December 2020

Brexit Update

After 9 months of intense negotiations both parties reached an agreement on the new EU-UK Trade and Cooperation Agreement which goes well beyond traditional free trade agreements and provides a solid basis for future cooperation on key issues such as: reciprocal healthcare for UK/EU citizens; information-sharing around emerging health threats; standards on medicines; participation in medical research programmes; and future cooperation around nuclear medicine supplies, which is vital for securing medical radioisotopes for cancer diagnosis and treatment.

Ursula von der Leyen, who already signed the Agreement, said at a press conference in Brussels: *it was a long and winding road, but we have got a good deal to show for it.* Boris Johnson, in his message to EU27, stated: ‘we will be your friend, your ally, your supporter, and indeed, never let it be forgotten, your No. 1 market. Because although we will have left the EU, this country will remain culturally, emotionally, historically, strategically, geologically attached to Europe.’

On 1 January 2021 the UK left the EU Single Market and Customs Union, as well as all EU policies and international agreements. The free movement of people, goods, services and capital between the UK and the EU will come to an end. The EU and the UK will form two separate markets and two distinct regulatory and legal systems. This will create barriers to trade in goods and services and to cross-border mobility and exchanges in both directions.

After the BMA’s extensive work on both sides, in the aftermath of the EU referendum, the new EU-UK Agreement includes a number of measures which might mitigate, to some extent, the threats that Brexit poses to the medical profession and the patients it serves.

The new EU-UK Trade and Cooperation Agreement consists of:

- a free trade agreement (FTA)
- cooperation on economic, social, environmental and fisheries issues
- a close partnership for citizens’ security
- an overarching governance framework

The Agreement offers no more than the EU-Canada model in terms of Mutual Recognition of Professional Qualifications (MRPQs) and does not include automatic recognition of professional qualifications. It only establishes a process in which regulators and industry bodies can work with each other to establish MRPQs in the future but will require further detailed agreements and procedures. Consequently, doctors, nurses, dentists, pharmacists, vets, engineers or architects must have their qualifications recognised in each member state they wish to practice in. The UK side advised that from early 2021, the government will provide help and guidance to UK regulatory authorities and professional bodies on how to make use of the framework for MRPQs within the deal. In addition, the UK has unilaterally decided to continue to recognise EEA qualifications for up to two years post-transition. The Agreement speaks about no regression for fundamental rights at work, occupational health and safety standards and fair working conditions. The rules may diverge in future and there is no requirement to align going forward. UK will implement new points-based immigration system for people wanting to come and work in the UK from 1 January 2021.
The UK is no longer member of the European Atomic Energy Community (Euratom) however, both parties have agreed a Nuclear Cooperation Agreement (NCA) which provides a framework for trade in nuclear materials and technology, facilitates research and development, and enables exchange of information and expertise including on medical radioisotopes for cancer diagnosis and treatment. It provides mutual assurances that traded nuclear material will remain subject to safeguards and provides a comprehensive framework and other key assurances for transfers of nuclear materials and related items, including procedures for retransfers to third countries.

Both parties have agreed to work together on matters of health security, including allowing the UK ad hoc access to the EU’s Early Warning and Response System. In the event of a serious cross-border health threat, the EU may grant the UK temporary access to the system post-transition. The text also states that for the duration of a particular health threat, the EU may invite the UK to participate in a committee that shares information and supports coordination related to the threat. The European Centre for Disease Prevention and Control (ECDC), and the relevant body in the UK that takes over the ECDC’s responsibilities after the Brexit transition period, will also cooperate ‘on technical and scientific matters of mutual interest to the parties and, to that end, may conclude a memorandum of understanding.’

The Agreement will prevent unnecessary technical barriers to trade by providing for self-declaration of regulatory compliance for low-risk products and facilitations for other specific products of mutual interest, such as automotive, wine, organics, pharmaceuticals and chemicals. The trade deal includes an annex on medicinal products that sets out an agreement on mutual recognition of inspections and good manufacturing practice. These inspections of facilities and manufacturing practice documents should only be refused by the other party in very specific circumstances. The annex also states that with regard to medicinal products, the UK and EU will ‘endeavour to consult one another, as permitted by their respective law, on proposals to introduce significant changes to technical regulations or inspection procedures.’ It adds that the two will ‘endeavour to cooperate with a view to strengthening, developing and promoting the adoption and implementation of internationally agreed scientific or technical guidelines.’

