

## BREXIT BRIEFING

# The impact of leaving the EU on patients



## Key points

- Patients in the UK are currently treated and cared for, by a health and social care workforce that has many overseas doctors, carers and nurses, including from other countries in the EU. The UK health system also has important collaborations, safeguards and agreements with the EU that support patient care, such as the cross-border recognition of medical qualifications, the diagnosis and treatment of patients with rare diseases and cancer, and patients' ability to access healthcare elsewhere in Europe at no, or reduced cost.
- The UK's withdrawal from the EU will have the potential to significantly affect the care that patients can expect to receive in a variety of ways:
  - The uncertainty facing the status of EU doctors, nurses, carers and other health workers now and in the future, could undermine the ability of the NHS to retain and attract the best workforce for patients.
  - Placing at risk the current system of recognition of medical qualifications that allows doctors who qualified in other EU countries to readily work in the UK.
  - Patients may not be able to access healthcare arrangements such as the European Health Insurance Card, that allows for reduced or no cost healthcare elsewhere in the EU when UK patients are travelling there.
  - Weakening regulations post-Brexit with regards to clinical trials, working time regulations, environmental protection, regulation of food imports and exports, which are derived from EU legislation, could affect health and safety.
  - The quality of healthcare patients in the UK receive will also be affected by how the UK continues collaboration with the EU in terms of sharing data and emergency preparedness planning for cross-border threats; participating in European Reference Networks which are key for diagnosis and treatment of rare diseases; and, sharing and accessing information on doctors' fitness for practice.
  - Moving away from a collaborative approach regarding the licensing of medicines and medical devices will likely lead to delayed access to new treatments.
  - Loss of access to EU health-related research funding programmes could undermine the development of new or improved medicines and medical devices in the UK.
  - Working outside of EU bodies such as Euratom could increase the difficulty in obtaining radioisotopes which are vital for cancer diagnosis and treatment.
  - The potential for disruption of health services and provision for patients on the island of Ireland which has an integrated health system is considerable, which if impeded in future will have a significant effect on patient care.
- To minimise these potential impacts, the UK should:
  - Provide permanent residence and continuation of their current rights to EU doctors and medical academic staff in the UK and support a flexible future immigration system that considers the needs of the wider health and social care systems.
  - Maintain reciprocal arrangements for medical qualification recognition and access to healthcare for UK patients travelling to the EU.
  - Retain access to the Internal Market Information System to facilitate communication exchange on doctors' fitness to practise.
  - Ensure the UK continues to support and participate in the European Medicines Agency's assessments for medicines approvals, as well as the CE- mark scheme, so that there are no delays in the UK for patients to access medicines and medical devices.
  - Agree how the MHRA (Medicines and Healthcare products Regulatory Agency) participates in pan-European clinical trials.
  - Continue full access to EU research funding programmes.
  - Maintain a close working relationship with European Reference Networks.
  - Maximise continued information sharing and access to data, evidence and planning arrangements for pandemic preparedness with ECDC (European Centre for Disease Prevention and Control).

