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Brexit Update

Following a [statement](#) outlining the British government's intention to introduce a bill that gives British ministers the power to override parts of the Northern Ireland (NI) protocol, European Commission (EC) Vice-President Maroš Šefčovič [stated](#):

'Should the UK decide to move ahead with a bill disapplying constitutive elements of the protocol as announced by the UK government, the EU will need to respond with all measures at its disposal.'

The EU has not yet revealed what those measures might be, but in response to crossbench peer Charles Kinnoull's [letter](#) on concerning the UK's participation in EU RTD programmes, EU Commissioner for Innovation, Research, Culture, Education and Youth, Mariya Gabriel, reiterated in a letter (attached), that for as long as the dispute over post-Brexit trade rules for NI persists, the UK won't be part of the EU flagship research and innovation program – Horizon Europe. Under the EU-UK Trade and Cooperation Agreement (TCA), UK has secured association to the Horizon Europe programme 2021-2027 with a €95.5 billion budget, however two years into the seven-year span of the scheme, the UK has been unable to formalise its participation. The situation has attracted criticism from the UK and a number of European organisations and university lobby groups.

The BMA, together with its European partners, co-wrote and co-signed a [statement](#) calling on the EU to formalise the UK's association to Horizon Europe without further delay which was sent to the EU institutions. Most recently, BMA Chair of Council, Dr Chaand Nagpaul, signed a pan-European campaign, '[Stick to Science](#)', initiated in response to ongoing delays to the signature of association agreements with the UK and Switzerland, which to date received 5593 signatories across various sectors.

UK researchers can still apply for Horizon Europe calls, as the UK is technically in the process of association, but the lack of a formal agreement creates difficulties for UK successful entities in signing grant agreements with the EU and drawing down Horizon Europe funding. To mitigate the negative consequences emerging from the delay in UK's formal association of Horizon Europe, the UK government has established the UK Guarantee Fund confirming 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 the programme. The money will be delivered through the UK Research and Innovation (UKRI) budget, providing a 'safety net' for those who have successfully bid for Horizon Europe funded activities with grant agreements signed with the EU by December 2022.

The UK argues that a deal with the EU is still feasible but only if EU leaders give Šefčovič permission to renegotiate the NI protocol's text. However, that would take several months for EU leaders to agree on a new mandate and there is no sign that they intend to do so. The EU aims to resume talks on the operation of the NI protocol in the summer with a view to reaching consensus by the end of the year. Future talks are expected to take place in parallel to the passage of the bill, which the UK government plans to introduce in the Commons before the summer parliamentary recess.

Regardless of the outcome from the ongoing EU-UK talks on the NI Protocol issues, the recently adopted EU amended pharmaceutical legislation (as reported in [April's Eurobrief](#)), which allows for the uninterrupted supply of medicines to NI, and to Cyprus, Ireland and Malta post-Brexit, are expected to be unaffected by the political situation.

In addition, the EC is set to propose a broader revision of EU pharmaceutical rules by the end of this year, which is expected to set out more permanent structural solutions to ensure the security of supply of medicines in all smaller markets. Given that EU legislation continues to apply in NI, the BMA will engage in the upcoming revision to secure an uninterrupted supply of medicines to NI so that the medical profession can continue treating their patients to the highest possible safety levels.

COVID-19 Response

The BMA recently published two reports – [‘How well-protected was the medical profession?’](#) and [‘The impact of the pandemic on the medical profession’](#) – which document the experiences of thousands of UK doctors throughout the pandemic, drawing on real-time surveys carried out over the past two years, formal testimonies, data and evidence sessions. Chaand Nagpaul, BMA chair of council, stated:

‘A moral duty of government is to protect its own healthcare workers from harm in the course of duty, as they serve and protect the nation’s health. Yet, in reality, doctors were desperately let down by the UK government’s failure to adequately prepare for the pandemic and their subsequent flawed decision making, with tragic consequences. The evidence presented in our reports demonstrates, unequivocally, that the UK government failed in its duty of care to the medical profession.’

The reports form part of the BMA wider [review](#) into the impact of the Covid-19 pandemic on the medical profession and the government’s handling of the pandemic, with three further instalments to come.

The EC recently [announced](#) it will be including Covid-19 on its list of recommendations on occupational diseases. It comes after an agreement was reached between member states, workers and employers in the European Union Advisory Committee on Safety and Health at Work (ACSH). Recognising and compensating occupational diseases is within a member states’ competency but, as most EU countries already recognise Covid-19 as an occupational disease or accident at work, the EC hopes its recommendation will help get all member countries to take this approach.

