January 2022

Brexit Update

The talks between the UK and the EU continue on how to resolve long-lasting differences over the Northern Ireland (NI) Protocol. Both parties announced that the ongoing talks are taking place in a constructive atmosphere and ‘reaffirmed their shared desire for a positive EU-UK relationship underpinned by our shared belief in freedom and democracy and cooperation on common global challenges.’ However, Britain’s new Foreign Secretary, Liz Truss announced that she would be willing to trigger Article 16 and unilaterally override some trade rules for NI if ongoing talks with the EU failed.

Regardless of the outcome of the talks and as reported in the December European Brief, the European Commission (EC) published its unilateral proposal to continue with an interrupted medicines supply to NI and opened a public consultation on the proposed changes to EU legislation. The BMA is currently drafting its response to feed into the process and to reiterate its call for pragmatic solutions to be agreed between the two parties to ensure there will be an uninterrupted supply of medicines to NI, so that the medical profession can continue treating their patients to the highest possible safety levels.

Following the adoption, by the House of Lords, of the creation of the post-Brexit EU-UK Parliamentary Partnership Assembly (PPA), Prime Minister Boris Johnson announced the 35 UK lawmakers responsible, together with 35 lawmakers from EU side, for monitoring the implementation of the EU-UK Trade and Cooperation Agreement (TCA) within the Assembly. The PPA will be briefed on decisions by the EU-UK Partnership Council (the body that oversees the implementation of the TCA), which is co-chaired by Maroš Šefčovič and Liz Truss. The PPA will also be able to make non-binding recommendations for amending the TCA.

Bill Cash MP, chair of the House of Commons European Scrutiny Committee, recently wrote to UK Prime Minister to seek assurance the reviews, launched by David Frost, to ‘amend, replace or repeal’ all Brussels-derived laws that were automatically absorbed by the UK after Brexit, will go ahead as planned and he asked for clarification on who will lead them. The Prime Minister’s spokesman recently said all of Frost’s Brexit responsibilities would come under the responsibility of the Foreign, Commonwealth and Development Office. However, government officials later said it had not yet been confirmed whether this included the Cabinet Office’s newly-formed Brexit Opportunities Unit, which had been working on the reviews.

The British prime minister announced his plans for the ‘Brexit Freedoms Bill’, which is expected to bring an end to the ‘special status of EU law and ensure that it can be more easily amended or removed’. It adds that ‘changes to EU rules, many of which were kept on post Brexit, currently require lengthy primary legislation. The new bill would allow changes to be made more quickly and the government would make a catalogue of EU-derived law public in due course’

The BMA will keep a close watch on any potential future changes to the aforementioned legislation and intervene when these might potentially impact on the BMA’s cooperation with the EU.

The UK government recently announced that care workers, care assistants and home care workers will become eligible for the Health and Care Visa for a 12 month period. This announcement follows the recommendations of the Migration Advisory Committee (MAC) and added these positions to the Shortage Occupation List (SOL).
Public Consultation on European Health Data Space

The UK is a formal participant in the EU Joint Action Towards Sharing Health Data which is an implementation tool to feed into the EC’s legislative proposal on the European Health Data Space; the UK is represented by the NHS Confederation (NHSC). The Joint Action aims to develop and promote concepts necessary for the sharing of health data for citizens’ and public health, treatment, research and innovation in Europe. The selection of eligible organisations to take part in this Joint Action was concluded prior to 31 December 2020 and was therefore open to UK participation under the rules set out during the Transition Period.

The UK has a formal role and responsibilities in two thematic work packages - Sharing Health Data and iCitizen. The Sharing Health Data work package focuses on developing the operational framework to govern the exchange of secondary use of health data in Europe. The outputs of this work package include:

- a governance model for data-sharing at EU level
- guidelines on effective methods for enabling data use for public health and research
- options on the secondary use of health data, including the application of big data and artificial intelligence in health and long-term care.

The iCitizen work package focuses on better understanding citizens’ perception towards the sharing of their health data to identify ways to better inform and encourage citizens to engage with their health data. The UK is one of three countries, together with France and Belgium, conducting a public consultation (deadline 4 April) to better understand citizens’ perceptions of data sharing for secondary use. This consultation is inviting views, ideas and suggestions from everyone on the reuse of data and the role citizens want to play in the management and use of their data. The final report giving the findings of this working package is expected in June/July.

The BMA was amongst 20 digital expert organisations selected to determine the consultation questions, with the aim to establish the base and safeguards for appropriate use of health data for medical research. The results will inform both UK and European digital health and research policies, including the UK data protection reform proposals and GP data rollout. The UK’s access to the European Health Data Space is still unclear and will be confirmed in due course.

