Brexit Update

The UK government recently announced that it is prepared to trigger Article 16 - the part of the Northern Ireland (NI) Protocol giving the UK and EU an option to waive the rules unilaterally - if the EU doesn’t agree to reduce the scope of border controls being sought on goods shipped from England, Scotland and Wales.

It came in response to comments made by Maroš Šefčovič during his September visit to NI where he warned that NI would be plunged into ‘instability, uncertainty and unpredictability’ if the agreement setting out its post-Brexit trade arrangements was renegotiated. The European Commission (EC) is expected to put forward a new set of proposals on the Protocol by mid-October at the earliest, covering the supply of medicines, agri-food, customs and measures to increase the participation of NI’s institutions.

The BMA wrote to Lord Frost regarding the approaching deadline for the grace period on medicines supply from GB (Great Britain) to NI, which is due to end in December 2021. The letter called 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.

It stated that there is an increasing number of concerns within the medical profession, as any disruptions in the medicines supply to NI might be detrimental to health of the whole nation, including:

- The alarming number of medicines currently offered to patients in NI that are at risk of withdrawal due to the cost and complexity of duplicating regulation solely for the NI market, which remains in the European acquis for medicine regulation. Under the NI Protocol, drugs produced in GB will have to be licensed separately and be subject to safety inspections and other checks which, consequently, require additional warehousing, laboratory testing and the involvement of technical specialists as of 1 January 2022.

- Concerns around the restricted ability to authorise medicines for licence from the Medicines and Healthcare products Regulatory Agency (MHRA), as NI will also remain under the European Medicines Agency (EMA) licencing and regulations. There is increasing divergence between these two regulatory regimes and one can no longer assume that the same licence and regulations will apply as per the rest of the UK. This also has indirect effects on the Joint Committee on Vaccination and Immunisation (JCVI) and National Institute for Health and Care Excellence (NICE) guidance and recommendations.

- Any shortages in medicines supply risks patients’ needs not being met and could result in physicians prescribing medicines that are less than optimal for their patients. The situation could be worsened by the inability to access any alternative medication.

Lord David Frost announced that ministers are set to amend, replace or repeal all the retained EU law ‘that is not right to the UK.’ He signalled that Britain intends to diverge from EU rules on data protection, gene-editing organisms, clinical trials, medical devices and public procurement. On data protection, the UK government is about to overhaul the country’s privacy regulator as part of a wider reform of its data protection framework, which it hopes will boost innovation in sectors like healthcare and financial services. It plans to scrap the right to have a human review of some decisions made by computer algorithms, by rewriting or deleting Article 22 of the EU Data Protection Regulation Britain still abides by.

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.
Over 6 million applications were made to the EU Settlement Scheme (EUSS) by 30 June 2021, with a surge of 409,600 applications in the month of June (the previous month received 182,500 applications). 8% (464,000) of applications received were repeat applications (i.e. applicants moving from pre-settled to settled status or re-applications after a refusal/withdrawal). The Home Office has acknowledged in meetings with the EU Delegation to the UK and the member states’ embassies that the number of applications has been higher than expected, but also notes this application figure includes late applicants, joining family members and those moving from pre-settled to settled status. Nearly half a million applicants (483,200) are still waiting for a decision and the backlog appears unlikely to be cleared before the end of 2021.

Last August, the UK government announced that late EUSS applicants will have their rights temporarily protected whilst a valid application is determined. There is no deadline set for submitting a late application, but the Home Office has indicated that the further applicants move away from the EUSS deadline, the more justification will be required (unless the applicant is a child). The UK Government has set this new policy out in its guidance to ensure compatibility with the temporary protections, so EUSS applicants and joining family members will be able to take up new employment while they await the outcome of their valid application, but has not yet amended the underlying legislation. Consequently, there are limited details on how the UK government will implement the legal/policy changes and, therefore, it is unclear whether the requirements of the Withdrawal Agreement (WA) to protect late applicants will be implemented fully. The Home Office has indicated that there is no need to create new legislation as they state the necessary changes can be made via policy and guidance. The UK Government also updated the Landlords’ Guide to Right to Rent Checks. Landlords will need to check that a valid late application to the EUSS has been made and verify this with the equivalent Home Office service called the Landlord Checking Service.