The European Medicines Agency (EMA) advised that the first Covid-19 vaccines adapted to target new variants of concern are likely to be approved by the autumn. It adds that the main priority is that adaptive vaccines are approved by September at the latest in readiness for a rollout campaigns in the autumn, which would allow manufacturers to adjust their production lines accordingly. Currently, messenger RNA vaccines from Moderna and BioNTech/Pfizer are leading the race in their clinical development and are most likely to be approved first. The EMA expects to see the first clinical trial results from these vaccines in the coming months. Both manufacturers have developed vaccines that target Omicron as well as a second variant. Moderna has tailored its bivalent vaccine to target Omicron and Beta, while BioNTech/Pfizer are combining the Wuhan and Omicron targets. In addition, EMA added that any decision on adapted vaccines will be taken with the World Health Organisation (WHO) and the International Coalition of Medicine Regulatory Authorities (ICMRA). Regarding second generation vaccines - with longer lasting protection, preventing transmission, combinations with flu shots and broader protection against more coronaviruses - EMA said it is unlikely such vaccines will be ready for regulatory assessment before next year.

In addition, EMA has endorsed a [statement for healthcare professionals](#) jointly developed by the [International Coalition of Medicines Regulatory Authorities \(ICMRA\)](#) and the WHO. The statement is aimed to help healthcare professionals answer questions about the role of regulators in the oversight of Covid-19 vaccines and to reassure medical staff about the safety of Covid-19 vaccines that undergo a robust scientific evaluation to determine their quality, safety and efficacy. The statement also includes the most recent information together with questions and answers on:

- clinical trial data (including effectiveness studies)
- COVID-19 virus variants
- commonly reported adverse events for each vaccine type
- the latest advice on vaccine boosters and vaccine safety in children and pregnant women

The EC recently proposed [recommendations](#) to manage the Covid-19 pandemics current phase and prepare for future ones. Co-ordination will be crucial in the next phase of the pandemic, where preparedness and response must be sustained. As a result, the EC urges member states to take steps before autumn to ensure continuous monitoring and coordination of health preparedness and response which includes:

- Increase vaccine and booster shots
- Install integrated surveillance systems

- Invest in the health care systems recovery
- Apply EU-wide regulations to enable free and secure travel
- Increase co-ordination in the fight against mis-and disinformation about Covid-19 vaccines

In April 2020 a global initiative - [ACT-Accelerator](#) - was launched to develop, produce and ensure the equitable distribution of diagnostics, therapeutics and a vaccine for coronavirus. Supported by leaders from around the world, including a number of European countries, such as Italy, Spain, the UK and WHO, which was tasked to co-ordinate the effort. The ambition behind the ACT-A, of which COVAX is a part, was arguably never met and the initiative's facilitation council recently [met again](#) to reflect on the current situation and on how global Covid-19 targets can be met. Meanwhile, the likelihood of achieving targets such as vaccinating 70% of the population in every country by mid-2022 is receding. A recent [report](#) from the ACT-A Facilitation Council's Tracking & Accelerating Progress Working Group states that COVAX has delivered an additional >450m vaccines to the Advance Market Commitment (AMC) countries (total >1.4b doses), but in low-income countries still only 13% of the population is fully vaccinated. Consequently, ministers from Norway and South Africa, global health experts and EU Health Commissioner Stella Kyriakides are currently focusing on increasing access to Covid-19 tools and fully financing the ACT-A. The central objective is to *'drive an intensified push to reach the global Covid-19 targets and urgently call to close the ACT-A funding gaps.'*

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](#).

Humanitarian crisis following the war in Ukraine

To date, the [Ukrainian Medical Health Fund](#), set up by the World Medical Association (WMA), European Forum of Medical Associations (EFMA) and Standing Committee Of European Doctors (CPME) to coordinate the support from the medical community has received nearly €1m in donations. The first shipment worth €569,880 with essential medicines, training equipment, and medical equipment has been delivered to Lviv, Ukraine. The co-ordinating organisations are now focusing on maintaining communications with Ukrainian colleagues as it is expected that landlines might be destroyed as the war progresses.

European Medical Students Association (EMSA) recently launched its [Aid4U](#) website, available in many languages, to provide all displaced Ukrainian students, including medical students, with the streamline information about support available in various countries, including, housing, transportation, access to healthcare and education and various humanitarian initiatives. Another important feature on the website is the 'Check-in' option (still under preparations) to request information related to any specific support they might need, including which universities across Europe accept Ukrainian students.