- Negotiate a formal agreement with Euratom to ensure consistent and timely access to radioisotopes for medical purposes and facilitate close collaboration on radiation research and support.
- Continue ongoing cross-border co-operation across the island of Ireland for the delivery of healthcare and free movement for health workers who live and work on both sides of the border.
- Retain measures to protect public health standards and workers' rights, for example, through retention of the UK Working Time Regulations.
- **For the UK, negotiating a deal would:**
  - Create the stability necessary to allow the government to ensure the healthcare workforce can meet current and future demands.
  - Ensure continuity of care for UK citizens living abroad and ease of access to care for UK residents visiting the EU or EEA.
  - Provide assurances on the long-term source of funding for UK medical researchers collaborating with EU research institutions to develop and access new therapies and technologies, securing the UK's leading reputation for medical research.
  - Provide timely access to therapies and technologies developed in other EU countries and continued sharing of data, expertise and resources in European Reference Networks that support patients with rare diseases.
  - Limit potential delays incurred by pharmaceutical companies and device manufacturers seeking a licence for their products in the UK.
  - Minimise the risk of pharmaceutical companies based in the UK from re-locating to a country working within the jurisdiction of the EMA and prevent any lessening of the UK's capacity for pharmacovigilance by providing access to the EMA's networks.
  - Maintain ongoing access to ECDC's emergency preparedness systems ensuring that the UK can continue to share data with the EU and vice versa to protect its citizens.
  - Provide clarity and stability about the short-term future of environmental protection standards in the UK and ensure imported products continue to be regulated to a high standard and support exports of UK products.
  - Ensure consistent and timely access to radioisotopes for medical purposes; and facilitate close collaboration on radiation research and support.
  - Enable the current standard of healthcare and health workforce provision in Northern Ireland through continued cross-border collaboration and freedom of movement.
- **For the EU, negotiating a deal would:**
  - Secure access to reciprocal healthcare for EU citizens visiting or residing in the UK.
  - Underpin continued collaboration with UK research institutions in developing and accessing new therapies and technologies, as well as timely access to those under development in the UK.
  - Facilitate participation in UK-led clinical trials, particularly in relation to rare diseases.
  - Maintain access to the extensive network of expertise in the UK in medicines and medical devices regulation and pharmacovigilance.
  - Ensure pharmaceutical companies based in the EU can readily access the UK market and ensure medicines and devices developed in the UK reach EU citizens quickly.
  - Ensure ongoing access to UK data and evidence on communicable diseases.
  - Guarantee that the UK continues to take comprehensive and complementary action on regional environmental issues, such as water, waste and air pollution.
  - Ensure that food standards in the UK are sufficiently aligned such that additional inspection of UK food exports to the EU is not necessary.

## Background

The UK's membership of the EU has had significant impact on public health and healthcare in the UK. This has enabled medicines and medical devices to be traded freely across borders and healthcare professionals from other EU member states to easily work and live in the UK. Other benefits include collaboration in the way medicines and medical devices are regulated, reciprocal healthcare arrangements and co-operation on clinical trials and treatment of rare diseases. In addition, doctors who have qualified in one member state will have their qualifications recognised in another state which is particularly important on the island of Ireland where open-border arrangements allows clinicians to deliver care on both sides of the border. The EU also plays an important role in promoting good health, ensuring fair working time regulations, enabling collaboration on medical research, facilitating the trade of radioisotopes, and providing a mechanism for tackling cross-border threats. Finally, the EU protects patient safety by ensuring that information about doctors' fitness to practice is shared across authorities.

In September 2017, the BMA patient liaison group convened a meeting to explore what Brexit means for patients. Delegates were concerned that there is a lack of information available for patients about Brexit's potential impact on healthcare. The report of the symposium is available [here](#).

This briefing therefore provides a snapshot of the key issues facing patients and explores how the UK and EU can maintain a beneficial working relationship after Brexit, as well as the potential implications of a failure to agree a withdrawal agreement by March 2019.

It focusses on the following key issues:

- Workforce – recruitment and retention
- Medical qualifications
- Doctors working hours
- Reciprocal healthcare arrangements
- Fitness to practice
- Public health standards & regulations
- Rare diseases
- Medical research funding
- Medicines and device regulation
- Access to radioisotopes
- Healthcare on the island of Ireland

## Maintaining the current health workforce

### The BMA is calling for:

- Permanent residence and continuation of the current rights for EU doctors and medical academic staff currently working in the UK.
- Continued rights for EU medical students currently in the UK and those wishing to come to the UK in the future to live, train and work in the UK.

