royal College of Radiologists and Royal College of Physicians, expressed concern that the UK's withdrawal from the EU could lead to reduced availability of medical isotopes in the UK.[57] On 28 July 2017, the then Minister of State for Business, Energy and Industrial Strategy, Richard Harrington, stated in a letter to the chair of the House of Commons European Scrutiny Committee that the UK would continue to be able to import these products after it leaves the EU:

> Our ability to import medical isotopes from the EU will not be affected by our withdrawal from Euratom. It is correct that medical isotopes are currently governed and regulated under the Euratom framework, however Euratom places no restrictions on the export of these isotopes to countries outside of the EU. Moreover, these isotopes are not subject to Euratom Supply Agency contracts or to Euratom nuclear safeguards arrangements, meaning that there are no special arrangements that will need to be put in place ahead of the UK's withdrawal from Euratom.[58]

However, in evidence given to the House of Lords European Union Home Affairs Sub-Committee, Dr John Buscombe, President-Elect of the British Nuclear Medicine Society, emphasised that the short shelf-life of nuclear medical products means that streamlined importation procedures are important.[59] He expressed concern that increased border controls resulting from Brexit could lead to delays in these products reaching their destinations, leading to inefficiencies and disruptions to patient care.

In January 2018, the House of Commons European Scrutiny Committee considered documents relating to Euratom and the supply of medical isotopes. The Committee also expressed concern that the UK's exit from the Single Market could result in importation delays, and asked the Government "what assessment has been made of additional customs controls on transports of radio-isotopes from the EU to the UK after Brexit, and how those would be mitigated in view of the short half-life of the

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[56] House of Commons European Scrutiny Committee, *European Atomic Energy Community*, 15 January 2018, HC 301-viii of session 2017–19, p 18.
[57] British Nuclear Medicine Society, 'British Nuclear Medicine Society Statement on Leaving Euratom', July 2017.
[58] Minister of State for Business, Energy and Industrial Strategy, 'Letter to Chair of House of Commons European Scrutiny Committee', 28 July 2017.
[59] House of Lords European Union Home Affairs Sub-Committee, *Brexatom: The Health Implications of Leaving Euratom*, 22 November 2017, Q3.

product".[60]

The Committee also noted that the Euratom Supply Agency (ESA) had an important function in relation to the coordination of security of supply, and stated that the ESA is at the forefront of efforts to consider future EU supply of enriched uranium, which is required for the production of medical radio-isotopes. The Committee asked the Government:

- how, in the light of the serious 2008–10 supply shortage and the shutdown of supply reactors in Canada and the Netherlands, the Government plans to replace the security of supply function currently fulfilled by the Euratom Supply Agency; and
- in the absence of engagement in the Euratom Supply Agency, what steps the Government plans to take to assure the supply of enriched uranium.[61]

At the time of publication the Committee had not received a response from the Government.

3. Further Reading

- House of Commons Health and Social Care Committee, *Brexit: Medicines, Medical Devices and Substances of Human Origin*, 21 March 2018, HC 392 of session 2017–19
- The King's Fund, *Brexit: The Implications for Health and Social Care*, 13 December 2017
- British Medical Association, *Healthcare First—A Brexit Blueprint for Europe*, 22 November 2017
- Nuffield Trust, *How Will Our Future Relationship with the EU Shape the NHS?*, November 2017

[60] House of Commons European Scrutiny Committee, *European Atomic Energy Community*, 15 January 2018, HC 301-viii of session 2017–19, pp 19–20.
[61] ibid, p 20.