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Brexit Update

As reported in the September European Brief, the BMA wrote to Lord Frost calling for pragmatic solutions to be agreed between the two parties to ensure there will be an uninterrupted supply of medicines to Northern Ireland (NI), so that the medical profession can continue treating their patients to the highest possible safety levels. In response to the BMA's letter, David Frost stated:

I share your concern around the current operation of the Protocol and am acutely aware of the important issues that you raise and the risks to patient care. It is paramount that medical professionals and patients have the same access to medicines in Northern Ireland as the rest of the UK.

The issue of the European Medicines Agency's role in taking licensing decisions for Northern Ireland Patients is of course of particular concern. It is just one reason why the Government's Command Paper, published on 21 July, proposes that medicines should be removed from the scope of the Protocol altogether as a matter of urgency. This would mean that UK rules apply for medicines moving between Great Britain and Northern Ireland and that the Medicines and Healthcare products Regulatory Agency is responsible for all regulatory decisions.

With that in mind, we are in intensive discussion with the Commission to try to resolve this range of challenges. In the meantime, we are continuing to have close contact with suppliers to ensure that medical professionals and patients have access to the medicines they need. We will keep you up to date on progress.

Both parties continue negotiating on solutions to tackle post-Brexit disruptions to trade between Great Britain (GB) and NI. European Commission (EC) Vice-President Maroš Šefčovič recently stated that the EU wants to conclude as soon as possible a post-Brexit deal with the UK to secure uninterrupted medicines supply to NI but is ready to move ahead unilaterally before the grace period ends on 1 January 2022. At his recent meeting with the Northern Ireland Assembly in Belfast he shared their concerns that hundreds of British medical products soon could stop being distributed to NI because they do not meet EU regulatory requirements. He stated that resolving the medicines supply problem had been top of his negotiating agenda for the past four weeks, adding that the EU had submitted proposals to the UK pledging to pass new EU legislation as part of broader solutions in [late June](#) and [mid-October](#).

In addition, citing unacceptably high regulatory costs, British generic drug makers already have [notified](#) NI's Department of Health they will stop shipping more than 2,000 products in the event of no legal solutions being in place before 1 January 2022.

The House of Lords Commission has [formally adopted](#) the creation of the post-Brexit EU-UK Parliamentary Partnership Assembly (PPA), which follows the European Parliament's formal [adoption](#) back in October. The PPA, which will include 35 policy-makers from each side, is responsible for monitoring the implementation of the EU-UK Trade and Cooperation Agreement (TCA) and 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 David Frost. The PPA will also be able to make non-binding recommendations for amending the TCA.

As reported in September's European Brief, Lord Frost announced that ministers are set to amend, replace or repeal all the retained EU law, including EU rules on data protection. The BMA has responded to the [public consultation](#) - 'Data: a new direction' – focusing on the following main themes:

- The UK's adequacy agreement with the EU must not be placed in jeopardy
- The UK's current high standards for protection of health data must be maintained
- Legislative change may have unintended consequences for medical researchers.

COVID-19 Response

The European Centre for Disease Prevention and Control (ECDC) recently [announced](#) that there have been 44 confirmed cases of infection with the Omicron variant of the coronavirus in 11 European countries and added that there have been no reports of severe disease or death from the cases for which there is information. Among those cases for which the severity of disease has been reported, all were either asymptomatic or mild.

The EU/EEA countries so far having detected Omicron are Austria, Belgium, the Czech Republic, Denmark, France (Reunion), Germany, Italy, the Netherlands, Portugal, Spain and Sweden.

The UK already has found at least 32 cases of the Omicron variant despite implementing a swift travel ban on many southern African nations after the variant was first reported in South Africa and Botswana

The ECDC [announced](#) that the Omicron variant could become the dominant strain in Europe within months. Based on its mathematical modelling of the variant there are '*indications that Omicron could cause over half of all SARS-CoV-2 infections in the EU and the European Economic Area within the next few months.*' It concluded that the more transmissible the variant is, the greater its circulation will be across Europe, and the shorter the time it will take for the variant to become dominant over the existing Delta variant.

According to [Regeneron](#), early indications suggest that monoclonal antibody medicines developed to date against the coronavirus may not be as effective against the Omicron variant. The US pharmaceutical company said that there had not yet been direct testing of how the variant interacts with antibody drugs. But previous lab testing, as well as modelling based on the individual mutations found in the variant, suggest that Omicron may be more resistant to monoclonal antibodies.