At the April 2022 Council Meeting of the European Union of Medical Specialists (UEMS), Secretary of the Ukrainian Medical Association (UEMS) presented on the situation in Ukraine which included the following:

- 324 damaged hospitals, including 14 children's hospitals,
- 24 health facilities not subject for restoration, 60 emergency medical teams under the attacks leaving 6 doctors dead,
- Clinical trials affected – 400 ongoing studies temporarily suspended due to difficulties in medicines supply and patients' visits,
- Main challenges: shortage of medicines and portable equipment, electricity issues and logistic problems.

In addition, in the aftermath of the decision of the Russian association of scientists to support the Russian invasion of Ukraine, Secretary of the UMA appealed to all international partnerships to exclude Russian scientific to prevent the spread of Russian propaganda.

According to the [UN High Commissioner for Refugees](#), 6.5m refugees fled Ukraine to seek refuge in neighbouring countries. Among them are people in need of medical attention, adding pressure to receiving countries' health care systems. In response to calls for support from Poland, Slovakia, Moldova and Ukraine, the EC [confirmed](#) that the patients are being transferred to Germany, Ireland, Italy, Norway, Denmark, Sweden, Romania, Luxembourg, Belgium, Spain and Portugal. The evacuations are being carried out via the EU Civil Protection Mechanism.

The WHO's European members, including the UK, [voted overwhelmingly](#) to relocate the organisation's European office for non-communicable diseases out of Moscow, as well as the temporary suspension of regional meetings in Russia. Hans Kluge, the WHO's regional director for Europe advised that he is currently considering this in consultation with member countries and the organisation's legal department. He added that any bigger decisions that could further isolate Russia have to be

taken by the World Health Assembly. The meeting of all the WHO's member countries is currently taking place in Geneva (22-28 May) when the issue will be discussed, together with a separate resolution proposed by Ukraine to condemn Russia's attacks on health care facilities in Ukraine and raises the prospect of suspending Russia's voting rights. For the resolution to be adopted, it would need to either secure consensus, or be passed by a two-thirds majority. While much of Europe is likely to endorse the text, it's unclear how other countries would respond.

ECDC risk assessment on monkeypox

The European Centre for Disease Prevention and Control (ECDC) has [urged](#) countries to prepare contact tracing, vaccines, treatments and diagnostics as ways to combat an increasing number of monkeypox cases. In the UK a further 36 cases have been identified, bringing the total number of monkeypox infections to 56, according to the UK Health Security Agency. In the EU, 67 cases have been identified since May 15 in nine countries: Austria, Belgium, France, Germany, Italy, the Netherlands, Portugal, Spain and Sweden. The ECDC advised that countries should update their contact tracing mechanisms and diagnostic capacity for orthopoxviruses (which includes monkeypox) and review the availability of smallpox vaccines, antivirals and personal protective equipment for health professionals. It adds that while the virus, which causes a rash, fever and malaise, usually disappears after about three weeks, it can be serious in certain groups of people, including young children, pregnant women and those with weaker immune systems.

The EC is currently in talks with EU countries, alongside the [Health Emergency Response and Preparedness Authority \(HERA\)](#), the ECDC and the EMA to ensure countries can effectively respond to any outbreaks and the key concerns are vaccines and treatments. As part of HERA's mandate, the EU's newest authority 'is on stand-by to work on procurement' of medical countermeasures, according to the EC. That includes tackling challenges relating to the availability of and distribution of antivirals and vaccines, and to increase stockpiling capacity to avoid shortages and bottlenecks in deployment.

Bavarian Nordic, is the only manufacturer of a monkeypox vaccine - Imvanex - available in the EU and is approved in the US and Canada to protect against monkeypox and smallpox, but so far only authorised for smallpox in the EU. The EMA advised that data exists on the prevention of monkeypox in animals and that data also shows that smallpox vaccines can also prevent monkeypox in humans. It added that there is just one drug which is also licensed to treat monkeypox in the EU - Tecovirimat from SIGA -and it can treat smallpox, monkeypox and cowpox — three infections caused by viruses belonging to the orthopoxviruses family. It can also treat complications following vaccination against smallpox.

In the UK, 1,000 doses of Imvanex have already been administered. Public health authorities are immunising high-risk contacts of people who have been infected and the country has 3,500 doses left.

The ECDC recommends that close contacts of monkeypox cases should self-monitor for the development of symptoms for 21 days after the last exposure. The UK takes a more stringent approach, [advising people to isolate](#) for three weeks.

The ECDC stated that if human-to-animal transmission occurs, and the virus spreads in an animal population, there is a risk that the disease could become endemic in Europe and urged both veterinary and public health authorities to collaborate to carefully manage pets exposed to the virus, to prevent transmissions into wildlife.

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