Brexit Update

Last month the European Commission (EC) Vice President Maroš Šefčovič and UK Cabinet Office Minister David Frost held the eight meeting under the Joint Committee, which oversees the implementation of the Withdrawal Agreement (WA), and the first meeting under the EU Partnership Council, which governs the implementation of the EU-UK Trade and Cooperation Agreement (TCA).

Regarding post-Brexit differences in relation to the Northern Ireland protocol, both parties remain stuck on areas including sanitary and phytosanitary checks on fresh food and plants entering Northern Ireland from Great Britain, and a ban on imports to the region of chilled meats like sausages and mince from the rest of the UK. The EU has proposed a temporary Swiss-style veterinary agreement that would mean the UK follows EU agri-food rules, and eliminates about four-fifths of potential checks on goods shipped to Northern Ireland. The UK has rejected this proposal pushing for an equivalence arrangement in which the EU would recognise British standards on food production as equivalent to its own.

Both parties continued talks and on 30 June agreed a three-month extension to a grace period allowing chilled meats to continue to move from Britain into Northern Ireland until 1 October. However, Maroš Šefčovič stressed the EU is ‘not issuing a blank cheque’ and the UK will have to ‘fulfil clear obligations’ during the coming three months. David Frost officially welcomed this development but called for a ‘permanent solution’. In exchange for the extension, the EU will ask the UK to remain aligned with the EU food production rules and standards during the three months, a condition the UK government is yet to formally endorse.

On medicines supply, the EC has announced a change to the EU legislation to create a specific scenario for Northern Ireland by the autumn. Under the Northern Ireland protocol, EU regulations on medicines will apply to pharma companies supplying drugs to Northern Ireland from Great Britain, on top of UK rules. Britain secured a 12-month grace period, until 31 December 2021, to adapt to new batch-testing rules and importation and falsified-medicines requirements. Commission officials have held talks with pharmaceutical companies based in Great Britain, which have expressed reluctance to shoulder the costs involved to meet the requirements of the Northern Ireland protocol, including hiring experts in pharmacovigilance and batch-testing in the region. Under one possible solution proposed by the EC, pharma companies that wish to sell drugs in Northern Ireland based on a British authorisation would be exempt from at least some of these requirements. Any new deal, however, will still need to be approved by EU Health Commissioner Stella Kyriakides and national governments.

Both parties also discussed the structure and functioning of the all the nineteen Specialised Committees, which will each meet at least once a year and comprise two chairs (UK and EU), as well as Commission officials and UK delegates. The first meetings of the committees are planned end of this year but the UK side has suggested that the Specialised Committee on EU programmes meet before the summer recess to finalise the UK’s participation in such programmes, notably Horizon Europe, as the formal agreements have not been yet officially signed.

At the recent meeting of the EU and the UK Specialised Committee on Citizens’ Rights, the EU asked the UK for reassurance that EU citizens who applied after the official deadline under the UK’s late application policy will be fully covered by the protection of the WA, from the moment they send their application until receiving the final response. The Cavendish Coalition, of which the BMA is a member, has written to the Home Office expressing its concerns about those who submit a late application and how they are protected in the interim. The EU also asked the UK to clarify why EU citizens who have already been granted pre-settled status will be requested to re-apply in order to gain the fully fledged settled status.
In addition, in early June more than 40 citizens’ support organisations sent a joint letter to the Prime Minister with a request to extend the EUSS deadline beyond 30 June 2021.

On 7 June, the Home Office published a short leaflet to assist citizens in understanding how to access the EUSS digital status through the View-and-Prove service, including how to generate ‘share codes’ that will need to be provided to employers and landlords from 1 July 2021 onwards. The leaflet confirms that some government departments such as the Department for Work and Pensions and NHS England are able to check a citizen’s immigration status without them needing to share the information from their digital profile.

The latest monthly statistics show five million grants of status have been approved through the EU Settlement Scheme so far. In 2019, the UK government estimated there were 3.7 million Europeans residing in Britain.

