Brexit Update

The European Commission (EC) has recently published its preliminary positive adequacy decision on the UK data protection regime. Before the EC can finalise the decision, first the European Data Protection Board will need to scrutinise the preliminary decision before it receives the approval from national governments.

This decision should have been included in the TCA but the EU ran out of time to grant the UK, before the end of the transition period, an adequacy decision which would permit personal data to be sent from an EEA state to a third country without any further safeguards being necessary. Therefore, the TCA includes an interim agreement to ensure the continued free flow of personal data from the EU and EEA/EFTA States to the UK (as now) either until the EU provides an adequacy decision, or for no longer than six months. This will remain a unilateral decision of the EU and it is not subject to negotiation. In addition, data adequacy decisions are granted for a period of four years, at which time a renewal decision will be required. Separately, the UK had already deemed the EU and EEA/EFTA States to be adequate. This allows for data flows from the UK to the EU and EEA/EFTA States on a transitional basis.

The GDPR will not apply to the UK after the end of 2020. Instead, it will be saved into UK domestic law via the European Union (Withdrawal) Act 2018 as retained EU law. This means that, for the most part, UK data protection law (known as the UK GDPR) will be the same as data protection law in the EU.

The BMA, together with our European partners, including the Standing Committee of European Doctors (CPME), European Union of General Practitioners (UEMO), European Union of Medical Specialists (UEMS) and European Junior Doctors Association (EJD) contributed and co-signed a statement to highlight the vital importance of a positive adequacy decision on the UK data protection regime during these stages in order to secure a final, approved decision.

The statement has been also featured in POLITICO Europe, which is a leading political journalism company reporting on EU affairs with its headquarters located in Brussels, London, Berlin, Warsaw, Paris, and Frankfurt:

‘FUTURE OF HEALTH DATA EXCHANGE: European health groups have backed a call to support the Commission’s draft adequacy decision on the U.K.’s data protection regime, saying that without it, there’d be a massive effect on how health data is shared between the U.K. and the EU. The statement — signed by the NHS Confederation, EFPIA, the BMA, the Standing Committee of European Doctors and over 10 others — states that the formal adoption of the draft decision will mean that EU organizations can continue to transfer personal data to the U.K. It’s also vital for the pandemic, write the signatories, noting that “the free exchange of personal health data under a mutually recognised data protection regime plays a critical role in understanding transmission, infection, and symptoms, and in identifying drug targets, developing vaccines and designing public health responses.”’

The statement has now been sent to the European Data Protection Board ahead of their meeting (where this issue will be discussed) on 9 March. A copy of the statement will also be sent the key decision-makers, national government health and digital ministers and the relevant European Parliament (EP) committees’ MEPs.
The newly created UK-EU Partnership Council has recently agreed to extend the date on which provisional application of the Trade and Cooperation Agreement (TCA) will cease from 28 February 2021 to 30 April 2021 followed by an official request from European Commission (EC) Vice-President Maroš Šefčovič. In a letter, Cabinet Office Minister Michael Gove agreed to extend provisional application and said:

‘provisionally applying the Agreement was not the United Kingdom’s preferred outcome given the uncertainty it creates for individuals and business and indeed the Parties. Extending the period of provisional application prolongs that uncertainty.’

The EU Council of Ministers recently requested the EP’s consent to its decision on the conclusion of the TCA. As reported in last month’s European Brief, the EP’s Committee on Foreign Affairs (AFET) and Committee on International Trade (INTA), who lead on this dossier, are still working on a final text of the EP’s consent after receiving opinions from the sixteen EP committees. Separately, the EP will vote on an accompanying resolution, outlining its political position, prepared by the political groups in the UK Coordination Group and the Conference of Presidents.

In the aftermath of an EU attempt to trigger Article 16 of the Northern Ireland Protocol, which could have led to checks on the island of Ireland and temporarily halted the special border arrangement intended to preserve the Good Friday peace agreement, Ireland demanded the EU provide an ‘early warning system’ on the use of Article 16. The Irish plan is seeking a new safety clause, to prevent a repeat of those events, and calls for the EU’s Financial Services Commissioner Mairead McGuinness to be included more centrally in any EC actions that could impose restrictions on Irish cross-border trade.

EC President Ursula von der Leyen, talking to the European Parliament (EP) about the EU’s COVID-19 Vaccination Strategy, stressed:

‘and as far as the mechanism goes, allow me a word on the island of Ireland. The bottom line is that mistakes were made in the process leading up to the decision. And I deeply regret that. But in the end, we got it right. And I can reassure you that my Commission will do its utmost to protect the peace in Northern Ireland. Just as it has done throughout the entire Brexit process.’