Freedom of movement has enabled many health and social care professionals from EU/EEA<sup>1</sup> countries to study and work in the UK. A significant proportion of the UK health and social care workforce comes from other EU countries with around 140,000 non-UK EU nationals currently working in the NHS and social care system across the UK.<sup>2</sup> They provide a valuable contribution to our health and social care systems which are under immense pressure due to rising demand and limited resources. It is also important to note that Brexit will affect doctors in non-NHS roles such as in research, private practice, pharmaceutical and biotech industries, government departments, and occupational health.

The UK government has indicated that freedom of movement will end on 29 March 2019. This will have a significant impact on the rights of EU nationals to study and work in the UK, as well as their family members. Evidence shows that many EU doctors are planning to leave the UK following the UK's decision to leave the EU. A BMA survey of doctors from EEA countries found while 45% said they were thinking about leaving the UK that one in five of the respondents had made plans to leave.<sup>3</sup> The top three reasons cited for considering to leave were the UK's decision to leave the EU, a current negative attitude towards EU workers in the UK and continuing uncertainty over future immigration rules.

If the UK and EU do not reach a deal on residency rights within the Withdrawal Agreement by March 2019, health and social care staff without documentation proving entitlement to remain in the UK would be at risk and employers may lose a proportion of their workforce. Therefore, a formal agreement on citizen's rights must be reached as soon as possible.

### Latest developments

In December 2017, EU and UK negotiators agreed in a joint report that their overall objective in the negotiations would be to provide reciprocal protection to EU citizens in the UK and vice versa.<sup>4</sup> This included that EU member states and the UK can require people to apply for status conferring right of residence and to obtain a residency document. Administrative procedures for applications for status should be transparent, smooth and streamlined. Where an application is required to obtain status, EU and UK nationals will have at least two years to submit their applications. The UK government has issued guidance that EU citizens who have had five years of continuous residence in the UK will be eligible to apply for 'settled status'. Details of the immigration rules for EU citizens who arrive after 29 March 2019 are yet to be agreed. The joint report in December 2017 sets out a direction of travel that will lead to further negotiations this year, which aim to prepare the way to a final agreement that will need to be agreed by the EU and the UK. The BMA has welcomed the progress made in the talks.

## Recruiting the best workforce to care for patients

### The BMA is calling for:

- A coherent future immigration system that will provide the flexibility necessary to address NHS workforce shortages and considers the needs of the wider health and social care systems.

Hospitals across the UK have been getting busier, with increased numbers of emergency and elective admissions, and outpatient attendances. Against this background, the health service is facing workforce shortages in key specialties and it is becoming increasingly difficult to recruit and retain medical staff across the system, even with the current level of migration.

The number of people applying to medical school has decreased by more than 13% since 2013 and nearly three quarters of all medical specialties faced under-recruitment in 2016.<sup>5</sup> There are significant gaps in recruitment of consultants, particularly psychiatric specialties, among physicians and emergency medicine. Some A&E departments have already had to impose temporary closures due to lack of medical staff. A survey by GP magazine Pulse found that around 12% of GP posts are vacant, the highest ever levels of unfilled posts.<sup>6</sup> Efforts to increase the domestic supply of doctors are underway but they will not address likely shortages in the short to medium term given the length of time it takes to train senior doctors. It will therefore be vital that the NHS continues to recruit doctors from the EU and overseas to fill vacant posts.

The Royal College of Nursing has found that nursing vacancy rates are increasing too. As of December 2016, there were approximately 40,000 registered nurse vacancies in England.<sup>7</sup> A Freedom of Information request from the Health Foundation also showed that the number of EEA nurses registering to practice in the UK dropped by 96% between July 2016 and April 2017.<sup>8</sup>

The social care system is also under strain with the vacancy rate at 6.6% in England (approximately 90,000 vacancies at any one time).<sup>9</sup> Workforce shortages in the social care sector could mean that patients end up in A&E or face delayed discharge from hospital. If the Home Office demands a minimum income level for EU citizens to qualify for a work visa the social care sector in particular will be affected. Furthermore, merely using salary levels to determine the shape of the immigration system is a crude measure and any future review of the labour market must consider the needs of the health and social care sector for both skilled and unskilled labour.