In addition, the deadline for UK nationals to apply for their Luxembourg residency has been pushed back from 30 June 2021 until the end of the year, as is currently the case in Belgium, Denmark, Austria, Romania, Hungary, and Slovenia. The Netherlands, Sweden, Finland set a deadline of 30 September. The June 30 deadline remains for UK nationals living in France, Malta and Latvia. There were 7,400 UK nationals in France yet to apply as of May 28, according to the latest statistics released by the EU-UK Joint Sub-Committee on Citizens’ Rights. A further 700 British nationals in Latvia and 4,400 in Malta were believed not to have applied by May 31 and June 18 respectively. The British in Europe, a campaign group for the rights of British nationals living in the Continent, urged the French government to clarify its position on British citizens who will miss the June 30 deadline, saying there have been contradictory communications over a potential extension.

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**EU approves UK data flows agreement**

On 28 June, the EC officially adopted the EU adequacy decision on the UK data protection regime, which came only days before an interim solution (30 June) was due to run out. The decision means the EU considers the UK’s privacy laws to be as protective of people’s privacy as the EU’s, through its own General Data Protection Regulation (GDPR). It also means that the flow of personal data from the EU to the UK will continue as before. This comes after the BMA’s intensive engagement with our European partners, including co-writing a statement and co-hosting a pan-European webinar on 6 May, where Professor Michel Coleman represented the BMA and outlined the importance of the continuation of data flows for the European medical profession and the patients it treats.

The whole procedure had been in jeopardy after a London court ruled that the UK government’s practice to exempt immigration data from British data privacy rules was ‘unlawful’ and failed to comply with the EU’s own standards. However, in light of this, the EC amended its decision and removed transfers of data that could fall under the illegal exemption to British data protection standards. The amended decision states the following:

‘This conclusion does not concern personal data transferred for United Kingdom immigration control purposes or which otherwise falls within the scope of the exemption from certain data subject rights for purposes of the maintenance of effective immigration control. The validity and interpretation of the immigration exemption under UK law is not settled following a decision of the UK Court of Appeal of 26 May 2021. Once the incompatibility with UK law is remedied, the immigration exemption should be reassessed, as well as the need to maintain the limitation of the scope of this Decision.’

In addition, the EU’s decision requires both sides to renegotiate the deal in four years’ time which means the EU in the meantime could suspend its decision if the UK significantly diverged from the EU’s privacy rules.

A joint statement, co-signed by the BMA, to welcome the decision is available here.

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**EU Cross-Border Healthcare Directive temporarily reinstated**

The Northern Ireland Health Minister recently announced a temporary framework for 12 months, based on the EU Cross-Border Healthcare Directive, that will allow patients in Northern Ireland to seek and pay for treatment in the private sector in Ireland and have the costs reimbursed by Northern Ireland’s Health and Social Care Board.

Under the Directive, patients in EU countries can seek access to treatment in any other member state. It was especially favoured by those who lived close to the Irish border; however, in the aftermath of Brexit, Northern Ireland residents lost that right.
All treatments are subject to prior authorisation and the scheme will exclude, among other things, long-term care, access to and allocation of organs, and public-vaccination programmes against infectious diseases.

**UK report on EU legislation**

The Taskforce on Innovation, Growth and Regulatory Reform, set up to advise on post-Brexit regulatory opportunities, recently published its report stating that the UK should replace EU rules on clinical trials and data protection and make it easier for pension funds to invest in innovative firms.

Amongst about 100 recommendations, the report suggests a reform of data rules to give ‘stronger rights and powers to consumers and citizens, place proper responsibility on companies using data, and free up data for innovation and in the public interest.’

That would mean a departure from the EU’s GDPR, described by the task force as out of date and in need of a revision to promote the development of artificial intelligence and blockchain. It adds that future UK rules on data protection should place fewer compliance obligations on charities, small and medium-sized enterprises, and voluntary organisations.

The report also states that EU rules on clinical trials should be repealed and replaced with a new UK framework to help make Britain a world leader. New rules should allow quicker access to patients for those conducting trials, by introducing an ‘opt-out’ from medical research instead of an opt-in; speed up the process to approve trials; and increase the use of health data for medical research and trials.