Both parties continue to discuss issues around Ireland and Northern Ireland in the Joint Committee (JC), including the UK’s recent plans to unilaterally extend grace periods on post-Brexit customs checks at Northern Ireland’s ports for at least six months. The co-chair of the JC, Maroš Šefčovič, has recently expressed his views advising that the move is ‘a clear departure from the constructive approach’ to ongoing talks on Northern Ireland trade, and that this would undermine trust. Leaders of the EP’s political groups have recently announced their intention to postpone a decision on when to vote to ratify the TCA following accusations the UK risks breaking international law over Northern Ireland. The EP will have another chance to decide on the date at a meeting mid-March, but the decision might be delayed further if the UK does not backtrack on its decision.

Further information about our extensive work in this area is available here.

COVID-19 Response

With efforts now 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.

At a meeting of the G7 leaders, EC President Ursula von der Leyen has proposed doubling the EU’s contribution to the COVAX facility that aims at sharing coronavirus vaccines with the developing world, by another €500m, bringing its total financing to €1bn. Currently, the EU budget is contributing €500m to the common pot set up by the World Health Organisation (WHO), with another €350m added by member countries. The 92 low and middle-income countries that are set to receive at least particularly subsidised vaccines through COVAX may take part of the scheme, which is set to go live by March 31 at www.covaxclaims.com.
The EU intends to invest €150m for research to counter coronavirus variants through the HERA incubator program, which aims at providing the means to detect and counter further coronavirus mutations and help ensure access to effective vaccines when a new virus or variant has emerged. The initiative establishes the European Health Emergency Preparedness and Response Authority (HERA). In detail, the European bio-defence preparedness programme aims to ensure:

- rapid detection of variants
- swift adaptation of vaccines
- setting up a European Clinical Trials Network
- fast-tracking regulatory approval of updated vaccines and of new or repurposed manufacturing infrastructures
- enable upscaling of production. The contribution of research will be not only to detect, characterise and adapt to virus variants; but also inform vaccination strategies

EC President, Ursula von der Leyen, met in late January with CEOs of pharmaceutical companies that have signed advance purchase agreements with the EC. The discussion explored requirements of the future HERA to deliver a more structured approach to pandemic preparedness while anticipating threats and identifying responses.

The EU Council of Ministers has recently made a statement on COVID-19 and health with the focus on the management of the pandemic and future resilience of health systems. The statement calls for ensuring travel restrictions are coordinated and aligned with Council recommendations dated 1 February 2021. The EU Council requests the EC to present a report by June 2021 on ‘information-sharing, coordination, communication and joint public procurement, as well as how to ensure adequate production capacity in the EU and build up strategic reserves while supporting the diversification and resilience of global medical supply chains.’ Access to medicines and related logistics and policies remain a key priority.

The European Medicines Agency (EMA) has published guidance for vaccine manufacturers looking to adapt their vaccines to provide protection against new coronavirus variants. The guidance assumes that new variant vaccines would rely on the same technology and platform as the original approved vaccine, and that the main change would be in the antigen chosen to set off an immune response. The EMA’s human medicines committee has advised that there won’t be the need to submit new large-scale safety and efficacy studies. Instead, immunogenicity studies can be used to indicate the efficacy of the variant vaccine, with the suggestion that researchers need at least one small clinical trial on the vaccine, with people receiving either the new variant vaccine or the original one. The EMA added that manufacturers should also look at the efficacy of a single dose — a so-called booster — to people who have had the original vaccine. The immune response elicited by this shot should be compared with that shown in the original trial for the first approval of the vaccine.

The European Ombudsman, Emily O’Reilly, has revealed the findings of the six-month inquiry into the European Centre for Disease Prevention and Control’s (ECDC) performance during the COVID-19 crisis and makes the following proposals for improvement:

- greater transparency on the evolution of its risk assessments
- greater transparency on the completeness of the data underlying its risk assessments
- greater transparency around its interactions with international partners, such as the WHO and the Chinese CDC
- a revised communication strategy more directly aimed at the general public
- an updated language policy to include as many official EU languages as possible
- systematic publication of survey results.

The Ombudsman has also suggested that EU legislators reflect on whether new powers for the agency are needed to improve its capacity to deal with similar future public health crisis as planned under the recent EC’s proposal on European Health Union (as reported in November 2020 Eurobiref).

The ECDC has mapped the detection and characterisation capability and capacity for SARS-CoV-2 variants across the EU/EEA; this shows that, in most member states, the sequencing capacity for identification of SARS-CoV-2 variants is below the recommendation set by the EC to sequence 5-10% of SARS-CoV-2 positive specimens. In addition, the ECDC has provided a first update on the effectiveness of using face masks in reducing transmission of COVID-19. The report recommends that, although the evidence for their effectiveness is limited, face masks should be considered as a non-pharmaceutical intervention in combination with other measures as part of efforts to control the COVID-19 pandemic.