The Agreement obliges both parties to uphold common high standards on labour and social protection, environmental protection, the fight against climate change, including carbon pricing, and tax transparency but no requirement to align in future. It also contains detailed principles on state aid to prevent either side from granting unfair, trade-distorting subsidies. These standards and principles are associated with domestic enforcement and dispute settlement mechanisms to ensure businesses from the EU and the UK compete on a level playing field. The parties have the right to take unilateral measures to safeguard their economies against unfair competition from the other party.

On mobility, the Agreement provides a non-discrimination clause which ensures equal treatment of EU citizens for short-term visas. UK visitors to the EU need a valid passport and visas are required for stays over 90 days in a 180-day period. There will be additional border checks and EU pet passports are no longer valid. There will be coordination of some social security benefits (old-age and survivors’ pensions, pre-retirement, healthcare, maternity/paternity, accidents at work) making it easier to work abroad and not lose rights.

UK travellers to the EU, and EU travellers in the UK, will have access to emergency and necessary healthcare when they travel operating on the European Health Insurance Card (EHIC) scheme. A new UK Global Health Insurance Card (GHIC) will be available as from 2021 in recognition of the new agreement with the EU, replacing the existing EHIC. However, people will still be able to use their EHIC after 1 January 2021 when travelling to the EU, as current cards will remain valid until their expiry date. Those travelling to the UK from the EU will also be able to continue to use their EHICs.

Frontier workers (people who commute across borders to work) and their family members will also be covered for cross-border treatment. People needing pre-planned treatment such as dialysis or chemotherapy while on either side of the UK/EU border will be able to arrange in advance to have it paid for by their own country, without paying upfront themselves. Retirement pensions can be exported, aggregated and paid abroad.

With the ending of free movement, EU citizens who move to the UK from 1 January 2021 for more than six months will be subject to immigration control and pay the immigration health surcharge as part of any visa application. However, certain groups, where a member state continues to cover their healthcare costs in full, will be able to seek reimbursement of the surcharge. Short-term visitors to the UK who are not covered by the new Agreement on reciprocal healthcare, including former UK residents, may be charged for NHS treatment.

The UK has secured participation in five EU programs, including Euratom Research and Training and association to Horizon Europe, which will run between 2021 and 2027 with a €95.5 billion budget. It is not yet confirmed whether the UK will have full access to the entire scheme and the UK’s involvement Horizon Europe will be subject to its financial
contribution. Currently, the UK’s contribution to Horizon Europe remains unknown, but it will include a participation fee which will go toward the administration costs of the scheme.

The UK decided not to stay in Erasmus+ exchange programme and instead is working on its own alternative scheme – the Turing programme. This is expected to be operational from September 2021 and was announced in government’s November Spending Review (section 7.3 Department for Education). It would fund outbound mobility only, so sending UK learners abroad (worldwide – not just the EU), but bilateral deals with each participating must still be agreed. UK organisations wishing to take part in the Turing program need to submit their bids by early 2021. Successful participants will receive funding for administering the scheme, while students will receive grants to cover part of the costs of their international placement. However, students in Northern Ireland can continue to participate in the Erasmus+ scheme under an arrangement with the Irish government.

The EU’s PEACE PLUS programme, which builds upon previous PEACE INTERREG programmes, continues its focus on contributing to a more prosperous and stable society in Northern Ireland and the border region of the Republic of Ireland until at least to 2027. However, this UK’s government commitment to support the programme does not form part of any ‘future relationship agreement’.

In addition, UK public procurement markets are open to EU bidders established in the UK, on an equal footing, and vice versa, including for small contracts. Public procurement can include social, environmental and labour conditions if these apply equally to all.

The UK requested that the Agreement does not cover cooperation on foreign policy, external security and defence, despite being initially foreseen in the Political Declaration. In addition, the Agreement does not cover any decisions relating to equivalences for financial services. Instead, the declarations include a commitment to try and reach a memorandum of understanding by March 2021 that might mean the two parties agree to recognise each other’s rules, a process known as ‘equivalence,’ which would allow the finance industry to trade across the UK and EU border. The Agreement also does not cover possible decisions pertaining to the adequacy of the UK’s data protection regime, or the assessment of its sanitary and phytosanitary regime for the purpose of listing it as a third country allowed to export food products to the EU. These are and will remain unilateral decisions of the EU and are not subject to negotiation. Consequently, the UK will stay governed by the EU’s data transfers framework for a maximum of 6 months while the EU decides whether there is equivalence or adequacy between EU’s and UK’s data protection regimes. The Agreement prohibits either side requiring that data be stored or processed in their territory and specifies there should be high standards of protection for personal data and privacy. Under the terms of the provisional data flows agreement, the UK is effectively barred from developing an independent data transfer regime as it is locked it into the EU system until it gets an adequacy decision.