The text of Certificates of Application has recently been updated to cover late applicants being allowed to exercise rights of employment, rent, access to health and social services in the period leading up to the decision on their application. The Home Office also confirmed that it will re-issue late applicants already provided with a previous version of the Certificate (incorrectly suggesting that there are limitations on their rights) with a new one in due course (no timing given).

The EU Delegation to the UK registered a number of cases where EU students, who have already applied to the EUSS and currently await their decision, have been advised by their universities to apply for a UK student visa and pay the much higher international fees. University organisations claim that the Home Office guidance is not accurate enough for universities and this could lead to issues with its implementation. Last August, ‘the3million’ organisation, formed in the aftermath of the EU referendum to represent EU citizens in the UK, submitted its report to the Independent Monitoring Authority which includes individual cases from students on these matters (see page 65).

The Scottish Government’s Minister for Culture, Europe and International Development, the Welsh Government’s Minister for Social Justice and the Northern Ireland Executive’s First and Deputy First Ministers sent a joint letter to the UK Immigration Minister requesting a physical proof for EU citizens getting a residence permit under the EUSS. The letter argues that a physical proof is necessary as a safeguard, in addition to a digital status.

In addition, the Home Office Grant Funded Organisations (GFO) scheme, which was due to end in September 2021, has now been extended to 5 April 2022. The GFO network provides help for vulnerable citizens making successful applications to the EUSS. However, there is no specific funding available to assist vulnerable citizens appealing to the immigration tribunal against EUSS refusals.

**COVID-19 Response**

The European Medicines Agency (EMA) continues to recommend administrating a second dose of the Vaxzevria vaccine, after concluding a review of rare blood-clotting events linked thrombosis with thrombocytopenia syndrome (TTS). The EMA confirmed the second dose should be given from four to twelve weeks after the first. It added there is no evidence that delaying the second dose decreases the risk of TTS. The agency was unable to identify risk factors that make TTS more likely, due to limited data. Women and young people appeared to be at a higher risk of the rare blood-clotting events, and the risk looked likely to decrease when receiving the second dose, but the agency advised that there were limitations on how the data was collected. When countries do use a different vaccine for a second dose, the EMA advised that it could not give a ‘definitive recommendation’ on which vaccine should be used.
The EMA advised that healthy adults can receive a third, booster dose of the BioNTech/Pfizer COVID-19 vaccine six months after the second dose. The EMA’s medicines committee said the recommendation was based on data from a study of 18 to 55-year-olds, showing an increase in antibodies after a third dose. Data has shown that immunity wanes with the vaccines currently in use and appears to wane more quickly with the BioNTech/Pfizer vaccinations. It adds, that people with severely weakened immune systems may be given a booster dose of either the BioNTech/Pfizer or Moderna just 28 days after their second dose. While there is no direct evidence linking antibody levels to stronger protection in those with weakened immune systems, the EMA advised that it is expected that the extra dose would increase protection at least in some patients. In its announcement, the EMA warned that the risk of inflammatory heart conditions, observed after the BioNTech/Pfizer doses, or other very rare side effects after a booster was not yet known and is being carefully monitored.

The World Health Organisation (WHO) announced adding three new drugs - artesunate, imatinib and infliximab - to its study investigating treatments for coronavirus. The new drugs are approved for other indications: artesunate for malaria; imatinib for certain cancers; and infliximab for diseases of the immune system such as Crohn’s Disease.

The EC extended the EU’s vaccine export authorisation programme, which permits monitoring and control of shipments of coronavirus vaccines outside the bloc. The EU set up its authorisation mechanism last January after AstraZeneca underdelivered on its contract with the EU. The EC had already extended the mechanism for an extra three months until September and it is now extending it for another three months until the end of the year.