The landmark ‘Healthy Data’ consultation, co-designed with the BMA, is inviting views on the reuse of data and the role citizens play in the management and use of health data. By completing a quick three-minute quiz and sharing views, everyone can inform decisions on how public health data will be used in the UK and across Europe. Please encourage others to participate by sharing your quiz result on social media.

In addition, the NHSC has convened an informal UK Working Group of academics, researchers, policy makers and regulators specialising in health data sharing to gather views and expertise from UK experts, including the BMA.

Horizon Europe Update

The official signing of Britain’s association agreement to Horizon Europe is still being delayed due to a wider political dispute over the implementation of the NI Protocol.

The UK Government announced that successful UK applicants for Horizon Europe grant awards will be guaranteed funding regardless of the outcome of the UK’s efforts to associate to programme. The money will be delivered through UK Research and Innovation (UKRI), providing a ‘safety net’ for researchers and their partners to continue pursuing their project plans.

Recently, 397 early-career researchers won European Research Council (ERC) Starting Grants. Those grants, worth on average €1.5m, will support younger researchers to launch their own projects covering all disciplines of research. The successful candidates from universities and research centres come from Germany (72 projects), France (53), the UK (46) and the Netherlands (44). Following the termination of the exploratory talks, Switzerland is considered a non-associated third country. Consequently, host institutions established in Switzerland are not eligible for funding, exceptionally for this call, since it was already closed before the termination of the negotiations between the EU and Switzerland.

In the event of no UK association to Horizon Europe the UK candidates will be asked to move their ERC grants from the UK to an eligible EU member state/associated country, or they can remain in the UK with the support from the UK guarantee fund.
Chair of Council, Dr Chaand Nagpaul, signed a pan-European campaign, ‘Stick to Science’, initiated in a response to the delayed progression of association agreements with Switzerland and the UK, stating:

‘Global health threats don’t respect borders and patients mustn’t become collateral damage in EU-UK relations. The BMA calls for formal association of the UK to Horizon Europe to continue exchanging ideas and life-changing research by the European medical profession together’

The campaign aims to urge the European Council, European Parliament and EC to make rapid progress on finalising Horizon Europe association by demonstrating that delays and even possible non-association have damaging effects on European science and health as a whole.

**COVID-19 Response**

As of 1 February, the EU introduced a set of new measures on digital Covid certificates allowing travel throughout the EU with proof of vaccination, recovery or a negative test, without having to face quarantine or additional testing measures. Travelers will be able to freely enter one EU country from another if they have had their first course of vaccination a maximum of 270 days ago, or if they have received a booster shot. This also applies to people who have recovered from Covid-19 in the last 180 days, and passengers who have had a PCR test 72 hours before arriving or an antigen test 24 hours before. One exception will be countries in the highest ‘dark red’ category of the European Centre for Disease Prevention and Control’s (ECDC) color-coded risk map. The new measures also modify the ECDC’s existing map that currently serves as the basis for travel restrictions. Under the new metrics, the map, which assesses the coronavirus-related risk levels in different European regions, will also consider vaccination rates when weighing new cases. EU member states also agreed to modify the existing ‘emergency brake’ procedure that allows countries to impose temporary restrictions on travellers in order to delay the spread of new variants. Under the new framework, the EC could propose a coordinated approach to travel from the areas concerned. According to the new measures, EU countries should try to step up sequencing efforts to detect any variants that account for 1 percent or less of cases.

The European Medicines Agency (EMA) has recommended seven medicines for approval, including coronavirus antiviral Paxlovid, which is expected to be available in the UK for high-risk patients as of 10 February. In its early studies, done across six countries, MSD/Ridgeback announced that antiviral molnupiravir is still effective against the Omicron variant. It adds that the drug’s efficacy against the now-dominant variant remains to be seen in real humans. Molnupiravir is already authorised for use in the UK and the EMA has issued emergency guidance for the drug, pending its marketing authorisation evaluation.

The ECDC provides an updated overview of the progress with national Covid-19 vaccination strategies and deployment in the EU/EEA countries, including updates on:
- overall vaccine uptake and uptake by target group
- vaccination strategies and policies
- challenges and good practice with the roll-out, including vaccine acceptance and uptake

The World Health Organisation launched its new WHO online course dedicated to Infodemic Management 101, where global experts explore the growing field of infodemic management activities and explain how to fight misinformation.

A new study, by the US National Institute of Allergy and Infectious Diseases, suggests that omicron-specific vaccine is not needed. The study, which has not yet been peer-reviewed and was done in animals, found that boosting with an Omicron-tailored Moderna vaccine didn’t significantly change neutralising antibody levels compared to a booster of Moderna’s original vaccine. The authors said: ‘therefore, an Omicron boost may not provide greater immunity or protection compared to a boost with the current [Moderna] vaccine.’

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 and from WHO Europe here.

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