If the UK and EU do not reach a deal on immigration, workforce shortages will be exacerbated impacting the quality of care and patient safety. The BMA is calling for a deal to be agreed which will consider the needs of the wider health and social care systems and provide the flexibility necessary to address NHS workforce shortages. A deal on the lines the BMA is calling for will help to not increase these and enable patients to have continued access to high quality care.

**For more information see the BMA briefing “[Workforce and future immigration policy](#).”**

## Recognising medical qualifications

### The BMA is calling for:

- The maintenance of reciprocal arrangements, such as the Mutual Recognition of Professional Qualifications (MRPQ) to facilitate the ongoing exchange of medical expertise across the EU.

In 2007, the EU directive on Mutual Recognition of Professional Qualifications (MRPQ) came into force in all EU member states. The directive 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, up to 10% of doctors gained their medical qualification from another EEA country.<sup>10</sup> Mutual recognition of qualifications of doctors is a particularly vital issue in Northern Ireland where clinicians move freely between both jurisdictions.

If medical qualifications gained in the EEA are not recognised in the UK and vice versa following Brexit, this would disrupt the UK's health workforce pipeline and create particular challenges on the island of Ireland. The maintenance of the current arrangements will enable the facilitation of medical expertise between the UK and EU member states, including on the island of Ireland. This will ensure that medical practitioners in the UK can move as now into the EU and EU experts can come to the UK, continuing to provide the range of services and care that is currently on offer to patients.

### Latest developments

In December 2017, EU and UK Brexit negotiators agreed that existing arrangements concerning recognition of qualifications would continue until 29 March 2019. Further discussions will decide what happens to those who qualify after this date.

## Doctors having safe working hours and time for rest to care for patients

### The BMA is calling for:

- The retention of the UK Working Time Regulations, and protection of existing workers' rights, as well as retaining employment directives in UK law for the current and future workforce.

EU law provides employee safeguards on working hours and minimum standards for annual leave, as well as enshrining equal pay and maternity rights. The Working Time Regulations, which were introduced in 1998, ensured that the European Working Time Directive was implemented into UK law. These regulations ensure that doctors are limited to working no more than 48 hours a week (averaged across 26 weeks) and that they are entitled to a holiday allowance, rest breaks and limits on night work. Having statutory protections against dangerously excessive working hours is particularly crucial for doctors, as overwhelming evidence demonstrates the damaging impact fatigue can have on the quality of service they can deliver to patients. Junior doctors in particular value these safeguards: the phenomenon of junior doctors working unsafe 90 hour weeks was only curtailed with the introduction of the regulations. Although doctors can opt out of Working Time Regulations (up to a top limit of 56 hours on average per week) it has to be voluntary and it is not possible to opt out of rest requirements. Even with the regulations, a GMC national survey shows that around 25% of junior doctors feel short of sleep at work on a daily or weekly basis, and this percentage is increasing.<sup>11</sup>

After Brexit, the UK will be free to repeal or amend the working time legislation. In December 2017, 13 medical associations and royal colleges, including the BMA, wrote to the Prime Minister warning that weakening the protections introduced by the working time regulations could put patients and doctors at risk.<sup>12</sup>

## Accessing free or reduced cost healthcare when travelling to Europe

### The BMA is calling for:

- The retention, or comparable replacement, of reciprocal healthcare arrangements with the EU.

The EU provides common rules to protect social security rights when citizens move within the EEA (as well as Switzerland<sup>13</sup>), including that they will be covered for healthcare when they visit or move to another EU country.