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.

**Horizon Europe update**

The EC has launched five ‘Missions’ which aim to address some of the greatest challenges facing society, including cancer. The Cancer Mission will aim to improve the lives of more than 3 million people by 2030 through prevention and cure, as well as support for the cancer sufferers and their families. The Cancer Mission, jointly with Europe’s Beating Cancer Plan, will:

- Implement a strategic research and innovation agenda for a better understanding of cancer
- Design effective prevention strategies
- Develop new methods for screening and early detection
- Enable optimised diagnosis and better treatment
- Improve the quality of life of patients and their families
- Provide tailor-made support to countries, regions and communities
- Establish a high level of collaboration within the cancer community

The Horizon Europe programme will provide €378.2m in the period 2021-23 to support the implementation of the Cancer Mission, which aims to set up the EU platform UNderstanding CANcer.eu (UNCAN.eu), the European Cancer Patient Digital Centre and support a network of Comprehensive Cancer Infrastructures.

Under the EU-UK Trade and Cooperation Agreement (TCA), UK entities are eligible to apply for this funding scheme.

The UK Government’s Department for Business, Energy and Industrial Strategy (BEIS) made available up to £5,000 grant funding under the Horizon Europe Pump Priming call for proposals. The funding is to help develop collaborative activity between UK and EU/associated countries’ entities who are intending to apply to specific call topics under the 2021-2022 Horizon Europe Pillar 2 Work Programmes, including Health, which open between 1 September 2021 and 7 September 2022.

Applicants will need to identify a specific upcoming call for proposals in this Pillar as the focus of their proposed collaboration with the goal of applying to that upcoming call, building on this pump-priming funding. This funding is not to implement the proposed projects that will be submitted to Horizon Europe, but to give the UK-based partners the resources needed to collaborate with EU organisations and stakeholders to further develop the idea and the market opportunities. The expectation is that the funding will be used in a variety of ways but these could include feasibility studies, application advice and training, partnership building, and dedicated time to take forward an application. The call states:

‘Proposals are welcome from research institutes and universities based in the UK, and proposals that involve working closely with any other type of organisations eligible for Horizon Europe funding (based in the UK and/or the EU/Associated Countries), including third parties, end users and similar bodies/organisations such as hospitals, libraries, regulators, commercial partners, small and medium-sized enterprises (SMEs), creative industry partners, museums, local authorities and associations, NGOs, charities and companies are particularly encouraged.’
The call will remain open on a rolling 2-week basis until all funding has been utilised, with the first deadline on 13 October, the second on 27 October, and further applications considered every two weeks from 10 November if funding remains available.

Report on clinical research in the UK

The Association of the British Pharmaceutical Industry (ABPI) recently published its report which shows that the UK has delivered life-saving clinical research during the pandemic but that this has been at the expense of studies into other disease areas, in contrast with some EU countries. According to the report, the UK is a European leader in terms of numbers of Phase 1 trials, but numbers have been declining over recent years and the UK is dropping down globally. It ranked fourth in 2020 for the number of Phase 1 trials, behind the US, China and Australia. The next European countries are Spain, Germany and France, ranked sixth, seventh and eighth, respectively. Germany and Spain score better, in third and fourth places, for the number of Phase 2 trials, ahead of the UK, ranked fifth. Italy and France also overtake the UK for Phase 3 trials, pushing the UK into seventh place.

The report argues that the intense focus on COVID-19 has had a detrimental impact on other research across many diseases. Oncology, which comprises most of the UK’s research portfolio, was the most affected, with enrolment in May 2020 down 88% compared with May 2019.

While other countries also saw a drop in their research activity during the pandemic, the pause was less severe and they have recovered faster, the report finds.

The ABPI is calling on the UK government to mandate, in the Health and Care Bill, for: NHS organisations to conduct and resource clinical research; a more streamlined application and approval process for clinical trials; and greater diversity in study recruitment.

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