The WA remains in place, protecting amongst other things the rights of EU citizens and UK nationals, the EU’s financial interests and peace and stability on the island of Ireland. In the aftermath of intensive discussions between the EU and the UK in the recently agreed Joint Committee (which oversees the WA), the WA, including the Protocol on Ireland and Northern Ireland, will be implemented on 1 January 2021.

The FTA negotiations could only be finalised at a very late stage before the expiry of the transition period. The European Parliament (EP) and the Council of the EU have to examine and ratify the text before it can fully enter into force. Considering these exceptional circumstances, the European Commission (EC) proposes to apply the Agreement on a provisional basis, for a limited period until 28 February 2021, which had been already agreed by EU ambassadors on 28 December 2020. MEPs said they will scrutinise the deal early 2021.

The BMA will be working with both, UK’s government and its European partners, to secure long-term arrangements for the mutual recognition of medical qualifications between the UK and EU member states so that that doctors from across the continent have the freedom to be able to work in the NHS once shorter-term measures come to an end in 2 years. This includes the need for information-sharing agreements between regulators which are instrumental in reinforcing patient safety and maintaining the reputation of the medical profession.

The BMA will produce more detailed briefings on the adopted Agreement and its various clauses, which will be available in due course.

Further information about our extensive work in this area is available here.
COVID-19 Response

With efforts now focussed on controlling the virus, we are continuing to work with our European partners to ensure that all relevant intelligence is collated and shared with our members and support staff. A copy of this database is available upon request. In addition, the Standing Committee of European Doctors (CPME), which the BMA is a member of, published the European Doctors’ Recommendations to the EU on pandemic preparedness build on the reports provided by national medical associations on Covid-19.

As part of the EU Vaccines Strategy, vaccinations in all 27 member states countries began on 27 December 2020 after regulators approved the Pfizer-BioNTech vaccine on 21 December 2020. While a few countries started giving doses a day earlier, the coordinated rollout for the EU aimed at projecting a unified message that the vaccine was safe and Europe’s best chance to emerge from the pandemic and the economic devastation caused by months of lockdown. Member states will receive 12.5 million doses by the end of 2020 which will be divided based on population. The EU has secured contracts for more than two billion vaccine doses from a range of drug companies. After December 2020, deliveries of the Pfizer/BioNTech vaccine will continue on a weekly basis, with the full order of 200 million expected to be out by September 2021. The EC and member states are also working to secure an additional 100 million doses. Regarding Moderna’s vaccine, the EC advised that the first deliveries of some of the EU’s advance purchase contracts are expected in the first quarter of 2021. The European Medicines Agency EMA) is expected to review that vaccine’s application on 6 January 2021.

As from 17 December 2020, ECDC moved to a weekly reporting schedule for the COVID-19 situation worldwide, EU/EEA and in the UK publishing updates on the number of cases and deaths reported every Thursday. In addition, the Agency has recently stated that new variants of the coronavirus from the UK and South Africa pose a high overall risk to Europe. In its recent risk assessment, advises that while there is no evidence at this point that the new variants cause more severe illness, they do appear to spread more easily. To date, the variant from the UK has been detected in Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, the Netherlands, Norway, Portugal, Spain and Sweden. Regarding the South Africa variant, two cases has been recorded in the UK and one in Finland which are all directly linked to travel from South Africa. To improve detection of new variants, the ECDC urged EU/EEA countries to emulate the UK’s timely and broad approach to sequencing the genomes of coronavirus cases. The Agency stressed that the impact on vaccine efficacy is one of many unknowns about the new strain and while age-specific data for the new UK variant is still pending, school closures should be a ‘last resort.’

Updates on the BMA’s extensive work and guidance on this area can be found here with updates on the EU’s response here, from the ECDC here, from EMA here and from WHO Europe here.

Health Priorities for the Portuguese Presidency of the EU

As Portugal assumed (January/June 2021) the rotating Presidency of the EU, its government has detailed those areas of health policy which it will be prioritising during its tenure.

Digital transformation continues to be a key priority for the health sector with the main focus on the development of the EU Health Data Space, a common approach for capacity building on the exchange of medical information as well as on how to access and reuse health data for better research and public health outcomes, particularly the use of telehealth.

The Presidency will be hosting the following events:

- June 2021, eHealth Summit in June 2021 with the focus on telehealth, EHR interoperability and data reuse
- June 2021, 19th meeting of the eHealth Network with the expected outcome to draft a policy statement on the EU digital transformation in healthcare and the removal of barriers to cross-border telehealth.

Further information about the Portuguese Presidency can be read here.

For further information on any of these news items, please contact:
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