There are around 53 million visits a year from the UK to the EU and around 25 million incoming visits. The European Health Insurance Card (EHIC) allows those visiting another EEA country to access reduced or low cost healthcare on the same basis as the citizens of that country if they fall ill or have an accident. Under the EHIC scheme, the vast majority of claims (90%) are settled between the EU countries concerned, and not with the insured person. The EHIC covers the provision of oxygen therapy, renal dialysis and routine medical care. It also covers visitors for treatment of pre-existing medical conditions and for maternity care, provided the reason for the visit is not specifically to give birth. There are currently about 27 million people in the UK who have an EHIC card.

UK residents in other EU countries can access the same healthcare as citizens of the country they reside in under 'S1 form' arrangements. Those residents in another EU country who receive an exportable UK pension, contribution-based Employment Support Allowance or another exportable benefit, are entitled to state healthcare paid for by the UK. There are currently an estimated 190,000 UK pensioners living in EU countries who are receiving healthcare under the reciprocal 'S1' scheme. Evidence given to the House of Commons Health Select Committee has suggested that many of these pensioners will be unable to fund private healthcare and so will be forced to return to the UK.<sup>14</sup> If these pensioners were all to return to the UK for their health this would cost the NHS an estimated £979 million around twice the amount that the UK government currently reimburses to other EU countries for their care.<sup>15</sup>

Patients also have the option to receive NHS-funded treatment in another EEA country. This is particularly important for patients with rare diseases who may require specialist treatment that is not available in their country of residence. Patients are also able to access this route where the NHS cannot provide the treatment in a medically justified timeframe for the patient's condition.

If no deal is reached on reciprocal healthcare, UK citizens planning to visit or move to another EEA country may need to purchase health insurance or risk paying for expensive healthcare bills if they fall ill or have an accident. Alternatively, UK patients living abroad may need to return to the UK in order to access free healthcare. For UK patients with long-term conditions, for example, patients with kidney condition who require regular dialysis, travelling or moving to Europe could become unaffordable with travel insurance being expensive. Therefore, retaining reciprocal healthcare arrangements needs to be an important consideration during the Brexit negotiations.

### Latest developments

In December 2017, EU and UK negotiators agreed that temporary visitors or residents from the EU to the UK and vice versa will continue to be eligible for equal treatment with respect to social security and healthcare rights. This includes being eligible for healthcare reimbursement, including under the EHIC scheme.

For more information see the BMA briefing "[Reciprocal healthcare arrangements.](#)"

## Ensuring transparency around doctors' fitness to practice

### The BMA is calling for:

- The maintenance of the Internal Market Information (IMI) alert system.

EU legislation makes it mandatory for member states to assist their counterparts with information. The IMI system, an IT-based network, was developed in order to facilitate cross-border communication. The system enables the UK's General Medical Council to send and receive alerts about doctors' fitness to practise across the EU.

Losing access to the information alert system could undermine cross-border communication on patient safety issues. Without the alert system in place, a doctor deemed unfit to practise (or who has had restrictions imposed on their practice) by one member state authority could potentially circumvent this restriction by attempting to work in another EU country, that is unaware of the situation due to delays in the transfer of information.

## Maintaining health protection and health security

### The BMA is calling for:

- An agreement to continue to share data and pandemic preparedness planning with ECDC (European Centre for Disease Prevention and Control) in relation to cross-border threats.
- The Government to maintain an aligned approach to the EU on environmental standards in the EU Withdrawal Bill and then working with experts and stakeholders to develop the UK's environmental plan including how it affects water, waste and air quality.
- An agreement to continue to work with the EU, and specifically the EFSA (European Food Standards Agency) to maintain health standards on imports and exports.

All countries face global hazards and threats which they need to plan for, and respond to, in order to protect the health of the population. Health protection and health security issues include tackling infectious diseases, antimicrobial resistance, climate change, water, waste and air pollution, and maintaining high food standards. The EU works with its members in the following three key areas to ensure Europe is working together in a coordinated and complementary way:

### – Pandemic preparedness planning and response

Public Health England works to fulfil the UK's obligation under EU law to provide evidence and data on communicable diseases – for example, AMR, influenza outbreaks and infectious diseases – to ECDC. The EU's centralised pandemic preparedness planning ensures that member states are sharing information and best practice with each other in order to tackle cross-border threats.

