May 2021

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Brexit Update

The UK chief negotiator, David Frost, has recently warned there is a risk of gaps in regulation between Northern Ireland and the rest of the UK referring to new cancer treatment. The Medicines and Healthcare products Regulatory Agency (MHRA), has licensed a drug, called Osimertinib, for use in lung cancer patients across the country but not in Northern Ireland. There have been reports this was not possible because of the grace period on medicines agreed with the EU, due to expire at the end of the year. However, the EC spokesperson recently denied that the Northern Ireland protocol creates a barrier to this process and advised that there are derogations in EU law for Northern Ireland, e.g. for market authorisation requirements. David Frost accused the EU of asserting their right to regulate cancer drugs in Northern Ireland rather than the UK.

This remains one of a number of Brexit-related issues which are currently being debated by both parties. European Commission Vice President Maroš Šefčovič has advised the UK officials of growing impatience among EU countries over Northern Ireland trade issues:

‘It’s quite clear that, if we do not see positive developments, that the atmosphere would be sourer, making it more difficult to look for political compromises. The political environment would be much more challenging.’

He added that the next meeting of the EU-UK Joint Committee, a forum which oversees the Withdrawal Agreement (WA), scheduled for 7 June should agree a joint ‘road map’ for settling differences over the operation of the Northern Ireland trade border. To date discussions on how to avoid trade obstacles have not resulted in concrete solutions. David Frost, the UK chief negotiator, confirmed that the European Commission (EC) had rejected UK proposals on sanitary and phytosanitary (SPS) measures and argued that Britain should commit to align with the EU on food, plant and environmental standards, to which the UK has strongly objected.

The UK government has recently published its quarterly immigration figures, the first since the end of free movement with the EU. While the data has been heavily affected by the coronavirus pandemic and international-level travel restrictions and therefore does not provide long-term trends, it does reveal that the uptake of the new points-based visas for long-term, skilled work was quite low among EU nationals. The Home Office received just 1,075 applications between January and March, including for working in the health and social-care sectors. These represented about five percent of the total 20,738 applications for this type of visas.

The Independent Monitoring Authority (IMA), established under the WA to protect the rights of EU and EEA/EFTA citizens in the UK and Gibraltar, published the results of its survey on the EU Settlement Scheme (EUSS) together with a press release and summary infographic. Almost 3000 respondents took part of the survey with the following findings:

- 50% are not aware of their citizens’ rights
- 25% of respondents feel that they are not treated equally with UK citizens
- 10% are considering leaving the UK after 30 June

The IMA identified the lack of trust in public bodies as the key issue and recognised the need for public services to reassure EU citizens of their rights and build their confidence while engaging with authorities. The IMA is currently considering possible solutions to resolve the issues, including conducting a public enquiry or announcing a call for evidence.
In addition, the UK is planning to introduce a new Electronic Travel Authorisation (ETA), in force by 2025 (which will require a fee to be paid by visiting EU citizens and other foreign nationals, except Ireland) as part of a wider reform aimed at making the border more secure. The EU is also introducing a similar program, known as the European Travel Information and Authorisation System (ETIAS), which is due to launch on 1 January 2022 and will apply to UK citizens, with a fee of €7.

COVID-19 Response

With efforts focused 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.

The EC has recently presented its proposal to streamline travel policies across the EU ahead of the summer season. Under the recently reached agreement, the EU Digital COVID Certificate scheme (previously Digital Green Certificate) - proving whether travellers have had a recent test, been vaccinated or are immune following an infection - becomes operational as of 1 July (Ireland plans a full implementation from 19 July). The gateway that allows EU countries to issue and verify COVID certificates is already live for those who wish to start using the system earlier on a voluntary basis.

Travellers with a certificate proving they’re fully vaccinated, defined as 14 days after their final dose or recovered from the coronavirus (maximum of 180 days after their positive COVID test) should be able to travel without testing or quarantine requirements. For other travellers, the EC calls on EU member states to base travel restrictions on a color-coded map that ranks areas within the EU from safe (green) to very high-risk (dark red) based on the health risk. Travelers from green areas should not face any restrictions; travellers from orange areas could be required to get tested before travel; and travellers from red areas could be required to quarantine unless they have proof of a negative test result. Travel from very high-risk areas, meanwhile, should be strongly discouraged. The EC also asks EU countries to agree on how long coronavirus tests are valid, suggesting 72 hours for a PCR test and 48 hours for a rapid antigen test. In addition, a so-called ‘emergency brake’ would allow countries to reintroduce measures, also for people who have been vaccinated or have recovered, if the epidemiological situation in a country deteriorates rapidly.