The report will be examined by the Cabinet Better Regulation Committee, led by Chancellor Rishi Sunak.

The BMA will monitor any future plans for legislative changes and act accordingly, in order to protect the interest of its members and maintain patient safety.

**COVID-19 Response**

The EC has recently published a communication on early lessons learned from the COVID-19 pandemic. It foresees establishing: a new European pandemic information-gathering system; a European chief epidemiologist; an annual state-of-preparedness report; a new toolbox for emergency situations; and a Health Important Project of Common European Interest (IPCEI) to enable innovation in the health and pharmaceutical sector and making it more resilient.

The EC has also identified five promising COVID-19 therapies as part of a larger plan to secure a portfolio of ten potential COVID-19 treatments by year-end. Four of these are monoclonal antibodies currently undergoing rolling review by the European Medicines Agency (EMA). The fifth is an immunosuppressant, currently possessing an EMA marketing authorisation, which could be extended to include COVID-19. The medicines include: a combination of bamlanivimab and etesevimab from Eli Lilly; a combination of casirivimab and imdevimab from Regeneron and Roche; regdanivimab from Celltrion; sotrovimab from GlaxoSmithKline and Vir Biotechnology; baricitinib immunosuppressant from Eli Lilly.

The World Health Organisation (WHO), the World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO) are set to create a joint platform to provide technical assistance to countries in relation to coronavirus medical technology. The agreement, reached between the three bodies at a meeting on 15 June, is expected to take the form of a one-stop shop with information on access, IP and trade matters. It aims to help countries to assess their needs for COVID-19 vaccines, medicines and other products and ensure that countries facing similar challenges can coordinate. Alongside the technical support platform, the agencies have also agreed to hold workshops to share information on current developments and responses to ensure equitable access to coronavirus products.

The European Centre for Disease Prevention and Control (ECD) published a brief on implications for the EU/EEA of the spread of the Delta variant of concern, confirming the need for continued non-pharmaceutical measures alongside continued roll-out of vaccinations in order to manage the spread of the variant.

The BMA has recently published a report on moral distress and moral injury which includes:

- a definition of the terms ‘moral distress’ and moral injury
- the findings of the recent BMA survey of UK doctors on moral distress and moral injury
• the impact of COVID-19
• recommendations, both structural and individual, on tackling moral distress

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.

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**Horizon Europe launched**

The EC has just published the main Work Programmes for 2021-2022, outlining the objectives and specific topic areas that will receive a total of €14.7bn in funding, along with a press release with related information and background. The Programme Guide includes sections, amongst other, on: terminology; structure and budget; the Strategic Plan; international cooperation and association; gender equality and inclusiveness; Social Science and Humanities (SSH); social innovation; ethics and integrity; security; dissemination and exploitation of research results; open science; innovation procurement; and key digital technologies. The Programme Guide also includes a document with the list of 115 Low and Middle Income Countries (LMICs) whose organisations can be automatically funded through Horizon Europe and a list of the 18 countries currently in the process of association.

The €1.75bn Health Work Programme has six sub-areas, known as destinations:

1) Staying healthy in a rapidly changing society (€289 million)
2) Living and working in a health-promoting environment (€350 million)
3) Tackling diseases and reducing disease burden (€490 million)
4) Ensuring access to innovative, sustainable and high-quality health care (€240 million)
5) Unlocking the full potential of new tools, technologies and digital solutions for a healthy society (€270 million)
6) Maintaining an innovative, sustainable and globally competitive health related industry (€113 million)

The budgets indicated above are for 2021-2022.

In the Health Work Programme, the deadlines are 21 September 2021, 1 February 2022 or 21 April 2022, depending on the topic. The EC is holding a series of Information Days about Horizon Europe between 28 June and 9 July, with the Health Cluster Information Day scheduled for 2 July; this will provide more detailed information on the published and future calls under the Health Cluster.

In addition, a partner-search function on the EU Participant Portal is now available for the 2021-2022 calls. Under the page for each call topic, a partner-search section allows for organisations to introduce themselves and look for partners/expertise (instructions here).

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