In addition, Greens in the EP and in the British Green Party have issued a joint letter calling for the UK and the EU to avoid battling each other for vaccine supplies, opining:
“We deplore recent aggressive behaviour since a trade war over vaccines can only lead to some of the most vulnerable in our communities suffering.”

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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### EU Cancer Plan Published

Last month the EC published its [Europe’s Beating Cancer Plan](https://ec.europa.eu/health/plan) setting out the EU’s strategy to support, coordinate and complement member states’ efforts to tackle cancer over the coming years. It isn’t a legislative proposal, but it does set intersect with a number of existing and proposed initiatives, including the [European Health Data Space](https://ec.europa.eu/health/plan) (expected in the fourth quarter of 2021) and the recently proposed [European Health Union](https://ec.europa.eu/health/plan). The EC is also planning to review the EU Tobacco Products Directive, EU legislation on the taxation of tobacco and alcohol, and the legal framework on cross-border purchases of tobacco and alcohol by private individuals.

The strategy, published one year after the launch of the EC’s public consultation, to which the BMA sent its own submission in addition to previously co-signing a [statement](https://www.bma.org.uk/news/2020/09/02/uk-cancer-plan-publication) with more than 30 European public health organisations, reflects to a high extent the BMA asks including, amongst others, putting prevention at the centre of the new Plan, prioritising policies to reduce harm from alcohol, smoking, obesity and air pollution and reducing the affordability of alcohol/tobacco by increasing duty above the rate of inflation.

The Plan has a €4 billion budget and includes the following actions:

- to create a ‘Tobacco-Free Generation’ where less than 5% of the population uses tobacco by 2040, compared to around 25% today
- to implement best practices and capacity-building activities to reduce harmful alcohol consumption in line with the targets of the UN Sustainable Development Goals – a reduction of at least 10% in the harmful use of alcohol by 2025
- to eliminate cancers caused by human papillomaviruses through large-scale vaccination campaigns with the aim to vaccinate at least 90% of the EU target population of girls and to significantly increase the vaccination of boys by 2030
- to create an EU network of national cancer centres in each member state by 2025 with the goal of ensuring that 90% of eligible patients have access to one by 2030 and to facilitate the uptake of quality-assured diagnosis and treatment, including training, research and clinical trials
- to launch, by the end of 2021, a new ‘Cancer Diagnostic and Treatment for All’ initiative to help improve access to innovative cancer diagnosis and treatments
- to create a programme in 2023, funded through Horizon Europe, to identify priorities for research and education in personalised medicine
- to create a roadmap for personalised prevention that will help with identifying gaps in research and innovation, and will support an approach to mapping all known biological anomalies leading to cancer susceptibility, including hereditary cancers
- to create next year a ‘Cancer Inequalities Registry’ that will help identify differences in the provision of cancer care among different countries and regions
- to create a ‘Better Life for Cancer Patients Initiative’ focusing on follow-up care
- to launch the ‘Helping Children with Cancer Initiative’ to ensure that children have access to rapid and optimal detection, diagnosis, treatment and care.

In addition, the EC is planning to propose a mandatory labelling of alcoholic beverages, listing the ingredients and nutritional information by the end of 2022 and health warnings by the end of 2023; the BMA, together with its European partners, has long-standing lobbying activities calling for such measures. Member states will also be supported in implementing evidence-based brief interventions on alcohol in primary healthcare, the workplace and social services.

To reduce the exposure of young people to alcohol marketing, the EC will closely monitor the implementation of the EU [Audio-visual Media Service Directive](https://ec.europa.eu/health/plan) (AVMSD) provisions on commercial communications for alcoholic beverages, including on online video-sharing platforms. Under the terms of the Withdrawal Agreement, the UK government has implemented the AVMSD, as its implementation date (19 September 2020) fell prior to the end of the transition period. As of 1 January 2021, the measures in the Directive will become retained in [UK law](https://www.gov.uk/guidance/impl).
However, audio-visual services are excluded from the scope of the services and investment and digital trade provisions of the TCA, which is in line with well-established EU practice in trade negotiations. As of 1 January 2021, the EU rules in the field of audio-visual and media services, and in particular the AVMSD, no longer apply to the UK as stated in the EC’s Communication (point B.3). As a result, UK-based audio-visual media service providers need to comply with each of the rules of the relevant member states in which they want to provide their services. EU providers wishing to supply services in the UK will need to abide by UK rules.

In addition, as part of the Europe’s Beating Cancer Plan initiative, the EC has launched a public consultation on EU tax rules on alcohol and tobacco purchased abroad.

We will continue to monitor all relevant developments, including future UK’s plans to assess the AVMSD, and ensure that our members’ views continue to be heard at EU level on these issues by engaging with our European partners and responding to the aforementioned public consultation.

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