If the UK decreases its level of collaboration and information sharing with the EU after Brexit, this would reduce the ability of both the UK and EU to respond to threats effectively. Therefore, the UK and EU should negotiate an agreement to maximise continued information sharing and access to data, evidence and planning arrangements with ECDC.

#### – Environmental protection standards

EU public health initiatives have helped to shape UK public health standards for many years, affecting a wide range of regulations. After Brexit, it is not clear how the UK will engage with these standards. The standards currently protected by EU membership, may not be retained which could affect chemicals and pesticide use, waste management, recycling, and emissions standards.

If the UK diverged from EU regulations relating to public health, this could weaken the standards currently enjoyed by the public. For example, EU legislation is currently much stricter than in countries such as the USA in relation to the use of pesticides. Therefore, the UK should maintain an aligned approach to the EU on environmental standards.

#### – Regulation of food imports and exports

The Food Standards Agency is responsible for food safety and food hygiene across the UK and works with the EFSA to ensure domestic standards are in line with EU regulations. The EFSA ensures that products imported from within or outside the EU have been regulated and are in line with robust standards. The European Commission also provides wide ranging supply chain surveillance for all food products imported into the EU from all countries with a free trade agreement.

If the UK takes a divergent approach to the EU, this may introduce low-cost products from countries with lower standards into the supply chain. For example, the EU has previously rejected US imported products on the grounds of public health safety including beef from hormone treated cattle and poultry dipped in chlorinated disinfectant. Weaker domestic standards would raise concerns about UK products exported to the EU (currently worth £9.9bn per annum<sup>16</sup>) while raising standards in the UK could create barriers to importing products from the EU (currently around 30% of food consumed in the UK is imported from the EU<sup>17</sup>). Therefore, the UK should negotiate a formal agreement to continue to work with the EU, and specifically the EFSA to maintain standards on imports and exports.

For more information see the BMA briefing "[Health protection and health security.](#)"

## Keeping the public healthy

### The BMA is calling for:

- The retention of measures to protect public health standards, including those affecting food, alcohol and tobacco regulations, and seek opportunities to go further than the EU to improve the health of the population.

Improving the health of the population is a key challenge for governments. While countries across Europe may face unique challenges, there is a common interest in collaborative working, implementing regulations and directives and agreeing EU-wide strategies. Membership of the EU has influenced health improvement in the UK in a number of key areas: alcohol, diet and obesity, and tobacco. This includes the EU Tobacco Products Directive, taxation and advertising directives on tobacco and alcohol and regulations on nutrition labelling, food standards and advertising.

Exiting the EU may be viewed as an opportunity to dilute or repeal these key measures intended to improve health in the UK. On the other hand, leaving the EU may also present opportunities for the UK to go further than the EU, for example, in introducing traffic light labelling for food and drink products on a mandatory basis. The UK should therefore seek to retain EU measures vital for improving public health, while going further than the EU where there is a clear public health rationale to do so.

## Diagnosing and treating patients with rare diseases

### The BMA is calling for:

- Ongoing access to and participation in the European Reference Networks (ERNs).

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 245,000.<sup>18</sup> Worldwide, about 1 out of 15 people could be affected by a rare disease.<sup>19</sup> 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. In order to support these patients, EU legislation encouraged the development of European Reference Networks so that health professionals and researchers can share expertise, knowledge and resources.

There are 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 Norway.<sup>20</sup> 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.

If the UK ceases to be part of these networks, there is a risk that patients with rare diseases in the UK and the EU will not receive the best care.

## Supporting medical research

### The BMA is calling for:

- Continued full participation in current (Horizon 2020) and future EU research funding programmes.
- Immediate certainty for UK-based researchers currently funded through, and those aiming to collaborate through, EU research funding programmes and how such a guarantee will work in practice.