The EU institutions had taken very different positions on the scheme, with the European Parliament (EP) arguing they should prevent EU countries from imposing further travel restrictions such as quarantines and demanding free testing for travel. Both of those proposals were rejected by the European Council. Consequently, the compromise deal allows EU countries to decide on additional measures.

At the recent Integrated Political Crisis Response (IPCR) meeting, France and Germany objected to adding the UK to EU’s green list despite Cyprus, Greece and Spain’s support. EU leaders previously said that the UK would be green-listed mid-May however, they now advised that there is a need to wait longer to do so over concerns of the B.1.617 variant, known as the Indian variant, which is spreading across the country.

The European Centre for Disease Prevention and Control (ECDC) has published a data dashboard which shows the levels of different coronavirus variants across Europe. It provides information about the B.1.1.7, B.1.251, and P.1 variants, known as the British, South African, and Brazilian variants, respectively. It also provides information on sequencing efforts throughout the EU. According to the dashboard, for the latest available data, only two of the countries included, Norway and Denmark, have sequenced enough cases to draw conclusions, as most other countries lack any sequencing data. The threshold is set as at least 500 cases or ten percent of the total sample. In both countries, the British variant makes up over nineteen percent of sequenced cases.

The European Medicines Agency (EMA) has published an opinion for healthcare professionals advising that there is not enough evidence on whether inhaled corticosteroids benefit non-hospitalised people with COVID-19. In addition, the EMA published a new assessment report for its review of reported cases of blood clots with COVID-19 Vaccine Janssen and the updated product information for Vaxzevria (previously AstraZeneca) in all EU languages.

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.
EU-UK data flows post-Brexit

As reported in last month’s Eurobrief, on 6 May the BMA, together with its European partners, co-hosted a webinar to consider the implications of data adequacy on European health outcomes. More than 380 participants, including key decision-makers in the EU-UK data transfers approval process, attended the webinar. A Commission official presented on the ongoing process toward an EU adequacy decision in respect of the UK’s data protection regime and advised that the EC, together with the European Data Protection Board (EDPB), had already issued positive decisions supporting free flow of personal data between the UK and EU post-transition without the need for any further safeguards. Such a decision should have been included in the EU-UK Trade and Cooperation Agreement (TCA) but the EU ran out of time to grant it to the UK, before the end of the transition period, therefore the TCA includes an interim agreement to ensure that continued flow of personal data remains legal until the end of June 2021.

Professor Michel Coleman represented the BMA and stated the following:

- In the aftermath of Brexit, free movement of professionals has changed, but it is still possible to travel from the EU to the UK for work, clinical and research experience. Nearly ten per cent of medical professionals are EU citizens and the BMA strongly supports incoming professionals from the EU in all health sectors, especially medical. It is clear that if the EU adopts an adequacy decision in respect of the UK data protection regime, such data transfers will be able to continue for the foreseeable future. This will be of benefit for EU medical professionals and the patients they treat.
- Health professionals will face significant administrative difficulties if they wish to come to the UK if an adequacy decision is not adopted. It needs to be recognised that the UK data protection regime is well managed and the GDPR is fully enshrined in UK law as the UK GDPR, with all its principles, safeguards and responsibilities.
- The UK has long-standing experience and engagement in multinational research with EU Member States. If an adequacy decision is not adopted, many such collaborations would be forced to stop, because data exchanges would only be possible if standard contractual clauses are in place between each research organisation in the UK and collaborating EU institutions. This would require substantial administrative capacity on both sides.

On 21 May, the European Parliament (EP) Committee on Civil Liberties, Justice and Home Affairs (LIBE) voted in Plenary (full session) on its resolution which formally objects to the EC’s decision to grant the UK a data flows agreement. The LIBE’s resolution states that the EC has gone beyond its implementing powers, points out inconsistencies with EU law and raises concerns about exemptions in the UK data protection regulations for national security and immigration.

The EC does not need to act on the EP’s decision, since the latter is not part of the formal process of adopting the adequacy decision. To finalise this process, now EU national governments now have to issue their binding decision, expected in early June.

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