January 2021

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Brexit Update

Following the European Council’s decision on the signing of the EU-UK Trade and Cooperation Agreement (TCA) and its provisional application as of 1 January 2021, the Council of EU Ministers has recently reiterated that an extension of the provisional application of the TCA is unavoidable in order to make sure the translations of the deal into all EU languages are correct and to ensure proper scrutiny at EU level. It is now likely that the ratification process, with the initial deadline of 28 February 2021, could be extended until mid-April.

The TCA is now pending the consent of the European Parliament (EP) and MEPs are currently debating the deal with the aim of voting on their decision on 23 February 2021 in plenary (full session). The EP’s Committee on Foreign Affairs (AFET) and Committee on International Trade (INTA) lead on this dossier. Several other EP Committees have been requested to table their opinions to feed into the final EP’s position which is being drafted by AFET and INTA Committees. Once the EP has given its consent and once all procedures necessary for the agreement to come into force have been completed, the European Council will adopt its decision on the TCA.

The opinion adopted by the EP’s Committee on the Environment, Public Health and Food Safety (ENVI) gives its consent to the draft Council decision on the conclusion of TCA and it:

- ‘Regrets that the Agreement does not contain a comprehensive Mutual Recognition Agreement (MRA) on medicines regulations as this would have limited the duplication of regulatory and quality related work and processes for companies marketing products in the EU and in the UK; encourages EU and UK relevant authorities to continue parallel discussions to agree on a MRA following the example of existing models between the EU and other third countries; further deplores that the Agreement is silent on medical devices, as this will mean no mutual recognition of notified bodies, or of the certificates that they issue’
- ‘Underlines that the agreement provides that the UK will cease to participate in the centralised EMA procedure of market authorisation for medicines; calls on the Commission to be available for ongoing monitoring and dialogue with UK bodies including the UK Medicines and Healthcare Regulatory Agency (MHRA)’
- ‘Stresses that, given that the Regulations on the transfer of personal data for medical research is currently overseen through the EU General Data Protection Regulation (GDPR), further clarification is needed in relation to UK implementation of the provisions of the EU Clinical Trials Regulation, the EU blood safety standards and future access to EU networks that help with organ donation’

The EP’s Committee on Employment and Social Affairs (EMPL) has recently adopted its opinion welcoming the EU and UK negotiators’ efforts to reach the TCA and MEPs:

- ‘Recall that under the TCA any lowering of social and labour standards in a manner affecting trade or investment, including by failing to effectively enforce its law and standards, is a breach of the non-regression principle and of the level playing field provisions’
- ‘Deplore that recently adopted Union legislative acts whose transposition deadlines was during the transition period, such as the Directive on work-life balance for parents and carers and the Directive on Transparent and Predictable Working Conditions in the European Union, have not been transposed in the UK thus has deprived UK citizens of part of newly established rights’
• ‘Encourage the continued participation by the UK as a third-country observer with no decision-making role in the agencies which are within the remit of Parliament’s Employment Committee, such as the European Foundation for the Improvement of Living and Working Conditions as this would allow both Parties to share data, best practices and methodologies’

• ‘Recommend that the European Parliament gives its consent to the TCA, but insists for annual reports on its implementation before the European Parliament, especially as regards the level playing field issue with regards to social and labour standards’

The EP’s Committee on Industry, Research and Energy (ITRE), in its opinion, also gives its consent to the TCA and welcomes the continuation of European cooperation with the UK in the fields of science, research and innovation. However, MEPs add:

‘benefits of Horizon Europe cannot exist without excellent education; we believe therefore that UK participation in Horizon Europe should go hand in hand with participation in Erasmus+, and that additional efforts should be made to convince the UK to also sign up to Erasmus+’

Currently, both parties are focusing their efforts on establishing a horizontal institutional framework to govern and enforce all aspects of the TCA. It consists of the Partnership Council which will be assisted in its work by 19 specialised committees and 4 working groups. The Partnership Council is co-chaired by a member of the European Commission (EC), recently appointed Vice-President Maroš Šefčovič, and a representative of the UK at ministerial level (tbc). It meets at least once a year, but can meet more often at the request of either the EU or the UK, and any decision is taken by mutual consent between both parties. The future framework will also comprise of the Parliamentary Partnership Assembly, between the EP and the UK Parliament, to exchange views on the TCA and make recommendations to the Partnership Council. In addition, the Civil Society Forum has been created as a commitment to regularly consult civil society organisations on the implementation of the TCA. The Agreement remains flexible and adaptable to the specific needs that may arise in different areas of cooperation and its overarching structure is expected to help sustain the EU-UK relationship over the long term, ensuring thorough implementation across all sectors.

As of 1 March 2021, the Task Force for Relations with the United Kingdom (UKTF) will be replaced by a new Service for the EU-UK Agreements (UKS) which form a part of the presidential services’ Secretariat-General of the EC. In addition, as of 1 February 2021 the EU’s chief Brexit negotiator Michel Barnier becomes a special adviser overseeing the ratification of the post-Brexit trade deal.