For the past decade, UK researchers have received the highest level of funding (£1.2 billion), among all EU countries, for health-related research projects from EU funding programmes (Horizon 2020 and Framework Programme 7).<sup>21</sup> Beyond providing financial resources, these programmes facilitate and actively promote international collaboration. Cross-border collaboration and EU funding has led to the development of innovative therapies, for example, for patients with breast cancer.<sup>22</sup>

The EU facilitates cross-border collaboration on clinical trials which are particularly important for rare and paediatric cancers where patient numbers are smaller. For example, in enabling enough patients to take part in trials so that there is sufficient evidence to provide new treatments to patients. Cross-border networks are particularly important for developing these collaborative partnerships – nearly 50% of all UK cancer research involves international collaboration.<sup>23</sup>

After Brexit, maintaining researcher mobility will be fundamental to ensuring the UK continues to be able to attract global scientific talent. The UK is currently world-leading in its medical research workforce, much of which is international and flows freely across borders. Enabling medical academics and businesses in the UK and the EU to work closely together with continued ease of movement is critical to ensuring that the UK retains its key involvement in European research projects and networks.

The loss of access to EU health-related research funding programmes would undermine the development of new or improved medicines and medical devices in the UK and EU. It would also damage the UK's scientific reputation and appeal to researchers and limit the UK's ability to translate research on medicines and medical devices into products to bring to market. It would increase the burden of conducting multi-centre clinical trials and create barriers to working collaboratively and sharing expertise, facilities and datasets, ultimately delaying the development of and access to new medicines and devices across Europe.

#### Latest developments

In December 2017, EU and UK negotiators agreed that following the UK's withdrawal from the EU, the UK will continue to participate in EU funding programmes, such as Horizon 2020, until the end of such programmes in the current budget cycle at the close of 2020.

For more information see the BMA briefing "[Medical research.](#)"

## Ensuring access to medicines and devices

#### The BMA is calling for:

- A formal agreement between the UK and the EMA (European Medicines Agency) to continue to support and participate in their assessments for medicines approvals.
- Mutual recognition of, and ongoing participation in, the CE-mark scheme for medical devices.
- Consistency and close alignment with EU clinical trials regulations.

The regulation of medicines in the UK – including those under development and approved for use – derives from EU regulations and directives, and is overseen by the MHRA (Medicines and Healthcare products Regulatory Agency). Harmonised regulations enable patients to get timely access to safe and effective medicines and technologies developed anywhere in the EEA. Any medicine licensed by the EMA is valid across all EU member states whereas a license issued by the MHRA is valid in the UK only.

The licensing of medical devices is also governed by EU regulations, and works via a system where they are approved by a registered notified body in a member state. Once approved, devices can be sold across the EU and EEA through the CE marking scheme.

The EMA also coordinates a large network of pharmacovigilance, which is responsible for collecting and sharing real-time data on approved medicines and devices enabling it to identify trends and quickly take action to inform patients and healthcare professionals about any safety concerns. The specific advantage of this collaboration at an EU level is the wider coverage area for surveillance and reporting of adverse effects, as there is a greater number of patients using a drug compared to within an individual country.

If, after Brexit, the UK adopts a different regulatory framework, cross-border EU collaboration on licensing and pharmacovigilance and integrated supply chains for medicines and medical devices could be disrupted. With the UK being a smaller market, this could lead to delays accessing medicines and medical devices in the UK, as pharmaceutical companies and device manufacturers prioritise the EU market.<sup>24</sup> For patients in the UK this could mean that they face delays in accessing new medicines and devices.<sup>25</sup>

For more information see the BMA briefing "[Medicine and medical device regulation.](#)"

## Diagnosing and treating patients with cancer

### The BMA is calling for:

- A formal agreement with Euratom (the European Atomic Energy Community) to ensure consistent and timely access to radioisotopes for medical purposes and facilitate close collaboration on radiation research and support.