An emergency meeting of G7 health ministers, called by the UK, reiterated previous pledges relating to the pandemic, such as strong support to set up an international pathogen surveillance network within the World Health Organization (WHO). A brief [statement](#) issued by the UK praises the work of South Africa in both detecting the variant and alerting others. The leaders also discussed the importance of access to vaccines, including '*vaccines absorption and country readiness for receiving and deploying COVID vaccines*' but no concrete commitments have been agreed.

World Health Organisation (WHO) member countries have agreed to start negotiations for a pandemic treaty, initially proposed by EU Council president Charles Michel a year ago, but last May the US succeeded in its effort to delay the pandemic treaty discussions. The WHO Director General Tedros Adhanom Ghebreyesus announced that the issue of fairness is at the very core of a future pandemic treaty with a better system for incentivising the sharing of information related to disease outbreaks and for equity to be written into how countries respond to crises. The [final text](#) states that countries will establish '*an intergovernmental negotiating body open to all member states and associate members (the "INB") to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to adoption under Article 19, or under other provisions of the WHO Constitution as may be deemed appropriate by the INB.*'

Article 19 of the WHO's constitution gives the World Health Assembly (WHA) the authority to adopt binding international treaties. This has only been done once, for the Framework Convention on Tobacco Control, which took three years of negotiations before it was adopted by the WHA in 2003 and came into force in 2005.

There is a broad agreement for the draft decision, including the EU (strongly in favour of a legally binding treaty), member countries of the African Group and the UK. Several countries that had expressed their reservations about the treaty have also signed onto the text, namely the US, India, Brazil and Monaco. Formal discussions are expected to begin next year with the body set up to negotiate the treaty meeting by no later than 1 March to elect two co-chairs and four vice-chairs to work on a text. The second meeting of the body will be held by no later than 1 August, by which time a working draft is expected. At the later meeting the body will identify under which provision of the WHO's constitution the treaty will be decided.

The EC recently published an updated [framework](#) for travel from outside the EU proposing a nine-month threshold for vaccine certificates for travel. Spokespeople from the EC appealed to EU countries to avoid introducing new restrictions and

to coordinate their actions to avoid chaos and the end of free travel, refraining from imposing additional travel restrictions on holders of the EU digital COVID-19 certificate.

Ireland has already tightened pandemic [controls](#) on people traveling to Ireland, including from the UK, requesting all passengers over age 11 proof of a negative COVID-19 test even if they are fully vaccinated. British authorities have begun requiring travellers from all other countries to self-isolate upon arrival and produce a negative PCR test; they are [exempting travellers](#) arriving from Ireland. In addition, Portugal has pulled the emergency brake on the EU COVID-19 travel pass less than six months after it was introduced, requiring a negative coronavirus test for all new arrivals trying to enter the country by land, sea, or air.

The [latest data](#) from the ECDC shows a decrease in antibiotic consumption across EU/EEA during COVID-19 pandemic by more than 15% between 2019 and 2020. This overall decrease, reported from 26 countries, showed a decline in consumption of penicillin as well as reduced consumption of other beta-lactams. The investigators suggest that possible reasons for this decline could include a general drop in the number of primary care consultations during the COVID-19 pandemic or difficulties among the general population in getting medical appointments.

In the aftermath of ECDC's [advice](#) that children at risk of severe COVID-19 disease should be prioritised for vaccination, and the European Medicines Agency's [recommendation](#) of BioNTech vaccine to be approved for children aged 5-11, EC President Ursula von der Leyen announced that children's doses of the BioNTech/Pfizer will be available from 13 December. She added that two-thirds of the EU's total population are currently vaccinated. The technical report highlights that children make up an increasing proportion of both cases and hospitalisations, a rise that could be due to factors including the emergence of the highly transmissible Delta variant and increased vaccination coverage in older age groups.

The ECDC has also [released](#) an updated version of its COVID-19 Vaccine Tracker with additional information, new indicators, and improved features for visualisation.

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 UK Government recently [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, which is still being formalised. The money will be delivered through UK Research and Innovation, providing a 'safety net' for researchers and their partners to continue pursuing their project plans.

The BMA, together with a number of European partners, co-signed a statement urging the EC to formalise the UK's association to Horizon Europe without further delay. The statement highlights that many profound and long-lasting EU-UK research partnerships are at stake which are of high value to Europe as a whole and refers to a [letter](#) to EC President Ursula von der Leyen sent by the EU's research and innovation community, as reported in the [October European Brief](#).

For further information on any of these news items, please contact:
Robert Delis: rdelis@bma.org.uk