Currently, the BMA is identifying its priority actions on issues of concern emerging from the TCA and will be engaging nationally and with our European partners to mitigate the negative impact of Brexit on the medical profession and patients.

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.

The EC has published its communication setting out a number of actions needed to fight against the pandemic. It aims at having a minimum 80% of people over 80 and of health and social care professionals in every member state vaccinated by March 2021, and a minimum of 70% of the adult population by summer 2021. The EU countries, with the support of the EC, have already adopted guidelines on proof of vaccination for medical purposes. These guidelines aim to support the interoperability of vaccination certificates, meaning the contents of the vaccination certificates is uniform, and establish a minimum dataset for each certificate. The EC calls on member states to continue to apply physical distancing, limit social contacts, fight disinformation, coordinate travel restrictions, increase testing and contact tracing as well as genome sequencing (to 5% or preferably 10% of positive test results), given the increasing risks of mutations. Member states are also urged to adapt testing strategies in light of new mutations and expand the use of rapid antigen tests.

The EC also underlines measures to reduce the risk of transmission linked to travel, stating that all non-essential travel should be strongly discouraged until a considerable improvement of the epidemiological situation. The EC announced its
plans to establish a Team Europe mechanism to structure provisions of vaccines shared by member states with partner countries to ensure early access to vaccines. In addition, the EC proposes to update the Council Recommendation adopted last October to coordinate the approach on free movement restrictions in the EU. The EC is proposing to add dark red colour (in addition to green, orange, red and grey) to indicate areas where the virus is circulating at very high levels. This would apply to an area where the 14-day notification rate is more than 500 per 100,000 people. This action is part of the EC’s ongoing efforts to ensure better coordination of travel measures across the EU.

On 29 January 2021 the EC published its transparency and authorisation mechanism for exports of COVID-19 vaccines applying to companies with whom the EU has concluded Advance Purchased Agreements. Such exports outside the EU of COVID-19 vaccines will require authorisation by member states until the end of March 2021. However, later that day the EC took reverse course on part of its plan after it originally sought to override the Brexit deal by triggering a provision of the Northern Ireland Protocol known, as Article 16, imposing an effective trade border with the Republic of Ireland. Consequently, the EC issued a statement, confirming that it would no longer trigger the override provision and that the Withdrawal Agreement would remain intact. The statement adds that the final version of the regulation on vaccine export authorisation scheme will be published shortly.

The European Centre for Disease Prevention and Control (ECDC) has recently created a dedicated webpage to track vaccination levels throughout Europe providing a near-live view on vaccination progress. As of 1 February, a total of 8.2 million doses had been administered throughout Europe. Ireland led the way in the number/proportion of first doses administered, with 11.5% of the adult population vaccinated. The UK, which is leading Europe overall, is not among the countries included on the ECDC tracker. Member countries can provide vaccine data to the ECDC, preferably at least twice a week. The agency noted that lags in reporting, as well as the time needed to process the data, can lead to discrepancies between national figures and those from the ECDC. The EMA’s statement adds that monitoring the rollout of vaccines will be further developed as more information on vaccine coverage becomes available.

Late January the European Medicines Agency (EMA) published its first safety update on a COVID-19 vaccine — Comirnaty. The update states that safety data collected on Comirnaty use in vaccination campaigns is consistent with the known safety profile of the vaccine, and no new side effects were identified. It includes the assessment by EMA’s safety committee (PRAC) of deaths reported after vaccination with Comirnaty, including deaths in frail and elderly people. The assessment concluded that the data did not show a link to vaccination with Comirnaty and the cases do not raise a safety concern. The EMA’s statement adds that monitoring the rollout of vaccines will be further developed as more information on vaccine coverage becomes available.

The EMA has announced it is reviewing pre-clinical data in support of the first potential monoclonal antibody therapy for COVID-19 in the EU. The agency’s human medicines committee (CHMP) has started scrutinising laboratory and animal studies for Regeneron’s antibody cocktail, partnered with Roche in Europe. The agency has not yet received the full clinical efficacy data for the marketing authorisation application. However, it is anticipating evidence from a study in hospitalised patients with COVID-19 and other clinical trials as they become available. The EMA advised that it is unable to forecast a decision date, but the review would be faster than for a standard submission. Regeneron and Roche’s therapy is a combination of casirivimab and imdevimab, two antibodies designed to mimic the body’s own response to coronavirus infection. They bind to the spike protein on the virus and prevent it from entering the cells to replicate and cause disease.

In addition, EMA has endorsed a joint statement by the International Coalition of Medicines Regulatory Authorities (ICMRA) highlighting the key role of healthcare professionals in fostering confidence in COVID-19 vaccines. The aim of the statement is to support healthcare professionals when talking to members of the general public to reassure them that the regulatory processes for the authorisation and safety monitoring of COVID-19 vaccines are robust, independent and driven by patient and public health needs. The statement explains how COVID-19 vaccines undergo scientific evaluation to determine their safety, efficacy and quality.

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.

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