Euratom facilitates a secure and consistent supply of radioisotopes which have a range of applications in medicine. They are vital for diagnosing diseases through nuclear medicine imaging techniques, treatment of cancer through radiotherapy, as well as palliative relief of pain, and biochemical analysis of blood, serum, urine, hormones and antigens in clinical pathology. The UK relies on international supplies of nuclear radioisotopes – for example, its supply of Technetium 99 (which is the most common radioisotope used in nuclear diagnostic imaging in many UK hospitals) is imported largely from the Netherlands, France and Belgium. As isotopes have a short half-life and cannot be stock piled, continuous and timely access is vital for patient safety.

Membership of Euratom guarantees the UK's compliance with the standards and safety regulations on nuclear material, as established by the International Atomic Energy Agency. Euratom also provides a key network that supports research and training in areas such as nuclear safety, clinical radiation protection and the safe disposal of radioactive waste, as well as the free movement of nuclear sector specialists. In addition, Euratom provides funding – through the Horizon 2020 programme – for extensive research development programmes.

In the event of a no deal scenario, the UK would lose the guarantee of consistent and timely access to radioisotopes, as is currently provided by membership of Euratom, potentially resulting in delays in diagnosis and cancelled operations for patients. In addition, its collaborative links on nuclear-medicine research would be weakened.

### Latest developments

In December 2017, EU and UK negotiators agreed that the UK would be responsible for international nuclear safeguards in the UK, currently overseen by Euratom, and these safeguards will be equivalent to the current regime.

## Delivering the best health services on the island of Ireland

### The BMA is calling for:

- Continuation of the existing open border arrangements between Northern Ireland and the Republic of Ireland.
- Ongoing cross border co-operation in the delivery of healthcare to patients on both sides of the border.
- Freedom of movement for healthcare workers to live and work on both sides of the border.
- Ongoing MRPQ to provide doctors the means to work in both jurisdictions.

Health services work collaboratively for the benefit of patients in Northern Ireland and the Republic of Ireland. The existing open border arrangements, alongside an expansion in the provision of all-island healthcare, provide a number of benefits for patients, including access to specialist medical services and highly trained clinicians. Current arrangements also allow patients living on both sides of the border to access emergency and specialist services care that is closest to them rather than facing lengthy journeys.

In the event of a no deal scenario, the establishment of a hard border on the island of Ireland could disrupt the joint delivery of health services, movement of medical staff and create new hurdles to coordination.

### Latest developments

In December 2017, the EU and the UK in their joint report recognised that cooperation between the Republic of Ireland and Northern Ireland must be protected and a hard border should be avoided. Any future arrangements must be compatible with these aims. In the absence of other solutions, the United Kingdom will ensure that no new regulatory barriers develop between Northern Ireland and the rest of the United Kingdom. The report also recognises that the United Kingdom and the Republic of Ireland may continue to make arrangements between themselves relating to the movement of persons between their territories (the existing Common Travel Area) in particular with respect to free movement for UK and Irish citizens.

## Summary

The issues facing the health service and patients following the UK's withdrawal from the EU are considerable and are therefore a key focus for the association. This briefing highlights the possible implications if the UK does not agree a final deal or future partnership agreements with the EU. In addition, there are issues of a global nature, for example, regarding health security, which will require continuing cross-border collaboration. It is vital that the UK government's negotiations with the EU prioritise the ability for the UK and EU to continue to work closely across these areas and that measures are put in place that provide stability to essential health services, patients, and the workforce when the UK leaves the EU in March 2019. Otherwise, the potential impacts of Brexit could have severe consequences for patients, healthcare professionals and the NHS more widely.

## References

- 1 The EEA includes EU countries and Iceland, Liechtenstein and Norway. These are part of the EU's single market which allows free movement of good, capital, services and people between member states.
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